Integrating Nurse-Directed Diabetes Management Into a Primary Care Setting

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Objective: To compare outcome measures of nurse-directed diabetes management for 9 to 12 months between a nonintegrated model (patients removed from the primary care clinic and followed up in a separate diabetes clinic with supervision by an endocrinologist) and an integrated model (nurse placed in the primary care clinic with supervision by primary care physicians).

Study Design: Observational.

Methods: A nurse trained to follow approved detailed treatment algorithms (glycemia and dyslipidemia algorithms for both models plus a hypertension algorithm for the integrated model) was given prescription authority.

Results: A total of 367 patients were randomly selected from a primary care clinic for the nonintegrated model, and 178 patients were referred to the nurse by primary care physicians for the subsequent integrated model. Ultimately, one quarter of patients in the nonintegrated model were using insulin (mostly bedtime insulin only), while three quarters of patients in the integrated model were using insulin (mostly intensified regimens). The initial mean (SD) glycosylated hemoglobin (A1C) levels fell from 8.9% (2.6%) to 7.0% (1.2%) of total hemoglobin in the nonintegrated model and from 11.1% (2.3%) to 7.2% (0.9%) of total hemoglobin in the integrated model (to convert A1C level to proportion of total hemoglobin, multiply by 0.01). Taking initial values into account, the final A1C levels were not statistically different ($P = .61$). In the nonintegrated and integrated models, respectively, 60% and 49% met the American Diabetes Association (ADA) A1C goal, and 82% and 96% met the low-density lipoprotein cholesterol (LDL-C) goal. In the integrated model, 90% met the blood pressure (BP) goal, and 47% met all 3 goals (ADA A1C, LDL-C, and BP).

Conclusion: An integrated model of diabetes care is generalizable and should be considered by policy makers to improve diabetes outcomes, especially among underserved minority populations.

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For author information and disclosures, see end of text.

Diabetic complications can be devastating.[1] Microvascular complications of diabetes are the leading causes of blindness (in adults aged 20-74 years), end-stage renal disease, and lower extremity nontraumatic amputations. Macrovascular complications (coronary artery disease, strokes, and peripheral arterial disease) are increased 2-fold to 4-fold in patients with diabetes mellitus versus age-matched control subjects without diabetes. Meeting the goals of the American Diabetes Association (ADA) for outcome measures (glycosylated hemoglobin [A1C] level <7.0% of total hemoglobin, low-density lipoprotein cholesterol [LDL-C] concentration <100 mg/dL, and blood pressure [BP] <130/80 mm Hg)[2] markedly diminishes these complications[3] (to convert A1C level to proportion of total hemoglobin, multiply by 0.01; to convert LDL-C concentration to millimoles per liter, multiply by 0.0259). These goals are not being met by most patients with diabetes.[1] Efforts to improve outcome measures of diabetes care have generally been ineffective.[1] A major reason is that these efforts do not usually lead to timely and appropriate treatment decisions.[4] A notable exception is case managers who could adjust medications without waiting for physician approval.[1,5]

Observational investigations have demonstrated the effectiveness of an integrative model (ie, patients were cared for in their usual primary care settings), with reduced 1-year utilization and costs and improved process measures (A1C level, LDL-C concentration, and eye and kidney screenings), as well as a decrease in the percentage of the population with A1C levels exceeding 9.5% of total hemoglobin.[6] The investigators have taken the next step by evaluating outcome measures in randomized clinical trials and have shown that nurses and pharmacists (under the supervision of physicians) following approved treatment algorithms and given prescription authority (ie, they can prescribe medications independently according to the algorithms) can lower A1C levels among patients with diabetes 3-fold more than is typical with patients in usual-care control groups.[1,7] However, in these approaches, patients were followed up in a nonintegrated model in which they were removed from their primary medical home to receive diabetes care, and the nurses and pharmacists were almost always supervised by endocrinologists. This nonintegrated model of diabetes care is not generalizable because (1) there

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are far too few endocrinologists to provide adequate supervision, and (2) most important, patients are removed from their medical home so that care is fragmented (ie, important aspects of healthcare are being performed at separate sites, with duplication of care, suggestions of conflicting treatments that result in patient confusion, potential communication problems between the patient and more than 1 provider, etc).

