Interventions Among Primary-Care Practitioners to Improve Care for Preventable Complications of Diabetes

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The National Diabetes Advisory Board recommends that diabetes prevention and control programs focus on the preventable complications of diabetes, i.e., visual impairment, lower-extremity problems, renal problems, ketoacidosis, and adverse outcomes of pregnancy. The Florida Diabetes Control Program chose to focus its efforts on the first three of these complications at the federal- and state-funded primary-care programs in Florida because these programs had access to targeted, public-sector patients and because of fiscal restraints that make the care provider the logical source of entry to the health-care system. This study sought to document the current level of care for complications of diabetes in primary-care settings, provide state-of-the-art professional education along with patient education, and evaluate changes in practice habits. Three intervention and three control primary-care centers were selected. Medical records in each center were reviewed over a 2-yr period. At intervention sites, retinopathy referrals increased from 9 to 43% ($P < .001$), urinalyses increased from 69 to 94% ($P < .001$), and examinations of lower extremities increased from 66 to 94% ($P < .001$). There were no such changes in the control sites. Hypertension was diagnosed in nearly two-thirds of patients, and a last blood pressure of >140 mmHg systolic or >90 mmHg diastolic was present in 64% of the intervention group at yr 1 and declined to 56% at yr 2 ($P < .05$). The following problems were identified. *1)* Despite referrals to ophthalmologists approaching 100%, the actual rate of compliance was only 43%. *2)* Significant hypertension existed after intervention. *3)* The clinic drop-out rate was 37% after only 1 yr. This study documents the actual care delivered in this sector of medicine and the willingness of providers to change practice habits to comply with recommended standards.
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The primary prevention of diabetes is a desirable goal, but the prevention of the disease's numerous complications remains the cornerstone of most diabetes prevention and control programs. The National Diabetes Advisory Board (NDAB) recognized the need to reduce the morbidity and mortality resulting from diabetes. Consequently, NDAB convened a conference in 1980. The focus was on five major complications: visual impairment, adverse outcomes of pregnancy, lower-extremity and kidney problems, and ketoacidosis. It was felt at that time that many patients could materially benefit from an effective transfer of research findings to the health-care provider. *The Prevention and Treatment of Five Complications of Diabetes: A Guide for Primary Care Practitioners* (*Guide*) was the result of that conference (1). The *Guide* was produced and distributed by the Centers for Disease Control from 1983 to 1984 and is generally recognized as the first national consensus document on diabetes patient-care and education protocols.

In late 1983, the American Diabetes Association developed a clinical education program (CEP) for practitioners. The topic was type II (non-insulin-dependent) diabetes. Included in the program was a major section about prevention and treatment of complications (2). This section occupied ~2 h of the meeting. As an adjunct to this program, an evaluation component was implemented to follow the participants' delivery of care after the CEP and to compare data collected before the program. The study's poignant, yet overwhelming, finding was the suggestion that primary-care providers were

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not delivering adequate levels of care for the preventable complications of diabetes. Perhaps more significant, however, was the study's conclusion that these participating practitioners were willing to change their practice habits once peer-derived protocols were clearly outlined and demonstrated (3).

Because primary-care physicians seemed to be willing to initiate practice changes based on a single workshop, the Florida Diabetes Control Program (DCP) wanted to be certain of the foundation of its strategy of introducing the tenets of the *Guide* before initiating statewide efforts to alter diabetes care and education in all primary-care sites operated by state and/or federal funds. The DCP therefore first sought to adequately determine and describe the current level and patterns of care related to complications of diabetes in primary-care centers in Florida and follow this description with an intervention designed to change care patterns. Data gathered in this three-site study would direct the design or alteration of specific and statewide programs. The data would also form a baseline for evaluation of change in professional behavior over time.

METHODS

Medical records were audited in 6 of the 27 federally funded primary-care centers in Florida. The 3 centers with the most diabetic patients, as evidenced by encounter reporting, were asked to participate in this intervention. All accepted. The 3 intervention sites consisted of 2 rural centers serving a significant number of migrant individuals and an urban health department. The control sites were the centers with the next largest number of diabetes encounters matched in order that 1 be urban and the other 2 be rural and serve migrant patients. The 3 control sites consisted of an urban teaching hospital's primary-care center and two rural primary-care centers. The use of control sites was deemed necessary to determine the degree of change of care patterns and levels at non–model-implementation centers. This was fundamental in ascertaining the influence on care at those centers by other factors such as staff training obtained outside the intervention program.

