The background is a watercolor-style illustration of a mountain range. The mountains are rendered in various shades of blue and cyan, with white highlights suggesting snow or light reflecting off the peaks. In the upper left corner, there is a circular, textured orange and yellow shape representing a sun or moon. Small, dark green evergreen trees are scattered across the lower slopes of the mountains. The overall style is soft and artistic.

Early Resolution & Disclosure of Unanticipated Outcomes

Kathy Kenady, CPHRM

MIEC

Disclosures

- Nothing to disclose



Learning Objectives

**Kathy Kenady, Patient Safety & Risk Management Specialist,
MIEC Insurance**

Early Resolution and Disclosure Of Unanticipated Outcomes

List common perceived or actual barriers to disclosure of unanticipated medical outcomes with patients and/or their families.

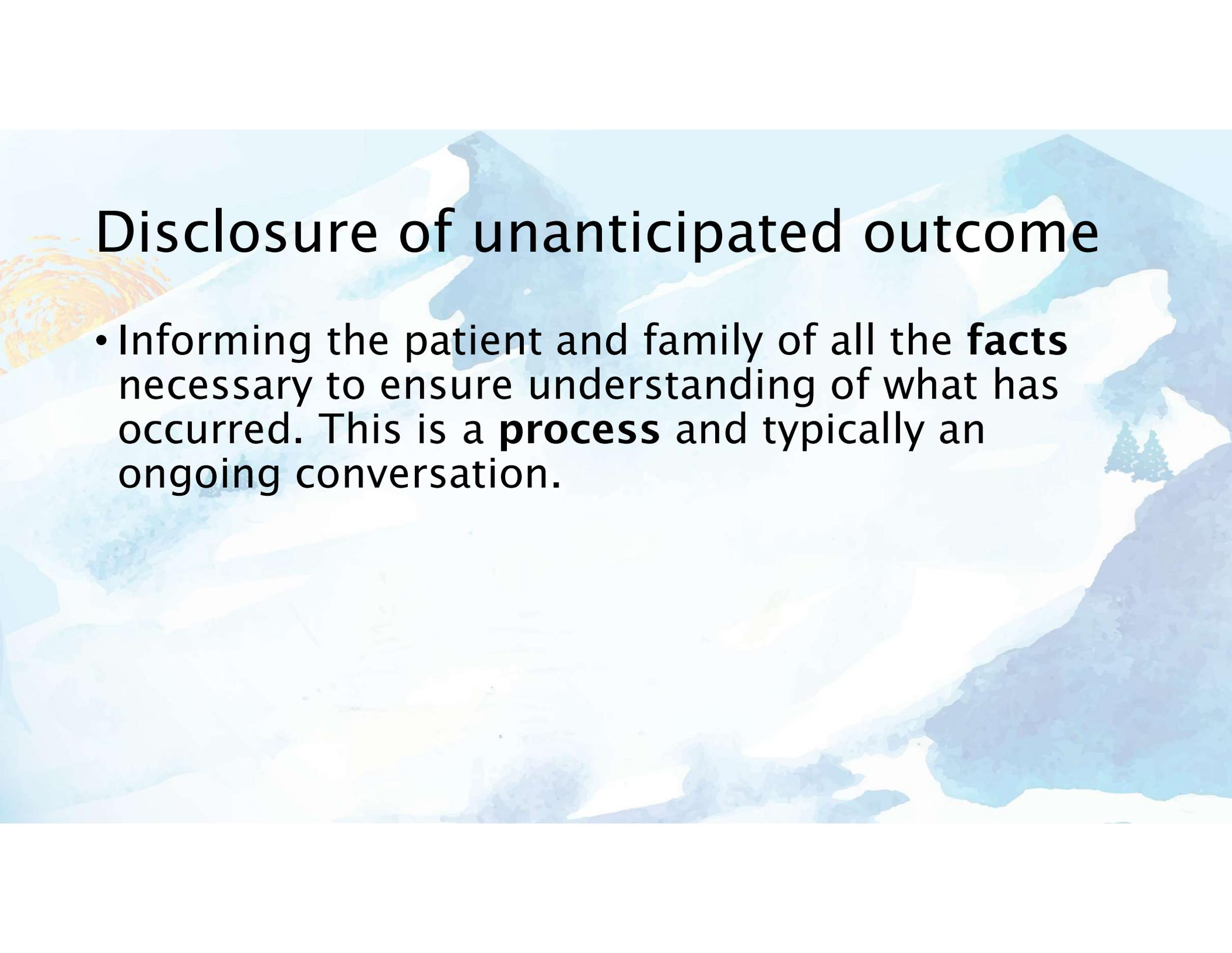
The Paradigm Shift

- from delayed → to immediate reporting
- from delay, deny & defend → to immediate and ongoing communication
- from shame, blame & train → to human factors/event review and system redesign
- from suffering in isolation → to immediate support and care for the caregiver

Communication & Resolution Programs

- CRPs focus on responding to an adverse medical outcome through:
 - **prompt** and **ongoing** communications (transparency)
 - correction of systemic errors (patient safety improvement), and
 - recognition of **all parties needs** following the event (doing no further harm).

