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# CLAIMS Rx

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## Unexpected Outcomes:

Investigate, Communicate, Document

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# TABLE OF CONTENTS

**INTRODUCTION** ..... 2

 **CASE ONE:**  
Unexpected Death Following a Procedure ..... 4  
**RISK REDUCTION STRATEGIES** ..... 6

 **CASE TWO:**  
Unexpected Injury at a Nonsurgical Site ..... 7  
**RISK REDUCTION STRATEGIES** ..... 8

 **CASE THREE:**  
Unexpected Outcome After a Meniscus Repair ..... 9  
**RISK REDUCTION STRATEGIES** ..... 12

**CONCLUSION** ..... 13

**ENDNOTES** ..... 14

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# Unexpected Outcomes:

## Investigate, Communicate, Document

## INTRODUCTION

Physicians and caregivers have been managing unexpected outcomes of care, treatment, and medications since prehistoric times. Written records, which emerged in 18th to 16th centuries B.C., and paper charting from the late 1700s captured these outcomes long before our modern-day digital record keeping.<sup>1</sup>

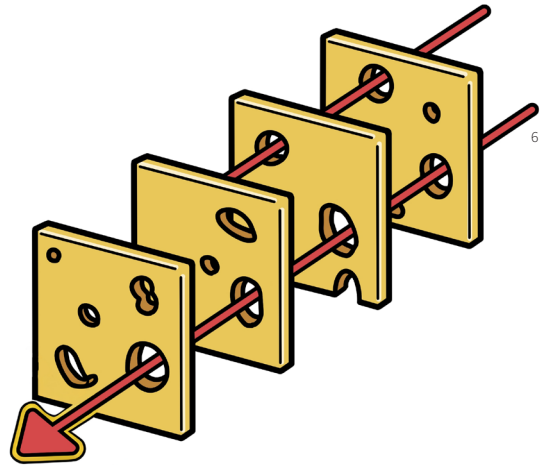
Today, the World Health Organization notes that one in every ten patients is harmed in healthcare, with more than three million deaths occurring annually due to unsafe care. Over half of the harm cases are preventable.<sup>2</sup> Typically, the cause is not the actions of one person, or even a group of people. Errors and harm are more likely to occur due to faulty systems rather than careless or untrained people.<sup>3</sup>

Many providers experience feelings of self-doubt, remorse, failure, and fear of litigation after an unexpected event has occurred.<sup>4</sup> Patients and families may feel mistrust, anger, and confusion especially if communication from the physician and healthcare team is delayed. This article will introduce the reader to a method for investigating unexpected outcomes. It will also discuss techniques for properly disclosing an adverse situation to patients and families.

### A SYSTEMS APPROACH TO REDUCE ERROR

Historically in healthcare, the belief was that an error occurred because someone failed to do their job correctly. Errors were not evaluated from a systems perspective. For example, if a nurse had a predefined number of medication errors, she was reprimanded, or even fired. When errors occur, it is important to identify all contributing factors, individual and system, in order to target risk reduction strategies. A safety culture starts with identifying the behaviors that lead to human error and making systemic changes to address those behaviors. Standardizing, simplifying, and reducing the reliance on memory help a process become stronger. Risk is reduced when processes are easy to do right and difficult to do wrong.<sup>3</sup> The goal is to implement tools, such as time-outs and checklists, to support the delivery of safer healthcare.

Psychologist James Reason evaluated catastrophic errors in various fields of work. He found that a series of small errors that go unrecognized and break through safeguards can lead to patient harm events.<sup>5</sup> This is known as the “Swiss cheese model.” In Reason’s model, each slice of cheese represents a chance to stop an event from happening. The first slice is the **organization influence**: negative culture, inadequate leadership support, and lack of available resources. The second slice is **supervisory factors**: inadequate supervision and training, mismanaged assignments, and failure to correct a known issue. The third slice of cheese is **preconditions for an unsafe act**: the current physical environment or tools, interruptions, distractions, and stress. The final slice of cheese represents the **unsafe act** itself: wrong decisions, violations, and skill-based errors. The holes in the cheese represent places an error might be stopped but was not. It is a set of system failures having poked enough holes in the cheese that when the holes align, the error reaches the patient.<sup>5,6</sup>



For illustrative purposes, consider this example: A leader just told everyone that hiring is on hold. Everyone will have to work smarter as a full patient census must be maintained (**organization influence**). In order to get things done faster, the supervisor does not monitor how patients are being roomed. Staff are rushing through vital signs and not thoroughly documenting the reason the patient is visiting the provider (**supervisory factor**). There is also only one mobile computer station and one vital sign machine, with three providers scheduled (who have full patient rosters). Several staff members make comments throughout the day on the chaotic flow. Those rooming patients report feeling stressed, skipping breaks, and having little time to stop for bathroom breaks, leading to lack of focus (**preconditions for an unsafe acts**).

