SEPTEMBER

RISK MANAGEMENT PERSPECTIVES



Diagnostic Challenges: Understanding Contributing Factors to Reduce Risk



Claims Rx is published for the benefit of ProAssurance policyholders, featuring claims-based learning.

Our writers and editors constantly review industry trends and closed claims information for ideas to help reduce risk and increase positive outcomes.

Typically each *Claims Rx* provides an opportunity for our insureds to earn .5 *AMA PRA Category 1 Credit*[™] at no additional cost.

ACCESS YOUR ONLINE ACCOUNT:

Sign in to your ProAssurance account and select "Claims Rx" from the "Seminars" menu for access. Read the article, and complete a post-activity quiz and evaluation to receive a CME certificate.

SIGN IN

RELEASE DATE SEPTEMBER 1, 2024

EXPIRATION DATE SEPTEMBER 1, 2027

TABLE OF CONTENTS

| | 2 |
|---|----|
| CASE ONE: | |
| Implicit Bias Complicates an | |
| Already Challenging Diagnosis | 4 |
| RISK REDUCTION STRATEGIES | 7 |
| CASE TWO | |
| CASE I WU: | • |
| Cognitive Blas Contributes to Delayed Diagnosis | 8 |
| RISK REDUCTION STRATEGIES | 10 |

CASE THREE:

| Patient Factors Complicate Diagnosis and Treatment | . 11 |
|--|------|
| RISK REDUCTION STRATEGIES | 13 |
| CONCLUSION | 14 |
| ENDNOTES | 15 |

By Kelly Riedl, PA-C, CPHRM

The information provided in this publication offers risk management strategies and resource links. Guidance and recommendations contained in this publication are not intended to determine the standard of care but are provided as risk management advice only. The ultimate judgment regarding the propriety of any method of care must be made by the healthcare professional. The information does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about this topic should be directed to an attorney. ProAssurance makes no representation regarding compliance with state or federal law by offering this publication and the links to resources contained therein. This article and links are provided for your convenience and reference only, and the provision of these links does not mean ProAssurance is affiliated or associated with these organizations.



Diagnostic Challenges: Understanding Contributing Factors to Reduce Risk

INTRODUCTION

The diagnostic process has been defined as a "complex and collaborative activity that unfolds over time and for most patients occurs within the context of the health care work system."¹ In 2014, the Institute of Medicine appointed an independent committee to define the complexities of this process with the objective of improving diagnostic accuracy among clinicians. Their diagnostic process map serves as an important reminder that both patients and clinicians play a role in ensuring diagnostic accuracy. The map contains the following steps:^{1,2}

- 1. Patient experiences a health problem
- 2. Patient engages with healthcare system
- 3. Iterative process of information gathering, integration, interpretation, and working diagnosis
- 4. Communication of the diagnosis
- 5. Treatment
- 6. Outcomes

Breakdowns occurring at any of these steps may result in a diagnostic error, but this does not necessarily equate to patient harm. The definition of diagnostic error varies, but according to the National Academies of Sciences, Engineering, and Medicine; it is "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."^{2,3} Since patient harm is a required element in a medical malpractice cause of action, a review of closed malpractice claims was completed to gain further insight into what may be most challenging for clinicians during the diagnostic process. This claims data from the Medical Professional Liability Association Data Sharing Project revealed that the top primary allegations for nonsurgical specialties were diagnostic errors.⁴ Nonsurgical specialties include emergency medicine, family medicine, internal medicine (including its subspecialities), and pediatrics.⁴ Most commonly, these diagnostic error claims were related to incomplete or inadequate diagnosis.⁴ The top presenting medical conditions associated with claims in these specialties were abdominal and pelvic pain, dorsalgia, and encounters for general examination in which patients presented without a specific complaint.⁴

This article will explore closed malpractice claims centered around diagnostic allegations. The selected cases intend to illustrate both patient and clinician factors that complicated the diagnostic process and ultimately contributed to patient harm.