Collaborative for Accountability & Improvement



Disclosure of unanticipated outcome

- Informing the patient and family of all the **facts** necessary to ensure understanding of what has occurred. This is a **process** and typically an ongoing conversation.

CRP success stories

- **The University of Michigan Health System has become national leader in early disclosure or errors.**
- Litigation costs have dropped from \$5M to \$1M at University of Michigan since instituting early disclosure. (Thomas Gallagher, M.D., University of Washington)

COPIC “3Rs” Recognize, Respond & Resolve (2015 data)

- **5 years, 4,000 Incidents Voluntarily Disclosed**
- **Only 500 payments**
- **average \$5,600 Payment per incident***
- **None of 4,000 proceeded to trial**
- **Both physicians and patients report happy with results**

Barriers to Effective Disclosure

- A natural aversion to confronting angry people
- Concerns that disclosure might invite a claim that otherwise would not be asserted.
- Anxiety that the discussion will later compromise courtroom defenses.
 - TBD, but physicians trying to do right by patients generally well perceived in litigation.

Barriers to effective disclosure cont'd

- Fear that the conversation may lead to loss of malpractice insurance or higher premiums.
- What's the result? Adverse event occurs, physician avoids the discussion with the patient, patient becomes angry and a lawsuit is filed.

Practical considerations

- Idaho Board of Medicine – no reporting required (MIEC)
- Idaho “apology” law
 - Expressions of sympathy, apology, condolence, etc. not admissible as admission of liability
 - Does **not** include “statement of fault”
- NPDB
 - Exchange of money (waiving fee is not an “exchange” but refund is)
 - In response to a written “claim” from patient
 - Patient must sign a settlement agreement

Why should you disclose?

- Patients often present their most vulnerable self to their doctor. Communication is at the heart of the physician-patient relationship.
- The relationship is rooted in trust.
- There is an expectation of professionalism, privacy and honesty.



Why disclose cont'd

- Disclosure increases the trust of patients and the public.
- Disclosure involves patients as partners.
- Disclosure drives providers and organizations to improve.

