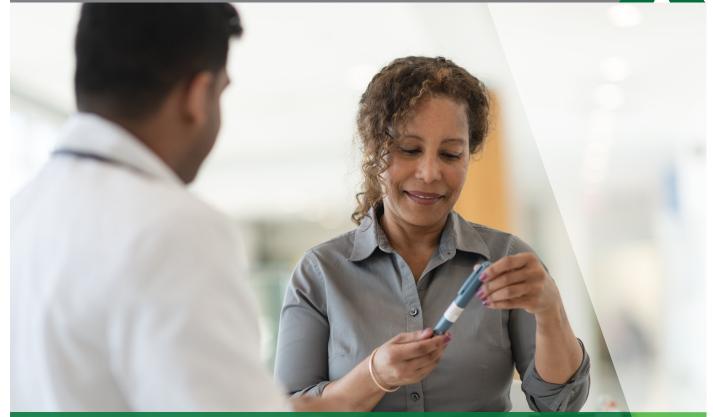
# RISK MANAGEMENT PERSPECTIVES



## **Diabetes:**

**Risk Reduction Across the Continuum of Care** 



DIABETIC PATIENT ACTIVATION AND ENGAGEMENT



Improving Self-Management

**CASE ONE** Unsuccessful Management of Diabetes in Primary Care

**DIABETIC FOOT ULCER** Increasing Vigilance



**INPATIENT DIABETIC FOOT TEAMS** Using a Multidisciplinary Approach

## 

### **CASE TWO**

Inadequate Inpatient Teamwork/Hand-offs During the Care of a Diabetic Patient with Foot Infection





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## **Diabetes:**

**Risk Reduction Across the Continuum of Care** 

## **INTRODUCTION**

According to the Centers for Disease Control and Prevention (CDC), 37.3 million Americans currently have diabetes—11.3% of the population. The percentage increases with age—26.8% of U.S. adults aged 65 and older have diabetes.<sup>1</sup> Over time, the incidence of diabetes has continually increased. In 1958, the percentage of the population with diagnosed diabetes was just under 1%; by 1980, it was 2.5%; and by 2000, it was 4.4%.<sup>2</sup> Projections for the future are grim. For example, a 2017 study estimated the prevalence of diabetes would increase by 54%, to more than 54.9 million Americans, by 2030.<sup>3</sup> "If plaintiff does not change his lifestyle and behavior, he is going to end up losing his whole leg."

 consultant opinion from a closed claim

Diabetes causes approximately 85% of nontraumatic amputations.<sup>4</sup> The rate of lower-extremity amputation is an important index of comprehensive diabetes care because it is negatively associated with glycemic control, cardiovascular risk factor management, early detection of diabetes-related complications, appropriate treatment of foot ulcers, and patient self-care.<sup>5</sup> The number of diabetes-related nontraumatic lower extremity amputations increased by 50% from 2009 to 2015.<sup>5</sup> (There are approximately 150,000 nontraumatic lowerextremity amputations every year in the U.S.)<sup>6</sup> As the number of patients with diabetes increases, particularly diabetic patients requiring amputation, the number of professional liability claims involving diabetes appears to be increasing.<sup>7</sup> Amputation claims can be problematic for the defense because the mere fact of the amputation can evoke an inordinate level of jury sympathy, which can result in inflated damages. Furthermore, hindsight bias can make it difficult for jurors to consider the facts of the case as they were unfolding and available to the defendant. Defendants are often judged based on the outcome and facts that would not have been available to the defendant but rather have been discovered during litigation.<sup>7</sup>

Among the closed claims involving diabetic patients that were analyzed for this article, most involved patients with poorly controlled type 2 diabetes mellitus, who presented with or developed lower-extremity infections that resulted in amputation. This is not surprising. Up to 45% of patients with type 2 diabetes fail to achieve adequate glycemic control.<sup>8</sup> Hyperglycemia is linked to factors causing foot ulceration (e.g., peripheral neuropathy and peripheral vascular disease) and contributes to poor wound healing, which is a major contributor to lower-extremity amputations.<sup>9,10</sup> It stands to reason that improving glycemic control could reduce the number of amputations, which could reduce the number of malpractice claims.

This article includes two case studies based on closed malpractice claims that were settled due to lack of standard of care and causation expert consultant support. The first case involves a noncompliant patient who alleged her primary care physician's (PCP) negligent treatment of diabetes resulted in her kidney failure. The second case involves a patient who entered the hospital with a diabetic foot infection who alleged his hospital team caused his amputation. The cases are meant to be considered together. The patient with uncontrolled diabetes in the first case could easily have developed a foot infection (instead of kidney failure), landing her in the hospital in a situation similar to the patient in the second case. These claims may have been avoided

by improving the patients' diabetes treatment compliance. However, diabetes treatment compliance is complicated and difficult to achieve for both the patient and healthcare team. When a patient develops a foot ulcer, timely and appropriate treatment reduces the risk of amputation. Research seems to indicate that the key to avoiding poor outcomes is teamwork among the patient's inpatient and outpatient healthcare teams and patient involvement/activation in their diabetes treatment. Strategies to improve patient involvement/activation and diabetes care teamwork are provided for consideration and implementation as a means to reduce diabetes-related injuries and the lawsuits they prompt.