All medical records at the intervention sites with any diagnosis of diabetes were identified. Records at the intervention sites were audited at the beginning of the program, and follow-up data were collected after 1 yr of project activity. Records at the three control sites were audited once, but data were collected for patient care in the calendar years 1984 and 1985, which is the same period as the data covered for the intervention centers. This data was collected as two separate data files. For this phase of the study, all records with at least one visit in each of 2 consecutive yr were defined as eligible for review.

A procedural manual and a standardized data-collection instrument were developed. The nurse coordinator from the three intervention sites and DCP professional staff were trained to perform chart audits. As an additional measure to ensure audit standardization and to verify data validity, each auditor's work was sampled by another auditor. This involved a random sample of 25 records per site. Data were compared for item agreement. The correlation rate was 98%.

Data collected included patient demography, duration of diabetes, treatment method, weight change in past year, and documentation in the patient record of examination within the last 12 mo for retinopathy, nephropathy, hypertension, and lower-extremity problems. Appropriate referrals to specialists were noted. Referral to a specialist was defined as a record in the chart documenting a visit to a specialist. In addition, nutrition and diabetes education were recorded.

For each complication, the recommendations of the *Guide* were used as the standard. For retinopathy, a history of problems, a dilated fundal examination, a referral to an ophthalmologist, and the extent of problems were noted. For nephropathy, a urinalysis, the presence of proteinuria, and the measurement of blood urea nitrogen (BUN) and creatinine were recorded. For lower-extremity care, a history of problems, an examination of the lower extremities, and the indicated pathology were recorded. Hypertension was also included because of its relationship to the above complications. Regardless of whether a measurement of blood pressure was recorded, the diagnosis of hypertension, treatment method, auditor's assessment of patient blood pressure control, and last blood pressure reading for the year were recorded.

Interventions for the primary-care staff were activities that the DCP felt it could afford to institute statewide if proven successful. The program consisted of, first, the identification of a specific nurse to serve as liaison and coordinator for the diabetes program at each intervention center. Professional education was the second component that consisted of 2 days of seminars for professional staff of the intervention centers at one of Florida's Diabetes Research, Education, and Treatment Centers; this education program focused on diagnosis and treatment of the five preventable complications of diabetes as defined in the *Guide*. Each intervention center sent its chief physician, one staff physician, nurses, and dietitians. The third component was quarterly consultation with program staff of the Florida DCP. The consultation provided ongoing encouragement and opportunities to solve problems. The final component, although not expressly designed for professionals, consisted of a packet of education modules targeted at the preventable complications of diabetes. These modules served as a nidus for patient-education programs. Each intervention center set up a patient-education program that utilized the modules but was directed as an individualized form of instruction.

Data were entered into a microcomputer (Apple Macintosh). Statistical analysis was performed with an available package (Statview, Brainpower, Calabasas, CA).

Statistical significance was tested with unpaired t tests and χ^2-analysis and defined at $P < .05$ level.

RESULTS

The intervention sites consisted of clinics with an average of 35,000 patient encounters. For control sites, the average number of visits was 25,000. The staff consisted of family physicians, internists, pediatricians, and obstetricians. The average number of physicians was eight, and three were National Health Service Corps assignees. Five of the physicians were internists or family physicians. The only difference for control sites was that the average number of physicians was six, and two were assigned by the government.

At the three intervention sites, 648 cases were identified and reviewed in the 1st yr and represent a census of active records of patients with diabetes at the time of the survey. At the end of the 2nd yr, 600 records were available, but among these, 399 were for patients followed for the 1st and 2nd yr. This means that 249 patients from the first census were no longer active (defined as seen during the year), and 201 new patients were seen during the year.

At the three control sites, the same sort of patient turnover seemed apparent. There were 381 records available for review during the 1st yr, but only 237 of the patients were seen during the 2nd yr.

