

Labor Characteristics and Program Costs of a Successful Diabetes Disease Management Program

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Background: Organizations have invested in disease management programs to improve quality and to reduce costs, but little is known about the labor characteristics and the program costs necessary to implement a program.

Objective: To examine the labor characteristics and the program costs of a successful diabetes disease management program.

Study Design: We performed a labor and cost analysis within a randomized controlled trial of a primary care-based diabetes disease management intervention.

Methods: Participants included 217 patients with type 2 diabetes mellitus and poor glycemic control (glycosylated hemoglobin levels, $\geq 8.0\%$). The intervention group received 12 months of intensive management from clinical pharmacists and a diabetes care coordinator who provided education, applied algorithms for medication management, and addressed barriers to care. The control group attended a single session led by pharmacists, followed by usual care from their primary providers. The process outcomes included the number of patient care-related activities, time spent per patient, and number of drug titrations or additions. The program costs were calculated based on Bureau of Labor Statistics wage data using a sensitivity analysis.

Results: The disease management team performed a mean of 4.0 care-related activities for a mean of 38.6 minutes per patient per month for intervention patients and performed a mean of 1.1 care-related activities for a mean of 10.7 minutes per patient per month for control patients ($P < .001$). Intervention patients had a median of 7 drug titrations or additions during the study. The incremental program cost for the intervention was \$36.97 (sensitivity analysis, \$16.22-\$88.56) per patient per month.

Conclusion: A successful diabetes disease management program can be integrated into an academic clinic for modest labor and cost.

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Large studies,¹⁻⁴ such as the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study, have demonstrated that intensive diabetes care can reduce the complications associated with diabetes mellitus. However, translating this evidence into practice can be difficult, and many patients continue to receive inadequate care.^{5,6} One strategy to improve care has been the implementation of disease management programs. Rather than the traditional model of healthcare delivery that often focuses on acute problems and on visit-based care, disease manage-

ment creates an organized system tailored to the complex problems of chronic illness.⁷ Such programs are characterized by the use of evidence-based algorithms, multidisciplinary teams providing integrated care, and information systems that allow the tracking of patient-oriented outcomes and the adjustment of treatments.⁷⁻⁹ Most previous diabetes management programs have focused on glycemic control and have reduced glycosylated hemoglobin (A1C) levels by as much as 1 to 2 percentage points.¹⁰⁻¹⁴

Government and private sector organizations have recently invested in disease management programs with the goals of improving quality of care and reducing costs.¹⁵⁻¹⁸ However, implementations of these programs have often been hampered by economic concerns. Academic institutions and other healthcare delivery systems have been concerned that the development of disease management programs will require significant logistical planning and a large outlay of labor resources and initial costs. In addition, there are concerns about developing a model that can be financially, organizationally, and clinically sustainable for the long term. To date, only limited studies¹⁹⁻²⁵ have evaluated the labor characteristics and the costs needed to develop and implement a successful program. Most evaluations have focused on health maintenance organizations or other closed systems with select populations and provide limited details about the actual components of a successful program. In addition, most studies have examined the costs using a

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before–after design, without the added strengths of a randomized controlled trial.

A successful randomized controlled trial of a pharmacist-led, primary care–based, diabetes disease management program was recently conducted.²⁶ This program significantly improved care for a vulnerable population with type 2 diabetes mellitus, poor glycemic control, and multiple comorbidities.^{26,27} At 12 months' follow-up, intervention patients improved A1C by almost 1 percentage point, and systolic blood pressure by 9 mm Hg, compared with control patients. Intervention patients also had more than a 40% absolute increase in aspirin use compared with control patients. There were no statistically significant differences in adverse events or in the use of clinical services such as emergency department visits, hospitalizations, or clinic visits.²⁶ The objective of this study was to examine the labor characteristics and current program costs of this successful disease management program. This study was not designed as a comprehensive cost-effectiveness analysis; instead, we focused on describing the labor demands needed to operate a successful disease management program and on providing a gross estimate of the costs to operate this program.

