

DISCLOSURE

The issue of disclosure of medical errors or unanticipated outcomes of care compels us to closely examine the essence of the relationship between clinician and patient as it plays out within the medical, legal, and ethical domains. It brings to the forefront the fundamental rights and responsibilities of all parties involved and forces us to reexamine the accepted standards of general conduct when such events occur during the clinical process. This chapter walks you through the relevant considerations when deciding, as an institution, whether or how to disclose information to patients and their families if a medical error or unanticipated outcome of care occurs.

KEY ISSUES

◆ **The Right to Disclosure**

In the State of Michigan, there is no statutory law or legislative enactment in place that explicitly mandates the disclosure of medical errors or unanticipated outcomes of care to the patient. Rather, the response to this type of clinical event is governed by common or case law that has evolved through the judicial system based on legal precedent.⁽¹⁾ The determination of the courts is twofold in this regard. First, the relationship between patient and clinician is considered by the courts to be "fiduciary" in nature, in that the clinician holds a position of trust given to him/her by the patient, which implies an obligation for truth-telling. As the patient's trustee, the clinician "...has a legal duty to act primarily for the benefit of another in matters connected with his undertaking".⁽²⁾ In other words, the clinician's primary and legal responsibility is to act in the best interest of the patient, which includes informing the patient about medical conditions, treatments, procedures, and even medical errors or unanticipated outcomes of care. Under the principle of autonomy, patients have a right to know their complete medical history without any misrepresentations concerning past, present, or future medical conditions which is essential in order to make reasonable, unencumbered decisions about their health care. When warranted, patients' rights also extend to receiving just compensation for any injuries that may have been sustained in terms of pain, suffering, loss of function, lost income, and resulting costs of necessary care and rehabilitation. Without proper disclosure, justifiable compensation to those harmed by medical error or unanticipated outcomes of care may be impeded.⁽³⁾ The second ruling made by the courts around the issue of disclosure is the legal determination that withholding pertinent information from the patient may be interpreted as an act of fraud and fraudulent concealment.⁽¹⁾ Thus, it is not only in the best interest of the patient, but also of the clinician and the affected institution, to disclose all relevant information.

◆ **Benevolent Gestures -versus- Admission of Fault**

When an error or other unanticipated event occurs in the course of giving care to patients, clinicians may feel compelled to express regret and sympathy to the patients and their families, both from a personal need to do so and from the need to comply with legal, ethical, and other external imperatives. However, the manner in which this expression is conveyed is critical. There is a fine line separating what are considered acceptable and legally innocuous benevolent

gestures and those statements that can be misconstrued as admissions of fault in the court of law. If misspoken, the clinician's own words may be considered equivalent to expert testimony that can be used in favor of a plaintiff in a malpractice suit, satisfying the burden of proof requirement against the clinician. ⁽⁴⁾⁽⁵⁾ There have been inconsistent rulings in various state appellate and supreme courts concerning what are referred to as "extrajudicial admissions", or those conversations between clinician and patient that occur outside of the courtroom, where an alleged admission of fault takes place. ⁽⁴⁾ In the State of Michigan, Court Rule of Evidence 801 states that an admission of responsibility by a party can be used as evidence in the court of law if it includes a statement of guilt. ⁽⁶⁾

In an effort to address concerns around expressions of sympathy by clinicians, some states have created laws that effectively limit the admissibility of these benevolent gestures as evidence of liability in litigation involving medical malpractice or other tort cases. ⁽⁷⁾ In the State of Michigan, in the absence of explicit legislation in this regard, one can look to the established Court Rules of Evidence, which speak to the issue of the admissibility into court of certain related actions that follow after an event. One such rule (Rule 407) states that corrective or preventive actions that are taken after an event occurs are not proof of negligence even if those actions, if taken prior to the event, would have made the event less likely to occur. An example of this would be the recent reports from health care organizations that had experienced medical errors related to chemotherapy. After experiencing these events, many organizations implemented standard order forms and protocols to eliminate or reduce the errors associated with the ordering of chemotherapy. Another rule (Rule 408) states that "*Evidence of conduct or statements made in compromise negotiations is likewise not admissible.*" A "compromise negotiation" may be the offer of some form of reparation or compensation for the impact of an injury. Engaging in this kind of negotiation is not to be construed as an action that implicates one's negligence. ⁽⁶⁾

