NOTES

Pharmacist management of patients with diabetes mellitus enrolled in a rural free clinic

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Purpose. The impact of pharmacist management of patients with diabetes mellitus enrolled in a rural free clinic was evaluated.

Methods. Data from 95 patients continuously enrolled in a new pharmacist service were analyzed over 24 months. Patients were at least 18 years old, qualified for free care on the basis of income or insurance status, and had a diagnosis of type 2 diabetes mellitus upon clinic entry. Under a collaborative agreement, pharmacists educated patients on diabetes, counseled patients on lifestyle modifications, assessed appropriateness of drug therapy, and managed drug therapy for diabetes and associated comorbid conditions. Clinical impact was measured by changes from baseline glycosylated hemoglobin (HbA_{1c}) levels, blood pressure, and lipid levels over a 24-month period. Using published cost estimates, the economic impact of the clinic was calculated based on expected savings for each patient who had a decrease of ≥1% in HbA_{1c} value.

Results. Significant reductions from baseline in HbA_{1c} values ($p < 0.0001$), systolic blood pressure ($p = 0.0011$), diastolic blood pressure ($p = 0.0015$), low-density-lipoprotein cholesterol ($p < 0.0001$), and triglyceride levels ($p = 0.0001$) were achieved in clinic patients. Based on an expected savings of $1,118 per patient who had a decrease of ≥1% in HbA_{1c} value ($n = 67$), the pharmacist service was estimated to provide a savings of $74,906 per year.

Conclusion. Pharmacist management of patients with type 2 diabetes significantly influenced clinical and economic outcomes in an uninsured population living in a rural area with few health care resources.

Am J Health-Syst Pharm. 2013; 70:43-7

Diabetes mellitus affects an estimated 25.8 million persons, or 8.3% of the population, in the United States and is the seventh leading cause of death.[1] Diabetes mellitus is a costly condition, with recent estimates showing a total financial impact of approximately $174 billion. Direct medical costs account for $116 billion (2.3 times higher than what expenditures would be in the absence of diabetes). Indirect costs secondary to disability, work loss, and premature mortality account for $58 billion.

The majority of patients with diabetes have type 2 diabetes and the comorbidities of hypertension and dyslipidemia, all of which increase the chances for cardiovascular morbidity and mortality.[2] A comprehensive approach aimed at controlling multiple cardiovascular risk factors has been proven to be the most beneficial approach for lowering morbidity and mortality among patients with diabetes.[3] Further, guidelines recommend specific goals for blood pressure (<130/80 mm Hg), lipids (low-density-lipoprotein [LDL] cholesterol concentration of <100 mg/dL or <70 mg/dL in the presence of overt cardiovascular disease, triglyceride concentration of <150 mg/dL, and high-density-lipoprotein cholesterol concentration of >40 mg/dL for men and >50 mg/dL for women), and glycosylated hemoglobin (HbA_{1c}) (<7%).[2] Attainment of these goals can be difficult for patients, even in ideal circumstances, and is made more challenging in the presence of certain social issues,

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Supported by BlueCross BlueShield of South Carolina Foundation.

Presented at the International Society for Pharmacoeconomics and Outcomes Research 16th Annual International Meeting, Baltimore, MD, May 2011, and the American College of Clinical Pharmacy Annual Meeting, Pittsburgh, PA, October 2011.

The authors have declared no potential conflicts of interest.

DOI 10.2146/ajhp120221

such as loss of income and lack of insurance.

Diabetes and its common comorbid conditions affect both the insured and uninsured in the United States. Patients without insurance are more likely to have poorly controlled hypertension and elevated LDL cholesterol levels compared with their insured counterparts.[4] Uninsured patients with diabetes are more likely than their insured counterparts to have uncontrolled diabetes when the HbA_{1c} thresholds of 8% and 9% are used. A 2009 analysis found that, in the United States, the percentage of adults age 25–61 years who were uninsured was highest in the South (18.3%).[5]

Diabetes management provided by pharmacists has been shown to improve HbA_{1c} levels, blood pressure, and lipid control in health care systems, community pharmacies, community health centers, primary care clinics, and large urban free clinics.[6-17] Pharmacist management of diabetes in a rural free clinic has yet to be described fully in the literature. The purpose of this observational analysis was to assess the impact of education, monitoring, and management by pharmacists of patients with type 2 diabetes enrolled in a free clinic that serves a rural population.

