DISCLOSURE OF UNANTICIPATED OUTCOMES

Medical Protective

Clinical Risk Management Department

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INTRODUCTION

Many providers worry that disclosing unanticipated outcomes (including clinical errors) will lead to litigation. Yet, increasingly, accrediting bodies, healthcare professional organizations, healthcare leaders, and insurers are emphasizing early and honest disclosure of these events.

For example, the American Medical Association emphasizes disclosure in one of its published ethical opinions, which states:

> When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient–physician relationship, and may help reduce the risk of liability.[1]

However, not every unanticipated outcome 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 knowledge 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 adverse events may be apparent only to the clinical staff members who provided care.

In situations where it is reasonable to conclude that the outcome might surprise or distress the patient, the provider should decide how best to discuss the situation with the patient.

Medical Protective insureds who have questions about whether disclosure of an unanticipated event or "near miss" is appropriate should contact their Medical Protective Risk Management Consultants.

OBJECTIVES

The objectives of this guideline are to:

- Explain the reasons for disclosing unanticipated outcomes;
- Discuss an appropriate process for disclosure, including preparing for disclosure, having the disclosure conversation, and following up after disclosure; and
- Describe essential components of disclosure documentation.

[1] The American Medical Association. (2003, December). Opinion 8.121 — Ethical responsibility to study and prevent error and harm. Retrieved from http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8121.page?

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 adverse events;
- Maintain a commitment to open and honest communications in response to unanticipated outcomes;
- Avoid an adversarial relationship that an approach focused on withholding patient information may foster;
- Attempt to reduce legal actions through transparent communication;
- Restore patient and family trust by providing (a) an explanation of the event, (b) an apology for the event, and (c) an assurance that an action plan is in place to prevent future similar events; and
- Ensure accurate reporting to regulatory entities.

THE PROCESS OF DISCLOSURE

Timely disclosure that includes emotional support for patients, families, and clinicians 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.

Preparation for Disclosure

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

When preparing for an actual disclosure conversation:

- Contact Medical Protective to provide notification of the event and discuss specific details related to the disclosure process.
- 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. 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 administrative staff members should be present for the disclosure conversation. In a hospital setting, risk management and other nonclinical staff may not be appropriate for the initial meeting.
- 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 physician or a provider who has an established relationship with the patient. Other parties to consider 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.
- Prior to the meeting, agree on an agenda for the meeting and the information that will be communicated during the meeting.
- Select a location that is conducive to privacy and no interruptions.

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 and eye contact.
- 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; and
    - 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 the error if an obvious error occurred.[2]

[2] Many states have laws related to apology and disclosure of unanticipated outcomes. Healthcare providers should be aware of the laws in the states in which they practice. For more information, visit http://www.sorryworks.net/apology-laws-cms-143.

- Explain the plan of action relative to either continued investigation or changes being implemented to prevent similar future errors.
- Ask whether the patient/family has questions, or whether any information needs to be clarified.
- 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 continued follow-up with the patient/family. This is a critical element in restoring trust and confidence.

Keep in mind that the disclosure may not be well received, and the encounter could potentially be volatile. Further, the existing clinical relationships may not be sustainable. If so, or if the patient/family requests different providers, create a plan for transitioning care to alternative providers.

Disclosure Follow-Up

Following disclosure, conduct a postdisclosure debriefing with the disclosure team and clinical staff to determine clinical staff 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 necessary 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 Medical Protective.
- 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 caregiver should document the unanticipated outcome in the medical 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 medical record, including:

- Time, date, and place;
- The information that was communicated;
- The patient's/family's understanding, and any questions they asked and responses given;
- Names of those present for the disclosure conversation, and who will be responsible for follow-up communication;
- Next steps; and
- A notation that disclosure was based on information available at the time of the conversation with the family.

CONCLUSION

When done properly, disclosure can reduce the impact of an unanticipated outcome on the patient, his or her family, and the healthcare provider(s). As part of the disclosure process, identify the facts, prepare for the conversation, put a plan in place for follow-up, and offer support as needed.

Medical Protective insureds who have specific questions about disclosure or who would like to request more information should contact their Medical Protective Risk Management Consultants.

RESOURCES

- Brigham and Women's Hospital, the Center for Professionalism and Peer Support: Disclosure and Apology — http://www.brighamandwomens.org/medical_professionals/career/cpps/ApologyDisclosure.aspx
- American Health Lawyers Association: Considerations in the Disclosure of Serious Clinical Adverse Events — http://www.healthlawyers.org/hlresources/PI/InfoSeries/Pages/ConsiderationsintheDisclosureofSeriousClinicalAdverseEvents.aspx
- Agency for Healthcare Research and Quality: Full Disclosure of Medical Errors Reduces Malpractice Claims and Claim Costs for Health System — http://www.innovations.ahrq.gov/content.aspx?id=2673
- Institute for Healthcare Improvement: Disclosure Toolkit and Disclosure Culture Assessment Tool — http://www.ihi.org/resources/Pages/Tools/DisclosureToolkitandDisclosureCultureAssessmentTool.aspx

APPENDIX A. SAMPLE TIMETABLE FOR ERROR OR UNANTICIPATED OUTCOME COMMUNICATION