

Effect of Nurse-Directed Diabetes Care in a Minority Population

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OBJECTIVE — To determine whether diabetes care directed by nurses following detailed protocols and algorithms and supervised by a diabetologist results in meeting the evidence-based American Diabetes Association (ADA) process and outcome measures more often than care directed under usual care in a minority population.

RESEARCH DESIGN AND METHODS — Studies were mainly conducted in two Los Angeles County clinics. In clinic A, nurse-directed diabetes care was provided to 252 patients (92% Hispanic and 2% African-American) referred by their primary care providers. These patients were hierarchically matched with 252 diabetic patients in clinic B (79% Hispanic and 19% African American). When nurse-directed care was abruptly discontinued in clinic A for administrative reasons, it was reestablished in clinic B. Those patients were randomly selected from a teaching clinic, and the outcomes in 114 patients who completed 1 year were compared with outcomes derived the year before receiving nurses' care. The following process and outcome measures were assessed in the study: 1) number of visits, 2) diabetes education, 3) nutritional counseling, 4) HbA_{1c}, 5) lipid profiles, 6) eye exams, 7) foot exams, 8) renal evaluations, and 9) ACE inhibitor therapy in appropriate patients.

RESULTS — For patients under nurse-directed diabetes care in both clinics A and B, almost all process measures were carried out significantly more frequently than for the appropriate control patients. Under the care of nurses in clinic A, HbA_{1c} levels fell 3.5% from 13.3 to 9.8% in the 120 patients who were followed for at least 6 months, as compared with a 1.5% fall from 12.3 to 10.8% under usual (physician-directed) care in clinic B. During the year before enrolling in nurse-directed care in clinic B, mean HbA_{1c} levels decreased from 10.0 to 8.5%. At the end of a year under the nurses' care, the values fell further to 7.1%. The median value fell from 8.3 to 6.6%.

CONCLUSIONS — Specially trained nurses who follow detailed protocols and algorithms under the supervision of a diabetologist can markedly improve diabetes outcomes in a minority population. This approach could help blunt the increased morbidity and mortality noted in minority populations.

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Diabetes has a profound effect on the health of our population and the well-being of our economy. Diabetic retinopathy is the leading cause of blindness in people between 20 and 74 years of age (1). Diabetic nephropathy is the leading cause of patients undergoing dialysis for end-stage renal disease (ESRD) (2). Diabetic peripheral neuropathy

is the underlying cause of nontraumatic lower-extremity amputations in diabetic patients (3). More than half of lower-extremity amputations occur in people with diabetes (4), even though only 5.1% of the population ≥ 20 years of age have been diagnosed with diabetes (5). The prevalence of coronary artery disease is twofold higher in men with diabe-

tes and fourfold higher in women with diabetes compared with appropriate non-diabetic control subjects (6). Strokes are two to three times more common in people with diabetes than in those without the disease (7). Peripheral vascular disease (8) and congestive heart failure (6) are also much more common in diabetic patients compared with nondiabetic individuals.

Unfortunately, minority populations bear an excessive brunt of these morbidities and mortality due to diabetes. Compared with non-Hispanic Caucasians, African Americans had significantly more diabetic retinopathy in population studies (10,11), though not in a study that evaluated diabetic patients referred for retinal screening (12). African-American type 1 diabetic patients were almost twice as likely to develop proliferative diabetic retinopathy (13). ESRD was also much more common in this population (10,14–18). Not surprisingly, the precursors of ESRD, microalbuminuria and clinical proteinuria, were also increased (10,19). African Americans also suffer more lower-extremity amputations (4,10,17,18,20), and, proportionately, more of those amputations are proximal (20). Many studies have documented that glycated hemoglobin levels were significantly higher in African Americans (13,21–27), which may account, at least in part, for the above-cited differences. Rates of diabetic ketoacidosis were also increased in African-American type 1 diabetic patients (17,18,21). Lastly, mortality was significantly higher in African-American diabetic patients than in their Caucasian counterparts (28).

Diabetic retinopathy was significantly increased in the Hispanic diabetic patients surveyed in the third National Health and Nutrition Examination Survey (NHANES III) population study (11) and in a cohort of Hispanic patients living in Texas (28); inexplicably, however, it was not increased in Hispanic patients from Southern Colorado (30,31). Both microalbuminuria and clinical proteinuria (10,19,32), and ESRD in particular (10,16,33), were significantly more prevalent in Hispanics compared with non-

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Abbreviations: ADA, American Diabetes Association; ARB, angiotensin receptor blocker; DMCP, Diabetes Managed Care Program; ESRD, end-stage renal disease.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Hispanic Caucasians. As in the African-American population, diabetic control was worse in the Hispanic population (26,34), which may again partly account for the increased microvascular complications in this population.

