References

1. EMT Associates Inc. *San Francisco Lesbian, Gay and Bisexual Substance Abuse Needs Assessment: Executive Summary*. Sacramento, Calif: EMT Associates Inc; 1991.
2. Skinner WF. The prevalence and demographic predictors of illicit and licit drug use among lesbians and gay men. *Am J Public Health*. 1994; 84:1307–1310.
3. Skinner WF, Otis MD. Drug and alcohol use among lesbian and gay people in a southern US sample: epidemiological, comparative, and methodological findings from the Triology Project. *J Homosex*. 1996;30:59–91.
4. Yankelovich Partners. *Gay and Lesbian Consumers: Prepared for Community Focus*. Yankelovich Partners; 1996.
5. Prestage G, Kippax S, Crawford J, et al. *A Demographic and Behavioural Profile of Young Men, 25 and Under, in a Sample of Homosexually-Active Men in Sydney, Australia*. Sydney, Australia: HIV, AIDS and Society Publications; 1995. SMASH Report Series G: Report B.2.
6. Royce R, Winkelstein W. HIV infection, cigarette smoking and CD4+ T-lymphocyte counts: preliminary results from the San Francisco Men's Health Study. *AIDS*. 1990;4:327–333.
7. Elliot S. A campaign urges gay men and lesbians to resist tobacco ads. *New York Times*. June 4, 1997.
8. Goebel L. Lesbians and gays face tobacco targeting. *Tobacco Control*. 1994;3:65–67.
9. Lipman J. Philip Morris to push brand in gay media. *Wall Street Journal*. August 13, 1992.
10. Stall R, Hoff C, Coates TJ, et al. Decisions to get HIV tested and accept antiretroviral therapies among gay/bisexual men: implications for secondary prevention efforts. *J Acquir Immun Defic Syndr Human Retrovirol*. 1996;11: 151–160.
11. Derogatis L, Melisaratos N. Brief Symptom Inventory (BSI): an introductory report. *Psychol Med*. 1983;13:595–605.
12. Centers for Disease Control and Prevention. Cigarette smoking among adults—United States, 1992, and changes in the definition of current cigarette smoking. *MMWR Morb Mortal Wkly Rep*. 1994;43:894–898.
13. Centers for Disease Control and Prevention. State-specific prevalence of cigarette smoking—United States, 1995. *MMWR Morb Mortal Wkly Rep*. 1996;45:962–967.
14. Centers for Disease Control and Prevention. Cigarette smoking among adults—United States, 1994. *MMWR Morb Mortal Wkly Rep*. 1996;45:588–590.
15. Zuckerman M. *Sensation Seeking: Beyond the Optimal Level of Arousal*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1979.

The Effect of Health Education on the Rate of Ophthalmic Examinations Among African Americans With Diabetes Mellitus

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ABSTRACT

Objectives. This study evaluated a multicomponent educational intervention to increase ophthalmic examination rates among African Americans with diabetes.

Methods. A randomized trial was conducted with 280 African Americans with diabetes, enrolled from outpatient departments of 5 medical centers in the New York City metropolitan area, who had not had a dilated retinal examination within 14 months of randomization (65.7% female, mean age = 54.7 years [SD = 12.8 years]).

Results. After site differences were controlled, the odds ratio for receiving a retinal examination associated with the intervention was 4.3 (95% confidence interval = 2.4, 7.8). The examination rate pooled across sites was 54.7% in the intervention group and 27.3% in the control group.