DIAGNOSTIC CHALLENGES: COMMON COMPLICATING FEATURES

Multiple studies have attempted to explore the root cause of diagnostic errors. In the primary care setting, studies suggest that there are multiple causes leading to diagnostic errors but that cognitive errors stemming from mental processing and bias are the most common.^{5,6,7,8} While a full discussion on cognitive bias is beyond the scope of this article, The Joint Commission (TJC) associates anchoring, availability heuristic, framing effect, and premature closure as the most common cognitive biases associated with diagnostic errors. These terms are further defined below:⁹

| Anchoring Bias: | Giving weight to and relying on initial information/impressions, and not adjusting from this anchor despite availability of new information—"jumping to conclusions" |
|------------------------------|---|
| Availability Heuristic Bias: | Judging the likelihood of a diagnosis based on the ease with which examples can be retrieved—considering more common or recent diagnoses, and not considering less common diagnoses |
| Framing Effect: | Being influenced by how information is presented (e.g., the source and context) in decision-making |
| Premature Closure: | Ceasing to look for findings/signals once something has been identified—accepting a diagnosis before considering all of the information and verifying the diagnosis |

Another type of bias which may impact diagnostic errors is implicit or unconscious bias. According to TJC, this type of bias "refers to the attitudes or stereotypes that affect our understanding, actions, and decisions in an unconscious manner."¹⁰ Examples of patient characteristics associated with this type of bias include but are not limited to age, disability, education, health status, and obesity.¹¹ Every person has implicit biases, including healthcare providers who strive to treat all patients equally and who believe they treat all patients equally. Healthcare provider implicit bias may contribute to patient injury by negatively influencing diagnosis and treatment decision-making.¹²

Finally, there may be certain presenting features that increase diagnostic difficulties, as shown in a study of literature addressing diagnostic error or delay. The authors determined that atypical presentations, nonspecific presentations, very low prevalence, the presence of a comorbidity, and perceptual features that could be missed all increase the risk of a diagnostic error.⁸





CASE ONE: Implicit Bias Complicates an Already Challenging Diagnosis

Back symptoms were among the top 10 leading primary reasons for emergency department (ED) visits from 2016 to 2022 based on data from the National Center for Health Statistics.¹³ During this same period, opioid misuse and deaths were on the rise, resulting in the Department of Health and Human Services declaring the opioid crisis a public health emergency by 2017.¹⁴ The following case gives insight into diagnostic challenges faced by emergency medicine physicians forced to determine true pathologic origins of pain versus drug-seeking behavior amid a synthetic opioid crisis.

What patient characteristics may have contributed to implicit bias in this case?

- May 30,A 52-year-old patient with a history of chronic low back pain, hypothyroidism, obesity, asthma, COPD,2016anxiety, depression, post-traumatic stress disorder (PTSD), and multi-substance abuse presented to the
ED with complaints of a five-day history of worsening severe low back pain, rated an 8/10. Associated
symptoms included weakness and difficult ambulation. Exam revealed normal vital signs, intact distal
pulses, and multiple skin lesions with scarring noted on bilateral lower extremities. The patient was
diagnosed with chronic lower back pain, prescribed a short course of opioids, and advised to follow up
with her primary care physician (PCP). No labs were obtained during the visit.
- June 3, 2016 The patient presented to the same ED after being referred by her PCP who saw her earlier that day for fever, chills, diaphoresis, and shortness of breath. Vitals revealed hypotension and tachycardia. Labs revealed leukocytosis, elevated liver function tests, elevated creatinine, and hypokalemia. The patient's urine drug screen was positive for cannabinoids, opiates, and benzodiazepines. Exam revealed tenderness to palpation along the lumbar spine and sacrum. X-ray of the lumbar spine was obtained and revealed moderate degenerative disc disease, decreased disc spacing from L2 to L4, and minimal convexity of lumbar curvature. The patient was diagnosed with bronchitis and chronic back pain. She was discharged with antibiotics and opioids and advised to follow up with her PCP.
- June 6, 2016 The patient saw her PCP with continued complaints and requested refills of pain medication. Her PCP documented a conversation with the ED physician prior to referring the patient back to the ED. The PCP had stated that he felt she should be transferred to a university center for pain management due to her complex medical picture. He also stated concerns for her and her son's safety at her home due to her condition. The ED physician agreed to evaluate her and likely facilitate a transfer to a higher level of care. The patient presented to the ED and was evaluated by this physician. She continued to report low back pain, now with radiation into her legs with associated numbness in her perineum. She was also noted to have erythema and swelling of the left foot with 2+ pitting edema, as well as multiple sores on her arms and legs from dermatillomania. Her vital signs were normal, and no labs were obtained. The patient was diagnosed with back strain and chronic back pain. She was discharged with NSAIDs and opioids and given instructions to seek additional care if there was no improvement over the next week, or if new symptoms arose. She was also advised to follow up with her PCP.
- June 10, The patient returned to the same ED with continued symptoms and similar findings. Her vital signs were normal, and no additional labs or imaging were obtained. She was again discharged home with a diagnosis of low back strain, chronic back pain, and substance abuse. She was provided a prescription for opioids and was told future pain medication would need to be handled by a pain management clinic. An appointment was made at the pain clinic for her on June 27, 2016.
- June 19, 2016 The patient returned to same ED in a wheelchair with her mental health caseworker. Her chief complaint was altered mental status. She continued to complain of severe low back pain, but the focus of her evaluation shifted to her mental health. She admitted to feeling down and depressed and having suicidal ideations in the past two weeks. Labs were obtained and revealed mild anemia. Urine drug screening was again positive for cannabinoids, opiates, and benzodiazepines. On exam she was noted to be alert, oriented, and anxious, in moderate distress. She had positive meningeal signs and tenderness along her lumbar paraspinal muscles. She was diagnosed with chronic back pain, lumbar spondylosis without myelopathy, and PTSD. Orders were placed for transfer to an inpatient mental health center. She stayed in the ED until transfer the following day.

