

Pharmacist Collaborative Management of Poorly Controlled Diabetes Mellitus: A Randomized Controlled Trial

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Objective: To investigate the effect of pharmacist management of poorly controlled diabetes mellitus in a community-based primary care group.

Study Design: Randomized controlled trial of pharmacist management of diabetes compared with usual medical care.

Methods: Patients 18 years or older with glycosylated hemoglobin (A1C) levels of 9.0% or higher were enrolled. Patients were randomly assigned to an intervention group (n = 52) or a control group (n = 51). Management in the control group included the use of registries and targeted patient outreach. The intervention group participated in the same outreach program plus medication management, patient education, and disease control by a pharmacist.

Results: Nonparametric data showed median A1C decreases of 1.50% for the intervention group and 0.40% for the control group ($P = .06$). Significantly more patients in the intervention group improved their A1C level by at least 1.0% relative to the control group (67.3% vs 41.2%, $P = .02$). Most of this benefit was seen for patients of nonwhite race/ethnicity compared with control subjects (56.3% vs 22.7%, $P = .03$). Male patients showed significantly greater benefit as well, with a median A1C decrease of 1.90% vs 0.15% for controls ($P = .03$).

Conclusions: Patients with poorly controlled diabetes improved A1C levels significantly when pharmacist management was added to an aggressive organizational diabetes management program. Our results suggest that clinically trained pharmacists can help primary care providers improve diabetes management, especially among male patients and among patients of nonwhite race/ethnicity.

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Diabetes mellitus affects 23 million people in the United States.¹ Adjusting for population age differences, survey data between 2004 and 2006 indicate that 6.6% of non-Hispanic whites, 7.5% of Asian Americans, 10.4% of Hispanics, and 11.8% of non-Hispanic blacks have diabetes mellitus.¹ Totalling \$174 billion in 2007, diabetes care accounts for 19% of total healthcare costs.¹ Among patients with diabetes, 21% to 43% have glycosylated hemoglobin (A1C) levels exceeding 9.0% according to a 2004 study²; evidence suggests that attempting to achieve A1C levels below 7.0% will delay, ameliorate, or prevent the microvascular and neuropathic complications of diabetes.^{3,4} Data on trying to lower A1C levels below 7.0% are inconclusive.⁵ American Diabetes Association⁶ guidelines recommend a goal of less than 7.0% for A1C control.

The medical literature demonstrates improvement in patient A1C levels with the use of clinical databases and case managers.⁷⁻⁹ Case managers coordinate all disease-related care and education, as well as support patient self-management. Early investigations showing the value of nurse case managers were conducted in an era of fewer medications and less aggressive management, usually involving patients enrolled in health plans, notably health maintenance organizations.⁷ Patients in the nurse case management group attained significantly lower A1C levels by 0.6% to 1.0% compared with the control group.

More recent studies¹⁰⁻¹⁵ have used a model whereby pharmacists work in collaboration with primary care physicians. Given the ever-increasing options for treating diabetes, pharmacists should be well positioned to evaluate the merits of each therapeutic option and to provide patient education. Studies showing the benefit of pharmacists serving as case managers have been small and often nonrandomized. The few randomized controlled trials have been performed in large urban academic or diabetes referral centers. As an example, Choe et al¹⁰ showed improved A1C levels and process outcome measures in a single-university ambulatory internal medicine clinic for patients with diabetes. We add to the literature a randomized study that describes pharmacist management of patients with diabetes who failed to respond to systematic patient outreach using a regularly updated all-payer registry in the primary care setting.

METHODS

Study Design and Setting

This was a 12-month prospective randomized controlled study. The pri-

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mary outcome measure was the change in A1C level at the end of 1 year. Secondary outcomes were the percentage of patients with a 1.0% decrease in A1C level. This outcome was assessed in the population as a whole and as a function of minority racial/ethnic group status. The research committee and the institutional review board of Saint Mary's Health Care, Grand Rapids, Michigan, approved this study.

