Disease Management for Diabetes Mellitus: Impact on Hemoglobin A_{1C}

Jaan Sidorov, MD; Robert Gabbay, MD, PhD; Ronald Harris, MD; Robert D. Shull, PhD; Sabrina Girolami, RN, BSN; Janet Tomcavage, RN, MSN; Ralph Starkey, MD; and Roberta Hughes, MSN, RN

Abstract

Objective: **To describe outcomes associated with a health maintenance orgainization (HMO)-sponsored disease management program for diabetes.**

Study Design: **Descriptive study that compared outcomes of patients with diabetes before and after entry into a disease management program.**

Patients and Methods: **The study was conducted in a mixed-model HMO with 275,000 members. The disease management program included a Steering Committee, clinical guidelines, primary care site–based diabetes education, coverage of glucose meters and strips, simplified outcomes reporting, and support of clinical leadership. Data were obtained for 5332 continuously enrolled patients who voluntarily entered the disease management program; 3291 patients (61.7%) received 3 months or more of follow-up, and 663 (12.4%) received 1 year or more of follow-up. The primary outcomes were change from baseline of mean hemoglobin A_{1c} (HbA_{1c}) and medication use after 3 months and 1 year of follow-up.**

Results: **The mean baseline HbA_{1c} for all program participants was 8.51% (standard deviation [SD] = 1.86%). At 3 months of follow-up, the mean HbA_{1c} value for 2794 of 3291 participants (84.0%) had decreased to 7.41% (SD = 1.33%; *P* =.0001). At 1 year of follow-up, the HbA_{1c} value, available for 605 of 663 patients (91.3%), had decreased from a mean baseline value of 8.76% (SD = 1.87%) to 7.41% (SD = 1.24%; *P* = .0001). Among 663 patients with 1 year of follow-up, insulin use increased from 30.0% to 31.6%, and sulfonylurea use decreased from 40.7% to 33.8%. Troglitazone and metformin use increased from 7.7% and 23.8%, respectively, to 16.4% and 28.8%, respectively.**

Conclusions: **Our data suggest that a multifaceted disease management program for diabetes can result in significant short-term improvements in glycemic control in the managed care setting. While the improvement in the HbA_{1c} was accompanied by an increase in the use of insulin, troglitazone, and metformin, we suggest the influence of disease management on glycemic control among our participants was significant and should be considered in future studies in this area.**

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Diabetes mellitus affects up to 7.8% of all adults in the United States, and the number of patients with this disease is expected to grow significantly over the next decade[1] because of both the increased incidence of diabetes mellitus with age[2] and the longer life span of the American population. Healthcare costs associated with diabetes mellitus were approximately $98 billion in 1997,[2-7] a majority of which were attributed to potentially avoidable complications of diabetes.[8]

Published data suggest aggressive glycemic control may decrease the frequency of complications.[9-15]

From Care Coordination, Geisinger Health Plan, Danville, PA (JS, RDS, SG); the Division of Endocrinology, Hershey Medical Center, Hershey, PA (RG); Department of Endocrinology, Penn State Geisinger Wyoming Valley Hospital, Wilkes-Barre, PA (RH); and Department of Endocrinology, Geisinger Medical Center, Danville, PA (JT, RS, RH).

Address correspondence to: Jaan E. Sidorov, MD, Medical Director, Care Coordination, Geisinger Health Plan, Geisinger Office Building 1, Danville, PA 17822-3035. E-mail: jsidorov@geisinger.edu.

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Tighter glycemic control for patients with diabetes, however, requires significant healthcare expenditures. Financing appropriate care for this population poses a significant challenge, particularly for managed care organizations, which combine the delivery and financing of healthcare with a greater emphasis on primary care services.[16] Recently published data from managed care settings suggest improved glycemic control can only be achieved through significant increases in healthcare costs.[17,18] The Diabetes Control and Complications Trial also demonstrated that the incidence of complications from diabetes could be reduced significantly with more intense care, but this was associated with short-term costs estimated at $4000 to $5800 per patient per year.[19]

Disease management has been advocated as a compelling healthcare strategy whereby managed care organizations can simultaneously optimize costs and improve the quality of care for patients with chronic illnesses such as diabetes.[20-27] Disease management is defined as the coordination of all healthcare services across the continuum of care for a population with a chronic disease. Preliminary results from disease management programs for diabetes mellitus are promising, demonstrating improved glycemic control and resulting in lower healthcare costs.[28-30]

