RESEARCH

# Pharmacist Recommendations to Improve the Quality of Diabetes Care: A Randomized Controlled Trial

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## ABSTRACT

BACKGROUND: Diabetes mellitus continues to result in substantial morbidity and mortality despite receiving much attention from health care providers. Automated clinician reminder systems have been developed to improve adherence to diabetes care guidelines, but these reminder systems do not always provide actionable information and may be unable to detect relevant, subjective patient information that affects clinical decision making. Face-to-face visits with pharmacists, who have knowledge of care guidelines and medication management strategies, may assist in improving diabetes care. It is unknown if the combination of pharmacist chart review and clinician reminders could improve diabetes care without requiring face-to-face visits.

OBJECTIVE: To assess the effects of a comprehensive, pharmacist-delivered, primary care, physician-focused intervention in a large hospital-based primary care practice to improve the quality of care for patients with diabetes including rates of semiannual hemoglobin A1c testing and other biomarker and process measures.

METHODS: This was a prospective, randomized, controlled study conducted in a hospital-based, primary care practice, composed of 37 faculty primary care physicians (PCPs) and 95 internal medicine residents. The initial sample included 346 patients with diabetes and 72 PCPs caring for them. PCPs were randomized to receive either a personalized letter from a practicing pharmacist containing treatment recommendations for patients with upcoming primary care visits (intervention, n = 33) or to usual care without the letters (control, n = 39). The letter included patient-specific recommendations regarding overdue testing as well as drug therapy to achieve diabetes-related treatment targets. The intervention included addition of the letter to the electronic medical record (EMR) and presentation of the letter to the PCP at the time of the index primary care visit that occurred between November 2003 and August 2004. Follow-up chart review was performed after the primary care visit to determine changes in 5 process and 3 biomarker outcome measures of diabetes care within 30 days of the index visit. The primary study outcome was a process measure, change in rates of semiannual A1c testing from baseline to 30-day follow-up. Baseline differences were tested for statistical significance using Pearson chi-square. The statistical significance of the intervention's effect was tested using logistic regression models predicting achievement of each study outcome, with randomization status (intervention vs. control) as the predictor variable of interest, controlling for baseline performance for each measure.

RESULTS: 171 patients were in the 4 medical clinic suites with 33 PCPs who received the intervention, and 175 patients were in the 4 suites with 39 PCPs in usual care. 30-day outcomes were analyzed for 301 patients (87.0%) who attended their scheduled index primary care visit. Of these 301 patients, 44.5% were black, 65.8% were female, and the mean age was 63 years. At baseline, there were no significant differences between the intervention group (n = 150) and the usual care (control) group (n = 151) in the 3 biomarker measures (proportion with A1c less than 7%, proportion with low-density lipoprotein cholesterol [LDL-C] less than 100 milligrams per deciliter [mg per dL], or blood pressure less than 130/80 millimeters mercury [mm Hg]). There were no significant baseline differences in 4 of the 5 process measures; however, the rate of annual LDL-C testing was significantly higher for the intervention than for the control group at baseline (86.0% vs. 74.8%, respectively, $P = 0.015$). In logistic regression analysis, rates of semiannual A1c testing were not significantly different between the intervention and control groups, increasing from baseline to follow-up by 16% in the intervention group and 9% in the control group ($P = 0.146$). The proportion of patients with A1c less than 7% at follow-up was 43.3% in the intervention group versus 37.7% in the control group (intervention effect $P = 0.099$). The only statistically significant difference between the 2 groups in the 8 outcome measures was a higher proportion with an annual eye exam at follow-up in the intervention group (60.0%) versus the usual care group (50.3%, intervention effect $P = 0.017$).

CONCLUSIONS: Pharmacist-generated recommendations delivered by letter to PCPs in an academic medical practice were not associated with statistically significant improvements in most quality measures for diabetes care assessed at 30 days following the intervention. Further research is needed with more patients and a longer follow-up time to determine how best to improve the quality of care of patients with diabetes using focused recommendations for therapy changes and reminder notices to clinicians.

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### What is already known about this subject

- Diabetes mellitus is a common condition amenable to specific interventions aimed at control of blood pressure, lipid, and glycemic parameters. Despite this, care for patients with diabetes remains inadequate.
- Automated clinician reminder programs have been shown to improve measures of diabetes care by 30%, but such interventions can be limited by lack of actionable information or inaccurate or out-of-date reminders.
- Pharmacist participation in the diabetes care team has been associated with positive clinical outcomes on hemoglobin A1c, resulting in an additional A1c lowering of mean (SD) 0.62% (0.29%) over controls, but additional study is needed to determine the most effective and efficient use of pharmacists in diabetes care.

