The Role of Pharmacist-Managed Clinics

Improving Diabetes Care

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Tight blood glucose control often requires extensive patient education, close monitoring, and frequent therapeutic adjustments. Can pharmacists take on this responsibility in a specialty clinic setting and achieve favorable outcomes?

Over the past two decades, clinicians' understanding of the pathophysiology of diabetes mellitus has increased substantially—accompanied by improvements in standards of diabetes care. At the same time, advances in diabetes monitoring, from home blood glucose tests to widespread use of glycosylated hemoglobin (HbA_{1C}) testing, have enhanced the ability of providers and patients in various settings to control the disease and slow its progression.[1,2]

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Despite these strides, in 2000, diabetes was the sixth leading cause of death—with the number of diabetes-related deaths believed to be underreported at 213,062.[3] And according to a 2003 CDC estimate, 29% of all diabetics in the United States (or 5.2 million people) still are unaware of their disease.[3] Furthermore, in an era of rapidly rising health care costs, a diabetes diagnosis increases these costs by three to six times. A 1992 American Diabetes Association (ADA) estimate placed average annual health care expenses for a nondiabetic at $2,604 while a diabetic's average annual expenses were $11,157.[4] With some experts projecting a rise in the prevalence of diabetes from the current 6.3% (18.2 million people) to over 12% (about 30 million people),[3,5,6] it's likely that the need for improved diabetes management strategies will only intensify in the coming years.

Research has shown unequivocally that tighter blood glucose control makes a difference. In the 1993 Diabetes Care and Complications Trial (DCCT), "intensive" blood glucose control significantly decreased the incidence of microvascular and macrovascular complications in patients with type 1 diabetes.[7] In 1998, researchers from the United Kingdom Prospective Diabetes Study (UKPDS) published similar results for 5,102 patients with type 2 diabetes followed for an average period of over 10 years.[8] Overall, the results showed a 35% reduction in the risk of complications for every 1% drop in HbA_{1C}.[8]

Previous studies indicate pharmacists can play an important role

in helping patients achieve tight blood glucose control. For example, in a retrospective study involving 81 VHA patients with type 2 diabetes, those enrolled in a pharmacist-managed diabetes disease management clinic had significantly greater reductions in HbA_{1C} compared with those whose diabetes care was managed by a primary care provider (1.6% versus 0.4%).[9] Davidson and colleagues also reported improved diabetes outcomes in patients followed by pharmacists in a free medical clinic.[10] And a 1998 analysis by Gerber and colleagues suggested that pharmacist consultations provided to diabetic patients can decrease total health care costs in a health maintenance organization.[11]

In this article, we present data from a pharmacist-managed diabetes specialty clinic initiated by the 62nd Medical Group at McChord Air Force Base, WA in 2001. The purpose of this study was to determine whether outcomes of patients seen by a pharmacist in a specialty clinic setting would be at least equivalent to those of patients seen by physicians in a traditional primary care environment. Specific objectives were to monitor trends in HbA_{1C} and fasting blood glucose as well as completion of annual monofilament and dilated retinal exams and annual microalbuminuria screening.

FORMATION OF THE CLINIC

Considering the serious and costly sequelae of inadequately controlled diabetes and the proven benefits of intensive diabetes treatment, leaders at the McChord Air Force Base (AFB) Clinic, identified diabetes as an important area of focus to improve patients' quality of life and decrease health care costs. Initial efforts to target this disease began in December 1999 when the *VHA/DoD Clinical Practice Guideline for the Management of Diabetes Mellitus in the Primary Care Setting* became available.[12] The principles of prevention and coordinated care contained in this guideline aligned well with the medical group's vision of primary care optimization (PCO), a concept of health care delivery that emphasizes prevention and has been the primary thrust of the U.S. Air Force Medical Service's efforts to streamline care over the past few years.

A working group was established to examine how best to improve diabetes care delivery. This group determined that a specialty clinic run by a nontraditional care provider—in this case, a pharmacist—would serve patients' needs while minimizing interference with the PCO process. In conjunction with clinic formation, the working group recommended conducting a study to examine whether frequent visits with a pharmacist following an evidence-based guideline (the VHA/DoD guideline) would result in comparable outcomes to those seen when patients are followed by the PCO team, and whether this pharmacist-managed specialty clinic would be a better tool for ensuring that patients with diabetes completed their annual monofilament and dilated retinal exams and microalbuminuria screening.