Interventions commonly included in diabetes disease management are clinical guidelines and patient education. Clinical guidelines can improve quality of care and reduce variation[31-33]; guidelines for diabetes mellitus have been widely disseminated[33-37] and have played a significant role in improving blood glucose control.[38-40] Education for diabetes includes individualizing treatment programs and enabling patients to be active participants in their own care.[41-45]

In this paper, we describe the effect of a multifaceted health maintenance organizaiton (HMO)-sponsored disease management program on mean hemoglobin A_{1c} (HbA_{1c}) levels and medication use over 1 year in a population of patients with diabetes mellitus.

··· METHODS ···

Patients and Setting

The Penn State Geisinger Health System (PSGHS) owned 3 hospitals and a multispecialty group practice clinic with more than 400 primary care providers in 115 clinic sites. In addition, there were 6 hospital-based endocrinologists and 3 clinical nurse specialists certified in diabetes education. This system also operated the Penn State Geisinger Health Plan (PSGHP), a federally qualified, not-for-profit mixed-model HMO serving 275,000 enrollees in 41 counties in northeastern and central Pennsylvania. A variety of pharmacy benefit packages could be purchased as a rider, and 72% of enrollees had a pharmacy benefit that was under a preferred formulary. No diabetes medications were excluded, and patients' formulary status did not change over the time period of this study. Furthermore, at the time of this report, glucose monitors and strips were considered durable medical equipment and were not covered, unless specifically negotiated under a third party administrator arrangement or mandated by law (eg, Medicare risk). No baseline survey of health status was performed on this Health Plan population to determine the presence of diabetes. An analysis of insurance claims from fiscal year 1998 determined that 7037 PSGHP enrollees had claims submitted for diabetes care or medications.

In September 1995, the Penn State Geisinger Health Plan created a separately funded network of primary care nurse-educators.[46] This grew to 19 registered nurses and 4 licensed practical nurses who provided patient education services exclusively at primary care sites owned by the Penn State Geisinger Clinic. Each nurse provided internally developed patient education in cessation of tobacco use, management of migraine, asthma, congestive heart failure, and insomnia, and using living wills and was responsible for 1 to 3 primary care sites. In all, 55 sites were served by these nurses. Outcomes for tobacco cessation and advance directives using this approach have been reported previously.[47,48]

Diabetes Disease Management Program

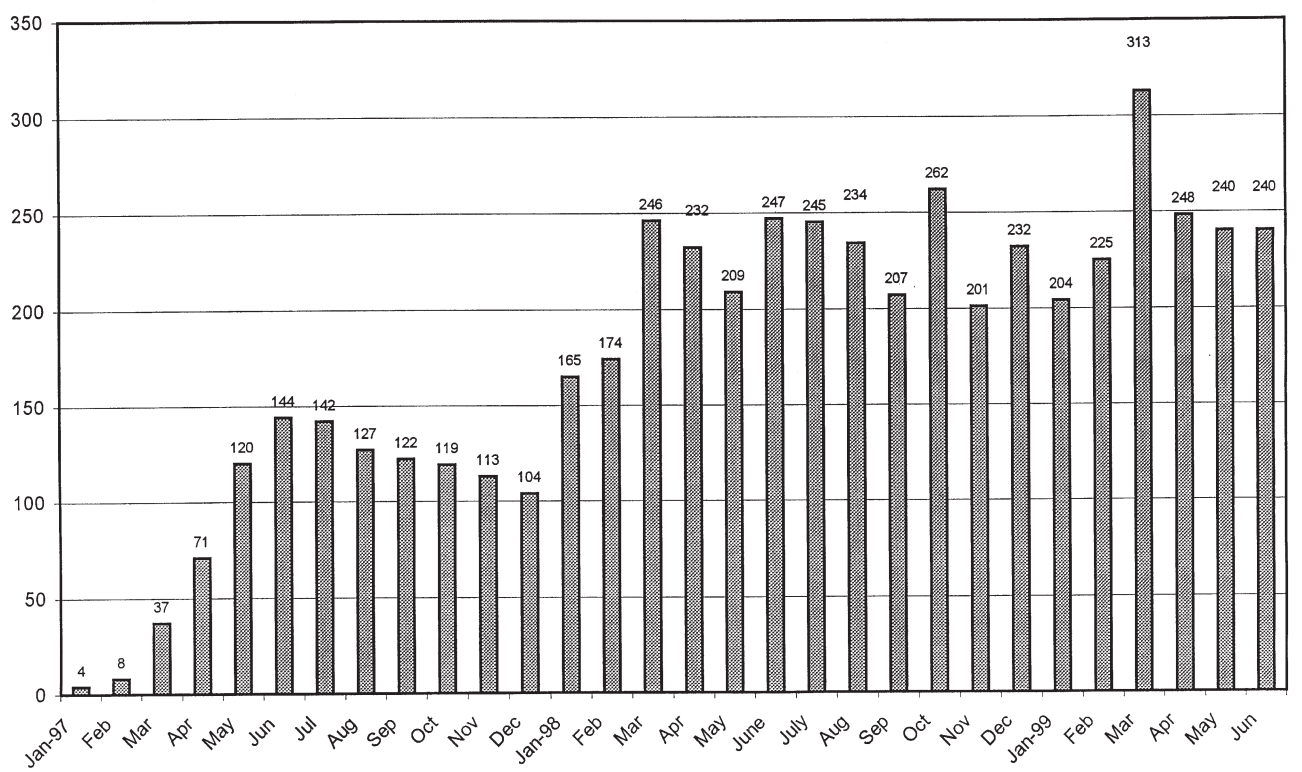
In March 1996, a Steering Group of primary care physicians, endocrinologists, clinical nurse specialists, dieticians certified in diabetes, and HMO representatives was created to initiate a combined program of interventions that have been shown to result in better outcomes for patients with diabetes mellitus. The components for the disease management program endorsed by the Steering Committee are described next.