It is important to stress that benevolent gestures and statements of regret or apology, such as "I'm sorry" or "I'm sorry this happened to you", are essentially non-incriminating and do not constitute admissions of fault in the eyes of the courts. What they do represent are sincere expressions of sympathy that are highly appropriate and fitting, given situations where something negative and unanticipated has occurred in the process of giving care. In effect, benevolent gestures honor the essence of the relationship between clinician and patient.

◆ **Ethical Principles**

Many professional organizations have developed Codes of Ethics and Statements of Principles urging their members to be open about disclosing errors to patients. While each organization's position may have varying nuances, the overarching theme is one of advocating integrity and holding true to their guiding principles.

In its *Ethics Manual*, the American College of Physicians - American Society of Internal Medicine (ACP-ASIM) states: "...physicians should disclose to patients information about procedural or judgement errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may." The Manual further states: "*The patient-physician relationship entails special obligations for the physician to serve the patient's interest because of the specialized knowledge that physicians hold and the imbalance of power between physicians and patients.*" ⁽⁸⁾ Among the guiding principles that define physicians' moral duties to their patients are the duties to do no harm, to place the best interests and welfare of patients foremost, to honor patients' right to autonomy, and to preserve their right to seek justice. ⁽⁸⁾

The American Medical Association's Council on Ethical and Judicial Affairs advocates that: *"It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgement. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care."*⁽⁹⁾

There are principles that outline standards for other professions as well. The Code of Ethics of Pharmacists states *"A pharmacist has a duty to tell the truth and to act with conviction of conscience."*⁽¹⁰⁾ The Code of Ethics for Nurses states *"The nurse owes the same duties to self as to others, including the responsibility to preserve integrity and safety."*⁽¹¹⁾

The National Patient Safety Foundation issued a Statement of Principle strongly encouraging: *"When a health care injury occurs, the patient and the family or representative are entitled to a prompt explanation of how the injury occurred and its short and long-term effects. When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error and the remedies available to the patient. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients. Health care professionals and institutions that accept this responsibility are acknowledging their ethical obligation to be forthcoming about health care injuries and errors."*⁽¹²⁾

◆ **Accreditation Standards**

As of July 2001, The Joint Commission (TJC) required that information related to "unanticipated outcomes" of care be disclosed to patients. The new disclosure language resides in the chapter on Patient Rights. TJC Standard RI.1.2.2 states that: *"Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."* The intent of the standard reflects that: *"The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatment or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes."*⁽¹³⁾

When a serious incident occurs, the patients and their families are not the only ones affected. The clinicians involved in the incident may experience significant emotional responses since they may feel an overwhelming sense of responsibility for what has happened. Recognizing the impact that such events have on clinicians, TJC Standard LD.5 requires that there be *"...defined mechanisms for support of staff who have been involved in a sentinel event"* as part of the organization's patient safety program.⁽¹³⁾

◆ **Informed Consent**

In the words of Bogardus et al in their discussion around medical risk, *"Virtually every course of medical action is associated with some adverse risk to the patient."*⁽¹⁴⁾ This reality makes the legal concept of informed consent paramount. Informed consent is defined as: *"The permission or refusal granted by a patient or a patient's legally authorized representative after being fully informed about the possible benefits, possible substantial risks, possible alternative treatments, and the probability of success of the treatment or procedure."*⁽¹⁵⁾ First and foremost, informed

consent is a fundamental right of the patient and a duty of the clinician. The relationship between patient and clinician embodies a decision-making partnership that is dependent on patients receiving from their clinicians pertinent information that enables them to make informed judgements affecting their personal health and welfare. The informed consent process is the venue for that information exchange and helps build the foundation of trust between patient and clinician. Care must be given to ensure that patients comprehend the information and that their concerns are properly addressed, including any cultural or communication issues they may have. For example, treatment plans should take into consideration cultural beliefs and practices, any potential language barriers, and the impact of these factors on a patient's response to health care decision making and follow through on care planning. The manner in which clinicians respond to patients' concerns will have an affect on the success of the therapeutic relationship. Ultimately, the strength of this relationship may be a determinant of how events play out if a medical error or unanticipated outcome of care occurs.