Because we were interested in the changes in healthcare delivery over time, we have chosen to analyze and present the data from individuals followed for at least 2 yr from the intervention and control centers. The mean age of patients at the intervention sites was 60.1 yr. Thirty-three percent were male. Of the intervention population, 32% were White, 45% were Black, and 23% were Hispanic. Duration of diabetes in the total population was 10.4 yr.

The mean age of patients at control sites was 57 yr. Twenty-four percent were male. Of the control population, 29% were White, 53% were Black, and 18% were Hispanic. Duration of diabetes in the control population was 8.4 yr. The mean age, duration of diabetes, and sex distribution of the populations were different at the .05 level.

Treatment at the intervention sites for the 1st yr consisted of 43% of patients on insulin, 48% on oral agents, and 8% treated with diet alone. For the control sites, therapy was similar, with 48% on insulin, 42% on oral agents, and 9% on diet alone.

Complication-related care at both intervention and control sites was recorded for retinopathy, nephropathy, and lower-extremity care (Tables 1 and 2). Hypertension was included because of its relationship to all three complications.

At the intervention sites, 28% of records for yr 1 contained data that documented queries regarding visual problems, whereas at the control sites, only 5% had data to support such a query (χ^2 $P < .001$ for intervention vs. control). This rate improved to 38% at the intervention sites and only to 7% at the control sites in yr 2 (χ^2 $P < .01$ for intervention yr 2 vs. yr 1 and control). Forty-five (11%) records at intervention sites described a fundal examination, but dilation of the pupil was not a listed factor. Twenty-four percent of control-site patients were actually examined, but there also, no evidence of dilation was provided (χ^2 $P < .001$ for intervention vs. control). This rate improved to 46% at the intervention sites and remained essentially the same at 23% at the control sites in yr 2 (χ^2 $P < .001$).

TABLE 1
Documentation of search for complication in clinical record

	Intervention group (n = 399)		
	yr 1	P value	yr 2
Retinopathy			
History	114 (28)	<.01	152 (38)
Exam	45 (11)	<.001	187 (46)
Referral	34 (9)	<.001	168 (43)
Nephropathy			
Urinalysis	277 (69)	<.001	379 (94)
If urinalysis then proteinuria	85 (30)	NS	124 (32)
If proteinuria then BUN/creatinine	60 (71)	NS	88 (71)
Lower-extremity care			
History	182 (45)	<.001	289 (73)
Exam	123 (66)	<.001	372 (94)
Hypertension			
Blood pressure taken	399 (100)	NS	399 (100)
Hypertension diagnosed	262 (66)	NS	268 (68)
Last blood pressure reading			
>140 or >90 mmHg	257 (64)	<.05	225 (56)
>160 or >95 mmHg	85 (21)	NS	68 (17)

Values for yr 1 and 2 are number of observations with percentages in parentheses. (From the Florida Diabetes Control Program, Primary Care Complications Program.)

For the most important factor, i.e., referral to an ophthalmologist, 9% of the intervention population had such a referral or a consult letter on the record after yr 1, whereas at control sites, 21% were referred to an ophthalmologist (χ^2 $P < .001$ for intervention vs. control). After yr 2 this rate improved to 43% at the intervention sites compared to 33% at the control sites (χ^2 $P < .01$ for both intervention and control). The nurses did report that all patients at the intervention sites were specifically instructed to see an ophthalmologist.

Because the control sites consisted of a federally funded primary-care clinic in a teaching hospital and two federally funded and rurally located primary-care centers, the data were further divided and analyzed. During the 2nd yr, only 6% of the patients at the teaching hospital had retinal examination by primary-care physicians, compared to 40% at the rural primary-care centers (χ^2 $P < .001$). Thirty-eight percent of patients were referred for this exam at the teaching hospital, compared to 5%

TABLE 2
Documentation of search for complication in clinical record

	Control group (n = 237)		
	yr 1	P value	yr 2
Retinopathy			
History	12 (5)	NS	17 (7)
Exam	58 (24)	NS	55 (23)
Referral	49 (21)	<.01	78 (33)
Nephropathy			
Urinalysis	152 (64)	NS	141 (59)
If urinalysis then proteinuria	48 (31)	NS	42 (30)
If proteinuria then BUN/creatinine	38 (81)	NS	34 (80)
Lower-extremity care			
History	25 (11)	<.05	40 (17)
Exam	64 (27)	<.05	97 (41)
Hypertension			
Blood pressure taken	232 (99)	NS	236 (99)
Hypertension diagnosed	143 (60)	NS	152 (64)
Last blood pressure reading			
>140 or >90 mmHg	91 (38)	<.01	119 (50)
>160 or >95 mmHg	48 (20)	NS	47 (20)

