## Financial Implications of Implementing Standards of Care for Diabetic Eye Disease

LAWRENCE I. RAND, MD

This article reviews practical financial issues surrounding the implementation of published standards of care for diabetic patients concerning examination for detection of retinopathy. Issues such as the financial basis of referral patterns and the fear of patient loss are raised. The role of the primary physician in coordinating care is discussed. The strategies of ophthalmic screening at the site of primary care are presented as alternatives to published standards. There is a need for development of low-cost screening for low-risk patient groups. All effective means of detecting retinopathy and implementing sight-saving therapy in a timely manner is cost-effective compared with the cost saved of disability payment alone.

umerous organizations have developed standards of care which, in general, are similar, but with differing slants that favor the perspective of the issuing organization (1–3). This article refers specifically to the standards developed by the American Diabetes Association, and does not make specific dollar projections on costs or savings that might result from implementing these standards. These projections are dependent on the specific assumptions made and will be explained by others (4). The goal herein is to address broader financial issues related to practice patterns or other "real-world" concerns that will influence our ability to implement these standards or will alter the effectiveness of their implementation. Suggestions are made as to where the standards might be altered for financial and other reasons.

Standards of care are needed because we now have treatments for diabetic retinopathy that, even 13 yr after being proved effective, are still not being applied in a timely fashion to all diabetic patients who need them. In 1976, the Diabetic Retinopathy Study proved panretinal photocoagulation to be effective for high-risk proliferative retinopathy (5). In 1985, the Early Treatment Diabetic Retinopathy Study (ETDRS) proved focal macular photocoagulation effective for clinically significant macular edema (6). Today, people are still losing vision from these conditions unnecessarily.

The first sentence of the American Diabetes Association guidelines reads, "eye care in diabetic patients reflects a partnership between the primary physician

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From Diabetic Eye Care, West Newton, Massachusetts.

Address correspondence and reprint requests to Lawrence I. Rand, MD, Diabetic Eye Care, 164 Bigelow Road, West Newton, MA 02165.

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and eye doctor." What is the nature of that partnership? Does the partnership imply an obligation to send patients to the best-qualified individuals in the area? How qualified is qualified enough? Are there financial pressures to keep the patient local, or be involved in an "I'll refer to you, if you refer to me" relationship? Are there financial pressures not to send a patient to a center of known expertise for fear of losing the patient?

These unspoken factors, most with financial implications, play a major role in determining the nature of the partnership formed and the quality of care received by the diabetic patient as a result of that partnership. The solution is that patients should be referred to individuals with specific and demonstrated interest and expertise in diabetic eye disease. This helps to ensure the greatest care is provided for the health-care dollar.

The primary physician plays a fundamental role in medical management, education, and coordination of care for the person with diabetes mellitus... and should be familiar with the indications for ophthalmic care in patients with diabetes. Who is going to pay for that coordination? It is timeconsuming and tedious. If we want a professional to coordinate care, we probably need to pay for this by establishing a global fee for being a primarycare provider for a diabetic patient, or have physicians bill like lawyers on a hourly rate for these types of services, which are not currently covered by third-party payors. In an idealized system, the diabetes management physician would track the eye status of each patient, and be aware of the eye care they are or should be receiving, and attempt to ensure that it is taking place. Is there any real responsibility associated with this type of coordination? Does failure to coordinate imply liability? The financial implications of responsibility are enormous. Aside from the cost of liability insurance, once liability is established, costs escalate because of increased testing and referral. In the care of diabetic eye disease, however, responsibility may be the key ingredient to save sight. Despite increased treatment costs of between \$90 and 290 million annually, when the savings in disability payments are considered, screening for diabetic retinopathy results in a net savings of between \$62 and 109 million annually to the federal government, and between 71,000 and 85,000 yr of sight saved (4).

**GENERAL EXAM**—In referring patients for routine evaluation, the practitioners should be guided by the expertise and qualifications of the eye doctor to perform the examinations described. This statement implies that referral is the routine, almost obligatory, way of achieving the standard of care for the general exam. Although it may be true that only ophthalmologists and retina specialists, in particular, can be routinely counted on to have the skills to detect all forms of diabetic retinopathy, other individuals can be trained to provide adequate screening for potentially treatable retinopathy and at a reduced cost. Many trained optometrists claim to have these skills and cite at least one small study (7). Diabetologists, other MDs, nurses, and technicians can certainly be trained to do so (8,9). There are circumstances where screenings by individuals other than an ophthalmologist can be used. These are situations where the likelihood of finding treatable disease is small. In these cases, photographic documentation that will allow for subsequent review by an ophthalmologist is preferable. This is particularly true in rural areas that may have few professional eye care providers.

