

R I S K M A N A G E M E N T

PEARLS

on

DISCLOSURE OF ADVERSE EVENTS

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ASHRM[™]

American Society for
Healthcare Risk Management
of the American Hospital Association



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Each edition of the ASHRM Pearls series includes tips on how to minimize liability exposures in the subject areas identified by the titles. These easy-to-use pocket guides cover risk management and legal issues that busy health care practitioners may encounter on a day-to-day basis.

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Pearls on Disclosure of Adverse Events

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Foreword

The importance of effective disclosure of medical events must not be understated. It is characterized by a culture of safety and defined by trust, respect for human rights and forgiveness. It is enabled by ongoing and transparent communication with patients and families.

The following pages represent the work of the American Society for Healthcare Risk Management since 2001 to identify emerging practices for disclosure. We invite you – the risk manager, patient safety officer, clinician, administrator, trustee, underwriter or policy expert – to share this document with your patient safety team, keeping in mind that patients and family members also are on the team.

We believe that *Risk Management Pearls on Disclosure of Adverse Events* – by describing organizational scenarios and strategies for implementing and enhancing the communication of disclosure in your organization – will further inform and facilitate the dialogue around the practice of disclosure and draw us all toward ASHRM’s vision of “safe and trusted health care.”

This vision is grounded in our patients’ perspectives, as presented during the December 2005 Institute for Healthcare Improvement Forum “Reflections of Patient and Family Voices”:

Patient Expectations: 100 Percent of the Time

- To be listened to, taken seriously and respected as a care partner
- To be told the truth – always
- To have my care timely and impeccably documented
- To be supported emotionally as well as physically
- To receive high quality, safe care

Your colleagues in safety,

Peggy Martin
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Introduction

The disclosure of adverse events, or unanticipated outcomes, is an evolving process in health care. Issues center on when, how and what to say during disclosure.

This booklet does not address the legal considerations surrounding disclosure, which should be part of each facility's planning process based on local law and practice. Rather, it is designed to help health care providers understand the regulatory background of disclosure and the interpersonal concerns it raises.

A Growing Concern in Health Care

“Disclosure” has been part of health care for many years. Physicians and other health care providers disclose daily. They share information about diagnoses, prognoses or complications of treatment.

However, physicians have long debated the extent to which devastating prognostic information should be revealed. Once malpractice liability first became a particular concern in the late 1970s, the decision whether to disclose unanticipated treatment outcomes, especially when there was possible error and therefore litigation potential, was pre-empted by legal considerations and emphasis on evidentiary protection.

Nevertheless, professional organizations have long promulgated ethical statements that required full disclosure of outcomes and the providers' role in them. (1)

Joint Commission Standard amplifies debate

In 2001, Standard RI.1.2.2 of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required accredited facilities to establish a process for the disclosure of unanticipated outcomes of care. This new standard amplified the debate about the roles of patients and providers in a new, patient- and family-focused health care world, forcing providers to re-think their former responses. Accredited health care organizations were suddenly required to be forthcoming about information often viewed

as potentially damaging. Now compelled to disclose, health care providers are learning that the practice may be less detrimental to malpractice outcomes than predicted and that it may be beneficial to reasonable claim management efforts. In spite of earlier fears, experience is demonstrating that disclosure actually may be viewed favorably by jurors and the community. (2, 3)

Unfortunately, the infrastructures that respond to such honesty are not changing so quickly. The legal system still functions in a punitive mindset. Licensure and professional boards still hold individuals, not systems, accountable for error. The availability of emotional support for those involved in treatment gone awry has lagged the need. Insurance companies and claims committees may respond slowly with the financial follow-up to a smooth disclosure.

Concerns remain about the legal damage that can result from a poorly conducted disclosure discussion. Providers (and their attorneys) fear that hearsay may become “fact” by virtue of thoughtless comment or patient misunderstanding. Apology may be misinterpreted as culpability. Discloser discomfort may be interpreted as dishonesty. Fortunately, careful education, process development and training can overcome these concerns.

The purpose of disclosure

Health care providers must focus on the overriding purpose of disclosure: to provide patients and families complete information about their care. Appropriate treatment decisions and planning require this level of honest communication. The decision to disclose shouldn't revolve around efforts to avert litigation, but rather around the shared goal of providing patients and families information needed to make decisions about next actions.

This educational booklet is intended to help providers disclose in ways that provide the most effective communication with the least risk, based on research about techniques for effective communication with patients and families.

EMERG

Current State of Affairs

What We Have Learned

A search of the literature on disclosure from the release of the Institute of Medicine (IOM) report in December 1999, “To Err Is Human: Building a Safer Health System,” to the present reveals more than 450 published articles related to disclosure, apology and the impact of disclosure on litigation.

Most of the literature reiterates what has been assumed intuitively and established by early research: Patients want to know what has happened during care. They want the health care entity and their providers to assume responsibility for errors. Patients and their families want an explanation, apology, and assurance that the health care organization is making steps to assure that system problems are addressed so that their suffering is acknowledged and not taken lightly.(4)

But it's not that easy. Legal constraints and human fear inhibit the transparent discussion of adverse/unanticipated events. Moreover, the nature of medical care which complicates the discernment of error from outcome renders discussion a delicate and tricky matter.