### What this study adds

- Of 8 biomarker and process measures of clinical quality in diabetes care, pharmacist-delivered, provider-focused interventions derived from review of an electronic medical record and provided for a small sample of patients with either type 1 or type 2 diabetes were associated with significant improvement only for the process measure of the proportion of patients with annual dilated eye exams (60.0% vs. 50.3% assessed at 30 days after the intervention for intervention and control, respectively, $P = 0.017$).
- The intervention was not associated with statistically significant improvement in 3 biomarker measures (proportion with A1c <7%, proportion with LDL-C less than 100 milligrams per deciliter [mg per dL], or blood pressure less than 130/80 millimeters mercury [mm Hg]) or in 4 of the 5 process measures (semiannual A1c testing, annual lipid testing, annual urine microalbumin screening, or pneumococcal vaccination).

Diabetes mellitus is an increasingly common condition among adults in the United States and is associated with substantial morbidity and mortality. As of 2007, more than 23 million people in the United States had either diagnosed (17.9 million) or undiagnosed (5.7 million) diabetes.[1] The microvascular and macrovascular complications of diabetes lead to significant disability and early mortality, in addition to substantial costs to the health care system.[1,2] These complications can be reduced through specific interventions aimed at achieving designated glycemic, lipid, and blood pressure goals.[3-7] Despite this evidence, outcomes for patients with diabetes remain inadequate. National data indicate that almost 30% of patients with diabetes have inadequate control of hemoglobin A1c values; 51% do not meet lipid management goals; and about 40% have inadequate blood pressure control (defined as more than 140/90 millimeters mercury [mm Hg]).[8]

Previous quality improvement efforts involving automated clinician reminders have produced increased compliance with diabetes care guidelines.[9,10] However, these efforts have been most successful in improving process measures of care such as annual laboratory testing,[9] and significant gaps remain in outcomes of care such as appropriate glycemic control. A meta-analysis by Shojania et al. (2006) of 66 studies of the effect of quality improvement (QI) strategies in diabetes care concluded that most QI strategies produce only modest improvements in glycemic control.[11] Of 11 categories of QI strategies assessed, the researchers identified 2 QI strategies in particular that were associated with the greatest reductions in A1c. First, team changes, in which changes are made to the primary structure of the health care team (e.g., adding routine visits with medical personnel other than the primary care provider [PCP]) or in which a team member's role is expanded to allow for greater involvement in patient monitoring or adjustment of regimens, were associated with a mean reduction in A1c of 0.67% (95% confidence interval [CI] = 0.43-0.91, n = 26 studies). Second, case management was associated with a mean reduction in A1c of 0.52% (95% CI = 0.31-0.73, n = 26 studies). The use of clinician reminders (with or without an accompanying recommendation) was associated with a reduction in A1c of 0.4%-0.5%, but this effect was not statistically significant.[11] Possible explanations for the inability of these strategies to fully close the quality gap include a failure of providers to attend to clinical reminders; the lack of provision of actionable reminders (e.g., not only provide a clinical recommendation for an overdue laboratory test but also facilitate electronic ordering of that test via a direct link to a computerized physician order entry module); or the provision of inaccurate or out-of-date recommendations in clinician-targeted reminders.[12,13]

The active participation of pharmacists in the care of patients with diabetes has been summarized in several systematic reviews and has been shown to improve outcomes of care.[11,14,15] Shojania et al. conclude in a post hoc analysis of the aforementioned meta-analysis that QI interventions in which pharmacists or nurse case managers could adjust medications without waiting for physician approval were associated with a mean reduction of A1c of 0.80% (95% CI = 0.51%-1.10%) compared with a mean A1c reduction of 0.32% (95% CI = 0.14%-0.49%) in interventions where this was not allowed.[11] A meta-analysis by Machado et al. (2007) showed that A1c and possibly also systolic blood pressure and fasting plasma glucose were sensitive to pharmacists' interventions.[15] The authors concluded that pharmacists' interventions reduced A1c by an additional mean (SD) 0.62% (0.29%) over controls ($P = 0.03$). A systematic review was performed by Wubben and Vivian (2008) to determine if strategies used by pharmacists in the outpatient setting improve glycemic control as measured by A1c. Twenty-one studies, including 9 randomized trials, of pharmacist interventions were included in the analysis. All interventions consisted of face-to-face or telephonic visits with a pharmacist. Changes in A1c as a result of these interventions ranged from +0.2% to −2.1%.[14]

These studies illustrate that pharmacist-delivered interventions for patients with diabetes can improve several indicators of quality diabetes care. Other studies document that such interventions may be conducted in a variety of settings, including community pharmacies and ambulatory clinics.[14-18] Most of these studies have also involved interventions delivered during face-to-face pharmacist appointments, which require available clinical staff and space. It is possible that an intervention combining pharmacist recommendations with clinical reminders provided to physicians at the time of office visits could impact a large patient population while conserving use of pharmacist resources.

The goal of the present study was to assess the effects of a comprehensive, pharmacist-delivered, provider-focused intervention to improve the quality of care for patients with diabetes in a large primary care practice. We hypothesized that an intervention consisting of a chart review and tailored recommendation letter provided to the PCP could improve process and outcome measures of diabetes care.

