clinical
series

a risk management distance learning cme course

Diabetes: Managing Comorbidities

clinical & risk management perspectives

NORCAL Mutual Insurance Company

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Introduction

Needs Assessment

Activity needs were assessed from the following sources:

- Statistics from the Centers for Disease Control and Prevention (CDC)
- American Diabetes Association (ADA) Standards for Medical Care of Diabetes (2006)
- NORCAL claims data and experience

Why a Risk Management CME Course on Management of Type 2 Diabetes?†

Diabetes is a major public health concern. According to the CDC, 20.8 million people—7 percent of the population—have diabetes. Type 2 diabetes accounts for 90-95 percent of these cases. Diabetes was the sixth-leading cause of death listed on US death certificates in 2002, and overall the risk of death among people with diabetes is about twice that of people without diabetes of similar age.[1]

The ADA published new clinical practice recommendations in 2006.[2] Among the additions to the standards of medical care in diabetes were:

- Medical nutrition therapy
- Diabetes self-management education (DSME)
- Physical activity
- Neuropathy screening and treatment

Among the revisions to the standards were:

- Assessment of glycemic control
- Glycemic goals
- Nephropathy screening and treatment

Finally, while the management of gestational diabetes mellitus has been a known professional liability issue, the management of type 2 diabetes is an emerging issue. In 2002, the Physician Insurers Association of America presented a program about claims and risk management aspects of diabetes. Medical misadventures that were reported as being associated with diabetes included:[3]

- Failure to diagnose diabetes mellitus
- Improper performance (e.g., treatment errors in basic diabetic care)
- Failure to monitor
- Failure to communicate

Claims Against Primary Care Physicians Indicate Need for Improvement in Diabetes Management

Primary care physicians not only treat diabetic patients, but they also coordinate the care those patients receive from specialists. Diabetes management has surfaced as a professional liability issue for family practice, general practice and internal medicine physicians. A NORCAL-

† There is some controversy over the terms type 1 and type 2 diabetes. Some authors prefer the terms insulin-dependent diabetes mellitus (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM), simply because many patients with type 2 or NIDDM will eventually require some form of insulin therapy at some point in the duration of their disease. However, the material published by the American Diabetes Association uses type 1 and type 2, and NORCAL has chosen to use these terms in this monograph.

specific report for the period of 1985-2003 revealed that claims against these specialties that are related to *diagnosis errors* in diabetes mellitus accounted for $375,874 in indemnity paid. Among claims related to *failure/delay in hospital admission* for diabetes mellitus, $460,000 in indemnity was paid on behalf of these specialties. Among claims related to *failure to supervise or monitor* a diabetes case, $191,000 in indemnity was paid on behalf of these specialties. Adding indemnity paid for *medication errors* related to diabetes mellitus ($50,999) and indemnity paid for other categories of diabetic disease (e.g., diabetes with neurological manifestations or other complications), brought the total indemnity paid on behalf of these specialties for diabetes cases to $1.46 million.

How Was This Course Developed?

All of NORCAL's CME courses are rooted in an analysis of NORCAL and industry-wide claims experience. When we develop a course, we examine claims data and analyze the financial loss by condition/procedure and outcome. Then we look at closed cases in which there was a significant dollar loss. These cases are used to write clinical vignettes which explore the outcome from both clinical and risk management perspectives. The objectives are the same for each case study:

1. Identify instances during a patient's treatment that compromise a good outcome.
2. Suggest methods and strategies that may have improved the outcome of the case.
3. Prevent similar outcomes from occurring in the future.

Because negligent management of diabetes and its comorbidities can result in such serious consequences, it is important to examine the causes from both clinical and risk management points of view. While it is neither our intention nor our scope of practice to set the standard of care, this course does contain summarized national practice guidelines and specific risk management recommendations. In NORCAL's extensive claims experience, these are the areas in which physicians continue to leave themselves vulnerable to allegations of malpractice.

What Forms the Basis for the Standard of Care?

In order for a physician to be sued and found liable for a diabetes-related claim, four elements must be established: duty, negligence, damages and causation. First, there must be an established doctor-patient relationship that creates a **duty** to care for the patient. If the physician's involvement in the patient's diagnosis and/or treatment is not consistent with the standard of care in the community where he or she practices, that care is deemed **negligent**.

Finally, the patient must have sustained verifiable **damages** that were caused by the physician's **negligence**.

Whether or not the standard of care was met is determined through the testimony of medical experts. Clinical practice guidelines are playing an increasing role in expert assessment of physician negligence, especially since their publication on the Internet makes them widely available regardless of the physician's location. These guidelines are produced by panels of specialists in the medical field after an exhaustive review of the latest research.

The acknowledged primary sources of clinical information about the management of diabetes mellitus include the American Diabetes Association (ADA), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP) and the American Association of Clinical Endocrinologists (AACE). The guidelines set by these organizations are based on evidence gleaned from clinical experience and published, peer-reviewed articles. These evidence-based guidelines (particularly those of the ADA) and NORCAL's decades of claims and risk management experience form the backbone of the recommendations made in this course.

How Is the Course Organized?

This course contains three closed cases that illustrate adverse outcomes related to negligent diabetes management. Each case comprises

the following:

- **Learning objectives**
- **A chronological narrative** that outlines the patient's care
- **A case analysis** that explores errors made on the part of the physician and lessons that can be learned from those mistakes

In addition to the closed cases, there is a general discussion of diabetes management as it relates to professional liability risk.

CME Information

Sponsored by NORCAL Mutual Insurance Company
Original release date: November 2006
Expiration date: November 2009
Estimated time to complete this activity: 2 hours
This enduring material is a monograph.
The method of physician participation in this activity is to read the monograph and complete the Evaluation and CME Attestation Form.

Learning Objectives

- With the goal of increasing patient compliance and reducing the public health burden of diabetes, improve your ability to communicate about the seriousness of this disease, using patient medical records as documentation of your efforts.
- Given the numerous complications and comorbidities associated with diabetic patients, implement a diabetes management protocol and tracking system that is based on evidence-based clinical practice recommendations.
- To reduce professional liability associated with diabetes management, evaluate your communication, follow-up and documentation practices and implement the 11 risk management-based strategies listed on pages 18-19 of this course.