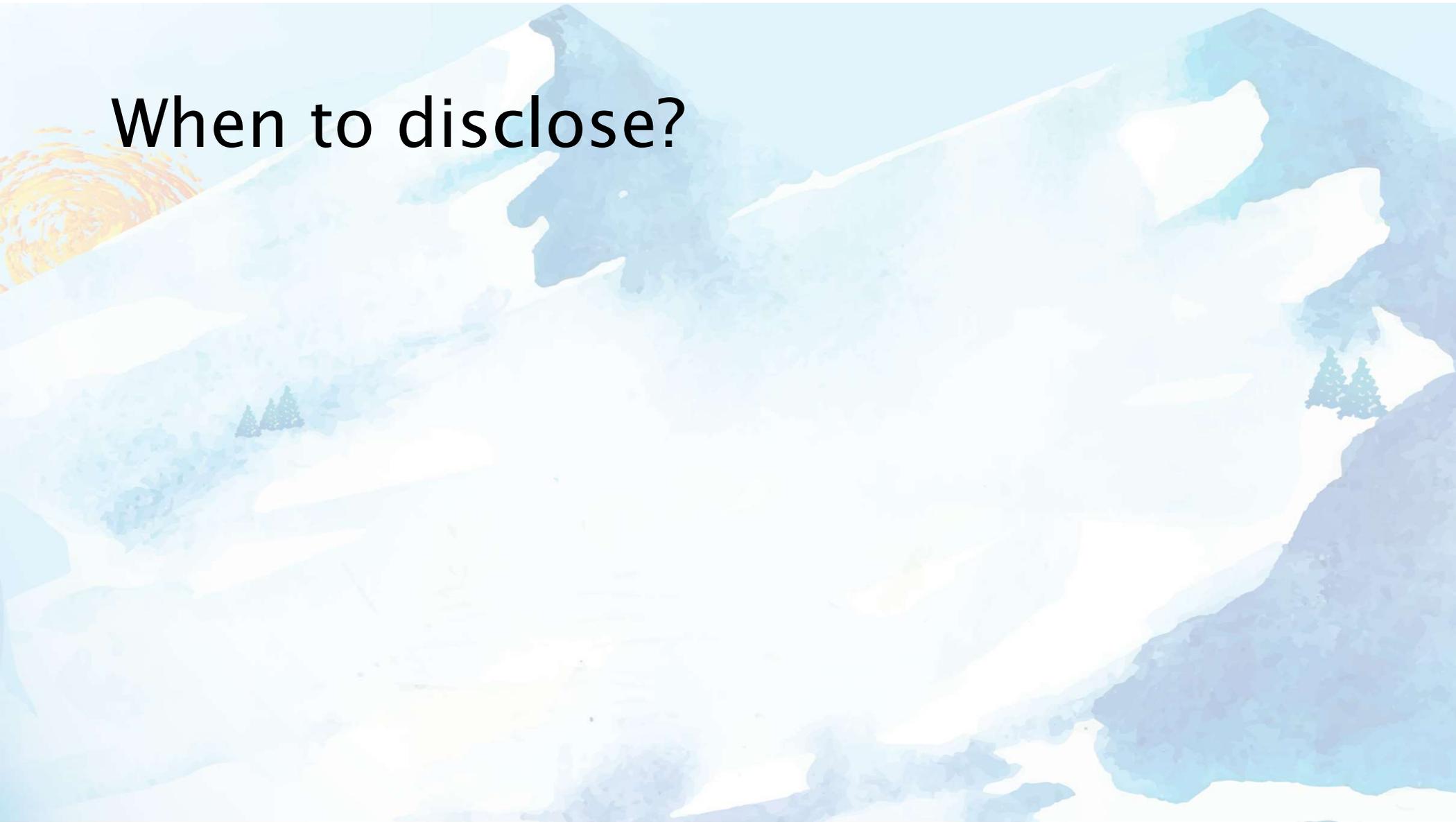
Legal and ethical reasons

- **AMA Code of Medical Ethics, Opinion 8.12:** It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Only through full disclosure is a patient able to make informed decisions regarding future medical care.
- **In the words of the Fifth Circuit,** the fiduciary relationship of the doctor to the patient imposes a duty to disclose “known facts,” which includes “the discovery of any adverse condition afflicting the patient.”

Legal and ethical reasons, cont'd

- **AMA Council on Ethical and Judicial Affairs:**
“Concern regarding legal liability which might result following truthful disclosure should not affect the physician’s honesty with a patient.”