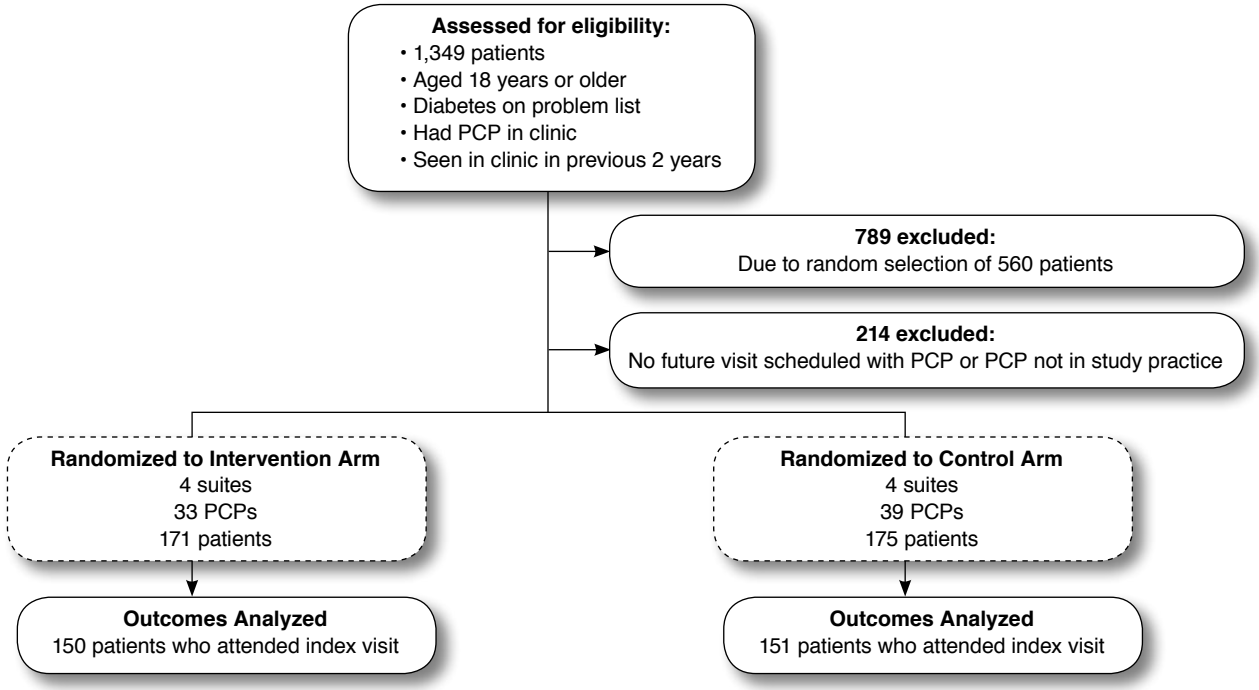
## Methods

### Study Setting

The study was conducted from November 2003 through August 2004 in a hospital-based primary care practice, located in Boston, Massachusetts, on the main campus of a large academic teaching hospital. The clinic provides care to a diverse patient population and includes 37 faculty PCPs and 95 internal medicine residents, who together conduct a total of approximately 40,000 patient visits per year. The clinic is divided into 8 distinct clinical "suites," which are defined by a group of physicians who share common space and support staff. Providers in all suites practice primary care, and there is no difference in the type of medical care provided in the various suites.

The clinic is staffed by a registered clinical pharmacist and pharmacy student interns who are available to all providers and

**FIGURE 1** Sample Selection Flow Chart




*PCP = primary care provider.*

patients for assistance with medication-related problems. The pharmacist and interns had been working in the clinic for 2 years prior to the start of the study and continued in the clinic during and after the study. Usual pharmacy services in the clinic were not limited to patients with diabetes but were available by referral from the PCP or upon request by the patient. Typically, patients were referred to the pharmacy service for assistance with smoking cessation, medication review and education, and diabetes education. Usual visits with the pharmacy service were done face-to-face in individual appointments, and documentation of the visit was filed as a note in the patient's electronic medical record (EMR).

These pharmacist services were separate from those described in the present study. Usual diabetes care in the clinic does not routinely include pharmacist consultation for patients. Although some diabetes patients see an endocrinologist for diabetes care, the majority of patients in the practice have diabetes managed by PCPs.

### Patient Selection and Enrollment

In July 2003, we identified patients for inclusion in the study who (a) were aged 18 years or older, (b) had a diagnosis of diabetes on the active problem list in the EMR at the time of randomization, (c) had a PCP practicing within the study clinic according to a coded field in the EMR, and (d) were seen in the practice at least once during the 2 years prior to the start of the study. As we were attempting to improve care for all patients with diabetes in the practice and because treatment goals are similar regardless of type of diabetes, we did not distinguish between those with type 1 and type 2 diabetes mellitus. In July 2003, we identified 1,349 patients meeting these criteria and used a random number generator to randomly select 560 being cared for by 72 PCPs for inclusion in the study (Figure 1). Of these, 346 had a future visit scheduled with their PCP. A sample size of 292 subjects in each study arm was needed to provide greater than 80% power to detect a difference between the intervention and control arms of 10% in rates of semiannual A1c testing, assuming a baseline screening rate of 70%.

