The “I’m Sorry” Dilemma

Disclosing & Remediating Unanticipated Outcomes in Healthcare
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Today’s faculty, as well as CE planners, content developers, reviewers, editors, and Patient Safety & Risk Solutions staff at MedPro Group have reported that they have no relevant financial relationships with any commercial interests.
Objectives

At the conclusion of this program, you should be able to:

- Define an unanticipated outcome and differentiate between the types of situations that can lead to unanticipated outcomes
- Describe the current ethical standards for disclosing unanticipated outcomes in healthcare settings
- Explain the concept of the “second victim” of unanticipated outcomes and identify strategies to support second victims
- List the components of the “communication and resolution” approach to disclosure
- Identify the key steps in the disclosure process and who should participate
Definitions

Unanticipated outcomes include:

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

A near miss is an unplanned event that does not result in patient harm, but has the potential to do so. — National Safety Council
Disclosure vs. admission of liability

**Understanding the Difference**

**Disclosure and apology**

“I’m sorry, Mrs. Jones, but your child became unresponsive and stopped breathing during the procedure. We had to resuscitate her. She is doing fine now, and we are going to closely watch her for the next several hours.”

**Admission of liability**

“I’m sorry, Mrs. Smith, but it is my fault that your child became unresponsive during the procedure. I must have given her too much medicine.”
Disclosure: Laws, standards, and expectations
Disclosure through time

- **1999**: Institute of Medicine “To Err Is Human” Report
- **2001**: The Joint Commission initiates requirement to disclose unanticipated outcomes of care
- **2006**: The National Quality Forum endorses full disclosure of serious unanticipated outcomes
- **2007**: Stanford PEARL program launched
- **2010**: University of Illinois Medical Center at Chicago launches communication and resolution program
- **2016**: AHRQ releases CANDOR toolkit

- AHRQ funds several demonstration projects to test the communication and resolution approach
In the United States, 36 states and the District of Columbia have apology laws.

State apology laws are intended to protect certain statements, expressions of sympathy, and other evidence from being admissible in malpractice litigation.

State apology laws differ in the types of information and statements covered. (Consult your attorney for information specific to the state in which you practice.)

Six states have laws with provisions directly related to accidents (California, Florida, Massachusetts, Tennessee, Texas, and Washington)

Ten states mandate disclosure of unanticipated outcomes to patients (Connecticut, Florida, Maryland, Nevada, New Jersey, Oregon, Pennsylvania, South Carolina, Tennessee, and Washington)

Joint Commission standards

Patient Rights

- Patients or their surrogate decision-makers are informed about unanticipated outcomes of care, treatment, and services that relate to sentinel events as defined by The Joint Commission.

- The practitioner who is responsible for managing the patient’s care, treatment, and services (or his/her designee) must inform the patient about unanticipated outcomes of care, treatment, and services that relate to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed.

## Other disclosure “standards”

<table>
<thead>
<tr>
<th>Source</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMA Code of Ethics</td>
<td>“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.” (Opinion 2.1.3)</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>“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.”</td>
</tr>
<tr>
<td>The Leapfrog Group</td>
<td>Policy on never events includes apologizing to the patient, reporting the event, and performing a root cause analysis (RCA).</td>
</tr>
</tbody>
</table>

Thoughts on disclosure

Agency for Healthcare Research and Quality (2016)

• “Increasing the amount and quality of error disclosure will require addressing physician discomfort with disclosure and fear of lawsuits. This may also require changes in how organizations approach error disclosure.”

Patient Safety & Quality Healthcare (2014)

• “The framework for good disclosure should always be determined from the patient’s perspective. Healthcare organizations should have a plan to respond rapidly to medical errors and provide timely disclosure to patients and families.”

Medical Economics (2015)

• “Good patient-physician relationships and open disclosure are the keys to responding successfully to a bad outcome.”

Disclosure expectations

According to ECRI Institute, when an unanticipated outcome occurs, patients and families want a representative from the healthcare organization to:

- Acknowledge the event truthfully.
- Express empathy.
- Assume responsibility.
- Apologize if an error occurred. (Note: Apology is appropriate only after an investigation has proven a mistake.)
- State that corrective actions will be taken to prevent similar occurrences.

Full vs. partial disclosure

Full disclosure includes:

- Disclosure of all harmful incidents
- Acknowledgment of responsibility and apology (when a known error has occurred)
- An explanation of why the event happened
- How the effects of the event will be mitigated
- Steps the healthcare provider/organization will take to prevent similar occurrences

In a survey of more than 2,600 medical and surgical physicians who were given scenarios depicting serious errors:

- 56% would partially disclose the event (mention adverse event but not error).
- 42% would fully disclose the error.
- 3% would provide no disclosure.

