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CLINICAL & RISK MANAGEMENT PERSPECTIVES

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INSIDE

RESPONDING TO UNANTICIPATED OUTCOMES: FIRST CONVERSATIONS

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By reviewing medical professional liability claims and/or emerging topics in healthcare risk management, this enduring material series will support your ability to:

- Assess your practice for risk exposures.
- Apply risk management best practices that increase patient safety and reduce medical professional liability claims.

TARGET AUDIENCE

All clinicians, healthcare staff and administrators.

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Introduction

Physicians in every medical specialty, at every level of experience, face unanticipated outcomes to medical treatment. Managing the disclosure of an unanticipated outcome is one of the primary reasons why policyholders contact the NORCAL Risk Management Department.

Over the past few years, unanticipated outcome calls to the NORCAL Risk Management Department have included:

- The biopsy specimen I sent to the pathologist was lost in transit. I think it was cancer.
- My medical assistant handed me the wrong medication and I injected it.
- I injected the patient with a medication she specifically refused.
- I prescribed a medication to which my patient had a known allergy.
- My patient had an unexpected reaction to a medication.
- I did a procedure on the wrong vein.
- I stopped the patient's anticoagulant prior to surgery and she had a stroke.
- I missed a wrist fracture/cancer lesion/birth defect.
- I treated the patient two years ago for skin cancer and cancer has returned.
- I failed to remove the patient's fallopian tubes.
- My patient died following a successful surgery.
- We just found out we never communicated a portion of last year's lab results.
- My patient died during dialysis.
- I used unsterile instruments.
- I nicked a baby's cheek during a C-section.
- My patient had a stroke during surgery.
- My patient fainted during an injection and chipped her tooth.
- My patient had an additional blood draw by mistake.
- I gave a vaccination to a newborn too early.
- My patient got pregnant after I implanted an IUD.

Physicians who call are generally worried that disclosure will increase liability risk. This is understandable, as disclosure is a significant departure from the traditional liability risk management "deny and defend" paradigm.[1] However, there is evidence that disclosure diminishes liability risk.[2] Patients file lawsuits against physicians for various reasons.[3] For example, patients who feel that physicians do not care about them are more likely to sue.[3] Avoiding a patient following an unanticipated outcome (i.e., deny and defend) may indicate a lack of caring. Additionally, the longer a physician waits to talk to the patient about an unanticipated outcome, the longer the patient has to speculate about the cause of the outcome with family, friends and possibly other clinicians who do not have access to the patient's medical record.[4] The involved physician will always have a more accurate perception of what occurred. Sincere efforts to answer patient questions and provide needed support following an unanticipated outcome can decrease the patient's anger and frustration, as well as make patients feel cared for.[3,4] This, in turn, can decrease the likelihood of the physician being disparaged, reported to the medical board or sued.[5]

This article provides strategies for early conversations with the patient following an unanticipated outcome.

NORCAL Nine Steps

When physicians call the Risk Management Department for disclosure advice, they are usually focused on the act of telling the patient what caused the unanticipated outcome. However, disclosure discussions are just one part of a multi-step process for responding to unanticipated outcomes.

NORCAL has developed a guidance document that covers the entire process entitled "Nine Steps for Responding to Unanticipated Outcomes". This document is available to all NORCAL policyholders within the MyACCOUNT portal. Often, the process of responding to an unanticipated outcome does not unfold linearly, with various steps occurring simultaneously. Although this article focuses on Step Six (Disclose) of the Nine Steps, completing all of the steps is important for long-term patient safety and liability risk management.

The Agency for Healthcare Research and Quality also has resources for addressing the various stages of responding to an unanticipated outcome in its Communication and Optimal Resolution (CANDOR) Toolkit. The CANDOR online toolkit includes eight different modules that contain various implementation resources. It is available at: www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html (accessed 8/31/2017).

Definitions

Medical error: "The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."[6] A medical error does not necessarily cause a patient injury.

Unanticipated outcome: A negative or unexpected result stemming from a diagnostic test, medical judgment or treatment, surgical intervention, or the failure to perform a test, treatment, or intervention. An unanticipated outcome can occur with or without a medical error. For example, a patient can suffer from a known but rare side effect of a medication. An unanticipated outcome may or may not be the result of medical negligence.

Preventable unanticipated outcome: An unanticipated outcome caused by medical error or systems failure. When organizations perform root cause analyses, they can learn why the incident occurred and how to prevent it from occurring in the future.