- June 20-27, Throughout her stay at the mental health facility, labs revealed leukocytosis and mild anemia. She was discharged in time to make her scheduled pain management clinic visit later that day.
- June 27, The patient explained to the pain clinic physician that she had had chronic low back pain for many years, but the recent pain she had been experiencing was different and more severe. The physician refused to prescribe additional pain medication. The patient became upset and left abruptly.
- July 4, The patient was taken to the same ED via emergency medical service after a fall. She complained of continued severe low back pain with radiation down the left lower extremity into the calf and foot. Labs revealed significant leukocytosis. Blood cultures were obtained, and a lumbar spine x-ray revealed a new compression fracture at L3. The patient was transferred to a university medical center for further care that day. Blood cultures were ultimately positive for *Staphylococcus aureus* (*Staph aureus*).

The patient was evaluated by an ED physician at the university medical center. He diagnosed systemic inflammatory response syndrome, lower extremity weakness, and low back pain. She was admitted and further evaluated by an orthopedic surgeon. CT scan of the lumbar spine was obtained and revealed bony erosion at L3 concerning for osteomyelitis. A pelvic CT revealed an abscess of the psoas without involvement of the adjacent intra-abdominal structures. MRI of the lumbar spine revealed osteomyelitis from L2-L4, scattered epidural abscesses, and myositis of bilateral psoas and paraspinous musculature. She underwent laminectomy, duraplasty, and evacuation of the ventral epidural abscesses. Cultures from surgery were positive for *Staph aureus*. She did well over the course of this hospitalization and was discharged with a PICC line in place for continued antibiotic therapy on July 17, 2016.

The patient filed a lawsuit against the ED and all her treating physicians at the ED. She claimed her symptoms were not taken seriously, that she was treated as a drug-seeking addict, and that their negligence led to the delayed diagnosis and progression of her infection.



DISCUSSION

Multiple experts were unsupportive of the medical care provided by the ED physicians from May 30 to July 4, 2016, who failed to recognize obvious signs of infection and sepsis. Most commented that spinal abscesses are difficult to diagnose, particularly in the setting of acute or chronic back pain in a patient with multi-substance drug use and underlying psychiatric disorders. Expert opinions differed on when the patient may have ultimately developed the spinal abscess. However, they all agreed that the ED physicians fell below the standard of care by failing to include this in their differential diagnosis with her progressive neurologic complaints, and failed to rule it out accordingly. Additionally, there was limited documentation regarding active drug use in the patient's social history. There was concern for the ease at which plaintiff's counsel could link multiple open skin lesions to *Staph aureus* bacteremia, even in the absence of active drug use. For these reasons, the case was settled.