## Barriers to disclosure

### Journal of Patient Safety (2014)

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Intrapersonal barriers</strong></td>
<td>Lack of knowledge regarding the tenets of professionalism (including transparency), hesitation to participate in whistleblowing, erosion of empathy, emergence of defensive coping strategies</td>
</tr>
<tr>
<td><strong>Interpersonal barriers</strong></td>
<td>Physician–patient communication breakdowns, perceived lack of empathy/sensitivity, hesitation to report or improper reporting of unanticipated outcomes</td>
</tr>
<tr>
<td><strong>Institutional barriers</strong></td>
<td>Culture that perpetuates fear, blame, and secrecy; policies/advice that discourage disclosure and apology; fear of malpractice litigation and loss of malpractice coverage; uncertainty about how to report unanticipated outcomes; resistance to transparency</td>
</tr>
<tr>
<td><strong>Societal barriers</strong></td>
<td>Damaged reputation, legal punishment, financial losses, lack of confidence in error reporting systems and apology laws</td>
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## Barriers to disclosure

### Tangible sanctions for physicians

- Punitive workplace policies, damage to reputation and career, fear of litigation, legal/financial damages assessed by the courts

### Healthcare norms and attitudes toward medical error

- Fear of retaliation or career damage from reporting unanticipated outcomes; uncertainty of role in reporting; concerns about loss of authority, damaged reputation, and criticism; effect of disclosure on patients’ idealized perceptions of healthcare providers; different notions of what constitutes an error

### Causal uncertainty surrounding the error trajectory

- Lack of definitive answers about what occurred, how it occurred, why it occurred, and who played a role; uncertainty about the responsibility for disclosure; lack of accountability for systemic origins of errors; questions about preventable errors vs. nonpreventable illness complications

### Physician weighing of harms and benefits of disclosure

- Uncertainty about duty to disclose near misses or errors that are caught and corrected prior to harm, fear of unwarranted patient distress, concern for patient understanding of unanticipated outcome

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Second victims
Don’t forget “second victims”

Unanticipated outcomes can have three victims:

• Patients/families (first victims)
• Healthcare providers (second victims)
• Healthcare organizations (third victims)

Second victim

A healthcare provider who is involved in an unanticipated patient outcome and feels traumatized by the event. The provider may experience feelings of blame, anger, shame, failure, depression, inadequacy, and distress.

Following errors, physicians reported:  

<table>
<thead>
<tr>
<th>Condition</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Increased anxiety about future errors</td>
<td>61</td>
</tr>
<tr>
<td>Loss of confidence</td>
<td>44</td>
</tr>
<tr>
<td>Problems sleeping</td>
<td>42</td>
</tr>
<tr>
<td>Reduced job satisfaction</td>
<td>42</td>
</tr>
<tr>
<td>Harm to their reputation</td>
<td>13</td>
</tr>
</tbody>
</table>

Only 10% of participants felt that their healthcare organizations adequately supported them in coping with error-related stress.

Second victim support: organizational strategies

Support a culture of safety that encourages transparency, respect, and honesty.

Survey staff and conduct an organizational assessment to determine how best to support healthcare providers involved in unanticipated outcomes.

Develop written policies for second victim support and resources.

Implement a comprehensive program to support providers before, during, and after disclosure of unanticipated outcomes, including rapid response provisions.

Establish confidentiality standards for information shared as part of second victim support programs.

Educate and train providers on the organization’s disclosure policies so they are prepared to handle a disclosure scenario.

Second victim support: program considerations

<table>
<thead>
<tr>
<th>Unit- or department-based support systems</th>
<th>Rapid response teams</th>
<th>Peer support/mentoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee assistance programs</td>
<td>Easily accessible support contact/hotline</td>
<td>Professional review/feedback</td>
</tr>
<tr>
<td>Expert consultants (e.g., risk managers, patient safety experts, mental health professionals)</td>
<td>Support materials (e.g., tips for coping with stress, self-care guidance, crisis management)</td>
<td>Professional counseling</td>
</tr>
</tbody>
</table>

**Sources:** AHRQ, *Support for clinicians involved in errors and adverse events (second victims)*; Conway, et al., *Respectful management of serious clinical adverse events*, Institute for Healthcare Improvement.
Communication and resolution programs
Communication and resolution program

• A comprehensive approach to the resolution of potentially compensable events (PCEs)

• Pioneered at the VA hospital in Lexington, Kentucky

• Currently in place at:
  • The University of Michigan
  • The University of Illinois
  • Stanford University
  • Several AHRQ-funded demonstration sites
Elements of a communication and resolution program