Target Audience

The target audience for this activity is general/family practice physicians, internal medicine physicians, other physicians who practice primary care and allied healthcare practitioners.

Credit Designation Statement

NORCAL Mutual Insurance Company designates this educational activity for a maximum of *2 AMA PRA Category 1 Credits™*. Each physician should only claim credit commensurate with the extent of their participation in the activity.

ACCME Accreditation Statement

NORCAL Mutual Insurance Company is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Instructions for Completing the Course and Receiving CME Credit

After reading through the closed cases and discussion, complete the CME Evaluation and Attestation Form.

Important: You must attest to the number of hours you spent in this educational activity on the form. CME certificates will be issued approximately seven to ten business days after the form has been received.

Mail your CME Evaluation and Attestation Form to:

NORCAL Mutual Insurance Company
Attn: Risk Management
560 Davis Street, Suite 200
San Francisco, CA 94111

Expert Reviewer

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Disclosures

There are no commercial supporters for this activity. The sponsor, expert reviewer, planners and authors have nothing to disclose. This activity does not include a discussion of unapproved drugs or devices.

Disclaimer

The information in this course has been obtained from sources generally considered to be reliable; however, accuracy and completeness are not guaranteed. The information is intended as risk management advice. It does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about topics covered in this course should be directed to your attorney.

Guidelines presented should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of the individual circumstances presented by the patient.

Case One

Learning Objectives

After reading this case and associated discussion, consider implementing the following risk reduction measures:

- Develop and implement a diabetes education toolkit and/or have educational resources readily available for the patient (e.g., hospital or certified diabetes educator). The American Diabetes Association provides free patient education resources to healthcare providers.
- Reinforce the patient's knowledge about his or her disease and care regimen on a regular basis.
- Utilize a "master problem list" in patient charts to track ongoing diagnoses, test results, specialty referrals, complications and comorbidities, and to facilitate communication between multiple providers.

Allegation: Failure to inform patient of diagnosis of diabetes resulting in delayed treatment and peripheral neuropathy in a 40-year-old.

A then 38-year-old hardware store employee presented to his family practice physician (Physician #1) after he had been rejected for a life insurance policy when lab work indicated that he had elevated blood sugars. The physician documented that he discussed the diagnosis of diabetes with the patient, gave him advice regarding diet and weight loss, and advised the patient to return in two months for a follow-up on his blood sugar and reevaluation.

The patient failed to return to this physician's care but his next contact with this clinic was 10 months later when he spoke to a physician (Physician #2) by telephone concerning an injury to his foot. Physician #2 made a chart note approximately one inch below Physician #1's diagnosis of diabetes, but she did not take any steps to follow-up with the evaluation or treatment of his diabetes during this phone call or afterward.

The patient's next visit to this clinic occurred six months after the telephone contact, now 16 months from the first physician's diagnosis of diabetes. At this time the patient was seen by a nurse practitioner who treated him for an infection under his right fingernail. The patient had lost 20 pounds since the previous visit, but was not asked whether this was intentional or not. The nurse practitioner did not review prior chart entries or make any inquiries with regards to the patient's diabetes at this visit.

One year later, the patient was seen by the nurse practitioner again. The patient had lost over 12 pounds since the prior visit—32 pounds since the diagnosis—but, again, there was no inquiry regarding the weight loss. During this visit he

complained of a painful lump around his nipple and was prescribed antibiotics. The nurse practitioner called the patient a few days later for follow up. Over the telephone the patient indicated that the lump was improved.

The patient was seen by another physician (Physician #3) and the nurse practitioner on two other occasions, both for sinus and throat symptoms. On both occasions the diabetes diagnosis was not followed up.

Five years after the original diabetes diagnosis, the patient presented to a fourth physician (Physician #4) in the medical group. The patient reported that he had lost a total of 40 pounds on a diet, but had complaints of fatigue, back pain and poor sleep. During this visit the patient also complained of erectile dysfunction of three weeks as well as some queasiness after a recent platelet donation, and he questioned whether he might have a thyroid problem.

A screening urinalysis revealed 2+ glucosuria and Physician #4 ordered additional lab work which revealed a blood sugar of 459mg/dL. (Normal range is 54-110mg/dL.) Physician #4 documented a diagnosis of diabetes and started the patient on glipizide (5mg daily) and arranged to see the patient one week later. At the follow-up visit, the patient's blood sugar was still elevated (322mg/dL). Physician #4 doubled the patient's glipizide dose to 5mg twice daily and subsequently referred him to a local diabetes clinic for closer monitoring and medication adjustment.

The patient did not return to the clinic thereafter and one year later made the allegation that the peripheral neuropathy in his lower extremities and sexual dysfunction were due the medical clinic's failure to diagnose and treat the patient's diabetes for a period of five years. The case went to trial and was won on behalf of the plaintiff. A substantial sum was spent in indemnity and defense.

Case Analysis

Expert reviewers criticized the care provided to this patient by the first three physicians, the nurse practitioner and the practice in general.

Physician #1

Diabetes mellitus is a chronic disease that involves multiple systemic manifestations involving multiple organ systems. Thus, any symptom of a patient with diabetes could potentially be related to low blood sugar, high blood sugar and/or a propensity for infection or one of many diabetic complications, such as eye disease, kidney disease, vascular disease or neuropathy. In order for a practitioner to be able to make an accurate diagnosis, it is imperative that the practitioner is aware a patient has been diagnosed with diabetes. It was generally believed by reviewers of this case that the first physician did not clearly advise the patient that his condition was serious and could result in complications, required very close follow up, and that the patient needed to be involved with self-management and inform other medical providers of his diabetes.

Furthermore, this physician did not monitor or ensure the patient followed up in two months. The most significant problem had to do with the medical practice's lack of an effective follow-up system and provider-provider communication tool (see analysis below). Nevertheless, in the absence of an effective system-wide follow-up system, the burden of follow up falls on the individual physician.

Physician #2

The second physician only had contact with this patient one time (over the telephone) but was implicated in the lawsuit because she did not review the prior entry made by Physician #1 and, as a result, did not follow up whatsoever on the diagnosis.