Provider Guidelines. The Staged Diabetes Management Guidelines®,[37] could be modified to reflect local physician consensus, and hence, a work group of clinicians was appointed by the Steering Committee to alter the guidelines to reflect local clinical opinion and to emphasize the role of the

education nurses, as described later. The modified guidelines were presented at a series of meetings for which continuing medical education (CME) credits were also offered and which were attended by 218 (69.6%) PSGHS primary care physicians. These guidelines advocated aggressive blood glucose control, emphasized the value of patient education and skills in self-management, proposed medications for aggressive blood glucose control, and suggested quarterly assessments of HbA_{1c}. The final version of the guidelines reflected feedback from the meetings and rested on a broad consensus of opinion. Furthermore, clinicians were committed to reporting all outcomes to local physician leadership for dissemination. Copies of the guidelines were provided to every clinic and were also posted on the system intranet.

Self-Management Education. Although blood glucose control may be improved by specialty care,[49-51] access of patients to endocrinologists and certified diabetes educators was limited because these clinicians practiced in hospital settings and because primary care providers were not likely to support mandated referrals of their patients. Therefore, a diabetes clinical nurse specialist and dieticians from the Steering Committee conducted a 2-day training program to provide basic diabetes education to primary care HMO education nurses. Topics covered during the training included criteria for referral to a certified diabetes educator, dietician, or endocrinologist, use of a glucose meter, role of diet and exercise, significance of HbA_{1c} and need to assess it on a quarterly basis, medications for glycemic control, management of hypoglycemia, and teaming closely with physicians to facilitate use of clinical guidelines. This approach was also adopted by the certified diabetes educators (CDEs) in their clinical practice. Although not all primary care clinics had a nurse educator or CDE on site, the majority of enrollees had access to these educators because

Figure 1. Monthly Enrollment in Diabetes Disease Management Program



nurses were widely distributed in the HMO service area and patients could access other clinics with an on-site education nurse by traveling a modest distance.

Patients received individual counseling from education nurses and were encouraged to meet at least quarterly, so that the appointment coincided with the test for HbA_{1c}. Patients could drop out of the program at any time by notifying their education nurse that additional follow-up visits were refused. Reasons for refusal were not tracked at the time this program was developed. Unless patients indicated they wished to drop out, they were considered to have remained in the disease management program even if there were delayed or skipped follow-up visits. To aid timely follow-up, lists of patients with delays in scheduled follow-up were provided to each education nurse on a monthly basis.