As the number of patients with diabetes increases, particularly diabetic patients requiring amputation, the number of professional liability claims involving diabetes appears to be increasing.<sup>7</sup>



## **DIABETIC PATIENT ACTIVATION AND ENGAGEMENT** Improving Self-Management

Patients enter diabetes treatment with varying degrees of ability and willingness to engage in day-to-day self-management. Patient activation is defined as: "An individual's knowledge, skill and confidence for managing their health and healthcare."<sup>11</sup> Activated patients understand their role in achieving a healthcare outcome and feel capable of fulfilling their role.<sup>12</sup> The most commonly used measure of patient activation is the Patient Activation Measure<sup>®</sup> (PAM).<sup>13</sup> The PAM categorizes patients into four activation levels. Level 1 patients have low healthcare knowledge, weak goal orientation, and poor adherence. They play a passive role in their own health, believing their health is their physician's responsibility. Level 2 patients believe their healthcare management is mostly out of their control, but they can set simple goals. They are aware they could do more to improve their health. Level 3 patients are trying to achieve self-management skills. They believe they have a role on their healthcare team. Level 4 patients are focused on maintaining a healthy lifestyle and have adopted recommended behaviors to support their health. They may have trouble maintaining healthy behaviors when stressed.<sup>13</sup> Research indicates that diabetic patients with higher PAM scores had better glycemic control and were more likely to engage in self-management behaviors, such as physical activity, healthy diet, foot care, blood glucose self-monitoring, foot checks, and eye examinations.<sup>14</sup>

Measuring a diabetic patient's activation level provides a physician with a sense of how much help the patient needs to comply with treatment recommendations. Support, health information, and advice can be tailored to the patient's activation level.<sup>15</sup> Health interventions tailored to patient activation levels appear to positively impact the health outcomes and experiences of patients.<sup>15,16,17</sup> Diabetic patients who are more activated are more likely to have better outcomes<sup>14</sup> and greater satisfaction with their healthcare experience.<sup>18</sup> Satisfied patients are less likely to file malpractice lawsuits.<sup>19</sup> Research indicates that diabetic patients with higher PAM scores had better glycemic control and were more likely to engage in self-management behaviors, such as physical activity, healthy diet, foot care, blood glucose selfmonitoring, foot checks, and eye examinations.<sup>14</sup>



## **Unsuccessful Management of Diabetes in Primary Care**

In the following case, it is safe to assume that the diabetic patient was not engaged and most likely had low patient activation. For this type of patient, it is imperative to provide individualized, ongoing self-management education, including strategies for weight loss, physical activity, glycemic control, and other diabetes-related self-care. Consider which strategies could have been used to achieve a better outcome.

## **CASE ONE**

Allegation: Negligent management of diabetes resulted in renal failure.

A 47-year-old female patient who was taking insulin and metformin to control her diabetes started treatment with a family physician (FP) in 2010. Her presenting blood glucose was 220 (her target range was 70-130); therefore, the FP increased the patient's metformin and decreased the insulin dose. The physician provided the patient with home blood sugar testing supplies, referred the patient to a diabetes education program, and ordered blood tests. During the next six years, the patient presented only when she had a health complaint. In addition, the FP regularly ordered blood tests and made recommendations about diet and exercise, but the patient never followed through. The FP refilled the patient's diabetes prescriptions on a regular basis.

In 2017, the patient had her blood tested. Her blood glucose was 280 and HbA1C was 9.3 (her target range was <7). The FP did not document discussing the abnormal results and did not make any changes to the patient's medications. Over the next two years nothing changed in the way the FP managed the patient or in the way the patient managed her diabetes—she took the prescribed medication, but did nothing else.

In August 2018, the patient presented for peripheral numbness in her hands, which the FP attributed to diabetic neuropathy. He prescribed gabapentin and ordered blood tests. Her blood glucose level was 270, BUN was 33 (normal is 7-20 mg/dL) and creatinine was 2.6 (normal is 0.6 to 1.1 mg/dL for women). The FP did not document discussing the abnormal results with the patient.

In May 2019, the patient was taken to the emergency department (ED) by ambulance after she collapsed at work. The ED admitting diagnosis was chronic renal insufficiency due to diabetes, azotemia, and renal failure. The patient thereafter required dialysis and was told she would eventually need a kidney transplant. The patient sued the FP, alleging the FP's failure to monitor her kidney function was below the standard of care and resulted in kidney failure.

### DISCUSSION

Citing the longitudinal follow-up as disorganized and sporadic, experts who reviewed this case could not support the FP's prescription of diabetes medications with no baseline labs or information concerning potential adverse effects on the patient's kidney function. They also believed the medical records were not only sparse, but failed to document the FP's thought process and care planning.