METHODS

Study Design

The data for this analysis were derived from a randomized controlled trial that examined the effect of an intensive diabetes management program.²⁶ The study was conducted in a university general medicine practice that serves a wide socioeconomic range of patients with public, private, and no insurance. The study was initiated in February 2001 and was completed in April 2003. All patients were followed up for 1 year. The study was approved by the institutional review board at The University of North Carolina at Chapel Hill.

Participants

Eligible patients included all adults (≥ 18 years) with type 2 diabetes mellitus who were followed up for their diabetes care in the practice, had poor glycemic control (A1C levels, $\geq 8.0\%$), spoke English, and had a life expectancy of at least 6 months. Primary care providers referred eligible patients for possible participation. Of 285 patients referred, 217 were enrolled and randomized.²⁶ The remaining patients were not enrolled because of physician refusal (10 patients), patient refusal (25 patients), or failure to meet eligibility criteria (33 patients). Of the 217 patients randomized, 12-month follow-up data were available for 193 patients (89%).

Intervention

The intervention has been previously described in detail.^{26,27} After obtaining informed consent and collecting baseline measures, all study patients had an initial management session led by a clinical pharmacist. The pharmacist provided individualized diabetes education to patients and gave treatment recommendations about glycemic control and cardiovascular risk reduction to the patients' primary care providers. After this session, patients were randomized. Patients in the control group received usual care from their primary care providers and had no further contact with the disease management team. For patients in the intervention group, usual care was supplemented by intensive diabetes management from 3 clinical pharmacist practitioners and a diabetes care coordinator. This disease management team operated within the general medicine clinic. The pharmacists had training in outpatient disease management, and 2 were certified diabetes educators. The diabetes care coordinator was an entry-level medical assistant who was trained by the clinical pharmacists to address issues related to health behavior and health education. A pharmacist or the diabetes care coordinator contacted intervention patients by telephone or in person every 2 to 4 weeks or more frequently as indicated.

The intervention included 1-on-1 educational sessions, application of evidence-based treatment algorithms, and strategies to address patient barriers to care. Treatment algorithms (see <http://www.med.unc.edu/medicine/edursrc/algor.htm>) were used to help manage glycemic control and cardiovascular risks and allowed pharmacists to initiate and titrate aspirin and blood pressure, cholesterol, and glucose-lowering medications. The diabetes care coordinator provided telephone reminders, collected clinical data, promoted adherence, and addressed difficulties with transportation, communication, and insurance when needed.

Measures

During the study, the disease management team documented all "patient care–related activities" that they performed on patients participating in the study. This included recording the type of activity (eg, education and medication management) and the time spent by the disease management team in direct contact with the patients or in activities related to patient care. Each patient-related activity, including such activities as scheduling an appointment, attempting a telephone call, or reviewing a medical chart, was documented as a separate encounter. The disease management team also documented if an activity was performed by the pharmacist, diabetes care coordinator, or both staff members. The team further documented if an activity, such

as a telephone call, had been successfully completed or not. The disease management team also documented all medication changes that they made during the study (eg, initiation of new medications and titration or alteration of current medications). For all activities documented, the time involved was coded in 5-minute increments. The minimum time recorded for each activity, including incomplete actions, was 5 minutes.

We collected data only on activities that were performed by the disease management team and did not collect data on activities performed by the patients' primary care providers. For the intervention group, our examination of labor activities and time consisted of activities performed during the initial management session, all intervening management (including direct patient contact or management), referrals, database maintenance, and other care-related activities, as well as data collection visits at 6 and 12 months. For the control group, our assessment of labor activities and time only consisted of activities performed during the initial management session and collection of study-related data at 6 and 12 months.

Statistical Analysis

We performed all analyses using STATA 7.0 (StataCorp LCP, College Station, Tex). We used descriptive statistics to summarize the frequency of patient care-related activities and the time spent on these activities. These process variables were normally distributed, and we performed parametric bivariate analyses to compare these variables by intervention status. We then calculated an estimate of the program costs for the intervention and control groups. Finally, we estimated the marginal costs of implementing the program by subtracting the program costs of the control group from the program costs of the intervention group. Subtracting the control group costs allowed us to obtain a better estimate of the program costs without performing an expensive randomized trial (including data collection, follow-up scheduling, etc). All analyses were performed based on the patients who completed the study.