Need for provider support, too

Health care providers live in a very stressful environment, with huge personal responsibility and the constant threat of burnout.(5, 6) After an event, any provider is devastated, often feeling as much pain and anguish as the family or patient. Support systems are notably absent. Providers refrain from talking about their involvement in an untoward event because of fear of judgment, being ostracized or being considered incompetent.(7) Consequently, there is a second “victim” of the event in need of guidance and support.

Resources are appearing to meet that need for support. A multitude of articles, books, videos and training programs have emerged that approach this delicate issue. Furthermore, organizations such as Medically Induced Trauma Support Services (www.mitss.org) and Consumers Advancing Patient Safety (www.patientsafety.org) have come forward to support providers as well as patients. Other organizations such as the Sorry Works! Coalition (www.sorryworks.net) have been formed to encourage change in legislation such that apology and transparency are supported and rewarded instead of punished by the legal system.

Impact of Disclosure on Patient Safety

Safety science and aviation industry models show that health care providers can prevent the re-occurrence of system breakdown only through evaluating the full range of latent failures that led to the ultimate outcome.(8) To move health care from a “craft” to a science, the focus should be on becoming “high reliability organizations,” preoccupied with failure and its prevention.(9) This ideal can be achieved only in an environment of transparency and open dialogue about misadventures.

Roles in root cause analyses

Disclosure of adverse/unanticipated events to patients and families includes them in the discussion of system failure. It makes them partners in efforts to improve care. Furthermore, when they are included in a root cause analysis (RCA) or other evaluation of the process, they are engaged in the patient safety process.

The patient safety movement is predicated upon the concept that errors occur in complex systems and that information must be received from all parts of the system in order to avoid error and to correct latent system failures.(10) Initiatives such as The ASHRM Foundation’s Patient Safety Toolkit (www.ashrmfoundation.org) and JCAHO’s Speak Up Initiative (www.jcaho.org) are designed to teach patients and families how to be advocates and partners. Nonetheless, the best-designed programs are doomed to failure unless both parties to the communication are willing and able to trust the other to be honest and forthright with information.

Although many organizations maintain that the results of an RCA should be protected for quality assurance and peer review purposes, other organizations have opened up the RCA process for inclusion of family members. Others have openly shared their findings with families in an effort to communicate the organization's sincere efforts to assure the same injury will not re-occur to another patient.

The seminal Vincent study (1994) (11) implied that patients and families not only wanted an explanation for their own knowledge, but also wanted assurances that the same mistake would not be experienced by another patient. This leads to the question: What is the best way to prevent liability, if by including the patient and family we satisfy their deep-seated desire for involvement and improvement?

The ramifications of sharing the results of the RCA are subject to state laws. If sharing would jeopardize the confidentiality or privilege attached to the entire quality assurance process, then the organization should make steps to communicate key findings with the persons involved.

Impact of Disclosure on Litigation

Health care is fraught with a history of distrust between providers and patients/families they serve, reinforced by the notion of medical authority. (12) The legal system has exacerbated this tension through litigation procedures. Plaintiff's attorneys are quick to say that fear of conspiracy or cover up is a primary motivator for families to seek legal counsel after an unanticipated event.

This journey of transparency and disclosure is still new. Few completed studies accurately measure the impact of disclosure and transparency on litigation. The evolution of an event to a claim and suit with its commensurate litigation lag is long. In addition, the number of people who are adequately trained to lead an effective disclosure is still small, although it is growing. There simply is not a sufficient amount of data to make long-term predictions about the effect of disclosure on litigation at this time.

A few things are known:

- The Lexington, KY, Veterans Administration Hospital made significant changes in its approach to communicating with patients and families about unanticipated events when risk managers saw their claims activity rising. The hospital began to offer full and spontaneous disclosure of all relevant information. Thereafter, the claim volume remained consistent with other similar VA facilities, while the total indemnity payments did not increase. Lexington apparently substantially reduced the defense costs associated with its claims. The Lexington protocol is now the rule in all VA hospitals. (13)
- A mock trial of a 2002 suit that resulted in a multi-million dollar judgment in favor of the plaintiff was conducted before two juries, one including disclosure, the other without disclosure. The disclosure trial yielded a judgment millions of dollars smaller than the original award to the plaintiff. The jury de-briefing revealed that where there was no disclosure, the jury assumed the organization was hiding information. In the trial involving disclosure, the jury process was less adversarial to the hospital. The jury expected honesty and therefore centered the discussion on the actual needs of the plaintiff and not on how much money was required to punish the organization. (14)
- A more recent study reviewed the literature on the impact of disclosure on litigation. It found that:
 - Disclosure did not necessarily reduce the likelihood of litigation.
 - Where litigation was pursued, the discloser was seen more favorably than the non-discloser, resulting in lower awards. (15)

New Expectations

Disclosure has become expected behavior for the health care system. With the JCAHO standard and growing public awareness, people within and outside the system expect that adverse/unanticipated events should be disclosed to patients and families. This moves health care away from the “medical authority” model where the physician is expected to have all the answers, to a “system authority” model where the physician is part of a group of people who provide services in an effort to restore health and provide safe, humane care. In this new model, the expectations for disclosure have grown from simple adherence to a standard to a new height of personal commitment and compliance.