Immediate reporting of unanticipated outcomes to risk management staff

Rapid investigation and evaluation of the PCE

Full disclosure

Full apology (if appropriate)

Full compensation (if appropriate)
The University of Illinois Medical Center approach

- **Reporting**
  - Notifying patient safety or risk management personnel about unexpected outcomes involving patient harm

- **Investigation**
  - Undertaking a rapid, detailed investigation using standard RCA techniques to determine whether an error was made

- **Communication**
  - Creating programs for providing ongoing communication with patients/families after an unexpected outcome without regard to the cause of the event

- **Apology and remedy**
  - In the event of an error, providing an apology and an appropriate remedy

- **Improvement**
  - Linking process improvements identified in the RCA with patient/family involvement

Stanford’s PEARL

Process for Early Assessment and Resolution of Loss (PEARL)

• Designed to address significant, unanticipated, or adverse medical outcomes
• Based on principles of open communication, transparency, and integrity
• Helps patients understand their care by addressing complex medical concerns in a comprehensive, compassionate, and confidential manner

Between 2009 and 2014, Stanford's frequency of malpractice lawsuits dropped by 50 percent compared with the frequency from 2003 to 2008. Further, a 40 percent decrease occurred in the average cost of individual malpractice claims.

AHRQ’s CANDOR

Communication and Optimal Resolution (CANDOR)

- A process to help healthcare organizations and providers respond in a timely, thorough, and just way to unanticipated outcomes.

- Based on expert input and lessons learned from an AHRQ Patient Safety and Medical Liability grant initiative launched in 2009.

- Process and materials tested and applied in 14 hospitals across 3 U.S. health systems.

- Includes eight different modules that cover topics such as obtaining organizational buy-in; gap analysis; event reporting, investigation, and analysis; response and disclosure; second victim support; resolution; and more.

- Each module contains PowerPoint slides with facilitator notes. Some modules also contain tools, resources, or videos.

AHRQ’s CANDOR

Watch the CANDOR Video: Introduction to Communication and Optimal Resolution

www.youtube.com/watch?v=xeMWizTodYw
The disclosure process
Disclosure should begin with the informed consent process. Informed consent is:

- An opportunity for patients/families to develop reasonable expectations for their treatment results
- An excellent reference point to begin the disclosure discussion (e.g., “Remember when we discussed the possibility of [x] outcomes?”)
- Your opportunity to build a strong provider–patient relationship, which can support future disclosure discussions
Is honesty always the best policy?

Error Without Harm

- The facts are in the medical record.
- Disclosure can be used as a “relationship builder.”
- There is a risk in *not* disclosing.
Communication of an unanticipated outcome

- Who?
- When?
- Where?
- What?
Disclosure — Who should participate?

The physician or other practitioner who is primarily responsible for the error or is familiar with the unanticipated outcome

A representative from the healthcare practice or hospital, depending on the event

Patient and family (consider the patient’s desires and federal/state privacy regulations)

The person who will be responsible for following up with the patient/family
Disclosure — When should it happen?

- As soon as practical following the event
- As soon as basic facts about the event are known
- As soon as the patient and/or family is able to receive the message
Timetable for communicating an unanticipated outcome

- **Event**
  - Patient Stabilization
  - Staff Briefing

- **24 hours**
  - Secure Implicated Drugs, Equipment, Records
  - ID Communicator/Just-in-Time Training
  - Patient Notice/Apology

- **48 hours**
  - MedPro Group Notice
  - Billing Hold
  - Analysis of Causation
  - Documentation

- **5 days**
  - Patient Support Initiation
  - Patient Support
  - Regulatory Reporting per State Requirements
  - Staff Support

Sample
Disclosure — Where should it happen?

A quiet, comfortable room that provides privacy

- Make sure the room is not scheduled for something else
- Hang a “Do Not Disturb” sign on the door
Disclosure — What should happen?

- Provide simple, concise facts in layman’s terms.
- Discuss current medical status of the patient and anticipated treatment.
- Be empathic and offer an apology (if appropriate).
- Acknowledge that the information currently available is incomplete, and commit to further meetings with the patient/family as more details are known.
Disclosure — What else should happen?

- Solicit feedback from the patient/family throughout the disclosure discussion.
- Indicate that this can be an ongoing conversation, and provide the patient/family with the name and phone number of a contact person.
- Ask whether the patient/family has any immediate unmet needs.
Don’t forget

Healthcare providers and staff involved in the medical error may require support counseling.

