THE MEDPRO GROUP DIFFERENCE

Guideline

Disclosure of Unanticipated Outcomes

MedPro Group
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Contents

Introduction

Patient safety and high-quality care are top priorities for healthcare organizations, providers, and staff. Yet, even with a strong focus on these principles, errors and untoward events can occur, leaving those involved with the difficult task of determining what information — and how much information — to disclose.

Many healthcare providers are hesitant to disclose unanticipated outcomes for a variety of reasons, including fear of litigation and punitive actions, concerns about reputation, lack of knowledge about duty to disclose and error reporting systems, and uncertainty about the cause of an error or accountability.[1]

Defining Unanticipated Outcomes

In the context of this guideline, unanticipated outcomes refer to:

- Outcomes of care that differ significantly from anticipated outcomes
- Medical errors caused by deviations in the standard of care
- Patient harm that results from medical mismanagement or system failures

Yet, accrediting bodies, healthcare professional organizations, healthcare leaders, and insurers are increasingly emphasizing honest disclosure of unanticipated outcomes. For example, the American Medical Association's Code of Medical Ethics states that "Withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy."[2]

A report from the National Patient Safety Foundation's Lucian Leape Institute notes that "In addition to developing improved methods for disclosure of incidents and apology for errors, doctors and nurses need better training and resources for providing emotional support to patients and their families when things go wrong."[3]

Patient-centered approaches, such as the Agency for Healthcare Research and Quality's Communication and Optimal Resolution (CANDOR) process, emphasize early disclosure and a proactive method of achieving an amicable and fair resolution for the patient/family and healthcare providers.[4]

Other organizations, such as the Leapfrog Group and ECRI, also have advocated for disclosure of unanticipated outcomes as part of increased transparency and a culture of safety.

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Although disclosing pertinent medical information is an essential aspect of patient-centered care, healthcare providers should be cognizant that not every situation can or should be managed through disclosure. For example, "near-miss" events should be managed on a case-by-case basis, and disclosure may depend on whether the patient is aware of the situation and whether disclosure can help prevent a recurrence.

Further, many patients do not understand that an unanticipated outcome does not always imply actual injury or negligence. For example, some unanticipated outcomes might be the result of a known, but uncommon side effect of treatment. In some cases, unanticipated outcomes might be apparent only to the clinical staff members who provided care.

Healthcare providers should consider the context of each unanticipated outcome and then determine how best to address the situation.

Objectives

The objectives of this guideline are to:

- Explain the reasons for disclosing unanticipated outcomes
- Discuss the importance of training healthcare providers and staff on the disclosure process
- Review an appropriate process for disclosure, including acknowledging the unanticipated outcome, preparing for disclosure, having the disclosure conversation, and following up after disclosure
- Describe essential components of disclosure documentation
- Define second victims in relation to unanticipated outcomes and discuss the importance of emotional support programs

Purpose of Disclosure

The reasons for disclosing unanticipated outcomes to patients are multifold. Some common reasons are to:

- Develop a patient-centered organizational response to unanticipated outcomes
- Support a commitment to transparency and honest communications in relation to unanticipated outcomes
- Maintain patient and family trust by (a) acknowledging the event, (b) providing an explanation of the event, and (c) offering assurance that an action plan is in place to prevent future similar events
- Avoid an adversarial relationship with the patient/family, which may result from dishonesty or lack of transparency
- Ensure accurate reporting to regulatory entities
- Attempt to reduce liability exposure

Training for Disclosure

Healthcare providers and staff that will be directly involved in any disclosure conversation should be well-versed and trained in their organization's disclosure policy and process. Without appropriate training or knowledge, providers and staff may speculate about causes of an unanticipated outcome, which could negatively affect the situation. Further, without training, providers and staff may feel ill-prepared for the disclosure conversation, which can create undue anxiety and stress.

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Healthcare organizations might want to consider role-playing or simulation exercises to offer providers and staff hands-on disclosure training. Additionally, many professional organizations and associations have training programs for disclosing unanticipated outcomes and implementing effective communication strategies.

The Process of Disclosure

Timely disclosure that includes emotional support for patients, families, and healthcare providers and staff is critical. The process of disclosure, including an analysis of unanticipated outcomes as a quality improvement and patient safety learning tool, will support a culture of transparency and safety.