The Nurse Practitioner

At deposition, the nurse practitioner stated that it was not her habit to review the prior chart entries before seeing a patient. This practice was highly criticized by the plaintiff's attorneys and expert

reviewers alike. Especially in a multi-practitioner group, there is no situation in which a practitioner would not want to briefly scan the chart to see what other medical interactions had occurred, including laboratory data.

Had the nurse practitioner made even a cursory check of the patient's medical record, she would likely have found the laboratory results and perhaps arrived at the conclusion that the patient's boil or furuncle was related to his diabetes mellitus. The nurse practitioner's lack of inquiry regarding the patient's weight loss was also deemed negligent.

Physician #3

The third physician was criticized for the same breach as the other two physicians and the nurse practitioner: failure to review the medical chart or laboratory tests which indicated the patient had diabetes.

The Medical Group

Many of the problems in this case stemmed from the fact that the clinic had no "master problem list" where active, ongoing or past diagnoses were listed. A master problem list, along with an updated medication list, allergy list and healthcare maintenance flowsheet would have facilitated communication among the multiple healthcare providers involved in this patient's care, and would certainly have allowed each of them to see that the patient had diabetes and act accordingly.

Furthermore, the practice didn't have any follow-up system to speak of. After his diagnosis, this patient was asked to return in two months for reevaluation, but he did not return and there was no documentation or other indication that the medical practitioners or other staff made any effort to follow up with him. On case review it was unclear whether the patient made an appointment which he later canceled, or failed entirely to make an appointment to follow up on his diagnosis of diabetes. In either scenario, the lack of a system to follow up with this patient who had a serious condition contributed to a delay in treatment.

Finally, with regard to the nurse practitioner, there was clearly a problem of supervision. Proper supervision would have revealed her general practice of not reviewing the patient's prior medical history and would have allowed for the appropriate educational intervention.

Case Two

Learning Objectives

After reading this case and associated discussion, consider implementing the following risk reduction measures:

- Adhere to the ADA Standards of Medical Care in Diabetes.
- When necessary, do not hesitate to refer to specialists. Appropriately document your referrals, including the tracking of tests results, in patient medical records.
- Document conversations contemporaneously with patient encounters, including advice given, treatment proposed and your decision-making rationale.
- Never alter records.

Allegation: Failure to properly manage and treat diabetes resulting in kidney failure secondary to uncontrolled diabetes in a 38-year-old male.

Starting in his twenties and over the period of nearly 14 years, an obese insulin-dependent diabetic was treated by an internist. The patient had a family history of diabetes (both his mother and father), with his father having died of complications from diabetes.

The patient was noted to be poorly compliant and over the years developed complications related to his uncontrolled diabetes. He was hospitalized five times during the first seven years of his diagnosis, each time followed by the same internist whom he saw during office visits. On the last of these hospital stays the patient was admitted because of a large groin abscess with fever and uncontrolled diabetes. On admission the patient's complete blood count (CBC) showed a white blood count (WBC) of 18,500/uL [normal: 4.8-10.8 x 10(3)] and hematocrit (Hct) of 37 percent (normal: 42-54 percent). The patient had a glucose level of 342mg/dL (normal: 65-110 mg/dL), blood urea nitrogen (BUN) of 14mg/dL (normal: 7-21mg/dL) and a serum creatinine level of 0.9mg/dL (normal: 0.7-1.5mg/dL). Urinalysis showed 1+ protein. This was the first time that protein was present in the patient's urine. The abscess was drained in the hospital and the patient's blood sugar normalized. He was released two weeks after admission.

Over the next three years the patient's glucose, creatinine and blood sugar levels varied between the normal ranges. At the end of this period, now 10 years after the original diagnosis of diabetes, the patient's creatinine level spiked to 2.0mg/dL (glucose level:147mg/dL and BUN:23mg/dL), but over the next year the levels once again varied between the normal ranges.

The patient was started on lisinopril 5mg per day and over the following year the patient's creatinine level fluctuated between 2.5 and 3.5mg/dL and glucose level between 95 and 200mg/dL. On two consecutive visits that were spaced four

months apart, the patient's creatinine levels were 4.7 and 7.4mg/dL respectively. After the following visit, now 13 years into his treatment, the internist referred the patient to his choice of three different nephrologists, but the patient never saw any of them.

Nearly a year after the nephrology referral, the patient was involved in an automobile accident and was admitted to the hospital. During his hospitalization he was found to have renal failure. On admission the patient's creatinine level was at 12.6 and he was started on dialysis. The patient brought suit against the internist for failing to properly manage the patient's diabetes and elevated BUN and creatinine levels, thereby resulting in renal failure and the need for dialysis. In addition, the patient's wife brought suit against the internist for loss of consortium. The case was settled on behalf of the plaintiffs for a significant sum of money.

Case Analysis

Among other things, the plaintiff's attorney alleged that the internist had altered the patient's medical record with regard to the original nephrology referral, and that after the record was summoned, he made entries with the intention of demonstrating that he had cautioned the patient regarding the risk of kidney failure and the importance of adhering to a diabetes regimen. Forensic experts on both sides of the case determined that the ink used to note the nephrology referral was the same ink used in several notes regarding the patient's noncompliance, but was an altogether different ink than other notes in the chart.

Another criticism of the internist was that he never tested the patient for microalbuminuria, which is recommended by the ADA to be done at least once per year from onset.[2] The expert felt that evidence of microalbuminuria may have warranted a prescription for an ACE inhibitor at a much earlier point than when it eventually was ordered for the patient, and that the dose was inadequate.

Furthermore, the internist failed to refer the patient to an ophthalmologist for screening for diabetic retinopathy or to adequately assess cardiac risk factors, both of which are also part of the ADA guidelines for management of diabetics. Finally, the nephrology referral in question was also scrutinized by expert witnesses, who largely agreed that it should have happened much earlier due to the progressive rise in serum creatinine.

With regard to the ACE inhibitors that were prescribed, the physician never adjusted doses or documented an action plan concerning the medication. While it was ultimately agreed that the medication the patient was taking was beneficial, the physician's lack of monitoring of diabetes control and renal function, failure to document decision-making rationale (and, of course, the records alteration), severely compromised his credibility.