The study was approved by the Partners Human Research Committee and the Northeastern University Office of Human Subject Research Protection, including waiver of informed consent for both patients and physicians.

### Randomization Process

We randomized the intervention at the level of clinical suites within the study practice immediately after patients were identified in July 2003. This randomization unit minimized the potential for contamination of the intervention that might occur if

physicians received recommendation letters for some, but not all, of their patients. There were 33 physicians practicing in 4 suites assigned to the intervention arm, and 39 physicians practicing in 4 suites assigned to the control arm.

### Description of Intervention

Prior to each patient's next scheduled visit with his or her PCP, the "index visit," a comprehensive review of the EMR was performed by trained clinical staff, including the study pharmacist (Kirwin), 1 of the study physicians (Cunningham), and 14 trained pharmacist interns using a structured data collection form (copies of chart review and data collection forms are available from the corresponding author by request). The study pharmacist trained all clinical staff. Training topics included operation of the EMR, orientation to the project, data collection forms, and the data entry program. The data collection forms were annotated with information to remind clinical staff where various data could be located within the chart. Index visits for study patients had been scheduled on a usual care basis that was not part of the study protocol and occurred from November 2003 to August 2004.

For each patient, the baseline review by the study's clinical staff occurred about 1 month prior to the visit. In addition to collecting information on overdue screening exams, the review included information not easily captured by automated clinician reminder programs, such as patient preferences (e.g., not willing to use insulin) or comorbid conditions (e.g., presence of a terminal diagnosis) that might affect disease management decisions. A patient-specific list of diabetes care recommendations was then prepared by the clinical pharmacist for each patient, including both overdue screening exams as well as recommendations regarding drug therapy to achieve diabetes-related treatment targets. These specific recommendations included appropriate use and dosing of lipid-lowering therapy and antihypertensive agents according to current clinical practice guidelines at the start of the intervention period (see Appendix for a template of the letter with all possible recommendations listed).[2] Recommendations included initiation of new medications as well as titration of existing medications.

For intervention patients, a copy of the recommendation letter was entered into the EMR, and a brightly colored print copy was given to the PCP at the time of the index visit. The intervention differed from usual care available from the clinic pharmacist because the review and recommendation process took place for all intervention patients regardless of whether they were referred by the PCP for a face-to-face visit with the pharmacist. Also, the review was abstracted from EMR information only—that is, patients were not interviewed to help create the recommendations. For usual care patients, EMR reviews were conducted but the resulting recommendations were not included in the EMR, and the PCPs did not receive recommendation letters.

A follow-up review was conducted by the pharmacist interns using a structured data collection form (available from the corresponding author by request) to determine which recommendations had been implemented in both the intervention and control groups. Although the follow-up review was conducted 12 months after the intervention because of staff workload, the review evaluated data only within 30 days immediately following the index visit to increase the likelihood that clinical changes made were actually a result of the recommendation letters. Patients whose baseline review indicated an overdue semiannual or annual screening test were counted as having received the test at follow-up if it occurred within the 30-day follow-up period.

The project was endorsed by the clinic's medical director as well as the clinic's group of attending physicians.

### Study Outcomes

Our primary study outcome was the process measure of semiannual A1c testing. Additional outcomes included 4 process and 3 biomarker measures of diabetes care. The 4 additional process measures included annual low-density lipoprotein cholesterol (LDL-C) testing, annual dilated eye exams, annual urine microalbumin testing, and rates of pneumococcal vaccination. The 3 biomarker measures included achievement of A1c less than 7%, LDL-C less than 100 milligrams per deciliter (mg per dL), and blood pressure less than 130/80 millimeters mercury (mmHg). We chose these measures because they represent important markers of disease control, and they are linked to long-term diabetes-related morbidity. We used the Healthcare Effectiveness Data and Information Set (HEDIS) definition to determine rates of outcomes measures being met.[19] In accordance with HEDIS standards, in cases where an outcome result was not available, it was assumed to be greater than goal. Pre- and post-intervention study outcomes were collected for 301 of the original 346 randomized patients because 45 patients (13.0%) did not attend their index primary care visit.

### Statistical Analysis

Baseline characteristics for patients in the intervention and control groups were compared using the Pearson chi-square test for categorical variables and Student's t test for continuous variables. We analyzed the impact of the intervention by fitting patient-level multivariable logistic regression models to predict achievement of each study outcome. The independent variables in these models included randomization status (intervention vs. usual care) as well as the baseline performance of that given measure, both coded as binary variables. These models also adjusted the standard errors for clustering of patients by clinical suite using generalized estimating equations. All analyses were conducted using SAS version 9.2 (SAS Institute, Inc., Carey, NC). We report 2-tailed *P* values with an a priori statistical significance of 0.05.