To estimate the program costs, we made the following assumptions and performed a sensitivity analysis. To estimate the labor costs, we converted our time inputs into labor costs using national wage data. Salaries of the team members were based on current wage data from the Bureau of Labor Statistics.²⁸ For the base case, we used the median national salaries for pharmacists (\$77 050 [sensitivity analysis, \$54 110-\$94 570]) and medical assistants (\$23 940 [sensitivity analysis, \$17 640-\$34 130]), 49 annual working weeks (sensitivity analysis, 46-50 weeks), and a fringe benefit rate of 25% (sensitivity analysis, 20%-30%). We also assumed an

efficiency rate of 80% (sensitivity analysis, 60%-100%) based on previously published time and motion studies²⁹⁻³² of pharmacist management teams. This means that we added 20% more time to our analysis to account for time not directly related to specific patient-based activities, such as database maintenance, personal time, and general program-related activities. For activities that were recorded by both the pharmacist and the diabetes care coordinator, we conservatively assumed that both members worked on that activity for the entire time recorded. For activities that were marked as "incomplete," we conservatively maintained for the base case (ratio, 1:1) the minimum time allotment of 5 minutes, but we assumed in the sensitivity analysis (ratio, 1:1-1:2) that incomplete actions could take less time. In further sensitivity analyses, we considered the case in which control patients did not receive the initial pharmacist education session, because many healthcare providers may not offer this service as standard of care. Finally, to determine the total program costs, we applied a 45% indirect rate (sensitivity analysis, 35%-60%) (based on the National Institutes of Health indirect rate for our institution at the time of the study) to include costs such as space, depreciation, and administrative support. In sensitivity analyses, we examined best- and worst-case scenarios. We focused only on the program costs and did not examine other costs such as patient-related charges or outpatient pharmaceutical costs.

RESULTS

As summarized in **Table 1**, intervention patients had significantly more patient care-related activities per patient per month (mean, 4.0 vs 1.1 activities) and more minutes per patient per month (mean, 38.6 vs 10.7 minutes) from the disease management team ($P < .001$ for both). Among intervention patients, 46% of this time was spent for in-person contact, 42% for telephone management (such as health assessment, adherence promotion, and medication changes), and 11% for medical chart review, appointment setting, referrals, and other activities. **Table 2** summarizes how minutes were stratified by staff and by level of completion. Among control patients, the time was split equally between the pharmacist and the diabetes care coordinator; among intervention patients, 68% of the time was covered by the pharmacist, 19% by the diabetes care coordinator, and 13% by both staff members. Overall, the disease management team spent 18.75% of their time on incomplete actions, such as uncompleted telephone calls.

Among intervention patients, 50% of the pharmacists' time was spent on education, referrals, and other care-

Table 1. Total Program Minutes

Variable	Control Group (n = 95)		Intervention Group (n = 98)	
	Encounters	Minutes	Encounters	Minutes
Patient visit	455 (36%)	7585 (62%)	1208 (26%)	20 740 (46%)
Telephone management	295 (23%)	1767 (15%)	2521 (54%)	19 132 (42%)
Medical chart review and scheduling	496 (39%)	2655 (22%)	894 (19%)	4820 (11%)
Letter and e-mail	21 (2%)	150 (1%)	70 (1%)	740 (2%)
Mean no. per patient per month	1.1	10.7	4.0	38.6

related activities. The other 50% of the pharmacists' time (17 644 minutes) was spent on specific medication management. Most of this medication management time was spent assessing drug efficacy (20.2%), evaluating patient health status (19.8%), and writing prescriptions (18.2%). Other medication management activities included identifying opportunities to start new medications (14.0%), assessing adherence (10.1%), providing advice related to drug safety (3.2%), and other activities. During the study, the pharmacists made 500 drug titrations and 348 new drug additions (median, 4 drug titrations and 3 new drug additions per intervention patient). Most of these drug titrations and additions were for glycemic control medications (393 titrations and 128 additions), blood pressure medications (66 titrations and 53 additions), cholesterol medications (10 titrations and 24 additions), and aspirin (35 additions). Of the 500 drug titrations, 388 were performed according to the treatment algorithm, and 112 required discussion with the provider (usually because pharmacist prescribing exceeded the boundaries of the treatment algorithm). Of the 348 new drug additions, 115 were by protocol, and 233 required discussion with the provider (often for adding medications not included on the algorithms).