In his defense, the FP testified he instructed the patient to make regular appointments and follow up on ordered blood tests, but she failed to do so. The FP also believed he would have talked to the patient about her kidney disease when her 2017 blood tests indicated it. However, the patient testified the FP never suggested a set schedule for appointments. She also denied the FP regularly ordered blood tests, and claimed she was never informed of the risks of nephrotoxicity or that she had kidney disease. Her responses to questions during deposition indicated her general ignorance about effective diabetes self-care. Unfortunately, the patient's side of the story was consistent with the FP's medical record, which did not indicate efforts to establish regular visits or increase the patient's adherence to a diabetes management regimen. Defense experts conceded the patient shared responsibility for her outcome, but her inability to be engaged in follow-up and better self-care was facilitated by the FP's minimalist approach to management.

Defense experts conceded the patient shared responsibility for her outcome, but her inability to be engaged in follow-up and better self-care was facilitated by the FP's minimalist approach to management.

Defense experts believed the defense of the case would depend heavily on how well the FP could explain the patient's history of noncompliance and his efforts at counseling the patient on diabetes management and risks of noncompliance. Having a well-documented medical record to back up the defendant physician's testimony would have strengthened his defense.



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### **RISK REDUCTION STRATEGIES**

Diabetes treatment compliance is complicated. Achievement of treatment goals can be challenging for both the patient and healthcare team. The patient must be an active participant in meeting diabetes management goals. Helping patients play an active role in their diabetes management is a key aspect of improving their engagement in treatment. But patients come to the healthcare arena with varying abilities to engage in their self-care. Clinicians must meet patients where they are. When a clinician assigns a self-care task to a patient who is unwilling/unable to accomplish it, the whole process can be frustrating and needlessly time-consuming for both patient and physician. Improving patient activation should be viewed as a journey accomplished with a multitude of small steps. The following risk reduction strategies are provided for consideration with the full acknowledgement of a clinician's difficult position when patients fail to follow recommended treatment. Although patients are expected to contribute to their own well-being by complying with healthcare team recommendations, patient noncompliance alone cannot be relied on as a complete defense to malpractice allegations. Consider the following strategies to gauge and increase activation, engagement, and compliance among diabetic patients:<sup>20,21,22</sup>

- Educate patients about diabetes, how nutrition and exercise impact the wellness of diabetics, the risks of not following recommended treatment and lifestyle changes, and other aspects of the disease and its treatment.
  - Ensure education is at an appropriate health literacy level to maximize comprehension.
- Make sure the patient understands why medication, self-care, follow-up tests, consultations, and appointments are necessary.
  - Confirm comprehension by asking patients to repeat back instructions in their own words: "We talked a lot about how to measure and record blood sugar. I want to make sure I explained this clearly. When you are at home, how will you measure and record your blood sugar?"
    - > Numerous teach-back resources are available online (e.g., the <u>Always Use Teach-Back! Toolkit</u><sup>23</sup> describes principles of plain language, teach-back, coaching, and system changes necessary to promote consistent use of teach-back and includes videos of clinicians using teach-back).
  - Document education given and patient responses regarding self-care recommendations and improvement strategies.
- Help patients identify their own concerns and challenges about treatment and self-care.
  - Use motivational interviewing techniques.
    - Various motivational interviewing resources are available online (e.g., <u>Motivational Interviewing:</u> <u>How Physicians can Reach the Most Challenging Patients<sup>24</sup> discusses how motivational interviewing can</u> improve the health of patients with complex chronic conditions).
- Provide the patient with ample opportunities to ask questions.
  - Before moving to another topic, ask the patient about other concerns and questions about the information you have just covered.
    - > Instead of asking the patient, "Do you have any questions?" try asking, "What questions do you have?"
  - ► Help patients feel comfortable about asking questions.
    - > For example, patients can be directed to the <u>Ask Me 3</u><sup>®25</sup> educational program, which encourages patients and families to ask three specific questions of their providers to better understand their health conditions and what they need to do to stay healthy.
- Align patient goals with patient activation level.
  - Quantify patient activation levels to better allocate resources and measure improvement using a tool such as the PAM.<sup>13</sup>
- Make adherence with treatment and self-care recommendations as easy as possible, particularly for patients who have low activation levels, low health literacy levels, or who struggle with compliance in other ways.
  - ► Arrange for laboratory tests onsite and on the day of the appointment whenever possible.
  - Have staff meet with less-activated patients prior to their appointment to help formulate questions for the clinician and after the appointment to discuss and review medications and other treatment recommendations.
  - When discussing self-care, demonstrate the skill (e.g., monitoring blood sugar, administering insulin, or documenting diet and exercise habits), then watch the patient perform the task to ensure comprehension.
    - > Because patients understand and learn in different ways, supplement discussions with visual aids.
  - After obtaining the patient's consent to do so, include family members—especially spouses—in discussions and education. Ensure these individuals understand firsthand the scope of the patient's condition and the importance of self-care. Patients may minimize their disease when reporting it at home to family members after the physician appointment.