The Executive Committees of the medical staff and the AFB clinic approved the proposal to open a pharmacist-managed diabetes specialty clinic, with the stipulation that data on patient outcomes would be provided at the end of six months. The diabetes working group identified HbA_{1C} levels as the primary metric for the clinic. This metric was selected based upon its established value as a surrogate measure of disease control.[7,8] An HbA_{1C} threshold of 8% or higher was set as a criterion for entry into the clinic.

The next step was to identify and analyze results of HbA_{1C} testing at the AFB clinic over the previous six months. An ad hoc report from the Composite Health Care System (the computer system used at the AFB clinic) indicated that, during this time frame, an HbA_{1C} level of 8% or higher had been documented for 42 patients. The working group then drafted a letter of invitation to the diabetes clinic, which was signed by the chief of the medical staff and sent to the 42 eligible patients. Of these patients, 19 responded and scheduled initial appointments at the diabetes clinic.

CLINIC OPERATION

The clinic operated for two half-days each week. Patients' diabetes care was managed primarily by the pharmacist, with a nurse or dietitian providing additional education. An exercise physiologist was available at the base's Health and Wellness Center to initiate fitness programs for appropriate patients. The chief of the medical staff functioned as the clinic preceptor and performed peer review. As the clinic moved forward, providers referred additional patients (beyond the 42 identified initially), but these were not included in the study.

The clinic pharmacist was credentialed using the facility's standard credentialing process and granted privileges to order and interpret laboratory tests and to start, monitor, and discontinue medications relating to the treatment of diabetes, hypertension, or dyslipidemia. In addition to these duties, the pharmacist obtained weight and

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blood pressure (BP) measurements and performed routine foot exams and annual monofilament tests. Patients with medical problems unrelated to diabetes, hypertension, or dyslipidemia were referred to their primary care manager (PCM) for evaluation and treatment. The pharmacist also consulted patients' PCMs regarding other diabetes complications (such as neuropathy or nephropathy) prior to treating these conditions.

DATA COLLECTION

For the purposes of the study, the 19 patients who self-enrolled in the diabetes clinic by responding to the letter of invitation formed the treatment group, while the 23 nonrespondents who continued to have their care managed by their PCMs constituted the control group. Although this method of selection had the potential to introduce bias into the study, the working group was concerned that random assignment of patients to the diabetes clinic would confuse patients who had been assigned only recently to a PCO team, possibly undermining the PCO process. All of the study patients were either retirees or dependents.

In addition to the changes in HbA_{1C} and fasting blood glucose levels, and the completion of annual dilated eye and monofilament exams and microalbuminuria screening, the study team selected secondary variables relating to some of the most common diabetes comorbidities—which include hypertension, dyslipidemia, heart disease, obesity, retinopathy, nephropathy, and neuropathy. Such comorbidities can have a significant impact on patients' quality of life and are monitored routinely in the diabetes clinic. The study, therefore, analyzed changes in weight; systolic and diastolic BP; and serum levels of total cholesterol, high-density lipoprotein (HDL), triglycerides, and low-density lipoprotein (LDL). We also recorded patients' age and gender.

Data were collected on these variables at the beginning of the study and at the end of six months. At the conclusion of the study, a records review was undertaken to determine whether patients had received their annual dilated eye exam, microalbumin screening, and monofilament exam.

Baseline data were collected between January 1, 2001 and May 31, 2001. For patients whose last documented HbA_{1C} level was less than six months old at the time the clinic began operating, this value was used as the baseline value for the study. Patients with levels taken more than six months earlier underwent a repeat measurement, with the result used as the baseline value. Patients were not excluded from the study if their repeat HbA_{1C} level was below 8% (Figure).

Outcome data were collected between December 1, 2001 and January 31, 2002. Patients were included in the final analysis if they had baseline and outcome HbA_{1C} values documented. Patients missing other data were assigned a value equivalent to the mean of the remainder of their group.