The study site was the Advantage Health Physician Network (AHPN), which uses an electronic registry that identifies all adults with diabetes mellitus. Thirteen AHPN offices participated, including 3 urban, 9 suburban, and 1 rural site. Clinical practice guidelines, diabetes indicators, and performance thresholds are tracked routinely and are shared regularly with providers and staff. Each office has specific personnel budgeted to support diabetes quality-related initiatives. The latest quality indicators for individual patients are available at each office visit. In addition, there is systematic telephone and mail outreach to patients who are due for diabetes-related care.

Patients and Randomization

Patients with diabetes 18 years or older having A1C levels of 9.0% or higher or no office visits within 12 months were contacted by a study nurse. The nurse saw the patient at his or her home and determined study eligibility. Patients were excluded from the study if an endocrinologist was managing their diabetes or if they were not expected to live for the duration of the study. Eligible patients were tested using a Bayer DCA 2000 (Bayer Corporation, West Point, CT) point-of-care A1C instrument and were offered enrollment if their A1C level was 9.0% or higher. The study nurse obtained institutional review board–approved informed consent at this point from patients who agreed to participate and to attend all study visits.

Using sequential envelopes containing computer-generated group assignment, the research nurse randomized patients to the intervention group or to the control group. Envelopes were opened after patients were deemed eligible for the study. Both study groups received the aggressive outreach already described.

One pharmacist (JPJ) provided all diabetes-related care for the intervention group. The pharmacist is a board-certified pharmacotherapy specialist, who participated in an American Society of Health-System Pharmacists diabetes management traineeship, an American Diabetes Association postgraduate course in diabetes management, and an American Association of Diabetes Educators training program.

Take-Away Points

Pharmacist management resulted in improved glycosylated hemoglobin level among patients who had failed systematic outreach and regular use of an all-payer registry.

- Improving management of patients with poorly controlled diabetes mellitus using pharmacist intervention is time intensive and resource intensive.
- Our data suggest that male patients and patients of nonwhite race/ethnicity are the greatest responders to pharmacist management. This finding needs to be confirmed by further research.

Patients in the intervention group also met with the pharmacist at their respective primary care site for an assessment of adherence, barriers to optimizing blood glucose levels, and current medication regimen. All intervention patients received individualized education regarding diabetes self-management, including diet, exercise, blood glucose level testing, medications, and insulin. The pharmacist followed guidelines of the Management of Hyperglycemia in Type 2 Diabetes.¹⁶ This included early switching to insulin therapy after failure of 2 oral medications. The patient's primary care physician approved any changes in medication or therapy, although the pharmacist was given autonomy to adjust insulin doses as needed. The number of subsequent visits with the pharmacist was based on the need to further educate the patient about diabetes control or to monitor therapeutic changes. Follow-up visits were supplemented with telephone calls as needed for medication management. Patients were followed up for 12 months after study enrollment. We were unable to assess adverse events in the control group. There was 1 severe hypoglycemic event in the intervention group. *Severe adverse events* were defined as those requiring assistance from another person.

Statistical Analysis

A power analysis indicated that at least 39 patients were needed in each study group to show a clinically significant decrease in A1C level of at least 1.0% ($\beta = 0.20$ and $\alpha = 0.05$). χ^2 Test and Fisher exact test were used where appropriate for nominal data. Mann-Whitney test was used for nonparametric quantitative data and unpaired *t* test for parametric quantitative data. Significance was set at $P < .05$. The statistical software used was NCSS 2004 (Kaysville, UT).