The following are well-known barriers to health care (35): 1) health care provider knowledge; 2) communication between patient and health care provider; 3) attitudes and beliefs of the patient, community/culture, health care provider, and health care system; 4) racial and ethnic disparities; 5) variations in settings, including the health care system; 6) clinical traditions; 7) socioeconomic status; and 8) cost. Indirect evidence that these barriers can be overcome was provided by Karter et al. (36), who showed that in an employed population followed in a prepaid Kaiser Permanente medical care program, minorities (African Americans, Hispanics, and Asians) did not have an increased 3-year incidence of stroke, congestive heart failure, myocardial infarction, or lower-extremity amputations compared with Caucasians. Only ESRD was higher in the minority population, but that was thought to be due to genetic factors (36).

This study evaluated whether specially trained nurses following detailed algorithms for diabetes care could overcome barriers in a mostly uninsured, poorly educated, poverty-stricken population so that the process and outcome measures recommended by the American Diabetes Association (ADA) (37) were more likely to be met than in a similar population cared for by physicians in the usual county clinic setting. This is particularly important since mortality from diabetes increased by 48% in persons living in Los Angeles County (the majority of whom are minorities) from 1990 to 2000, whereas mortality from coronary heart disease, stroke, pneumonia/influenza, lung cancer, emphysema, cirrhosis, and HIV/AIDS all decreased by 4–77% during this same period (38).

RESEARCH DESIGN AND METHODS

Diabetic patients from three county clinics were studied. The cohort of diabetic patients from clinic A was referred to the Diabetes Managed Care Program (DMCP) by their primary care physicians. No particular referral criteria were given to them. Thus, these patients in their practices were probably the more

difficult ones to control. The cohort of control diabetic patients in clinic B was identified as those receiving oral antidiabetic drugs and/or insulin after assessing the computerized pharmacy database. They were hierarchically matched with the DMCP patients treated at clinic A during the same period of time (November 1998 through October 2000). Hierarchical matching means that the parameters are listed in decreasing order of importance and each parameter is matched only after the preceding ones are met. The following hierarchical parameters were used for matching: type of diabetes, diabetes therapy, duration of diabetes, ethnicity, sex, and age.

A second group of diabetic patients at clinic B was also studied. These patients were randomly selected from a teaching clinic by identifying the first person with diabetes (who agreed to be in the study) in each morning and afternoon clinic. Their outcomes after 1 year in the DMCP were compared with their outcomes during the previous year.

Diabetic patients from clinic C were used as controls to compare two process measures (urine dipsticks and foot exams) with the DMCP patients in clinic A. This was done because in clinic B these two process measures were included as check boxes on a diabetes-specific progress note. Because using flow sheets for diabetes outcomes improves care (39), diabetic patients from clinic C, in which no such flow sheets or check boxes are used, were considered more appropriate as controls for clinic A for these two process measures.

The structure of the DMCP is for specially trained nurses (and pharmacists) delivering diabetes care to follow detailed protocols and algorithms under the supervision of a diabetologist (40–43). The algorithms covering glycemic control include those for diet therapy alone; sulfonylurea agents; metformin; acarbose; glitazones (all drugs either alone or in combination); insulin regimens including split/mixed, preprandial short (regular)- or rapid (analog)-acting, and evening NPH or ultralente insulin; single injection of NPH insulin; mixture insulins (e.g., 70/30); and insulin pump therapy. There are also algorithms and protocols for evaluating and managing lipid disorders, evaluating nephropathy, treating microalbuminuria, diagnosing and managing the glycemic status of women with gestational diabetes, and

managing the glycemic status of pregnant women with pregestational diabetes. The protocols and algorithms used in this study were the glycemic ones, the ones for lipid disorders, and those for evaluating nephropathy and treating microalbuminuria.

The patients in clinic A were managed by a full-time nurse, a part-time nurse, and a part-time pharmacist. The experimental patients in clinic B were managed by one full-time nurse. All of them were specially trained and supervised by the author.