As with the first case, the patient alleged that the potential for a devastating outcome (specifically kidney failure) and the importance of adhering to lifestyle recommendations were not communicated to him. He said that if he had been aware of the seriousness of his disease, he would have been more proactive with the diabetes regimen and he would have followed through with the nephrology referral.

Patient noncompliance regarding diet was obviously an issue in this case, and is frequently noted as a factor in diabetes-related professional liability cases. However, in over 150 encounters with this patient, most with laboratory results to go along with them, it was difficult to prove that the patient was at fault here. Therefore, it would have been wise for this physician to clearly document this patient's noncompliance, especially within the framework of informed refusal. In this case, demonstrating that informed refusal was obtained properly would include documentation that a referral was made and that by way of discussion/patient education, the patient understood the reasons for the referral and the long-term consequences of not following

through. (For more information on informed refusal, refer to NORCAL's February 2006 *Claims Rx*, titled "When a Patient Refuses Medical Treatment." Available at: www.norcalmutual.com/claimsrx.)

Case Three

Learning Objectives

After reading this case and associated discussion, consider implementing the following risk reduction measures:

- Identify patients who are at an elevated risk for amputation and communicate this risk, including the treatment plan and contingencies, in plain language. Document all patient conversations, including educational materials provided, in the medical record.
- In patients with a nonhealing ulcer, do not delay laboratory testing or wound culture, or assume that they can be managed on an outpatient basis.
- Document your conversations with consultants, treatment plans and decision-making rationale in the medical record.
- In addition to patient report, always rely on your objective clinical impressions.

Allegation: Negligent treatment of a diabetic right foot ulcer resulting in below-the-knee amputation in a 55-year-old male.

Beginning at age 44 and continuing over a period of nearly 12 years, a male patient was seen by a doctor of osteopathic medicine (DO). At his first visit, the patient was noted to be approximately 5'7", weighed 278 pounds and was on no medications. Social history was significant for smoking $1^1/_2$ packs of cigarettes per day. The patient was referred to a weight loss program and advised about the health risks related to obesity.

The patient continued his care with this physician on a regular basis. He was subsequently diagnosed with type 2 diabetes mellitus, peripheral vascular disease and diabetic neuropathy. He suffered a myocardial infarction at age 47, underwent shoulder surgery at age 49, and hand surgery at age 54. There are numerous chart notes throughout the years indicating that the patient had poor weight and diet control, and that his blood sugar was frequently elevated. Numerous referrals to nutritionists were made to reiterate the importance of control and potential complications of failing to do such.

Pertinent to this litigation, the patient presented to his physician at age 54, with complaints of right leg pain and an injury to the sole of his right foot. Physical examination revealed right lower extremity swelling and tenderness. The wound itself was a puncture wound, less than $^1/_2$ centimeter in size. The patient had no fever, but his fasting blood sugar was elevated at 180. Peripheral pulses were decreased. Sensation was present in both feet, but diminished. The diagnosis was cellulitis of the right lower extremity. The physician instructed the patient to apply a warm compress to the area, elevate his foot, and take Augmentin® 875mg twice per day. Follow up

was recommended in four days or sooner if the condition worsened.

Six days later, the patient returned to this physician. Also present in the examination room was a fourth-year osteopathic medical student who was rotating through the office for one week. The medical student authored a chart note that indicated that the patient reported a decrease in both pain and swelling. The patient's temperature, however, was measured at 100.4°, prompting the physician to order an arterial duplex scan to assess circulation and an x-ray to rule out a possible foreign body. The physician's assessment was right foot cellulitis, resolving. Augmentin® was continued as previously prescribed, and in addition, the physician consulted by telephone with an infectious disease specialist who recommended adding Cipro® to the patient's course. This consultation was not documented in the medical record.

The physician ordered laboratory studies and the results were received the next day, which revealed a white blood count of 17.8k/uL and a sedimentation rate of 116mm/hr, consistent with an infectious process. The arterial duplex scan revealed significant circulatory problems, and the x-ray ruled out a foreign body. The patient was seen a day later by both the physician and the medical student. His temperature had returned to normal and he reported an improvement in pain and swelling. Physical examination confirmed a decrease in swelling, but persistent redness. The patient was instructed to continue with both antibiotics, and told to follow-up in one week, at which point the physician would obtain another sedimentation rate to compare with the previous study.

When the patient returned the following week, he complained of increased foot pain since the previous day. Physical examination revealed increased swelling and a dusky appearance. The patient had no fever, but his pulses were nonpalpable. The physician referred him to the hospital for admission and further care. Upon admission, a hospitalist assumed medical management of the patient, and over the course of the patient's stay, he underwent amputation of his right toes, then his right foot, and ultimately a below-the-knee amputation. The patient's postoperative course was stable, and after discharge he continued seeing his osteopathic physician who referred him for prosthesis.

At deposition, the physician noted that he was shocked when he received plaintiff's California Code of Civil Procedure §364 Notice of Intent to Commence Litigation. Not only did he believe all medical care and treatment he provided to the patient was appropriate and within the standard of care, but he enjoyed a good relationship with the patient as well. Notwithstanding, this litigation ensued and resulted in a substantial payment to the plaintiff.

Case Analysis

The patient testified that during the period of visits that commenced with his right foot injury, his foot continued to worsen, and the deterioration was both clinically apparent and reported to his healthcare providers. He asserted that there was a failure to recognize the significance of his problem and that, in fact, it was he who told the physician on the last of these visits that the pain was unbearable and that he wanted to go to the hospital. The patient claimed that he was advised by physicians at the hospital that he should have been hospitalized and started on IV antibiotics earlier. The patient and his attorneys argued that as a result of the delay, the infection was essentially out of control, requiring amputation.

Reviewers of the case established that the standard of care was breached when the patient presented with a fever of 100.4° and had developed an abscess. Most reviewers felt that at this point, laboratory tests should have been obtained on a stat basis, or ready by the next day. Furthermore, after the results were obtained and the patient had an elevated white blood count and sedimentation rate, reviewers agreed that the required treatment was to hospitalize the

patient, administer IV antibiotics, perform a culture and sensitivity of the foot wound, deroof the callous, and debride and drain the abscess.