- Propose self-care improvements in small steps that may be easier to accomplish—success is an important aspect of increasing activation level.
  - > For less-activated patients, start with easy behaviors or take a complex behavior and break it down into much smaller steps (e.g., if diet change is an objective, learning how to read a food label would be a small step).
- Monitor patient success with treatment and self-care recommendations.
  - If a patient's report of adherence is not resulting in improvement, try to determine whether the patient is performing the task incorrectly and provide further training as necessary.
  - Regularly revisit treatment and self-care recommendations and determine if modifications are necessary.
  - ► Help the patient explore why interventions are not working.
    - > For example, instead of asking the patient, "Are you exercising?" or "Are you watching your sugar intake?" ask open-ended questions that cannot be answered with "yes" or "no": "What have you tried for exercise?" or "What worked?" or "What didn't work?"
- Document the patient's adherence or nonadherence to recommended treatment.
  - Include in every progress note a brief statement about the patient's adherence to diet, exercise, glucose monitoring, and medication.
    - > Quantify the degree of compliance to each aspect of the patient's diabetes care regimen by using percentages or number of days per week, asking the patient to estimate these measures.
  - Include which issues were addressed; how well the patient understood his or her diagnosis and instructions for self-care, follow-up, tests, or medication regimens; and decision-making rationale.
  - Confirm and document the patient's understanding of the risks of nonadherence.
- Refer patients to specialists (e.g., diabetes educators, diabetes programs, health coaches, nutritionists/dieticians) to enhance treatment.

### ADDITIONAL RESOURCES

### National Institute of Diabetes and Digestive and Kidney Diseases: <u>Guiding Principles for the Care of People with or at</u> <u>Risk for Diabetes</u><sup>22</sup>

Identification and synthesis of areas of general agreement among existing guidelines to help guide primary care professionals and healthcare teams in delivering quality care to adults with or at risk for diabetes, see particularly PRINCIPLE 4: Provide Ongoing Self-Management Education and Support for People with Diabetes (p. 27) and PRINCIPLE 5: Encourage Lifestyle Modification for People with Diabetes (p. 31)

### American Association of Clinical Endocrinologists (AACE): <u>Comprehensive Type 2 Diabetes Management</u> <u>Algorithm (2020)</u><sup>26</sup>

Algorithm supplementing the AACE and American College of Endocrinology (ACE) 2015 Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan organized into discrete sections that address the following topics: the founding principles of the algorithm, lifestyle therapy, obesity, prediabetes, management of hypertension and dyslipidemia, and glucose control with noninsulin antihyperglycemic agents and insulin

### American Diabetes Association (ADA): 2022 Standards of Medical Care in Diabetes<sup>27</sup>

ADA's current clinical practice recommendations for various audiences and various aspects of diabetes prevention and management

### Insignia Health: Patient Activation Measure (PAM)<sup>13</sup>

Licensed product that assesses activation for an individual or collectively for a population, see alternatively <u>Health Confidence<sup>28</sup> and Stanford Self-Efficacy for Managing Diabetes scale</u>,<sup>29</sup> which measure similar concepts and are available to use without a license or fee



## **DIABETIC FOOT ULCER** Increasing Vigilance

Diabetic foot ulcer (DFU) is the most common complication of diabetes, and studies indicate that adequate attention is not being given to the feet of diabetics in the primary care setting.<sup>30</sup> Since sensory loss due to neuropathy may mask the early signs of infection, skin breakdown, and ulcer formation, clinicians should not rely on their diabetic patients to prompt foot care services. Instead, clinicians should routinely examine the feet of diabetic patients and increase vigilance for DFU in diabetic patients with the following additional risk factors:<sup>31</sup>

- Poor glycemic control
- Poor nutrition
- Peripheral neuropathy with loss of protective sensation
- Cigarette smoking
- Foot deformities
- Pre-ulcerative callus or corn
- Peripheral artery disease
- History of foot ulcer
- Amputation
- Visual impairment
- Chronic kidney disease (especially patients on dialysis)



Prevention is optimal, but proper management can reduce the severity of DFU complications,<sup>32</sup> which can in turn reduce liability risk. Failure to provide DFU treatment, inappropriate treatment, and failure to refer or delay in referring to the correct specialist can support a negligence claim. Anyone on the patient's healthcare team (and their employers) who should have recognized and addressed a DFU can become a defendant in these claims.

### **RISK REDUCTION STRATEGIES**

Consider the following strategies:<sup>30,32,33</sup>

- Understand the etiopathogenesis of DFU.
- Flag diabetic patients' medical records in an obvious way so that foot care is less likely to be overlooked.
- Evaluate patient risk factors on a regular basis.
- Carefully inspect diabetic patients' feet at every visit.
- Integrate foot care education into diabetic self-care education, for example:
  - Ensure patients are aware of risk factors and the importance of foot care, including the need for self-inspection, foot temperature monitoring, appropriate daily foot hygiene, and proper footwear.
  - Explain how inadequate blood sugar control can increase the frequency and morbidity of limbthreatening complications.
  - Document the patient's response and understanding.