Conclusions. The intervention was associated with a rate of ophthalmic examination double the rate achieved with routine medical care. (*Am J Public Health*. 1999;89:1878–1882)

Diabetes-related eye disease is the leading cause of new cases of blindness among adults in the United States,[1] resulting in loss of vision for an estimated 12 000 to 24 000 people[2] and generating almost $500 million in health care and associated costs annually.[3] From 1980 to 1994, race-specific, age-adjusted prevalence rates for diabetes mellitus were higher for African Americans than for Whites, and the percentage increase in age-adjusted prevalence was greater for African Americans than for Whites.[4] African Americans may have a lower quality of diabetes care[5] and suffer increased morbidity and mortality associated with diabetes compared with Whites,[6,7] including a 40% higher frequency of severe visual impairment[8] and twice the rate of blindness caused by diabetic retinopathy.[8] Most diabetes-related vision loss is due to diabetic retinopathy, a microvascular disorder of the retina[9] that to some degree eventually affects almost all people with diabetes.[10] Initial damage to the retina occurs during an asymptomatic stage,[8,11,12] but timely laser photocoagulation can prevent the extensive neovascularization, hemorrhage, and traction and detachment of the retina by adhesions that lead to loss of vision.[13–17]

Currently, the American Diabetes Association (ADA), the Centers for Disease Control and Prevention (CDC), Health Plan Employer Data and Information Set, and the US Public Health Service all support annual dilated retinal examinations for persons with diabetes. In particular, current ADA standards of diabetic eye care stipulate that all persons with type 2 (non–insulin-dependent) diabetes mellitus have an annual dilated retinal examination, beginning at diagnosis, and that individuals with type 1 (insulin-dependent) diabetes who are 10 years or older should begin to receive annual ophthalmic examinations within 3 to 5 years of diagnosis.[18]

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Nevertheless, regional[19,20] and national[5,21] data indicate that most people with diabetes do not receive annual dilated ophthalmic examinations and that African Americans may be less likely to be examined than Whites.[5] The ADA, the National Eye Institute, the American Academy of Ophthalmology, the CDC, and various local organizations have disseminated awareness programs for the general public as well as for health care providers to promote annual ophthalmic examinations. None of these programs have been formally evaluated in a randomized controlled trial.

We developed a multicomponent educational intervention to promote ophthalmic examinations among persons with diabetes and conducted a randomized controlled trial to evaluate its efficacy. Our goal was to enhance patients' motivation to receive examinations, while bolstering their ability and social support to act on that motivation.[22,23] The intervention was designed specifically for African Americans with diabetes.

Methods

General Design

The evaluation was designed as a randomized controlled trial with the individual as the unit of assignment and analysis. Diabetes patients receiving care at general medical outpatient clinics were randomized to either the control or the intervention group. The control group received routine medical care as provided by their clinic. The intervention group received routine medical care plus the educational intervention. The study outcome was documented receipt of a dilated retinal examination within 6 months of randomization.

Site Selection and Characteristics

Subjects were recruited from the general medical clinics at 5 different sites in the New York City metropolitan area. Criteria for site selection were as follows: (1) substantial African American population served; (2) on-site availability of ophthalmology services; (3) cooperation vis-à-vis access to medical records and on-site recruitment; (4) medical director's stated expectation that no independent intervention to increase rates of ophthalmic examination would be initiated during the course of the study; and (5) approval from the respective institutional review boards.

We did not formally assess "routine medical care." Each medical center had patient education services within the department of nursing and printed diabetes patient education materials available in the clinic. Three of the 5 sites also had certified diabetes educators on the staff who offered free periodic diabetes education programs.

Recruitment and Randomization

Between December 1993 and November 1995, we recruited and randomized 280 subjects. Research staff reviewed patient charts on the day of an already-scheduled clinic appointment. Eligibility criteria based on chart audits included a diagnosis of diabetes mellitus, being African American, being 18 years or older, having no documentation of a dilated retinal examination in the preceding 14 months, and having been seen at the clinic at least 1 other time in the past year. Prospective subjects were approached about participating in a study of the effectiveness of an educational intervention to prevent complications of diabetes.

