Evaluation of a diabetes management program using selected HEDIS measures

Lourdes G. Planas, Kimberly M. Crosby, Kevin C. Farmer, and Donald L. Harrison

Abstract

Objective: To evaluate the efficacy of a community-based, pharmacist-directed diabetes management program among managed care organization enrollees using National Committee for Quality Assurance (NCQA)–Healthcare Effectiveness Data and Information Set (HEDIS) performance measures.

Design: Randomized controlled trial.

Setting: Regional community pharmacy chain in Tulsa, OK, from November 2005 to July 2007.

Patients: 52 participants with diabetes and hypertension who were enrolled in a managed care organization.

Intervention: Diabetes management versus standard care.

Main outcome measures: Comprehensive diabetes care measures of glycosylated hemoglobin (A1C <7.0%), blood pressure (<130/80 mm Hg), and low-density lipoprotein (LDL) cholesterol (< 100 mg/dL). A composite research outcome of success was created by determining whether a participant achieved two of the three HEDIS goals at the end of 9 months.

Results: 46.7% of intervention group participants achieved the A1C goal, while 9.1% of control group participants achieved the goal ($P < 0.002$). More than one-half (53.3%) of intervention participants achieved the blood pressure goal compared with 22.7% of control participants ($P < 0.02$). Among control group participants, 50% achieved the LDL cholesterol goal compared with 46.67% of intervention group participants. The odds of the intervention group attaining the composite goal were 5.87 times greater than the control group.

Conclusion: A community pharmacy–based diabetes management program was effective in achieving A1C and blood pressure goals measured by NCQA–HEDIS performance standards. Program participants were statistically significantly more likely to achieve two of three HEDIS standards during a 9-month period.

Keywords: Diabetes, Healthcare Effectiveness Data and Information Set, interventions, medication therapy management, pharmacists.

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Lourdes G. Planas, PhD, is Assistant Professor, College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City. **Kimberly M. Crosby, PharmD, BCPS, CGP, CDE, BC-ADM,** was Clinical Services Coordinator, USA Drug Stores, Tulsa, OK, at the time this study was conducted; she is currently Associate Professor, College of Pharmacy, University of Oklahoma Schusterman Center, Tulsa. **Kevin C. Farmer, PhD**, is Professor; and **Donald L. Harrison, PhD**, is Associate Professor, College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City.

Correspondence: Kimberly M. Crosby, PharmD, BCPS, CGP, College of Pharmacy, University of Oklahoma, 4502 East 41st St., Suite 2H38, Tulsa, OK 74135. Fax: 918-660-3009. E-mail: kimberly-crosby@ouhsc.edu

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Diabetes is a complex disease that affects many Americans and consumes a major portion of health care dollars. The Centers for Disease Control and Prevention estimated the prevalence of diabetes in 2010 to be 25.8 million cases and concluded that it was the seventh leading cause of death.[1] Complications from diabetes (e.g., heart disease, stroke, hypertension, nerve damage, blindness, kidney disease, amputation) can be severe. Adults diagnosed with diabetes have cardiovascular death rates roughly two to four times higher than adults without diabetes. Diabetes is the principal cause of adult blindness, end-stage renal disease, and nontraumatic lower-limb amputations. Consequently, diabetes also is a key driver of health care expenditures. The total cost of diabetes in the United States for 2007 was $218 billion.[2]

Maintaining control of glycemic index, blood pressure, and lipid levels is critical for managing diabetes and its complications.[2-4] The U.K. Prospective Diabetes Study (UKPDS) demonstrated that a 1% reduction in glycosylated hemoglobin (A1C) is associated with an approximately 21% risk reduction for diabetes-related macrovascular and microvascular complications.[5-8] Additional outcomes from UKPDS indicated that for every 10 mm Hg reduction in systolic blood pressure (SBP), the risk of such diabetes-related complications is reduced by 12%.[9] With regard to cardiovascular events, elevated low-density lipoprotein (LDL) cholesterol is associated with the development of coronary heart disease.[10] The American Diabetes Association recommends achieving the following values: A1C less than 7.0%, blood pressure less than 130/80 mm Hg, and LDL cholesterol less than 100 mg/dL.[4]