Acknowledging the Unanticipated Outcome

As soon as possible after an unanticipated outcome, healthcare providers should offer an empathetic acknowledgment to the patient/family. For example, this acknowledgment might be in the form of "I'm sorry the outcome of the surgery was not as we expected." However, providers should not prematurely admit fault, assign blame, or get defensive.[5] Providers also should not guess or speculate about the underlying causes of the unanticipated outcome when talking with the patient/family.

Although many of the details and facts might not be known immediately following the event, the purpose of acknowledgment is to connect with the family, treat the situation with empathy, and indicate that an investigation will occur.

Preparing for Disclosure

Healthcare organizations should establish a threshold for situations requiring disclosure. For example, organizational policy may require disclosure for (a) outcomes considered "reportable" according to regulatory requirements, (b) outcomes that result in a change in the patient's treatment plan, and/or (c) outcomes that an individual would reasonably want to know about.

Apology Laws

When facing disclosure, providers should keep in mind the relevance of apology laws, if applicable to the state(s) in which they practice. These laws protect certain statements, expressions of sympathy, and other evidence from being admissible in malpractice litigation, and they differ in the types of information and statements covered. Some states cover expressions of empathy or sympathy; others go further and protect admissions of fault. Providers should consult with an attorney to get a correct interpretation of state laws.

When preparing for an actual disclosure conversation:

- Contact the organization's professional liability carrier to provide notification of the event and to discuss specific strategies related to the disclosure process. For example, the hospital or office practice staff might want to discuss whether to cover certain expenses for the patient/family (e.g., lodging, transportation, etc.).
- Gather information about the event from staff members who were involved and from the formal investigation of the incident.
- Select an optimal time for the disclosure conversation. Initial conversations should occur as soon as any substantive information is available, but generally not longer than 24 hours after the event.
- Determine which clinicians and staff members should be present for the disclosure conversation. (Note: Risk management staff should be involved in the initial disclosure conversation and subsequent patient follow-up.) Offer emotional support to any providers or staff members that are involved in the conversation.
- Consider who should be present to support the patient/family. Ask the patient/family who they would like to have present, and consider having a chaplain or interpreter available (as appropriate).
- Discuss with the disclosure team the need for a unified presence.
- Identify who will lead the conversation. In most cases, the lead should be the attending doctor or a provider who has an established relationship with the patient (even if that provider was not involved in the underlying event). Other participants might include the patient's primary care nurse, the nurse manager, the patient advocate or representative (in a hospital setting), or the practice manager (in an outpatient setting).
- Prior to the meeting, agree on an agenda and the information that will be discussed during the meeting.
- Select a quiet, comfortable location that is conducive to privacy.

Having the Disclosure Conversation

Disclosing an unanticipated outcome to a patient/family can be daunting and stressful. However, the guidance below can help frame the conversation and provide useful reminders about essential disclosure information:

- Use compassion, empathy, and good communication skills, including mindfulness of body language.
- Establish direct eye contact with the patient/family.
- Sit during the meeting if possible.
- Avoid distractions such as staff interruptions, phone calls, texts, etc.
- Use “I” instead of “we,” and speak clearly using terms the patient/family will understand.
- Communicate the facts as they are known at the time of the disclosure, including:
    - The nature of the event
    - The time, place, and circumstances
    - The proximal cause, if known
    - The known consequences
    - The actions that have been or will be taken to treat the consequences
    - The management of the patient’s ongoing care
    - The implications for short- and long-term prognosis
- Offer an apology for the occurrence of the event even if all of the facts and causes are not known. Offer an apology for an error *only* if (a) an obvious error occurred, or (b) a full investigation confirms that an error occurred. If an error has occurred, the provider should apologize and take responsibility, explain what happened, and specify what actions will be taken to reduce the risk of the event happening again.
- Acknowledge the emotions observed in the patient/family. For example, “This must be very frightening (or upsetting, scary, overwhelming, sad, difficult, etc.) for you.” Avoid statements like “I know how you feel.”

- Explain the plan of action relative to either continued investigation or changes being implemented to prevent similar future events.
- Pause periodically to ask whether the patient/family has questions or whether any information needs clarification.
- Avoid absolute statements, commitments, or assurances, such as “We’ll take care of everything” or “You don’t need to worry.” These types of statements might seem dismissive and can be difficult to honor.
- Offer to help with any additional counseling needs, and provide the patient/family with the names of agencies they can contact to address their concerns or complaints.
- Provide assurance that as more information becomes available, it will be shared with the patient/family.
- Identify for both the team and the patient/family a contact person who will have primary responsibility for ongoing follow-up. This is a critical element in restoring trust and confidence.
- Establish a date and time for follow-up communication as more information becomes available based on developments from investigating the event, changes in the patient’s condition, or modifications in the treatment plan.

