

Medical Malpractice in the Failure to Manage Diabetes

by Patrick A. Malone¹

What do these three Americans have in common? One has just gone blind, one has lost a foot to amputation, and one is going to the kidney dialysis clinic for the first time. All are victims of the preventable consequences of diabetes, and all may have good grounds to complain that they might not have lost an eye, a limb or a kidney if they had received quality care by the physicians who managed their diabetes.

Eighteen million Americans – one in 16 – have diabetes mellitus. The number grows rapidly each year with an aging, sedentary, obesity-prone society. Diabetes cannot be cured: Once a patient needs medications to treat their body's resistance to insulin or insulin itself to supplement their body's natural supply, they face a life-long regimen of treatment. How expertly that treatment is managed will decide whether these patients lead a normal life or one hobbled with disabilities.

For more than three decades, the American Diabetes Association (ADA) has been preaching the gospel of diabetic preventive care. A cornerstone of prevention is keeping the diabetic's day-by-day and hour-by-hour blood sugar level as close as possible to that of a non-diabetic. High levels of blood sugar are poison to the body's vasculature, particularly the tiny blood vessels that feed sensitive areas like the retina of the eye, the filtering system of the kidney, and the peripheral nerves in hands and feet. In a position statement published in 1976, the ADA wrote: "[T]he weight of evidence strongly supports the concept that microvascular complications of diabetes are decreased by reduction of blood glucose concentrations. The goal

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of appropriate therapy should include a serious effort to achieve levels of blood glucose as close to those in the nondiabetic person as feasible.”¹

Anyone treated with insulin should monitor their own blood glucose on a daily basis. This has been accepted standard of care at least since 1986, when a consensus conference was convened by the National Institutes of Health with the ADA, the Centers for Disease Control and the Food and Drug Administration.² Yet more than a decade later, a 1999 survey by the CDC found that barely 40 percent of diabetics tested their own blood sugar regularly.³ There are striking regional variations, with self-monitoring much less prevalent in the South and New England than in the upper Midwest and West. These variations relate to how strongly primary care physicians push their patients to do self-monitoring, and how effectively patients are educated. Patients who learn the toll on their bodies from poor blood sugar control nearly always become religious in their testing habits.

The consequences of the lack of more consistent blood sugar control are profound:

- * Diabetes is the leading cause of adult-onset blindness in the United States, causing as many as 24,000 new cases of blindness each year.⁴

- * Diabetes is the leading cause of non-traumatic amputation in the United States, accounting for around 82,000 new lower-limb amputations each year.⁵

- * Diabetes is the leading cause of end-stage kidney disease, accounting for 44 percent of new cases each year.⁶

Tight control of blood sugar dramatically affects the risk of each of these complications. The gold standard for measuring the efficacy of sugar control is a blood test called glycosylated hemoglobin, or hemoglobin A1C, which measures the percent of hemoglobin in the blood that

has sugar molecules attached to it, a good measure of average blood sugar levels over the last six weeks. (The American Diabetes Association has considered regular glycosylated hemoglobin testing as standard practice since at least the late 1980s.⁷ Yet CDC surveys show the test is currently given to fewer than 20% of patients.⁸)

The combination of daily home blood sugar testing by the patient and glycosylated hemoglobin by the doctor gives the tools needed to make the small adjustments in insulin timing, dose and mix of short-acting and long-acting insulin that can bring most diabetics' blood sugar under good control. Diet and regular exercise are two other major components for self-care.