Methods

Service site. The Good Shepherd Free Medical Clinic (GSFMC) is the only safety-net provider of health care services for rural Laurens County, South Carolina. Laurens is home to approximately 69,567 people, with 14.3% of the population below the poverty level. The person:pharmacist ratio is approximately 4969:1. To qualify for services at GSFMC, the patient's household income must be no greater than 150% of the federal poverty level. Eligible patients have no insurance benefits, veteran's benefits, or state or federal health care aid. GSFMC receives no federal or state funding and is solely supported by private donations and grants from private businesses. Care is provided at GSFMC by a part-time nurse practitioner, a volunteer medical director, and other volunteer physicians, nurses, and pharmacists from the local community. The clinic currently serves approximately 1,800 patients.

Clinical pharmacotherapy services. Clinical pharmacotherapy services focused on anticoagulation and diabetes management were initiated at GSFMC in fall 2009 as part of a community outreach program from the Presbyterian College School of Pharmacy in Clinton, South Carolina. Clinical pharmacists with residency training in ambulatory care and additional credentials (certified diabetes educator or board-certified pharmacotherapy specialist) provide services two to three days each week on a volunteer basis. In order to be referred for one-on-one diabetes management with a clinical pharmacist, patients must be at least 18 years old, qualify for free care, have a diagnosis of diabetes, and have a baseline HbA_{1c} value of >9%. Under a collaborative practice agreement, pharmacists educate patients about diabetes, counsel patients on lifestyle modifications, assess the appropriateness of drug therapy, and manage drug therapy for diabetes and associated comorbid conditions. Patients are scheduled for an initial 90-minute visit with subsequent 30-minute follow-up visits, which are scheduled as often as required to reach the patient's goals. Once a patient is enrolled in the pharmacy clinic, the pharmacist solely conducts medication adjustments for the patient's diabetes, dyslipidemia, and blood pressure. However, a patient may be seen by his or her primary care provider for management of other diseases or complaints after enrollment into the clinical pharmacy service. All clinical pharmacist notes are cosigned by the referring primary care provider. Once enrolled, patients are maintained on the clinic schedule of the clinical pharmacists until one of the following occurs: obtainment of insurance or other health care benefits by the patient, making him or her ineligible for services at GSFMC; the patient misses two or more clinical pharmacist appointments; and achievement of clinical targets for HbA_{1c}, blood pressure, and cholesterol.

Clinical impact evaluation. Clinical impact was measured by changes from baseline HbA_{1c} levels, blood pressure, and lipid levels over a 24-month period. Paired *t* tests and McNemar's tests were used to compare baseline values with the most recent laboratory test value of record. All enrolled patients were included in this evaluation as long as there was a baseline and follow-up HbA_{1c} measurement available.

The amount of time spent with patients was tracked by medication therapy management Current Procedural Therapy (CPT) billing codes (99605, 99606, 99607). The number and types of interventions (education, counseling, medication therapy change) were also captured. Any change to a current medication or the start of a new medication was recorded, and data were aggregated by medication class.

Economic impact evaluation. Using published cost estimates, economic impact was calculated based on expected savings resulting from a ≥1% decrease in HbA_{1c} levels. A study by Wagner et al.[18] found that patients who had a decrease of ≥1% in HbA_{1c} levels realized an annual cost savings of $685–$950 per patient per year (1997 dollars) in total health care costs. The medical care component of the Consumer Price Index was used to inflate the average $820 per year in 1997 dollars to $1118 per year in 2011 dollars. The number of patients who had a decrease of ≥1% in HbA_{1c} levels was determined and multiplied by this estimated savings to calculate a predicted annual savings for GSFMC patients.