When considering the cost of ophthalmic exams, the inconvenience of seeing an additional doctor in another location, the 35% noncompliance rate for screening exams, the 22% of insulindependent diabetes mellitus in a population-based study who had never had an eye exam, and the 26% (11% with

vision-threatening retinopathy) who had not had an eye exam in 2 yr (10), it would appear to be desirable to establish effective ways of accurately screening patients for diabetic eye disease, without referral, at the site of the diabetes care provider. The advantages of this model would be numerous. There would be increased patient convenience and, hopefully, greater compliance leading to increased detection. There would be decreased cost, because a more focused and limited exam would be conducted. An ophthalmologist is capable of looking at, and is responsible for, the whole eye. Therefore, a more comprehensive examination is required than would be needed just to detect diabetic retinopathy. Although cataracts and glaucoma are more common among individuals with diabetes, cataract screening is unnecessary in the absence of visual symptoms, and examination of the optic disc while screening for retinopathy will detect most severe glaucomatous changes. Because the exam is more limited, it can be less expensive. Another advantage of retinopathy screening at the site of the diabetes care provider is that, because the diabetes care provider will be doing (and being reimbursed for) the screening, the issue of eye care and its necessity is more likely to be emphasized. Also, pathology detected by the diabetes care provider will stimulate greater emphasis on and responsibility for ensuring appropriate follow-up treatment.

Visual acuity measurement, along with ophthalmoscopy through a dilated or undilated pupil, nonmydriatic 45° photography, or mydriatic photography, are all options that might be used for retinopathy screening. All of these methods will detect retinopathy sufficiently to save sight and be cost-effective relative to the cost of visual disability. Ophthalmoscopy is the least costly for equipment, but takes the greatest training and there is no documentation. It is ~80% sensitive in detecting severe retinopathy (11). In one study, the detection of any retinopathy by internists through an undi-

lated pupil warranted ophthalmologic referral and was considered comparable to more elaborate means of screening (9). Caution should be emphasized when implementing such a program as a standard of care without replicating the ability of other internists to see retinopathy through an undilated pupil. Nonmydriatic photography takes the least training, does not require dilation, but cannot be done on about 15% of older individuals. It does require purchase of a \$12,000 piece of equipment. In those individuals in which it can be done, it is about 90% sensitive in detecting severe retinopathy (12). It may be the best alternative where trained personnel are just not available. Forty-five degree photography through dilated pupils is only slightly more sensitive, but would have fewer individuals in whom it could not be performed. Thirty degree photography would be even more sensitive; in general, it requires greater skill, more costly equipment, and a greater number of photographs. Techniques resulting in photographic images can be read by highly trained specialists in diabetic retinopathy, allowing the transfer of the highest level of expertise to the most remote places. Technological advances will soon allow instantaneous transfer of high-quality digitized images by phone line or on videodiscs to enhance potential networking even further.

The financial implications of the specific American Diabetes Association guidelines follow.

Guideline 1: All patients should be informed that sight-threatening eye disease is a common complication of diabetes mellitus and is often present even with good vision, and that early detection and appropriate treatment of diabetic eye disease greatly reduces the risk of visual loss.

The issue of responsibility and the potential impact participation of primary-care providers in screening may have in emphasizing these issues to patients are important. The role of the primary physician as a patient educator and counselor in this area cannot be over emphasized.

Guideline 2: People between 12 and 30 yr of age with a diagnosis of diabetes mellitus of at least 5 yr duration should have a baseline ophthalmic examination that includes 1) history of visual symptoms, 2) measurement of visual acuity and intraocular pressure, and 3) ophthalmoscopic examination through dilated pupils.

The likelihood of proliferative retinopathy or clinically significant macular edema is small before 10 yr of diabetes in insulin-dependent diabetes mellitus. The efficacy of screening for the rare patient with early progressive retinopathy, using alternative screening methods, should be investigated.

Guideline 3: People >30 yr of age should have baseline ophthalmic examinations, as specified in guideline 2, at the time of diagnosis of diabetes.

For the older onset patient, earlier examination is indicated. A population-based study estimates that 40% of this group are not receiving ophthalmic care (10). For this group, any nonophthalmologist screening should probably incorporate measurement of intraocular pressure that would increase the cost. For older onset patients not taking insulin, the largest group of diagnosed diabetic subjects, proliferative diabetic retinopathy is uncommon, and nonophthalmologic screening would probably result in considerable savings. In a random sample of non-insulin-dependent diabetes mellitus drawn from general practice offices, in patients without significantly elevated HbA<sub>1c</sub>, or evidence of microalbuminuria or hypertension, only 2% of those screened showed severe retinopathy warranting ophthalmologic referral. When these tests were significantly abnormal, 11% showed this level of disease (13). For older onset patients, in general, because severe disease is less common, the cost-effectiveness of any screening for treatable disease will be less, but still probably resulting in a net savings to society.

Guideline 4: After the initial eye examination, it is suggested that people

with diabetes mellitus should receive the above ophthalmic exams annually, unless more frequent exams are indicated by the presence of abnormalities.

The cost of implementing annual ophthalmic exams is high, particularly in groups where the likelihood of treatable retinopathy is small. Fifty percent of diabetic subjects are estimated to receive annual care. Implementation of this guideline could increase the cost of care by  $\geq 30\%$ . This is an important component of the program and should not be altered without careful thought. However, adult-onset patients not taking insulin without retinopathy on first exam and without evidence of poor control or other complications would probably lose little more sight if seen every 2 yr rather than annually.