## Results

171 patients were in the 4 medical clinic suites with 33 PCPs who received the intervention, and 175 patients were in the 4 suites

**TABLE 1** Baseline Patient Characteristics[a]

| | Intervention Group n = 150 | Usual Care Group n = 151 | *P* Value[b] |
|---|---|---|---|
| Mean age, years [SD] | 62.9 [12] | 62.8 [14] | 0.965 |
| Female, n (%) | 106 (70.7) | 92 (60.9) | 0.075 |
| Race, n (%) | | | |
| White | 44 (29.3) | 35 (23.2) | 0.354 |
| Black | 67 (44.7) | 67 (44.4) | |
| Hispanic | 26 (17.3) | 26 (17.2) | |
| Asian | 1 (0.7) | 4 (2.6) | |
| Unknown | 12 (8.0) | 19 (12.6) | |
| Insurance, n (%) | | | |
| Medicare | 80 (53.3) | 68 (45.0) | 0.568 |
| Commercial | 37 (24.7) | 45 (29.8) | |
| Medicaid | 23 (15.3) | 23 (15.2) | |
| Uninsured | 8 (5.3) | 13 (8.6) | |
| Other | 2 (1.3) | 2 (1.3) | |

[a]*Baseline measures assessed 1 month prior to the index primary care visit.*
[b]*Comparisons performed using Pearson chi-square test for categorical variables and Student's t test for continuous variables.*

with 39 PCPs in usual care (Figure 1). Outcomes were analyzed for 301 patients (87.0%) who attended their scheduled index primary care visit. Of these 301 patients, 44.5% were black, 65.8% were female, and the mean age was 63 years (Table 1). The randomization process achieved good balance between the intervention and control groups across a spectrum of baseline characteristics with the exception of a difference in rates of annual lipid profiles (86.0% intervention vs. 74.8% control, $P=0.015$; Table 2). At baseline, rates of monitoring A1c and LDL-C were relatively high compared with rates of screening eye exams and urine microalbumin exams. Rates of achieving A1c, LDL-C, and blood pressure control goals were low for both the intervention and control arms.

At follow-up, the rates of achieving each of the 5 process measures improved in both the intervention and control groups (Table 2). In logistic regression analysis, rates of semiannual A1c testing were not significantly different between the intervention and control groups, increasing by 16% in the intervention group and 9% in the control group ($P=0.146$). Only rates of annual eye exams were significantly higher in the intervention group compared with the control arm (60.0% vs. 50.3%, $P=0.017$). There were no significant differences between the intervention and control groups in achieving glycemic, cholesterol, and blood pressure targets.

## Discussion

Improving quality of diabetes care remains a priority given the morbidity, mortality, and costs associated with this condition. We found that the majority of measures of diabetes quality were not significantly improved following the provision to PCPs of timely, pharmacist-developed, patient-specific recommendations regarding both overdue testing and medication management. While the processes of care improved for the entire patient population during the study period, there was significant improvement for intervention patients relative to control patients only in the rates of annual diabetic eye exams. In addition, rates of optimal control of A1c, LDL-C, and blood pressure were not significantly improved during the 30-day follow-up period as a result of the intervention. However, it is important to note that these results may be due to the lack of sufficient statistical power in our study.

These results provide some insights into the challenges associated with improving outcomes in the measures of diabetes care. First, while we did not significantly increase performance on the majority of process measures, there was substantial improvement in the rate of annual screening exams for diabetic retinopathy. This finding is in contrast to our prior study of automated electronic reminders (without pharmacist intervention) in this clinic, which found improvements in annual cholesterol monitoring (hazard ratio [HR] = 1.41, 95% CI = 1.15-1.72, $P<0.001$) but no effect on eye exam rates (HR = 1.38, 95% CI = 0.81-2.32, $P=0.230$).[10] This difference is likely due to the increased accuracy of the recommendations delivered by the pharmacists as compared with the automated reminders, which can often fail to detect exams performed at outside health centers.

A second important null finding in our study is the failure to significantly increase performance according to the important measures of controlling glucose, cholesterol, and blood pressure. These measures have been shown to be resistant to change in multiple prior studies, likely due to the need to address multiple elements of care, including medication management and lifestyle changes.[20]

Our findings also add to the growing literature regarding the role of pharmacists in improving quality of diabetes care. Prior studies have demonstrated a benefit to the participation of pharmacists, including positive effects on important measures of disease control such as a reduction in blood pressure[17,18] and increases in healthy behaviors (e.g., healthy diet and self-care activities) that can ultimately improve diabetes control.[16] However, it is important to highlight that these prior interventions were more resource intensive than our intervention and involved dedicated office visits or telephone calls with the clinical pharmacist. Our intervention was designed to test the effectiveness of a less resource-intensive program, where a single pharmacist could provide detailed recommendations for a large patient population without the need for dedicated office visits. These recommendations were directly entered into an existing EMR, improving integration with the PCPs' workflow.