Unpreventable unanticipated outcome: An unanticipated outcome that can be traced back to known risks of treatment. Liability risk from unpreventable adverse events can be mitigated by engaging in a thorough informed consent process.[7]

Disclosure: The process of providing information to a patient and/or family member about an unanticipated outcome.

Apology: Acknowledging responsibility and reflecting remorse. An apology is appropriate when an error has caused harm or there is a potential for harm as a result of an error.[8]

Empathy: In medicine, empathy refers to the experience between physician and patient, during which the physician becomes attuned to the patient to understand what the patient is feeling. Patients also use empathy to describe a physician's ability to understand their feelings and opinions and express compassion and concern for their well-being.[9]

Disclosure without Admitting Fault

When physicians call the NORCAL Risk Management Department about an unanticipated outcome, they usually seek advice about what they can and cannot say to the patient. They are concerned about prompting litigation or saying something that can be used against them if a lawsuit is filed. Unfortunately, there is no standard script for responding to an unanticipated outcome. What to say often depends on the stage in the disclosure process and the event itself. In the immediate aftermath of an adverse outcome, causation or fault is usually unknown. Therefore, it is best to focus on the medical and emotional needs of the patient. In the following case, when the error was discovered, how it occurred was not known. However, initial disclosure discussions with the two affected patients needed to occur while the cause of the error was being investigated.

Case One

Unanticipated Outcome:

Two patients received incorrect test results.

A family practice physician (FP), after mixing up the results of Patient 1 and Patient 2, called Patient 1 to inform her that her Pap test result indicated low-grade squamous intraepithelial lesions (LSIL). The FP performed a colposcopy and recommended an HPV test. Both the colposcopy and the HPV test were negative. Patient 2 was informed of a normal Pap test result in the patient portal. Six months later, the practice was auditing charts for quality purposes and discovered the error. The FP called the NORCAL Risk Management Department for advice about how to disclose the errors.

Discussion

The physician was encouraged to have disclosure conversations with both patients. The physician had a couple of disclosure script options — one appropriate, one not. For example:

1. Disclosure with Compassion and Empathy:

Patient 2: "In reviewing your chart, we saw that you received a notification through the portal that your Pap test result was normal. I have to let you know that the test result itself does not match that notification. The result shows that you have some slightly abnormal cells on your cervix. I realize this may sound frightening, but let me go through the different types of Pap test findings with you, and we can put it in perspective. I want you to know that I'm going to take steps right now to make sure we understand what's going on and take care of you appropriately. I'd like to do a repeat Pap test as soon as possible. If you agree, I'd also like to schedule you for a colposcopy, which will let us take a detailed look at the anatomy. We'll also do an HPV test. These are the most important things to do right now because they concern your health. The next task will be for me to look at how this happened and make sure it doesn't happen in the future."

Patient 1: "We conducted a review of charts, which revealed something about your Pap test results. Where we thought they were abnormal, they were, in fact, normal. You received another patient's results, and she received yours. I'm so sorry that you went through that worry and stress – and through those additional tests. I know that we're certainly glad everything is normal; however, I take this very seriously and realize this has not been a pleasant experience. I am looking into how this happened so that we make sure it doesn't happen again and, of course, we're in the process of re-evaluating the other patient to ensure she gets appropriate care."

2. Disclosure with Admission of Fault and Blame:

Patient 2: "I'm sorry we didn't let you know sooner that your test result was positive. Your test result came in with a large batch of other results, and I'm thinking the MA didn't double-check what she filed in the charts with the information that went into the patient portal."

Patient 1: "I'm sorry that we thought your results were abnormal. Your test results came in with a large batch of other results, and the MA probably matched yours with the abnormal one. I know you had to go through the colposcopy and the HPV test, but, if you look on the bright side, at least those were normal."

In the first statements the physician is telling each patient what happened and relaying the facts that she knows at that point in time — she is not offering her opinion or guessing at how the error occurred. She does not blame her staff, the office system or the electronic health record (EHR) for failing to catch the discrepancy, although any or all of these might have contributed to the situation. Instead, she is conveying compassion for Patient 2's likely feeling of fear and focusing on the patient's needs without accepting blame. In the second statements, the physician uses "I" statements to admit fault. Although it might be tempting to throw staff under the bus, this strategy can backfire. Setting an antagonistic tone is likely to increase the risk of litigation. Blaming staff or someone else in the practice will not protect the physician from being named in a lawsuit. It is best to keep opinions about blame private.