Expectations in this new environment include:

- Disclosure is the normative expectation for behavior, not the exception, in the minds of patients and families.
- Disclosure goes beyond legal compliance to fully meet ethical requirements. The culture in the United States values autonomy, or the right to direct what is done to one’s person. Individuals have the right to know what has happened that was not within their control.
- If a party has been injured at the hands of another and compensation is appropriate, patients/families expect that remuneration to be forthcoming. Increasingly, patients and families are heard to say that the goal is not litigation, but appropriate acceptance of responsibility and appropriate remuneration.
- Disclosure can reduce the severity, and possibly the frequency of litigation, although that is not its primary goal.
- Disclosure is both a process (technique) and art (interpersonal communication skill). Patients and families recognize the difference between sincere and insincere communication.
- The future of patient safety as a pervasive cultural influence is contingent on transparent communication and disclosure. Without open communication with patients and families, errors will continue to be hidden and impede the full exploration and evaluation of error components.

Facing Challenges

The barriers to disclosure fall into two primary areas: psychological and legal. Although both are important, the psychological barriers are more entrenched in the individual and are more difficult to address. The legal barriers, although genuine and important, are often the excuse to avoid disclosure. Both come into play in organizations' struggles to improve the culture of safety. When both are addressed, the culture of transparency can move forward.

Psychological Barriers

Psychological barriers to disclosure are the stronger of the two. They are no different from barriers to any other difficult communication that involves bad news. Physicians and other providers have difficulty deciding what to say to patients and families, how much to disclose and when to disclose. Psychological barriers may include:

- **Fear of retribution from the recipient of the news.** “Will the recipient try to punish or harm me?”
- **Fear of retribution from colleagues or peers.** “Will I be ostracized or otherwise criticized for my involvement in the unanticipated event, or for my action as part of the disclosure discussion?”
- **Fear of conducting the conversation poorly.** “What if I upset the patient or family if I don't convey the information effectively? Will the hospital be angry with me for communicating ineffectively?”
- **Fear of having to handle the recipient's as well as their own emotions.** “What if the patient or family member cries, becomes angry or threatens me?”
- **Belief that the disclosure is unnecessary.** “If we didn't tell the family, they would never know this had happened.”

- **Belief that disclosure is primarily a factual conversation and not a complex interpersonal conversation.** “If I just state the facts, haven’t I disclosed adequately?”
- **Belief that the outcome is not related to action on the part of the discloser.** “If I were not directly involved in the event leading to the outcome, why should I be involved in disclosing the outcome?”
- **Belief that the outcome would potentially have occurred without the error or intervention.** “What difference would it make? The patient might have had the outcome anyway. He/She was very old and/or sick.”

Legal Barriers

Legal barriers to disclosure are a moving target with a history. Unfortunately, the legal system in the United States is entrenched in a culture of blame and punitive approaches. After decades of litigation-phobia, health care providers are finding that responses based on relationship rather than fear of litigation may be the best. In other words, the “legal” barriers to disclosure are based on our fears, not necessarily on the law.

The system rewards itself (attorneys) through payment based upon how much time is spent on a claim, or with a piece of the take (plaintiff’s counsel). In neither case does the reward depend on the benefit to the parties.

Additionally, the legal system is based upon a system of discovery that relies on the protection of information as a tool for defense. When providers began searching for a risk management and loss control model 30 years ago, they turned to their defense lawyers for advice. Health care organizations arguably learned how to defend cases, but learned very little about preventing litigation in the first place. That history has generated some unfortunate perceptions among health care providers about the impact of their actions after an incident.

The following fears have overtaken the management of events:

- **Fear: There is no legal protection for any information provided during the disclosure of a medical error.**

Reality: It is true that information we share with the patient will be admissible.

- **Fear: Information about the disclosure in the medical record may be used in court.**

Reality: It is true that information in the medical record is admissible.

- **Fear: Disclosure increases our risk if there is a suit.**

Reality: This is not clear. Simply because information is admissible does not mean that it will be either used against us or perceived by the jury as indicative of guilt or greater culpability. In fact, the failure to disclose information that later becomes known is much riskier.

- **Fear: An apology is an admission of guilt; therefore you automatically lose a lawsuit.**

Reality: An apology is simply an expression of emotion, not a legal conclusion. It may or may not support a factual determination of negligence, but the apology cannot alter the facts.

Though there are no real studies of the issue, anecdotal evidence is quickly mounting that most juries find an apology and full disclosure the most humane approach and that they may actually help the defense of a suit. Unless the defense is based on different facts than those disclosed (a separate problem), dealing with the facts in an open and honest manner generally helps the defense. (16)

Because so many providers fear apology, some states have enacted statutes that prohibit the use of an apology as evidence of guilt, or prohibit its introduction into evidence. In 2006, SorryWorks reported that 18 states have law governing the use of apologies in trial. In most states, the laws protect apologies of sympathy, but not apologies of responsibility. A person could apologize that the plaintiff had been harmed, but would not be protected if the apology included an admission responsibility for the harm.

More recent statutes (for example, Colorado Revised Statutes Title 13, Article 25) may protect some statements of responsibility or fault. Organizations such as SorryWorks are lobbying to get as many states as possible to support legislation like Colorado's.



States With Apology Laws

Arizona
California
Colorado
Florida
Georgia
Illinois
Maryland
Massachusetts
Montana
North Carolina
Ohio
Oklahoma
Oregon
Texas
Virginia
Washington
West Virginia

Vermont has no apology statute; however, case law provides immunity for a doctor's apology.



Source: SorryWorks, 2006

Managing the Process

Every organization has a unique culture and a unique path to addressing the issues in patient safety and disclosure. Needs and available resources vary dramatically. No one model for disclosure will satisfy all facilities' needs; four are presented here, together with a discussion of their benefits and drawbacks. Generally, other activities will be concurrent with the disclosure process. For example, if there is likely liability, the facility and its carrier should be evaluating necessary settlement authority and the best person to present the financial position.