On the last patient of the day, a provider asks for assistance with a new in-office biopsy procedure. Despite none of the present staff having completed their training, a staff member goes to the room to assist. The procedure is successful, and the doctor requests the specimen be sent out for pathology. The biopsy specimen is discarded (**unsafe act**) as the room is cleaned. With the office closing for the day, staff ask the patient to call tomorrow to schedule her next appointment (a second **unsafe act**). She agrees but never calls. Two years later, the patient returns to see the provider and receives a diagnosis of metastatic melanoma. Using a systems thinking approach, the practice investigates the entire two years of the patient’s care. Their analysis provides opportunities to add risk reduction strategies—or new slices of cheese—to prevent a recurrence.

The opportunity of a system review of an event requires a change in error management, moving from personal blame to systems-based thinking. How has the system in place contributed to each person’s actions? Unexpected outcomes should be reviewed, and systems adjusted, to allow for all steps being completed safely. Keeping a checklist, implementing an established education and training system, or monitoring standard work processes can help create a culture where safety is a priority. Using a teach-back method—where the person receiving the training can return the teaching to the instructor to verify what was learned—creates confidence the learner understands what was taught.<sup>7</sup>

This change in error management begins at the top and requires the commitment of leadership; it includes the working environment, procedures, and processes. Leaders need to ensure competency of workers and focus on teamwork, communication, and leveling of hierarchy. Any member of the team should be able to speak freely—without retaliation or fear—if a safety concern is identified. Reporting of incidences and near-miss situations allows for a deeper dive into preventability and for developing systems to reduce error.<sup>3</sup> By identifying events or errors, accepting that they do occur in your organization, then learning from them and addressing how to prevent them from occurring again, you will improve patient safety.<sup>8</sup>



## CASE ONE:

# Unexpected Death Following a Procedure

In the following case, the healthcare team had multiple opportunities to reduce the risk of potential liability before, during, and after the patient's surgery. These included addressing comorbidities, being aware of the patient's medical history, conducting a thorough informed consent, adequately documenting, and engaging in an appropriate disclosure process.

Consider what could have occurred differently if relevant patient information was known and considered by the operating room (OR) team. Think about the best way to manage disclosure of the unexpected event. Where would you start the investigation?

A 55-year-old morbidly obese woman with a history of hypertension, type 2 diabetes, congestive heart failure, and obstructive sleep apnea presented to a local hospital emergency department (ED) after a fall. She had been gardening, and her right leg fell into a sinkhole in her flower bed. She complained of pain in her right hip, knee, and thigh. Hip and knee x-rays were negative for injury, and the patient was discharged home. The patient followed up with her PCP two days later with complaints of continued pain in the right knee and the inability to walk. Additional x-rays were done, including below the knee, revealing a right tibial plateau fracture. She was referred to an orthopedic surgeon who recommended an open reduction and internal fixation (ORIF). The patient had a preoperative clearance from a cardiologist on the day before surgery. The family expressed concern to the anesthesiologist that a breathing issue might occur due to her sleep apnea diagnosis. The spouse offered to bring in the patient's CPAP for the OR team to use since his loved one could not lie flat or sleep without the CPAP.

The patient was scheduled for surgery with IV sedation and spinal anesthesia four days after the initial fall once preoperative clearance was received. Intraoperatively the patient had a bradycardic event and hypotension. A code blue was called, and the healthcare team was able to stabilize the patient. Postoperatively she was transferred to a tertiary hospital for critical care and neurology consultations. Further testing revealed a non-STEMI and anoxic brain injury had occurred.

Documentation was minimal for the day of the surgery; however, three days after the event a surgical team member added a note to the medical record. The note stated that the propofol infusion was found empty during surgery. The surgical team member mentioned that while someone was assisting to refill and replace the propofol, a sidebar conversation was occurring. When everyone turned back to the patient after two to three minutes, the patient was in respiratory arrest, her heart rate in the 50s, and she continued to decompensate resulting in a code blue.