Apology Laws

Most states have statutes addressing the admissibility of physician apologies. These laws are excellent liability risk management tools because they can keep physician statements to patients about unanticipated outcomes — that might otherwise be used against them — out of evidence in malpractice litigation. Unfortunately, these laws can also confuse the process of responding to an unanticipated outcome, and can result in a physician avoiding the patient out of fear of saying the wrong thing. Most state laws protect expressions of sympathy, compassion or regret, but few protect statements of fault. Apology has become a term of art, the definition of which may be at odds with a physician's definition of apology. To confuse things further, the definition of apology is not consistent among the apology laws. Additionally, apologizing for an unanticipated outcome without admitting fault can be difficult, which is why it is probably best not to think of sympathetic statements associated with disclosing unanticipated outcomes as apologies. A simple rule of thumb is that empathy is always appropriate when discussing an unanticipated outcome; and apology is appropriate when an investigation proves an error was made.[10]

Apology has become a term of art, the definition of which may be at odds with a physician's definition of apology.

Risk Management Recommendations

In the immediate aftermath of an unanticipated outcome, it is important to pay attention to the patient. Even though the cause of the unanticipated outcome may not be known, physicians can monitor patient well-being and express sympathy in the early stages of disclosure. Consider the following recommendations:

- Convey compassion for the patient's suffering, focusing on their needs, for example:
  - "I am sorry for what you are going through."
  - "I am sorry this happened. It's terrible."
- Avoid "I" statements, for example:
  - "I'm sorry that I ordered the wrong medication."
  - "I'm sorry that your mother suffered a loss of oxygen to her brain. I should have been monitoring her anesthesia more closely."

A more thorough discussion of handling patient questions about the cause of unanticipated outcomes is addressed later in the article.

Disclosure Using the Oregon Early Discussion and Resolution Program

In 2014, Oregon instituted an Early Discussion and Resolution (EDR) program to provide a framework for resolving unanticipated medical outcomes. This voluntary program, which is administered by the Oregon Patient Safety Commission, is available to patients, clinicians and health care facilities.[11] The following case was resolved without litigation or patient compensation through EDR. Consider how the fundamentals of this program and the defense attorney's disclosure strategy advice to the physician could be applied to your own disclosure policies and protocols.

Case Two

Unanticipated Outcome:

During percutaneous transluminal angioplasty, the patient's aorta ruptured.

An obese 45-year-old female patient presented with a history of claudication pain. She had coronary artery disease, hypertension, diabetes and was a pack-a-day smoker. Examination revealed blackish discoloration of two toes on each foot and absent pulses bilaterally in her lower limbs. Peripheral vascular examination suggested aorto-iliac occlusive disease. Computed tomography (CT) angiography confirmed a high-grade, eccentric, calcified stenosis ending approximately just above the iliac bifurcation in the infrarenal aorta, which had compromised the aortic lumen by approximately 90%.

The surgeon recommended percutaneous transluminal angioplasty (PTA) and stenting. The risk of surgical complication from open surgical endarterectomy or aortobifemoral bypass was high. Regardless of operative approach, the calcified lesion in the abdominal aorta was believed to be at high risk for rupture. The surgeon engaged the patient in an extensive informed consent discussion, including the risk of aortic rupture, which was well documented.

During the procedure, the aorta ruptured. The surgeon converted to an open procedure. The renal arteries were clamped while the surgeon struggled to repair the damage to the aorta. The surgeon knew that the kidneys could be damaged by the length of time the clamps were in place, but reperfusion would have caused the patient to bleed out. He eventually repaired the injury to the artery and was able to control the hemorrhage, but the kidneys had been irreparably damaged. By the time the patient had been stabilized, the surgery had gone from a planned two-hour to a 10-hour procedure. The patient spent a month in the ICU, followed by a month in a rehabilitation facility. She would require dialysis for the rest of her life, unless she underwent kidney transplant.

The patient filed a complaint with the Oregon Patient Safety Board requesting EDR, describing the adverse event as follows:

"I went in for surgery for occluded arteries. The surgeon told me I would be in the hospital for a day or two. The surgery was only supposed to take two hours, but it took 10 hours. After the surgery, the surgeon told my husband he had made a mistake and it almost killed me. I was in the ICU for a month, and then in a nursing home for another month. Now I need dialysis for the rest of my life because my kidneys were so badly damaged during surgery."

The surgeon informed NORCAL that he would like to participate in the EDR process.

Discussion

Experts who reviewed the case believed the complication did not develop because of any surgical error in technique, and that the risks, benefits and alternatives had been appropriately discussed with the patient.