Coverage for Glucose Meters and Strips. Despite the high cost of glucose meters and strips,[18,52,53] routine coverage under the durable medical equipment benefit was provided by the HMO for participants in the disease management program. Since proper use of the glucose meter can be assured only through proper patient instruction, the Steering Committee recommended that this benefit be limited to patients seen by one of the HMO education nurses or a CDE (with the exception of Medicare risk enrollees for whom these devices are a mandated benefit). Initially, there was no direct communication to patients about this program, but interest in using the meters and strips generated significant numbers of patient self-referrals. Enrollment in the program grew from 4 patients per month initially to a maximum of 313 per month (Figure 1).

Management of Outcomes Data. HbA_{1c} data were collected by the education nurses and clinical nurse specialists using a specially designed disease management data collection sheet that was completed during patient encounters. These data, as well as information from quality-of-life instruments, a satisfaction questionnaire, and financial insurance claims were stored in a computer registry (SAS Version 6.12).[54-59] The most recent HbA_{1c} value and other laboratory results (if available) in the medical record before entry of a patient into the disease management program were recorded as baseline values. HbA_{1c} was measured with the Diamat HPLC method in a central clinical laboratory located in one of the 3 PSGHS-owned hospitals. If HbA_{1c} data were not available in the patient's chart for the previous 3 months, the education nurses arranged for the test by using protocol-derived standing orders, and results were reported

Table. Baseline Data on Participants of the Diabetes Disease Management Program

Characteristic	Patients at Entry (n = 5332)	Patients with 3-Month Follow-up (n = 3291)	Patients with 1-Year Follow-up (n = 663)
Mean age (range)	60.6 (9-95)	57.1 (9-86)	58.2 (19-85)
Sex			
Male	2699 (51)	1680 (51)	328 (49.5)
Female	2633 (49)	1611 (49)	335 (50.5)
Type of insurance			
Commercial*	2591 (48.6)	1528 (46.4)	324 (48.9)
Medicare risk	2351 (44.1)	1535 (46.6)	295 (44.5)
Third-party administration	386 (7.1)	228 (7.0)	44 (6.6)
Unknown†	4 (0.2)	0 (0)	0 (0)
Pharmacy benefit	3161 (59.3)	1887 (57.3)	398 (60.1)
Type 1 diabetes	276 (5.2)	165 (5.0)	40 (6.1)
Receiving insulin at entry§	1166 (21.9)	756 (23.0)	199 (30.0)
Receiving oral hypoglycemic medications at entry§	3239 (60.7)	1956 (59.4)	332 (50.1)

Data are expressed as the number (percentage) of patients with the particular characteristic, except for age, which is expressed in years.
*Includes group, individual, and small business.
†Line of business unknown.
§Of those on medication.

to the primary care provider. All baseline and follow-up data were entered manually, and individual patient printouts were provided to the patient education nurses to be checked for accuracy. Separate lists of patients with delayed or skipped visits that resulted in loss of follow-up data were also provided to each nurse on a monthly basis to aid rescheduling of patients.

Mean HbA_{1c} values were compared with the standard *t*-test. The paired *t*-test was used to compare 3-month and 1-year mean HbA_{1c} values to the mean baseline HbA_{1c} value for individual participants. Medication use after 1 year was also compared to baseline use for each patient. These data were summarized and reported to the Steering Committee and System clinical leadership on a monthly basis.

··· RESULTS ···

Baseline Data

From January 1997 through June 1999, 5332 patients assigned to 186 primary care sites entered the diabetes disease management program, and 726 patients (13.6%) dropped out of the program. Follow-up data at 3 months were not available for 1315 patients because 728 were not followed 3 months or longer and the remaining 587 patients either had follow-up appointments that were rescheduled or had delays in data completion by education nurses. Demographic data, type of HMO insurance, and use of medications for all patients at baseline and those reported in follow-up are displayed in the Table.

The mean HbA_{1c} value for the entire population at baseline was 8.51% (standard deviation [SD] = 1.86%). The baseline HbA_{1c} for 276 patients with Type 1 diabetes mellitus was 8.92% (SD = 1.92%). For the 5044 patients with Type 2 diabetes mellitus, the baseline HbA_{1c} was 8.50% (SD = 1.85%). Four patients had gestational diabetes and 8 patients had diabetes that was not characterized. The mean HbA_{1c} for 4405 patients receiving hypoglycemic medications at entry was 8.52% (SD = 1.86%), which was not significantly different from the HbA_{1c} of the entire population.