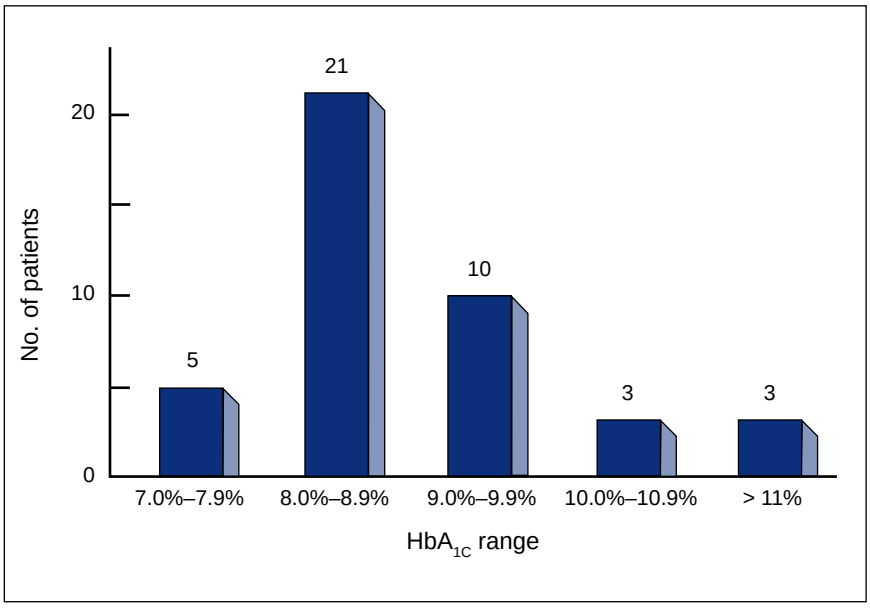

Figure. Distribution of baseline glycosylated hemoglobin (HbA_{1C}) values for patients in the study of the pharmacist-managed diabetes specialty clinic at McChord Air Force Base. (All patients had a level of 8% or higher documented during the six months prior to clinic invitation.)

ENCOURAGING RESULTS

Of the 19 patients in the original treatment group, two moved out of the area during the study period. In addition, four control patients moved from the area and four had no follow-up HbA_{1C} test performed. All baseline and outcome data, therefore, were analyzed for the 17 patients remaining in the treatment

group and the 15 remaining in the control group. There were no statistically significant differences between these groups in any of the study variables at baseline (Table 1).

For nearly all outcome variables, patients in the treatment group demonstrated greater improvement than did those in the control group (Table 2). The difference in HbA_{1C} reduction between the two groups was significant: The treatment group experienced a mean HbA_{1C} decrease of 1.28% ± 0.96 (standard deviation), compared with a decrease of only 0.23% ± 0.90 in the control group ($P < .003$). The treatment group also showed greater improvements in fasting blood glucose, total cholesterol, triglycerides, LDL, and both systolic and diastolic BP. Although not statistically significant, differences were marked in the areas of fasting blood glucose and diastolic BP.

In previous studies, intensive diabetes treatment has been associated with significantly more weight gain compared with conventional treatment. In our study, however, both the treatment and control groups actually lost weight (a mean of 0.7 and 4 lb, respectively). Finally, patients in the treatment group were significantly more likely than those in the control group to receive an annual eye exam ($P < .003$), annual microalbuminuria screening ($P < .001$), and an annual monofilament exam ($P < .023$) (Table 3).

Table 1. Baseline data for patients included in the final analysis of the pharmacist-managed diabetes specialty clinic at McChord Air Force Base

Variable	Treatment group* (n = 17)	Control group* (n = 15)
Age (years)	55.47 ± 6.55	52.53 ± 13.75
HbA_{1C} (%)	8.91 ± 0.80	8.29 ± 0.91
Fasting blood glucose (mg/dL)	194.41 ± 55.47	171.14 ± 55.91
Total cholesterol (mg/dL)	194.12 ± 37.20	205.54 ± 45.24
High-density lipoprotein (mg/dL)	47.47 ± 13.78	50.09 ± 7.16
Triglycerides (mg/dL)	172.06 ± 88.98	247.92 ± 166.32
Low-density lipoprotein (mg/dL)	112.29 ± 37.98	102.45 ± 19.68
Systolic blood pressure (mm Hg)	137.88 ± 20.17	143.87 ± 20.42
Diastolic blood pressure (mm Hg)	79.47 ± 11.30	76.33 ± 11.74
Weight (lb)	201.53 ± 44.56	184.50 ± 46.15
Gender Male Female	 9 (52.94) 8 (47.06)	 5 (33.33) 10 (66.67)

*All values given as mean ± standard deviation, except for gender, which is given as number (percentage) of patients.

WHY THE DIFFERENCES?

The data clearly show that patients followed by a pharmacist in the diabetes clinic had similar or better outcomes when compared with patients followed by a physician in a traditional primary care environment. The study does not explain, however, why this occurred. While the skill of a pharmacist in this role probably played a part, we cannot ascribe these results completely or conclusively to this cause.

Because the diabetes clinic was the first specialty clinic opened at this location and was the first use of a pharmacist in a more clinical role, the clinic was certainly under a high level of scrutiny. This likely contributed to the pharmacist's diligence in following the appointed clinical practice guideline. It's conceivable, therefore, that more faithful following of the guideline by the pharmacist as compared with other providers contributed to the successes of the clinic—and that similar results could be achieved by any provider who followed the guideline so closely.

