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Medical Error Disclosure: Acknowledging Mistakes Can Help Promote Optimal Resolution

Medical error disclosure programs are the norm in many healthcare practices, as "apology laws" proliferate, and healthcare practitioners and business owners increasingly recognize that candor represents an appropriate course of action from both an ethical and business perspective. Disclosure is now widely viewed as a critical risk management measure, helping defuse patient anger and uncertainty. Such programs are also designed to facilitate the movement from a culture of blame toward an emphasis on transparency, accountability and prevention. This shift in communication habits and professional norms is reinforced by research demonstrating that medical error disclosure programs have tended to reduce lawsuits, legal expenses and judgments. (See "Successful Initiatives in Error Disclosure," below.)

By acknowledging mistakes and associated patient suffering, healthcare entities can help restore strained relationships, promote improvements in safety and quality, and reduce litigation. This edition of *Healthcare Perspective* provides guidance on creating effective policies and procedures governing apology and the admission of error. The goal of these interventions is to create a disclosure program that promotes candor while recognizing the possible constraints imposed by state apology laws.

LEGISLATIVE AND COVERAGE CONSIDERATIONS

To allay provider concerns that an apology for a medical error may precipitate a lawsuit, thirty-six states have enacted laws making such apologies inadmissible as evidence of fault or negligence in subsequent litigation.[1] However, these laws vary considerably in terms of both the type of statement covered and the degree of legal protection extended. Therefore, healthcare business owners must carefully review the relevant state statute with legal counsel when formulating a medical error disclosure policy and protocol. Providers must be cognizant of any potential inconsistency between their protocols, their insurance coverage and governing state laws, noting especially the following issues:

What is covered by state statutes

Some state statutes relate only to unanticipated outcomes, as opposed to "harmless" errors. Also, some state laws apply to statements of *fault* offered by healthcare providers and their employees, while others specifically address statements, writings or other benevolent gestures that express *sympathy* to the patient and/or the family. Laws may apply to conduct – e.g., offers to provide remedial treatment and other benevolent acts – as well as to oral and written statements of apology for adverse outcomes.

Extent of legal protection under state statutes

A number of statutes specifically declare that a statement of fault is not inadmissible in court. Others make apologies inadmissible but potentially discoverable. In some states, the communication is inadmissible in litigation as an admission of liability or admission against interest. Other state laws declare that the communication is inadmissible to prove negligence. Some states place a time limit on protected expressions of grief or explanation, based upon when the healthcare provider knew or should have known of the potential cause of the outcome.

Successful Initiatives in Error Disclosure

For more than a decade, medical error disclosure programs have been in the national spotlight, including the widely recognized initiatives of the ***Veterans Affairs Hospital*** *in Lexington, Kentucky and the* ***University of Michigan Health System*** *(UMHS). Following its adoption of a disclosure protocol in 2001, UMHS* ***reported*** *a decrease in the number of professional liability claims, the time required for claim resolution and the total liability costs. Given its documented success, a case study of the Michigan model was highlighted in the 2015 white paper published by the National Patient Safety Foundation, entitled* ***Shining a Light: Safer Health Care Through Transparency****. In May 2016, the Agency for Healthcare Research and Quality introduced the* ***CANDOR Toolkit****, which is based, in part, on the Michigan model and designed to help healthcare businesses achieve full disclosure of medical errors.*

1 For a listing of states with apology laws, visit the website of the Sorry Works! Coalition.

Insurance provisions to consider

The medical professional liability policy may expressly prohibit insureds from voluntarily assuming liability or entering negotiations regarding a claim without advice and/or consent of the carrier. Therefore, healthcare business owners and providers should review their professional liability insurance coverage with legal counsel before formulating an apology protocol.

