

### 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
- Identify the difference between expressions of empathy and expressions of apology
- Explain the concept of the "second victim" of unanticipated outcomes and identify strategies to support second victim
- $\ensuremath{\text{\textbf{o}}}$  List the componence of the "communication and resolution " approach to disclosure
- disclosure

  Identify the key steps in the disclosure process and who should participate
- Discuss the essential components of communication to assure the effectiveness of the disclosure

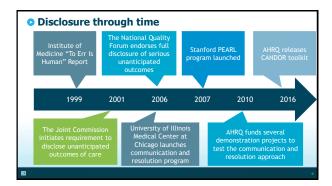
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### Unanticipated outcomes include: Outcomes of care that differ significantly from anticipated outcomes include: Medical errors caused by standard of care deviations Patient harm that results from medical mismanagement or system failures Near Miss Not Preventable Unanticipated Outcome A near miss is an unplanned event that does not result in patient harm, but has the potential to do so. — National Safety Council

### Understanding the difference Disclosure and empathy "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."

In my 1. There is value in proactively disclosing unanticipated outcomes
<ol><li>Disclosing unanticipated outcomes just creates more problems and unnecessary stress.</li></ol>
3. I have no opinion about disclosing unanticipated outcomes.







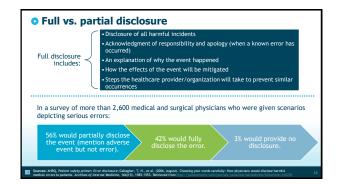
# 2014 Oklahoma Statutes Title 63. Public Health and Safety 563-1-1708.1H. Statements, conduct, etc. expressing apology, sympathy, etc. – Admissibility – Definitions. Universal Citation: 63.0K Stat 5-63-1-1708.1H. (2014) A. In any medical liability action, any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health care provider or an employee of a health care provider to the plaintiff, a relative of the plaintiff, or a representative of the plaintiff and which relate solely to disconfort, pain, suffering, injury, or death as the result of the unanticipated outcome of the medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest. B. For purposes of this section, unless context otherwise requires, "relative" means a spouse, parent, grandparent, stepfather, child, grandchild, brother, sister, half-brother, half-sister or spouse's parents. The term includes said relationships that are created as a result of adoption. "Representative" means a legal guardian, attorney, person designated to made decisions on behalf of a patient under a durable power of attorney or health care proxy, or any person recognized in law or custom as an agent for the plaintiff.

• The	The Joint Commission standards		
! !	"Though Joint Commission standards do not require disclosure, evidence suggests that patients benefit—and are less likely to pursue litigation—when physicians disclose harm, express sympathy and apologize."		

AMA Code of Ethics	"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)
The American College of Obstetricians and Gynecologists	"The disclosure and discussion of adverse events are critical t create and maintain high-quality health care and to preserve the integrity of the patient-physician relationship."
The Leapfrog Group	"Leapfrog asserts that regardless of its environment, setting, or type of patients it treats, 100% of hospitals should comply with all nine elements of Leapfrog's Never Events Policy."

# © Disclosure organizational plan ECRI Culture of safety "Disclosure culture" Clinical crisis management plan Disclosure policies and procedures Educate staff Prepare staff for disclosure conversations Support staff Document and communicate disclosure Service recovery

### "Studies using hypothetical designs have suggested that a gap exists between clinicians' and patients' views of what is appropriate incident disclosure. Clinicians tend to consider unexpected clinical outcomes as less serious and therefore less in need of disclosure than do patients. Clinicians also err on the side of caution, whereas patients expect openness and admission of responsibility. Such breakdowns in the disclosure process exacerbate the distress patients experience from the event itself."



## Barriers to disclosure Austin Journal of Pathology & Laboratory Medicine (2014) 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 efficiency 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



• 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 patie outcome and feels traumatized by the event. The provider may experience feelings of blame, anger, shame, failure, depression inadequacy, and distress.			
Sources: Says, C., et al. (2011, May). Supporting involved health care professionals (second stating) following an adverse health enert: A literature server. International Journal of Muning States, 2023, and 2021. Network from a common control of the control of			



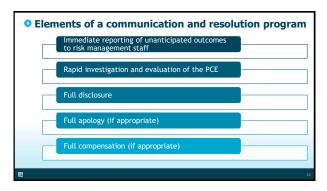
### Support a culture of safety that encourages transparency, respect, and honesty. Survey staff and conduct an organizational assessment to determine how best to support healthcare providers involved in unanticipated outcomes. Develop written policies for second victim support and resources. Implement 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.