When to disclose?





Before treatment begins

- Disclosure begins with informed consent – the **discussion** is key.
- Establish a partnership with the patient.
- Make recommendations, confirm patient's agreement or continue discussion.



During treatment

- Elicit and respond to concerns
- Empathize with disappointments and doubts
- Demonstrate attentiveness and thoroughness
- Decide together on the best approach

After an unexpected event/outcome

- Attend to care of the patient
 - Charting of facts
 - Preserving material for investigation
- Address physician's own emotions
- Develop clarity about what happened
- Prepare for discussions with patient and family



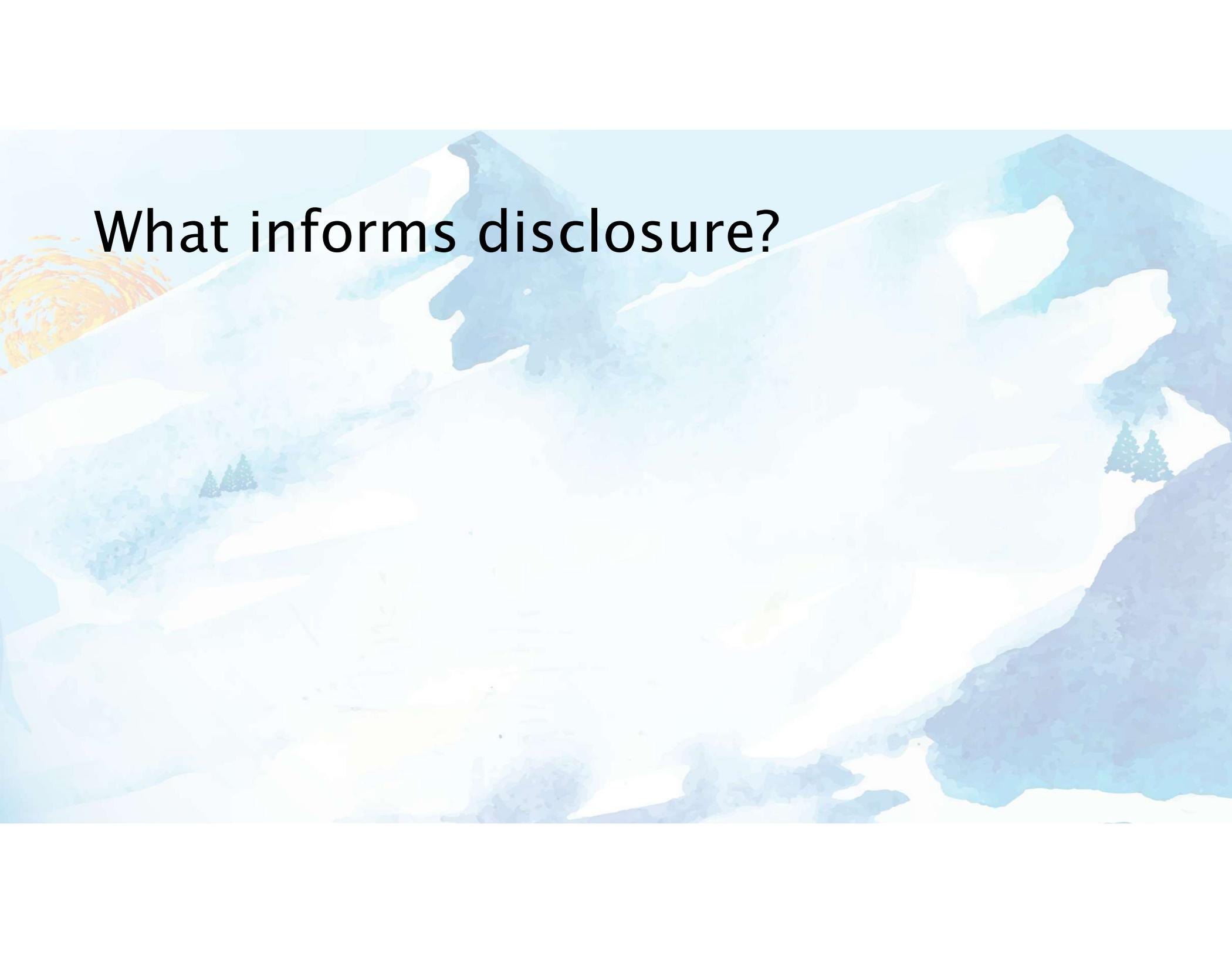
What needs to be disclosed?