The physician testified that because the patient demonstrated improvement (e.g., normal temperature, decreased pain, erythema and swelling), that the patient could be appropriately managed in an outpatient setting. Expert reviewers opined that actually the patient appeared clinically worse during this course of visits, and the physician relied on the patient's report of improvement (and perhaps the medical student's chart note) rather than making his own objective evaluation.

The physician was also criticized for not documenting the infectious disease consult. While this fact did not have a direct negative impact on the patient's care, the failure to document demonstrated carelessness and lack of attention on the part of the physician, thereby diminishing his credibility.

It can certainly be argued that this was a patient who was responsible for his vascular compromise, considering his history of uncontrolled diabetes, obesity and smoking. However, it was ultimately determined that his physician did not treat him as high-risk based on these factors, and did not act accordingly with respect to the timeliness of laboratory testing, the abnormal results that were obtained and the clinical worsening of the foot abscess.

About Diabetes

Key Points

- Diabetes is a significant and growing public health problem.
- About 90-95 percent of diabetes cases are type 2 diabetes mellitus, associated with obesity, heredity, sedentary lifestyle and older age.
- Adults over 45 (especially those who are overweight) and adults younger than 45 (if they have another risk factor) should be screened for diabetes using a fasting plasma glucose (FPG) test or 2-h oral glucose tolerance test (OGTT) (75-g glucose load) or both.
- The ADA Standards of Medical Care for Diabetes are available to guide practitioners in providing care to diabetic patients, including the management of numerous complications and comorbidities of diabetes.

Diabetes mellitus comprises a group of chronic metabolic disorders, characterized by high blood sugar levels and resulting from problems with insulin secretion and/or insulin action.[2,5] Unchecked diabetes is associated with serious and sometimes fatal complications, but often the disease can be controlled which may lower the risk of complications.

Diabetes Types, Incidence and Prevalence

According to the Centers for Disease Control and Prevention (CDC), 20.8 million Americans—7 percent of the population—have diabetes. That figure encompasses diagnosed cases (of which there are 14.6 million people) and undiagnosed cases (estimated at 6.2 million people). Furthermore, in 2002, diabetes was the sixth leading cause of death on U.S. death certificates, and this figure is widely considered underreported due to the fact that diabetes may be a contributing factor in deaths from other conditions (e.g., heart disease or stroke).[1] By all accounts, the incidence of diabetes is on the rise nationally and internationally.

There are four main types of diabetes:

- Insulin-dependent diabetes mellitus (IDDM) or “type 1”
- Non-insulin-dependent diabetes mellitus (NIDDM) or “type 2”
- Gestational diabetes mellitus (GDM)
- Diabetes secondary to other conditions

Type 1 diabetes comprises approximately 5 to 10 percent of all diagnosed diabetes cases. This type of diabetes usually occurs when its victims are children or young adults, but can occur at any age, and there is no recognized way to prevent it. Risk factors are thought to be genetic, autoimmune or environmental. People with this type of diabetes must take insulin to stay alive.[1]

Type 2 diabetes accounts for approximately 90 to 95 percent of all diagnosed cases. This type of diabetes is usually related to obesity, disorders of glucose metabolism, history of gestational diabetes, family history, sedentary lifestyle and

older age. Some reports show that children and adolescents are being diagnosed with type 2 diabetes at higher rates, but it is still relatively uncommon in these age groups. Hispanics/Latinos, African-Americans, Native Americans and some Asian Americans and Pacific Islanders have a high risk for type 2 diabetes and its complications.[1]

Gestational diabetes is diagnosed in some women during pregnancy. To avoid complications in labor, delivery and in the neonate, treatment for GDM requires the stabilization of blood sugars in the mother. Certain ethnic groups have a higher incidence of GDM—African Americans, American Indians and Hispanics—and the disease occurs more frequently in women who are obese and who have a positive family history for diabetes. Women with GDM have an increased likelihood of developing diabetes after pregnancy.[1]

Secondary diabetes accounts for 1 percent to 5 percent of all cases, and can result from genetic conditions (e.g., cystic fibrosis, chromosomal defects, neuromuscular disorders), pancreatic disorders (e.g., pancreatitis and hemochromatosis), endocrinopathies (e.g., hyperthyroidism), drugs (e.g., diurectics, antihypertensive agents, hormones, anticonvulsants and hormones) and illnesses or infections (e.g., HIV and hepatitis C).[6]

Screening

This CME activity concerns itself primarily with type 2 diabetes mellitus. The ADA has made clear recommendations for screening for type 2 diabetes in individuals at-risk. Individuals at-risk are defined by these guidelines as:[2]

- Adults older than 45 years of age, chiefly those with a body mass index [BMI] >25 kg/m^2, or overweight adults who are younger than 45 years of age, if they have another risk factor for diabetes.
- Children with a BMI greater than the 85th percentile for age and sex, or whose weight for height ratio is greater than the 85th percentile, or whose weight is greater than 120 percent of ideal for height, plus two additional risk factors.

According to ADA guidelines, to screen for diabetes/pre-diabetes, a fasting plasma glucose (FPG) test or 2-h oral glucose tolerance test (OGTT) (75-g glucose load) or both are appropriate. (ADA).[2]

The ADA screening guidelines are available on the internet at www.guideline.gov and www.diabetes.org.

Complications/Comorbidities of Diabetes

Numerous complications and comorbidities of diabetes make this disease difficult to manage. Again the ADA Standards contain guidelines regarding diabetes care, including prevention and management of diabetes complications. These are the standards that physicians are likely to be held to if they are named in a diabetes-related medical professional liability claim.

The following known complications of diabetes were listed in Maureen I. Harris, *Diabetes in America* (2nd Ed).[4]

- **Disability.** At all ages, people with type 2 diabetes are less likely to be employed than people without diabetes, including work loss due to activity limitation. Diabetic individuals with disabilities also burden healthcare services at a more frequent rate than those not limited in activity.
- **Acute metabolic complications.** Diabetics are at risk for numerous acute metabolic complications including diabetic ketoacidosis (DKA). DKA is more common in young diabetic patients.† Other conditions that fall under this category include hyperosmolar nonketotic coma, lactic acidosis and hypoglycemia.