OVERCOMING POTENTIAL BARRIERS TO DISCLOSURE

While apology laws may mitigate some legal exposures, they do not necessarily overcome the healthcare community's reluctance to acknowledge and discuss medical mistakes. The following strategies, among others, can help healthcare business owners actively address barriers to honest disclosure:

Define error

The lack of consensus within the healthcare community about what constitutes medical error presents one obstacle to disclosure. Many business entities reserve apologies only for those incidents that could have been avoided through adherence to professional standards of care. Others assert that an error causing minimal harm, or harm to a patient who is already near death, need not be disclosed. Finally, some healthcare practices have instituted a lower threshold, offering apologies whenever the course of care, whether reasonable or not, fails to go as planned. An effective disclosure policy thus begins with a clear definition of "medical error." Perhaps the most widely utilized definition comes from The Joint Commission, which considers as an error any unintended act, either of omission or commission, or any act that does not achieve its intended outcome.

Definitions for *medical error*, *clinical misadventure*, *near-miss* and *sentinel event* should be clearly delineated and reviewed regularly to identify possible sources of confusion and to clarify reporting protocols. One effective strategy is to frame disclosure parameters in terms of objective patient outcome, and to issue an apology for events that:

- Cause actual patient harm.
- Possess clear or potential clinical significance.
- Constitute an unexpected safety event.
- Result in an unanticipated outcome.
- Involve an unwanted treatment or substance reaching the patient.

Support providers

Another common barrier to disclosure relates to the isolation experienced by many providers in the wake of a medical mishap. A disclosure support team can help assuage this feeling, ensuring that policies and procedures are implemented in a consistent and timely manner. Deployed in the immediate aftermath of an event, the team compiles pertinent information, working close with providers to determine whether a disclosure statement and apology are indicated. Support team members should represent such areas as business/clinical operations, risk management, patient safety and quality improvement. Whatever their specific area of expertise, all members should be team players with strong communication skills presented in a courteous, straightforward manner.

Draft written protocols

In order to be effective, disclosure policies must be universally binding, widely publicized and integrated into the healthcare entity's overall program for managing adverse events. By making disclosure a formal protocol, equivalent to such practices as informed consent and privacy notice documentation, healthcare businesses signal the importance of openness and provide staff members with necessary guidance when discussing a matter as sensitive as medical error.

QUICK LINKS

- "Medical Error Calls for Honest Disclosure," American Medical News. Posted September 12, 2011.
- Moyes, A. et al. "Disclosure of Adverse Events and Medical Errors." *emDocs*, June 16, 2016.
- Rodak, S. "4 Tips to Implement a Transparent Medical Error Disclosure Policy." *Infection Control & Clinical Quality*, July 30, 2013.

RESPONDING TO AN EVENT

Medical error disclosure programs take many different forms, but they all share the goal of establishing and/or maintaining positive rapport between patients/family members and providers when events threaten to undermine communication. The following suggested strategies can help healthcare business owners initiate discussions between leadership and clinical staff about how to improve the process of acknowledging significant occurrences:

Analyze the sequence of events

When a qualifying event occurs, staff members must act quickly and decisively to collect facts and establish communication with the patient and/or family. A sequence-of-events analysis, conducted expeditiously, can provide answers to basic questions and facilitate timely scheduling of the initial patient/family meeting. Unlike a comprehensive investigation, which aims at definitively determining the source of a harmful error, the initial analysis provides critical information without acknowledging fault or assigning blame. The preparatory review should permit staff to:

- Report the known facts of the occurrence to the patient and/or family.
- Explain any clinical implications.
- Extend a sincere apology for the unexpected nature of the event.
- Commit the healthcare practice to a thorough investigation.