On postoperative day 12, the patient passed away. The patient's spouse sued various members of the patient's healthcare team and the hospital for negligence.



## DISCUSSION

There were opportunities in this case to reduce the likelihood of an unexpected outcome. These included addressing comorbidities, obtaining and documenting a more thorough informed consent, and reviewing the patient's previous medical history. During the informed consent process, the provider did share with the patient that there was a possibility of her having a cardiac event. Her comorbidities (sleep apnea, hypertension, diabetes, and obesity) put her at a higher risk of respiratory compromise despite only receiving spinal anesthesia and a nerve block, with no general anesthesia. Studies have demonstrated that patients undergoing surgery with a history of sleep apnea have an increased risk of complications including hypoxemia, difficult intubation, MI, PE, and arrhythmias.<sup>9</sup> Had the physician and staff been more prepared for complications based on the patient's comorbidities, there could have been an awareness and plan by the team to react to any of those complications—if encountered. This is where The Joint Commission's recommendation for a Universal Protocol would have helped.

The Universal Protocol consists of three components: The first is a pre-procedure verification process, and a review of the history and physical, pre-procedure labs, radiology results, and special needs for the patient. The second component is marking the procedure site before starting surgery. The third component is performing a time-out immediately before starting surgery. All members of the OR team stop what they are working on to participate in the time-out. This is the last chance to ensure everyone at the table has all the correct information about the surgery.<sup>10</sup> The Universal Protocol is designed not only to prevent an incorrect surgery, but also to ensure that the correct patient is undergoing the correct procedure, on the correct body part. Additionally, it includes discussing the patient's medical history, current medications, and a possible emergency plan.

Listening to patient and family concerns can shed light on facts that may be helpful in treating the patient. In this case, had the team listened to, documented, and communicated the family's concerns of the patient being unable to lie flat without her CPAP, it may have provided important information during the time-out process. This may have better prepared the OR team to vigilantly prevent and respond to a cardiopulmonary event knowing this information before anything occurred. During his deposition, the patient's spouse had no memory of anyone telling him what happened to his wife in the OR. Prompt follow-up with families, which includes disclosing as much factual information as possible, helps build and sustain trust between the patient and family members impacted by the unexpected outcome and the hospital providers involved. A designated provider should assure the family of the day and time he or she will provide further contact, and identify who among the family will serve as contact person. The provider should also give the patient or spokesperson appropriate contact information in case additional questions arise.<sup>11</sup>

Lastly, complete, timely, and accurate documentation in the medical record about what happened with the patient was an additional opportunity for preventing an unexpected outcome in this case. The medical record should reflect what was observed during the unanticipated event, what interventions were administered, and the patient's response. Documentation should be completed before the end of a writer's shift. There should not be opinions or feelings documented as they are subjective. It is important to document the disclosure provided to the patient and named family members for consistency when further discussions occur.

A note made three days later looks suspicious as the writer knows the patient's outcome and can add or omit items to align the note with what should have happened instead of what really happened. Documenting that no one was watching the patient under anesthesia is more than concerning. When the values on the monitors started to drop, there was no mention of alarms. There was no mention of calling for help to other providers or supervisors. By documenting promptly and factually, and involving additional help immediately, a staff member can demonstrate recognition of urgency and a prompt response to the patient's needs.



## RISK REDUCTION STRATEGIES

Consider the following strategies when providing disclosure:

- Plan what you intend to say before you enter the room to disclose the facts.
- Consider having a fact witness present during the discussion.
- Allow plenty of time with the patient and family to listen to their questions and provide answers as factually as possible.
- Focus on the patient, not yourself. This is not a time to be defensive.
- Use empathy and acknowledge patient and family suffering. Don't minimize their feelings or point fingers at others.
- Apologize that the incident occurred: "I'm sorry this has happened to you, and I want to assure you I will continue to oversee your care."<sup>12</sup>
- Don't speculate. Let the family know that more investigation is occurring.<sup>13</sup>
- Know that disclosure is a process, not a one-time meeting, especially after serious events.<sup>11</sup>

## ADDITIONAL DISCLOSURE RESOURCES

ProAssurance Guidelines: [Disclosure](#)

ProAssurance Physician Seminar: [Medical Error: Reducing Liability Risk by Changing the Narrative](#)

ProAssurance Two-Minute Video: [Unexpected Outcomes](#)



## CASE TWO:

### Unexpected Injury at a Nonsurgical Site

Sometimes in a malpractice claim, the surgery is successful, but a peripheral aspect of the surgery causes an unexpected outcome. During the surgery at issue in this claim, no one noticed the IV infiltration that would ultimately cause significant patient injuries.