The target for glycosylated hemoglobin is 7 percent or under, and 6 percent – the normal level in a non-diabetic – is considered ideal. According to the Centers for Disease Control and Prevention, every one-point reduction in the glycosylated hemoglobin value – for example, from 8 to 7 percent – lowers the risk of eye, kidney and nerve disease by 40 percent.⁹ This is based on a series of large, well-controlled scientific trials with consistent results in both the United States and Great Britain. The most prominent of these is the multi-center Diabetes Control and Complications Trial, which focused on juvenile-onset (Type One) diabetes.¹⁰

Other preventive measures can be even more dramatic in their impact on diabetic complications, particularly to prevent blindness from diabetic retinopathy. Annual dilated-pupil eye examinations of all diabetic patients have been “standard of care” since the 1980s.¹¹ These exams can show the early signs of diabetic disease in the retina (the viewing screen at the back of the eye) years before the patient notices any loss of vision. Ophthalmologists can readily see the abnormal blood vessels that proliferate in the retina and can seal off these vessels before they destroy the retina, with simple outpatient laser treatments.

In 1993, the Journal of the American Medical Association published a review of several studies and concluded that patients with proliferative diabetic retinopathy had a 50 percent chance of becoming legally blind within five years if they had no laser treatment, but only a 5 percent risk if they were regularly seen and treated by ophthalmologists – a 10-fold risk reduction.¹² The article concluded: “This remarkable finding lends even greater urgency to current efforts to ensure that virtually all persons with diabetes receive at least yearly dilated eye examinations....” Yet a decade later, the latest survey by the CDC shows that three in 10 diabetics do not receive this basic annual eye examination (2001 data).¹³ (Only two years before, the number not receiving annual eye examinations was 40 percent,¹⁴ suggesting a positive but belated trend.)

The 1993 JAMA report was actually old news in the diabetes world. The first major study reporting the efficacy of laser treatment to prevent diabetic blindness was published in 1976,¹⁵ and recommendations for annual eye examinations for diabetics followed soon after.

Preventive care for other microvascular complications of diabetes also yields striking results.¹⁶ An annual foot exam combined with good foot hygiene reduces amputation rates by 45 to 85 percent, according to the CDC,¹⁷ yet one in three diabetics still do not get an annual foot exam.¹⁸ Early detection and treatment of diabetic kidney disease – with ACE inhibitors and angiotensin receptor blockers to lower blood pressure – can have a major impact on reducing the decline in kidney function.¹⁹ Better blood pressure control also slows the progression of diabetic retinopathy.²⁰

These statistics can spell proximate cause for the plaintiff who never received these basic preventive treatments. An even stronger case can be made where the physician failed to address

multiple preventive measures and the patient, for example, went blind from the additive effects of poor blood sugar control and lack of routine ophthalmic exams.

In the *Daubert* era, some courts require statistical evidence that an alleged cause of a disease has more than doubled a patient's risk – a “relative risk” of 2.0 or higher – in order to prove “more likely than not” causation.²¹ (Flipping the arithmetic the other way, an intervention that lowers the risk of an injury or disease by at least 50 percent – as from 60 percent to 30 percent – meets the same relative-risk-of-2.0 standard.) This standard of proof, often hotly contested in “toxic tort” and drug product liability cases, is actually easy to meet in a diabetes malpractice case, because of the dramatic statistics developed in a variety of studies of the value of preventive care. For example, the reduction of the risk for blindness from 50 percent to 5 percent by routine ophthalmic examinations and laser treatment means that the “relative risk” of non-treatment is 10. Non-treatment for the diabetic is, in effect, a toxic agent with deadly consequences for the patient.

Another defense in a diabetes malpractice case is the patient's own negligence in failing to manage their diabetes. Indeed, probably no other disease requires more intense involvement by the patient for a successful outcome than diabetes. The patient who alleges that he or she was not properly educated on matters like home blood sugar testing is likely to be met with a defense that the doctor raised the matter and the patient refused. Plaintiff lawyers need to be aggressive in meeting this defense. The doctor is unlikely to have documented this alleged conversation in the patient's chart, and this makes for a strong line of questions on why such an important matter would be omitted from the chart when everything else of consequence is recorded there. But even accepting for the sake of argument that some such conversation took

place, it remains the physician's job to make sure that their education efforts are effective, and if not, to refer the patient to a specialist in diabetes education. The American Association of Diabetes Educators includes nurses, pharmacists, dieticians, social workers and other professionals whose mission is to train diabetics to effectively manage their disease in partnership with their health care providers.²² Standards for effective diabetes education programs were first developed in the early 1980s.²³ A diabetes educator can be an important expert witness for the plaintiff in a diabetes malpractice case. Few patients who are properly taught the consequences of poor diabetes control and the techniques for good self-care are self-destructive enough to persist in poor habits.