Three-Month Follow-Up

HbA_{1c} data were available for 2764 of 3291 patients (84.0%) followed 3 or more months in the program. After 3 months, the mean follow-up HbA_{1c} value for this group decreased from 8.56% to 7.41% (SD = 1.69%; *P* =.0001, compared with all patients at baseline and compared with baseline HbA_{1c} for patients followed 3 or more months) (Figure 2a). For 2712 patients receiving hypoglycemic medications at the time of entry who completed 3 months or more of follow-up, the mean baseline HbA_{1c} of 8.60% was lowered to 7.53% (SD = 1.67%; *P* = .0001, compared with baseline values for all patients in this group), (Figure 2b). For 165 patients with Type 1 diabetes mellitus, the baseline HbA_{1c} of 8.83% (SD = 1.84%) decreased to 7.90% (SD = 1.41%), a statistically significant change (*P* = .0001). For patients with Type 2 diabetes mellitus, the mean HbA_{1c} of 8.54% (SD = 1.83%) at baseline was reduced significantly to 7.39% (SD = 1.33%; *P* =.0001) (Figures 3a and 3b).

One-Year Follow-Up

HbA_{1c} data were available for 605 of 663 (91.3%) patients who completed 1 year of follow-up. In this group, the baseline HbA_{1c} of 8.76% (SD = 1.81%) decreased to 7.41% (SD = 1.76; *P* =.0001, compared with baseline) after 1 year (see Figure 2a). For 531 patients who were receiving hypoglycemic medications at time of entry, the mean HbA_{1c} decreased from 8.83% at baseline to 7.50% after 1 year (SD = 1.78%, *P* = .0001) (see Figure 2b). For 38 of 40 patients with Type 1 diabetes mellitus who were followed for 1 year, the HbA_{1c} dropped from a mean baseline value of 8.66% (SD = 1.54%) to 8.01% (SD = 1.47%), a decrease that was not statistically significant. For patients 567 with Type 2 diabetes mellitus, the mean HbA_{1c} of 8.76% (SD = 1.90%) decreased to 7.37% (SD = 1.22%; *P*= .0001 compared to baseline) (see Figures 3a and 3b).

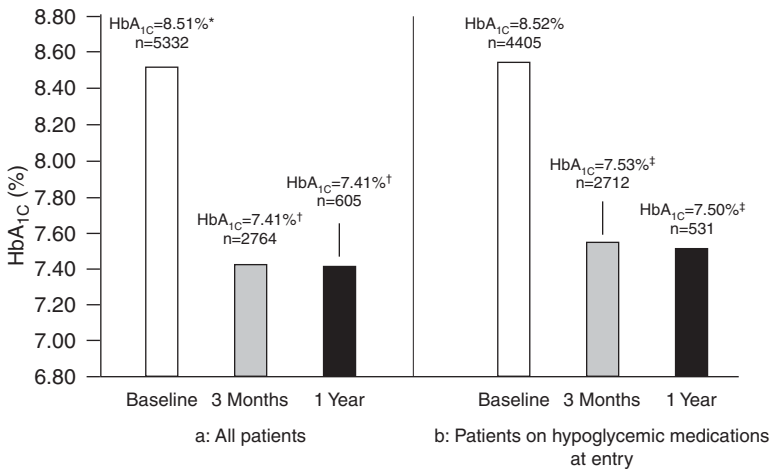
Medication Use

Insulin use among 663 patients with 1 year of completed follow-up increased from 30.0% to 31.6%, and sulfonylurea use decreased from 40.7% to 33.8%. Troglitazone and metformin use increased from 7.7% and 23.8%, respectively, to 16.4% and 28.8.3% respectively (Figure 4).

