GUIDELINE
Disclosure of Unanticipated Outcomes
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## CONTENTS

- **INTRODUCTION** ................................................................. 1
- **OBJECTIVES** ..................................................................... 2
- **PURPOSE OF DISCLOSURE** ............................................... 2
- **TRAINING FOR DISCLOSURE** ............................................. 3
- **THE PROCESS OF DISCLOSURE** ........................................ 3
  - Acknowledging the Unanticipated Outcome ...................... 3
  - Preparing for Disclosure .................................................. 4
  - Having the Disclosure Conversation ................................. 5
  - Disclosure Follow-Up ....................................................... 6
- **DISCLOSURE DOCUMENTATION** ...................................... 7
- **SECOND VICTIM SUPPORT** ............................................... 7
- **CONCLUSION** ................................................................. 9
- **RESOURCES** .................................................................... 9
- **ENDNOTES** ..................................................................... 10
INTRODUCTION

Patient safety and high-quality care are a top priority 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 — 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

Yet, increasingly, accrediting bodies, healthcare professional organizations, healthcare leaders, and insurers are emphasizing honest disclosure of unanticipated outcomes. For example, the American Medical Association’s Code of 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

The National Patient Safety Foundation 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) program, 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, Patient Safety & Quality Healthcare, and ECRI Institute also have advocated for disclosure of unanticipated outcomes as part of increased transparency and a culture of safety.

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

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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
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, although 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 for 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 institutional response to unanticipated outcomes
- Maintain a commitment to transparency and honest communications in relation to unanticipated outcomes
- Restore patient and family trust by (a) acknowledging the event, (b) providing an explanation of the event, and (c) offering an 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.

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/staff is critical. The process of disclosure, including 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

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.

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. In a hospital setting, risk management and other nonclinical staff might not be appropriate for the initial meeting. 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. Other participants might include the patient’s primary care nurse, nurse manager, or patient advocate in a hospital setting — or the practice manager in an outpatient setting.

Apology Laws

When facing disclosure, keep in mind the relevance of apology laws, if applicable to the state(s) in which you 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. Consult with an attorney to get a correct interpretation of the laws in your state.
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 slowly using layman’s terms.
- Communicate the facts clearly 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 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 a root cause analysis shows the standard of care was not met, the provider should apologize and take responsibility, explain what happened, and specify how it will be fixed.
- Acknowledge the emotions observed in the patient/family. For example, “This must be very frightening (or upsetting, scary, overwhelming, sad, difficult, etc.) for you.”
- Explain the plan of action relative to either continued investigation or changes being implemented to prevent similar future incidents.
• Pause periodically to ask whether the patient/family has questions or whether they need clarification of any information.

• Avoid absolute statements, such as “We’ll take care of everything.” 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.

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.

• If the unanticipated outcome was preventable, implement changes to ensure the event does not recur, and communicate those changes to the patient/family.

• Consider indemnification, waiver of fees, or expense reimbursement on a case-by-case basis, after conferring with the organization’s professional liability carrier.

• Report to regulatory agencies, such as the Centers for Medicare & Medicaid Services, 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:

- Time, date, and place that the conversation occurs
- 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 will be 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 organizational response.

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.
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.

Healthcare organizations can take proactive steps to establish policies and programs to support second victims in the aftermath of unanticipated outcomes. Suggested strategies include the following:

- Establish a culture of safety that encourages transparency, respect, and honesty. Punitive policies and measures in relation to unanticipated outcomes can create barriers to disclosure of incidents and emotional coping.
- Survey healthcare providers and staff and conduct an organizational assessment to determine how best to support individuals involved in unanticipated outcomes.
- Develop written policies and procedures for second victim support and resources. Educate organizational leaders, providers, and staff about these protocols.
- Implement a comprehensive program to support providers before, during, and after disclosure of unanticipated outcomes. As part of program development, consider potential support options such as:
  - Unit- or department-based support systems.
  - Tiered levels of response to address a range of emotional outcomes and support needs.
  - Rapid response teams.
  - Peer support/mentoring.
  - Employee assistance programs.
  - Easily accessible support contacts/hotlines.
  - Professional review/feedback.
  - Expert consultants (e.g., risk managers, patient safety experts, mental health professionals).
  - Support materials (e.g., tips for coping with stress, self-care guidance, crisis management).
  - Professional counseling.8
- Establish confidentiality standards for information shared as part of second victim support programs.
For more information about supporting second victims of unanticipated outcomes, see the Agency for Healthcare Research and Quality’s *Patient Safety Primer: Support for Clinicians Involved in Errors and Adverse Events (Second Victims)* and the Institute for Healthcare Improvement’s *Respectful Management of Serious Clinical Adverse Events*.

**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.

MedPro Group insureds who have specific questions about disclosure or who would like to request more information should contact their patient safety and risk consultants.

**RESOURCES**

- Continuing Education On-Demand Webinar: The I’m Sorry Dilemma: Disclosing and Remediating Unanticipated Outcomes in Healthcare (MedPro Group)
- Disclosure and Apology (Brigham and Women’s Hospital)
- Disclosure of Unanticipated Outcomes Checklist (MedPro Group)
- Disclosure of Unanticipated Outcomes Resource List (MedPro Group)
- Disclosure Toolkit and Disclosure Culture Assessment Tool (Institute for Healthcare Improvement)
- Full Disclosure of Medical Errors Reduces Malpractice Claims and Claim Costs for Health System (Agency for Healthcare Research and Quality)
- Patient Safety Primer: Error Disclosure (Agency for Healthcare Research and Quality)
- Patient Safety Primer: Support for Clinicians Involved in Errors and Adverse Events (Second Victims) (Agency for Healthcare Research and Quality)
ENDNOTES


8 AHRQ, *Patient safety primer: Support for clinicians involved in errors and adverse events (second victims).*