Take-Away Points

Incorporation of an integrated model of diabetes care (nurse placed in the primary care clinic with supervision by primary care physicians) will markedly improve diabetes surrogate outcome measures of glycemia, lipids, and blood pressure (BP) in the short term and will decrease clinical events and save money in the long term.

- In the nonintegrated model (patients removed from the primary care clinic and followed up in a separate diabetes clinic with supervision by an endocrinologist) and integrated model, respectively, 60% and 49% met the American Diabetes Association (ADA) glycosylated hemoglobin (A1C) goal, and 82% and 96% met the low-density lipoprotein cholesterol (LDL-C) goal.
- In the integrated model, 90% met the BP goal, and 47% met all 3 goals (ADA A1C, LDL-C, and BP).

Our group published results of a nonintegrated model of nurse-directed diabetes management in this journal several years ago.[7] Herein, we evaluate an integrated model of diabetes management based on the nonintegrated model in which the same registered nurse (not a nurse practitioner), MB-C, still with prescription authority and following treatment algorithms, was placed in the primary care site and was supervised by primary care physicians. Outcome measures of the nonintegrated and integrated models of diabetes management are compared. If the results are similar, the more generalizable integrated model of care has the potential to markedly reduce morbidity and mortality associated with diabetic complications, especially among an underserved minority population such as that studied herein.

METHODS

The site for these models of diabetes care was a county health center serving a challenging, mostly uninsured minority population. The glycemia-, dyslipidemia-, and hypertension-detailed treatment algorithms followed by the nurse have recently been published.[8] The hypertension algorithm was unavailable in the nonintegrated model. The nurse was able to follow approximately 175 patients at any one time in both models. (Among a more middle-class population, a nurse following these algorithms can manage up to 250 patients at a time because many of the interactions can be performed by telephone, fax, or e-mail, which is often not possible among the minority population studied herein.) A special computer program (NuMedics, Inc, Tigard, Oregon) was used to provide weekly reports of patients who missed appointments or laboratory tests so that appropriate follow-up could be performed by a medical assistant, who also entered data into the computer program.

For the nonintegrated model of diabetes management, patients were randomly selected from an internal medicine clinic. The first person with diabetes from morning or afternoon clinic sessions who agreed to participate was placed under the care of a Spanish-speaking nurse trained to follow the glycemia and dyslipidemia treatment algorithms at a separate clinic in the health center. The nurse was supervised by an endocrinologist (MBD), who met with her weekly and was available by telephone at all other times. All other patient care unrelated to diabetes was performed by a primary care provider in the internal medicine clinic. For the integrated model of diabetes management, this same nurse was placed in the family medicine clinic and was supervised by the primary care physicians there, who referred their patients to her. The nurse cared for these patients in the family medicine clinic. (Both the internal medicine and family medicine clinics in this county health center were primary care clinics but were staffed by physicians with different training.) In addition to the glycemia and dyslipidemia treatment algorithms, a hypertension algorithm was used in the integrated model of care. The endocrinologist was not involved in the care of these patients. It is important to point out that results are compared between randomly selected patients in the nonintegrated model and referred patients in the integrated model.

Patients were followed by the nurse for 9 to 12 months before being discharged back to usual care in both models. Patient education occurred at individual visits with the nurse and could be focused on specific problems encountered by the patient. For patients taking pills, the first goal of the glycemia treatment algorithm is a fasting plasma glucose (FPG) level of less than 130 mg/dL, which necessitated measurement every 2 to 3 weeks until that goal was achieved (to convert glucose level to millimoles per liter, multiply by 0.0555). At that point, patients were seen every 3 months to determine if the A1C goal of less than 7.0% of total hemoglobin was achieved. If the FPG level remained at least 180 mg/dL at 3 weeks after maximal (tolerated) doses of metformin plus a sulfonylurea agent were reached—or if the FPG level was less than 180 mg/dL but the A1C level was 7.0% or higher of total hemoglobin 3 months later—a maximal dose of pioglitazone hydrochloride (45 mg) was added, and the A1C level was measured 4 months later. If that value was 7.5% or higher, bedtime insulin was added, and pioglitazone was discontinued. Patients starting insulin regimens were seen every week