At the conclusion of the study, charts were abstracted for the following process measures: frequency of testing for glycated hemoglobin, LDL cholesterol, and triglycerides; evaluating microalbuminuria/clinical proteinuria; number of visits (blood pressures are routinely measured in these clinics at every visit); and recorded eye and foot examinations. The following outcome measures were also assessed: glycated hemoglobin, LDL cholesterol, and triglyceride levels; and ACE inhibitor or angiotensin receptor blocker (ARB) treatment of microalbuminuria or clinical proteinuria.

Statistical analyses were performed by SPSS, Version 11.5, using independent *t* tests, paired *t* tests, and differences between two proportions when appropriate. Significance was accepted at the 0.05 level (two-tailed).

RESULTS — A total of 335 diabetic patients were referred to the DMCP in clinic A. Despite repeated phone calls and a letter, 83 failed to return for ongoing visits and were considered inactive. The demographics and diabetes treatment of the DMCP patients in clinic A and the control patients in clinic B, as well as the demographics of patients in clinic C, are shown in Table 1. There were no significant differences in any of the patient demographics between the 83 inactive and the 252 active patients in clinic A. The demographics are similar among the patients from the three clinics except for the racial/ethnicity composition. There were significantly more African Americans among the patients in clinics B and C, reflecting the populations they serve in different geographic areas of Los Angeles County. According to a census study in 1995, clinic B served a population of 165,690 people, 75.0% of whom were Hispanic, 23.4% of whom were African American, 0.6% of whom were Caucasian, and 1.0%

Table 1—Patient demographics and diabetes treatment*

	Clinic A	Clinic B	Clinic C
No. of patients	252	252	209
Type 2 diabetes	252 (100)	252 (100)	207 (99)
Female	189 (76)	181 (72)	152 (66)
Age (years)	52.0 (26–79)	52.6 (27–79)	53.8 (19–84)
Duration of diabetes (years)	7.7 (0–32)	7.2 (1–26)	NA
African American	4 (2)	49 (19)	29 (14)
Hispanic	230 (92)	198 (79)	178 (85)
Other	15 (6)	4 (2)	2 (1)
Diet only	2 (1)	0 (0)	NA
One oral drug	52 (21)	54 (21)	NA
≥2 oral drugs	94 (37)	94 (37)	NA
Insulin plus oral drug(s)	67 (27)	67 (27)	NA
Insulin only (≥2 injections)	34 (13)	33 (13)	NA
Insulin only (1 injection)	2 (1)	4 (2)	NA

Data are n (%) or mean (range) for age and duration. *Race/ethnicity data missing in 3 patients in clinic A and 1 patient in clinic B.

of whom were Asian-Americans/other. Since that time, the Hispanic proportion of the area has increased. (This corresponds to the ethnic/racial distribution in Table 1.) In 1995, 70% of those ≥18 years old had less than 12 years of school; 49.9% of the population lived below the poverty level, as defined by the federal government. The population served by clinic A is almost entirely Hispanic; many were not born in the U.S. The socioeconomic status of these patients is almost assuredly lower than those seen in clinic B.

The process measures met in the patients receiving nurse-directed care and usual care are shown in Table 2. Of the 10 process measures in Table 2, 7 were sig-

nificantly better met in patients receiving nurse-directed care. Only 1 (a subsequent measurement of an albumin-to-creatinine ratio in patients whose dipstick results were negative or trace) was significantly better met in patients receiving usual care. Although the ADA guidelines do not specifically address the issue, it may be unnecessary to document microalbuminuria or clinical proteinuria in patients already receiving an ACE inhibitor or an ARB. In that regard, in patients receiving nurse-directed care, 19 of the 37 patients whose urine was not tested by dipstick and 65 of the 129 with negative or trace results on the dipstick in whom no albumin-to-creatinine ratios were subsequently mea-

sured were already receiving ACE inhibitors. The corresponding numbers for patients under usual care were 15 of 43 and 45 of 98, respectively.

The HbA_{1c} outcome measure in the two groups of patients is shown in Table 3. Regardless of whether the ADA HbA_{1c} goals were met, patients in the DMCP in clinic A were tested significantly more frequently than those under usual care in clinic B. The patients receiving nurse-directed care had significantly higher glycemia than the control group initially. Although there was no difference in the final HbA_{1c} levels, the decrease in the DMCP was twice as great as under usual care. The DMCP was abruptly shut down in clinic A for administrative reasons. The average time that the patients were followed by the nurses was 7 months. Because the intensity of treatment was gradually increased and the HbA_{1c} level reflects the preceding 3–4 months of glycemia, patients followed for at least 6 months provide a better indication of the effectiveness of nurse-directed care. The average HbA_{1c} value in those 120 patients was 0.5% lower.