RISK REDUCTION STRATEGIES

Consider the following strategies to reduce the effects of implicit bias on patient encounters and medical decision-making:^{10,12,15}

- Identify your level of implicit bias with the Implicit Association Test,¹⁶ other tools, or training.
- Neutralize your implicit bias by forming a common identity with patients (e.g., shared hobby, sport, family size), gaining perspective into individual patient lives, and spending time with people from groups toward which you may have bias but admire.
- Avoid stereotyping and instead individualize patients by discovering their unique qualities (e.g., view your patient as a mother of three grown children instead of an elderly Hispanic female).
- Gain an understanding of cultures different from your own, especially those most common to your patients.
- Consider the impact your diagnoses (or missed diagnoses) can have on the future care of a patient after hand-off. For example, transferring a patient from the ED to an inpatient psychiatric facility may lead to the assumption that an acute process was ruled out, thus minimizing the urgency of evolving symptoms.
- Consistently practice evidence-based medicine.
- Promote training and diversity at all levels of the organization.

Consider the following spinal epidural abscess diagnosis issues:¹⁷

- The hallmark triad of back pain, fever, and neurological deterioration is only present in 8%-15% of cases.
- Salient red flags are unexplained fever, neurological deficits, and active infection.
- Major risk factors are diabetes, IV drug use, indwelling vascular catheter, recent spinal intervention, immunosuppression, and active infection elsewhere.

ADDITIONAL RESOURCES

National Institutes of Health: <u>Health Disparities Calculator (HD*Calc)</u>¹⁸—Statistical software designed to generate multiple summary measures to evaluate and monitor health disparities

American Academy of Family Physicians: <u>The EveryONE Project Implicit Bias Resources</u>¹⁹—Training resources and tools for healthcare organizations to decrease the impact of implicit bias on patient care

NetCE CME Course #97000: <u>Implicit Bias in Health Care²⁰—A</u> course that brings awareness to implicit and explicit bias and provides suggested interventions for clinicians to reduce these biases



A

CASE TWO: Cognitive Bias Contributes to Delayed Diagnosis

Communication is a vital element of patient care and can impact both patient compliance and medical professional liability risk when breakdowns occur. Common themes observed in malpractice claims include physicians failing to adequately educate or warn patients on the importance of a test, and patients failing to listen or comply with the recommended test. A study investigating lessons learned from diagnostic errors in primary care found that "[t]he most common pathway leading to error ... was the assignment of common benign diagnoses to patients with uncommon serious diseases."⁵ Keep in mind this concept as the details of the next case unfold. Also consider how this assumption may impact adequately communicating risks of noncompliance.

What specific cognitive biases may have contributed to the delayed diagnosis in this case?

| August 15, | A 35-year-old patient with a history of irritable bowel syndrome, acid reflux, obesity, recurrent ear |
|------------|---|
| 2013 | infections, and multiple ear surgeries in childhood presented to his family medicine clinic with a complaint |
| | of bilateral ear pain for the past week. He was diagnosed with bilateral ear infections for the third time in |
| | the past two months, and uncontrolled acid reflux. He was prescribed cefdinir and omeprazole and was |
| | referred to an ear, nose, and throat (ENT) specialist. He was also advised to follow up in six months for |
| | fasting lab work. One month later he returned with continued ear pain. He was prescribed prednisone and |
| | azithromycin and again referred to ENT. |

December 12, The patient presented again with ear pain and new complaint of shortness of breath on exertion. An EKG and urinalysis were obtained and were both normal. He was prescribed azithromycin and instructed to return in the morning for fasting blood work. A Hemoccult® test kit was provided along with instructions to return the card in three days. His lab results revealed anemia, and additional testing revealed iron deficiency. He was prescribed iron and told to follow up in one month for repeat labs.

February 20, The patient presented again for a sick visit. At this visit his complaint was sore throat and earache. Rapid
2014 strep test was negative. He was diagnosed with tonsillitis and prescribed amoxicillin and magic mouthwash.

May 6,The patient presented for follow-up regarding the iron deficiency anemia and for refills of omeprazole. Repeat2014labs were drawn to evaluate the anemia. These labs revealed continued iron deficiency. The results were
relayed to the patient over the phone. He was instructed to continue the iron replacement and return the
Hemoccult cards. Four days later he returned one of three Hemoccult cards, and this was negative.

September 20, The patient presented for a sick visit with a chief complaint of productive cough, runny nose, and
wheezing. He was diagnosed with bronchitis and prescribed azithromycin plus an albuterol inhaler. Over the next two months he returned twice with a sore throat. At both visits his rapid strep test was positive, and he was treated with antibiotics.