The costs per patient per month (with sensitivity analyses) were estimated for the disease management intervention. Among control patients, the labor costs were \$7.06 (sensitivity analysis, \$3.59-\$12.73) per patient per month, and the total costs (labor plus indirect costs) were \$10.23 (sensitivity analysis, \$4.84-\$20.37) per patient per month. Among intervention patients, the labor costs were \$32.56 (sensitivity analysis, \$15.60-\$59.95) per patient per month, and the total costs were \$47.21 (sensitivity analysis, \$21.06-\$95.92) per patient per month. The marginal costs of implementing the disease management program were \$25.50

(sensitivity analysis, \$12.01-\$55.35) per patient per month in labor costs and \$36.97 (sensitivity analysis, \$16.22-\$88.56) per patient per month in total costs.

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DISCUSSION

The results of this study suggest that a successful disease management program can be implemented for reasonable labor resources and costs. For modest labor inputs and a program cost of approximately \$37 per patient per month in marginal cost, A1C levels, cardiovascular risks, and satisfaction among patients with diabetes significantly improved during the course of a year. This program did not appear to significantly increase adverse events or the use of clinical services among patients. The success of the program appears to be related to frequent patient contact and assessment and to frequent medication changes. Frequent telephone and in-person contact from the disease management team, with emphasis on algorithm-driven medication management, may help to overcome the clinical inertia that is often seen in standard ambulatory care delivery models.^{33,34}

Some may consider the estimated program cost of \$37 per patient per month to be too expensive for implementation. However, Medicare pays \$80 to \$375 per member per month to support novel coordinated care or chronic disease management programs.¹⁸ Furthermore, initiating a new blood pressure or glucose-lowering medication for a patient with diabetes typically costs at least \$60 per month and often will not improve outcomes by as much as this program was able to accomplish.³⁵ Although we did not find immediate differences in the clinical utilization of services (such as hospitalizations or emergency department visits), we would expect that maintained success of the intervention on improving

Table 2. Program Minutes by Staff and by Level of Completion

Variable	Control Group (n = 95)			Intervention Group (n = 98)		
	Pharmacist	DCC	Both	Pharmacist	DCC	Both
Complete actions	5057 (95%)	4230 (79%)	1230 (90%)	24 851 (81%)	6520 (74%)	4797 (84%)
Incomplete actions	275 (5%)	1095 (21%)	240 (10%)	5970 (19%)	2250 (26%)	940 (16%)
Total	5332 (44%)	5325 (44%)	1470 (12%)	30 821 (68%)	8770 (19%)	5737 (13%)
Mean minutes per patient per month	4.7	4.7	1.3	26.2	7.5	4.9

DCC indicates diabetes care coordinator.

blood pressure and glycemic control would result in improvements in patient utilization and costs over time. This expectation is supported by a recent study³⁶ modeling the cost-effectiveness of intensive diabetes control that found that intensive glycemic or cholesterol control is cost-effective (with an incremental cost-effectiveness of \$40 000-\$50 000 per quality-adjusted life-year), while intensive blood pressure control is actually cost-saving (saving almost \$2000 per quality-adjusted life-year gained). If sustained, the program could be even more cost-effective because it was able to significantly improve outcomes for patients with low socioeconomic status and with multiple comorbidities, who may be at higher risk for diabetes-related complications and morbidity.^{37,38}