During the time this study was carried out, accepted lipid goals were those promulgated in a 1993 Consensus Statement by the ADA (44). These were an LDL cholesterol of <130 mg/dl in those without evidence of macrovascular disease and <100 mg/dl in those with evidence of macrovascular disease. Because the medical records in these community clinics did not contain copies of inpatient admis-

Table 2—Process measures

Measure	ADA guidelines	Nurse-directed care	Usual care	P
HbA _{1c}	Goal-yes, 1 per 6 months; Goal-no, 1 per 3 months	227/252 (90)	66/252 (26)	<0.001
Lipid profile	At least yearly	244/252 (97)	148/252 (59)	<0.001
Eye exam	At least yearly	240/252 (95)	200/252 (79)	<0.001
Renal profile*	Yearly	215/252 (85)	148/209 (71)†	<0.001
	If dipstick negative/trace, measure albumin-to-creatinine ratio	54/183 (30)	76/174 (44)	<0.01
	If dipstick negative/trace, or albumin-to-creatinine ratio >30 mg/g, ACE treatment	19/28 (68)	59/93 (63)	NS
Foot exam	At least biannually	245/252 (97)	202/252 (80)†	<0.001
≥2 visits	At least biannually	248/252 (98)	241/252 (96)	NS
Diabetes education	No frequency stated	239/252 (98)	122/252 (48)	<0.001
Nutritional counseling	No frequency stated	224/252 (89)	14/252 (6)	<0.001

Data are n (%). *Dipstick or albumin-to-creatinine ratio; †clinic C.

Table 3—HbA_{1c} (% ± SD) outcome measure

	Nurse-directed care	Usual care	P
All patients			
Percent of patients	249/252 (99)	201/252 (80)	<0.001
Initial	13.5 ± 3.7	12.1 ± 3.1	<0.001
≥2 tests			
Percent of patients	201/249 (81)*	145/201 (72)	<0.05
Initial	13.3 ± 3.5	12.3 ± 3.4	<0.02
Final	10.3 ± 6.0	10.8 ± 3.2	NS
Change	-3.0 ± 6.6	-1.5 ± 2.9	<0.01
Followed ≥6 months			
Number of patients	120	145	
Initial	13.3 ± 3.4	12.3 ± 3.4	<0.02
Final	9.8 ± 3.0	10.8 ± 3.2	<0.01
Change	-3.5 ± 3.8	-1.5 ± 2.9	<0.001

Data are n (%) or means ± SD. *Some of these patients were followed for <3 months.

sions (and, hence, ascertainment of documented macrovascular disease was not possible), the less stringent LDL cholesterol goal of <130 mg/dl was used. The triglyceride goal was <400 mg/dl (44).

A total of 98 patients in the DMCP had initial LDL cholesterol concentrations ≥130 mg/dl and 76 (77%) of them were tested at least twice. The final LDL cholesterol concentration remained >130 mg/dl in 33 (43%) of these patients. Fifty-three of the patients under usual care had initial LDL cholesterol concentrations >130 mg/dl and 25 (47%) were tested at least twice with final values remaining >130 mg/dl in 14 (56%) individuals. Obtaining a second measurement was significantly higher ($P < 0.001$) in patients under nurse-directed care, but the percent remaining above goal was not significantly different between the two groups.

Twenty-two patients under nurse-directed care had initial triglyceride concentrations >400 mg/dl, 18 (82%) had at least one more test, and in 3 patients the final value remained >400 mg/dl. In those under usual care, 16 had initial triglyceride concentrations >400 mg/dl, 8 (50%) received at least one more measurement, and the final value remained >400 mg/dl in 3 patients. Significantly more ($P < 0.05$) patients under nurse-directed care were tested at least twice as compared with those under usual care; no difference in those with more than one measurement remaining >400 mg/dl was observed.