Select a spokesperson

To avoid intimidating or overwhelming the patient, one person – such as a manager or the business owner – should be designated to serve as the entity's spokesperson. As primary caregivers often experience their own emotional distress following an event, some business owners select an individual who is not connected to the incident, and thus is better qualified to describe the event and its possible causes and consequences in a clear and unbiased manner. Meet promptly with the patient and/or family. Initial disclosure involves an expression of understanding and empathy intended to re-establish trust and communication after an event. The message should be neither fully scripted nor completely improvised. Essential points should be decided in advance, but the discussion should flow naturally and all patient/family questions should be answered. It is important to be as candid as knowledge and circumstances permit, as partial disclosure can lead the patient to believe that important information about an error is being withheld. If questions cannot be answered in full due to the timing of an investigation, the spokesperson should acknowledge such and indicate to the patient/family that additional information will be forthcoming when available.

Productive encounters will generally include the following elements:

- *Acknowledge that something unexpected has occurred,* without prematurely inferring its cause (e.g., "you experienced a reaction after taking the medication").
- *Describe the nature of the event,* referring to established facts only and indicating what is not yet known (e.g., "we are not yet sure of exactly what happened, but we will be reviewing the event over the next few days and will keep you informed").
- *Explain the clinical implications of the event, including possible harm to the patient* (e.g., "the following symptoms are associated with the reaction").
- *State the actions that have been and will be taken to treat or ameliorate the consequences of the event,* focusing on the patient's immediate care needs and condition.
- *Offer a sincere "I'm sorry" for the situation* (e.g., "I am sorry this happened; you certainly didn't expect something like this to happen during rehabilitation").
- *Convey sympathy for the patient's or relatives' feelings* (e.g., "you must be under considerable stress") and ask the patient or relatives to share their questions and concerns.
- *Promise a swift and thorough investigation,* citing business policy and procedure regarding timeframes, if possible.
- *Provide the names and telephone numbers of key contact persons,* including those responsible for managing the patient's ongoing care and for addressing complaints or concerns the patient or family may have.
- *Identify where the patient/family can obtain support services* for immediate needs, including lodging and counseling.
- *Suspend charges and expenses* related to the event, pending a full investigation.

Occasionally, a healthcare business owner learns of an event only after the patient has left the facility. If the patient has engaged legal counsel in the interim, providers should consult with defense counsel before meeting with the patient and their attorney, in order to appreciate legal and tactical considerations that may be required by statutory law. Providers who attend patient/attorney meetings are often joined by their legal counsel and other designated representatives. At the meeting, attendees should review all information known to date and answer factual questions about the event in the same candid manner as when meeting with the patient alone. Regardless of when the exchange occurs, prepare a written account of the meeting, specifying who was present at the meeting, what was said, what was promised, and what questions were asked and answered.

Investigate thoroughly

Only a comprehensive investigation can reveal the system weaknesses that caused the event, thus minimizing the likelihood of recurrence. Depending on the resources, the investigation may be conducted by appointed staff members, individuals involved, and/or outside experts. Every incident should be thoroughly and objectively reviewed in order to:

- *Understand more fully the event itself* and the actions that precipitated it.
- *Verify whether the patient's condition was adversely affected by the event,* and identify possible future ramifications.
- *Determine whether the care provided was reasonable under the circumstances,* and if not, how it could have been improved.

During the investigative phase, the designated spokesperson should serve as an intermediary between the organization and the patient, with responsibility for relaying findings and answering questions.

Provide closure

A meeting at the close of the investigation sets the stage for an open discussion of findings and a final resolution of the incident. If the process concludes that treatment did not fulfill the standard of care, then the business owner, in concert with advice of legal counsel, should determine whether it is time to acknowledge fault, express regret and offer redress. As with all other encounters in the disclosure process, the summary meeting requires careful consideration of how to describe the event and its aftermath. The spokesperson should be prepared to answer all reasonable patient questions, including queries on such sensitive topics as whether disciplinary measures were taken against any providers and what the healthcare practice and providers have learned from the event. A copy of the patient healthcare information record should be given to the patient or attorney, if it is requested.