RESULTS

Recruitment began in May 2006, and final 1-year follow-up for the last patient was in December 2007. Among all AHPN patients with diabetes, 902 had an A1C level of 9.0% or higher or had not been seen by their primary care provider within the previous 12 months. Of these, 491 patients were successfully contacted and were invited to participate in the study. Two hundred thirty-five patients were excluded; 191

■ **Table 1.** Baseline Characteristics of the Study Population^a

Characteristic	Intervention Group (n = 52)	Control Group (n = 51)	P
Demographic			
Age, mean (SD), y	49.3 (10.8)	49.7 (10.9)	.09 ^b
Weight, mean (SD), lb	223 (50)	209.5 (60)	.20 ^b
Male sex, No. (%)	25 (48.9)	25 (49)	.92
White race/ethnicity, No. (%)	36 (69.2)	29 (56.8)	.19
Baseline glycosylated hemoglobin level, mean (SD), %	10.4 (1.2)	11.1 (1.6)	.02 ^b
Glycemic management, No. (%)			
Oral medications	29 (55.8)	23 (45.1)	.23
Insulin	23 (44.2)	28 (54.9)	.28
Basal, alone or with oral medications	11 (21.1)	6 (11.8)	.20
Basal-bolus	17 (32.7)	17 (33.3)	.94
Insurance type, No. (%)			
Private	29 (55.7)	36 (70.5)	.12
Medicare or Medicaid	3 (5.8)	4 (7.9)	.71
None	20 (38.4)	11 (21.6)	.06

^aThe only significant difference between study groups at baseline was lower glycosylated hemoglobin level in the intervention group.
^bUnpaired *t* test. All other *P* values are by χ^2 test.

(39.0%) declined participation, and 44 (9.0%) were managed by a specialist. An additional 152 (31.0%) had an A1C level of less than 9.0% at the time they saw the study nurse. The remaining 104 patients were randomized, 52 to the control group and 52 to the intervention group.

One patient in the control group was excluded as an outlier based on A1C level exceeding 3 SDs from the mean A1C change. This patient was hospitalized for 3 weeks because of diabetes complications and subsequently attained an 8.6% decrease in A1C level. Therefore, the final analysis was based on 103 patients, 52 in the intervention group and 51 in the control group. Baseline demographic data are given in **Table 1**. The only significant difference between study groups at baseline was lower A1C level in the intervention group.

The A1C changes were not normally distributed, so median values were used as the measure of central tendency. The overall median A1C reduction in the intervention group was 1.1% greater than that of the control group. This difference approached but did not achieve statistical significance. Post hoc subgroup analysis showed that male patients in the intervention group achieved a statistically significant improvement in their A1C level (median, -1.90%; interquartile range, -0.05% to -2.95%) versus the control group (median, -0.15%; interquartile range, 0.98% to -1.38%). **Table 2** gives details of these results.

From the perspective of individual patient improvement, statistically more patients in the intervention group achieved at least a 1.0% improvement in A1C level overall. Twice as

many patients of nonwhite race/ethnicity and male patients (post hoc) in the intervention group exceeded the 1.0% improvement mark. No treatment effects using this measure were seen for patients of white race/ethnicity or for female patients (**Table 3**).

This intervention required considerable effort. The pharmacist averaged 6 office visits and 3 telephone calls per patient over the course of a year. Office visits lasted between 30 and 60 minutes. Telephone calls were 10 to 20 minutes in length. The pharmacist changed the drug regimen to basal-bolus insulin in 15 patients (28.8%) and discontinued oral medications completely in 15 patients (28.8%). In the control group, only 1 patient's regimen was changed to basal-bolus, oral medications were discontinued in 1 patient, and insulin was added for 1 patient. As evidence of aggressive treatment in the control group, there were 6000 patients in the all-payer registry in 2007, and 55.1% had both an A1C level of less than 7.0% and low-density lipoprotein cholesterol (LDL-C) level of less than 100 mg/dL (to convert cholesterol level to millimoles per liter, multiply by 0.0259). This is substantially better than 2007 data in Medicaid beneficiaries, among whom the 90th percentile is 30.2% A1C control and 42.3% LDL-C control.¹⁷