- Improve the patient's nutritional status.
  - > Promote sustained healthy eating habits and explain how nutrition affects healing.
  - ► Refer the patient to a dietician or nutritionist.
- Keep up to date on advancements in wound treatment and dressings.
- Know when to refer the patient for wound treatment.
- Thoroughly document assessments, patient education, and interventions in the medical record.

### ADDITIONAL RESOURCES

ADA: Retinopathy, Neuropathy, and Foot Care: Standards of Medical Care in Diabetes-2022<sup>33</sup>

Current clinical practice recommendations

ADA: Diagnosis and Management of Diabetic Foot Complications<sup>34</sup>

Causes and management of diabetic foot ulceration, pathways, contributory risk factors, strategies for screening, wound classification, referral, and treatment approaches

Miller, JD et al.: How to Do a 3-Minute Diabetic Foot Exam<sup>30</sup>

Description, support, and instructions for a brief exam designed to detect major risks

National Institute for Health and Care Excellence: Diabetic Foot Problems: Prevention and Management<sup>31</sup>

A guideline for preventing and managing foot problems

American Limb Preservation Society: Nutrition Interventions in Adults with Diabetic Foot Ulcers<sup>35</sup>

Guidelines designed to assist clinicians in accomplishing improved outpatient nutrition to support the healing of DFU wounds



## **INPATIENT DIABETIC FOOT TEAMS** Using a Multidisciplinary Approach

Diabetic foot is defined as "infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or peripheral artery disease in the lower extremity."<sup>36</sup> The diagnosis and treatment of diabetic foot may require the involvement of multiple specialists, including endocrinology, vascular surgery, orthopedics, podiatry, infectious disease, and general surgery.<sup>36</sup> Based on the results of multiple studies of a multidisciplinary team approach to diabetic foot, common elements of successful teams include:<sup>37</sup>

- Medical and surgical specialists who can address four key tasks: glycemic control; wound management, including surgical debridement and minor amputation; vascular disease diagnosis and management, including revascularization; and infection diagnosis and management
- A team leader

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- Clear referral pathways and care algorithms
- Working conditions that support consistent, collaborative, and rapid team-based care

A multidisciplinary team approach to diabetic foot can significantly reduce the rate of amputation,<sup>36</sup> which could reduce liability risk.



## Inadequate Inpatient Teamwork/Hand-offs During the Care of a Diabetic Patient with Foot Infection

In the following case a consultant observed, "there is no question that 'the ball was dropped," and asked, "but by whom?" Each physician defendant, while acknowledging that diabetic foot issues were best managed by a team, also testified that their role and responsibility for the plaintiff patient was limited—including the vascular surgeon, whom everyone else assumed was leading the team. Consequently, when the patient required debridement, and later amputation (according to experts during litigation), each team member assumed someone else was responsible. The composition of diabetic foot team members varies depending on region. In some places in the U.S., podiatrists and vascular surgeons are very involved in the care of diabetic foot ulcers, while in other regions, they are not. Risk reduction strategies should be adjusted accordingly.



## **CASE TWO**

**Allegation:** Delayed diagnosis and treatment of the patient's toe infection led to above-the-knee amputation.

### MONDAY

A 60-year-old patient presented to the ED. Her left foot was swollen and painful. She had an open wound on her left first toe, and two blood-filled blisters on her instep. She told the ED physician that a new pair of shoes had given her a blister on her toe a few weeks earlier. The blister had turned into a sore that kept getting worse. She could not explain the blisters on her instep. They had simply appeared. Her medical history was significant for poorly controlled diabetes, coronary artery disease, high cholesterol, high blood pressure, quadruple bypass surgery, and smoking. She was admitted by a hospitalist, whose impression was left foot cellulitis, diabetes mellitus, uncontrolled atrial fibrillation, diabetic neuropathy, and chronic kidney disease. He ordered an infectious disease (ID) consultation and IV antibiotics.

The ID specialist's impression was diabetic foot, left first toe cellulitis, and instep blisters with inflammation. He ordered a bone scan, changed the antibiotics, and requested a vascular surgery consult to advise on whether the patient's vascular condition might inhibit her ability to heal. The vascular surgeon described the patient's foot in a similar manner to the ID specialist. He ordered duplex ultrasound of the lower extremities and CT angiography of the chest, abdomen, and pelvis to evaluate for plaque. A nurse noted the first toe was very edematous, dusky, seeping bloody discharge, and necrotic. The medial aspect of the foot was described as discolored blotchy red and purplish, and edematous. Redness extended up to the calf. The bone scan showed no evidence of osteomyelitis.

### TUESDAY

A nurse noted that the skin was cracked between the patient's toes. The left first toe was dark bluish black. The first toe and cracks between the toes had slightly odorous serosanguineous drainage. The ID specialist recommended long-term antibiotics and close observation.

