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When Things Go Wrong – Transparency and Responding to Adverse Events

Presented by:
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Disclosure to Learners

No planner, reviewer, faculty, or staff for this activity has any relevant financial relationships with ineligible companies.

Objectives

- Define an adverse event.
- Critically review and analyze cases for regulatory reporting requirements after an adverse event.
- Apply immediate mitigation steps to reduce risk exposure after an adverse event.
- Incorporate the components of patient disclosure and explain its importance in post-event monitoring.
- Prioritize the importance of maintaining a positive physician—patient relationship.

What is an Adverse Event

- California Department of Public Health (CDPH): 28 Never Events
- Joint Commission: Sentinel Event
  - A patient safety event that reaches a patient and results in any of the following:
    - Death
    - Permanent Harm
    - Severe temporary harm and intervention required to sustain life
- CAP defines an “adverse outcome” as either a known risk of medical care (a complication) or medical error.

What is an Adverse Event

Not all adverse events are a result of an error.

Some adverse events are known complications of treatment or procedures.

Examples:

- Anaphylactic or allergic reaction to a medication or vaccine.
- Tooth injuries during anesthesia from bruxism.
- Post-operative infections

System Failure

- 1000 times the recommended dose.
- $750,000 from Cedars Sinai Medical Center
- Sued Baxter

Other challenges that lead to adverse events.

- Labeling
- Scheduling delays
- Failure to track/recall
- Scope of practice
- Front office processes

Old and New Labeling Hep Lock 10 units/ml and Heparin 10,000 units/ml

Dennis Quaid newborn twin case, Heparin overdose, 2007

Tall Man Lettering

Examples

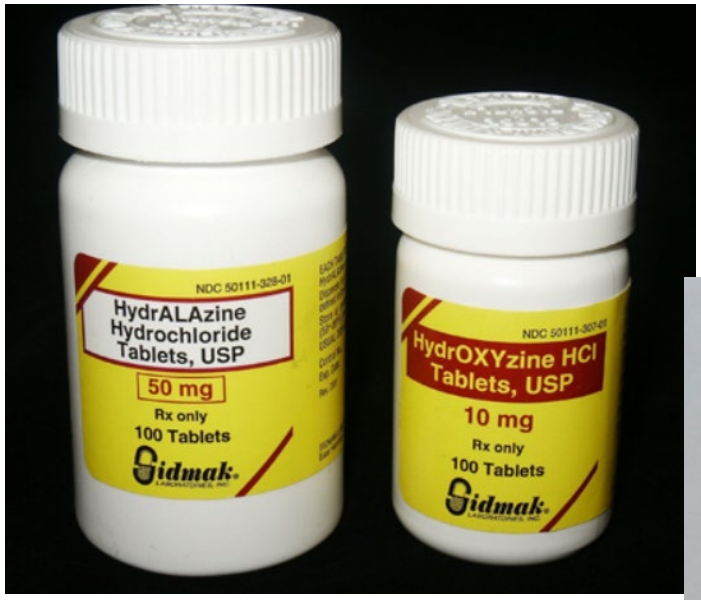
DOBUTamine vs. DOPamine

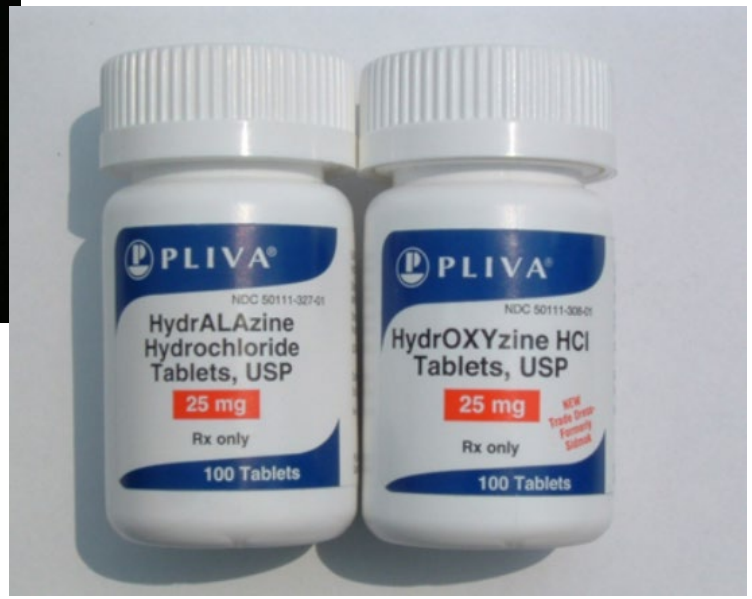
glipiZIDE vs. glyBURIDE

EPHEDrine vs. EPINEPHrine

traMADol vs. TraZODone

morphine vs. HYDROmorphone





Brooke Schmidt: Patient Safety & Quality Healthcare July 2010
https://www.psqh.com/analysis/look-alike-drug-name-errors/

Regulatory Reporting

California Medical Association California Physician's Legal Handbook, Section 3602 & 3603 (2022)

Private Practices

- OSHA requirements
- Adverse Vaccine reactions—VAERS VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Radiology Facilities