Although a large number of health care dollars are directed toward diabetes care, the therapeutic management of glycemic index, blood pressure, and lipid levels by patients and health care providers is frequently less than ideal.[11] This lack of management leads to poor health outcomes and higher costs as a result of diabetes complications.[12] The majority of patients with diabetes do not collectively meet A1C, blood pressure, and LDL cholesterol goal levels. National Health and Nutrition Examination Survey data published for 2003 –06 indicated that less than 15% of patients with diabetes had achieved goal levels for the composite of the three outcomes. Approximately 60% of patients achieved A1C goals (<7.0%), 46% achieved blood pressure goals (<130/80 mm Hg), and 47% achieved LDL cholesterol goals (<100 mg/dL) for the same period.[11,13]

Disease management programs have been developed to improve outcomes among patients with difficult-to-manage chronic diseases such as diabetes. Diabetes management programs have been shown to improve patient outcomes and have been delivered by physicians, nurses, diabetes educators, and pharmacists.[14] Pharmacist-directed diabetes management programs have demonstrated the value of pharmacists in achieving tighter glucose control, improving provider adherence to practice guidelines, reducing overall health care costs, and minimizing patient complications. Many programs have included medication therapy management (MTM) services, in which pharmacists seek to optimize therapeutic outcomes for individual patients by managing medications to improve response to therapy and limit adverse effects and by providing patient education to improve medication adherence.[15]

Health services researchers have been critical of MTM studies from a research design perspective.[16] Many studies evaluated a pharmacist-directed diabetes management program without sufficient control[17-20] or used a cohort research design.[21-23] The internal validity of cohort studies, which compare a selected group of participants to an intervention group, may be at risk of selection bias. For example, patients referred to the program may be very different from those not in the program. Variability between groups may be accentuated when participants are not randomized. Very often, the studies published in the literature use a pre/post study design, not a randomized controlled design. In addition, studies often do not evaluate diabetes management programs based on comprehensive clinical measures, such as A1C, blood pressure, and LDL cholesterol levels.[14] One recent study that evaluated the achievement of the three goals in a clinic population was conducted as a retrospective analysis and did not evaluate the impact of a specific diabetes management program on those outcomes.[24] Although statistical improvements in reducing A1C, blood pressure, and LDL cholesterol are beneficial, stud-

At a Glance

Synopsis: Researchers compared a community pharmacy–led diabetes management program with standard care. Three endpoints recognized by the National Committee for Quality Assurance–Healthcare Effectiveness Data and Information Set (HEDIS) were used to measure for effective health care intervention: glycosylated hemoglobin less than 7.0%, blood pressure less than 130/80 mm Hg, and low-density lipoprotein cholesterol less than 100 mg/dL. Participants in the intervention group were significantly more likely to attain two of the three endpoint goals (for A1C and blood pressure) compared with the control group. The intervention group was nearly six times more likely to achieve those goals.

Analysis: *Diabetes is a serious and growing problem affecting the health of the population and placing great demands on the health care system. With increasing numbers of people being diagnosed with diabetes or prediabetes, the need for management also will increase. The current study offers evidence that pharmacists can be an important part of that management paradigm, as participants in the intervention arm of this study not only met two out of three HEDIS goals for diabetes management, but they did so at a rate nearly six times that of the control group. Community pharmacy–led diabetes management programs may help to maintain greater patient health and help reduce the costs of treating uncontrolled diabetes.*

ies may not be evaluating defined objective goal parameters routinely used to evaluate and accredit health care organizations and providers.[25]

The National Committee for Quality Assurance (NCQA)–Healthcare Effectiveness Data and Information Set (HEDIS) is used by more than 90% of health care plans in the United States. HEDIS measures the effectiveness of comprehensive diabetes care as A1C less than 7.0%, blood pressure less than 130/80 mm Hg, and LDL cholesterol less than 100 mg/dL.[26] Few studies have compared the outcomes of these health care plans with HEDIS standards and followed multiple data points over time for adherence to these established standards.[25,27-29] In addition, acceptable reimbursement for pharmacist-provided diabetes education and management services has been slow to develop. One of the reasons often stated is lack of objective measures to demonstrate effectiveness. A randomized controlled study using well-accepted objective standards will aid health care organizations and payers in evaluating the effectiveness of pharmacist-provided diabetes management services.