Although the disease management program has been successful, many healthcare provider groups and academic clinics may still be wary to initiate a disease management program because of concerns about the logistics and the resources needed to develop a new program. In fact, the program was developed with only a small amount of resources. For 98 intervention patients who completed the intervention, only approximately one third of a pharmacist full-time equivalent (FTE) and one sixth of a diabetes care coordinator FTE were needed to provide intensive management. The treatment algorithms and standing orders that were implemented were developed by clinical pharmacists and by several interested physicians during a short period and were then approved by the rest of the clinical practice. Technological needs were also minimal and primarily involved the use of existing computer equipment, the addition of a dedicated telephone line, and the development of a simple patient database using Microsoft Access (Redmond, Wash). Space requirements for the program were limited to a small room utilized for administrative tasks and patient education, and patient contact often occurred within the existing clinic space, immediately before or after the patient saw his or her care provider.

Although the cost of the program was modest, the costs of other disease management programs may vary depending on the design of the program, the nature of the intervention, the patient population, and other factors. However, there are many opportunities to make a disease management program more efficient over time. For example, the use of automated telephone systems, increased point-of-care testing, and more efficient allocation of staff resources could reduce the costs.^{39,40} It was recognized in the program that pharmacists were spending too much time performing administrative tasks and incomplete activities (such as unanswered telephone calls), and many of these responsibilities have been shifted to the less expensive diabetes care coordinator. In addition, the disease management team has been able to reduce the frequency and duration of contacts for patients who received the initial comprehensive management and successfully attained treatment goals. The diabetes disease management team of 1.5 pharmacist FTEs and 2.5 diabetes care coordinator FTEs is providing varying levels of disease management services for more than 2000 patients with diabetes.

The cost of maintaining a sustainable disease management program is often raised as a potential barrier to implementation. Traditional payment structures that focus on physician payment using a fee-for-service structure are not well suited for the fundamental changes in care delivery that are required for successful chronic illness care. Although we believe that fundamental restructuring of payment mechanisms will speed adoption of practice-based disease management, disease management programs have been supported through a combination of the following: (1) appropriate fee-for-service billing for encounters with midlevel providers; (2) direct support for services from insurers, including Medicaid and the North Carolina State Health Plan; and (3) contractual support from the institution's healthcare system, which recognizes the importance of good chron-

ic illness care for meeting quality benchmarks and for reducing the costs from preventable admissions among uninsured and underinsured patients. Finally, recent trends suggest that insurers may be increasingly willing to consider appropriate compensation for telephone-based or Internet-based disease management.^{41,42}

A strength of our cost evaluation was that we examined the costs within the context of a randomized controlled trial. This allowed us to more rigorously examine the marginal costs between the control and intervention groups. By subtracting out the control group costs, we were able to estimate the program costs without incurring trial-related costs. However, there were several limitations to our study. Our assessment of the costs only focused on the program costs and was not designed as a comprehensive cost-effectiveness analysis. We focused on the labor costs of the program and did not include capital-related or start-up costs, healthcare provider costs, or patient costs. We were unable to include the medication costs, although the program increased medication use for intervention patients, and medication costs can be a significant contributor to the cost of diabetes care.⁴³ Our assessment of the program costs also does not include the costs related to medical utilization such as hospitalizations or general or specialty clinic visits. Our calculation of the marginal costs is based on a control group that received an initial management session, and this may not be the standard of care at other institutions, although we accounted for this in our sensitivity analyses. In addition, our assumptions of efficiency and indirect time may not be generalizable to other institutions. Our assessment of the program costs also assumes that labor can be partitioned in fractions of FTEs, although this may not be feasible at some institutions where staff are only available as full-time employees. Finally, implementing a disease management program such as this at a new institution or practice site could result in higher or lower labor needs and costs depending on the patient population, institutional parameters, design of the disease management program, and scalability issues. Disease management programs that used different allocations of program staff or that applied different levels of intervention could incur higher or lower costs than the costs presented in this study.

This study demonstrates that a disease management program can be successfully integrated into care for reasonable labor resources and costs. Funding support was obtained for creation of a sustainable disease management program at our institution. Since this analysis, the program has evolved into a more efficient system, and future research will help to determine the best models for improving care among our patients.

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