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When Things Go Wrong – Transparency and Management of Adverse Events

Presented by:
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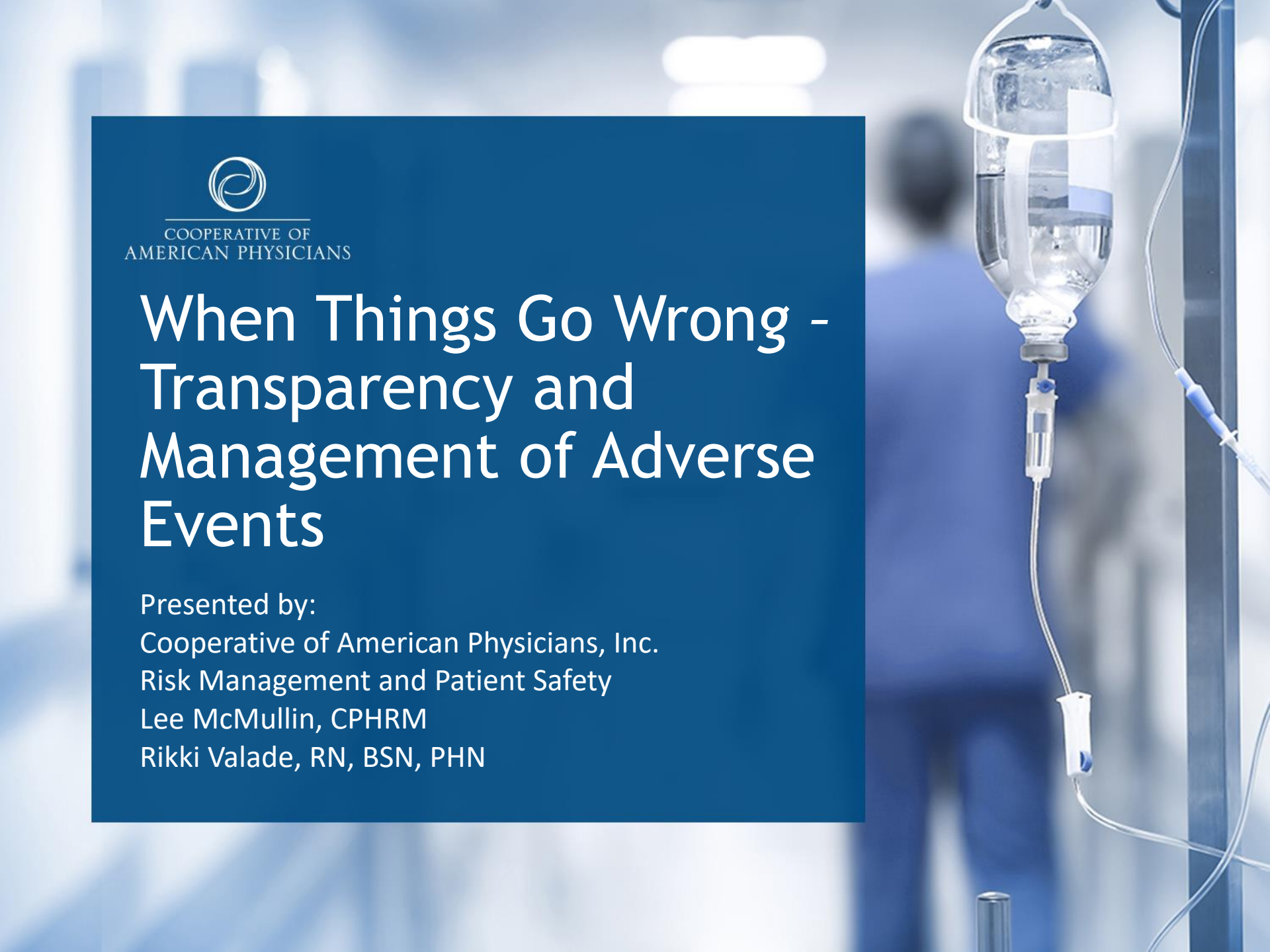

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Objectives

- Define an adverse event.
- Identify general regulatory reporting requirements after an adverse event.
- Discuss what immediate mitigation steps should be taken after an adverse event.
- Describe the elements of patient disclosure and why it is necessary in post event monitoring.
- Recognize the importance of maintaining a positive physician—patient relationship.

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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.