December 12, The patient presented with complaints of worsening anxiety and depression and for refills of omeprazole. At this visit he explained he was having difficulty sleeping, had lost his appetite, and had no energy. He was noted to have lost 25 pounds unintentionally over the past three months. The patient was started on antidepressants and referred to a mental health counselor. He was also reminded to return the Hemoccult cards, and labs were drawn. These labs revealed continued iron deficiency anemia. The patient was advised to increase his iron supplementation and was referred to a gastroenterologist (GI) for possible endoscopy.

January 21,
The patient presented with complaints of vomiting, abdominal pain, and constipation. He explained he had not yet seen a GI but had an appointment coming up on February 1, 2015. A one-view abdominal x-ray was ordered and was negative. The patient was prescribed sucralfate and simethicone and advised to follow up with a GI as planned.

February 4, The patient presented to the ED with worsening nausea, vomiting, and constipation. A CT scan of
the abdomen and pelvis was obtained and revealed a 6.3 cm constricting lesion in the ascending colon in the region of the hepatic flexure, with adjacent enlarged lymph nodes. He underwent an esophagogastroduodenoscopy (EGD) and colonoscopy three days later which revealed a short segment of Barrett's esophagus, hiatal hernia, and a mass in the right colon at the hepatic flexure.

February 8, The patient underwent a right hemicolectomy with reanastomosis. He was ultimately diagnosed with stage IVB adenocarcinoma of the sigmoid colon and given a poor prognosis.

The patient and his wife originally filed a medical malpractice and loss of consortium claim, but while the case was pending the patient passed away. The medical malpractice claims were subsequently converted to wrongful death and survival claims.



DISCUSSION

Experts agreed that the standard of care may have been breached by failure to refer this young, otherwise healthy male, with no overt signs of bleeding, to a GI specialist sooner. They agreed this likely caused a delay in the diagnosis of cancer. Experts disagreed, however, on how this may have changed the patient's ultimate prognosis or impacted his five-year survival rate. Some felt an earlier diagnosis may have improved the prognosis, but others felt this form of cancer was so aggressive that an earlier diagnosis would not have mattered. Others commented the patient's underlying comorbidities and age made this a more difficult diagnosis.

What complicated the defensibility of this case were patient survey records brought forth by plaintiff's counsel during discovery. These suggested that the practice could not keep up with the number of patients seen daily and that patients were frustrated with follow-up practices that did not keep patients assigned to their previous clinician for continuity. This, coupled with requests for the family care clinic to produce tax returns, income statements, and balance statements, made it clear that plaintiff's counsel planned to pursue punitive damages, arguing profits over patient care. For these reasons, the case was ultimately settled.



RISK REDUCTION STRATEGIES

Consider the following risk reduction strategies to help improve patient compliance:

- Make sure your practice or organization has a reliable procedure to track patients with pending tests or referrals.
- Educate patients about ordered tests and consults including why these are important and how the results will likely affect further care, including the possible consequences of noncompliance.
- Always document patient education about tests and consultations.
- If a patient declines to comply with an ordered test or treatment, discuss and document that you advised the patient of the risks involved in refusing treatment, and note the patient's rationale for their decision.
 - ► Have the patient sign a <u>refusal of treatment form</u>, and provide a copy to the patient.

Consider the following risk reduction strategies to improve diagnostic accuracy:²¹

- Acknowledge that the diagnostic process inherently involves uncertainty, and share this with patients.
- Create "diagnostic safety nets" to aid in missed diagnosis prevention, such as alerting patients of red flags to be aware of, when and where to seek help for worsening symptoms, and expectations for the suspected course of their illness.
- Plan to rule out the "do-not-miss" diagnoses, regardless of how unlikely they may be.

Consider the following colorectal cancer diagnosis issues.²²

- Incidence in young adults is increasing.
- It has moved up as the leading cause of cancer in men under age 50.
- In 2021, colorectal cancer screening age moved from age 50 to age 45.



P

CASE THREE: Patient Factors Complicate Diagnosis and Treatment

Treatment and patient outcomes are part of the diagnostic process. Sometimes surgery is necessary to not only treat a problem, but also to definitively determine the diagnosis. Regardless of the reason for surgery, it is important that the correct procedure occur on the intended person at the intended site. TJC introduced the Universal Protocol in 2003 to aid in the prevention of wrong site, wrong procedure, and wrong person surgery.²³ As of 2004 TJC began to include these elements in its accreditation process for healthcare organizations.²³ While the overall incidence of wrong-site surgeries (WSS) is low, they still accounted for 7.9% of sentinel events voluntarily reported to TJC from 2018 to 2021.²⁴ WSS also ranked third on the list of top allegations associated with the ambulatory surgical setting in an internal ProAssurance closed malpractice claim analysis. Many factors contribute to the occurrence of a WSS, which can lead to delays in treatment and thus complicate the diagnostic process. The following case exemplifies how patient factors may contribute to the occurrence of a WSS and how use of the Universal Protocol can help clinicians overcome these factors.