Objectives

The goal of this study was to evaluate the efficacy of a community-based, pharmacist-directed diabetes management program among enrollees of a managed care organization (MCO) using HEDIS comprehensive diabetes care performance measures for A1C, blood pressure, and LDL cholesterol. A primary objective was to determine whether attainment of individual HEDIS performance goals for A1C, blood pressure, and LDL cholesterol was associated with participation in the program. A secondary objective was to assess the influence of the program on the probability of participants achieving a composite research outcome, which was defined as successfully attaining any two of the three HEDIS clinical outcomes goals (A1C, blood pressure, and/or LDL cholesterol).

Methods

A randomized controlled study design was used. Participants in the control group attended visits at baseline and 3, 6, and 9 months, during which their A1C, blood pressure, and LDL cholesterol levels were recorded and they were informed of goal levels. In addition to the quarterly measurements, participants in the intervention group received diabetes education and management services on a monthly basis.

Study visits occurred at five community pharmacies in Tulsa, OK. These pharmacies were part of a regional pharmacy chain with 60 stores in the Tulsa area. The study pharmacy locations were distributed throughout the Tulsa metro area. Participants selected one of the five study pharmacies for their visits. Pharmacists were trained by the investigators to provide the study intervention. Pharmacists received 23.5 hours of training on diabetes management, including the most recent treatment guidelines for diabetes, hypertension, and dyslipidemia, and on study procedures.[3,10,28] A clinician investigator accompanied the pharmacists on their initial patient visit to ensure that care was delivered consistently. Pharmacists providing the education and management were compensated by the pharmacy chain and given time outside of their dispensing activities to provide the care.

Measurements of A1C were performed via fingerstick using DCA 2000 point-of-care devices. Blood pressure measurements were taken with aneroid sphygmomanometers at each study visit after the participant had been resting for a period of at least 5 minutes. Readings that were above the recommended goal of 130/80 mm Hg were confirmed by a second reading. Lipid panels were performed via fingerstick using Cholestech LDX point-of-care devices after the participant had been fasting for 9 to 12 hours. The point-of-care device used the indirect method to provide LDL cholesterol readings.

Study participants were members of a large MCO. Participants had to be at least 18 years of age, be currently insured by the MCO, be able and willing to come to visits during a 9-month period, and have their most recent A1C value in the previous six months be 7.0% or more. They could not be pregnant or currently enrolled in another diabetes program. Participants did not have to receive their prescriptions from the study site pharmacies. Three recruitment methods were used to enroll participants between November 29, 2005, and September 16, 2006 (Figure 1). Eligible individuals opted to participate.

The first recruitment procedure began with the MCO screening lab data from its members in the greater Tulsa area who had been continuously enrolled for at least 9 months. The MCO mailed recruitment letters to 872 individuals with A1C levels of 7.0% or more. The letter included a study description and a request to contact the investigators via telephone to find out if they were eligible to participate.

The second recruitment procedure involved screening attendees at a local health fair for city employees insured by the MCO. Point-of-care A1C testing was conducted by the investigators at no charge to attendees with diabetes. Individuals who had A1C test results of 7.0% or greater and who met the study inclusion and exclusion criteria were invited to participate in the study.

For the third recruitment procedure, the MCO faxed patient referral requests and a letter describing the study to its network primary care physicians (PCPs). Physicians were asked to fax a referral form for patients whose last A1C level within the previous 6 months was 7.0% or more and who agreed to be contacted by the investigators regarding study participation. Participants then were contacted by study investigators for further screening.

Eligible participants who provided informed consent were randomly assigned to the intervention or control group based on a previously generated random number list (Figure 1). Participants were scheduled at their preferred pharmacy location for study visits. The study was approved by the University of Oklahoma Health Sciences Center Institutional Review Board.