Aggressiveness of treatment and time between visits also may have played a role in the outcome differences seen. Initially, all patients in the treatment group were seen at least monthly. Patients who required more intensive monitoring, had severely uncontrolled glucose levels, or required insulin dosage adjustment were seen even more frequently. The implications of this are twofold. First, an in-

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Table 2. Change in primary and secondary outcome variables in the study of the pharmacist-managed diabetes specialty clinic at McChord Air Force Base

Measure	Baseline value*	Final value*	Change*	*P* value†
HbA_{1C}‡ (%)				
Treatment	8.91 ± 0.80	7.62 ± 0.76	–1.28 ± 0.96	.003
Control	8.29 ± 0.91	8.07 ± 1.16	–0.23 ± 0.90	
Fasting blood glucose (mg/dL)				
Treatment	194.41 ± 55.47	168.65 ± 56.98	–25.76 ± 68.66	.190
Control	171.14 ± 55.91	179.50 ± 63.16	+8.36 ± 72.57	
Total cholesterol (mg/dL)				
Treatment	194.12 ± 37.20	177.82 ± 40.01	–16.29 ± 47.44	.744
Control	205.54 ± 45.24	194.23 ± 37.91	–11.31 ± 30.67	
High-density lipoprotein (mg/dL)				
Treatment	47.47 ± 13.78	48.59 ± 12.67	+1.12 ± 7.83	.920
Control	50.09 ± 7.16	51.55 ± 12.98	+1.45 ± 9.79	
Triglycerides (mg/dL)				
Treatment	172.06 ± 88.98	158.00 ± 78.12	–14.06 ± 91.77	.228
Control	247.92 ± 166.32	354.38 ± 491.84	+106.46 ± 391.15	
Low-density lipoprotein (mg/dL)				
Treatment	112.29 ± 37.98	97.71 ± 38.12	–14.59 ± 33.50	.828
Control	102.45 ± 19.68	90.45 ± 10.51	–12.00 ± 24.78	
Systolic blood pressure (mm Hg)				
Treatment	137.88 ± 20.17	133.65 ± 12.54	–4.24 ± 16.78	.796
Control	143.87 ± 20.42	141.33 ± 19.53	–2.53 ± 20.20	
Diastolic blood pressure (mm Hg)				
Treatment	79.47 ± 11.30	74.12 ± 10.30	–5.35 ± 8.46	.185
Control	76.33 ± 11.74	77.13 ± 13.86	+0.80 ± 16.41	
Weight (lb)				
Treatment	201.53 ± 44.56	200.82 ± 43.57	–0.71 ± 13.36	.424
Control	184.50 ± 46.15	180.43 ± 44.10	–4.07 ± 8.67	

*Values given as mean ± standard deviation. †*P* values refer to the significance of differences in mean changes between groups (independent samples t-test). ‡HbA_{1C} = glycosylated hemoglobin.

creased amount of time spent with patients provides more opportunities for education and support. Second, a shorter period of time between appointments usually results in more aggressive treatment because it allows the provider to make finer adjustments in the patient's therapy.

SIGNIFICANCE OF THE RESULTS

Using the previous finding that a 1% drop in HbA_{1C} corresponds to a 35% decrease in the risk of diabetes complications,[8] we can conclude that patients in the treatment group, whose HbA_{1C} fell a mean of 1.28%, reduced their risk of complications by a mean of nearly 45% in only six months. Resources did not allow a study of longer duration, but the sustainability of these successes certainly would be an interesting area for future study.

Because diabetes frequently is associated with dyslipidemias and hypertension, which lead to stroke and heart disease, risk of these con-

ditions was monitored as well. In the treatment group, both systolic and diastolic BP dropped (by 4.24 and 5.35 mm Hg, respectively). By contrast, systolic BP dropped only 2.53 mm Hg and diastolic BP actually rose 0.8 mm Hg in the control group. While these differences did not reach statistical significance, their importance should not be underestimated. Since heart disease is the leading cause of death among patients with diabetes, treatment modalities that decrease BP are much more likely to effect a positive outcome in these patients than in nearly any other patient population. And when treating BP to the more aggressive goal of less than 130/80 mm Hg established by the ADA for diabetic patients, even small incremental differences can go a long way.[16]

A similar argument can be made for the results of cholesterol and triglyceride monitoring. Because diabetes is an independent risk factor for heart disease, a more rigorous standard of cholesterol control exists for diabetic patients than for others (the ADA recommends lowering LDL to less than 100 mg/dL).[16] In our study, the treatment group saw reductions in total cholesterol, LDL, and triglycerides of 16.29, 14.59, and 14.06 mg/dL, respectively. The control group, on the other hand, saw reductions in total cholesterol and LDL of 11.31 and 12 mg/dL, respectively, and an increase in triglycerides of 106.46 mg/dL.