Although patients may have been referred for an office visit with the pharmacist in our clinic at the discretion of the PCP, such visits were not included as a routine part of the intervention. Our intervention therefore relied on action being taken by the PCP during the office visit, potentially lessening its

**TABLE 2** Achievement of Diabetes Treatment Goals[a] at Baseline and Follow-Up

| | Intervention Group n = 150 | Usual Care Group n = 151 | *P* Value[b] | Model C Statistic[c] |
|---|---|---|---|---|
| **Process Measures[d]** | | | | |
| Baseline semiannual A1c | 70.7% (106) | 74.2% (112) | 0.496 | |
| Follow-up A1c | 86.7% (130) | 82.8% (125) | 0.146 | 0.661 |
| *Change* | +16% | +9% | | |
| Baseline annual lipid profile | 86.0% (129) | 74.8% (113) | 0.015 | |
| Follow-up lipid profile | 88.7% (133) | 80.8% (122) | 0.235 | 0.779 |
| *Change* | +3% | +6% | | |
| Baseline annual eye exam | 38.0% (57) | 37.1% (56) | 0.870 | |
| Follow-up eye exam | 60.0% (90) | 50.3% (76) | 0.017 | 0.662 |
| *Change* | +22% | +13% | | |
| Baseline annual urine microalbumin | 46.0% (69) | 47.0% (71) | 0.859 | |
| Follow-up annual urine microalbumin | 62.7% (94) | 57.6% (87) | 0.383 | 0.765 |
| *Change* | +17% | +11% | | |
| Baseline pneumococcal vaccination | 66.0% (99) | 60.9% (92) | 0.361 | |
| Follow-up pneumococcal vaccination | 74.7% (112) | 66.9% (101) | 0.186 | 0.927 |
| *Change* | +9% | +6% | | |
| **Outcomes Measures[d]** | | | | |
| Baseline A1c < 7% | 38.0% (57) | 38.4% (58) | 0.870 | |
| Follow-up A1c < 7% | 43.3% (65) | 37.7% (57) | 0.099 | 0.885 |
| *Change* | +5% | -1% | | |
| Baseline LDL-C < 100 mg per dL | 62.0% (93) | 55.0% (83) | 0.271 | |
| Follow-up LDL-C < 100 mg per dL | 57.3% (86) | 67.5% (102) | 0.084 | 0.897 |
| *Change* | -5% | +13% | | |
| Baseline BP < 130/80 mmHg[e] | 47.3% (71) | 45.0% (68) | 0.769 | |
| Follow-up BP < 130/80 mmHg | 44.0% (66) | 41.1% (62) | 0.332 | 0.643 |
| *Change* | -3% | -4% | | |

*[a]Sources: American Diabetes Association[2] and National Committee for Quality Assurance, Healthcare Effectiveness Data and Quality Measurement.[19]*

*[b]For baseline measures, comparisons were performed using Pearson chi-square test for categorical variables and Student's t test for continuous variables. For follow-up measures, P values represent the statistical significance of a coefficient representing randomization status (intervention vs. usual care) in patient-level logistic regression models predicting achievement of each study outcome, controlling for baseline performance for each measure. Models adjusted the standard errors for clustering of patients by clinical suite using generalized estimating equations.*

*[c]Obtained using logistic regression models of follow-up performance rates adjusting for intervention status and baseline performance rates, as described in footnote b.*

*[d]Baseline measures were assessed 1 month prior to the index primary care visit.*

*[e]The goal blood pressure for patients with diabetes is less than 130/80 mm Hg. To improve physician acceptance, 130/85 mm Hg was used as the trigger for a recommendation.*

*A1c = hemoglobin A1c; BP = blood pressure; LDL-C = low-density lipoprotein cholesterol; mg per dL = milligrams per deciliter; mm Hg = millimeters mercury.*

effectiveness. Altavela et al. (2008) describe a similar project in which a pharmacist reviewed patient charts and made recommendations to address medication-related issues.[21] This study included a control group for which the clinical pharmacist made recommendations for care improvement that were not disclosed to physicians. In this control group, nearly one-quarter of the concealed recommendations were enacted by physicians without pharmacist input. This pattern may have occurred in the present study sample and may have further reduced the intervention effect. Indeed, systematic reviews and other studies have shown a greater impact on diabetes care measures and improved medication safety when pharmacists are able to act independently within a collaborative practice agreement to initiate or change drug therapy or order laboratory tests.[14,15,22] These improvements may be due in part to increases in the intensity of care and the dedicated time available to address diabetes management.[11,14] Such collaborative practice was not supported by Massachusetts state law at the time of our intervention, although it has since been approved by the state legislature.

Although our intervention did not demonstrate the hoped-for benefits, as a result of this project we have shifted toward more active involvement of the pharmacist with patients. Rather than asking the pharmacist to review data and make suggestions to PCPs (because the present study showed this approach yielded little added benefit beyond the automated EMR reminder systems that we already have), we have focused on increasing the use of face-to-face consultative visits for patients with the pharmacist for diabetes education and medication titration.