Study visits and intervention

All participants in the control and intervention groups received A1C and fasting lipid panel testing at no charge in their selected community pharmacy during baseline and 3, 6, and 9 month

visits (Figure 1). Written test results were provided to participants in both groups. All participants were encouraged to discuss their results with their PCP. If any study participant did not own a glucometer, one was provided to them at no charge, and they were educated on the use of the device. At the baseline visit, all participants were provided with a comprehensive packet of written patient education materials on diabetes and hypertension and complications of these diseases, such as coronary heart disease.

The study intervention, which consisted of patient education and diabetes management services, occurred on a monthly basis (Figure 1). Intervention group participants met individually with the pharmacist in the community pharmacy of their choice for a 1-hour visit. Participants received diabetes education and coaching on self-management skills such as diabetes goals, blood glucose monitoring, diet and lifestyle modifications, foot care, and medication adherence at these visits. Intervention group participants diagnosed with hypertension or dyslipidemia also received education and coaching on self-management skills and goals specific to those diseases, such as weight loss, sodium restriction, exercise, and dietary decreases in saturated fat and cholesterol. For medication management services, the pharmacist completed a comprehensive assessment of prescription and nonprescription medications to identify drug therapy problems at each visit. The pharmacist subsequently contacted the participant's PCP via fax or telephone to recommend adjustments to therapy based on the assessment, such as adjusting medication doses and adding or removing therapeutic agents. Documentation of the participant's visit with the pharmacist, including education provided and recommendations for drug therapy changes, was sent to the participant's PCP. Participants were followed up at their next visit to monitor the status of drug therapy problem resolution (e.g., change in medication therapy by PCP) and clinical goal attainment.

Control group participant visits occurred at 3-month intervals and lasted approximately 30 minutes. However, these participants did not receive individual diabetes education from the pharmacist during subsequent visits. They also did not receive diabetes management services at any time during the study. If control group participants had specific questions regarding their diseases or medication therapies, they were answered by the pharmacist provider. Participants were encouraged to discuss their questions with their PCP as well. Control group patients who had an urgent issue (e.g., significantly elevated blood glucose) were referred to their PCP, and the pharmacist communicated information about the identified problem to the PCP.

Study variables

The primary objective was to assess the ability of the intervention to help participants attain A1C, blood pressure, and LDL cholesterol goals by the end of the 9-month study period. To this end, we used the most conservative HEDIS comprehensive diabetes care measures (A1C <7.0%, blood pressure <130/80 mm Hg, LDL cholesterol <100 mg/dL).[26,28] Dichotomous variables were used to indicate success for each research outcome measure. A composite indicator of success was created by assessing whether the participant attained the goal for at least two of the three measurements by the end of the study. A composite measure of all three achieved goals was not selected based on low incidence[11,13] and recognition of brevity of the 9-month study period.

Other variables of interest were intervention group membership, gender, age, ethnicity, length of time in study, and hypertension study group membership. The last variable was included because 78.5% of participants were also enrolled in a nested hypertension education and management study,[29] which was part of the larger diabetes study. Therefore, controlling for potential confounding effects on individual goals or the composite goal was important. Eligibility for the hypertension study was determined at the baseline diabetes visit. All intervention group participants in the diabetes study received the same intervention regardless of their involvement in the hypertension study.

Data analysis

Modified intention-to-treat analyses were conducted. Each participant had to attend at least the initial 3-month visit to be included in analyses. Participants who dropped out of the study before the 3-month visit were excluded from analyses because no effect of the intervention on the outcome measures could be determined. If participants who attended the 3-month visit did not complete all future study visits, their last outcome measures were carried forward to represent their 9-month levels.

Associations between group membership and goal attainment were assessed using chi-square tests. Bivariable analyses were conducted to assess the impact of demographic and study variables on composite research goal attainment. In addition, group differences in all clinical data changes from baseline to 9 months were compared using two-tailed independent *t* tests. Data were entered into a Microsoft Access database and imported into Stata version 10.1 (Stata, College Station, TX). For all analyses, the alpha level was 0.05.

