

MMAP NEWS



A Risk Management Publication of the Mississippi Medical Malpractice Availability Plan

Issue 7 – July 2006

Disclosure of Unanticipated Outcomes

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Introduction

All health care facilities and providers maintain processes which call for the reporting of adverse events. In virtually every instance, communication with the patient following the event is a requisite of the policy. The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) requires that institutions have a process in place to disclose unanticipated outcomes to patients and families. This standard has been in place since July 2001. The JCAHO interpretation of the intent of this standard states:

“At a minimum, the patient and when appropriate, the patient's family is informed about the following:

- 1. Outcomes of care, treatment, and services that have been provided that the patient (or family) must be knowledgeable about to participate in current and future decisions affecting the patient's care, treatment, and services*
- 2. Unanticipated outcomes of care, treatment, and services that relate to sentinel events considered reviewable by the Joint Commission*
- 3. The responsible licensed independent practitioner or his or her designee informs the patient (and when appropriate, the patient's family) about these outcomes of care, treatment, and services”*

Disclosure of errors and unanticipated outcomes has become an important element of the Patient Safety movement. That patients or their representatives

should receive a truthful and compassionate explanation about the error and remedies available has been universally endorsed by organizations such as the American Hospital Association, The Department of Veterans Affairs, the National Patient Safety Foundation, and many others.

The expectation of today's patient is that they will be more involved in healthcare decisions. Moreover, they want and expect their physicians to acknowledge errors even if they are not injured. A survey published in the Annals of Internal Medicine in March 2004, indicated that 91% of respondents agree with the following general statement about medical errors:

“Patients should always be told if an error is made even if the patient is not injured or harmed.”

In another survey conducted on behalf of the National Patient Safety Foundation, some 95% revealed that the respondents desired to be informed about even the most insignificant error. As such, it is clear the patients' full disclosure results in an increase in patient satisfaction, trust and a positive emotional response.

To be sure, many obstacles to compliance with JCAHO's mandate have surfaced. Such obstacles characterized as “psychological barriers” by the American Society of Healthcare Risk Management (ASHRM) in their May 2003 monograph titled

“Disclosure of Unanticipated Events. The Next Steps in Better Communication” include the following:

- fear of retribution from the recipient of the news
- the fear of retribution from colleagues or peers
- fear of conducting the conversation poorly
- fear of having to handle the recipients, as well as, their own emotions
- the belief that the disclosure is unnecessary
- belief that the outcome is not related to action on the part of the discloser
- belief that the outcome would potentially have occurred without the error intervention

In all likelihood, the most significant barrier to physicians and other care providers disclosing errors is the fear that the disclosure will increase the potential for a medical malpractice claim or lawsuit.

This article will address a number of aspects surrounding the disclosure of unanticipated outcomes. Specifically, the following areas will be addressed:

- Definition of unanticipated outcomes
- Who is responsible for the disclosure
- What must be disclosed
- When must disclosure take place
- Documentation of disclosure
- The disclosure policy
- Conclusions and recommendations

Definition of Unanticipated Outcomes

JCAHO defines unanticipated outcomes as outcomes which differ significantly from anticipated outcomes. This is an attempt to distinguish complications to a treatment from complications of disease. This has led to confusion. For example, interpretation of postoperative infections may very well be “anticipated” and as such, not require disclosure. Moreover, interpretations of the JCAHO standard as to events which require disclosure range from reviewable sentinel events to “anything and everything” whether or not of any clinical significance. Given the general, somewhat inexact nature of the JCAHO standard, most facilities have adopted its own operational definition of unanticipated outcomes.

For the purposes of this article the definition put forth by ASHRM is utilized:

Adverse Event: An injury that was caused by medical management rather than the patient’s underlying disease; also sometimes called “harm,” “injury,” or “complication.”

- An adverse event may or may not result from an error. See further classification of preventable and unpreventable adverse events below.
- “Medical management” refers to all aspects of health care, not just the actions or decisions of physicians or nurses.

Medical Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical errors include serious errors, minor errors, and near misses. (Note: A medical error may or may not cause harm. A medical error that does not cause harm does not result in an adverse event.)

In addition, we define the following:

Serious Error: An error that has the potential to cause permanent injury or transient but potentially life threatening harm.

Minor Error: An error that does not cause harm or have the potential to do so.

Near Miss: An error that could have caused harm but did not reach the patient because it was intercepted.

Preventable adverse event: An injury (or complication) that results from an error or systems failure. Even if one agrees that individual errors are often the end result of systems failures, they are still perceived by patients and caregivers as very personal events. It is useful to distinguish three categories:

- Type 1: Error by the attending physician.
Example: technical error during performance of a procedure
- Type 2: Error by anyone else in the healthcare team.
Examples: a nurse gives wrong medication to patient; a resident makes a technical or decision error; a radiologist misses a lesion.
- Type 3: Systems failure with no individual error.
Examples: IV pump failure that causes drug overdose; failure of system to communicate abnormal lab results to ordering physician.