EDR Strategy

The parties agreed that there would be no attorneys or mediators at the initial meeting. The meeting would include the patient, a hospital representative, the surgeon and a representative from the Oregon Patient Safety Board. Neither the surgeon nor hospital representative had any authority to discuss compensation or any other type of remediation. The patient was informed of this prior to the meeting. The defense attorney's strategy for the EDR patient meeting, which could easily be applied to other adverse outcome initial disclosure discussions, is outlined below:

Establishing an Appropriate Tone

The attorney advised the physician to:

- Keep the tone conversational and avoid lecturing the patient.
- Encourage the patient to ask questions.
- Thank the patient for providing an opportunity to directly explain what happened during surgery.
- Tell the patient you are very sorry for the complication and injury to the patient's kidneys.

Bringing the Correct Tools

The surgeon would bring diagrams, intraoperative fluoroscopic images, the operative report and a white board so that he could use drawings to help the patient understand what caused the outcome.

Preparing "Talking Points"

The surgeon and attorney prepared "talking points" for the meeting. Their talking point objectives included:

- Outline the nature of the medical problem, the reason for the surgery and why PTA and stenting was chosen instead of an open surgical procedure.
- Describe aspects of the aortic lesion that made the procedure difficult.
- Remind the patient that the difficulty of the procedure had been discussed during the informed consent process, including the risk of aortic rupture.
- Reiterate the lifestyle-limiting claudication of her bilateral lower extremities and the risk of eventual amputation without treatment.
- Describe the procedure using the operative note, which in this case was very complete, and set out in a logical fashion the procedure, including the complications and step-by-step outline of how the surgeon attempted to manage the complication.
- Explain when, why and how the decision to convert to open surgery occurred.
- Explain that a ruptured aorta can cause death.
- Explain the several attempts needed to correct the rupture.
- Explain how there was no alternative but to clamp the renal arteries, and how this caused damage to the renal arteries and aorta.
- Explain how the surgical team did everything possible to save the patient's life.

Discussion

continued

Anticipating Tough Questions

The surgeon and attorney also prepared for anticipated "tough" questions that could be asked by the patient, for example:

- Did medical devices contribute to or cause the injury?
- Why didn't the surgeon convert to open surgery earlier?
- Why didn't the surgeon perfuse the kidneys during the repair procedure?

Another issue they anticipated was the alleged admission by the surgeon to the patient's husband that his "mistake" had caused the patient's injuries. The surgeon knew that he would never say such a thing, and that he had instead attempted to explain the seriousness of the complication. He would have to make this distinction without insulting the patient's husband, becoming argumentative or appearing arrogant.

Outcome

The physician reported back to his attorney following the meeting with the patient. The patient was not angry, and seemed primarily interested in knowing how she ended up with kidney failure. The surgeon was able to describe what occurred during surgery using his talking points. The patient asked a number of the anticipated questions, and the surgeon answered as planned. The patient did not request compensation or threaten a lawsuit, and the surgeon left the meeting feeling that it had been productive.

No lawsuit was filed and no demand for compensation was made. The case was closed.

Risk Management Recommendations — Early Discussion Strategies

The EDR meeting strategies in the foregoing case can be used as a framework for early discussions following an unanticipated outcome. For example:

- Pick a disclosure strategy that suits the circumstances.
- Determine who will attend the meetings.
- Determine whether compensation or remediation will be part of the discussion.
- Establish an appropriate tone.
- Bring tools to help describe how the unanticipated outcome occurred, e.g. diagrams, images, medical record, grease board, etc.
- Prepare "talking points."
- Anticipate tough questions.

These points are discussed in greater detail in the risk management recommendations at the end of this article.

Unanticipated Medical Outcome Resolution Programs

In addition to the NORCAL Nine Steps and CANDOR Toolkit referenced previously, ideas about approaches to disclosure and resolution strategies can be drawn from early resolution programs operating in a number of states, for example:

- **Oregon EDR Program:** oregonpatientsafety.org/edr/about-edr/ (accessed 9/5/2017)
- **Massachusetts CARe Model:** macrmi.info/providers/#sthash.AoPrFExf.dpbs (accessed 9/5/2017)
- **Michigan Model:** uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs (accessed 9/5/2017)

Disclosure from a Daughter's Perspective: A Risk Management Colleague Shares Her Story

As a risk manager, I often tell physicians to stand in the shoes of the injured patient and ask: What would I want if I were the injured one? Sadly, I got a chance to experience an unanticipated outcome and disclosure delay first hand.

My dad is in his late 80s. He is frail and has multiple medical issues. Last autumn, he was in the hospital for surgery. He was getting multiple intravenous medications, but his veins were friable and the IVs infiltrated many times over his hospitalization. Although he never complained, I could tell that restarting the IVs was painful. It was hard to watch.