Consider how the outcome could have been different if the surgical team had adequately addressed issues such as potential IV safety risks considering the patient's body habitus and medical history, and responsibility for site assessment during surgery. After reading the case, think through where you would start in an investigation of this unexpected outcome.



A 21-year-old female with a history of Crohn’s disease and several abdominal surgeries was admitted to the hospital due to signs of a bowel obstruction. She underwent a robotic-assisted end ileocecal resection. The surgery lasted approximately seven hours and was considered successful. As the patient was undraped, it was noted that her right upper arm was severely swollen, pale, and cold to the touch because of a peripheral IV infiltration. An emergent consult was made to orthopedics while the patient was still in the OR, and fasciotomies were immediately done due to compartment syndrome.

The patient filed a lawsuit against the anesthesia team alleging failure to monitor the peripheral IV resulting in permanent scar the length of her right forearm and nerve damage to her third, fourth, and fifth fingers.



## DISCUSSION

Potential risk factors for a difficult venous access that apply to this patient include her being female, multiple hospital admissions, chronic illness, previous major surgery, dehydration, and low body mass index.<sup>14</sup> The patient was small with a BMI of 19 leading to a greater inability to maintain a peripheral line. Crohn’s is a chronic condition, and its management and treatment had required surgery and hospitalizations for this patient. Additionally, the fact that she had not had any food for the previous five days, or any oral fluid intake since midnight before the surgery, indicates she could have been dehydrated, also leading to difficulty in maintaining a peripheral IV site. Also, this surgery was scheduled to be at least six to seven hours long. The surgical team should have considered the length of the scheduled surgery and the likelihood of needing post-op antibiotics or maintenance fluids when deciding on the best IV access.

Another issue to consider is where the arm with the IV is secured during surgery and who is responsible for monitoring the site. The Association of periOperative Registered Nurses (AORN) advises that when positioning a patient in the supine position, as in this case, it is a collaboration of monitoring between the anesthesia and perioperative teams. Those teams identify and monitor the patients at risk for complications including pressure injuries, injuries related to medical equipment, and improper positioning injuries.<sup>15</sup> In this case, there was no documentation that anyone looked at the IV site, which was covered with a sterile drape during the seven-hour surgery. Knowing that the patient could not respond to pain or discomfort during the surgery due to sedation or general anesthesia, it was up to the surgical team to assign monitoring of the patient, including the IV site.<sup>16</sup> This is usually a team member from anesthesia.



## RISK REDUCTION STRATEGIES

Consider the following strategies:

- Review the patient’s history and physical, the length of surgery, and the length of time the IV will be needed to decide on the best IV access site and device.
- Verbally confirm who is monitoring the IV site during the surgery, whether it is the anesthesia provider, circulator, or other. Consider adding this action to your time-out checklist.
- Document the assessment of the IV site per facility policy.
- Look at the whole picture of the patient and how your special knowledge fits into all of the body systems.



## CASE THREE:

# Unexpected Outcome After a Meniscus Repair

Individuals who provide healthcare may wonder to what extent their documentation would matter if they were sued for medical malpractice. The following case is an example of a malpractice claim that was successfully defended in large part due to the documentation before, during, and after the patient's surgery.

Although this case was ultimately decided in favor of the defendants, consider what the members of the patient's healthcare team might have done to reduce the risk of patient injury.

The patient was a 42-year-old female with a history of diabetes, hypertension, hyperlipidemia, and morbid obesity with a BMI of 43. She presented to her PCP with left knee pain that was interfering with her ability to work as a housekeeper at the local hotel. Her PCP referred her to an orthopedic surgeon for consultation.

The patient first saw the orthopedic surgeon on August 7 with complaints of left knee pain. A thorough history and physical examination was completed. The surgeon wanted to rule out other possible causes of the knee pain, so he ordered labs for Lyme disease, a rheumatoid panel, and a C-reactive protein. He also ordered an MRI to better assess the knee.