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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.
- Tooth injuries during anesthesia from bruxism.
- Post-operative infections

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What is an Adverse Event

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

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Regulatory Reporting

Private Practices

- OSHA requirements
- Adverse vaccine reactions—VAERS

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

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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

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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

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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

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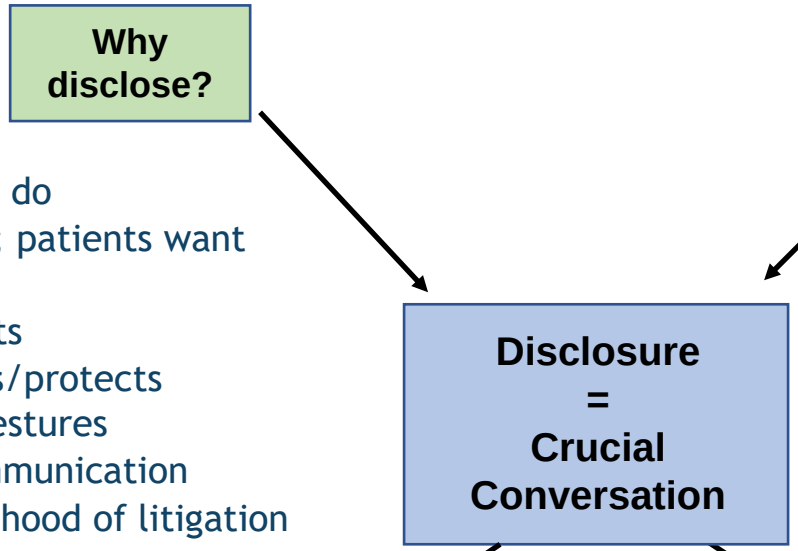
Disclosure



- 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

Approach

- Alone vs team approach
- Telephone vs return to office

Outcome

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

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Apology & Disclosure - What it is … What it's not

- Not a guessing game
  Everything you (and others) say that's wrong will become like concrete –all mixed up and permanently set. Never speculate.

- Not an expression of error (i.e., apology) until/unless after investigation determines a true error occurred

- Is an empathetic expression

- Is best done following a huddle

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Steps to Disclosure

Prepare for the conversation with patient/family

- What happened
- How did it happen – *if known*
- What will be done to prevent this from happening again
- Be transparent and honest
- Empathize with the experience (not an “apology”)
- Provide continuing support to patient & family

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Disclosure - Understanding the "Expectation Effect"

- When you have a problem…knowing the patient's expectations is crucial to the disclosure process…
- In disclosure – Your pre-game is crucial
- Blow it… and you're forever chasing perceptions
- Patients say they feel AMBUSHED

Risk Assessment - Measuring Patient Expectations

Successful surgeons are those who can judge if the patient has realistic expectations for the proposed treatment or procedure.

2009 Annual Benchmark Report

Malpractice Risks

In other words –

You avoid problems when you figure out what patient's ***think*** will happen vs. what ***will*** happen and balance the realities.

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Risk Assessment - Sources of Patient Expectations

Where do those perceptions come from ?

- Psycho-social/cultural composition
- Social Media – TV - Movies
- Us - It's "routine" surgery

USA TODAY

YouTube

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Risk Assessment – Social Behaviors Affecting Patient Expectations

Research shares we tend to be optimistic vs. realistic creatures

Optimism Bias…

Also known as *unrealistic* optimism

"…is a cognitive bias that causes a person to believe that they are less at risk of experiencing a negative event compared to others..."

Wikipedia

Aka – ***"It won't happen to me" – until it does***

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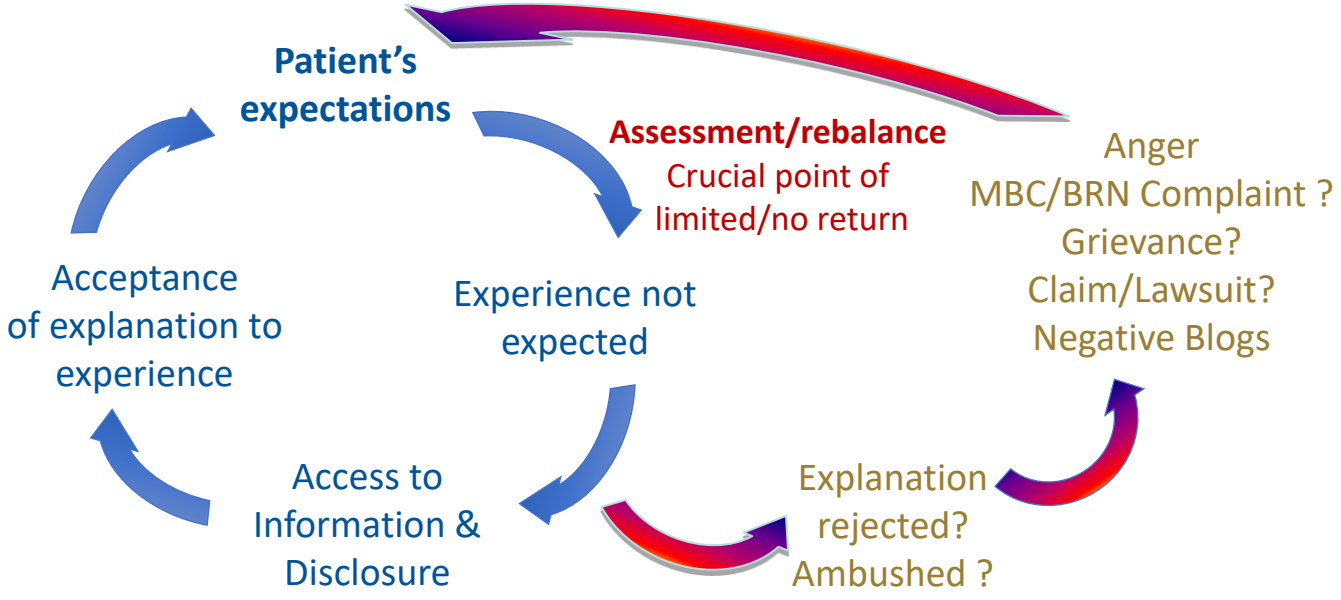
Risk Assessment - The Expectation Lifecycle