Clinicians and patients may have different understandings of the implication and resolution of medical problems, which can affect the types of concerns and levels of expectations of both parties. By engaging in a robust discussion around the realities of a patient's medical problem, the goals of a certain course of action, and the possible limitations and risks of medical interventions; the patient should walk away with a more, well-rounded picture of the situation. The patient may be enlightened to the fact that there is some level of uncertainty in the practice of medicine and adopt more realistic expectations about clinical outcomes. In the event an unavoidable adverse outcome occurs, the disclosure process should not be as painful, given that the patient already had knowledge of the inherent risks associated with the care he/she received. (8)

◆ Dispelling Fallacies

Fallacy #1: Disclosure has limited value

On the contrary, disclosure can have significant positive value. It can serve to enhance both individual clinician and overall institutional learning around error prevention, particularly if the disclosure process feeds into a quality improvement process. Since most errors arise from multiple systems shortcomings, discovery of their root causes could lead to significant improvements in patient care practices in multiple levels of the organization.⁽⁵⁾ Disclosure enables the patient to obtain timely and appropriate treatment, to better understand the situation and any future health concerns that may stem from an injury that has occurred, to be better informed about probable outcomes, and to be an active partner in making healthcare decisions.⁽¹⁾⁽³⁾ Research also points to the therapeutic value of disclosure to the clinician as a venue for expressing regret and for receiving forgiveness.⁽¹⁾⁽⁴⁾ On an organizational level, supporting an open disclosure policy speaks to the institution's integrity, which is demonstrated by a willingness to take ownership of its systems weaknesses and to deal with them in a constructive manner.

Fallacy #2: Disclosure always leads to litigation

Based on the results of a study of one Department of Veterans Affairs facility that had actively engaged in full disclosure over a period of several years; it was found that disclosing medical errors and unanticipated outcomes of care does not result in an increase in litigation.⁽¹⁶⁾ Disclosing events may actually lower ones exposure to litigation. Most patients want their care providers to admit medical errors, both large and small. Research in this area indicates that the risk of litigation substantially increases if patients and families believe they are being deceived or mistreated by a clinician and a breach of trust has occurred. Litigation is often pursued because it

is perceived as the only means of uncovering facts that weren't revealed and of obtaining an apology. Patients and families have an expectation that they should receive a formal acknowledgement of the error by the clinician - an expectation that increases in intensity with the severity of the incident. Generally speaking, the weaker the relationship is between clinician and patient, and the more inadequate the communication and delivery of information is on the part of the clinician, the greater is the chance that the patient or family will consider pursuing litigation.⁽¹⁾⁽⁴⁾⁽⁵⁾⁽¹⁷⁾⁽¹⁸⁾ Research also suggests that in addition to obtaining a better understanding of what went wrong and an apology, what patients and families often seek is an assurance that something has been done to lessen the likelihood of the same thing happening again to others. Many patients and their families have a strong desire to see constructive changes in clinical practice as a result of what they went through, so that some valuable lessons will be learned from the experience.⁽¹⁹⁾

Fallacy #3: Error always equates to negligence

Clinicians may believe that most medical errors or unanticipated outcomes will be perceived as negligent acts, the disclosure of which will increase their legal risk. While it is true that the manner in which a disclosure conversation plays out may enhance or minimize legal risk; if done properly, neither the disclosure of the error nor the error itself necessarily create liability. This is reinforced in the Ethics Manual of the American College of Physicians - American Society of Internal Medicine, which states: "*Errors do not necessarily constitute improper, negligent, or unethical behavior...*"⁽⁸⁾ Negligence may only be considered in a malpractice lawsuit if the courts determine that the following criteria are met:

- ♦ If a relationship has been established between a clinician and a patient, this implies a duty on the part of the clinician, by virtue of his/her special competencies, to exercise reasonable diligence, care, and skill.⁽²⁰⁾
- ♦ If there is a failure on the part of the clinician to deliver an acceptable "standard of care", which when compared to others practicing against the same standard, would render the clinician's practice invalid. The burden of proof is on the plaintiff to prove that the conduct of the clinician failed to meet recognized standards within the medical community.⁽⁴⁾⁽⁵⁾⁽²⁰⁾
- ♦ If there is a factual, logical, and foreseeable connection between the clinician's conduct (an act or an omission) and the injury.⁽²⁰⁾
- ♦ If there is actual physical, emotional, economic, and future injury to the patient.⁽²⁰⁾

Most near-miss incidents that occur in healthcare fail to meet the above criteria, as do many other incidents that actually reach patients, resulting in some minimal harm. Even if the errors necessitated additional testing/treatment or a more intense level of clinical observation and monitoring, these incidents would still oftentimes fail to meet the test of damages required by the legal system. For example, a patient may have been given Insulin that was meant for another patient. As long as there was no injury to the patient or the above criteria were not met, there would be no consideration of a malpractice claim afforded under the law. Past studies have examined the relationship between patient injuries and malpractice claims. One major study conducted out of Harvard evaluated 280 medical charts that pointed to patients being injured due to probable negligence. Their findings determined that only 47 of these actually resulted in the filing of claims against the clinician.⁽²¹⁾

CHALLENGES

◆ **The Disclosure Controversy – At what level of error should disclosure occur?**

The overwhelming consensus around disclosure is that it is the right thing to do. The critical question is, “*At what level of error should disclosure occur?*” Most organizations discover that a gray area emerges when attempting to translate what the right thing to do is into actual practice. Developing and implementing criteria that clearly determine whether or not specific types of incidents should be disclosed may be challenging. Guidelines offered by the Joint Commission and by professional organizations differ around the minimum event criteria for disclosure. The American College of Physicians – American Society of Internal Medicine suggests disclosing if it is “material” to the patient’s well being, but who decides on behalf of the patient what is material to his/her well being? The American Medical Association advises disclosing when there are “significant” medical complications, yet who decides what level of severity should be the cutoff point? The Joint Commission’s minimum event criterion is any “unanticipated outcome”. The National Patient Safety Foundation bases the disclosure threshold on the occurrence of an injury. Each institution must decide what criteria it will use in determining the threshold for disclosure.

There is also difference of opinion as to the causes of the errors as determinants of disclosure. Criteria range from disclosing incidents that are due to clinicians' mistakes, procedural or judgement errors, to any unanticipated outcomes. Wu argues for disclosure if a patient is harmed due to the individual clinician's own lack of adequate knowledge, skill or attentiveness.⁽³⁾ Furthermore, there is little guidance on what to do in the case of minor errors or near-misses. In an attempt to clarify the confusion, many organizations like the Pennsylvania Association for Health Care Risk Management (PAHCRM) have developed “event severity scales” that are used as decision aids around the issue of disclosure. Some of these scales are modeled after the “NCC MERP Index for Categorizing Medication Errors Algorithm” developed by the National Coordinating Council for Medication Error Reporting and Prevention. (The algorithm is included in this toolkit.) As to PAHCRM’s use of the scale, they have determined that disclosure is not required for errors that do no harm, which include errors that may necessitate increased patient assessments but with no change in vital signs and no patient harm.⁽²²⁾

Varying ethical theories can be applied in resolving this issue. One theory presents a framework for weighing the consequences of disclosure in terms of its potential benefits and harms, in relation to the “moral reference group” (the affected party/entity) as a means of determining in whose overriding best interest it would be to disclose. A second theory takes into consideration the guiding principles that should weigh into the disclosure equation. This theory generally places greater weight on the ethical duties of clinicians to their patients than on any negative consequences the clinician may experience, particularly when it upholds the rights of patients. The prevailing argument is that the fiduciary (trustee) duty to patients outweighs any possible negative effects of disclosure for the clinician.⁽³⁾⁽²³⁾