A key expert witness for any diabetes malpractice case is the diabetologist/endocrinologist. This expert can address standards of care for the primary care of a diabetic – which should be the same whether given by an internist, family practitioner or diabetes specialist – and also will be familiar with the statistical evidence about the prevention of complications. An expert who specializes in the complication at issue in the case – for example, an ophthalmologist who does retinal laser treatment – also is valuable.

Many courts hold that to constitute contributory negligence, a patient's negligence must coincide in time with that of the doctor.²⁴ If the patient's negligence precedes the doctor's, that just becomes the reason why the patient needs good care and is no more a defense than would a patient's smoking habits would be in a case against a radiologist for failing to detect lung cancer on a chest X-ray. If the patient's negligence comes after the doctor's care has caused an injury, that becomes an issue not of contributory negligence but a failure to mitigate damages.

Another defense concerns evolving standards of care over the years. Since a typical

diabetes malpractice client will have a history of 20 or more years of living with the disease, the plaintiff lawyer will need to be familiar with the extensive body of diabetes literature from the 1980s and before. In days past, a major concern used to be that overly aggressive efforts to bring down blood sugar could cause the opposite effect: a hypoglycemic crisis that could bring coma or death. The risk of injury from hypoglycemia has proven to be far less than that from high blood sugar. A related defense is that the evidence for the efficacy of tight sugar control in Type Two diabetes did not solidify until the mid-1990s, thus justifying more relaxed sugar control before then. These defenses are effectively countered by medical literature that consistently advocated for good sugar control in all diabetics well back into the 1980s, even before scientific proof of the efficacy of the practice was established.²⁵ The most authoritative standard of care documents are the annual guidelines published by the American Diabetes Association. Unlike some other medical specialty societies that sprinkle legal disclaimers throughout their practice guidelines, the ADA does not shrink from calling its care recommendations “standard of care.”²⁶

Other aspects of standard of care for diabetes are of more recent vintage. The use of ACE (angiotensin converting enzyme) inhibitors and ARBs (angiotensin receptor blockers) to stabilize diabetic kidney disease was first published in the early 1990s and became standard practice after three major studies appeared in the September 20, 2001 issue of the New England Journal of Medicine.²⁷

Negligent failure to prevent the complications of diabetes remains an uncommon cause of action. For example, the author could find no reported cases on blindness caused by failure to normalize blood sugar or failure to refer the patient for regular dilated-pupil eye examinations.

(Most of the reported cases about diabetes deal with short-term treatment issues, such as failure to properly treat a foot ulcer, leading to unnecessary amputation.²⁸) In light of government statistics that as many as 24,000 Americans go blind each year from preventable complications of diabetes, this represents a widespread failure not just of medical management, but of plaintiff lawyers to enforce appropriate standards of care. Aggressive pursuit of these issues by plaintiff lawyers will produce fair compensation for victims and, in the end, healthier lives for millions of diabetics.

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1. American Diabetes Association, "Position Statement: Blood Glucose Control in Diabetes," Diabetes 25:237 (1976).

2. See "Consensus Statement on Self-Monitoring of Blood Glucose," Diabetes Care 10:95 (1987).

3. Centers for Disease Control and Prevention, "Diabetes Surveillance, 1999," published at <http://www.cdc.gov/diabetes/statistics/surv199/chap10/fig1.htm>.

4. Centers for Disease Control and Prevention, "National Diabetes Fact Sheet," published at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2003.pdf.

5. Id.

6. Id.

7. American Diabetes Association, "Standards of Medical Care for Patients with Diabetes Mellitus," Diabetes Care 12(5):365 (1989).