In deciding on a model, a facility should evaluate the need for staff to also participate in quality activities, the role and identity of malpractice claims contacts and the realistic time commitment various staff members can make to the process.

One-Person Model

- **Description:** The organization designates one person as the anchor for all disclosure communication.
- **Benefit:** The organization can assure itself that the designated person can be trained to have the communication skills for effective disclosure.
- **Drawback:** Anything that happens to that person leaves the organization in a state of jeopardy. Furthermore, this model does not move the organization forward to having all communication with patients/families be transparent and all clinicians skilled at breaking bad news. If the risk manager is appointed, it will be difficult to separate the clinical disclosure discussion, with its emphasis on complete openness, from any later discussion of compensation in which the facility may have to take a more rigid position. This is less of a concern if the facility's carrier will provide the negotiator for the "money" discussion.
- **Typical fit:** A small organization.

Team Model

- **Description:** This approach involves intense training of a select group of individuals in the effective disclosure skills and the communication policies of the organization. They are likely to be from a variety of services and known for their interpersonal skills. Subsequent to training, team members are assigned to coach physicians/clinicians or staff and accompany them in disclosure discussions.
- **Benefits:** The organization can be assured that effective communicators are involved in every disclosure discussion. The team shares responsibility for participation and coaching of disclosure communication so the best “fit” for any situation can be selected to participate in that discussion.
- **Drawback:** Health care staff may be diverted from daily responsibilities to participate in a disclosure discussion. That diversion could be a burden.
- **Typical fit:** A small- to medium-sized organization.

Train the Trainer Model

- **Description:** The organization invests in the comprehensive training of a large group of physicians and other staff. The trained individuals train a certain number of people in the organization each year. They become more comfortable in the concepts of disclosure. In addition, they become mentors and role models.
- **Benefits:** This model uses individuals throughout the organization, including physicians and clinicians, to spread the skills and the philosophy of honest communication through the organization. In addition, it provides an economical way to ensure that all staff and employees are introduced to the concepts of honest communication with patients.

- **Drawbacks:** Quality control and distribution of responsibility are the main drawbacks. This model must include a single individual who is ultimately responsible to ensure that the trainers are training at the level expected and that training opportunities are scheduled throughout the organization.
- **Typical fit:** Large- to medium-sized organizations with several campuses might find this method the most efficient and effective for consistent education. In addition, this method could be effective to generate physician/clinician buy-in if respected members of the medical staff are trainers.

Just-in-Time Coaching

- **Description:** The individual practitioner at the site of the event discloses what is known at the time. The discloser may be a nurse, attending physician or other practitioner with whom the patient has a relationship depending upon the significance of the event and seriousness of the outcome. There generally is an in-house coach, frequently the risk manager, with whom practitioners can discuss the disclosure prior to the discussion.
- **Benefits:** It is direct and easy. It places the responsibility for effective communication skills at the point of care. It is the ultimate in mature patient/family partnering.
- **Drawbacks:** This model is dependent upon the skill of the individuals at the point of care. Where there is the potential to lay blame or fail to support the organization's improvement efforts, or where communication skills are insufficiently empathetic, this model can result in less effective patient/family partnering.
- **Typical fit:** Any organization that is mature in its patient safety and transparency culture could use this approach. By the time the organization has passed through the various stages of cultural maturation, the staff and physicians/ clinicians will be knowledgeable of their own strengths and shortcomings and will know when and how to seek coaching.



Risk Management Strategies

Determining a Model

Evaluate the organization's resources:

- Individuals in the organization who could be trained.
- Number of patients being treated/events reported.
- Number of clinicians needing support.
- Nature of support among departments.
- Nature of physician willingness to accept support.
- Which model could provide the most consistent, quick response and effective support given the organization's culture and volume of care.

Decide upon a measurement plan and periodically re-evaluate the efficacy of the model to meet the organization's specific needs in one year.



Specific Steps for Disclosure

The practical discussion that started with the release of the JCAHO standard in 2001 continues today. What and when should patients be told about their care? Who tells them? How should the process work?

Disclosure Triggers

What sort of event should trigger a disclosure process? The JCAHO standard explains that disclosure is appropriate when an outcome differs significantly from the anticipated outcome. Technically, this does not involve error, nor does it necessarily involve harm to the patient. The standard and its related explanations do not indicate if the standard is objective, or subjective to the patient.

Some hospitals disclose if there has been harm, which they may define as a condition requiring further treatment, treatment to reverse an inadvertent treatment, additional days of hospitalization or permanent injury or death. This definition may comfort health care providers because it significantly limits the conditions under which disclosure is required. However, it is not part of the JCAHO standard.

Other hospitals, in an effort to be transparent and inclusive, define “harm” as anything the patient or family might consider harmful. Furthermore, “unanticipated” is anything the patient or family might not have anticipated. This covers a wide range of conditions and situations, but is more likely to provide for a disclosure discussion and the resulting closure in situations when the patient/family subjectively has encountered an unanticipated situation.

The Physician's Role

The attending physician's required involvement in the disclosure generates a debate with many facets. Many physicians believe they are jeopardizing their own legal status if they disclose an error that is not of their doing. Other physicians lack the interpersonal skills to disclose effectively. Some physicians refuse to disclose believing that the JCAHO standard applies to organizations and not individuals. Each of these arguments has apparent validity, but each is false.