### WEDNESDAY

The vascular surgeon noted the studies he ordered showed no evidence of aneurysm. The ankle brachial indices were normal but relatively decreased on the left compared to the right. The arterial duplex showed possible greater than 50% stenosis in the distal left posterior tibial artery. He concluded the patient could heal completely with the antibiotics, but toe amputation was also possible if her condition worsened, or the toe became gangrenous. Later that day, the hospitalist noted that the toe was gangrenous, and that prognosis of the toe was very poor. The ID specialist noted the antibiotics were appropriate.

The vascular surgeon, who was leaving for a vacation, "signed out" to his partner, who was covering him for the next two days. There was no communication between the two physicians about the patient.

### THURSDAY

A wound culture that was taken on Day 1 grew out MRSA, enterococcus faecalis, and numerous diphtheroids.

### FRIDAY

The ID specialist noted the left foot was significantly inflamed, there was necrotic tissue, and a foul smell secondary to anaerobic bacteria. He believed a vascular surgeon should see the patient, although he did not directly contact anyone on the vascular surgery team.

### SATURDAY

A nurse noted the whole foot was blackened and swollen with large amounts of foul-smelling serosanguinous drainage and blood blisters with sloughing on the dorsal area of the foot. When the second vascular surgeon examined the patient, he immediately contacted a podiatrist at an affiliated hospital to get the patient transferred for probable amputation. At the second hospital, efforts were made to save the patient's foot and lower leg, but she ultimately underwent an above-the-knee amputation. She sued everyone on her healthcare team at the first hospital.

DAY

day 4

day 5

DAY

DAY

### DISCUSSION

Clinician notes describing the appearance of the patient's foot were limited. Any void left in the progress notes, however, was filled by photographs of the patient's foot taken by the patient and her family members throughout her hospitalization. The photographs, which showed in gruesome detail a progression from a collection of foot sores to a totally involved foot, to a stump, would make it more difficult to explain treatment delays, should the matter ever be presented to a jury.

The vascular surgeons, hospitalist, and ID specialist all testified that diabetic foot infection was ideally handled by a team, which included members of their own specialty. Although they included a podiatrist in descriptions of an ideal team, there were no podiatrists treating the plaintiff at the hospital. The physicians could not clearly describe how a diabetic foot infection team would function. The concept of such a team was not supported by policies or protocols at the hospital. The defendant clinicians on the ostensible team never met as a group and did not communicate other than by completing and reading each other's progress notes. Each member of the team assumed someone other than himself was responsible for the overall management of the patient's foot infection, debridement, and amputation decisions.

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### DEFENDANT VASCULAR SURGEON

The vascular surgeon described his role as making sure the blood supply to the foot was adequate. He determined the patient did not have a vascular blood supply problem, but rather, she had an infection. He considered his role on the patient's care team at the hospital as very circumscribed. For example, he would not drain an infected toe, debride devitalized tissue, or do foot surgery—that would be done by a podiatrist or general surgeon. However, if a patient required an above-/below-the-knee amputation, he would do it. He admitted that he did debridements, foot surgeries, and foot and toe amputations in diabetic foot cases at the other hospital where he had privileges. In other words, it was not unusual for a vascular surgeon to do these procedures. Although there were no written protocols or policies regarding his role in diabetic foot ulcer cases at this hospital, he had determined that these procedures were not his responsibility, and further believed someone else would engage a general surgeon or podiatrist to undertake these procedures.

In addition to teamwork problems, the vascular surgeons failed to communicate with each other during the hand-off on Wednesday, which essentially consisted of the second vascular surgeon receiving an email with a list of patients he was expected to manage. Defense of this case was particularly complicated by the absence of any vascular surgery consultations on Thursday and Friday. In the opinion of the first vascular surgeon, someone from the hospital should have contacted the covering vascular surgeon if they wanted him to see the patient. However, he also admitted that it was the responsibility of the vascular surgery service to independently follow up with the patient if they believed she needed to be seen. The oncoming vascular surgeon could not be certain why he did not see the patient for two days, but when he rounded on her that Saturday, he was shocked at the state of the patient's foot, and immediately arranged for surgery with a podiatrist at an affiliated facility.

### **DEFENDANT ID SPECIALIST**

In the ID specialist's opinion, his role was to treat the patient's infection, which consisted of starting/changing antibiotics, checking for osteomyelitis, and ordering wound cultures. He was focused on whether the antibiotics were appropriate. He did not do debridements. He believed the vascular surgeon was responsible for debridements and amputations. In his Friday progress note he recommended a vascular surgery consultation because he believed the patient's condition was worsening and, without surgical intervention, the necrosis would continue. He believed antibiotic therapy alone was not sufficient at that point. It was not his normal practice to contact other members of the care team outside of making observations in the progress notes. He did not notice that no one from the vascular surgery team had seen the patient on Thursday or Friday.