Triglycerides are known to be elevated in patients with uncontrolled diabetes. But while the control patients' fasting blood glucose did rise a mean of 8.36 mg/dL over the duration of the study, this group's small decrease in HbA_{1C} (–0.23%) suggests that there was no significant change, positive or negative, in disease control. This leaves the underlying cause of the increase in triglycerides a mystery.

Table 3. Frequency of annual preventive tests in the study of the pharmacist-managed diabetes specialty clinic at McChord Air Force Base

Test	No. (%) of patients tested	*P* value*
Dilated eye exam		
Treatment	16 (94.12)	.003
Control	7 (46.67)	
Microalbuminuria screening		
Treatment	17 (100.00)	.001
Control	8 (53.33)	
Monofilament test		
Treatment	17 (100.00)	.023
Control	11 (73.33)	

**P* values refer to the significance of differences in frequency between groups (chi-square).

In our study, significantly more patients in the treatment group had an annual monofilament exam, dilated eye exam, and microalbuminuria screening, compared with patients in the control group. Completion of these tests—especially the eye exam and microalbuminuria screen—is a key indicator of the level of preventive care a diabetic patient receives. Early intervention on behalf of a patient with microaneurysms can slow progression to nonproliferative diabetic retinopathy, ultimately becoming the difference between sight and blindness.[7,13] Similarly, a positive microalbuminuria test can yield significant results by allowing the opportunity for early initiation of angiotensin receptor blocker or angiotensin converting enzyme inhibitor therapy, which have demonstrated excellent control of nephropathy.[14,15]

Patients often find that their weight increases when they begin controlling their diabetes more aggressively. The fact that this did not occur in this study probably can be credited to the work of the dietitian and exercise physiologist.

Patients treated in the pharmacist-managed diabetes specialty clinic were more likely to see the dietitian or exercise physiologist than were control patients—though this was not an outcome explicitly targeted in the study and specific utilization of these staff members wasn't tracked. Subsequent studies should include monitoring of these resources to validate their contributions. Anecdotally, however, most patients who had seen the dietitian or exercise physiologist by the end of the study said that these staff members' contributions had been valuable. As a result, the clinic began investigating the possibility of "group appointments" that would include these other professionals.

An important part of this study was the use of home blood glucose

monitoring. At the time of the study, the DoD had a contract with Abbott Diagnostics (Abbott Park, IL) for the Precision Q.I.D. blood glucose meter and the accompanying Precision Link software, which allows providers to upload data directly from patients' meters onto a personal computer. Patients in both the control and treatment groups received a meter, testing strips, and training in how to use each.

The meter and, more importantly, the software played a vital role in the diabetes clinic. First, they were instrumental in educating the patient. Using these tools, the clinic staff produced various graphs of blood glucose values, which helped patients gain a better understanding of their disease.

These visual representations of patients' progress also helped drive home the effects of diet, exercise, and medications. Many patients looked forward to seeing the graphs because they provided validation, support, and reward for their efforts. In time, patients viewing cumulative data witnessed markedly improved values. We must not underestimate the positive reinforcement that patients receive when they see their readings trend down into the normal range and become tightly clustered.

Finally, the availability of a month's worth of trended data was extremely helpful to providers in selecting the appropriate therapy, including dose and timing, and in making therapeutic adjustments during the course of treatment.

SUMMING UP

The purpose of the study was to determine whether the use of a pharmacist-managed diabetes specialty clinic, in which patients were followed closely according to an evidence-based guideline, would produce similar or better outcomes compared with those achieved in a primary care setting. The data support the conclusion that credentialed pharmacists can provide care to patients with diabetes and achieve comparable outcomes to those achieved by traditional providers. With respect to meeting U.S. Air Force prevention goals, patients were significantly more likely to receive recommended annual prevention measures (dilated eye exam, monofilament exam, and microalbuminuria screening) when attending the pharmacist-managed diabetes clinic than when being treated by their PCMs. Additional research—ideally using a randomized methodology to control for selection and treatment bias—is needed to determine whether differences in patient outcomes in this study were related to more frequent visits with the pharmacist, more aggressive disease management, or stricter adherence to the clinical practice guideline. ●

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