After the fourth infiltration, an IV nurse was called in. While she was inserting the IV catheter, my father's gown fell over the tourniquet, hiding it. Out of sight, out of mind – the nurse forgot to remove the tourniquet before she left the room. An hour later, a different nurse discovered the tourniquet when the IV infusion pump alarm went off. Without saying anything about the obvious mistake that had been made, the nurse tended to my father's blown vein and infiltration. Then she left.

My father and I waited for someone to come in and explain what would happen next, why the mistake had occurred and when his pain medications would be restarted. No one asked how he was feeling. The situation was made worse by the fishbowl-like set-up of the medical unit. Through the glass door and windows, we watched the nurses walking back and forth. Everyone seemed to be averting their eyes and avoiding us. At one point, the IV nurse peeked into the room, but then ducked back out without saying anything.

As more time passed, we became more and more angry. All we wanted was for the nurse to own up to the mistake and apologize. We probably would not have been so angry if this had been the only mistake. But little errors and staff indifference had us at a slow simmer before the tourniquet issue occurred. About two hours after the tourniquet was discovered, a resident came into the room. He pulled up a chair and took my father's hand. He apologized for the tourniquet being left on and did not blame the nurse. He acknowledged my father's discomfort and difficult course during his hospitalization. He then explained why my father needed to have a central line placed. Before he left, he asked if either of us had questions. Once our questions had been answered, he left.

The resident's disclosure and apology diffused our anger. What made his disclosure so effective could be primarily attributed to his excellent bedside manner, sincerity, acknowledgement of my father's discomfort and willingness to listen to our concerns.

More Support for Disclosure

The fear of litigation and shame associated with making a mistake can be paralyzing for healthcare professionals. Increasing patient well-being and decreasing liability risk exposure are not the only benefits of disclosure — it is the right thing to do and can increase physician/provider well-being.

Disclosure and Ethics

According to the American Medical Association (AMA), "A physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred" if the patient suffers "significant medical complications that may have resulted from the physician's mistake or judgment."[12]

The four basic principles of healthcare ethics support disclosure:[13]

1. Autonomy — Respect the patient's right to know about healthcare provided.
2. Justice — Do what's fair.
3. Beneficence — Improve patient well-being.
4. Non-maleficence — Do no harm.

Disclosure and Physician Well-being

Patients should be the focus of disclosure, but it is also important to consider how disclosure affects physicians. "Second victim" syndrome — shame, anger, depression, inadequacy, loss of confidence — is well documented among physicians who are involved in an unanticipated outcome. Research indicates that disclosure may help physicians process the emotions associated with an unanticipated outcome.[14] Remaining silent and isolated from the patient can increase physician distress when it conflicts with the physician's perceptions of ethical and moral duties associated with disclosure.[11]

The Blame Game

When an unanticipated outcome occurs, the individuals involved often look for someone to blame. Blame provides a means to deflect responsibility and vent frustration.[15] However, blame can be irrational[15] and it can involve complex cognitive, social and emotional processes.[16] Consequently, it can be difficult to control the urge to place blame on someone else for an unanticipated outcome, even when the blame may be unwarranted. Therefore, it is important to question attributions of fault and keep those thoughts of blame private, particularly in the immediate aftermath of the event, when emotions are running high and many facts have not been established.

Case Three

Unanticipated Outcome:

A patient received another patient's medication and almost died.

It was a busy night in the emergency department (ED). An ED physician, who was an employee of a group that contracted with the hospital, examined a pregnant patient with an intractable migraine. He ordered IV hydration and morphine. Moments after entering the order, an ED nurse requested sedation for a different patient who was on a ventilator. Without noticing it, the ED physician entered an order for fentanyl, propofol and vecuronium into the pregnant patient's record.

Just as he was going off shift, he was informed that the pregnant patient had lost consciousness. He checked the EHR, noticed his mistake, and assumed all of the medications had been given to the patient. He administered naloxone and ventilated her. She responded, but did not regain consciousness before she was taken to the ICU.

The physician left a message for the hospital risk manager and the medical director of his medical group. When he called the NORCAL Risk Management Department later that day, he kept shifting the blame from himself to systems errors — an outdated, difficult to use EHR and chronically understaffed ED — and the nurse, who presumably gave the patient a near-lethal dose of medications without questioning it. He also advocated for having the hospital handle the entire process and avoiding confronting the patient.