At the other end of the spectrum, there are those who argue that in some cases the patient's autonomy may be undermined by disclosure and that the withholding of information may be justified. However, one must exercise caution when making this kind of decision. Withholding information on the grounds that disclosure would inflict such immense and irreversible harm to the patient, largely on the basis of the patient’s instability, is a rationale that must be employed judiciously. Even when this “therapeutic privilege” is determined to be highly appropriate at the time of an incident, the clinician must be prepared to justify this decision, and the question of whether or not to disclose should be revisited when the patient returns to a more stable

condition.⁽³⁾⁽²³⁾⁽²⁴⁾ (Included in this toolkit is an instrument designed to be used on an institutional level in establishing a policy for disclosure that walks organizations through the decision making process discussed above.)

◆ **What to Disclose?**

It is recommended that disclosure take place in a timely manner following the occurrence of an incident. Since it is unlikely that all of the potential root causes would have yet been uncovered at this juncture, there is a question of what exactly should be disclosed. Honesty is foremost, yet care needs to be given to the manner in which facts are revealed in order to minimize unnecessary distress for patients and clinicians alike, as well as to minimize the unnecessary creation of any adverse legal circumstances. Information should be conveyed in a factual manner, without any premature declarations of wrongdoing. The following is the suggested sequencing of how the information should be revealed. Factual statements should be made regarding:

- A. What happened
- B. How it happened
- C. Why it happened (To the best of your knowledge)
- D. What the professional or facility is going to do to assist the patient and family
- E. What steps have been or will be taken to reduce the likelihood of this happening in the future

◆ **How to Disclose?**

The process of disclosure involves numerous considerations that need to be made before, during and after the disclosure conversation. These include making decisions about who should deliver the information, the best timing for disclosure, how it should be articulated, how to remediate injury, and ascertaining the probable causes of the negative outcome. Each organization must determine what the proper protocol should be when an error or unanticipated outcome occurs. The most challenging part of this process is often the disclosure conversation itself, due to fear of repercussions, inexperience in delivering this kind of information, and uncertainty about how the patient and family will react. What follows after delivering the news is also a critical part of the entire disclosure process, both in terms of proper response to the reactions of patients and families, and support for the clinicians involved in the incident. (Included in this toolkit are detailed guidelines on how to engage in the process of disclosure.)

The process of disclosure should be approached with sensitivity to the patient's ethnic culture. This involves having a basic knowledge of how certain ethnic populations may prefer to communicate and involve themselves in patient care, what their perceptions are of medicine, what their beliefs and practices are, and how they may handle bad news, particularly death. Bear in mind that these are cultural generalizations and they serve only to heighten ones awareness of the possible inclinations of certain groups of patients. For example, in the Cayman culture, the preference may be to speak with physicians rather than other practitioners. The Spanish culture may prefer strong eye contact when communicating and the presence of family. The response by Chinese individuals to a question may be "yes" to indicate that they have heard what was said, not necessarily that the information was understood. In the Japanese culture, there may be a hesitancy to ask questions because of their perception of physicians as authority figures. The Russian culture tends to be averse to giving bad news to patients. According to the traditional norms of the Cuban culture, the proper protocol for delivering news of serious illness is to first inform the patient's spouse or eldest child, who is then responsible for informing the patient. Awareness of certain cultural characteristics is important to ensure that patients and families of

varying ethnic origins are treated in a manner that is respectful of their cultural norms. These generalizations are not intended to be a justification for deciding not to disclose.⁽²⁵⁾⁽²⁶⁾