† Anecdotally, NORCAL has seen several claims related to the failure to diagnose diabetic ketoacidosis in pediatric patients and young adults.

- **Vision disorders.** Diabetic retinopathy is a major risk factor for blindness, and this condition is the leading cause of new cases of blindness among adults nationwide. Hyperglycemia is the main risk factor for the development of diabetic retinopathy, and untreated hyperglycemia may be causing retinopathy in the preclinical period (approx. 10 years) between the onset of type 2 diabetes and its treatment.
- **Neuropathy.** Nerve damage is common in insulin-dependent and non-insulin-dependent diabetics, and will occur in approximately 50 percent of diabetics, at an average of 10-20 years after diagnosis.[7]
- **Kidney diseases.** Diabetes is the leading cause of kidney failure requiring either dialysis or transplantation (end-stage renal disease or ESRD), with 44 percent of ESRD arising in diabetic patients. According to the Centers for Disease Control, ESRD is an expensive and disabling medical condition (associated with high mortality) that disproportionately impacts racial and ethnic minorities.[8]

Standards of Medical Care for Diabetes

As a professional liability insurer, it is not NORCAL's intention or our place to set the medical care standard. This course has strongly emphasized the role of ADA practice guidelines for the screening, diagnosis, classification and treatment of diabetes. These care standards are likely to be what physicians and medical groups are held to in the event of a malpractice claim. The ADA Standards of Medical Care in Diabetes were updated and released in January of 2006, and can be downloaded for free on the Internet at both the National Guideline Clearinghouse www.guideline.gov and the American Diabetes Association www.diabetes.org.

The 2006 standards include the following chapters:

I. Classification and diagnosis
II. Screening for diabetes
III. Detection and diagnosis of gestational diabetes mellitus
IV. Prevention/delay of type 2 diabetes
V. Diabetes care
VI. Prevention and management of diabetes complications
VII. Diabetes care in specific populations
VIII. Diabetes care in specific settings
IX. Hypoglycemia and employment/licensure
X. Third-party reimbursement for diabetes care, self-management education, and supplies
XI. Strategies for improving diabetes care

- **Peripheral vascular diseases.** The incidence of lower extremity arterial disease (LEAD) is significantly higher in diabetic subjects than nondiabetics. LEAD can result in numerous mobility problems for diabetics, and compounded by peripheral neuropathy, this condition can lead to foot ulcers, gangrene and amputations.
- **Lower extremity/foot ulcers and amputations.** The lifetime risk for diabetic patients of developing a foot ulcer is approximately 15 percent.[9] Evidence supports the screening of all diabetic patients to identify those at high-risk for foot ulcers and to accordingly implement proactive patient education, prescription footwear, referral for podiatric care and evaluation for surgical intervention.[10]
- **Heart disease.** Adult men and women with diabetes are at a sharply elevated risk of developing heart disease—with the probability that it will appear earlier in life than in non-diabetics, and that it will more likely be fatal. Diabetic patients also have a higher incidence of silent ischemia than non-diabetic patients.
- **Stroke.** The risk of fatal and nonfatal stroke is higher in diabetic patients.
- **Digestive diseases.** Diabetics are more likely than non-diabetics to report digestive diseases (e.g., ulcers, irritable bowel symptoms, diarrhea, constipation, gallstones), but these diseases have not been explicitly linked to diabetes itself. Diseases of the pancreas (e.g., pancreatic cancer and chronic pancreatitis), however, significantly increase a patient's risk of developing diabetes. Diabetic gastroparesis, which can result in widely fluctuating serum glucose levels, and/or protracted nausea and vomiting, can be a debilitating complication of diabetes mellitus.
- **Infections.** Diabetic patients have an increased proclivity to infections, which is thought to be related to immunologic problems and neuropathy.
- **Oral complications.** Some studies have demonstrated that periodontal disease is more frequent and severe in diabetics.
- **Psychosocial aspects.** Some studies have demonstrated a potential link between diabetes and depression, but more research is required in this area, including the efficacy of psychiatric medication in the diabetic population.

Conclusion

Diabetes mellitus is a chronic and debilitating health condition that affects a significant percentage of the U.S. population. The prevention and management of diabetes' numerous complications is of primary concern to all physicians who treat diabetic patients. The ADA guidelines provide a framework for the medical care of diabetic patients.

Risk Management

Key Points

- Implementing risk management-based strategies can reduce professional liability exposure and increase your defensibility should a malpractice claim be alleged against you.
- The implementation of electronic health records can help facilitate the management of diabetes and its comorbidities, especially in large multi-practitioner practices.
- Assessing a patient's health literacy level can help tailor diabetic education.

For a chronic disease with as many complications and comorbidities as diabetes, it is wise for primary care physicians to use a systems-based approach to implement diagnostic and treatment protocols. Such implementation would typically involve a thorough review of current practices, both in the clinical care of patients as well as administrative processes (e.g., tracking of test results and referrals).

Keep the following risk management-based strategies in mind when developing such protocols:

- Follow the ADA guidelines. When a particular treatment differs from what is recommended in the published guidelines, document your decision-making rationale in patient medical records.
- Communicate about diabetes with your patients using plain language. Confirm patient understanding of their medical condition (and self-care requirements) on a regular basis.
- Develop a list of patient education resources specific to the community in which you practice. Such a list might include the Sweet Success™ program for gestational diabetes or a listing for the hospital diabetes educator. The ADA also has numerous patient education materials available on their website at www.diabetes.org.
- Develop and utilize a preventative care algorithm that guides routine referral of patients for common diabetic medical problems (e.g., eye screening and diabetic foot care) Such a tool can be integrated into an electronic health record system or developed into flowsheets that are used in paper records.
- Create and implement a policy and procedure for referral management, such as how referrals are made, followed up, and how information is shared between providers.
- Create and implement a policy and procedure for the tracking of laboratory data.
- Create and implement policies and procedures for working with allied health providers that include communication protocols and documentation guidelines.
- Consider your strategy for managing patient noncompliance. Enhance your ability to communicate with patients about diabetes, including prevention, diabetic self-care, and how to manage the maze of providers and prescription medications that they may encounter in the diabetic lifespan. Thoroughly document patient noncompliance in the medical record, including your efforts to obtain informed refusal from the patient.