<ul> <li>The University of Illinois Medical Center approach</li> </ul>			
Reporting	Notifying patient safety or risk management personnel about unexpected outcomes involving patient harm		
Investigation	<ul> <li>Undertaking a rapid, detailed investigation using standard RCA techniques to determine whether an error was made</li> </ul>		
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	<ul> <li>In the event of an error, providing an apology and an appropriate remedy</li> </ul>		
Improvement	Linking process improvements identified in the RCA with patient/family involvement		
Source: Mayer, D., et al. (2011, September 12) 20110912/profession/309129949/5/	Medical error calls for honest disclosure. American Medical News. Retrieved from <a href="https://www.amednews.com/article/">https://www.amednews.com/article/</a>	2	

### Stanford's PEARL

Process for Early Assessment and Resolution of Loss (PEARL)

- Designed to address significant, unanticipated, or adverse medical outcomes
- $\bullet$  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.

Source: How Starford Hospital cut malpractice lawsuits in half. Retrieved from

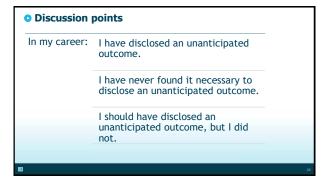
### AHRQ's CANDOR process

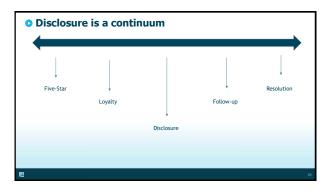
Communication and Optimal Resolution (CANDOR)

- $\bullet$  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.

Source: Agency for Healthcare Research and Quality, (2016, May). Communication and optimal resolution (CANDOR) toolkit. Retrieved from www.alexa.gov/professionals/coulity-patient-safety patient-safety associated resources/candor/introduction had







### • Five-Star culture

- Treating staff, colleagues, physicians and patients at the highest level of service - internal and external
- •Providing an unprecedented level of service
- Leaving a lasting positive fingerprint
- Consistent...pervasive...even on the worst days

### • When does the disclosure process begin?

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 that can support future disclosure discussions

### Is honesty always the best policy?

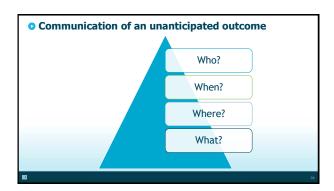
### Error Without Harm

- The facts are in the health record.
- Disclosure can be used as a "relationship builder."
- There is a risk in *not* disclosing.

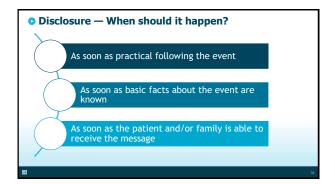


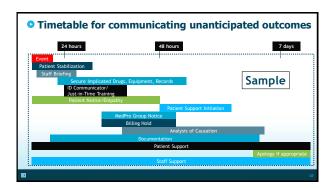


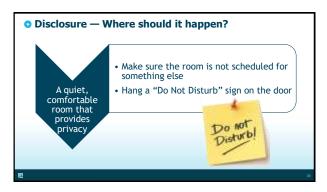
• Is honesty always the best policy?	
"Admitting mistakes can be difficult and can force physicians to confront their own perceptions of inadequacy, fallibility, and	
guilt. It can be easier to avoid acknowledging mistakes, especially when the event or potential error has a perceived	
minimal or no-harm effect. However, there are several reasons	
why minimal and even no-harm errors should be disclosed to the patient."	
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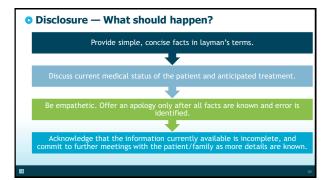


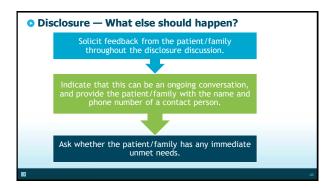


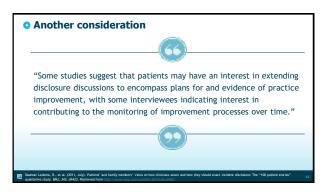


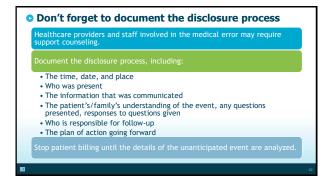






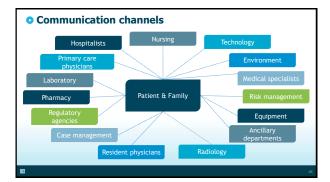












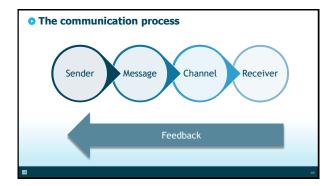
The failure to communicate is a catalyst for converting patients to plaintiffs.