··· DISCUSSION ···

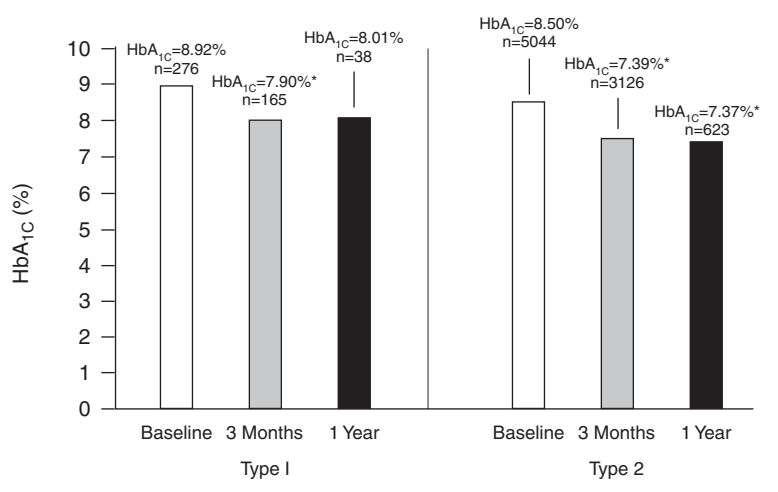
Our data indicate it is possible to achieve a clinically and statistically significant improvement in glycemic control among participants of an HMO-sponsored diabetes disease management program. The mean HbA_{1c} at 3 months and 1 year decreased to levels associated with significantly fewer long-

Figure 2. Decrease in Hemoglobin A_{1C} for Patients Completing 3 Months and 1 Year of Follow-up



*Mean HbA_{1C} for all program participants at baseline.
†$P < .001$ compared with 5332 patients at baseline.
‡$P < .001$ compared with all patients on hypoglycemic medications at baseline.

Figure 3. Change in Hemoglobin A_{1C} for Patients with Type 1 or Type 2 Diabetes Completing 3 Months and 1 Year of Follow-up



*$P < .0001$, compared with baseline value.

term complications from diabetes mellitus.[60-62] Furthermore, the decrease in the mean HbA_{1c} among patients already on hypoglycemic medications supports the value of disease management for patients with established diabetes. Because these data were obtained from a multifaceted clinical program located in multiple outpatient clinics, it is difficult to credit any single intervention for the observed changes. Our naturalistic study of the combined impact of primary care site–based diabetes education, clinical guidelines, facilitated access to diabetes clinical nurse specialists, and coverage for glucose meters and strips suggests these components can be successfully integrated in a managed care setting to improve the health of a diabetic population.

Although providers generally view guidelines with suspicion,[34,63] promotional strategies such as those used in this program, including opportunity for input, providing CME credit, and sending frequent reminders, can increase acceptance of guidelines.[64-66] The advocacy of nurses in the primary care setting appears to be a key ingredient for successful implementation of guidelines in a disease management program because the education nurses were specifically trained to rely on the guidelines in their interactions with patients and physicians. Physician staff meetings with opportunities for input and the use of an educational format with continuing education credit may have further contributed to the success of the program.

Support from health system leadership has been described as critical to the success of any multidisciplinary disease management initiative.[67] In our initiative, senior clinical leaders clearly conveyed their belief that guidelines were a required part of patient care, that attendance at the CME meetings was important, and that CDE- and HMO nurse–based patient education was critical to the success of diabetes care. Furthermore, providing coverage

for glucose meters and strips represented tangible support for our disease management program.

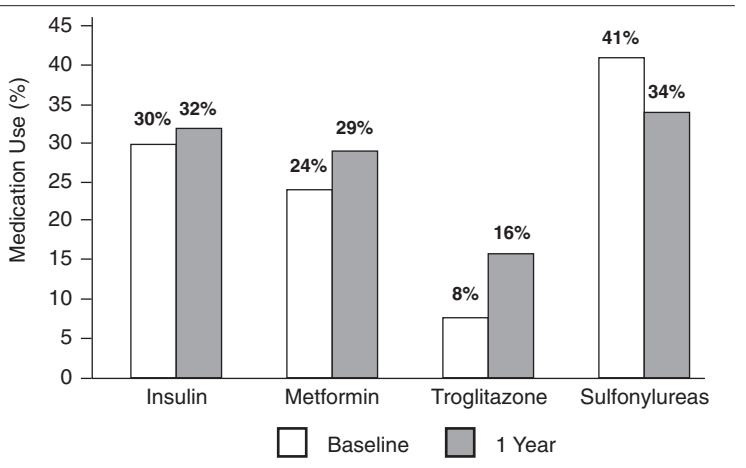
Although managed care has been credited with slowing the growth of healthcare expenditures in the United States, critics argue that this has been achieved by withholding needed medical care and delaying the inevitable long-term costs of chronic diseases, such as diabetes.[68-70] Since reliance on primary care settings for healthcare delivery is a strategy employed by managed care to contain costs, the correct balance of primary versus specialty care for patients with diabetes has been a controversial topic.[49-51,71-73] Our approach may offer an alternative, because we applied proven strategies to benefit a large population across both primary and specialty care settings. Although managed care settings vary in terms of leadership, financing, level of integration, and degree of insurance risk, networks of providers could include elements of our program when developing disease management programs for assigned populations.