The Results-to-Expectation Lifecycle



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Risk Assessment – Understanding Expectations

Recognition and management of optimism bias…

- Successful healthcare providers are those who can judge if the patient has realistic expectations.

- With many of the population being visual learners…*Why* do we *talk* to patients about consent?

The single biggest problem in communication is the illusion it has taken place.

-George Bernard Shaw; 1856-1950

Good consent ***is*** expectation management

-Lee McMullin; CAP-MPT/ SCAHRM

IMPORTANT - Apology vs Empathy

In some jurisdictions an “apology” or expression against oneself interests is admissible in legal proceedings – know what rule(s) apply to you.

Compare:

“I’m sorry you’re going through this. I feel terrible when complications happen. We knew it was a risk and this is what we’re doing about it.

vs.

“I’m sorry I did this…”

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What and How

We always know what…but not always why or how…

“While we do not know the cause at this time, we are working to understand what happened and will keep you informed as information is learned.”

- Never speculate
- No finger pointing

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Ongoing Monitoring

- Maintain open communication with your patient
- Monitor medical progress

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Patient-Physician Relationship

Why is this important:

- Reduces risk litigation
- Allows for continued communication
- Allows clinical monitoring

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Case Scenario

The Mystery Med – What Is This?

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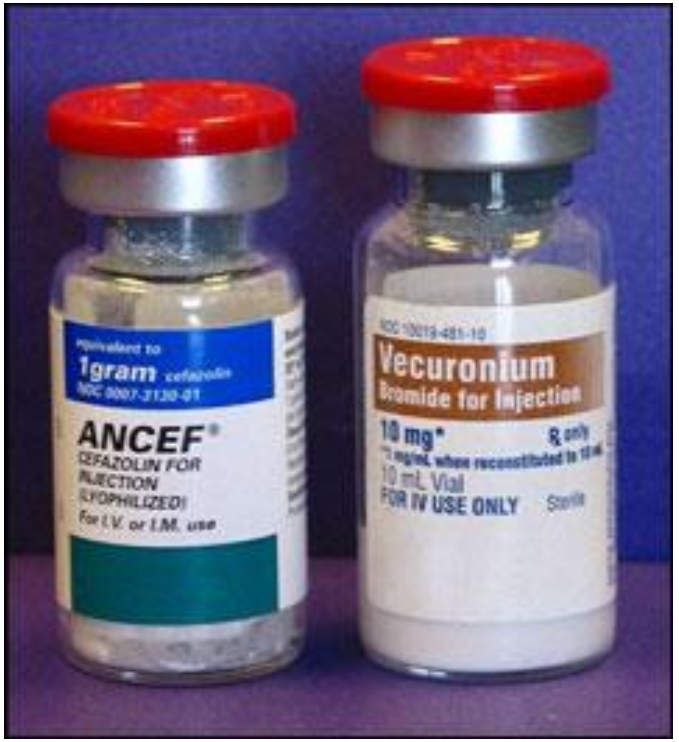
Case Scenario

Who moved my cheese?



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Case Scenario

The UFO -

- 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 Frag from a needle holder.
- Asymptomatic

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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.

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Question & Answer

- Send us your questions via the Q&A box.
- While we do our best to answer as many questions as possible, time constraints may not allow us to answer every question.

Thank you for understanding.

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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**.