How would you have approached the disclosure conversation after it was determined an error in diagnosis and treatment occurred?

| September 19, 2018 | A 29-year-old patient with history of sleep apnea, prediabetes, arthritis, and morbid obesity presented to her PCP with complaints of a lump on the back of her neck that was increasing in size. She explained it had been there for years, but now it was growing and beginning to cause neck pain. The PCP evaluated the area of concern which revealed a 4 x 6 cm, irregular, firm angiolipoma on the left posterior lateral neck. Due to the patient's symptoms, he referred her to a general surgeon. |
|-----------------------|---|
| October 19, 2018 | The patient presented to the surgeon for evaluation. He examined her and noted a 3 cm, deep lipoma of the neck. His impression was lipoma of the neck in a morbidly obese patient (BMI 48). His plan was for excision of the posterior neck lipoma. After a lengthy discussion about the risks, benefits, complications, and alternative options, the patient was noted to understand and agreed to proceed with the surgery. |
| November 11, 2018 | The patient presented for outpatient surgery at the ambulatory surgery center after obtaining surgical clearance from her PCP. Consent was obtained for excision of the posterior neck mass. During the surgery, the patient was positioned in the right lateral decubitus position and placed under IV sedation. The posterior neck was prepped and draped. An elliptical skin incision measuring 7 x 1.5 cm was made to remove the suspected lipoma and was subsequently closed with sutures. The patient tolerated the procedure well and was transported to recovery. |
| | Pathology results from surgery revealed fragments of skin and attached fibroadipose tissue with focal dermal fibrosis and no evidence of malignancy. No masses were identified in the specimen. |
| November 14, 2018 | The patient presented to her PCP and complained that the lipoma had not been removed. He examined the patient and noted a 5-6 cm healing incision at the left occiput. He also noted the 4 x 6 cm, irregular, firm angiolipoma in the left posterior lateral neck was still palpable. He advised her to follow up with the surgeon during her planned postoperative follow-up appointment. |
| November 16, 2018 | At the follow-up appointment the surgeon explained that he made a mistake due to the patient's positioning during surgery. He further explained the mass was difficult to identify due to her body habitus, resulting in thick neck fat obscuring the location. His documentation stated that the area of concern was not removed, and the plan was for re-excision. |
| August 15, 2019 | The patient presented to an ENT surgeon for evaluation of the neck mass. Examination revealed a 2 cm posterior cervical mass and a well-healed scar at the occiput. The surgeon ordered a CT scan and recommended excision of the mass after the patient had her diabetes under better control. The surgeon, too, suspected that this mass was a lipoma. |
| February 15, 2020 | The patient was cleared for surgery by her PCP and underwent excision of the mass by the ENT surgeon without complication. Pathology confirmed lipoma with no evidence of malignancy. |

The patient filed a suit against the initial operating surgeon claiming the surgery was needless and resulted in significant subsequent medical treatment, including additional surgery.



DISCUSSION

During deposition the general surgeon explained that the patient was a very large woman with a thick neck. He was able to palpate the area of concern and mark it preoperatively, and believed the incision was made in the area that he marked. In his opinion that due to the patient's body habitus and sleep apnea, it was not possible to position the patient's chin to chest intraoperatively for a full view of the operative site. The surgeon explained that this would have risked blocking the airway. He further testified that he offered to remove the lipoma for free after discovering the error at the postoperative follow-up visit, but the patient never returned.

The case was ultimately settled before trial due primarily to lack of defense expert support. Additional factors which would have likely complicated the defense included the patient's recollection of the disclosure conversation in which the surgeon attempted to blame his surgical error on the patient's body habitus.