Results

A total of 65 participants enrolled in the study (27 assigned to the control group and 38 to the intervention group). The majority of participants were white, women, college educated, and overweight (Table 1). Despite random assignment, the intervention group had a higher mean body mass index than the control group. Study enrollees who did not return for any appointments after the baseline visit were not included in analyses; at study conclusion, 52 participants were included (22 in the control group and 30 in the intervention group).

Drop-out rates were 29.6% and 36.8% among control and intervention group participants, respectively. Evidence for an association between group and dropping out of the study ($X^2 = 0.367$, $P = 0.545$) was lacking. Among the 57 participants recruited by letters from the MCO, 31.6% dropped out. None of the four participants recruited in person at the health fair dropped out of the study, and all four participants recruited by

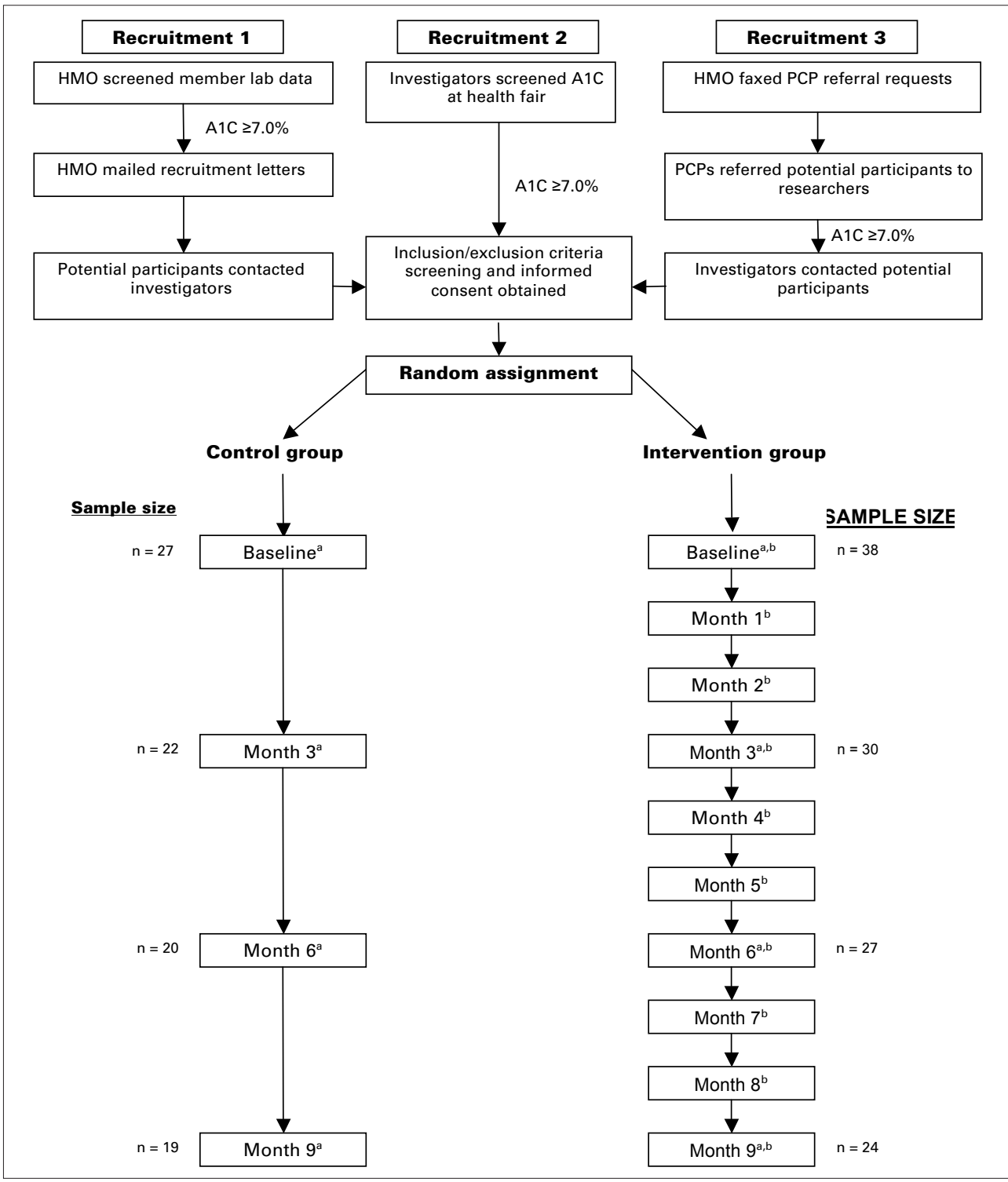

Figure 1. Recruitment methods used in diabetes management program

Abbreviations used: A1C, glycosylated hemoglobin; BP, blood pressure; HMO, health maintenance organization; MTM, medication therapy management; PCP, primary care physician.

[a]Received A1C, BP, and lipid testing and written results.

[b]Received monthly education and MTM services; their PCPs were sent visit documentation and drug therapy recommendations.

physician referral dropped out. The majority of participants who dropped out of the study did so between the baseline and 3-month visits (Figure 1). These participants comprised 62.5% of control group and 57.1% of intervention group participants who did not complete the study.

Table 1. Participant demographics and baseline characteristics

Characteristic	Control No. (%)	Intervention No. (%)
n	27	38
Gender		
Women	14 (51.9)	24 (63.2)
Men	13 (48.1)	14 (36.8)
Age (years)		
Mean ± SD	63.5 ± 14.5	63.3 ± 10.8
Range	34–84	41–82
Ethnicity		
White	25 (92.6)	28 (73.7)
Black	2 (7.4)	8 (21.1)
Hispanic	0	2 (5.3)
Education level[a]		
Attended high school	5 (19.23)	6 (16.67)
High school diploma	7 (26.92)	12 (33.33)
2-year college degree	5 (19.23)	10 (27.78)
4-year college degree	7 (26.92)	7 (19.44)
Graduate or professional degree	1 (3.85)	3 (8.33)
Baseline BMI[b]		
Mean ± SD[c] (kg/m^2)	29.5 ± 5.0	32.6 ± 6.5