After the DMCP was abruptly closed at clinic A, it was subsequently reestablished at clinic B. At this site, diabetic patients were randomly selected from a clinic in which county physicians teach internal medicine residents (the first patient who agreed to join the study each morning and afternoon clinic until 175 patients were enrolled). A total of 114 diabetic patients have completed 1 year in the DMCP (staffed by one nurse) and have been returned to usual care. As expected, their demographics were similar to the control patients in clinic B in Table 1; 99% had type 2 diabetes, 74% were female, their average age was 49.5 ± 10 (mean ± SD) years, the average duration

of diabetes was 6.7 years (range 0–30), 23% were African American, and 74% were Hispanic. Their medications before and after completing a year in the DMCP and the process measures during that year compared with the year before enrolling in the DMCP are shown in Table 4. Thirteen of the patients had newly diagnosed diabetes and therefore had received no prior diabetes care. Either the charts of the remaining 21 could not be located or they had been seen in urgent care only and no ongoing care was recorded in the year before randomization.

At the completion of the year in the DMCP, significantly more ($P < 0.001$) patients were on a combination of oral drugs compared with a single oral agent at enrollment. Because the eye exams took place on site at clinic B (as opposed to clinic A), it was possible to ascertain whether patients referred for the examination actually received it. Except for evaluation of albuminuria (a reminder of which was indicated in a check box on a diabetes-specific progress note), every process measure in Table 4 was met significantly more ($P < 0.001$) often under nurse-directed care than in the year prior. There was no difference between the two groups in the number of patients with negative or trace dipstick results receiving an evaluation for microalbuminuria. However, in those who had a dipstick result of ≥1+ or an albumin-to-creatinine ratio ≥30 mg/g, 95% (40 of 42) received an ACE inhibitor under nurse-directed care

Table 4—Medications and process measures during the DMCP and the year prior

Medications/measures	Nurse-directed care	Year prior	P
n	114	80	
Diet only	2 (2)	0 (0)	NS
One oral drug	16 (14)	28 (35)	<0.001
≥2 oral drugs	81 (71)	36 (45)	<0.001
Insulin plus oral drug(s)	13 (12)	12 (15)	NS
≥2 injections of insulin per day (no oral drugs)	2 (2)	4 (5)	NS
Diabetes education	114 (100)	20 (25)	<0.001
Nutritional counseling	113 (99)	1 (1)	<0.001
≥2 visits per year	113 (99)	65 (81)	<0.01
≥2 HbA _{1c} measurements per year	111 (97)	46 (58)	<0.001
≥1 lipid profile per year	113 (99)	41 (51)	<0.001
≥1 test for albuminuria per year	107 (94)	77 (96)*	NS
Eye exam referral	113 (99)	63 (79)	<0.001
Eye exam documented	99 (87)	37 (46)	<0.001
≥2 foot exams per year	111 (97)	58 (72)*	<0.001

Data are n (%). *Check box on diabetes-specific progress note.

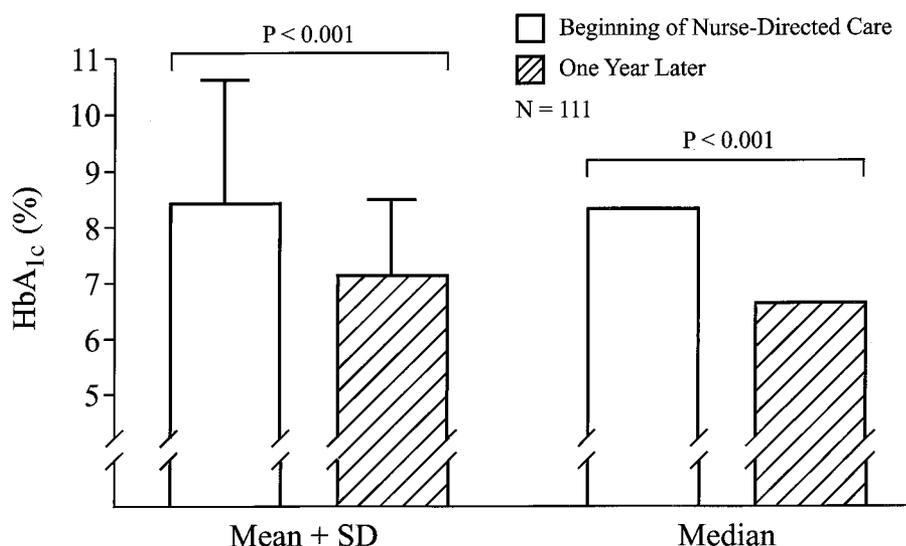


Figure 1—HbA_{1c} levels at the beginning of nurse-directed diabetes care and 1 year later.

compared with 80% (36 of 45) in the year prior ($P < 0.05$).