- Document. Document. Document. Do not forget to document all medical care including (but not limited to) diabetic screening, prevention plans, treatment plans, decision-making rationale, informed consent/refusal, patient compliance/noncompliance, referrals, communication with other providers, follow-up plans, telephone contacts and medications.
- Utilize a "master problem list" in patient charts to track ongoing diagnoses, test results, specialty referrals, complications and comorbidities, and to facilitate communication between multiple providers.
- Utilize a "medication summary" in patient charts to track all prescription medications and avoid medication errors.

Prescription Medication Issues

Numerous resources and continuing medical education activities are devoted to the pharmacological treatment of diabetes. The following drug-related issues stand out from a risk management perspective:

Tequin®

In a letter dated February 15, 2006, Bristol-Myers Squibb Company notified the Food and Drug Administration (FDA) of a contraindication for the use of this drug in diabetic patients. A warning was added to the product labeling that "[d]isturbances of blood glucose, including symptomatic hypoglycemia and hyperglycemia, have been reported with Tequin®, usually in diabetic patients…"[11]

The FDA responded to this letter by issuing a new patient information sheet warning patients and providers that Tequin® should not be taken by diabetic patients and should be closely monitored in patients who are at higher risk of developing blood sugar problems (e.g., due to older age, kidney problems, or while on other medications that affect blood sugar).[12]

In response, NORCAL makes the following recommendations:

- For patients taking Tequin®, send a letter advising them of the FDA warning and ask them to make an appointment to

The Benefit of Electronic Health Records (EHRs)

Electronic health records can be an effective solution for managing chronic, complicated health problems such as diabetes. From a risk management perspective, EHR systems can improve documentation (e.g., completeness and legibility), improve access to patient information (e.g., when there are multiple providers or sites), can decrease the incidence of medication errors, and can facilitate the utilization of practice guidelines and patient care algorithms.

There are also risks inherent to EHR systems (e.g., inadvertent data destruction, inaccurate data entry, unauthorized access). Not all EHR systems are created equal, and finding an EHR system that is right for a particular practice involves an extensive assessment of the practice's needs and wants, as well as a thorough review of vendors' services. For more information on the risk management aspects of implementing an EHR, refer to NORCAL's April 2006 *Claims Rx*, titled "Risk Issues for Implementing an EHR System." Available at: www.norcalmutual.com/claimsrx.

evaluate their use of the medication, including possible alternatives.

- Post a notice in a prominent location in your office advising patients of the FDA warnings on Tequin®.
- Implement a system to identify patients who take these medications so that when those patients call the office for any reason, a communication with the physician can be initiated.
- Remember, good communication between you and your patients is critical to reassuring them as much as possible and having their medications adjusted as clinically appropriate.
- Be cautious about what you say to patients (i.e., avoid speculation about the efficacy of the drugs or the timing of the recalls and warnings).
- Carefully document your conversations about medications in patient medical records.

Access to Medications

Ready access to diabetes medications is essential. Healthcare providers are encouraged to put systems in place to ensure that diabetics always have easy, immediate access to medication prescriptions and refills. These would include the following:

- Writing for an adequate number of refills when prescribing medications
- Easy phone or email access for patients to request refills
- Office protocols to ensure refill requests are completed within a short period of time
- Reliable and rapid communication with pharmacies
- Appropriate and thorough documentation of prescriptions and refills

Diabetic patients should not be given perpetual medication refills without periodic doctor visits and reevaluation of their condition. From a risk management perspective, it is important that physicians communicate with their patients about their prescriptions during office visits, to confirm that the medications are being taken and address any medication problems.

Resources for Physicians

American Diabetes Association (ADA)

www.diabetes.org

The ADA website has numerous resources for physicians and patients, available in both English and Spanish.

National Diabetes Education Program (NDEP)

http://ndep.nih.gov/resources/health.htm

The NDEP website contains clinical practice tools and patient resources, and is home to the popular “Guiding Principles for Diabetes Care for Healthcare Providers” and “Small Steps, Big Rewards: Your Game Plan for Preventing Type 2 Diabetes (Healthcare Provider’s Toolkit).”

National Institute of Health (NIH)/Making Systems Change for Better Diabetes Care

http://betterdiabetescare.nih.gov

Part of NDEP, this website provides information, models, links and resources to healthcare providers.

Health Literacy and Diabetes Education

As was demonstrated in the case examples, physicians need to take an active role in ensuring that diabetic patients understand their condition, the role of self-care, and the importance of compliance with referrals and treatments. This is made complicated by the fact that numerous studies have demonstrated that "the majority of patients do not fully comprehend the health information that is presented to them and that healthcare providers often make incorrect assumptions about patients' level of health literacy."[1]

Increasing the cultural and linguistic competency of physicians has become a national priority, and some states are now requiring that physicians obtain continuing medical education (CME) that specifically addresses this topic. Increased cultural and linguistic competency will help physicians address health literacy barriers experienced by their patients, and will hopefully result in enhanced patient safety and fewer allegations of negligence.

In communicating to your diabetic patients about their condition, it may be helpful to assess health literacy as part of the diabetic work-up. Leading health literacy researchers have recommended a test that can be downloaded for free at www.newestvitalsign.org.[2] This test can be administered by a medical assistant while he or she is taking vital signs. The test is based on the patient reading an ice cream label. The patient is asked to determine total calorie count and whether or not a person with a peanut allergy could eat the ice cream based on ingredients. Although simple, the test can identify whether or not the patient can read; do simple math (important for calculating doses for medicine); and use abstract reasoning.

The American Medical Association (AMA) health literacy manual for physicians offers the following six steps to improve communication with patients whose health literacy is limited[3]:

1. Speak slowly and spend a small amount of additional time with each patient.
2. Use plain, nonmedical language.
3. Show or draw pictures, which can improve the patient's recall of ideas.
4. Limit the amount of information provided to pertinent tasks at hand. Repeat the information to enhance recall.
5. Confirm patients' comprehension by asking them to repeat your instructions.
6. Create an intimidation-free environment by making patients feel comfortable asking questions. Enlist the aid of others (patient's family, friends) to promote understanding.