Normal (18.5–24.9 kg/m^2)	3 (11.5)	5 (13.2)
Overweight (25–29.9 kg/m^2)	13 (50.0)	7 (18.4)
Obese (≥30 kg/m^2)	10 (38.5)	26 (68.4)

Abbreviation used: BMI, body mass index.
[a]Missing education level for two control group participants.
[a]Missing BMI for one control group participant.
[c]$P < 0.05$ for t test of group mean differences in BMI.

Research goal attainment

The results of the chi-square analyses between the two groups are shown in Table 2. The percentage of individuals in the intervention group meeting the goal for A1C was significantly higher than in the control group at 9 months ($P < 0.002$). Nearly one-half (46.7%) of individuals in the intervention group met the A1C goal at 9 months compared with 9.1% in the control group. Similar results were seen for the blood pressure goal. A significant difference was achieved at 9 months when 53.3% of intervention participants achieved the blood pressure goal compared with 22.7% of control participants ($P < 0.02$). No significant difference occurred between the control and intervention groups regarding LDL cholesterol goal attainment (50.0% and 46.7%, respectively; $P = 0.46$).

Evaluation of the composite research goal at 9 months found 56.7% of intervention participants meeting the goal compared with 18.2% of control participants ($P < 0.004$). The odds of intervention group participants achieving the composite goal were 5.87 times greater than the odds of control group participants (95% CI 1.69 –20.36). All other variables of interest were not significantly associated with the outcome measure of composite goal attainment.

Changes in clinical outcome means

A *t* test to compare group changes in A1C values between baseline and 9 months was significant ($P < 0.02$). The mean A1C for control group participants increased 0.11% (from 7.79% at baseline to 7.90% at 9 months) and decreased 0.52% (from 7.61% at baseline to 7.09% at 9 months) for intervention group participants. Statistically significant group changes between baseline and 9 months were also found in SBP values. The mean SBP for control group participants decreased 0.87 mm Hg (from 141.05 mm Hg at baseline to 140.18 mm Hg at 9 months) and 15.2 mm Hg (from 139.20 mm Hg at baseline to 124.00 mm Hg at 9 months) for intervention group participants ($P < 0.01$). No significant changes in LDL cholesterol