Argument 1: A physician who discloses an error not of his/her doing may be psychologically associating himself with the error in the eyes of the patient/family and could increase the likelihood that he is named in a suit.

Fact: An angry patient/family is likely to sue because of the injury if they feel they have not been educated and respected or if they have damages requiring remuneration. If a suit is filed, the physician is likely to be named regardless of whether he/she was the discloser. If anything, the literature shows that the provider who discloses is more likely to be viewed favorably. (17)

Argument 2: The attending does not have the skills to disclose effectively therefore he/she should not be a participant in the disclosure discussion.

Fact: A physician who is an ineffective communicator should not be the leader in a disclosure discussion. Nonetheless, the attending should be present at the meeting to answer any questions about future care raised by the patient/family. In addition, the attending is the person the patient/family considers their caregiver, not the hospital. Their absence from the meeting sends a far louder message than their silent or limited participation in the discussion.

Argument 3: The JCAHO standard applies to the organization, not the attending.

Fact: The standard suggests that a licensed independent practitioner provide the information, implying that a person with a high level of medical information should be involved. Furthermore, the physician is governed by the medical staff by-laws, many of which now require the attending to participate in the disclosure of unanticipated outcomes.

Although the debate continues, in an ideal world, providers would feel comfortable discussing the full range of potential errors to actual errors with patients and families. This would increase the co-responsibility for collaborative care and involve patients and families in their own safety.

Nuts and Bolts of Disclosure

Responsibilities and caution

1. **Designate personnel roles.** Who is expected to be contacted prior to a disclosure conversation, and who is expected to participate in the discussion itself? Who is investigating the facts?

2. **Suggested conversation outline.** Each situation is unique and requires preparation. All participants should invest time preparing, including anticipation of the patient/family's reactions and questions. If there are unanswered questions about the situation, then plan for several conversations as facts are developed. Generally, the discussion should include:

- Objective statement of what happened (without speculation as to causes)
- Clear, honest communication of regret

- Discussion of change in the patient’s care plan (if any)
- Steps taken to take care of the patient (if appropriate)
- Identification of steps taken to prevent re-occurrence
- Identification of whom the family will hear from next or next steps they have to take
- Offer of appropriate support services to patient/family

3. Accommodations for special communication or cultural needs. Are there language, disability or health literacy needs that require interpreters, signers or other communication support? Some patients and families would be more upset and harmed by knowledge of the root cause findings – family ethnic, cultural and psychological needs have to be taken into consideration.

4. Support services available to the patient. When possible, support should be made available immediately. There will be future support needs and patients/families should be given information about that support.

5. Steps for follow-up conversations. It is not enough to say “Here’s my card. Call me with questions.” Patients and families may interpret that as empty invitation. It is more effective to both give a card and ensure a follow-up call is made to them within an agreed upon timeframe. In addition, the door should be left open for questions that come up in the interim.

6. Documentation of the conversation. The key components of the conversation should be included in the medical record, as would any family meeting or key patient discussion. The key elements of the discussion listed above, including what happened, changes in care, apology, identification of next steps and offer of services should be documented. *(See documentaion tips on Page 30.)*

7. Planning for subsequent meetings. Many times, the initial disclosure meeting is simply the meeting where events are revealed and sorrow is expressed. Often there will be a need for second or even a third meeting. Once the full weight of the event is grasped, the patient/family will experience expected and acceptable anger. At the same time, they will identify genuine needs. The steps for conflict resolution should be delineated not only for patient relations and possible claim management, but also in accordance with the Centers for Medicare & Medicaid Services Conditions of Participation (CMS CoPs).

8. Circumstances where disclosure may not be appropriate. Where the harm of disclosure outweighs the benefit, a decision may be made to defer the conversation. Those occasions are rare. Documentation of this decision including the rationale is essential.

Disclosure Techniques

What makes disclosure effective? In the early days of the disclosure journey, people believed that an effective disclosure averted litigation while an ineffective disclosure resulted in litigation anyway. It is now known that a claim or litigation may follow an effective disclosure because of the anger or genuine need of the aggrieved parties.

An effective disclosure provides the patient/family with the information they need about the patient's care outcome, allowing them to make decisions about appropriate next steps including the possibility of seeking appropriate compensation. It leaves them feeling respected, included and cared about.

An ineffective disclosure may include the same objective information. However, at the close of an ineffective disclosure, the patient/family may feel their views and values have not been respected, that they have not been provided the information in a way that is understandable and usable, and that their anger has been exacerbated because of the manner in which the information is delivered.

Benefits to Patients and Caregivers

Effective disclosure provides patients/families the opportunity to:

- Get information needed to make next decisions, including the possibility of pursuing litigation.
- Directly deal with issues of distrust through interaction with those whom they trusted.
- Directly deal with anger through direct interaction with those who are part of the injury, thus initiating the healing process.

Effective disclosure also provides clinicians and the organization the opportunity to:

- Build trust, communicate openly and demonstrate a patient/family-centered philosophy.
- Heal psychologically.
- Learn and improve systems so that mistakes are not repeated.

Effective Disclosure

Conducting an effective disclosure discussion is a multi-faceted activity. Part of the skill involves a thorough understanding of the mechanics of disclosure. How to prepare, what to say and what to document are process techniques that are easily understood and learned.

The other skills for effective disclosure are the interpersonal skills of communication. Those include initiating the conversation, ending the conversation and conducting the conversation so it supports rather than diminishes the relationship between the clinician and the patient/family.