In the year before entering the DMCP at clinic B, 69 of 80 (86%) patients received at least one HbA_{1c} measurement but only 46 (67%) of those patients had undergone at least one more test. This contrasts with all 114 patients under nurse-directed care receiving at least one test and 111 (97%) of those patients having undergone at least two tests (both number of initial and repeat tests significantly greater [$P < 0.001$] in the DMCP). The initial value ($\% \pm$ SD) in the year prior was 10.0 ± 2.5 and decreased to 8.4 ± 2.2 at enrollment for nurse-directed care. After 1 year of nurse-directed care, the HbA_{1c} level was lowered further to 7.1 ± 1.4 . The median value fell from 8.3 to 6.6% (Figure 1).

Forty-one patients entering the DMCP in clinic B had initial LDL cholesterol concentrations ≥ 130 mg/dl and 40 (98%) of those patients were tested at least twice. The final LDL cholesterol concentration remained above ≥ 130 mg/dl in 8 (20%) of those patients. Seventeen of the patients in the prior year had initial LDL cholesterol concentrations ≥ 130 mg/dl and only 4 (24%) were retested; 2 remained above that value. The percent of those retested was significantly higher ($P < 0.001$) under nurse-directed care, but small numbers precluded a significant difference in those who remained above the guideline after 1 year. Only three and one patient had initial triglyceride levels

≥ 400 mg/dl in the DMCP and the year prior, respectively. All four were retested, and the three under nurse-directed care had values below this guideline after 1 year, whereas the patient from the year prior remained >400 mg/dl.

CONCLUSIONS— The evidence-based ADA guidelines are not being met. In the early 1990s, the average HbA_{1c} level was 9.5% (45), which improved to only 8.6% more recently (46). One-quarter to one-third of diabetic patients still have HbA_{1c} levels $>9.5\%$ (45). Only 3% of patients met the combined ADA outcome measures for glycemia, lipids, and blood pressure at urban academic centers (47). ADA process measures are usually met in $<50\%$ of diabetic patients (46).

A number of approaches have been tried to increase the frequency at which patients meet the ADA process and outcome recommendations. These have included simply reminding patients to keep their doctors' appointments (48), having nurse educators call patients on a regular basis (49), providing specific information concerning the standards of care to both patients and physicians (50–53), alerting physicians at the time of the patients' visits that specific standards have not been met (54,55), and intensive education of physicians (56–58). All have been relatively ineffective.

In middle-class populations, the ADA process and outcome measures were

more likely to be met in patients under nurse-directed care compared with those receiving usual care (59–64). The present study clearly demonstrates that the same holds true for a minority population with lower socioeconomic status and education levels.

When evaluating the barriers to care (35), it is perhaps not surprising that nurses deliver better diabetes care than busy physicians. In general, they have better communication with patients because they can devote more time and are often more likely to share similar backgrounds. Thus, they are more likely to be attuned to the attitudes, beliefs, and cultures of the patients and their communities. Additionally, the protocols and algorithms represent enhanced provider knowledge since they are formulated by physicians knowledgeable in diabetes.

Furthermore, diabetes care is different from most other medical care in that it is largely preventive. Education is an important part of this preventive care, but it is a time-consuming task for which physicians are usually ill-suited. Our medical care system is geared toward diagnosing and treating acute problems. Diabetes, which is mostly asymptomatic until the complications develop clinically, often gets short shrift from the busy practitioner who usually also has to deal with other, more immediate problems in the diabetic patient. Even when physicians were presented with which process measures were unmet at the time that the patient was in his or her office, the guidelines were fulfilled in only one-third of cases because of time constraints (54). Specially trained nurses following agreed upon protocols and algorithms, under the supervision of a physician, can effectively concentrate on providing diabetes care that has a much better chance of meeting the evidence-based ADA guidelines than the harried physician left to his or her own devices. A recent survey (65) found that preventive care is increasingly being delivered by nonphysician clinicians. Since diabetes care is mostly preventive, specially trained nurses directing diabetes care would simply follow the national trend.

Of course, one must consider costs when proposing a change in delivering medical care. The direct medical care costs for diabetic patients reached \$98 billion in 2002 (66). Although better diabetes care translates into lower costs (67–

69), this will not occur immediately. We will need to make an initial investment of resources to realize later cost savings and decreased morbidity and mortality in our diabetic patients. Nurse-directed care may be particularly beneficial in minority populations in whom diabetes-related morbidity and mortality is increased above that of the general population.

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