Interested patients were interviewed about personal and demographic characteristics; recent eye, foot, and nutrition screening; and current telephone number. Exclusionary criteria included blindness in both eyes, advanced eye disease such as macular edema or proliferative diabetic retinopathy, progressive medical illness in which death was expected within approximately 2 years, impaired cognitive or functional ability, and stated intention to move from the area during the next 2 years. Written informed consent was obtained from interested individuals who met the eligibility criteria. After research staff confirmed that subjects could be reached by telephone, they were enrolled and randomized within site and sex groups. We randomized subjects in pairs by using tables of random permutations.[24]

Intervention

The intervention developed specifically for this study had 3 components: a low-literacy, 9-page color booklet,[25] a motivational videotape,[26] and semistructured telephone education and counseling. The booklet and videotape were mailed immediately following randomization; both were entitled *The World Is a Beautiful Place to See.* The booklet was didactic in nature, addressing 2 main points: (1) What is diabetic retinopathy? and (2) What can you do about diabetic retinopathy? The booklet emphasized that people with diabetes should have a dilated eye examination at least once every year. The videotape used emotional appeals through storytelling to increase motivation to have a yearly dilated retinal examination. A cover letter encouraged participants to read the booklet and watch the videotape.

The telephone outreach was initiated approximately 1 week after the mailing. Using a semistructured protocol, the health educator (C.J.H.) offered one-on-one, interactive education and counseling. Having established rapport, she worked to identify and understand each subject's reasons for and/or barriers to having a dilated retinal examination. Focused problem-solving then guided the subject toward making an informed choice about receiving an ophthalmic examination. The initial goal was to elicit a verbal commitment to schedule an eye examination. Progress toward actual receipt of the examination was monitored with follow-up calls. Individually tailored mailings of tip sheets provided practical strategies for overcoming specific barriers. When a subject reported having a dilated retinal examination, a congratulatory letter was sent. Subjects were encouraged to go for an examination each year. Phone calls continued until an examination was reported or 6 months had passed, whichever came first. The median number of calls was 4 and the median time spent was 53 minutes per person. Intervention implementation was documented in detailed monitoring logs.

Subjects in the control group were mailed an ADA meal-planning booklet.[27] Six months after randomization, control subjects were sent the intervention booklet along with a cover letter urging them to consult their physician if they had not had a dilated eye examination in the past year.

Outcome Measures

The main study outcome was a documented dilated retinal examination within 6 months of randomization. Research staff, unaware of subjects' group assignment, audited medical records. Clinical results of eye examinations were also recorded. Six months after randomization, all subjects were interviewed by telephone. If they reported being examined outside the recruitment site, written verification from the outside provider was sought. Definitive outcome assessments were completed for 273 subjects (97.5%). There were 26 written verifications from outside providers. For 7 subjects (3 in the intervention group and 4 in the control group), we were unable to obtain either the follow-up chart review (n = 2) or the requisite outside verification (n = 5). These 7 were classified as not receiving a dilated eye examination, regardless of the examination status reported in the telephone interview.

Data Analysis

Analyses were performed on an intention-to-treat basis; i.e., all subjects in the intervention group were assumed to have received a full dose of the intervention. Stepwise logis-

tic regression was used to identify predictors of examination status. Possible predictors were intervention status, age, duration of diabetes, sex, receipt of Medicare or Medicaid, education, employment, marital status, and income, as well as all corresponding interaction terms (i.e., intervention by demographic variable). Site effects for the n = 5 sites were controlled by forced entry of n – 1 = 4 dummy variables. Stepwise logistic regression was also used to identify predictors of examination status within the intervention and control groups separately. Computations were performed on a personal computer with SPSS/PC+ software.[28]

TABLE 1—Baseline Personal and Demographic Characteristics of 280 African Americans With Diabetes Mellitus Randomized to Intervention and Control Groups: New York Metropolitan Area, 1993–1995

	Intervention Patients (n = 137)	Control Patients (n = 143)
Male, %	34.3	34.3
Married, %	33.6	29.4
Unemployed, %	73.0	65.7
Completed high school, %	43.8	50.7
Receives Medicaid, %	43.0	41.1
Receives Medicare, %	22.4	21.1
Insured, %	70.1	67.8
Family income < $10 000, %	69.1	64.8
Mean age, y (SD)	55.6 (12.9)	53.9 (12.8)
Mean duration of disease, y (SD)	8.1 (7.4)	7.8 (7.3)