The closure meeting should encompass:

- *Investigative findings,* including the proximate cause and known consequences of the event.
- *The role of individual error* in the event, as well as system issues that contributed to the outcome.
- *Steps taken to prevent recurrence,* including changes in procedures and the level of resources.
- *Future monitoring and measuring of clinical care* to evaluate efficacy of improvements.
- *Names of parties informed of the event,* including regulatory agencies, accrediting organizations and external review bodies.
- *Redress for injuries, pain and suffering,* and any legal expenses.

Even if the investigation reveals that the care rendered was appropriate, a support person should offer to meet with the patient and/or a legal representative to discuss the findings. Full explanations and a sincere expression of empathy and compassion often will suffice in such situations.

Issue an apology, if warranted

Whether an apology should be offered and how it should be framed depend on the evidence compiled. Factors to consider include the degree of certainty surrounding the event, the severity of the incident, and the element of human and system error. Policy documents should outline the proper course of action. If the decision is made to offer an official apology, the apology should be given by an individual of stature serving as the authorized representative who can:

- *Take ownership of the incident on behalf of the healthcare practice,* acknowledging a connection between actions taken and the unintended outcome.
- *Speak forthrightly and clearly,* without gratuitous finger-pointing.
- *Prioritize the patient care needs* and otherwise commit to serve the healthcare needs of the patient.

For a risk control checklist addressing the disclosure process, see "Risk Control Checklist: The Four Rs Of Medical Error Disclosure," on page 6.

STRATEGIES FOR SUCCESS

1. Make disclosure mandatory

Honesty cannot be optional – telling patients and families the complete truth is the only way to safeguard a healthcare practice's integrity. Staff at all levels should be subject to the program's requirements without exception, as exemptions based upon employment status or position within the practice will undermine the program's success. While the provider's personal discomfort and emotional state should be considered, the needs and feelings of the patient and the family must take precedence.

By migrating from a culture of blame to one of openness and candor, the healthcare practice is better positioned to understand why medical errors happen and how they can be prevented.

2. Teach staff how to apologize effectively and sincerely

Many healthcare providers may be less likely to disclose a mistake due to a concern that patients ultimately will not understand what is being told to them. These fears may translate into an impatient or defensive attitude, defeating the purpose of the disclosure. Healthcare business owners and clinical staff should be encouraged to be clear and concise in their words, and sympathetic and unassuming in their tone. They also should understand the need to:

- *Speak candidly and directly,* avoiding medical jargon.
- *Maintain eye contact* and suitable body language.
- *Explain events thoroughly* without blaming or judging others.
- *Express personal feelings,* when appropriate.

For more tips on how to make effective apologies, see "Apologizing Dos and Don'ts," page 7.

3. Do not procrastinate

Time is of the essence in the age of the 24-hour news cycle. Reluctance to communicate in the wake of an event increases the likelihood that the patient or family will learn of the occurrence from an outside source, thereby derailing the disclosure process before it is initiated. Prompt intervention may involve telling a patient that while few facts about the event are currently known, an investigation is proceeding and additional information will be provided as it becomes available. Explain the sequence of steps to be implemented, including target dates, as this will help earn the trust of both the patient and the family.

4. Protect staff who report incidents

As the success of a disclosure program depends upon the willingness of staff members to report incidents, a business owner must dedicate itself to protecting employees against retaliatory actions. By migrating from a culture of blame to one of openness and candor, the practice is better positioned to understand why medical errors happen and how they can be prevented.

An effective medical error disclosure program can minimize the doubt and hesitation in the wake of an untoward event, encouraging providers to communicate swiftly and openly with patients. By offering information, accountability, empathy and emotional support to patients who have suffered an injury, healthcare providers and business owners demonstrate that they are worthy of trust and confidence at a critical moment.

Risk Control Checklist: The Four Rs Of Medical Error Disclosure

The following risk control checklist is designed to help healthcare business owners gauge their compliance with risk management recommendations in the area of medical error disclosure. For additional risk control tools and information, visit the websites of CNA, NSO and HPSO.