Table 1. Demographic Characteristics of the Patients

Characteristic	Nonintegrated Model (n = 367)	Integrated Model (n = 178)
Age, mean (SD), y	51.2 (10.0)	54.3 (7.1)
Duration of diabetes, mean (SD), y	6.9 (6.6)	11.5 (7.1)
Female sex, %	71	65
Race/ethnicity, No. (%)		
African American	80 (21.8)	32 (18.0)
Latino	283 (77.1)	144 (80.9)
White	2 (0.5)	0
Asian	2 (0.5)	2 (1.1)
Type 2 diabetes mellitus, No. (%)	365 (99.5)	176 (99.4)

or every 2 weeks initially until FPG levels measured at home were less than 200 mg/dL, every 3 weeks until they were less than 150 mg/dL, and then every 6 weeks. Three months after more than 50% of these values had dropped to less than 130 mg/dL, the A1C level was measured. If it was 7.5% or higher, insulin therapy was intensified by switching the patient to a split-mixed regimen (usually selected because it required only 2 insulin injections per day) or to a basal-bolus regimen with 4 injections per day for those with irregular eating patterns. The sulfonylurea agent and pioglitazone were discontinued, but metformin was continued in overweight and obese patients to mitigate weight gain.

In the dyslipidemia treatment algorithm, statins were adjusted monthly until the LDL-C target was reached (<100 mg/dL [<70 mg/dL for patients with clinical cardiovascular disease]), at which time lipids were measured every 4 to 6 months. In the hypertension treatment algorithm, BP medications were adjusted monthly until the goal of less than 130/80 mm Hg was achieved. All patients were seen at least every 3 months.

The final A1C levels were compared between the nonintegrated and integrated models of diabetes management by 1-way analysis of covariance, controlling for baseline values. The percentages of patients achieving the ADA A1C and LDL-C goals were analyzed by χ^2 test for homogeneity. Significance was set at the 5% level (2-tailed).

RESULTS

Demographic characteristics of the patients are given in Table 1. As expected, because they were drawn from the same population, the nonintegrated and integrated models served similar patients except for duration of diabetes. This difference, which has clinical ramifications, might be expected, because the patients in the nonintegrated model were randomly selected, while those in the integrated model were referred by their primary care physicians, who would be more likely to refer their more challenging patients, as reflected in the much higher initial A1C levels (Table 2). The referred patients had diagnosed diabetes for a mean of 4.6 years longer than the randomly selected patients, which was responsible for a much higher proportion receiving 2 or more insulin injections per day. The major change in therapy among patients in the nonintegrated model was progression from 1 oral drug to 2 or more oral drugs and from there to bedtime insulin. The major change in therapy among patients in the integrated model was progression from 2 or more oral drugs or bedtime insulin to 2 or more insulin injections per day. Ultimately, three quarters of patients in the integrated model were using an intensified insulin regimen. Despite the increased difficulty in controlling patients using intensified insulin regimens, there was no significant difference (P = .61) in the final A1C levels between the models of care when the initial values were taken into account.

The proportions of patients meeting the goals of the ADA are given in Table 3. In both models of care, the percentages of patients meeting the goals rose appreciably. Although the 49% of patients in the integrated model meeting the A1C goal was significantly less (P = .01) than the 60% of patients in the nonintegrated model, the former started with an A1C level that was 2.1% higher. Furthermore, only 2% of patients in the nonintegrated model ultimately were using 2 or more insulin injections per day, compared with 74% in the integrated model. Remarkably, 47% of patients in the integrated model of diabetes management met all 3 ADA outcome goals (A1C, LDL-C, and BP).