Acknowledging Strengths, Weaknesses

As with any skill-based activity, each person will be stronger in some areas and weaker in others. Potential participants must determine where their strengths and weaknesses lie. Once an area ripe for further development is identified, the organization should support further training to improve skill levels of those who will be involved in disclosure discussions.

Because some staff members and physicians have innate talent for the process, the facility should encourage involvement of those individuals as trainers and in the disclosure conversations. Similarly, if a physician lacks talent for interpersonal communication, he/she should consider bringing in a trained partner from the practice, possibly along with a higher level manager. It is counter-productive to force people into their weakest roles.

Preparing for Disclosure

Preparation is an important component of disclosure. Although circumstances may limit time for preparation, certain steps should always be taken to ensure the discloser enters the meeting ready for the types of questions and issues that may arise. Furthermore, proper preparation reduces the likelihood that the information given is inaccurate or based upon assumptions rather than knowledge. Information

provided during a disclosure discussion becomes fact in the mind of the patient/family. There is little room for recovery from a mistake, especially one that affects credibility.

The following are components of a thorough preparation:

1. Review the facts

- What is certain at this point?
- What do we know about causal factors?
- What are the outcomes of the treatment (injury, death, nothing permanent)?
- What further steps are being taken or recommended to care for the patient?
- What are the anticipated results of that treatment/intervention?
- When will we know more?

2. Identify appropriate participants

- Family members (if appropriate).
- Attending physician (although the attending may not conduct the meeting, he/she should be there to answer questions about care).
- Because the initial disclosure meeting often conveys the first information of injury, the risk manager's presence may convey a wrong message about the meeting's purpose. *After* the adverse event is explained, the risk manager can be introduced to address patient/family needs and/or financial expectations. The facility should balance this concern against potential advantages of including the risk manager from the start, including his/her communication skill level.
- However, the risk manager can assist in the preparation and subsequent support of the provider and patient. It's advisable to notify the risk manager in the event of disclosure, either before or immediately following.

3. Select an appropriate setting that is neutral, quiet, comfortable and free from interruptions.

Initiating the Conversation

People tend to remember clearly the beginning and end of experiences, so it is essential that the disclosure meeting be conducted from beginning to end in a very empathetic, humane manner – reflective of genuine concern and sorrow about what has happened.

When initiating a disclosure discussion:

- Ensure that participants from the organization are aware of and sensitive to HIPAA Privacy Rules (www.hhs.gov/ocr/hipaa) and the desire of the patient.
- Assess the patient/family's readiness to participate in the conversation:
 - Are they impaired by medication?
 - Are they too distraught?
- Assess the patient/family's general level of health literacy:
 - Look for signs of lack of understanding (terminology used, questions asked, the absence of questions, seeming to agree too readily).
 - Recognize that patients/families will often use terms that sound familiar from TV yet have limited understanding. This can lead the clinician to assume information is being understood when it is not.
 - Use simple, plain language. Avoid using medical terms except where absolutely necessary. (Example: "The test results were negative" implies to some people that they were bad. Instead: "The test didn't find anything out of the ordinary.")

Presenting the Facts

This is the core of disclosure.

- Describe simply, in plain language, what happened and the outcome.
- Describe simply, in plain language, the next steps:
 - What was done immediately for the patient.
 - What is being done now.
 - Changes in the treatment plan.
 - What the organization is doing to ensure this does not happen again.
- Apologize when appropriate (*See apology discussion on Page 31.*)

Ending the Conversation

- Summarize the facts simply.
- Repeat key questions asked.
- Describe follow up plans. Ensure that promises are kept. Remember: The trust of patients/families involved in these conversations has been shattered. A promise broken, no matter how small, will seriously impede the chances of salvaging the patient/family relationship. Clearly state:
 - From whom will the patient/family hear next.
 - When will they hear.
 - Anything they are expected to do themselves.
 - A plan for following up with them to address questions.
 - An invitation to contact you with questions (along with your card and a handwritten note or comment about contacting you written on it). If the discloser is not the appropriate person for follow-up, then the name and number of that person should be given along with information about when that person will contact the family.
- Offer support (spiritual services, family services, grief counseling, a place to stay, food, etc.).
- Repeat expressions of support, sympathy and concern. Sincere humility and empathy are keys to effectively ending a conversation.

Documentation

Documentation is vital to the disclosure process. It should describe the key components of the discussion, including:

- The facts given, including outcomes of the event and changes in treatment course.
- The key questions asked and answers given.
- Next steps.
- Services offered and accepted.
- The apology.

Documentation will become evidence should litigation occur so it is essential that the writing be factual, concise and professional. The entry will create an impression of how the disclosure discussion was handled, therefore opinions about causality not based in fact and emotional reactions to the event or the patient/family should not be included.

Apology

Apology is a sincere expression of regret. The specific words used are less important than their sincerity. Nonetheless, in our society, the words “I’m sorry” spoken truly and with accountability delineate whether an apology has occurred. Furthermore, although health care leaders have long taught that an apology can be focused on the patient/family experience and not on assuming responsibility for the experience, recent arguments are challenging that position, indicating that a “non-accountable” apology may do more harm than good. (18)

When is apology appropriate?

In health care it can be difficult to know when an apology is in order. Do we know if we have betrayed patient trust? Do we know if we have contributed to unmet expectations? For physicians who can tune into their own feelings, this is easier to determine. However, when fear of reprisal, belief that there is no responsibility or lack of empathy for the effect on the patient/family intervenes, then knowing that an apology is in order becomes a challenge.