8. See note 3, <http://www.cdc.gov/diabetes/statistics/surv199/chap10/fig1.htm>

9. National Diabetes Fact Sheet, note 5 above.

10. The landmark study was published in 1993 by the Diabetes Control and Complications Trial (DCCT) Research Group. "The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus," New Eng. J. Med. 329:977 (1993). The study found, among other things, that the risk of developing

diabetic retinopathy was reduced by 76 percent in the intensive therapy group. See also UK Prospective Diabetes Study Group, "Intensive blood-glucose control with sulphonylureas or insulin compared with convention treatment and risk of complications in patients with type 2 diabetes," Lancet 352:837 (1998).

11. American Diabetes Association, "Standards of Medical Care for Patients with Diabetes Mellitus," Diabetes Care 12(5):365 (1989).

12. Frederick Ferris, "Commentary: How Effective Are Treatments for Diabetic Retinopathy?" J. of the Am. Med. Assn., 269:1290 (1993).

13. CDC, "Prevalence of Preventive Care Practices per 100 Adults with Diabetes, 42 States, 2001," <http://www.cdc.gov/diabetes/statistics/preventive/fig1.htm> .

14. <http://www.cdc.gov/diabetes/statistics/surv199/chap10/fig1.htm>

15. Diabetic Retinopathy Study Research Group, "Preliminary report on effects of photocoagulation therapy: DRS report number 1," Am. J. Ophthalmology 81:383 (1976).

16. A good review article with citations to nearly 100 of the primary studies on prevention of diabetic complications is: Aaron Vinik, "Prevention of the Complications of Diabetes," Am. J. Managed Care 9:S63 (2003).

17. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2003.pdf.

18. <http://www.cdc.gov/diabetes/statistics/preventive/fig1data.htm>

19. Centers for Disease Control and Prevention, "National Diabetes Fact Sheet," published at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2003.pdf.

20. An excellent review article summarizing the many studies on prevention of blindness from diabetic retinopathy is: Lloyd Aiello and others, "Perspective: Systemic Considerations in the Management of Diabetic Retinopathy," Am. J. Ophthalmology 132:760 (2001).

21. See the Daubert decision on remand from the Supreme Court: *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1321 & n.16 (9th Cir. 1995). See the discussion of "relative risk" and its implications for proving proximate cause in Federal Judicial Center, Reference Manual on Scientific Evidence 348-50 (2d ed. 2000).

22. The association's web site is <http://www.aadenet.org>.

23. National Diabetes Advisory Board, "National standards for diabetes patient education programs," Diabetes Education 9:11 (1984).

24. See, e.g., *Durphy v. Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.* 698 A.2d

459, 467 (D.C. 1997).

25. One prominent study from a multi-year epidemiological survey of patients in Wisconsin was published in 1988. Ronald Klein and others, “Glycosylated Hemoglobin Predicts the Incidence and Progression of Diabetic Retinopathy,” J. of the Am. Med. Assn., 260:2864 (1988), which found consistent benefits from good blood sugar control in both younger-onset diabetics and older-onset, and even those not taking insulin. The ADA (see n. 1 above) and prominent internal medicine textbooks had advocated good sugar control for all diabetics well before this, even when the evidence for a causal relationship between hyperglycemia and complications was unsettled. See, e.g., Harrison’s Principles of Internal Medicine (10th ed. 1983) at 676: “It would appear prudent to maintain the plasma glucose as near normal as possible in all diabetic patients. About this there appears to be no disagreement.”

26. See, for example, note 11 above.

27. The Lewis, Brenner and Parving studies appear, respectively, at N. Eng. J. Med. 345:851, 345:861, 345:870 (2001).

28. See, e.g., *Wasserman v. Carella*, 307 App. Div.2d 225, 762 N.Y.S.2d 382 (2003); *Robinson v. Group Health Ass’n*, 691 A.2d 1147 (D.C. 1997).