Our approach contrasts with reports of "carve-out" diabetes disease management programs.[28-30] Carve-out programs typically use many of the interventions we describe, but differ in that the control, financing, and insurance risk are outside the local paneled healthcare delivery system. The "carve in" described in this paper may be a more attractive alternative, because it relies on existing primary care and endocrinology services for the delivery of diabetes care[74]; it is less likely to lead to fragmentation of medical care, is more convenient for patients who rely on primary care for other medical services, and is more efficient because of teaming of existing physicians with other healthcare providers.

The clinical program reported here was not designed as a rigorous research initiative that examined the efficacy of a disease management program for diabetes mellitus. Such a research program would need to prospectively compare outcomes with those obtained in a randomly selected and matched cohort. Our analysis relied on a pre-post evaluation of data, in which patients served as their own controls, and hence, there is no certainty that the improvement in HbA_{1c} was not the result of influences outside the disease management program or of regression to the mean. However, the improvement in the mean HbA_{1c} in this population was consistent with that in other reports describing similar interventions[11,37,75]; it is also highly unlikely that the changes we observed resulted from influences other than the effect of the disease management program. The change in the mean HbA_{1c} among our patients with Type 1 diabetes, although not statistically significant (most likely because of the limited number of observations), was still clinically relevant, and as more patients are followed for 1 year, this drop in the HbA_{1c} is likely to reach statistical significance.

Previous reports suggest that successful glycemic control in the primary care setting can result in increased costs related to use of additional healthcare resources and specialty care services.[17-19] This report provides no data on the costs of healthcare, training and work-effort of the primary care education nurses, and medications, or on other indirect measures of cost that should be assessed in any complete financial evaluation of a clinical program.[76] However, since the impact of improved glycemic control on diabetic complications can be assessed only after several years,[77] an accurate assessment of any cost savings for our population cannot be performed adequately for the time period of this study. The most tangible expense for this type of program

Figure 4. Medication Use at Baseline and After 1 Year (n = 663)



All patients were receiving medications at entry.

is the cost for education nurses; concerns over this expense can, however, be mitigated by considering the important role of these nurses in advocating the use of clinical guidelines, consolidating data collection, and conducting important disease management and patient education activities.

Although disease management should theoretically include all patients with a chronic illness, this program relied on self-referral, which often stemmed from interest in coverage for glucose meters and strips, and hence, enrollment and participation were voluntary. As outlined earlier, this HMO had more than 7000 patients with diabetes, and it could be argued that only a fraction of these patients realized a documented benefit from participation in this program. Our program had a significant number of dropouts, and hundreds of additional patients experienced delays in follow-up, problems that are not unusual in the primary care setting. Not all patients can enter a disease management program simultaneously, and among those that do enter, not all will agree to follow the mandates of guideline-driven, team-based care. This may, however, be a good first step in building a broader initiative. Coverage for glucose meters and strips was an important patient incentive for enrollment and participation, and it may be a useful strategy for other policy makers and healthcare systems considering the adoption of a disease management program for diabetes.

Our program was accompanied by a decrease in use of sulfonylureas and an increase in use of new hypoglycemic medications (metformin and troglitazone), as well as of insulin. While use of troglitazone has been discontinued, the widespread adoption of the novel antidiabetic drugs in typical practice was specifically advocated in this disease management program. This may be additional evidence of guideline compliance, but it also has implications for the management of the types and costs of pharmaceutical agents in this disease. Additional research is needed to gauge the full impact of medications in disease management.

The growing nationwide interest in disease management may necessitate formal clinical trials. Such research, however, would require considerable resources and a lengthy time-frame. Pending further research, we propose that key components of a successful disease management program should include guidelines, intensive primary care site–based patient education, data collection and outcomes reporting, coverage for glucose meters and strips, and support of health system leadership. Additional research may be warranted on minimizing program dropouts and assuring timely follow-up for patients who remain in disease management programs.

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