DISCUSSION

The nonintegrated and integrated models of nurse-directed diabetes management yielded similar marked improvement in the surrogate outcome measures of glycemia and lipids. Ninety percent of patients treated according to the hypertension algorithm met the ADA BP target, far in excess of reported figures.[9] Despite the fact that referred patients were even more challenging than the randomly selected patients in the nonintegrated model, impressive outcomes occurred in the integrated model. They had higher initial mean A1C levels (11.1% vs 8.9% of total hemoglobin), and many more were

Table 2. Initial and Final Glycosylated Hemoglobin (A1C) Levels and Diabetes Treatment

Variable	Nonintegrated Model (n = 367)		Integrated Model (n = 178)	
	Initial	Final	Initial	Final
A1C level, mean (SD), % of total hemoglobin	8.9 (2.6)[a]	7.0 (1.2)[a]	11.1 (2.3)	7.2 (0.9)
Diabetes treatment, No. (%)				
Diet only	14 (3.8)	9 (2.5)	0	0
1 Oral drug	108 (29.4)	71 (19.3)	7 (3.9)	9 (5.1)
≥2 Oral drugs	145 (39.5)	193 (52.6)	60 (33.7)	18 (10.1)
Bedtime insulin plus oral drugs	49 (13.4)	86 (23.4)	44 (24.7)	15 (8.4)
≥2 Insulin injections per day	15 (4.1)	8 (2.2)	53 (29.8)	132 (74.2)
Premixed insulin	0	0	14 (7.9)	4 (2.2)

SI conversion factor: To convert A1C level to proportion of total hemoglobin, multiply by 0.01.
[a]n = 361.

using an intensified insulin regimen with 2 or more injections per day (74% vs 2%), which is much more difficult to manage than bedtime insulin or oral medications alone. Overall, there would not seem to be any clinically important differences in outcome measures between the 2 models of nurse-directed diabetes management. Impressively, 47% of patients in the integrated model met all 3 of the ADA outcome targets (A1C, LDL-C, and BP) compared with the only 2% to 13% reported in the literature.[10-18]

Key components of good diabetes care include the following: (1) knowledgeable providers, (2) time to interact with patients, (3) communication with patients, (4) educated patients, (5) timely and appropriate treatment decisions, and (6) ability of patients to carry out treatment recommendations.[4,19] Nurses (not necessarily nurse practitioners) trained to follow treatment algorithms who are given prescription authority and are supervised by physicians admirably meet these requirements. The approved algorithms fulfill the knowledgeable provider and treatment decision components of diabetes care. Nurses who do not have to deal with nondiabetes issues can devote more time to diabetes-related questions. Moreover, nurses usually communicate effectively with patients. During successive interactions with patients, nurses provide ongoing relevant education specifically focused on patient issues at the moment. Nurses are then able to maximize the ability of patients to manage their diabetes and improve their outcomes within their individual limitations (eg, education, motivation, socioeconomic status, etc).

Outcomes of diabetes care are worse among minority populations.[20] The improvements detailed herein under nurse-directed diabetes management were in surrogate outcome measures, not clinical events. However, in several long-term observational studies,[21-25] lowering these outcome measures translated into robust reductions in morbidity and mortality associated with diabetes complications. Policy makers seeking to improve diabetes outcomes, especially

Table 3. Percentages of Patients Achieving Goals of the American Diabetes Association (ADA)

ADA Goal	% of Patients: Nonintegrated Model (n = 367)		% of Patients: Integrated Model (n = 178)	
	Initial	Final	Initial	Final
A1C level <7.0% of total hemoglobin	28	60	0[a]	49
LDL-C concentration <100 mg/dL	50[b]	82[b]	43	96
BP <130/80 mm Hg[c]				
Systolic	—	—	43	90
Diastolic	—	—	77	95

AIC indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol; BP, blood pressure.
SI conversion factors: To convert A1C level to proportion of total hemoglobin, multiply by 0.01; to convert LDL-C concentration to millimoles per liter, multiply by 0.0259.
[a]Criterion for referral was A1C level exceeding 8.0% of total hemoglobin.
[b]The ADA goal was less than 130 mg/dL during the first year of the 4-year nonintegrated study.
[c]A hypertension algorithm was not used in the nonintegrated model.

among underserved minority populations, and aiming to conserve limited resources should consider adopting an integrated model of nurse-directed diabetes care to address these issues.

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