Table 2. Participant clinical outcome means and goal achievements at baseline and 9 months (n = 52)

	Control group (n = 22)		Intervention group (n = 30)		
	Baseline	9 months	Baseline	9 months	*P*[a]
A1C					
Mean ± SD (%)	7.79 ± 0.96	7.90 ± 0.88	7.61 ± 1.03	7.09 ± 0.96	0.02
No. (%) at goal	3 (13.64)	2 (9.09)	7 (23.33)	14 (46.67)	0.002
Blood pressure					
SBP (mm Hg), mean ± SD	141.05 ± 24.92	140.18 ± 19.99	139.20 ± 17.89	124.00 ± 16.91	0.01
DBP (mm Hg), mean ± SD	75.27 ± 12.57	74.91 ± 10.29	78.13 ± 10.34	73.73 ± 9.94	NS
No. (%) at goal	5 (22.73)	5 (22.73)	6 (20.00)	16 (53.33)	0.02
LDL cholesterol					
Mean ± SD (mg/dL)	94.38 ± 38.17	90.50 ± 31.32	109.33 ± 36.83	97.31 ± 24.14	NS
No. (%) at goal	10 (45.45)	11 (50.00)	9 (30.00)	14 (46.67)	NS
Composite goal[b]	4 (18.18)	4 (18.18)	6 (20.00)	17 (56.67)	0.004

Abbreviations used: A1C, glycosylated hemoglobin; DBP, diastolic blood pressure; LDL, low-density lipoprotein; NS, not significant; SBP, systolic blood pressure.
[a]*P* value for *t* test of group difference in mean clinical outcome change between baseline and 9 months or χ^2 test of association.
[b]At least two of three (A1C, blood pressure, and/or LDL cholesterol) at goal.

means from baseline to 9 months were found between the two groups.

Discussion

This study evaluated the clinical outcomes of a pharmacist-directed diabetes program among MCO enrollees using NCQA–HEDIS comprehensive diabetes care performance measures. Diabetes management programs should address issues beyond glycemic control. Creating a composite goal (e.g., achieving two of three HEDIS goals) provides a more thorough comparison of complex disease management objectives. A far greater and significant percentage of participants in the intervention group achieved the individual A1C and blood pressure goals compared with participants in the control group. Within the intervention group, the percentages of patients at A1C and blood pressure goals at least doubled. The odds of achieving two of the three goals were almost six times greater for participants in the intervention group compared with the control group. The percentage of participants reaching the goal for the A1C and blood pressure HEDIS measures significantly increased from baseline to 9 months in the intervention group but remained approximately the same for participants in the control group. No significant changes in LDL cholesterol goal attainment were seen between groups. This lack of effect on LDL cholesterol may have been a result of the relatively high percentages of control and intervention group participants who met the HEDIS goal at the beginning of the study (45.5% and 30.0%, respectively). Also, the time frame of the study may have been too short to capture a measurable change in LDL cholesterol in the intervention group compared with the control group, especially if improving diabetes and blood pressure control were initially targeted in care plans because of a greater need.

The results achieved in the intervention group exceeded scoring criteria used by the NCQA Diabetes Recognition Program (DRP).[30] This program provides pharmacists with tools to support the delivery of high-quality diabetes care. Another function of the DRP is to recognize clinicians who deliver excellent diabetes care based on HEDIS comprehensive diabetes care measures. Clinicians receive points toward DRP recognition if they achieve 40% of patients at A1C less than 7.0%, 25% at blood pressure less than 130/80 mm Hg, and 36% at LDL cholesterol less than 100 mg/dL.[31] Achieving these results provides practicing pharmacists with data to approach reimbursement organizations, showing evidence that a program conducted by pharmacists may lead to improved attainment of clinical goals.