Discussion

The NORCAL Risk Management Specialist who took the call urged the physician to withhold blame, reminding him that blaming the hospital or nurse was not going to benefit the patient and could worsen an already challenging situation for him and the hospital. She urged him to speak with the patient's attending physician to determine what he knew about the cause of the loss of consciousness, and what the patient had been told. At this point, the ED physician was assuming the cause of the unconsciousness was an overdose, but he admitted that he did not have the facts.

After the physician had gathered whatever information was available at the time, the risk manager suggested that the physician have a discussion with the patient to inform her that he had entered the incorrect medication in the medical record. Because the cause of the patient's loss of consciousness was not known, she urged him to avoid speculating about causation. They also discussed the fact that the evidence of his entering the wrong medication order was in the EHR and there was little to be gained by pretending it didn't exist.

The risk manager further recommended that the physician be prepared for difficult patient questions about the cause of her loss of consciousness and the effect of the loss of consciousness on her unborn child. Because the nurse and systems issues were involved, the disclosure process would involve hospital administration and should be carried out in coordination with them. The causes of the patient's injury would be determined during the root cause analysis, the peer review process and, if it reached that point, litigation. Determining the cause of the patient's injuries and potential injuries to her unborn child could take months, which would be too long to wait to talk to the patient. In closing the conversation, the risk manager urged the physician to find a way to check in with the patient as soon as possible to provide emotional support and answer her questions to the best of his ability.

Risk Management Recommendations — Early Disclosure Discussions

Having a plan and a policy for disclosure is one of the most important aspects of early disclosure discussions. Lack of policies and procedures can lead to confusion and delay, which can diminish the effectiveness of the disclosure process. When the unanticipated outcome is discovered, it should trigger a series of administrative responses (see, for example, the NORCAL Nine Steps referenced previously). Strategies for early disclosure discussions include:[3,4,17,18,19,20,21]

Before Discussions with Patients

Preparation is a key to an effective disclosure discussion.

- Tell an administrator/risk manager about the unanticipated outcome.
- Encourage staff members to refer the patient directly to you when he or she calls.
- Plan for the discussion with the patient/family.
  - Refer to the disclosure policy and procedure in your office.
  - If disclosure conversations are very difficult, ask someone skilled to accompany you and/or get some coaching.
  - Prepare "talking points."
    - Outline the nature of the medical problem.
    - Review informed consent if the outcome was a risk of the procedure.
    - Describe any aspects of the procedure/patient's anatomy that increased the risk of the outcome.
    - Reiterate the risks of foregoing the treatment that resulted in the outcome.
    - Describe the procedure/treatment using the patient's medical record, including any complications and how the healthcare team responded to them.
  - Prepare for tough questions and demands — both reasonable and unreasonable.
    - Match the disclosure strategy to the unanticipated outcome, e.g., an obvious medication error that was discovered immediately will be handled differently than a surgical complication that was discovered months after the surgery.

Timing of the Initial Discussion

The disclosure process usually involves a series of conversations. The patient should be notified as information is gathered. This dialogue can go on for months. Even if little is known, it is important for the physician to make contact and show support.

- Reach out to the patient as quickly as practicable to avoid unnecessary additional distress; however, the patient should be coherent.
  - Trying to have this discussion in the recovery room following surgery is not advisable.
- Don't let lack of information stall initial and ongoing interactions with the patient.
- Choose a time that is convenient for the patient — physician convenience cannot be a priority. This discussion should take as long as necessary, which means that it most likely will not fit into an open 15 minute timeslot in a physician's schedule.

How to Discuss the Unanticipated Outcome

Many physicians are overwhelmed with guilt and sorrow (and sometimes anger) when they believe they (or someone else) caused an unanticipated outcome. Managing physician emotions is an important aspect of the disclosure process. It is important to honor and process them. However, it is also important to keep those emotions from spilling over into discussions with patients.

- Knock on the door before entering the room.
- Smile when you enter the room.
- Greet the patient using his or her name.
- If you must use a computer during the disclosure discussion, put the computer or patient in a position that allows you to face the patient. If that is not possible, invite the patient to join you while you look at the screen.
- Apologize for the time the patient had to wait to talk to you, even if it was a short time.
- Stay calm and contain your own emotional response.
  - If the patient/family is angry or combative, do not argue.
  - If you feel the patient contributed to the situation, do not blame the patient for the outcome.
- Exhibit "attending behavior" (i.e., show you are listening and interested), for example:
  - Sit at eye level with the patient — do not stand over a patient that is in bed.
  - Keep an open posture, lean slightly forward, relax without crossing your arms, hunching your shoulders or bending your head down.

- Talk in a voice and tone that the patient understands, try to soothe the patient and empathetically relate to what is being said.
- Maintain eye contact.
- Indicate responsiveness with your facial expressions and gestures (nod, raise your eyebrows, smile, frown, etc. when appropriate).