About two weeks later, the patient returned to see the surgeon to review the test results. The lab results did not indicate any reasons for the knee pain. Based on the radiology findings, the surgeon discussed three types of treatment options: a “watch and wait” approach, surgery for a meniscus tear, or a more significant surgery that would require a six-to-eight-week recovery. He reviewed the risks and benefits of each option. He also discussed the importance of a weight loss program, and how extra weight can affect the knees. In addition to using a consent form, the surgeon documented what was discussed. He also noted the patient’s responses, which allowed anyone reviewing the chart to know what was discussed. The surgeon and patient agreed to arthroscopic surgery to repair the left meniscus and the anterior cruciate ligament.

On September 16 the patient arrived as scheduled with her family member present. A reassessment was documented. The patient’s vital signs were stable. Her blood sugar was 176. (The physician’s cutoff for cancelling surgery was a blood sugar of 180 or greater, which agreed with the American Diabetes Association.)<sup>17</sup> There were no changes to the left knee pain from the previous assessment. The surgeon added to the informed consent form that risks specific to this patient for this surgery included bleeding, infection, failure to control the pain, failure to cure the decreased motion, and nerve or vessel damage. The surgery was uneventful except for one small bleeding vessel that was easily controlled. The patient was discharged home later that day. Prior to signing off on his operative note, the surgeon read his dictated note in the chart. He made an amendment to correct the surgical side from right to left.

On September 17 at around 4:00 a.m., the patient woke with swelling and significant pain in her surgical knee. Her family member took her to the ED. All exams were benign other than an x-ray revealing local swelling of the left knee. IV pain medication was given. She was diagnosed with postoperative effusion, prescribed new pain medications, and advised to see her surgeon in the office later the same day. The patient’s pain appeared to be controlled before she left.

The family member picked up the prescription when the pharmacy opened later that morning and called the surgeon’s office for an appointment. By 10:30 a.m., the patient and her family member were in the surgeon’s office. Her vital signs were stable. An exam did not demonstrate any unusual swelling or redness, except for what looked to be a hematoma on the knee. The surgeon aspirated 10 milliliters of blood, then followed with an injection of an anesthetic. The patient reported feeling better and returned home.

The patient’s family member called the surgeon’s office at 3:00 p.m. that day noting the patient had pain and swelling. The surgeon advised to elevate the patient’s leg and put ice on the knee while continuing the pain medication as ordered. The surgeon also advised that the patient go to the ED should the leg be painful to touch, a possible symptom for a deep vein thrombosis or arterial clot. The same instructions were provided when the patient called the surgeon with complaints of continued pain and a rash. The patient had not yet gone to the ED.

At 6:30 p.m. the patient returned to the ED with her family due to pain in her left leg and back, and she was not able to move her surgical leg. Upon assessment, the left surgical leg appeared swollen, and pain was reported as 10/10. IV pain medication was administered. The ED physician spoke with the on-call orthopedic surgeon, provided updates, and was advised to make another attempt to aspirate the knee. The specimen attained from the aspiration was sent to the lab for Gram stain and cultures. The lab called to say the Gram stain showed Gram-positive rods. The ED physician started antibiotics and again called the on-call orthopedic surgeon and asked him to come into the hospital to examine the patient.

The patient remained awake and alert but was tachycardic and tachypneic, with increasing edema of the left leg. Demarcation of the area, necessary for the on-call orthopedic surgeon's proper assessment and monitoring, was complicated due to the patient's morbid obesity. He ultimately determined that there was edema from thigh to calf of the surgical leg. Another aspiration of the knee was attempted, but only air was attained. All of the sites in the needle/syringe system were tightened to rule out a break in the system, but only air returned on the second attempt. The surgeon immediately ordered a CT scan, suspecting gas gangrene. With confirmation on the CT scan, arrangements were made for the patient to be airlifted to a tertiary hospital that had the ability to do additional surgery and monitor in an ICU. The tertiary hospital also had hyperbaric oxygen chambers that this hospital did not have access to. A central line was placed as there was concern the patient was developing septic shock.