RECOMMENDATIONS	YES/NO	COMMENT/ACTIONS PLAN
REPORTING		
The event involved one or more of the following:		
- Actual harm to the patient.		
- Potential clinical significance.		
- An unexpected safety crisis.		
- An outcome differing from anticipated results.		
The event was reported to a manager or business owner per policy requirements.		
A rapid analysis of the sequence of events is conducted and includes critical information in order to:		
- Explain current known facts to the patient/family in a timely manner.		
- Comment on clinical implications of the event.		
- Apologize for the unexpected nature of the event.		
- Commit to a comprehensive investigation.		
REACHING OUT		
A spokesperson is appointed who:		
- Demonstrates organizational accountability.		
- Acknowledges a possible link between actions and outcome.		
- Prioritizes the patient's care needs.		
- Outlines follow-up actions.		
- Commits to serving the patient's healthcare needs.		
- Avoids assigning blame or becoming defensive.		
A meeting is set up between the spokesperson and the patient, family and/or legal representative to:		
- Report that something unexpected has occurred.		
- Explain the nature and clinical implications of the event.		
- Describe the actions already taken.		
- Acknowledge the patient's/family's feelings.		
- Offer a sincere "I'm sorry" for the situation.		
- Promise a swift and thorough investigation.		
- Suspend charges and expenses.		

RECOMMENDATIONS	YES/NO	COMMENT/ACTIONS PLAN
REVIEW		
Personnel are appointed to:		
- Conduct a root cause analysis to identify major factors that triggered the even, as well as any latent errors.		
- Utilize peer review, quality improvement, risk management and safety experts to:		
– Understand the event and prior actions fully.		
– Verify whether the patient's condition was adversely affected by the event.		
– Determine whether the care provided was reasonable.		
– Evaluate the post-event response.		
– Identify opportunities for improvement.		
RESOLUTION		
A formal meeting is scheduled (following the investigation) with the patient, family and/or legal representative.		
All pertinent findings are imparted at the meeting, including:		
- Proximate cause of the event.		
- Known consequences of the event.		
- System issues that contributed to the mishap.		
- Steps taken to prevent recurrence, including changes in procedures, resource allocation and monitoring.		
- Parties informed of the event, such as regulatory agencies, accrediting organizations and external review bodies.		
Redress is offered for injuries suffered as a result of substandard care, as well as a copy of the patient healthcare information record (if requested).		
A written account of the meeting is prepared, including:		
- Who was present at the disclosure meeting?		
- What was discussed by the participants?		
- What was promised by the spokesperson?		
- What questions were asked and answered?		

Apologizing Dos and Don'ts

DO ...	DON'T ...
1. Think about and discuss with others what went wrong and what could have been done better before composing the apology.	1. Engage in blame-shifting, defensiveness or evasion.
2. Schedule a face-to-face apology whenever possible.	2. Add insult to injury by communicating primarily via voice mail or e-mail.
3. Ensure that the apology includes all significant information.	3. Discuss issues of marginal relevance to the patient.
4. Focus on the established facts and analysis.	4. Speculate beyond what is known to be true.
5. Write out key points before meeting with the patient and/or family.	5. Rush to the bedside and become over-emotional or lose control.
6. Consider the spokesperson's manner and strengths when composing an apology and disclosure statement.	6. Underestimate the importance of non-verbal communication (e.g., tone of voice, expression and posture) in expressing sympathy and candor.
7. Convey deep sympathy for the patient and an awareness of the effects of the event.	7. Seek sympathy for oneself or otherwise shift the focus away from the patient's plight.
8. Use everyday language that conveys both thoughts and emotions.	8. Utilize medical jargon that may confuse, intimidate or irritate the patient.
9. Acknowledge all known consequences of the event, including emotional, familial and monetary impact, as well as the potential effect on the physician-patient relationship.	9. Treat the issue as minor simply because the patient has not suffered a life-threatening injury.
10. Give the patient and family time to consider and respond to the apology.	10. Demand a quick response or ask the patient or family for forgiveness.

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