Results

Characteristics of the Sample

Eligibility was assessed for 1569 individuals. The main reasons for exclusion were as follows: dilated retinal examination within the preceding 14 months (n = 569), advanced eye disease (n = 169), specified medical or psychiatric problem (n = 130), and limited access to a telephone (n = 79). Thirty-eight individuals refused to participate. A total of 137 subjects were randomized to the intervention group and 143 to the control group. There were no significant differences between groups on any of the available personal and demographic variables (Table 1). The intervention was completed with 130 subjects (94.9% of those assigned to the experimental group). Four subjects could not be reached, and 3 refused calls at the very outset of the intervention process. Figure 1 shows subject flow through the

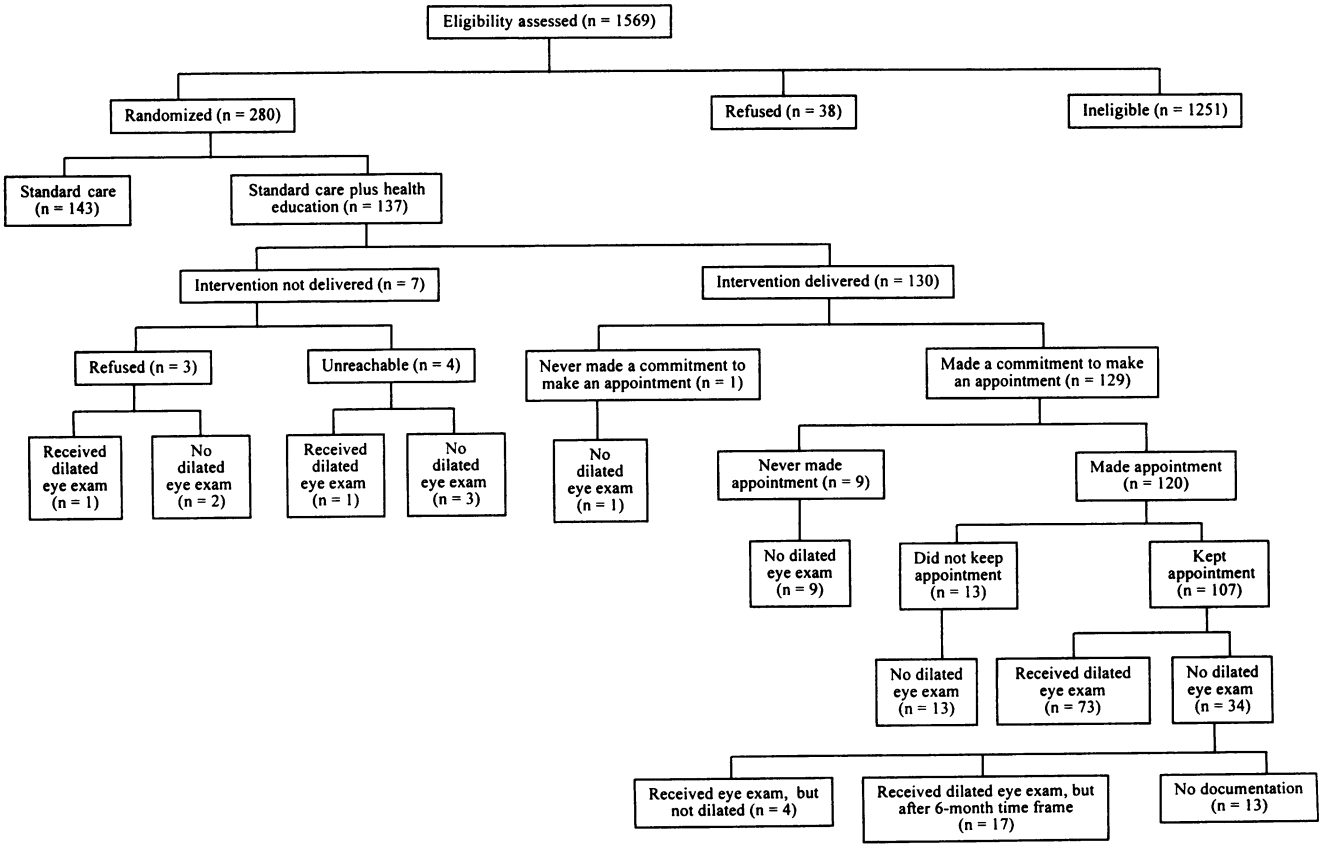

FIGURE 1—Flow of subjects through a randomized controlled efficacy trial of an educational intervention to increase rates of ophthalmic examination among metropolitan New York African Americans with diabetes mellitus: eligibility assessment to outcome measurement.

study from eligibility assessment to recruitment to 6-month follow-up.