### Limitations

First, the present study, although methodologically strengthened by a randomized design, was underpowered and assessed outcomes for only 30 days after the intervention. It was unlikely that changes in biomarker measures would be observed and subsequently documented in the EMR in this time frame. The methodological decisions to limit the sample size and follow-up time were made because of staff workload considerations, but these decisions limited our ability to detect significant differences between the intervention and control groups. Additional research with a larger sample size and longer follow-up period is necessary to reach definitive conclusions about the effects of pharmacist-generated letter reminders to PCPs. Second, this was a single-site study in a large, urban, hospital-based academic clinic with a fully implemented EMR, which may limit the generalizability of this intervention to other settings. Also, our patients were predominantly older, black women whose outcomes might not reflect those of other cohorts of patients with diabetes. Third, we chose to use multiple data abstracters, raising questions about interrater reliability. However, each abstracter was trained and used a structured form to collect data from the chart. Fourth, in an effort to maximize the number of patients whom the service could reach, we decided to use a simple, 1-time recommendation letter to the PCP, which may not have been enough to prompt meaningful change.

Fifth, we found relatively high baseline adherence rates for 2 of the process measures, rates of semiannual A1c measurement and annual lipid profile measurement, making it more challenging to further increase compliance with recommendations. Also, although detailed chart reviews were performed in an effort to provide tailored, relevant, and clinically meaningful reminders, it is possible that certain recommendations were not appropriate for particular patients, due to specific clinical circumstances not detected during the chart reviews. For example, a suggestion may have been made to institute a particular medication when that medication had already been attempted unsuccessfully by another clinician or was not tolerated by the patient. While we did provide recommendations in both electronic and paper formats for clinicians in the intervention group, we are unable to discriminate between those recommendations that went unnoticed and those that were deliberately deferred for clinical or other reasons. Our study was limited by lack of information on the acceptance of pharmacist recommendations by the physicians and by lack of information on patient acceptance or compliance with physician recommendations, prescriptions, and laboratory orders.

Finally, while we did randomize patients by practice suites in an attempt to reduce contamination, it is possible that physicians in the control group were exposed to other diabetes quality improvement initiatives unknown to the authors that may have diluted any effect of the study intervention.

## Conclusions

Pharmacist-generated recommendations delivered by letter to a small sample of PCPs in an academic medical practice were not associated with statistically significant improvement in most quality measures for diabetes care, assessed at 30 post-intervention days. Further research is needed with more patients and a longer follow-up time to determine how best to improve the quality of care of patients with diabetes using focused recommendations for therapy changes and reminder notices to clinicians.

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### DISCLOSURES

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Concept and design were performed by Kirwin and Cunningham, with the assistance of Sequist. Kirwin collected the data with the assistance of Cunningham. Sequist analyzed the data with the assistance of the other authors. All authors shared in writing the manuscript. Revisions were made primarily by Kirwin, with the assistance of the other authors.

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## APPENDIX Template of Letter to Provider (including all possible interventions as recommended by current clinical practice guidelines[1])

Dear _____,

As you are aware, we are currently conducting an internal quality improvement project designed to improve the care of patients who have diabetes. Below please find a brief summary of specific diabetes management recommendations for this patient, based on a detailed chart review. The guidelines underlying these recommendations are summarized in greater detail beneath the bulleted suggestions.

Please consider:

| Recommendations | Chart Review Findings |
|---|---|
| **A1c** | Last A1c _____ on _____ |
| • Check A1c at next visit | (No A1c within 6 months) |
| • A1c above goal – consider augmenting hypoglycemic Rx (Last A1c >8.0) | |
| Adjustments to consider: | |
| o Increase dose of _____ | |
| o Add metformin | |
| o Add sulfonylurea (glyburide or glipizide) | |
| o Add TZD (Actos or Avandia) | |
| o Add insulin secretagogue (Starlix, Prandin) | |
| o Add insulin | |
| • Lantus | |
| • NPH | |
| • Lispro | |
| • Regular | |
| • A1c above goal with FBS at goal | (Last A1c >8.0, FBS wnl) |
| o Have patient check postprandial BS | |
| o If postprandial BS elevated, add short-acting insulin | |
| **Metformin Use** | |
| • Check Cr in patient on metformin | (No Cr in past 12 months) |
| • Discontinue metformin in patient with elevated Cr | (Cr >1.5 in pt on metformin) |
| **Lipid profile** | Last LDL _____ on _____ |
| • Check lipid profile at next visit | (No lipid panel in 12 months) |
| • LDL above goal – consider augmenting lipid-lowering Rx | (LDL >130) |
| o Add statin | |
| o Increase dose of _____ | |
| o Add _____ | |
| **Blood pressure** | |
| • Check BP and document value at next visit | (No BP in past 6 months) |
| • BP >130/85 – consider augmenting antihypertensive Rx | (BP >130/85 on 2 occasions) |
| o Add a diuretic | |
| o Add an ACE inhibitor | |
| o Add _____ | |
| o Increase dose of _____ | |
| **Urine microalbumin** | |
| • Check urine microalbumin at next visit | (No umalb in past 12 months) |
| • Urine malb elevated – add an ACEI or ARB | (Umalb >30) |
| • Proteinuria – add an ACEI or ARB | (24-hour urine w/proteinuria) |
| **Preventive aspirin therapy** | |
| • Discuss preventive ASA 81 mg po qd at next visit | (ASA not on med list) |
| **Pneumococcal vaccination** | |
| • Administer pneumovax at next visit | (No pneumovax recorded) |
| **Influenza vaccination** | |
| • Administer influenza vaccine (in season) | (No flu shot in 12 months) |
| **Foot care/Eye care** | |
| • Perform foot exam or refer for foot care at next visit | (No foot exam in 12 months) |
| • Refer to ophthalmology at next visit | (No eye exam in 12 months) |
| **Lifestyle assessment** | |
| • Review smoking status at next visit and counsel as appropriate | (No smoking review in 3 yrs) |
| • Smoker with diabetes – refer to smoking cessation program | (No counseling in 12 months) |
| • Review alcohol/drug use at next visit and counsel as appropriate | (No EtOH review in 3 yrs) (and document in note) |
| **Other** | |
| • Other | |