RISK REDUCTION STRATEGIES

Consider the following strategies for reducing the risk of wrong-site surgeries:

- Incorporating these key elements from TJC's Universal Protocol²⁵ into your preoperative process:
 - Conduct a pre-procedure verification process in which you verify the correct surgery is done on the correct patient and at the correct place on the patient's body. Involve the patient in this process whenever possible.
 - ► Mark the correct procedure site before the procedure is performed. Involve the patient in this process whenever possible.
 - Perform a time-out in which you pause before the surgery to make sure that a mistake is not being made. This should occur immediately before the procedure begins, be a standardized process, and involve the immediate members of the procedure team.
- Foster a culture of safety where team members feel empowered to speak up if they notice discrepancies during any step leading up to the procedure.

Consider the following strategies throughout the disclosure process:

- Plan what you intend to say ahead of the discussion and consider having a fact witness present during the discussion, such as a nurse or other clinician.
- Spend plenty of time with the patient and family members. Listen to their questions and answer them to the best of your ability.
- Focus on the patient, not on yourself.
- Sincerely acknowledge the patient's and family's suffering. Do not belittle a complication. Do not point fingers or blame other physicians, staff members, or the patient.
- Apologize for the fact that the incident occurred when it is appropriate. For example: "I'm sorry this has happened to you, and I want to assure you I'll continue to oversee your care."
- Discuss the patient's current condition and continued treatment, as well as the event's definitive medical consequences on the patient's health (if known).
- Do not speculate. If you do not know what happened, admit this. Then tell the patient and family you are investigating the situation and will let them know as soon as you have answers.
- Document the discussion, including:
 - ► The date, time, and location of the discussion.
 - ► The parties and relationships of those present.
 - Your commitment to share additional information as it becomes available and to assist the patient and family.
- Do not make any admissions of liability or statements of blame.

ADDITIONAL RESOURCES

<u>ProAssurance Medical Error Webinar Series:</u>²⁶ Part One—Reducing Liability Risk by Changing the Narrative discusses strategies for preventing and mitigating the effects of medical errors. Part Two—A Defense Attorney's Perspective on Disclosure contains advice from a defense attorney on how to respond to a complication of treatment in a way that is most likely to reduce the risk of a future medical liability claim.



Diagnostic Challenges: Understanding Contributing Factors to Reduce Risk

CONCLUSION

Both patients and clinicians play a role in the diagnostic process. While the process itself and the root cause of diagnostic errors are complex, the case studies illustrate how faulty mental processing, cognitive bias, implicit bias, and certain presenting features can contribute to more challenging diagnostic scenarios. Increasing awareness to potential bias allows for implementation of strategies to neutralize them and thus decrease impact on the diagnostic decision-making process. Taking time to communicate diagnostic uncertainty and involving patients in the diagnostic process through education can also minimize impact by fostering a physician-patient relationship built on trust. When an error does occur, disclosing this in a way that ensures open, sincere, and effective communication with the patient and their family can reduce the risk of a resulting claim.

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 <u>RiskAdvisor@ProAssurance.com</u>.

- "The Diagnostic Process," Society to Improve Diagnosis in Medicine, accessed April 29, 2024, <u>https://www.improvediagnosis.</u> org/processes/the-diagnostic-process/.
- 2. Erin P. Balogh, Bryan T. Miller, and John R. Ball, eds, *Improving Diagnosis in Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.
- "What is Diagnostic Error?," Society to Improve Diagnosis in Medicine, accessed April 29, 2024, <u>https://www.improvediagnosis.org/what-is-diagnostic-error/</u>.
- "Review of Data Sharing Project MPL Specialty Snapshot— Nonsurgical Edition 2017-2019," MPL Association, 2021.
- John W. Ely, Lauris C. Kaldjian, and Donna M. D'Alessandro, "Diagnostic Errors in Primary Care: Lessons Learned," Journal of the American Board of Family Medicine 25, no. 1 (January 2012): 87-97, https://doi.org/10.3122/jabfm.2012.01.110174.
- 6. John W. Ely and Mark L. Graber, "Preventing Diagnostic Errors in Primary Care," *American Family Physician* 94, no. 6 (2016):426-32, <u>https://www.aafp.org/pubs/afp/issues/2016/0915/p426.html</u>.
- Satid Thammasitboon and William B. Cutrer, "Diagnostic Decision-Making and Strategies to Improve Diagnosis," *Current Problems in Pediatric Adolescent Health Care* 43, no. 9 (October 2013): 232-41, https://doi.org/10.1016/j.cppeds.2013.07.003.
- 8. Olga Kostopoulou, Brendan C. Delaney, and Craig W. Munro, "Diagnostic Difficulty and Error in Primary Care—A Systematic Review," *Family Practice* 25, no. 6 (December 2008): 400-413, <u>https://doi.org/10.1093/fampra/cmn071</u>.
- 9. "Quick Safety 28: Cognitive Biases in Health Care," The Joint Commission, accessed April 30, 2024, <u>https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-28/cognitive-biases-in-health-care/.</u>
- 10. "Quick Safety 23: Implicit Bias in Health Care," The Joint Commission, accessed April 30, 2024, <u>https://www.</u> jointcommission.org/resources/news-and-multimedia/ newsletters/newsletters/quick-safety/quick-safety-issue-23implicit-bias-in-health-care/implicit-bias-in-health-care/.
- David H. Chae et al., "Conscious & Unconscious Biases in Health Care, Module 2: What the Literature Is Telling Us," Georgetown University National Center for Cultural Competence, accessed April 30, 2024, https://nccc.georgetown.edu/bias/module-2/2.php.
- 12. Chloë FitzGerald and Samia Hurst, "Implicit Bias in Healthcare Professionals: A Systematic Review," *BMC Medical Ethics* 18, no. 19 (March 2017), <u>https://doi.org/10.1186/s12910-017-0179-8</u>.
- 13. "Estimates of Emergency Department Visits in the United States, 2016-2022," National Center for Health Statistics, generated interactively April 18, 2024, <u>https://www.cdc.gov/nchs/dhcs/ed-visits/index.htm</u>.