- Actively listen to the patient.
  - Respond to the topics raised by the patient before you pursue your own disclosure agenda.
  - Listen for at least a minute before interrupting.
- Use social touch (e.g., hand shake, pat on the back), but don't overdo it.
- Name and validate the patient's concerns and feelings, for example:
  - "Tell me what happened…"
  - "You must have many questions; how can I help you…?"
  - "I can understand your anger…"
- Invite the patient to correct your understanding of facts surrounding the unanticipated outcome, and then incorporate the correction into the discussion, if appropriate.
- Avoid using medical jargon and do not lecture.

What to Say about the Unanticipated Outcome

It is important to enter discussion with a method for describing what occurred, e.g., talking points, diagrams, medical record, white board, etc. Physicians are often more concerned about what not to say, than what to say.

- Share facts about what you know happened or definitely did not happen that contributed to the outcome.
  - Be objective.
  - Use medical record documentation as a guide.
- Talk about the next steps for patient care.
- Set up a plan for follow-up care.
  - Make an appointment for a phone call and/or visit to update the patient.
- If the cause of the unanticipated outcome is unknown:
  - Let the patient know what is being done to discover the cause.
  - Provide a realistic estimate of how long the analysis process may take.
  - Assure the patient that additional facts will be shared when they become available.
  - Explain actions that have been taken so the same thing won't happen again.
    - For example: "Right now, I don't know exactly how this happened, but we're going to find out and do all that we can to make sure it doesn't happen again. I'll share with you what we find as soon as I know, but that process could take some time."
- Plan for further discussion and make sure the patient and family know how to reach you (or an appropriate person) if they think of anything they want to ask or discuss later.
- If the outcome is a known complication of treatment that was discussed during the informed consent process, review the informed consent information.
- Affirm the patient understands what you have discussed.
  - More information about the Teach-Back Method is available at: www.teachbacktraining.org/ (accessed 9/6/2017).

What Not to Say during Disclosure Discussions

There are various topics and issues that should be avoided during disclosure discussions, including:

- Don't speculate about the cause of the event.
- Don't blame others, including staff, colleagues, prior treating physicians, healthcare facilities, office or medical equipment, computer systems, etc., even if their contribution to the cause of the outcome seems clear.
- Don't reveal confidential information (e.g., what's been discussed during a peer review or liability insurer, risk manager or defense attorney meeting).
- Don't provide opinions about whether a lawsuit should be filed or estimates of injury value.
- Don't agree to compensate the patient for his or her injuries.
  - If the patient has questions about monetary remedies or makes settlement demands:
    - Discuss this immediately with the organization's risk manager and with NORCAL's Claims Department.
    - Inform the patient that you're not in charge of the resolution process, but will contact the appropriate people.

Conclusion

Unanticipated outcomes occur every day. They are often not preventable and not the result of negligence. It is almost impossible to predict which incidents will turn into lawsuits, because patients sue their physicians for different reasons, and frequently not because of negligent treatment. Therefore, medical liability risk should not be a physician's primary concern following an unanticipated outcome. Patients want to feel cared for following an unanticipated outcome. Physicians should focus their attention on the patient's needs, both medically and emotionally. In most cases, the cause of an unanticipated outcome will not be immediately known, but that cannot be an excuse to avoid discussions of the outcome with the patient. Patients who are ignored in times of need have a tendency to become angry, and angry patients are more likely to sue their physicians. Consequently, the best risk management strategy during the early aftermath of an unanticipated outcome is to focus on being the patient's caretaker and ally. During disclosure discussions, the patient should feel like he or she is the most important part of the disclosing physician's day. It can be difficult to project that level of empathy, but it is important and achievable.

Endnotes

The NORCAL documents referenced in this article, along with many other Risk Management Resource documents and past editions of the *Claims Rx,* are available in the *Risk Solutions* area of MyACCOUNT, or by policyholder request at 855.882.3412.