Outcome Data

Site variables ranged in significance from $P = .07$ to $P < .001$. With the site variables included, the odds ratio for examination status associated with receiving the intervention was 4.3 (95% confidence interval [CI] = 2.4, 7.8). No other variables entered the equation. In the intervention group, no variables other than site predicted examination. In the control group, sex was a significant predictor: the odds ratio associated with being male was 0.3 (95% CI = 0.1, 0.9).

Discussion

This study demonstrates that a patient-targeted educational intervention can substantially increase rates of examination for ophthalmic complications of diabetes. The odds ratio for examination status 6 months after randomization associated with the intervention was 4.3. The examination rate calculated by totaling across study sites was 54.7% in the intervention group and 27.3% in the control group. There are no published reports of comparable success with other interventions.

Legorreta and colleagues[29] assessed the impact of a patient- and provider-targeted "reminder" intervention among adult diabetic patients in a large, network-based health maintenance organization. Patients (n = 19397) received educational materials and a report on their most recent dilated eye examination. Providers received a copy of the current ADA guidelines, a list of their own patients due for examination, and labels and a form letter to send to these patients. Postintervention rates of retinopathy examination, as documented by billing-claims data, were 27% higher than in the preintervention calendar year. The authors concluded that the intervention would likely need regular repetition to have a major impact in this population. A study by Brooks and colleagues,[30] with an almost identical intervention, produced similar results.

Newcomb, Klein, and Massoth[31] reported on a controlled intervention study of older-onset diabetes patients. The intervention group received educational materials and a report on their past dilated eye examinations. Examination results were also forwarded to primary care providers. Posttest levels of ophthalmic examinations, visual impairment, and knowledge of retinopathy were similar between the intervention and control groups. The authors concluded that a more intensive intervention was needed.

In our study, almost 75% of the control group and nearly 50% of the intervention group did not receive an examination within 6 months of randomization. Rates of ophthalmic examination for persons with diabetes are unacceptably low nationwide,[5,21] even among groups with ready access to medical care.[29–32] Just under half (49%) of 2405 individuals with diabetes responding to the 1989 National Health Interview Survey reported having a dilated eye examination in the preceding year.[21] A study in a large, network-based health maintenance organization, which analyzed 1993 and 1994 claims from ophthalmologists and optometrists, reported only 20% of patients with diabetes receiving a retinal examination.[29] The discrepancy in examination rates between these 2 studies suggests that self-reports may be inflated. In our population of low-income African Americans, just over one third of those considered for enrollment had received an ophthalmic examination in the past 14 months. This rate is consistent with that from a recent survey of Medicare recipients.[5]

Focusing on high-risk subgroups is a valid strategy for improving overall rates, but the fact that all population subgroups are underexamined suggests that this intervention could profitably be adapted for other, more diverse settings. To have real public health significance, the intervention, or its components, would have to be disseminated on a broad scale. A logical next step would be to investigate the relative costs and effectiveness associated with each intervention component in a larger medical setting, including managed care, and to assess the effect on preventing loss of vision.

Identification of those most and least likely to be influenced by the intervention would guide adaptation of the intervention to specific subgroups.[33,34] Of particular interest are subgroups that are most resistant to change. A common reason for not scheduling or keeping an eye appointment was an acute health problem that took precedence over preventive care. Other barriers mentioned during the telephone outreach included family crisis, lack of time, and inclement weather. Our data suggest that males may be less likely to be examined under usual-care circumstances (odds ratio = 0.3 for being examined in the control group), but we do not have the statistical power to properly address the effect of sex on the intervention's results.