Common “unexpected outcomes” for physicians:

- Performance errors
- Equipment malfunctions
- Small nicks
- Missed labs or cultures
- Misjudgments without negligence
- System issues
- Biological variability
- Surgical site infections
- Patient’s expectations were unreasonable

Common “unexpected outcomes” from patients:

- I was in more pain than expected.
- My hospitalization was longer than I thought it would be.
- My recovery took much longer than I thought it would.
- The impact on my immediate family was greater than I expected.
- I had to return to the OR.
- I had to have additional procedures.



What informs disclosure?

Approach initially bifurcated by SOC

Which track?

Care **reasonable**

**Natural progression
of medical condition**

Inherent risk of
investigations or treatments

Harm not preventable

Unanticipated
outcome

Care **unreasonable**

System failure(s)

Clinician
performance/errors
Equipment malfunctions

Harm preventable

What informs disclosure?

- While understanding if care was reasonable or unreasonable is necessary, we believe the first questions should be:
 - **Is the outcome what the patient expected?**
 - **Is the outcome what you (the physician) expected?**
- If either one answered **no**, regardless of the reason, an early conversation must take place.

Hindsight Bias

- Hindsight bias too often concludes that preventable errors were made when, in actuality, the physicians involved may have been making reasonable decisions in light of the information available to them at that time.
- Differentiate between injuries caused by negligence and those arising from complications of disease or intrinsically high-risk medical care.

How to disclose?



How to disclose unanticipated outcomes:

- Prepare



- Anticipate

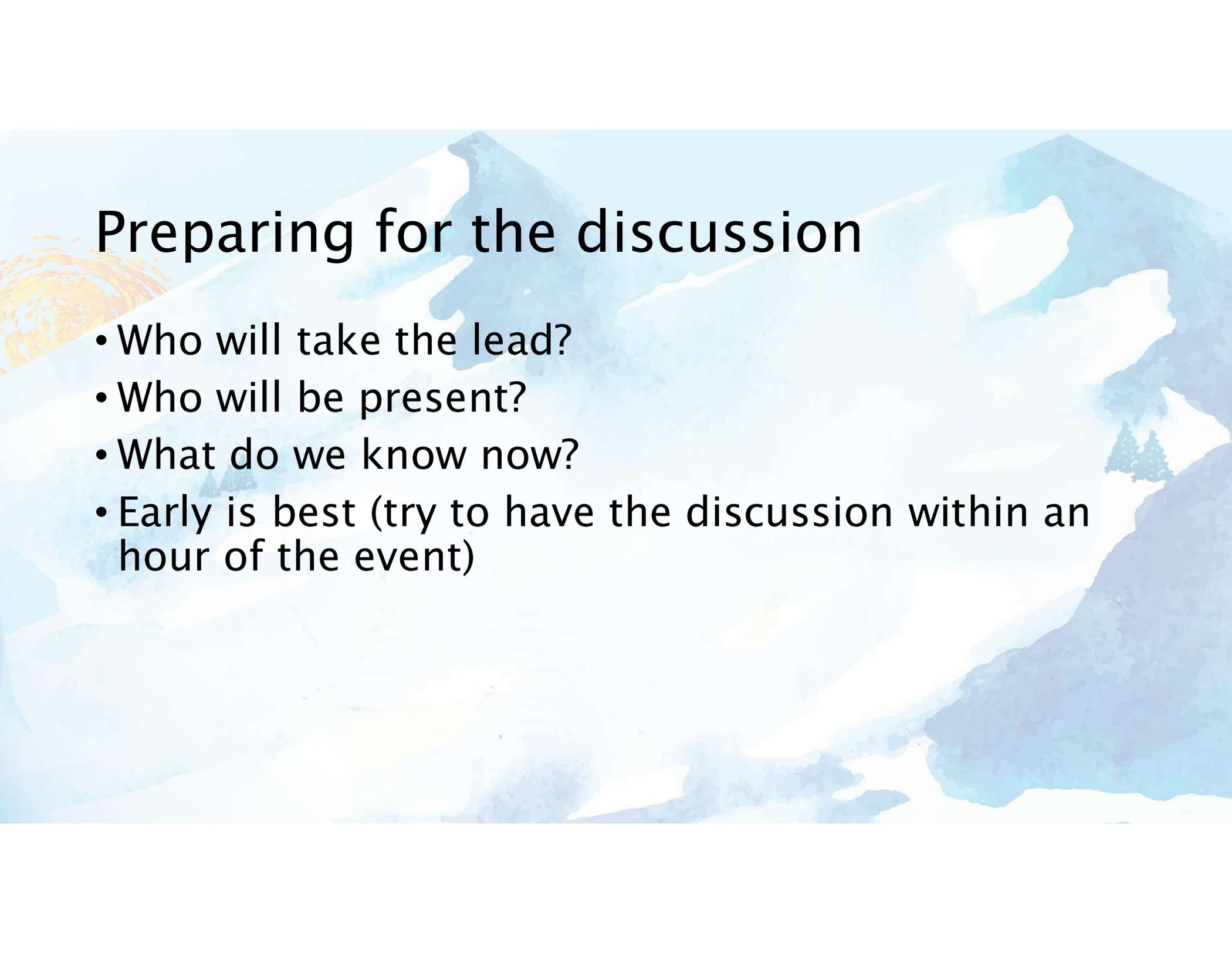


- Listen



- Empathize



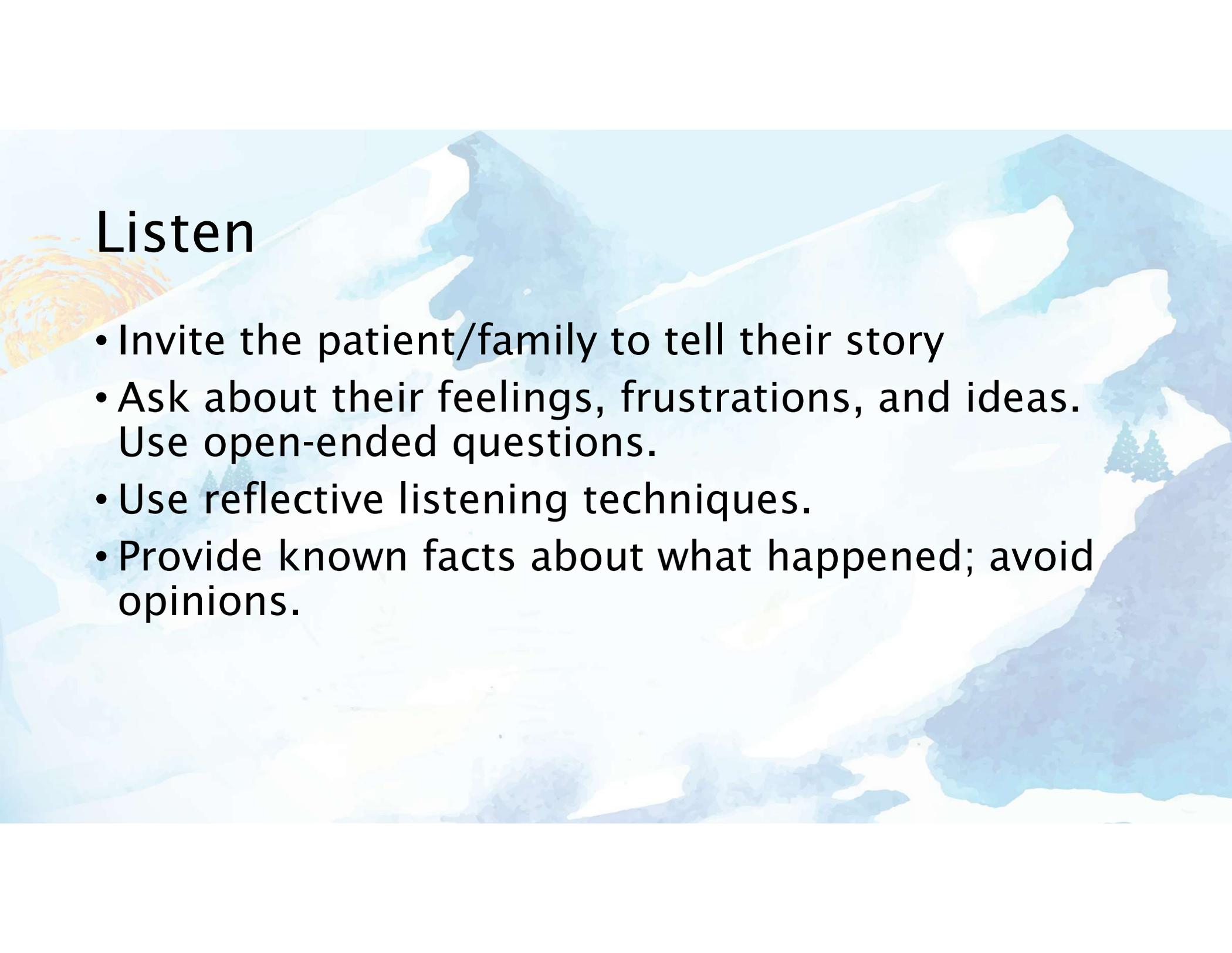


Preparing for the discussion

- Who will take the lead?
- Who will be present?
- What do we know now?
- Early is best (try to have the discussion within an hour of the event)

Anticipate

- What do you think the patient/family is thinking and feeling?
- Start with an expression of sympathy: *“I’m sorry you had such a difficult experience.”*
- Describe the situation or provide a clinical summary of the diagnosis and treatment.
- Are any quality improvement or patient safety changes being made as a result of the incident? If yes, share what they are. (This likely to occur at later discussions.)