DISCUSSION

This study was undertaken to ascertain the benefit of having a pharmacist work with primary care physicians to reduce

■ **Table 2.** Reduction in Glycosylated Hemoglobin Level by Study Group^a

Variable	Reduction in Glycosylated Hemoglobin Level, Median (Interquartile Range), %	P ^b
Overall		
Intervention group (n = 52)	-1.50 (-0.03 to -2.68)	.06
Control group (n = 51)	-0.40 (0.50 to -2.10)	
Patients of white race/ethnicity		
Intervention group (n = 36)	-1.8 (-0.2 to -2.7)	.05
Control group (n = 29)	-1.2 (0.0 to -2.5)	
Patients of nonwhite race/ethnicity		
Intervention group (n = 16)	-1.1 (0.1 to -1.9)	.07
Control group (n = 22)	-0.1 (1.4 to -0.9)	
Male patients		
Intervention group (n = 25)	-1.90 (-0.05 to -2.95)	.03 ^c
Control group (n = 26)	-0.15 (0.98 to -1.38)	

^aThere was a trend for greater improvement in the intervention group. Post hoc analysis showed significantly greater improvement among male patients in the intervention group.
^bMann-Whitney test.
^cStatistically significant.

A1C levels among patients with poorly controlled diabetes who failed to respond to systematic patient outreach in multiple community-based clinics. Greater health benefits accrue when moving from poor (A1C level >9.0%) to moderate glycemic control compared with moving from moderate to almost normal glycemic control. Vijan et al¹⁸ showed that 80% of reductions in blindness and in end-stage renal disease resulted from targeting less than 20% of patients with the worst A1C control. Our overall findings of significantly improved A1C outcomes among individuals in the intervention group are compatible with the findings of 2 recent comprehensive reviews^{13,14} of pharmacist management of diabetes. Our study was not originally powered to show subgroup differences. Despite this, statistically more patients of nonwhite race/ethnicity and male patients achieved at least a 1.0% improvement in A1C level. To our knowledge, this subgroup differentiation has not been previously identified and needs to be confirmed by future research. However, our finding of greater improvement with pharmacist intervention among patients of nonwhite race/ethnicity is congruent with results of studies that were limited to specific racial/ethnic groups. Studies^{9,19} among subjects of nonwhite race/ethnicity showed much greater improvement over control values than studies^{11,20} among subjects of white race/ethnicity. Minority racial/ethnic groups have not only poorer controlled diabetes but also more complications.²¹⁻²³ Compared with non-Hispanic whites having diabetes, Mexican Americans and African Americans with diabetes have at least a 4-fold greater incidence of kidney dis-

ease, and Mexican Americans with diabetes have a 1.8-fold greater incidence of peripheral vascular disease.²⁴ Given the disproportionate prevalence of diabetes and diabetic complications among patients of minority races/ethnicities, coupled with poorly controlled A1C level, case management with a pharmacist can be of benefit to these populations and is a tool that is likely to have clinically meaningful results.

The intervention group showed more improvement, despite having lower baseline A1C levels than the control group. This could mean that diabetes in the control group was more difficult to manage. However, previous investigations have found greater improvement with higher baseline A1C levels, suggesting that the intervention group was actually at a disadvantage.¹⁰ Among male patients, approximately 2 patients had to be treated by a pharmacy case manager for 1 year to have 1 patient improve his A1C level by at least 1.0%. Among minority races/ethnicities, 3 patients had to be treated by a pharmacy case manager for 1 year to have 1 patient improve his or her A1C level by 1.0%. Among patients in the United Kingdom Prospective Diabetes Study³ with type 2 diabetes mellitus, each 1.0% reduction in updated mean A1C level led to a 21% reduction in death, 14% reduction in myocardial infarction, and 37% reduction in microvascular complications. Therefore, male patients and patients of nonwhite race/ethnicity in our intervention group achieved A1C improvements that are likely to be clinically significant. We did not power the study to evaluate blood pressure, cholesterol, retinopathy, or nephropathy screening differences in the study