- CDPH—related to overexposure

Surgery Centers

- The Medical Board—Patient Deaths, Adverse Events, Transfer to acute hospital for treatment that exceeds 24 hours
- FDA—Safe Medical Device Act of 1990

Hospital

- CDPH— (Title 22/H&S 1279.1, & 70737)
- FDA—Safe Medical Device Act 1990

Extent of the Challenge

- Approximately 400,000 hospitalized patients experience some type of preventable harm each year.
- Medical errors cost approximately $20 billion a year.
- Medical errors in hospitals and clinics result in approximately 100,000 people dying each year.
- Missed diagnoses or injuries from medication are common in outpatient settings.
- Most malpractice claims in hospitals are related to surgical errors, whereas most claims for outpatient care are related to missed or late diagnosis.
- **Slightly more than half of the paid malpractice claims are related to outpatient care**.

NCBI Continuing Education Activity: Medical Error Reduction and Prevention 2021

Immediate Response

ENSURE PATIENT SAFETY

SEQUESTER ANY MEDICAL DEVICES THAT MAY HAVE CONTRIBUTED TO EVENT

DOCUMENT DETAILS OF EVENT

PARTICIPATE IN DEBRIEF

CALL YOUR RISK MANAGER

How to Minimize *Your* Risk Exposure

- Conduct the initial fact gathering with team.
- Thoughtfully analyze the occurrence.
- Anticipate discussions with patient and family.
- Prepare for questions likely to be raised.
- Determine appropriate patient disclosure—both initial and ongoing.
- Complete documentation, initial and ongoing.
- Is event reportable to any regulatory agencies?
- Risk Management strategies
- Care for the caregiver

A risk manager can provide important guidance

The Issues

- “Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a perceived or actual withholding of essential information.” -

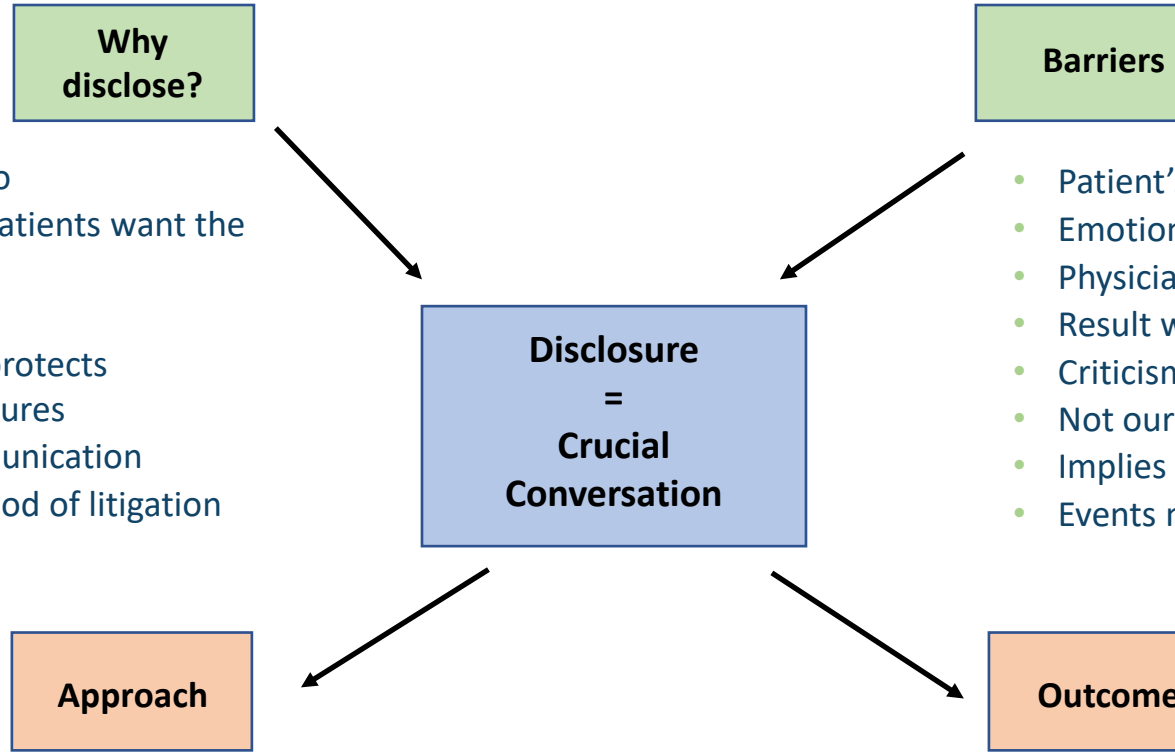
-Leibman & Hyman, 2004 – Boston MA

- Our response to injured patients rarely addresses their needs.