Be mindful that the disclosure may not be well received, and the encounter could potentially be volatile. Further, the existing clinical relationships might not be sustainable. If so, or if the patient/family requests a different provider, create a plan for transitioning the patient’s care.

Disclosure Follow-Up

Following disclosure, conduct a debriefing session with the disclosure team to determine support needs and to review the disclosure process. As part of the follow-up process:

- Ensure appropriate continuing care for the patient.
- Place billing on hold pending completion of the investigation, and evaluate for appropriate eventual resolution of billing.
- Schedule follow-up meetings to discuss patient progress.
- Continue to provide support to the patient/family and clinical staff as needed.

- Implement changes to ensure the event does not recur, and communicate those changes to the patient/family if the unanticipated outcome was preventable.
- Consider indemnification, waiver of fees, or expense reimbursement on a case-by-case basis, and only after conferring with the organization's professional liability carrier.
- Report the unanticipated outcome to appropriate regulatory agencies, such as the state department of health as well as other regulatory and accrediting organizations, as required.

Disclosure Documentation

An essential element of disclosure is documentation. An appropriate member of the healthcare team should document the unanticipated outcome in the patient's health record, including an objective summary of the pertinent clinical facts surrounding the event. These findings might include the patient's condition immediately before and after the event, subsequent treatment, and the patient's response to treatment.

The disclosure conversation also should be documented in the health record, including:

- The time, date, and place of the conversation
- The information that is communicated to the patient/family
- The patient's/family's understanding, any questions they ask or information they want clarified, and any responses provided to questions
- Names of those present for the disclosure conversation, and who is responsible for follow-up communication with the patient/family
- Next steps for patient treatment, care, and communication
- A notation that disclosure was based on information available at the time of the conversation with the patient/family

Documentation should be completed as soon as possible following the unanticipated outcome and updated accordingly as new information becomes available.

Second Victim Support

Healthcare providers and staff who are involved in unanticipated outcomes may experience an emotional impact or traumatic effect, thus becoming "second victims." The effects of unanticipated outcomes on healthcare providers are not predictable. How an individual will react can depend on various factors, including the seriousness of the circumstance, the person's role and perception of responsibility, the patient's outcome, and the organizational response.[6]

In some cases, providers might experience minor stress or anxiety that dissipates in the days and weeks following an incident. Other providers might suffer from strong emotional reactions and symptoms akin to those of posttraumatic stress disorder. The emotional toll of an unanticipated outcome can be so severe that it may even lead to suicidal thoughts or actions.[7]

Regardless of how the second victim phenomenon manifests, it can have a serious impact on healthcare providers' work and personal lives — and, as a consequence, can be detrimental to patient safety and organizational culture.

> "The second victim phenomenon . . . can be detrimental to patient safety and organizational culture."

Healthcare organizations can take proactive steps to establish policies and programs to support second victims in the aftermath of unanticipated outcomes. To learn more, see MedPro's article *The Toll of Adverse Patient Outcomes on Healthcare Providers: Supporting Second Victims*.

Peer Review

Peer review and quality improvement committees at healthcare organizations may review cases that involve unanticipated outcomes resulting from medical mismanagement at their facilities. Although the disclosure process to patients and families should include follow-up with findings from any investigation, healthcare providers should never inform the patient/family that they will receive results of peer reviews because those committees' opinions, communications, and documents may be privileged and protected from third-party discovery.

Conclusion

Unanticipated outcomes are a reality in healthcare and, although unpleasant, they should be addressed with honesty and transparency as part of a well-defined disclosure process. When

done properly, disclosure can reduce the negative impact of unanticipated outcomes on patients, their families, and healthcare providers and staff.

In preparation for disclosure, healthcare organizations should develop policies and procedures to reinforce the process, including provider and staff training, communication standards, documentation guidelines, and emotional support for individuals involved in unanticipated outcomes and disclosure conversations.

For more information about disclosure of unanticipated outcomes and second victim support, see MedPro's *Risk Resources: Disclosure of Unanticipated Outcomes*.

Endnotes

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