### **DEFENDANT HOSPITALIST**

The hospitalist described himself as the attending physician for the patient. As the attending, he believed he was responsible for arranging consultations with specialists to address the foot infection, while he managed the patient's underlying comorbidities. His understanding was that the ID specialist would manage the foot infection with antibiotic coverage. The vascular surgeon would be responsible for any decisions about revascularization and any other vascular issues. The hospitalist did not make decisions about or perform debridements or amputations, which he considered the responsibility of the ID specialist and vascular surgeon. He also expected someone from the vascular surgery group to contact him if a vascular surgeon was unable to follow the patient once the service had been brought on to consult. It was not his practice to check patient records to confirm that physicians who had been called in to consult were following up on patients. According to an endocrinology expert, the defendant physicians should have been more vigilant because infections can spread quickly in a diabetic, and they must be treated early and fast.

### **EXPERT OPINIONS**

If the defendant vascular surgeon was not going to fulfill the role of the patient's "foot doctor," a vascular surgery expert questioned why the vascular surgeon did not request a podiatry consult. He acknowledged that there is a gray area as to the role of a vascular surgeon on a diabetic foot team, but opined it is appropriate for a vascular surgeon to determine when amputation is appropriate, and to perform necessary amputations. Further, the expert believed the vascular surgeon allowed himself to be viewed as the "foot doctor" by the other team members, and the other physicians appeared to be looking to the vascular surgeon for surgical management of the foot in addition to vascular issues. Judging from the photographs, the expert believed the defendant vascular surgeon should have taken the patient to surgery by Wednesday and, in the least, he should have advised the oncoming vascular surgeon on Wednesday that the patient required surgical intervention as soon as possible.

According to an endocrinology expert, the defendant physicians should have been more vigilant because infections can spread quickly in a diabetic, and they must be treated early and fast. In this case, it appeared to the expert that the patient's infection spread much faster than the defendants anticipated. The ID expert believed it was reasonable to start treating the infection with antibiotics, but when the patient didn't respond by Friday, the team needed to be proactive, and the standard of care required surgery.

Nursing experts believed the nurses had a duty to escalate concerns until the patient received surgical interventions.



### **RISK REDUCTION STRATEGIES**

When a diabetic foot infection patient needs incision and debridement, a system should be in place to make it happen without confusion or delay. Studies indicate that interprofessional diabetic foot care teams can reduce the frequency of amputations.<sup>38</sup> Teams require an infrastructure that supports teamwork and communication, diabetic foot care tools, policies, and protocols. Care from specialists cannot be delivered in silos. Roles should be clarified, and responsibilities assigned in a predictable manner supported by policies and protocols. The success of an inpatient diabetic foot team program depends on physician engagement and compliance. When team members are passive and assume other members of the team will take responsibility for tasks, delayed diagnosis and treatment can occur. An important aspect of teamwork is hand-off. Ideally, all important patient information is consistently passed from one member of the team to another during hand-off, creating a state where each member of the team knows as much about the patient as the person who came before.

### **Operations**

Consider the following strategies: 15,16,39,40,41,42

- Create a care pathway for patients admitted with diabetic foot problems or at risk for developing them, including specifics for patients requiring urgent or emergent treatment of diabetic foot infections.
- Describe diabetic foot team member responsibilities in protocols.
  - Ensure team members have a shared mental model of the breadth and duration of responsibility for the patient's care, including when and how a team member's responsibility for a particular aspect of care concludes.
  - ► Designate the specialist who will be team leader.
- Allocate roles consistent with physician team member specialty.
  - Ensure coverage of glycemic control; wound management, including surgical debridement and minor amputation; vascular disease diagnosis and management, including revascularization; and infection diagnosis and management.
- Set forth expectations for routine communication between team members (e.g., briefs, huddles, and debriefs), including timing, method, and location.
  - Determine reliable methods for team member communication among themselves and expected response times.
- To reduce ambiguity in describing the foot ulcers, infections, and threatened limbs among team members, designate tools to stage/grade/describe them, for example: <u>University of Texas Diabetic Foot Ulcer</u> <u>Classification System</u>,<sup>43</sup> <u>International Working Group on the Diabetic Foot Classification System for Defining the</u> <u>Presence and Severity of an Infection of the Foot in a Person with Diabetes</u>,<sup>44</sup>or <u>Society for Vascular Surgery</u> <u>Lower Extremity Threatened Limb Classification System</u>.<sup>45</sup>
- Prioritize successful hand-offs and make them a performance expectation.
  - ► Define and provide examples of what constitutes a successful hand-off, both internally and if an external transfer is required (see, for example, <u>TeamSTEPPS</u>®46 for guidance on developing hand-off tools to meet the needs of unique teams).
- Create a process for conflict resolution, addressing both conflicts within the diabetic foot care team program as a whole and conflicts that occur during a patient's hospitalization (for conflict resolution tool examples, see TeamSTEPPS).<sup>46</sup>
- Establish methods for ensuring that tasks are accomplished.
- Evaluate diabetic foot team performance and adjust policies and protocols as necessary.
- Develop training methodologies and expectations for communicating diabetic foot team policies and protocols to physicians and staff.
- Provide teamwork training (see <u>TeamSTEPPS</u><sup>46</sup> for examples of training tools).