Values for yr 1 and 2 are number of observations with percentages in parentheses. (From the Florida Diabetes Control Program, Primary Care Complications Program.)

at the rural primary-care centers (χ^2 $P < .001$). For the urban intervention center the referral rate was 38%, compared to 44% for the two rural centers.

For yr 1, a urinalysis was available for 69% of the patients at intervention sites and 64% at control sites. Proteinuria among those with a recorded urinalysis was reported in 30% of the charts at the intervention sites and 31% of the charts at the control sites. For the 2nd yr, proteinuria was 32 and 30% at the intervention and control sites, respectively. Of those with proteinuria, 71% at the intervention sites and 81% at the control sites had BUN and creatinine recorded. This rate remained unchanged at 71 and 80% for the 2nd yr. Because one standard in the *Guide* calls for BUN and creatinine only if there is protein, another measure of performance is unnecessary laboratory tests. The *Guide* called for 124 BUN/creatinine tests in yr 2 at the intervention centers because of proteinuria. Eighty-eight (71%) of those patients needing the test actually received it, and 36 did not. Because a total of 207 patients had the test, 119 patients had the test who did not need it.

Lower-extremity care was defined as documentation of inquiry about problems with the feet and examinations of the feet and lower extremities. At the intervention sites, 45% documented inquiry, and 66% indicated an examination of the lower extremities was performed during the 1st yr. Documentation of questioning regarding lower-extremity problems was obtained at control sites only 11% of the time, and lower extremities were actually examined only 27% of the time (χ^2 $P < .001$ for intervention vs. control for history and examination of lower extremities). For the 2nd yr, history and examination increased at the intervention sites to 73% showing history taken and 94% having received an examination, compared to 17% histories taken and 41% examined at control sites (χ^2 $P < .001$ for history and exam).

Blood pressure was nearly universally recorded in yr 1 and yr 2. Intervention sites recorded blood pressure 99% of the time, whereas control sites recorded it in 98% of the charts reviewed. Hypertension was diagnosed for 66% of the patients at intervention sites and 60% at control sites in yr 1 and 68% of the intervention sites and 64% of the control sites in yr 2. Among patients diagnosed as hypertensive, a last recorded blood pressure measurement of ≥160 mmHg systolic or ≥95 mmHg diastolic was documented for 21% of intervention-site patients and 20% of control-site patients. The 2nd yr, 17% of intervention-site patients had the same last measured blood pressure as in yr 1 compared to 20% of control patients. For milder hypertension, i.e., ≥140 mmHg systolic or ≥90 mmHg diastolic, the intervention group proportion decreased from 64 to 56%, whereas the control group increased from 38 to 50% (χ^2 $P < .01$ for both intervention and control groups).

Because of the nature of the review at the control centers (retrospective) and the high drop-out rate noted [144 (38%) of 381], the staff at the intervention centers were asked to ascertain, as far as possible, the outcomes for all their patients. Two of the centers with 449 of the original patients were able to follow up on clinic drop-outs. After 1 yr, 164 (37%) patients were no longer active at the clinics. Sixteen had died, 60 had transferred to another clinic, health-maintenance organization, or private physician, and 88 were lost to any follow-up. For those lost to follow-up, there was no difference in age, race, sex, duration of diabetes, or treatment compared with those followed the 2nd yr.

DISCUSSION

The focus of diabetes control programs (secondary prevention) is essentially determined by the lack of effective primary prevention efforts such as most weight control programs for type II diabetic patients and the still limited effectiveness of experimental immunosuppressive therapy in type I (insulin-dependent) diabetic patients (4,5).

Conversely, good data exist that demonstrate the effectiveness of secondary prevention efforts (4–13). The validity of these secondary prevention activities was affirmed by NDAB's development of national consensus protocols.