These recommendations are based on widely accepted guidelines for quality of care for diabetic patients, but are at times limited by incomplete information in the computerized medical record. We apologize if any recommended interventions have already been performed elsewhere or have been deferred due to circumstances not readily detectable during our chart review.

Please feel free to contact us with any questions or concerns.

Thank you,
Jennifer Kirwin, Pharm.D., BCPS
BIMA Clinical Pharmacist
Diabetes Quality Project Team

## APPENDIX Template of Letter to Provider (including all possible interventions as recommended by current clinical practice guidelines[1]) *continued*

**Summary of guidelines:**

**Hgb A1c**
Guidelines recommend Hgb A1c measurement every 6 months in patients under good glycemic control, every 3 months in patients with poor glycemic control. Pharmacologic and dietary treatment should be aimed at meeting the goal of Hgb A1c <8.0. Lowering Hgb A1c to 7% has been shown to further reduce the risk of complications. Hgb A1c >9.5 is considered a marker of poor control.

Patients who have normal fasting blood sugar but elevated Hgb A1c often have post-prandial hyperglycemia. Checking post-prandial BS can confirm this phenomenon; adding short acting insulin can improve glycemic control. Lispro should be given 0-15 minutes pre-meal. Regular insulin should be given 30-60 minutes pre-meal.

**Metformin use**
Metformin is contraindicated in male patients with Cr >1.5 and in female patients with a Cr >1.4. It is recommended to check Cr annually in patients taking metformin.

**Lipid profile**
Guidelines recommend that lipid profile measurement be obtained annually. Goal LDL is <100 for diabetic patients. Statins are recommended first-line pharmacologic therapy for LDL lowering, particularly in patients with LDL >130.

**Blood pressure**
Guidelines recommend regular BP measurement at every routine visit for diabetic patients. While, the goal BP for diabetic patients is <130/80 mmHg, we suggested clinical action when a patient had a BP over 130/85 mmHg. Diuretics, ACE inhibitors, ARBs or beta-blockers may be used as first-line therapy for BP control in the absence of specific indications for particular agents, such as ACE inhibitors or beta-blockers.

**Urine microalbumin**
Guidelines recommend annual urine micralbumin measurement in diabetic patients. If urine microalbumin is elevated, treatment with an ACE inhibitor or ARB is recommended to reduce glomerular damage and proteinuria.
Preventive aspirin therapy
Daily aspirin use is recommended in all adult patients with diabetes and macrovascular disease. Aspirin therapy for primary prevention should be considered in all diabetic patients ages 40 and above who have one additional cardiovascular risk factor. Aspirin therapy may also be considered in patients between ages 30 and 40 with additional cardiovascular risk factors. Because the incidence of cardiovascular disease before age 30 is low, aspirin is unlikely to be beneficial for primary prevention in patients <30 years old.

**Pneumococcal vaccination**
Pneumococcal vaccination is recommended for all diabetic patients, regardless of age. Current guidelines also suggest that a one-time revaccination be given at or after age 65 in patients who received the pneumococcal vaccine before the age of 65. At least 5 years should pass between the initial vaccine and the one-time revaccination.

**Influenza vaccination**
Influenza vaccination is recommended for all diabetic patients, regardless of age.

**Foot care/Eye care**
Comprehensive foot exams on an annual basis are recommended for all diabetic patients. A careful foot exam by a primary provider is adequate provided that there are no foot or nail deformities, no signs of infection or injury, and no abnormalities on vascular exam or on sensory testing performed with a Semmes-Weinstein monofilament and a tuning fork. Podiatry referral is recommended in the presence of any significant abnormalities on foot exam. Visual inspection of the feet is recommended at each visit.

Annual ophthalmology exams are recommended for all diabetic patients.

**Lifestyle assessment**
Regular assessment of alcohol and tobacco use is recommended for diabetic patients. Brief, directed advice to quit smoking has been shown to increase quit rates, as has treatment with nicotine replacement or bupropion. Referral to the BWH Smoking Cessation Program may also be beneficial for smokers contemplating quitting. Both counseling and medications can be provided through this program.

(For more detailed summary of recommendations, see ADA Guidelines in *Diabetes Care,* Volume 26, Supplement 1, January 2003.)