### Clinicians

Consider the following strategies:<sup>39,41,42,47,48</sup>

- Follow the roles set forth in diabetic foot policies and procedures (e.g., if the protocol calls for the vascular surgeon on the team to do debridements, the vascular surgeon should take on that role, unless doing so compromises patient safety).
  - Do not assume another team member is taking responsibility for a task unless it has been spelled out in policy/protocol or discussed and documented (e.g., if the protocol calls for the vascular surgeon to do debridements, the vascular surgeon should not assume that the task will be undertaken by the ID specialist).
  - Do not pressure the other team members to undertake tasks outside of roles established in the policy and protocols.
  - ► Maintain a collegial, rather than a confrontational, tone.

- If there are no diabetic foot team policies and protocols, initiate and encourage a team approach.
  - When asked to consult, confirm with the physician requesting the consult which issues you are expected to manage.
  - Communicate the treatment plan among individuals addressing the patient's foot issues (e.g., vascular surgeon, podiatrist, ID specialist, hospitalist, etc.).
- Consistently use predetermined wound/disease classification tools to stage/grade wounds and compromised feet and limbs that allow everyone on the team to track progress in the same manner and identify patients who require interventions.
- Be familiar with the treatment venue's hand-off protocols and actively engage in the hand-off process, keeping in mind that other units and facilities may have different protocols.
- Before handing off a patient, critically assess the record.
  - Check the nursing documentation, and talk to the patient's nurse, to ensure you report an accurate patient status to the oncoming physician.
- During hand-off, communicate a succinct overview of the patient's diabetic foot course while he or she was in your care. Because infections spread quickly in diabetics, this will likely require a recent personal assessment.
  - Have laboratory and imaging studies and the patient's progress notes available for review with the person receiving the patient.
  - ► Highlight pending studies and consultations.
    - > Obtain agreement as to who will be responsible for following up on test results.
    - > Anticipate results and present contingency plans if the results are not as expected.
  - Draw attention to and have plans for patients with potential management issues that could arise shortly after hand-off (e.g., if foot amputations are done at a different hospital, and the need for amputation is likely, confirm the physician responsible for ordering the transfer is aware and available, and discuss the treatment plan with that physician).
  - ► Use a checklist for standardization.
- If a hand-off discussion with the receiving clinician member is not possible, supplement the hand-off documentation in the medical record to the degree necessary to highlight important issues. Confirm receipt of the information by the receiving provider and willingness to assume the care of the patient.
- If you are not provided with adequate hand-off information, either in a written report or in person, pursue complete information from the sender.
- Independently review the patient's records after the patient has been handed off to you.
- Document hand-off discussion in the record.

### ADDITIONAL RESOURCES

**Wukich DK, et al.:** <u>Inpatient Management of Diabetic Foot Disorders: A Clinical Guide</u><sup>39</sup> Describes the development of effective, systematic, interdisciplinary teams

**National Institute for Health and Care Excellence:** <u>Diabetic Foot Problems: Prevention and Management</u><sup>31</sup> Guidelines for the prevention and management of foot problems in diabetics, including the first 24 hours of inpatient treatment

### Agency for Healthcare Research and Quality (AHRQ): Team STEPPS<sup>46</sup>

Teamwork tools, aimed at optimizing patient outcomes by improving communication and teamwork skills among healthcare professionals

### NORCAL Group: Don't Fumble the Hand-off<sup>49</sup>

CME activity available to NORCAL Group insureds providing patient safety and risk reduction strategies for inpatient hand-offs

### **Diabetes:** Risk Reduction Across the Continuum of Care

## CONCLUSION

Diabetes risk management happens on a continuum. In meeting diabetes management goals, the patient must be an active participant. Helping patients play an active role in their diabetes management is a key aspect of improving their engagement in treatment, but patients have varying abilities to engage in their self-care. When a clinician assigns a self-care task to a patient who is unwilling/unable to accomplish it, the whole process can be frustrating and time-consuming for both patient and clinician. Sometimes, clinicians will have to adjust expectations and engagement strategies to help patients participate in their diabetes care. Patients, whose own failures to follow treatment recommendations contribute to their injury, can and do file malpractice lawsuits against their treating physicians. Documentation showing a treating physician managed the patient's noncompliance in a manner that met the standard of care (e.g., patient education, involvement/activation, and follow-up) can significantly aid the defense in those cases.

The key is improving diabetes treatment compliance. If that fails, quickly and appropriately treating the infections is the next best risk reduction solution. A multidisciplinary team approach to diabetic foot infections can significantly reduce the rate of amputation.<sup>36</sup> An important aspect of teamwork is hand-off, which ideally can ensure that each member of the team knows as much about the patient as the person who came before. Effective teamwork requires organization, training, and commitment to the team goals by its members. When team members are passive or organization and training is lacking, delayed diagnosis and treatment can occur, which can increase patient injury and liability risk.

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## **ENDNOTES**

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