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References

- (1) Porto G. Disclosure of Medical Errors: Facts and Fallacies. *American Society for Healthcare Risk Management*. 2001.
- (2) Gifis S. *Law Dictionary*. 3rd ed. Barron's Educational Series, Inc; 1991.
- (3) Wu A et al. To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine*. 1997;12:770-775.
- (4) Berlin L. Malpractice Issues in Radiology. *American Journal of Roentgenology*. 1999.
- (5) Kapp M. Medical Error versus Malpractice. *DePaul Journal of Health Care Law*. 1997.
- (6) State of Michigan. *Michigan Rules of Evidence*; as amended effective April 1, 1996.
- (7) Prager LO. New laws let doctors say "I'm sorry" for medical mistakes. *American Medical News*. 2000.
- (8) American College of Physicians - American Society of Internal Medicine. *Ethics Manual*. 4th ed.; 1997.
- (9) American Medical Association. *Current Opinions of the Council on Ethical and Judicial Affairs: E-8.12 Patient Information*. 1994.
- (10) American Pharmaceutical Association. *Code of Ethics for Pharmacists*. 1994.
- (11) The American Nurses Association. *Code of Ethics for Nurses-Provisions*. 2001.
- (12) National Patient Safety Foundation. *Talking to Patients About Health Care Injury: Statement of Principle*. 2000.

- (13) Joint Commission on Accreditation of Healthcare Organizations. *Revisions to Joint Commission Standards in Support of Patient Safety and Medical / Health Care Error Reduction*. Oakbrook Terrace, IL: JCAHO; 2002.
- (14) Wu A. Handling Hospital Errors: Is Disclosure the Best Defense? *Annals of Internal Medicine*. 1999;131:970-972.
- (15) Witman A et al. How Do Patients Want Physicians to Handle Mistakes? A Survey of Internal Medicine Patients in an Academic Setting. *Archives of Internal Medicine*. 1996;156:2565-2569.
- (16) Johnson C, Horton S. Owning up to errors: Put an end to the blame game. *Nursing*. 2001.
- (17) *Risk Management Handbook*. 3rd ed. Chicago, Il: AHA Press.
- (18) Brennan T et al. Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study 1. *New England Journal of Medicine*. 1991; 324: 370-376.
- (19) Bogardus S et al. Perils, Pitfalls, and Possibilities in Talking About Medical Risk. *JAMA*. 1999;281.
- (20) Opus Communications. *JCAHO Changes for 2002*. Marblehead: Opus Communications, Inc; 2002.
- (21) Rosner F et al. Disclosure and Prevention of Medical Errors. *Archives of Internal Medicine*. 2002;160:2089-2092.
- (22) Lee S et al. Medical Students and Remediation of Error. *JAMA*. 2001;286:1082-1083.
- (23) South Miami Hospital. *Culture Tool*; 2001.
- (24) Lipson J, ed, Dibble S, ed, Minarik P, ed. *Culture and Nursing Care Pocket Guide*. San Francisco, Ca: UCSF Nursing Press. UCSS Nursing Press. University of California, San Francisco; 1996.

PRIMERS – Recommended Reading

- ❑ Wu AW, Cavanaugh TA, McPhee SJ, Lo B, Micco GP et al. To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine*. 1997;12:770-775.
- ❑ Porto GG. Disclosure of Medical Errors: Facts and Fallacies. *American Society for Healthcare Risk Management*. 2001.
- ❑ Midwest Medical Insurance Company. Adverse Outcomes: telling your patients about mistakes. *Perspectives on Prevention*. 2000:1-5.
- ❑ Ott M. Key Considerations on Drafting a Policy on Disclosure of Unanticipated Outcomes. *American Society for Healthcare Risk Management*. 2001. (Refer to Tools & Templates section for a copy of Appendix A)

- ❑ NORCAL Medical Insurance Company. Responding to Medical Errors: Disclosure is the Best Medicine. *Claims Rx*. 2001: 1-7.
- ❑ *Informed Consent: A Medicolegal Primer*. University of Michigan Hospitals and Health Centers. Available at: <http://www.med.umich.edu/i/policies/medlaw/CONSENT.htm>. (Last updated: July 29, 1999) (Accessed: October 11, 2002).