Until her departure from the ED, the patient remained alert and talking. However, her vital signs were changing with increased heart rate and respiratory rate, and a decrease in blood pressure, with a worsening overall appearance. On arrival at the tertiary hospital, she was still able to talk, but this was limited due to her pain and respiratory distress. Her pulse oximeter was 95% while on a non-rebreather mask. The patient did not feel anything below her waist and had new onset labial swelling. Dopamine was started due to the hypotension, and antibiotics continued. The patient was taken to the OR within the hour of arrival where the surgeon did a left hip disarticulation. By 4:15 a.m. the patient was taken to the ICU for monitoring. The diagnosis was clostridial necrotizing fasciitis. She developed acute kidney failure and was placed on dialysis. Despite all care provided, the patient went into cardiac arrest and died at 12:16 p.m.

The family initiated a lawsuit against the original orthopedic surgeon, one of the ED providers, and the hospital. After close to five years of litigation, the court found in favor of the physicians and hospital for lack of causation.



## DISCUSSION

The documentation by the members of the healthcare team was clear, thorough, and contemporaneous. It included specific details and exact instructions communicated to the patient and family. The defense team was able to use the documentation to show the standard of care was met and the care did not cause the patient's outcome. Ultimately, the patient's death was determined to be an unfortunate and unexpected event; but the good medicine, complete documentation, and timely care provided revealed it was not preventable. Specific actions that aided in the defense of the defendants in the lawsuit included:

- The first orthopedic surgeon ordered tests to assess for an inflammatory or infectious process, which helped reduce the differential diagnosis list.
- The first orthopedic surgeon reviewed his dictation for errors and corrected the right/left leg mistake before signing the note.
- In addition to using a consent form, the first orthopedic surgeon documented what was discussed about the risks, benefits, and alternatives to each treatment option. He also noted the patient's response, which allowed for anyone who reviewed the chart to know what was discussed.
- Prior to surgery, the first orthopedic surgeon determined that nothing had changed since the last office visit.
- Seeing the patient the following day when she had complaints allowed for the surgeon to evaluate the surgical site in a timely manner.
- Once the cause of the pain was discovered, the response to transfer was started promptly, which showed the timely recognition that urgent, higher acuity level care was needed.



## RISK REDUCTION STRATEGIES

Consider the following strategies:

- Talk with your patient and their family. Try to understand any barriers to care or to moving forward with a procedure or recommendation.
- Ensure your informed consent is specific to this patient on the particular day of treatment. Each patient has unique features that change the treatment considerations. Document which risks, benefits, and alternatives you discussed, and indicate what you did to determine that the patient understood you.
- Be prepared for adverse outcomes. Have a plan to manage them.
- Educate patients about the signs and symptoms of postoperative complications, and how and when to follow up.
- Document to the extent necessary to show you complied with the standard of care. Include your plan, your differential diagnosis, and your thresholds to move forward and to stop. Be timely, clear, and factual.
  - ▶ Patients' physical exams change. Document what you see now at your exam so you and others reviewing your notes will know what you saw and when.
- Consult specialists in a timely manner to enable assessment and treatments to begin early.



## Unexpected Outcomes: Investigate, Communicate, Document

## CONCLUSION

One never knows for sure when an unexpected outcome will impact a patient. There are some key measures that can be taken to help reduce the risk of an unexpected outcome leading to a lawsuit. The first is to maintain good, open, honest communications with patients and families. Listen with intent to understand, not to answer. Respond to patient and family questions with facts and compassion. Involve the patient and family in decision-making, especially after an unintended outcome has occurred. By doing this, you build trust, and the patient feels safe putting their care in your hands.

Ensure that test results don't get lost in the office process. Some tests take days, weeks, or months, and an efficient office procedure for result management is imperative.<sup>18</sup> Because memories will fade, remember to take the time during a patient visit or immediately afterward to complete your documentation. Include your differential diagnosis, what you are thinking at the time of your assessment and why. Also include patient questions and your responses and instructions. Hundreds of patients later, you may not remember every detail discussed with this patient. Your notes provide a way to review your prior decisions and the way in which you communicated your plan and reasoning. As the case studies in this article indicate, documentation is a key aspect of defending medical malpractice claims following unexpected outcomes.

## ENDNOTES

The documents referenced in this article, along with many other risk management resource documents and past editions of *Claims Rx*, are available by calling Risk Management at 844-223-9648 or by email at [RiskAdvisor@ProAssurance.com](mailto:RiskAdvisor@ProAssurance.com).

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