© Components of human communication

7%

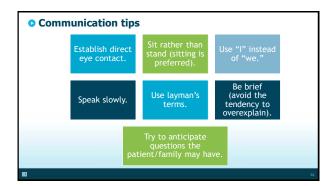
8Body Language
Tone of Voice
Words

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







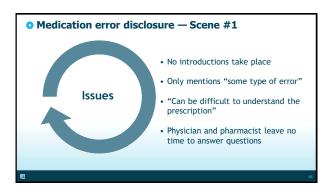






Mrs. Johnson receives the wrong med	ication.
She has no current adverse symptoms	
Future symptoms are unknown.	N 2 /
	Name of the last
	Mrs. Johnson receives the wrong med She has no current adverse symptoms Future symptoms are unknown.



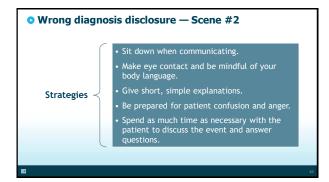


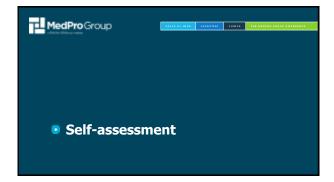
• Medication error disclosure — Scene #2	
<b>II</b>	
• Medication error disclosure — Scene #2	]
	-
<ul> <li>Meet with the healthcare team first to discuss and practice the disclosure.</li> </ul>	
At the meeting with the patient/family:	
<ul> <li>Introduce all parties at the disclosure.</li> <li>Explain the error and possible sequelae.</li> </ul>	
Empathize with the patient's emotions.	
<ul> <li>Reassure that corrective actions will take place.</li> </ul>	
<b>.</b>	
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• Case example #2 — Wrong diagnosis disclosure	
Carol had a chest X-ray 2 years ago and was diagnosed with pneumonia.	
Now Carol is informed that she also had a lung lesion at the time of the chest X-ray. Yet, this information was not previously	
the chest X-ray. Yet, this information was not previously communicated to Carol.	
Upon follow-up testing, the tumor is obvious.	
The surgeon explains the missed diagnosis of cancer and says surgery must be scheduled immediately.	

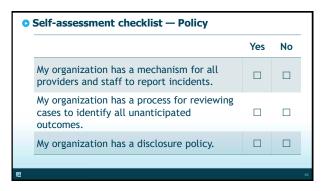












My organization's disclosure policy addresses:	Yes	No
Who will disclose unanticipated outcomes		
What information should be disclosed		
When to conduct the disclosure conversation		
How to manage ongoing communication with the patient/family		
How financial issues regarding the event will be managed		
What events trigger regulatory reporting		
How the organization will manage ancillary issues that arise, such as regulatory and litigation inquiries		

My organization includes disclosure education in new employee orientation, including the confidential nature of disclosure management.  The designated individual in my organization is notified immediately when an unanticipated outcome occurs and is known.  All involved providers and staff are interviewed after an unanticipated outcome to accurately determine the sequence of events.  My organization has a protocol in place for managing any outside inquiries related to unanticipated outcomes.	es	es No
immediately when an unanticipated outcome occurs and is known.  All involved providers and staff are interviewed after an unanticipated outcome to accurately determine the sequence of events.  My organization has a protocol in place for managing any		
unanticipated outcome to accurately determine the sequence of events.  My organization has a protocol in place for managing any		

	Self-assessment checklist — Documentation			
	Seir-assessment checklist — Documentation			
		Yes	No	
	Clinical documentation is completed as soon as possible after the unanticipated outcome.			
	Clinical documentation includes:			
	Date, time, and place.			
	Detailed, objective narrative of the facts of the event.			
	Details about any conversations with the patient, family, or other providers.			
	Additional steps to be completed and who is responsible.			
2				















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