1. Hammer S. Oregon Leads the Way: Getting Up to Speed on the Resolution of Medical Disputes. 2015 May. *Oregon State Bar Bulletin.* Available at: www.osbar.org/publications/bulletin/15may/tips.html (accessed 9/5/2017).
2. Robbennolt JK. Apologies and settlement. *Court Review.* 2009;45:90-97. Available at: http://aja.ncsc.dni.us/publications/courtrv/cr45-3/CR45-3Robbennolt.pdf (accessed 9/5/2017).
3. O'Rourke PT, Hershey KM. How to Stay Out of Litigation. *The Hospitalist.* 2007 Jan. Available at: www.the-hospitalist.org/hospitalist/article/123328/how-stay-out-litigation (accessed 9/5/2017).
4. Medical errors: Meeting ethical obligations and reducing liability with proper communication. *OBG Manag.* 2016;28(9):17-20,22,24. Available at: www.mdedge.com/obgmanagement/article/111323/practice-management/medical-errors-meeting-ethical-obligations-and/page/0/1 (accessed 9/5/2017).
5. Oregon Patient Safety Commission. Early Discussion & Resolution Annual Report July 2014-June 2016. 2016 Oct. Available at: https://oregonpatientsafety.org/docs/edr/EDR_Annual_Report_July2014-June2016.pdf (accessed 9/5/2017).
6. Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press; 2000. Available at: www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf_NBK225182.pdf (accessed 9/5/2017).
7. Massachusetts Coalition for the Prevention of Medical Errors. When things go wrong: responding to adverse events. A consensus statement of the Harvard Hospitals. 2006. Available at: www.macoalition.org/documents/respondingToAdverseEvents.pdf (accessed 9/5/2017).
8. Roberts RG. The Art of Apology: When and How to Seek Forgiveness. *Fam Pract Manag.* 2007;14(7):44-49. Available at: www.aafp.org/fpm/2007/0700/p44.html (accessed 9/5/2017).
9. Decety J, Fotopoulou A. Why empathy has a beneficial impact on others in medicine: unifying theories. Front. *Behav Neurosci.* 2005; 8:457. Available at: http://journal.frontiersin.org/article/10.3389/fnbeh.2014.00457/full (accessed 9/5/2017).
10. Bailey KJ, Parraz DC, Plant MD. "Sorry, Not Sorry": Tension between Transparency and Liability? Presented at: American Society for Healthcare Risk Management 2016 Annual Conference; September 27, 2016; Orlando, FL.
11. Hammer S. Oregon Leads the Way: Getting Up to Speed on the Resolution of Medical Disputes. 2015 May. *Oregon State Bar Bulletin.* Available at: www.osbar.org/publications/bulletin/15may/tips.html (accessed 9/5/2017).
12. American Medical Association. The AMA Code of Medical Ethics' Opinions on Patient Safety. Opinion 8.12 - Patient Information. *Virtual Mentor.* 2011 Sep;13(9):626-28. Available at: http://journalofethics.ama-assn.org/2011/09/coet1-1109.html (accessed 9/5/2017).
13. Althaus J. Johns Hopkins University School of Medicine. Medical Ethics. 2014. Available at: www.hopkinsmedicine.org/gynecology_obstetrics/pdfs/medstudent/rtc2014/8-4-14%20Bench%20to%20Bedside%20Ethics%20Lx.pdf (accessed 9/5/2017).
14. Han K, et al. The Surgeon as the Second Victim? Results of the Boston Intraoperative Adverse Events Surgeons' Attitude (BISA) Study. *J Am Coll Surg.* 2017;224(6):1048-1056.
15. Pickard H. Irrational Blame. *Analysis.* 2013;73(4):613-26. Available at: https://academic.oup.com/analysis/article-abstract/73/4/613/106497/Irrational-blame?redirectedFrom=fulltext (accessed 9/5/2017).
16. Tognazzini N, Coates DJ. Blame. The Stanford Encyclopedia of Philosophy (2014). Available at: https://plato.stanford.edu/entries/blame/ (accessed 9/5/2017).
17. Hardee JT, Platt FW. Exploring and overcoming barriers to clinical empathic communication. *Journal of Communication in Healthcare.* 2010; 3(1):17-23.
18. Bernard R. How To Be a Rock Star Doctor. 2015 Publisher: Author.
19. American Osteopathic Association. 15 Ways to Become a More Empathetic Physician. Available at: www.osteopathic.org/inside-aoa/empathy/Documents/empathy-checklist-for-physicians.pdf (accessed 9/5/2017).
20. Montague E, et al. Nonverbal Interpersonal Interactions in Clinical Encounters and Patient Perceptions of Empathy. *J Participat Med.* 2013; 5:e33. Available at: www.jopm.org/evidence/research/2013/08/14/nonverbal-interpersonal-interactions-in-clinical-encounters-and-patient-perceptions-of-empathy/ (accessed 9/5/2017).
21. Lussier M, Richard C. Reflecting Back: Empathic Process. *Canadian Family Physician.* 2007;53(5): 827-828. Available at: www.cfp.ca/content/53/5/827.full.pdf+html (accessed 9/5/2017).

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