The ultimate goal of this intervention is to promote sustained annual examination for ophthalmic complications of diabetes. A drawback of our study is that follow-up was limited to 6 months after randomization. However, controlled trials aimed at implementing care standards should be of brief duration so as not to jeopardize delivery of care to the control group.

To achieve the revised Year 2000 and Year 2010 Goals of the US Public Health Service, and to fully realize the benefits of sophisticated treatment technology, rates of ophthalmic examination must rise. Our intervention was associated with an odds ratio of 4.3 for receiving a documented dilated eye examination 6 months after randomization in a sample of low-income African Americans with diabetes. This intervention approach merits further dissemination and evaluation to assess its generalizability. □

Contributors

C. E. Basch directed the study and was involved in all phases of planning and implementing design and analysis methods and in preparing the manuscript. E. A. Walker codirected the study and worked closely with Dr Basch in all aspects of the study, including manuscript preparation. C. J. Howard assisted in conceptualizing the intervention methods and materials and conducted the interactive education and counseling by telephone. H. Shamoon assisted in designing the study, provided medical oversight throughout, and participated in writing the manuscript. P. Zybert assisted in designing the study, performed randomization of participants, managed and analyzed data, and assisted in writing the manuscript.

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References

1. Klein R, Klein BEK. Vision disorders in diabetes. In: Harris MI, ed. *Diabetes in America.* 2nd ed. Bethesda, Md: National Institutes of Health; 1995:293–338. DHHS publication 95-1468.
2. Marks JS. *Unrealized Prevention Opportunities: Reducing the Health and Economic Burden of Chronic Disease* [report]. Atlanta, Ga: Centers for Disease Control and Prevention; March 1997.
3. Javitt JC, Aiello LP, Chiang Y, Ferris FL, Canner JK, Greenfield S. Preventive eye care in people with diabetes is cost saving to the federal government. *Diabetes Care.* 1994;18: 909–917.
4. Centers for Disease Control and Prevention. Trends in the prevalence and incidence of self-reported diabetes mellitus—United States, 1980–1994. *MMWR Morb Mortal Wkly Rep.* 1997;46:1014–1018.
5. Chin MH, Zhang JX, Merrell K. Diabetes in the African-American Medicare population. *Diabetes Care.* 1998;21:1090–1095.