Special examination guidelines should result in increased medical costs, because increasing numbers of diabetic subjects at risk for visual loss are referred for evaluation and treatment in a timely fashion.

Guideline 1: Women with insulindependent diabetes mellitus, who are planning pregnancy within 12 mo, should be examined by an ophthalmologist.

Costs for Guideline 1 in anticipation of pregnancy could be reduced through alternative screening of women with short durations of diabetes. The likelihood of severe retinopathy is small in this group and would be detected by these methods.

Guideline 2: Women with diabetes who become pregnant should have an examination for retinopathy by an ophthalmologist in the first trimester and thereafter at the discretion of the ophthalmologist.

Probably <50% of pregnant women are receiving this level of care. Implementation will, therefore, result in increased costs. Retinopathy does tend to increase during pregnancy. This may be related to attempts to improve metabolic control (14,15). When retinopathy is mild at pregnancy onset, the likelihood of visual problems is extremely small.

Guideline 3: Patients should be under the care of an ophthalmologist for 1) unexplained visual symptoms, 2) deterioration in visual acuity, 3) increased intraocular pressure, 4) any retinal abnormality, and 5) any ocular pathology that threatens vision.

It is difficult to know how many patients with these conditions are not under an ophthalmologist's care and what the true cost of implementing this guideline would be.

Guideline 4: Patients should be under the care of a retinal specialist or other ophthalmologist experienced in the management of diabetic retinopathy when the following conditions are identified: 1) preproliferative retinopathy (multiple cotton wool spots, multiple intraretinal hemorrhages, intraretinal microvascular abnormalities, venous beading), 2) proliferative retinopathy (retinal neovascularization, preretinal or vitreous hemorrhage, fibrosis, traction retinal detachment), and 3) Macular edema (hard lipid exudates and/or retinal thickening inside the temporal vascular arcades).

ETDRS data analysis suggests that early treatment before high-risk characteristics develop results in some but not marked reduction in risk of severe visual loss and may result in early moderate visual loss. What impact do these findings have on the cost-effectiveness of referring patients with less than proliferative retinopathy to definitive care specialists. Many patients will be followed for years without treatment. However, proliferative retinopathy is frequently present on detailed inspection of eyes clinically called preproliferative. The closer time of referral gets to time of treatment, the more likely vision will be lost without treatment. Early referral appears to be preferable to late treatment.

Guideline 5: Patients with functionally decreased visual acuity should undergo low-vision evaluation and rehabilitation.

Visual rehabilitation is a team effort involving ophthalmologists, optometrists, social workers, and many others. These

teamed services are not readily available to many diabetic individuals. Implementation of this guideline will result in significant cost, and the help of state and local agencies. This cost should be more than outweighed by the functional and life-style improvements afforded these patients. However, they will not necessarily result in a decrease in disability payments.

Guideline 6: Laser photocoagulation therapy reduces the risk of visual loss and is generally effective in preventing blindness in patients with high-risk proliferative retinopathy and/or clinically significant macular edema. Vitrectomy can restore vision in certain patients with recent traction retinal detachment or vitreous hemorrhage. Laser therapy and vitrectomy should be performed by a retinal specialist or other ophthalmologist experienced in these procedures in people with diabetes.

One study suggested that only about one-half of patients with high-risk retinopathy had been treated (10), implying that thorough application of these guidelines could double treatment costs. Models of care that use varying assumptions show that, even under these circumstances, significant dollar savings to society will accrue from saving sight due to savings in disability payments.

**CONCLUSIONS**—The importance of implementing standards of care for diabetic eye disease should be emphasized. Now that effective treatments are available, we must do everything we can to ensure that patients receive this treatment in a timely fashion. Available guidelines are excellent, and their implementation will result in exemplary care and should reduce visual loss from diabetic retinopathy. The American Academy of Ophthalmology is aware of the importance of implementing standards of care and has developed a major initiative, Diabetes 2000, aimed at elimination of preventable blindness from diabetes by the year 2000 through implementation of these standards.

However, in today's economic

climate, exemplary care can also be defined as the best care people are willing to pay for. It may well be that everyone is not willing to pay for implementing these standards. In some places, the resources, both in people and dollars, may not be available.

The greatest potential financial danger to these standards may be prepaid health-care groups, where there is a negative incentive to screening because it will result in more laser surgery and increased costs. These plans do not benefit from decreased disability payments. However, when comparing laser surgery to the unlasered alternative (i.e., vitrectomy surgery, glaucoma surgery, and visual rehabilitation), the economics and ethics of screening and timely laser surgery should be the right choice. To ensure this, however, low-cost screening programs may be necessary.

The financial impact of implementing guidelines for diabetic eye care is wide ranging and will greatly influence how effective these guidelines will be in reducing blindness due to diabetic retinopathy.

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