The background of the slide is a watercolor-style illustration. It features a range of mountains in shades of blue and white, suggesting snow or mist. In the upper left corner, there is a bright, circular sun with orange and yellow rays. The overall style is soft and artistic.

Listen

- Invite the patient/family to tell their story
- Ask about their feelings, frustrations, and ideas. Use open-ended questions.
- Use reflective listening techniques.
- Provide known facts about what happened; avoid opinions.

Empathize

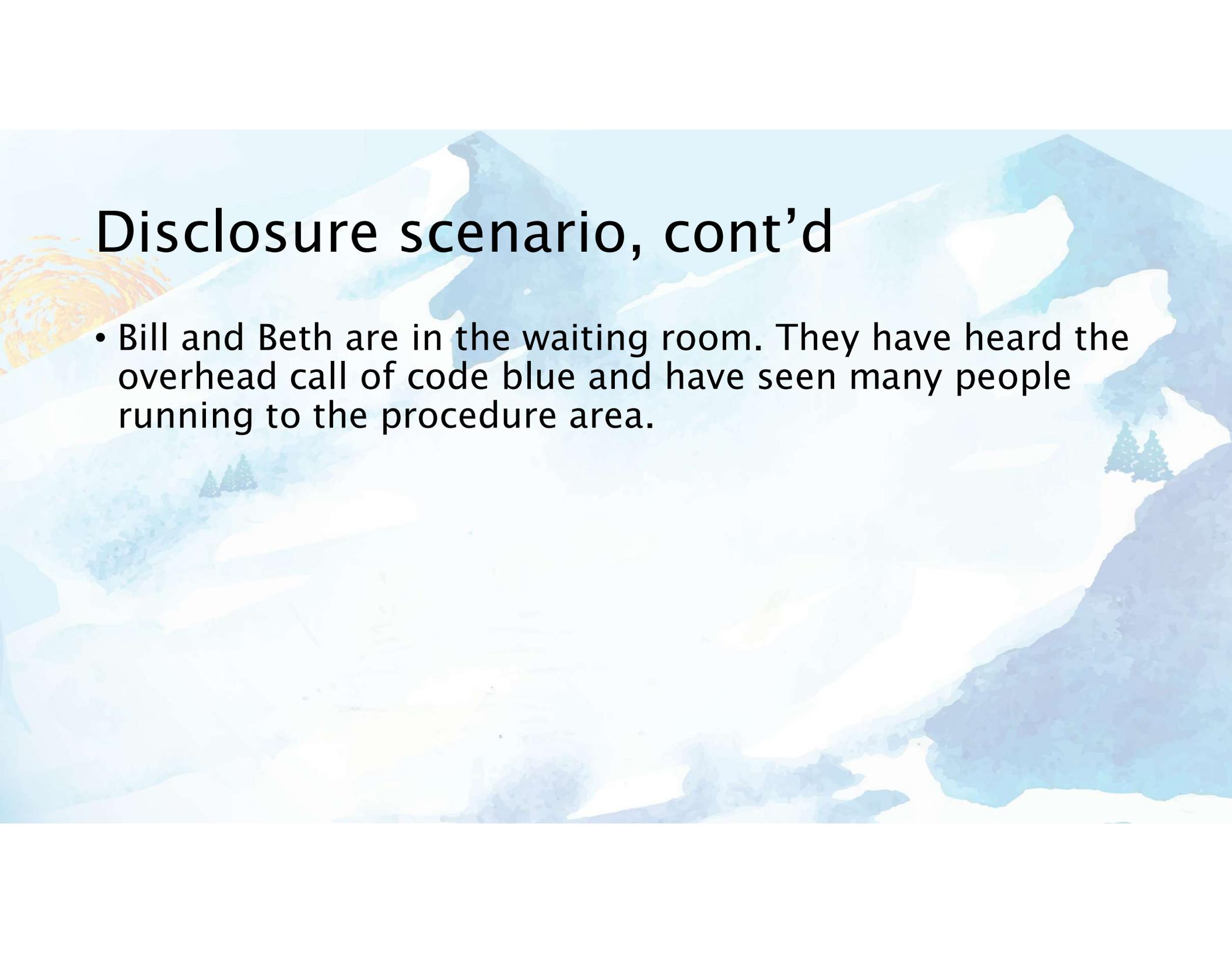
- Make sure the patient/family has the experience of:
 - Being seen
 - Being heard
 - Being validated for how they feel
- Avoid being defensive. If the patient or family gets emotional or angry, take a break and allow them space to calm down before coming back to the conversation.