- "Opioid Crisis: Status of Public Health Emergency Authorities," U.S. Government Accountability Office, September 26, 2018, <u>https://www.gao.gov/products/gao-18-685r</u>.
- 15. Regina Schaffer, "Everyday Solutions to Reduce Implicit Bias in Health Care," Healio, October 21, 2019, <u>https://www.healio.com/news/pulmonology/20191021/everyday-solutions-to-reduce-implicit-bias-in-health-care</u>.
- "Take a Test," Project Implicit, accessed April 30, 2024, https://implicit.harvard.edu/implicit/takeatest.html.
- Muhammad A. Ameer et al., "Spinal Epidural Abscess," in *StatPearls* (Treasure Island, FL: StatPearls Publishing, 2024), https://www.ncbi.nlm.nih.gov/books/NBK441890/.
- "Health Disparities Calculator (HD*Calc)," National Cancer Institute, updated June 5, 2024, <u>https://seer.cancer.gov/hdcalc/</u>.
- 19. "Implicit Bias Resources," American Academy of Family Physicians, accessed April 30, 2024, <u>https://www.aafp.org/family-physician/</u> patient-care/the-everyone-project/toolkit/implicit-bias.html.
- 20. "Implicit Bias in Health Care," NetCE, September 1, 2021, https://www.netce.com/courseoverview.php?courseid=2234.
- Ashley N.D. Meyer et al., "Patient and Clinician Experiences of Uncertainty in the Diagnostic Process: Current Understanding and Future Directions," *Patient Education and Counseling* 104, no. 11 (November 2021): 2606-2615, <u>https://doi.org/10.1016/j. pec.2021.07.028</u>.
- 22. Kathy Katella, "Colorectal Cancer: What Millennials and Gen Zers Need to Know," Yale Medicine, January 17, 2024, <u>https://www.yalemedicine.org/news/colorectal-cancer-in-young-people</u>.
- 23. Deborah F. Mulloy and Ronda G. Hughes, "Wrong-Site Surgery: A Preventable Medical Error," in *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Rockville, MD: Agency for Healthcare Research and Quality, 2008), chap. 36, <u>https://www.ncbi.nlm.nih.gov/books/NBK2678/</u>.
- 24. "Closed Claims Data Analysis Identifies Wrong-Site Surgery Risk Factors," The Joint Commission, April 25, 2023, <u>https://</u> www.jointcommission.org/resources/news-and-multimedia/ news/2023/04/closed-claims-data-analysis-identifies-wrong-sitesurgery-risk-factors/.
- 25. The Joint Commission, The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™: Guidance for Health Care Professionals, accessed April 30, 2024, <u>https://www.jointcommission.org/-/media/tjc/documents/standards/universalprotocol/up_poster1pdf.pdf.</u>
- "Medical Error: Reducing Liability Risk by Changing the Narrative," ProAssurance, December 2023, <u>https://riskmanagement.proassurance.com/seminars</u>.