Who Should Disclose

Regarding who is responsible for the provision for disclosure, hospitals have established policies, which clearly indicate persons responsible for disclosing medical errors. The intent of JCAHO is for the responsible licensed independent practitioner (LIP) to clearly explain the outcome of any treatment or

procedure to the patient and, when appropriate, the patient's family. The perception of the majority of facilities appears to be the physician is the most appropriate individual to provide the disclosure discussion.

To support the physician in this role, some facilities have established a "disclosure team" which includes, for example, representatives from risk management, patient safety, and legal departments, in addition to the LIP. The entire team does not necessarily take part in the actual disclosure conversation with the patient but assists the LIP in preparing for the discussion. To the degree possible, the team ensures that the task of delivering the "disclosure" will be conducted in the most open and effective manner for all parties.

One area where the preparation for disclosure is potentially of great utility is the manner in which an apology will be expressed. Physicians offer apologies to patients routinely during the disclosure process. There is no question that an expression of understanding and sympathy should be offered to the patient and family. Additional verbiage may, however, imply fault or guilt and should be scrupulously avoided.

Another aspect which has proven to be helpful in the disclosure process is where the practitioner can reference the consent discussion. This is especially useful in those circumstances where a thorough discussion of risks to the patient transpired. Where this has transpired, the practitioner is able to remind parties of the conversation that took place where the risks were discussed. The patient would be informed that unfortunately one of the risks referenced during that discussion has happened. The practitioner must then proceed to explain to the patient what steps will be taken to address this situation.

When Disclosure Should Take Place

Hospital policy should specify when disclosure is to be conducted. The delay of disclosure longer than 24 to 48 hours subsequent to the discovery potentially diminishes its impact. Clearly, the timing of the explanation is of great importance. The patient/family feels entitled to an explanation as soon as possible following an unexpected outcome. The longer the wait for accurate information; the greater potential for frustration and anger. Obviously, this is precisely what the disclosure process is designed to avoid. As such, timeliness of the disclosure communication is material to a successful process.

Disclosure Content

As regards to what to disclose, it is appropriate to discuss the facts as documented in the medical record. The patient should be educated as to clinical implications of the unanticipated outcomes, including the necessary therapies and treatment. Moreover, what the patient can expect in the future should be clearly addressed. The disclosure discussion might be structured to convey the following elements:

- the nature of the event/accident
- the time, place, circumstances surrounding the event/accident
- causation factors
- known consequences to the patient
- potential consequences to the patient
- actions taken in response to accident
- individual(s) who will manage the ongoing care to the patient
- individual(s) who will manage communications with the family
- actions taken to address system issues which possibly contributed to the accident in an effort to prevent future occurrences
- charges/expenses directly related to the accident that will be removed from the patients bill
- perhaps most importantly, the facility staff regrets that the unanticipated outcome has occurred

Documenting the Disclosure

Hospital policy should contain specific information on what to document relating to unanticipated outcomes. ASHRM advises that documentation be considered which includes the following:

- Documentation of the time, date, and place of the discussion.
- Recordation of the name and relationships of those present.
- Documentation that there was a discussion of the unanticipated outcome.
- Documentation in appropriate cases that as further information becomes available, this information will be shared with the patient, family, or legally authorized representative.

- Documentation of an offer of assistance and the response to it.
- Documentation of any questions posed by the patient, family, or legally authorized representative, and that answers provided by the caregiver.
- In specific cases in which a decision is made to withhold some or all information, appropriate documentation is made of the reason(s) for this decision. It is acknowledged that in some cases the documentation may be separate from the medical record to protect the safety or welfare of the patient or to prevent interference in law enforcement investigations.
- Any follow-up discussions should be documented, including time, date, place, and the names and relationships of those present.

Disclosure Policy

Whereas, JCAHO has not specifically mandated a written policy, it is generally acknowledged that a policy should be in writing. An unanticipated outcome policy/procedure should establish a framework for discussing anticipated outcomes. It should demonstrate that the process is in place which addresses the JCAHO standard and promotes consistency in interpretation. Policy elements should address who, what, when and where disclosure is to be provided.

The stated objectives of the disclosure policy should include assuring that patients and, where appropriate, their families are fully informed about the outcomes which are unexpected. The policy should define terms such as “disclosure” and “unanticipated outcome.” The policy should, moreover, identify responsibilities of individual's to inform patients about unanticipated outcomes of care. This includes specifically defining the role of the attending physician or other LIP.

Conclusion

It is clear that when unexpected outcomes happen, most patients want detailed explanations, a sincere apology, and assurances that steps will be taken to prevent recurrences.

Thus, if a patient suffers an unexpected outcome:

Act honestly. If the patient is not informed about an error by you, someone else, possibly an attorney, certainly will.

Act quickly to correct treatment errors, and to change policies and procedures to lessen the chance that an error will happen again.
Plan your conversation with the patient or family to ensure the information conveyed is factual, objective, complete, and free of medical jargon.

Don't make inaccurate statements or guess about causes.

Accurately document the disclosure conversation

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