6. Tull ES, Roseman JM. Diabetes in African Americans. In: Harris MI, ed. *Diabetes in America.* 2nd ed. Bethesda, Md: National Institutes of Health; 1995:613–629. DHHS publication 95-1468.
7. Centers for Disease Control and Prevention. Mortality patterns—United States, 1993. *MMWR Morb Mortal Wkly Rep.* 1996;45: 161–163.
8. National Institute of Diabetes and Digestive and Kidney Disease, National Institutes of Health. *Diabetes in African Americans.* Washington, DC: US Dept of Health and Human Services; 1997. NIH publication 97-3266.
9. Brownlee M. Advanced products of nonenzymatic glycosylation and the pathogenesis of diabetic complications. In: Porte D, Sherwin RS, eds. *Ellenberg and Rifkin's Diabetes Mellitus.* 5th ed. Stamford, Conn: Appleton & Lange; 1997:229–245.
10. Klein R, Klein BEK, Moss SE. Visual impairment in diabetes. *Ophthalmology.* 1984;91:1–9.
11. Bursell SE, Clermont AC, Kinsley BT, Simonson DC, Aiello LM, Wolpert HA. Retinal blood flow changes in patients with insulin-dependent diabetes mellitus and no diabetic retinopathy. *Invest Ophthalmol Vis Sci.* 1996;37:886–897.
12. Cogen DG, Toussaint D, Kuwabara T. Retinal vascular patterns, IV: diabetic retinopathy. *Arch Ophthalmol.* 1961;66:100–112.
13. Klein R, Moss SE, Klein BEK. New management concepts for timely diagnosis of diabetic retinopathy treatable by photocoagulation. *Diabetes Care.* 1987;10:633–638.
14. Early Treatment Diabetic Retinopathy Study Research Group. Techniques for scatter and local photocoagulation treatment of diabetic retinopathy. ETDRS report 3. *Int Ophthalmol Clin.* 1987;27:254–264.
15. Diabetic Retinopathy Study Research Group. Indications for photocoagulation treatment of diabetic retinopathy. DRS report 14. *Int Ophthalmol Clin.* 1987;27:239–253.
16. Early Treatment Diabetic Retinopathy Study Research Group. Early photocoagulation for diabetic retinopathy. ETDRS report 9. *Ophthalmology.* 1991;98:766–785.
17. Klein R, Klein BEK. Diabetic eye disease. *Lancet.* 1997;350:197–204.
18. American Diabetes Association. Diabetic retinopathy: position statement. *Diabetes Care.* 1998;21:157–159.
19. Wylie-Rosett J, Basch C, Walker E, et al. Ophthalmic referral rates for patients with diabetes in primary care clinics located in disadvantaged communities. *J Diabetes Complications.* 1995; 9:49–54.
20. Witkin SR, Klein R, Jensen SC. Ophthalmologic care for people with diabetes. *JAMA.* 1984;251:2531–2534.
21. Brechner RJ, Cowie CC, Howie J, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. *JAMA.* 1993;270:1714–1718.
22. Green LW, Kreuter MW. *Health Promotion Planning: An Educational and Environmental Approach.* 2nd ed. Mountain View, Calif: Mayfield Publishing Company; 1991.
23. Prochaska JO, Redding CA, Evers KE. The transtheoretical model and stages of change. In: Glanz K, Lewis FM, Rimer BK, eds. *Health Behavior and Health Education.* 2nd ed. San Francisco, Calif: Jossey-Bass; 1997:60–84.
24. Fleiss JL. *The Design and Analysis of Clinical Experiments.* New York, NY: John Wiley & Sons Inc; 1986.
25. Basch CE, Walker EA, Resnicow K, et al. *The World Is a Beautiful Place to See: An Eye Care Book for African Americans With Diabetes.* New York, NY: Brown Communications; 1993.
26. Fireman M, Basch CE, Walker EA, Howard CJ, Soet JE, Bogart JS. *The World Is a Beautiful Place to See: A Video.* New York, NY: Boulevard Productions; 1993.
27. American Diabetes Association and American Dietetic Association. *Exchange Lists for Meal Planning.* Alexandria, Va: American Diabetes Association; 1989.
28. Norusis MJ. *SPSS/PC+ 4.0 Base Manual for the IBM/XT/AT and PS/2.* Chicago, Ill: SPSS Inc; 1990.
29. Legorreta AP, Hasan MM, Peters AL, Pelletier KR, Leung K-M. An intervention for enhancing compliance with screening recommendations for diabetic retinopathy. *Diabetes Care.* 1997;20: 520–523.
30. Brooks RJ, Legorreta AP, Silver AL, Fabius RJ, Krakovitz J. Implementing guidelines for eye care of diabetic patients: results from an HMO intervention study. *Am J Managed Care.* 1996;2: 365–369.
31. Newcomb PA, Klein R, Massoth KM. Education to increase ophthalmologic care in older onset diabetes patients: indications from the Wisconsin Epidemiologic Study of Diabetic Retinopathy. *J Diabetes Complications.* 1992;6:211–217.
32. Moss SE, Klein R, Klein BEK. Factors associated with having eye examinations in persons with diabetes. *Arch Fam Med.* 1995;4:529–534.
33. Walker EA, Basch CE, Howard CJ, Kromholz WN, Zybert PA, Shamoon H. Incentives and barriers to retinopathy screening in African Americans with diabetes. *J Diabetes Complications.* 1997;11:298–306.
34. Walker EA, Wylie-Rosett J, Shamoon H, et al. Program development to prevent complications of diabetes: assessment of barriers in an urban clinic. *Diabetes Care.* 1995;18:1291–1293.