The Florida DCP chose to implement the NDAB *Guide* in state and federally funded primary-care centers. The most cost-effective target of the DCP efforts was determined to be the health-care professional. The DCP ap-

proach was based on a belief that examination for complications is the necessary first step in the recognition and treatment for the reduction of morbidity and mortality. A patient-education component was also established on NDAB guidelines at intervention sites because we felt the patient needed to participate in the overall structure of care.

The record review before intervention substantiated the need to improve the quality of care delivered to those people with diabetes. The data suggest a gap in the care and/or documentation of care offered to people with diabetes by the public-health sector. The distinction between care and the documentation of care was not made, because a practitioner must know *1*) whether a proper fundal examination, for example, was delivered and *2*) when it was delivered, so an annual reexamination can be performed on schedule. Failure to document leaves the physician with no information.

Retinal examination was the least adequately provided of the NDAB required examinations. This is not surprising because for most physicians, the proper examination of the fundus with dilation is a difficult task at the primary-care level. Although this rate improved significantly, over half the patients at the intervention sites, despite being urged by clinic staff to obtain ophthalmologic consultation, failed to receive this vital service. Referral to an ophthalmologist is the logical option, but for the public-health population, it is an option rarely taken. Although perhaps not surprising, there is nevertheless some irony in this fact because blindness from retinopathy is the one complication shown in a controlled clinical trial to be delayed or prevented by proper medical attention (11). Reasons for lack of proper care and referral may be financial, because of the need for the patient to pay for visits to specialists or difficulty in arranging for the patient to physically travel to the specialist. The teaching hospital used as a control site did have a much larger proportion of patients referred for visual examinations. The proximity of an ophthalmologist on staff is the most likely reason for the higher rate of referral.

These same teaching-hospital physicians documented examination of lower extremities in only 5% of patients. This compares with ~50% documentation of examination in the other control sites during yr 1. The intervention centers had a 66% examination rate for lower-extremity problems. Both increased during yr 2, but the differences in the control centers persisted. The differences are difficult to explain without further investigation.

The proportion of hypertensive patients is not surprising, but the number with a last blood pressure reading of 140/90 mmHg, indicative of hypertension despite therapy, and another fraction that essentially remained unchanged with a last measurement of 160/95 mmHg is cause for considerable concern. This rate is clearly unacceptable. Problems may include lack of funds to purchase necessary but frequently expensive medicines.

The observed levels of monitoring for complications are similar to those reported by Adamson and Gullion (14). Their study also attempted to influence physician behavior by providing tutorials in proper care for complications. The methods included patient surveys that may have biased the type of physician willing to participate. However, the rates of complication monitoring were no different than for DCP-study patients. Adamson and Gullion attribute the increase in foot care to their program, but the DCP observed similar rates of examinations of lower extremities in the intervention sites before the intervention activities. This might be explained by the presence of a general emphasis of complication prevention by the Centers for Disease Control and the American Diabetes Association's CEP offered during the 2 yr before this study.

Perhaps one of the least expected yet most significant aspects of this study was the number of patient participants lost to tracking after the initial record review. The finding is similar to that reported in a study of family-practice residency teaching programs (15). Because simple demography and information about the patients' diabetes did not predict continued clinic follow-up, the finding has two implications. *1*) Patients who are under the care of the public-health system are often transient and therefore should be offered the full range of services as if the practitioner expects never to see the patient again. *2*) Evaluative programs that seek to track patients for the purpose of long-range determination of morbidity and mortality are going to be difficult to conduct. This leads to an epidemiologically useful conclusion: the population served by these centers cannot be used for long-term studies without significant cost increases and improved tracking abilities.

The findings of this study confirm the importance of reaching the primary-care physician and professionals who work with the physician to improve the search for treatable complications of diabetes. The findings indicate the ability of the DCP to significantly improve complications-related care but also document significant barriers that must be overcome, especially in eye care and hypertension care, if further progress is to be made.

The studies not only confirm the need to improve primary care for people with diabetes but also strongly foreshadow the ability of the public-health sector to embrace the mechanisms of those changes. Most of these changes are prescribed in the *Guide* and accepted as applicable to general medical care as provided by all health professionals. These data provide the framework for intensive public health programs aimed at reducing complications of diabetes.

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