Requirements

For an apology to be effective, it must have specific components. Beverly Engel in *The Power of Apology* states that there are three vital factors: sincerely regretting, assuming responsibility and providing remediation. (20)

Engel’s components of an effective apology (“**ASAP**”) include:

- **Acknowledging the need for apology.**
 - Has there been a medical error?
 - Are patient/family expectations unmet due to something you have done or failed to do?

- **Sincerely expressing remorse for your role in the event.**
 - If there is an error that does not involve you directly, express remorse for the organization. At that moment, you represent the system in the eyes of the patient/family.
 - If it is an error of your judgment, then express sincere remorse.
 - Insincere remorse is worse than none. It will result in an apology that can do more harm than good by fueling greater distrust.
- **Assuming responsibility where appropriate.**
 - Has an error occurred? If so, unless otherwise advised that doing so would jeopardize your insurance coverage, assume responsibility. In the long run, the opportunity for both the health care provider and the patient/family to heal the psychological wounds of distrust is greater with sincere apology.
 - Is it unclear that an error has occurred? Then, say so. Assume responsibility for ensuring that the organization will find out what happened and will share that with the patient/family: “You must feel awful this has happened, and so do I. We do not know yet how this happened. When we have found out, we will share that with you and will take responsibility for anything that we did that contributed to this.”
 - If no error occurred, and there was nothing that could have been done differently, then express sincere sadness for the event, but no responsibility.
- **Pursuing remediation.** You may not be in the position at the initial disclosure meeting to know if financial remediation is called for. That may be a discussion at a second or subsequent disclosure. At a first disclosure meeting, the remediation may be the commitment to pursue finding answers, which will be shared.

Risk Management Strategies

- Find out if you have a state statute that protects apology and under what circumstances. Find out if your insurance company discourages or encourages apology. This is a financial decision as well as a philosophical decision.
- Do not take responsibility for an error if there has been no error. Not only is it legally a problem, but psychologically as well. Studies by Kim, Ferrin, Cooper, et al in 2004 showed that trust can be restored when an apology is made and subsequent evidence supports the responsibility for the act. However, when subsequent evidence shows that there is no responsibility on the part of the party apologizes, trust is not restored. (21)
- If it is unclear there has been an error, then express sincere regret for the outcome and assume responsibility to ensure that the facts will be pursued and findings will be shared.
- Feel free to use the words “I’m sorry.” Sincerely stated, they have the power to heal.
- Do not apologize without true concern, sadness and regret about the patient/family’s pain. This is about them – their needs, their expectations, their hopes. This is not about the caregiver except as sharing in the personal pain of the family. (The organization should have immediate support for the caregiver.)
- Recognize that for apology to be successful, we must separate our fear for our own survival from our human feelings about the suffering of others. This is the defining moment of the disclosure discussion. If we are not sorry for the patient/family and do not share in their pain, we lose the opportunity to heal their distrust as well as our own injured professional self-esteem and heart.

Other Considerations

Subsequent Discussions

As noted earlier, there will often be more than one meeting. The initial meeting should occur as soon after the event as possible, but that means some information will not be available and the patient/family will need time to process what you say. Subsequent meetings will cover a number of topics:

- Results of investigations to the extent that you can discuss them.
- Activities the organization is taking to prevent re-occurrence of the event.
- An exploration of the patient/family needs and mechanisms for remuneration or assistance.
- A further sincere apology for any role the physician and the organization had that contributed to the outcome.

These meetings can benefit from the application of dispute resolution skills or alternative dispute resolution processes. Mediators can facilitate contentious discussions about financial concerns. The risk manager should participate in these meetings because she/he can best understand the ramifications of decisions and facilitate the implementation of agreements.

Hints for Effective Communication

- Use simple language. There are two reasons to use non-technical language during a disclosure:
 - Health literacy. A 2004 IOM report indicates that nearly 50 percent of American adults have a health literacy level low enough to endanger their health and the health of their families. Though many individuals will not admit to lack of understanding of medical terminology, providers should assume this is an issue.
 - Human reaction to stress. People cannot listen effectively while processing difficult information.
- Select the most important information to share at the first meeting. Patients/families should receive all the information needed to make next-step decisions. Do not overwhelm them with information that is not useful at the time. There should be future meetings and those meetings can provide additional detail. An exception is where the patient/family asks for additional information or detail.
- Speak slowly to optimize the potential for patients/families to understand the implications of the information presented.
- Be aware of body language and non-verbal communication. Any message largely is conveyed through body language and other unconscious things we do as we speak. In addition, there are aspects of non-verbal communication about which speakers can do nothing, such as gender, age, ethnic background and education that may influence how people hear and accept a message. The key here is to be aware of controllable aspects and strive to present a caring and warm demeanor.