Document the disclosure process, including:

- The time, date, and place
- Who was present
- The information that was communicated
- The patient’s/family’s understanding of the event, any questions they had, and the responses given
- Who is responsible for follow-up
- The plan of action going forward

Stop patient billing until the details of the unanticipated event are analyzed.
Don’t forget

Consult your claims or insurance representatives when early resolution is indicated (as it relates to a medical error with damages).

A discussion of monetary settlement is not recommended at the first meeting with the patient/family.

Avoid absolute statements, such as “We’ll take care of everything.”
Communication: An essential component of disclosure
Communication channels

- Hospitalists
- Primary Care Physicians
- Laboratory
- Pharmacy
- Regulatory Agencies
- Case Management
- Resident Physicians
- Nursing
- Technology
- Environment
- Medical Specialists
- Risk Management
- Equipment
- Ancillary Departments
- Patient & Family
- Radiology
- Hospitalists
- Primary Care Physicians
- Laboratory
- Pharmacy
- Regulatory Agencies
- Case Management
- Resident Physicians
- Nursing
- Technology
- Environment
- Medical Specialists
- Risk Management
- Equipment
- Ancillary Departments
- Patient & Family
- Radiology
Components of human communication

- Body Language: 55%
- Tone of Voice: 38%
- Words: 7%

**NOTE:** Percentages may fluctuate depending on various factors. The numbers in the graph represent a general estimate, not an absolute formula.

**Source:** Thompson, J. (2011, September 30). Is nonverbal communication a numbers game? *Psychology Today.* Retrieved from [www.psychologytoday.com/blog/beyond-words/201109/is-nonverbal-communication-numbers-game](http://www.psychologytoday.com/blog/beyond-words/201109/is-nonverbal-communication-numbers-game)
The communication process

Sender → Message → Channel → Receiver

Feedback
Effective communication

The message is successful only when the sender and the receiver perceive it in the same way.
How important is good communication?

A healthcare provider might increase the risk of litigation if he/she:

- Has poor listening skills
- Delegates critical informed consent communication
- Fails to be timely in sharing information with the healthcare team
- Becomes defensive when a patient inquires about diagnostic and treatment options
- Lacks empathy when disclosing unanticipated outcomes

Communication tips

- Establish direct eye contact.
- Sitting is preferred.
- Use “I” instead of “we.”
- Speak slowly.
- Use layman’s terms.
- Be brief (avoid the tendency to overexplain).

Try to anticipate questions the patient/family may have.
Communication tips

Listen carefully and don’t interrupt.

Identify the emotion(s) observed in the patient/family (e.g., “This must be very frightening [upsetting, scary, overwhelming, sad, frustrating, difficult, etc.] for you.”)

Avoid saying: “I know how you feel; this is a blessing in disguise; these things just happen.”

Do not point fingers.

Do not avoid the patient/family in hopes of avoiding questions.
Self-assessment
<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>My organization has a mechanism for all providers and staff to report incidents.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My organization has a process for reviewing cases to identify all unanticipated outcomes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My organization has a disclosure policy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My organization’s disclosure policy addresses:</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------</td>
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<td>----</td>
</tr>
<tr>
<td>Who will disclose unanticipated outcomes</td>
<td></td>
<td></td>
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<tr>
<td>What information should be disclosed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When to conduct the disclosure conversation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to manage ongoing communication with the patient/family</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How financial issues regarding the event will be managed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What events trigger regulatory reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How the organization will manage ancillary issues that arise, such as regulatory and litigation inquiries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>My organization includes disclosure education in new employee orientation, including the confidential nature of disclosure management.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The designated individual in my organization is notified immediately when an unanticipated outcome occurs and is known.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>All involved providers and staff are interviewed after an unanticipated outcome to accurately determine the sequence of events.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>My organization has a protocol in place for managing any outside inquiries related to unanticipated outcomes.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Clinical documentation is completed as soon as possible after the unanticipated outcome.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>Clinical documentation includes:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date, time, and place.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Detailed, objective narrative of the facts of the event.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Details about any conversations with the patient, family, or other providers.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Additional steps to be completed and who is responsible.</td>
<td>☐</td>
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</table>
Final thoughts
When disclosing, remember . . .

1. Identify the facts.
2. Use a communications checklist to prepare yourself.
3. Consult your professional liability carrier to review possible indicators for early resolution.
4. Offer support counseling to healthcare providers and staff involved in the event.
5. It’s okay to say “I’m sorry.”
In summary

When done properly, disclosure can reduce the impact of unexpected outcomes on patients AND healthcare providers.
More resources

Article: When Apology Is Appropriate — And When It Is Not

Checklist: Disclosure of an Unanticipated Event

Guideline: Disclosure of Unanticipated Outcomes

Risk Resources: Disclosure of Unanticipated Events
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