Addressing the Need

- Patients/families desire:
- The Truth- what happened?
- The Facts
  - What do we know ***right now***?
- Human Experience & Connection
    - Empathy
    - Compassion
    - Acknowledgment
    - Validation
    - Availability
- Accountability, including sincere apology
    - Full explanation of what happened
    - Making things ‘right’ again
    - Future prevention

Disclosure



- Right thing to do
- Transparency; patients want the truth
- Patient's rights
- CA Law favors/protects benevolent gestures
- Improves communication
- Reduces likelihood of litigation

- Patient's reaction
- Emotions are high
- Physician concern over litigation
- Result was inevitable-NEVER
- Criticism from other colleagues
- Not our fault
- Implies error
- Events not clearly defined

- Alone vs team approach
- Telephone vs return to office

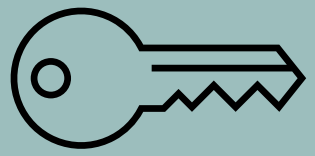
- Fosters just culture and accountability within your team
- Maintains the patient/physician relationship
- Historically shown: Again, reduces likelihood of litigation

Disclosure Considerations

- Transparency in disclosure does NOT mean:
  - Spontaneous conversations
  - Speculations about what happened
  - “Pointing fingers” at other providers, medical staff, technology, etc.

- Important Considerations:
  - Who? (Team vs. Single Provider vs. “Neutral” Party)
  - When?
  - Location?
  - Patient/family members present
  - Consistency & Clarity re: facts
  - Assess patient readiness, health literacy, language needs, cultural factors
  - “Plan B”
  - Anticipate challenging questions
  - Emotional energy

Disclosure- Key Elements



- What happened?
- How and why did it happen (if known)?
- What are the clinical implications (*acknowledging that all may not be known at the time of the disclosure*)?
- Investigation?
- What will you do to prevent it from happening again?
- Empathy/ “Apology” for the situation
- Time for patient/family to relay their experience, ask questions
- Documentation

Addressing Cultural Linguistic Competency & Implicit Bias

- Manifestation of Implicit Bias in Disclosure Conversations
  - Power imbalance in verbal and non-verbal communications ("experts indicated," "**we've** known," body posture, eye contact, etc.)
  - Biases related to a patient/family's health literacy, ability to afford treatments, adherence to care plan, pain management, etc.
  - Can lead to distrust and greater health disparities
- Addressing Implicit Bias
  - Awareness and Training
  - Person-centered communication & personalization
  - Cultural Humility

Maintaining the Patient-Physician Relationship

- Maintain open communication with your patient
- Monitor medical progress

→ Helps Rebuild Trust; Reduces Likelihood of Litigation

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Risk Mitigation- Managing Expectations

When Results Don't Meet the Expectation….

- Anger/Resentment
- MBC/BRN Complaint ?
- Grievance?
- Claim/Lawsuit?
- Negative Reviews/ Social Media

Sources of Patient Expectations

Where do patient perceptions come from?

- Psychosocial/cultural composition
- Social Media – TV – Movies
- Reputation
- Us – it's routine surgery

Case Scenario- Medication Complication

Adverse Event

- Patient called to complain that she has a “dent where you gave me a shot.” In this case right buttock.
- Injection was a steroid (Kenalog)
- Suspect-Fat atrophy from injection
- Patient asking how you are going to fix it.

Response

- *Physician-Apologize/Disclose*
- *Call CAP Hotline*
- *Service Recovery*
- *Mitigate damages (Derm Referral?)*
- *Investigate Root Cause (Wrong Z-Track Method?)*
- *Continue Monitoring progress*
- *Preventing Future Occurrence (Staff Education)*

Case Scenario—The RFO

Adverse Event

- Hip replacement
- Post-op x-ray noted metallic object in proximity – approx. 1-2 mm estimated
- Magnification views showed serrated teeth
- Best guess is a tungsten carbide Fragment from a needle holder.
- Asymptomatic

Response

- *Physician-Apologize/Disclose*
- *Involve facility Risk Team*
- *Call CAP Hotline*
- *Service Recovery*
- *Mitigate damages*
  - *Best course: Remove or keep.*
- *Investigate:*
  - *Root Cause?*
- *Continue Monitoring progress*

References

- Schmidt,B. Patient Safety & Quality Healthcare. Look-Alike Drug Name Errors. July/August 2010. https://www.psqh.com/analysis/look-alike-drug-name-errors/
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  - *Vaccines, Drugs, and Devices: Reporting Adverse Events* (Chap Adverse Events; section 3603)
- ECRI (April 2021) *Adverse Events in Outpatient Surgery: Staff Perceptions of Risk* https://www.ecri.org/components/HRCAlerts/Pages/HRCAlerts042821_Adverse.aspx
- ECRI (February 2021) *Essentials: Event Management* https://www.ecri.org/components/HRC/Pages/Essentials_Event-Management.aspx#improveapproach
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- Relis Media, Confirmation Bias Threatens Patient Safety (2014) https://www.reliasmedia.com/articles/110655-confirmation-bias-threatens-patient-safety-but-can-be-overcome
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Legal Codes

- SB 1301: http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_1301-1350/sb_1301_cfa_20060619_145732_asm_comm.html
- Health and Safety Code 1279.1: https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1279.1.&lawCode=HSC
- California Department of Public Heath: Title 22; section 70737a.

Thank You

For guidance on how best to handle an adverse event, manage exposure, or manage the risks involved,

CAP Members may contact CAP's Risk Management Hotline for 24/7 support at **800-252-0555**.

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