Disclosure Scenario

Mary is a 39-year old mother of two small children who has presented to the hospital's GI suite to undergo a procedure under moderate sedation. Her parents, Bill and Beth, accompany her. Toward the end of the procedure, the nurse notices that Mary is not breathing, and her EKG shows a heart rate of less than 30. The nurse calls for a code blue response while the team involved in the procedure begins to administer CPR. When the code team arrives, there are some delays in providing appropriate care as different physicians argue about the proper course of treatment. (Cont'd)

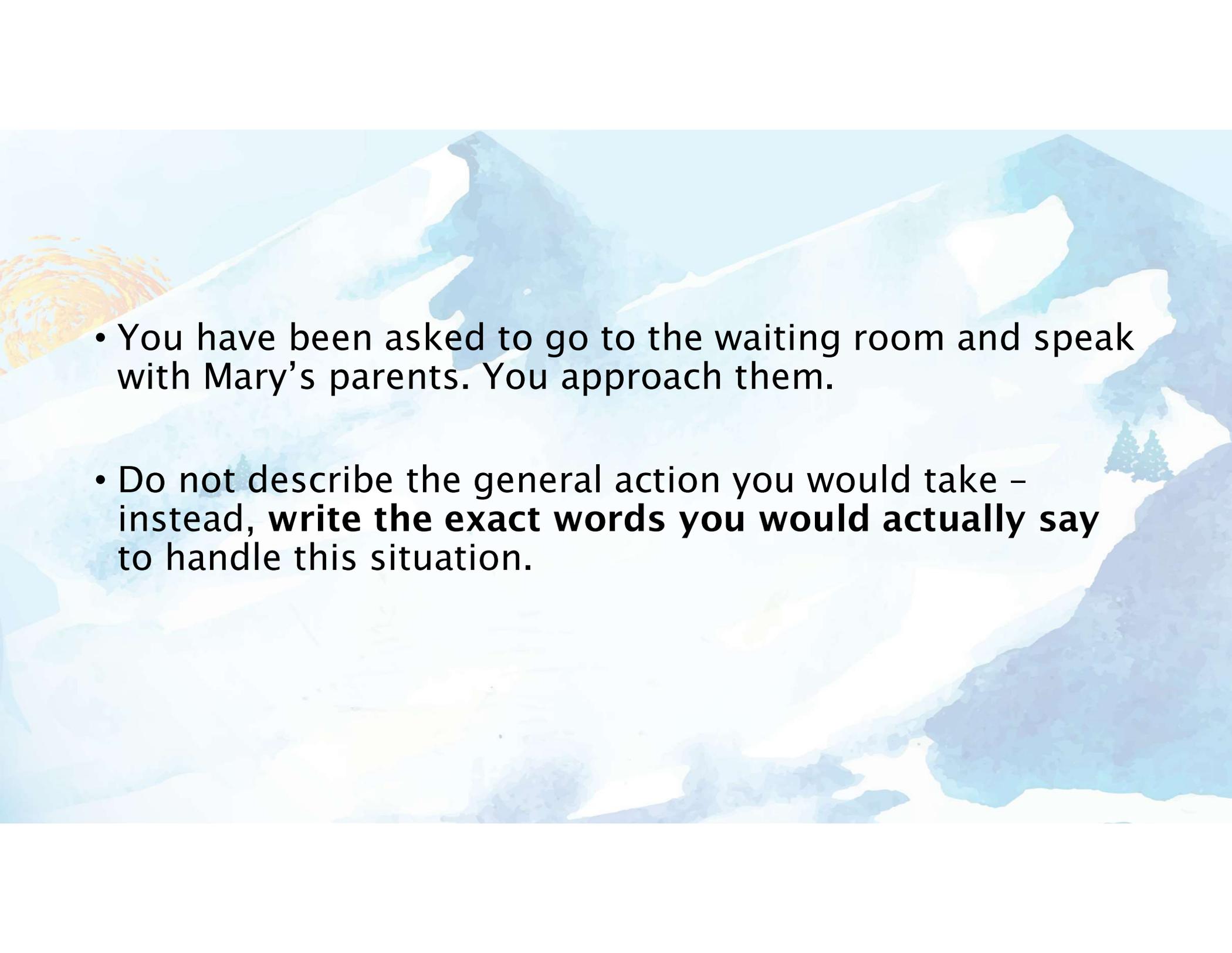
Disclosure scenario, cont'd

Eventually, they are able to re-establish a normal heart rate, blood pressure, and adequate blood oxygen level. During the resuscitation efforts, information obtained from the devices monitoring Mary's EKG, blood pressure, and blood oxygen levels reveals a period of approximately 7 minutes during which she may not have been breathing adequately, possibly from too much sedation medication during the procedure. The nurse involved in monitoring Mary appears visibly shaken and states that she was distracted during the procedure trying to obtain different pieces of equipment for the procedure. (cont'd)



Disclosure scenario, cont'd

- Bill and Beth are in the waiting room. They have heard the overhead call of code blue and have seen many people running to the procedure area.

- 
- You have been asked to go to the waiting room and speak with Mary's parents. You approach them.
 - Do not describe the general action you would take – instead, **write the exact words you would actually say** to handle this situation.

Disclosure example

- Offer privacy/suggest moving to private area/suggest sitting down.
- Frame the situation with a statement such as “*Regrettably, I have some bad news to share with you.*”
- Share known **facts** and express uncertainty about cause.
- Express uncertainty about prognosis/timeline for prognosis.
- Acknowledge difficulty of family hearing and assimilating bad news.
- Acknowledge/name family’s concern for patient.
- Affirm ongoing availability for questions/concerns/support.
- Offer sincere expressions of sympathy.

Disclosure response

“Are you Mary’s parents? My name is Dr. Jones. I am one of the doctors who work here at the hospital. Would you please follow me to a private area so I can update you about your daughter’s procedure? First off, right now Mary is stable; her heart rate, blood pressure, and oxygen level are all in normal ranges, but something did happen during her procedure. I am sorry to have to share this news with you. I am sure this is very overwhelming and you have many questions. (cont’d)

Disclosure response cont'd

I am going to tell you as much as I know right now, but I assure you this is only the first of many updates and I or someone else from the hospital will give you more information as we get it. At some point during the procedure, Mary's oxygen levels decreased and her heart rate slowed down enough that staff had to perform CPR on your daughter. That was the code blue you heard over the loudspeaker. (Cont'd)

Disclosure response

It looks like she was at these low levels of oxygen for around 7 minutes but, again, as of right now her vital signs returned to normal. We need to carefully look at each step to see what happened exactly, so I do not want to give you guesses that may turn out to be incorrect in the meantime. I will make sure that as we find out what happened you are both made aware. (cont'd)

Disclosure response

We also don't know right now if she has suffered any injury from what happened, but we are checking her out thoroughly to determine if this is the case. As soon as we are able, we will let you go be with her. Do you have any questions for me right now?

Important considerations

- Delaying can magnify problems
- Don't wait for a complaint or question
- Anticipate that more than one meeting with the patient/family may be needed
- Contact your facility/carrier risk management if you need help preparing for a disclosure discussion
- Assist patients with social worker, pastoral care, etc. as needed

Post disclosure considerations

- How can we support the physicians' needs in the wake of this event?
- How can we support the nurse's needs in the wake of this event?
- What patient safety improvements can be gleaned from this event?
 - Nurse distracted from monitoring during procedure
 - What else?

Questions?