■ **Table 3.** Patients Who Achieved at Least a 1.0% Decrease in Glycosylated Hemoglobin Level^a

Variable	No. (%)	<i>p</i> ^b
Overall		
Intervention group (n = 52)	35 (67.3)	.02 ^c
Control group (n = 51)	21 (41.2)	
Patients of white race/ethnicity		
Intervention group (n = 36)	25 (69.4)	.23
Control group (n = 29)	16 (55.2)	
Patients of nonwhite race/ethnicity		
Intervention group (n = 16)	9 (56.3)	.03 ^c
Control group (n = 22)	5 (22.7)	
Female patients		
Intervention group (n = 27)	16 (59.3)	.49
Control group (n = 26)	13 (50.0)	
Male patients		
Intervention group (n = 25)	18 (72.0)	.002 ^c
Control group (n = 25)	7 (28.0)	

^aStatistically significant differences were found in the intervention group overall. Secondary analysis showed significant improvement in the intervention group among male patients and among patients of nonwhite race/ethnicity.
^b χ^2 Test.
^cStatistically significant.

groups. Results of other studies^{25,26} suggest that pharmacists can improve these measures as well.

The fact that basal-bolus insulin was started in 28.8% of patients in the intervention group versus 2.0% in the control group indicates a different approach to diabetes management by the pharmacist. In addition to adding insulin, the pharmacist simplified medication regimens by discontinuing oral medications in 28.8% of patients versus 2.0% in the control group. The average patient was in contact with the pharmacist for more than 300 minutes during the 1-year intervention. This significant time and cost highlight the commitment it takes to help patients overcome the difficulty of intensifying treatment. The time commitment is similar to that seen in the Diabetes Control and Complications Trial.²⁷

This study extends findings of the Diabetes Ten City Challenge²⁶ and the Asheville Project²⁵ regarding the benefit of pharmacist intervention. We randomized all patients regardless of insurance status, whereas the Diabetes Ten City Challenge recruited volunteers and excluded one-quarter of them from their final outcomes because of missing economic data. In addition, our patients were selected as the most costly and challenging among patients with diabetes. As expected with higher baseline levels, A1C decrease was greater in our study than in the Diabetes Ten City Challenge. The Asheville Project studied a select insured population and evaluated the economic benefit of using pharmacists, certified diabetes

educators, and enhanced benefit plans in a community pharmacist diabetes care program.

Limitations of our study include the use of a single primary care group, although this is mitigated by the use of diverse sites (ie, urban, suburban, and rural). This study was not designed to prove whether a pharmacist (as opposed to other types of providers) is specifically needed to obtain the benefits of this case management approach. The subsidized nature of the pharmacist time and cost in this study threatens external validity. Finally, the participating pharmacist herein was clinically trained and experienced in patient care activities such as medication management and motivational interviewing. However, community pharmacists without specialized training in diabetes have been shown to improve outcomes in a health maintenance organization population.²⁸ Therefore, the pool of available pharmacists may be greater than expected. Overall, the results of this study should be generalizable to similarly equipped primary care groups employing an experienced clinical pharmacist.

The findings of this study should stimulate healthcare policymakers to evaluate the cost and benefit of including a pharmacist case manager in primary care networks as part of a systematic approach to diabetes management. Our study demonstrated improvement in disease management by a pharmacist for the most costly segment of the population with diabetes (those with A1C level >9.0%). This poorly

controlled group still represents 10% of patients in our baseline population with aggressive interventions already in place (55.1% with A1C level <7.0% and LDL-C level <100 mg/dL). The benefit was seen among insured patients and among uninsured patients. For reasons yet to be explained, male patients and patients of nonwhite race/ethnicity showed disproportionately greater improvement. Our study provides a foundation for future research into pharmacist case management in a community-based primary care practice rather than in a health plan or university setting.

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