- Be aware of cultural implications. Communication is interpreted through cultural filters.
 - Ethnic perceptions affect not only foreign born individuals, but even second and third generations. Often these perceptions are subconscious.
 - Different generations have different beliefs about the role of the patient and the relationship of the patient/family to the clinician as well as beliefs about authority and patient rights.
 - Different levels of education, perceived differences in life experiences and perceived differences in status affect whether an individual will believe the discloser appreciates their point of view. Educational differences also may affect the ability of the person to understand his or her role in the health care process.
 - Spiritual beliefs affect how a person interprets health and illness beyond the physical symptomatology. Those beliefs about causation and the role of faith in healing influence the way that communication is interpreted.
 - Research indicates that racial background may affect the patient/family's willingness to trust caregivers or to share problems. (21)
- There are areas where ethnic, generational, religious and socioeconomic influences exert an impact on how information is received:
 - Beliefs about the appropriate role of women in health care and in society; beliefs about the role of women as patients in relation to their husbands or male family members.
 - Beliefs about the etiology of ill health and purpose, if any, it serves in the spiritual world.
 - Beliefs about mechanical and chemical interventions.
 - Beliefs about death and permanent injury.

Managing Patient/Family Emotions

The discloser's primary job is to convey information, allow the patient/family to express emotions, and manage those emotions so they do not escalate to the detriment of both the patient/family and the organization. The most common emotional reactions are anger, denial and blame. It is also important to remember that while emotions may be based on incorrect facts or interpretations, the emotions are always real.

Anger is a difficult yet expected emotion. The best strategy is to allow the patient and family members to express themselves without becoming defensive. Direct accusations may reflect their frustration and helplessness. (Do not put yourself into a dangerous situation. Call for help if needed.)

Denial occurs because the information is too much to process. It is important in this situation to quietly and firmly reinforce the reality of the situation while giving the patient/family permission to take their time.

Blame is the most difficult reaction to handle, particularly for disclosers in an event for which they have no responsibility. As with anger, it is important to allow the patient/family to have their feelings without argument. Accept their right to hold those feelings, but do not accept the blame. An example might be: "I understand how you would see this as my fault. I just want to tell you that I feel terrible, and yet, I was not a part of what happened."

Risk Management Strategies

A health care organization's risk manager should:

- Assess organizational readiness for disclosure:
 - What is the current philosophy about transparent communication?
 - What is currently the behavior relative to transparent communication?
- Engage and educate leadership.
- Develop an effective communication policy that includes disclosure.
- Provide support for caregivers (education about the organization's philosophy, the litigation implications, available resources, and the components of the policy and the education plan).
- Ensure all staff are educated about the organization's communication policy, how to find it and its implications
 - Provide ongoing regular reinforcement through education, e-mails, etc.
 - Provide education about the role of staff other than disclosers in supporting the factual transmission of information about unanticipated events.
- Ensure that staff knows what to do immediately after an adverse event and with whom to speak prior to a disclosure.
- Ensure staff is educated about resources available to support them after an adverse event.
- Ensure that all staff is educated in disclosure techniques in order to support clinicians who are involved in a disclosure. In addition, staff may be called upon to participate with a provider during a disclosure discussion.
- Ensure that the organization has rapid access to support for disclosure when there are communication difficulties such as language barriers, disabilities or health literacy issues.

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Appendix

Building a Disclosure Policy

Policies guide acceptable behavior in any given situation. When realistic, they effectively provide staff with the philosophy of action, the legal or regulatory basis for any requirements, and the steps that will accomplish the task in the most appropriate manner under most circumstances. They also create a standardized way to communicate both regulation and philosophy to staff members who use the policies for information gathering, to guide behavior and for education.



Risk Management Strategies

- Use positive language reflective of the organization's philosophy. "We at ABC Hospital value and strive to provide honest communication with patients that includes disclosure of any and all information surrounding the outcomes of treatment or care."
- Consider the use of a "communication with patients" policy of which disclosure of adverse/unanticipated events is only one element. (Of course, it should be easily found when needed.) Use of the term "disclosure policy" implies that disclosure is a separate activity from communication. It might imply to some that "we disclose only when the policy says we must and the rest of the time we don't tell patients about their care."
- Ensure that policies have room for clinician decision-making about where and when to communicate within the parameters of acceptable behavior. For example: A policy that states, "The attending will talk with the patient within 12 hours of the event." creates expectations that may not be appropriate in a given situation.

- Ensure the policy reflects behavior that is feasible under normal circumstances.
- Ensure the policy includes description of the support that is available for physicians.
- Ensure that the medical staff and all levels of administration review and support the policy before implementation.



Components of an Effective Policy

A well-written policy may include the following components:

- **Policy statement/objectives.** An effective policy statement is a positively worded statement, usually no more than a sentence or two, that sets out what the policy is, when it applies, and what it is intended to do. Avoid negative wording such as, “Do not disclose medication errors where the error did not reach the patient.” Instead say, “All events are potentially disclosable even when the error does not reach the patient. Clinicians are recommended to use discretion when disclosing a near miss if the patient would be negatively affected by such information.”
- **Definitions of key terms.** Any term that is used within the policy and procedure that is not common usage in the organization should be defined. It is especially important to include any definitions unique to the region or the organization.
- **Criteria of an event warranting disclosure.** This is a brief, inclusive statement rather than a limiting statement. Those organizations choosing to base the necessity for disclosure on the presence of harm should further define the categories of harm in this section. For most organizations the range for disclosure includes harm that never reached the patient (no obligation to disclose) to natural sub-optimal outcomes from treatment or medical error, both of which must be discussed with the patient/family.
- **Outlining the necessary steps for disclosure.** This is a guideline, not a detailed blueprint, and should touch on issues such as individuals involved, content of the conversation, accommodation of special needs, planning for follow-up, documentation and conflict resolution planning.
- **Support services for providers.** They, too, are wounded by the unexpected turn of events and yet, the clinicians are often unable to ask for help. The policy should delineate the source of help available when possible.

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