Notes

1 Institute of Medicine (IOM). Health Literacy: A Prescription to End Confusion. Washington (DC); April 08, 2004.

2 Weiss BD, Mays MZ, Martz W, Castro KM, DeWalt DA, Pignone MP, et al. Quick assessment of literacy in primary care: the newest vital sign. Ann Fam Med. 2005 Nov-Dec;3(6):514-22.

3 Weiss BD. American Medical Association Foundation and American Medical Association. Health Literacy: A Manual for Clinicians, 2003. (Table 13, Page 27). Available at: www.ama-assn.org. Accessed: June 21, 2006.

Conclusion

As outlined in the introduction to this course, managing diabetes mellitus and its comorbidities is an emerging professional liability concern. As the percentage of patients with type 2 diabetes increases, it is expected that more claims will arise alleging negligent management, failure to supervise or monitor case, delay in diagnosis/treatment, and more. Prudent physicians will proactively inspect existing office systems—including lab tracking, follow-up systems, telephone contact protocols, etc.—and make changes that will improve diabetic continuity of care.

Adherence to national guidelines is important. Such guidelines play a central role in claims review, and when patient treatment falls outside the recommended standard of medical care, it is wise to take extra steps in documenting the thought process that led to that particular clinical judgment.

Finally, improved communication with patients is paramount. Patients should be assessed for health literacy and need to learn about their diseases and the importance of following through with medical advice (including diabetic self-care) in terms they can understand. Thorough documentation of conversations (including education given) contemporaneous with patient encounters will reinforce provider-provider information-sharing, and may strengthen the defense of a malpractice claim should one be initiated.

Endnotes

[1] Centers for Disease Control and Prevention (CDC). National Diabetes Fact Sheet: general information and national estimates on diabetes in the United States, 2005. CDC Website. Available at: http://www.cdc.gov/diabetes/statistics/ Accessed: 3/9/06.

[2] American Diabetes Association (ADA). Standards of Medical Care in Diabetes—2006. Diabetes Care, Vol. 29 Suppl 1, Jan 2006.

[3] Physician Insurers Association of America (PIAA). PIAA Risk Management/Claims Combined Meeting. Diabetes Mellitus. Presented by John B. Staunchfield, MD, FACE. San Francisco (CA), 2002.

[4] Harris MI. Diabetes in America (2nd Ed) Available at http://diabetes.com Accessed 2/22/06.

[5] American Diabetes Association (ADA). Diagnosis and classification of diabetes mellitus. Diabetes Care. Vol. 28, Suppl 1, Jan 2005.

[6] Trubo, R. Researchers investigate factors linked to development of secondary diabetes. JAMA Vol. 294, No. 6/August 10, 2005.

[7] Vinik AI. Diabetic neuropathies. Med Clin North Am. 2004; 88(4): 947-99.

[8] Centers for Disease Control and Prevention (CDC). Incidence of End-State Renal Disease Among Persons With Diabetes—United States, 1990-2002. JAMA Vol. 294, No. 23/December 21, 2005.

[9] Reiber GE. The epidemiology of diabetic foot problems. Diabet Med 1996;13(suppl 1):S6-S11.

[10] Singh, N, Armstrong, DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA Vol. 293, No. 2/January 12, 2005.

[11] Bristol-Myers Squibb. Letter to healthcare providers detailing contraindication of drug Tequin® for patients with diabetes mellitus. February 15, 2006.

[12] Food and Drug Administration (FDA). Patient Information Sheet Gatifloxacin (marketed as Tequin®). Available at: www.fda.gov. Accessed: 6/16/06.

Diabetes: Managing Comorbidities

CME EVALUATION AND ATTESTATION FORM

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Effectiveness in Meeting Identified Needs

Was the activity effective in meeting the identified needs (listed below)? ❑ Yes ❑ No

Diabetes is a major public health concern. The disease afflicts nearly 7% of the U.S. population, and by all accounts is on the rise. Claims of physician negligence have related to problems in diabetes management have also increased. Physicians, particularly primary care providers, need to be aware of the professional liability exposures related to diabetes management and take steps to reduce their risk of being named in a diabetes-related malpractice lawsuit. A review of current clinical practice standards by the ADA, as well as risk management-based strategies are presented in this course.

Learning Objectives and Learning Contract

Learning Objective	**Teaching Effectiveness** *Degree to which this presentation provided you with knowledge or skills to implement in your practice?*	**Learning Contract** *State a practice change you are committed to make based on these objectives.*	**Degree of Certainty** *How certain are you that you will make this change?*
With the goal of increasing patient compliance and reducing the public health burden of diabetes, improve your ability to communicate about the seriousness of this disease, using patient medical records as documentation of your efforts.	❑ 5 (Superior) ❑ 4 (Good) ❑ 3 (Satisfactory) ❑ 2 (Fair) ❑ 1 (Poor)		❑ 100% ❑ 80% ❑ 60% ❑ 40% ❑ 20% ❑ 0%
Given the numerous complications and comorbidities associated with diabetic patients, implement a diabetes management protocol and tracking system that is based on evidence-based clinical practice recommendations.	❑ 5 (Superior) ❑ 4 (Good) ❑ 3 (Satisfactory) ❑ 2 (Fair) ❑ 1 (Poor)		❑ 100% ❑ 80% ❑ 60% ❑ 40% ❑ 20% ❑ 0%
To reduce professional liability associated with diabetes management, evaluate your communication, follow-up and documentation practices and implement the risk management-based strategies listed in this course.	❑ 5 (Superior) ❑ 4 (Good) ❑ 3 (Satisfactory) ❑ 2 (Fair) ❑ 1 (Poor)		❑ 100% ❑ 80% ❑ 60% ❑ 40% ❑ 20% ❑ 0%

Continued on reverse….

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	True	False	Comments
Disclosure of faculty relationships with commercial organizations was made available to me.	❑	❑	
The activity was free of commercial bias.	❑	❑	
Any off-label drug use, and/or investigational drug use not yet approved by the FDA was disclosed before or during the activity.	❑	❑	

If you answered "false" to any of the above questions, please provide details in the comments section below.

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Please list any other topics that would be of interest to you for future educational activities:

_____

_____

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