This study appears to be the first that has evaluated clinical outcomes based on HEDIS comprehensive diabetes care performance measures among participants in a pharmacist-managed diabetes management program.[14] Two previous studies assessed the impact of pharmacist interventions using HEDIS measures; however, those studies either did not focus on interventions among patients with diabetes or did not assess multiple outcomes affecting diabetes control.[27,32] Previous studies that have focused on comprehensive goal achievement have not evaluated patients in pharmacist-managed diabetes management programs and have been performed as retrospective analyses.[24] The Centers for Medicare & Medicaid Services, as well as private health care organizations, use HEDIS measures to track performance. Payers and insurers are interested in achieving meaningful objective outcomes, such as HEDIS goals. Pharmacist-managed diabetes programs not only should report clinical outcomes, such as reduction in A1C and blood pressure, but also achievement of HEDIS nationally established standards for quality patient care. Such reporting is essential to justify and validate pharmacist-managed diabetes programs to achieve objective goals and national standards of effectiveness.

Achievement of HEDIS A1C, blood pressure, and LDL cholesterol comprehensive diabetes care measures has been linked with decreased total health expenditures and more cost-effective use of resources.[27,33] HEDIS administrative measures, such as receiving annual A1C and LDL cholesterol screenings, have been associated with higher pharmacy-related resources use.[34,35] Annual screenings may prompt health care providers to assess and adjust drug therapy. Additional research is needed that incorporates both clinical results (outcomes achievement) and economic impact (health care resource use), using a larger sample of patients.

Limitations

Several limitations should be considered when interpreting the study results. The generalizability of the results may be limited by factors related to sampling bias, specifically self-selection. Enrollees in a particular MCO whose diabetes had not been under control (A1C >7.0%) in the previous 6 months were recruited for the study and opted to participate. These individuals may have been more highly motivated and educated than the average patient. An opt-out program was not considered so as to preserve patients' autonomy to participate voluntarily in this research study.

Intervention participants were asked to come to monthly appointments. This may not reflect a practice that can or should be implemented for all patients. Future studies should assess the impact of diabetes education and management programs conducted on a less frequent basis, tailored to participant needs, and using telephone, e-mail, or written communications in addition to visits with pharmacists. Studies designed with more than two intervention groups that vary by pharmacist care or visit frequency levels may provide more specific evidence of effective program features.

Overall, one-third of the participants did not complete the study. However, the overall drop-out rate (33.8%) was comparable with previous pharmacy diabetes management studies.[17-23] The drop-out rate in this study may have been influenced by the type of recruitment method, with the highest percentage of participants who completed the study recruited face-to-face by study investigators at a health fair and the lowest percentage recruited through physician referral. This may indicate that participants are more likely to participate in a pharmacist-directed diabetes management program if they have previously engaged in a dialogue with a pharmacist to

discuss the program purpose, compare participation benefits and risks, and receive immediate answers to questions. Further, physician referrals may be more effective if preceded by pharmacist communication and collaboration with physicians rather than only by a request to the physician from an MCO.

Another limitation is that the study intervention was only conducted for 9 months. This time frame limited the ability to examine the long-term effectiveness and sustainability, both clinically and economically, of the intervention. Additional research using larger numbers of participants over a longer time frame is needed to fully document the impact and quality of these programs on health and economic outcomes. Further, research is needed examining relationships among HEDIS comprehensive diabetes care performance measures, diabetes-related complications, resource use, and costs.

A final limitation is the relatively small sample size. Although still able to detect a significant association between intervention group membership and clinical and goal outcomes, it is more difficult to be certain that none of the other variables of interest (e.g., demographic) were associated with the outcomes. The small sample size also prevented multivariable analyses from being conducted because of expected instability and unreliable results. Nonetheless, it is important to note that in various bivariable analyses, the intervention group achieved significantly more success than the control group.

Conclusion

A community pharmacy–based diabetes management program offered to a group of MCO enrollees was effective in achieving A1C and blood pressure diabetes care goals as measured by NCQA–HEDIS performance standards. The odds of participants who took part in the diabetes education and management program achieving two of three HEDIS standards during a 9-month period were almost six times greater than for those who did not participate in the program. The use of objective measures such as NCQA–HEDIS can be used to evaluate the effectiveness of pharmacist-managed diabetes programs. The results of this study indicate that these programs can be successful in helping patients achieve objective goals in controlling their disease.

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