Results

Patient demographics. Ninety-five patients with type 2 diabetes who had at least two sets of laboratory values for comparison were managed within the pharmacotherapy service between September 2009 and August 2011 (Table 1). The population was nearly evenly split between men and women and African Americans and Caucasians. The mean ± S.D. age of enrollees was 51 ± 8.3 years (range, 30–66 years). While 80% of enrollees were taking metformin at baseline, only 66% were taking an angiotensin-converting-enzyme inhibitor or angiotensin-receptor blocker, even though 81% of the population had a diagnosis of hypertension. Similarly, despite the fact that 75% of patients had dyslipidemia as a baseline problem, only 52% were receiving a hydroxymethylglutaryl–coenzyme A inhibitor (statin). Few patients (28%) were receiving an antiplatelet such as aspirin or clopidogrel at baseline. Only 38% of patients were taking insulin at the time of their referral, despite the fact that criteria mandated patients have an HbA_{1c} of ≥9% at the time of referral. Tobacco use was reported by 35% of patients upon enrollment.

Clinical outcomes. Table 2 provides the clinical outcomes for the clinic for the therapeutic goals that were followed. Significant reductions from baseline in HbA_{1c} values, systolic blood pressure (SBP), diastolic blood pressure (DBP), LDL cholesterol, and triglyceride levels were achieved in the population managed by the clinical pharmacists. Of note, the mean HbA_{1c} value at follow-up was 2.6 percentage points lower than the mean baseline value. Mean SBP decreased 7.3 mm Hg, and mean LDL cholesterol fell 22 mg/dL. Each measure went from above goal at baseline to below goal at the end of the two-year period. In fact, significantly more patients met the HbA_{1c} goal ($p < 0.0001$), SBP goal ($p = 0.016$), DBP goal ($p = 0.007$), LDL cholesterol goal ($p < 0.0001$), and triglyceride goal ($p = 0.0009$) at the end of two years compared with baseline. Table 3 reports the rates of goal attainment at the end of the two-year observation period for each of the clinical measures evaluated and compares them with goal attainment rates from the National Committee for Quality Assurance's State of Health Care Quality 2011 report.[19]

Over the two-year observation period, 1159 pharmacist interventions were documented. Most patient encounters were comprehensive, including disease education, changes in drug therapy, and medication counseling. Changes in current drug therapy accounted for 77.6% of medication interventions. Increasing the medication dosage was the most common medication modification documented (50.4%), followed by adding an additional medication (28.4%). Seventy-three referrals were written for eye examinations, and smoking-cessation counseling was provided during 112 patient visits.

Insulin initiations (50% of all new medications started) and insulin adjustments (50.7% of all medication dosage adjustments) constituted the majority of medication changes instituted by the clinical pharmacists. The second most common medication class for which adjustments were made was antihypertensives (12.8% of all new medications started and 19.1% of all dosage adjustments). Oral antidiabetic agents made up 0.09% of all new medications started and 18.5% of all dosage adjustments. Antihyperlipidemics accounted for 12.6% of all new medications started and 9.7% of all dosage adjustments. Antiplatelets (usually aspirin) comprised 0.07% of all new medications started and 0.9% of all dosage adjustments. Other drug therapy (e.g., antidepressants) was involved in 8.6% of new starts and 1.1% of adjustments.

Pharmacist time and economic impact. Billing codes for medication therapy management services were captured for 481 visits, which accounted for all pharmacist visits during the second year of the study period. Using these billing codes, pharmacist time spent on direct patient contact was calculated. During the last year of the study period, the vast majority of pharmacist visits (80.5%) lasted 30–45 minutes (57.8% lasted 30 minutes, and 22.7% lasted 45 minutes). The duration of the remaining 19.5% of visits varied (e.g., 90-minute initial visits, 15-minute follow-up telephone calls).

Cost avoidance was calculated using a savings estimate of $1,118 per patient for each patient who had a decrease of ≥1% in HbA_{1c} value. Sixty-seven patients had a sufficient HbA_{1c} reduction from baseline to be included in the cost-avoidance analysis. Assuming these patients were consuming resources at the rate of patients in the study by Wagner et al.,[18] the clinic is estimated to have

Table 1.
Demographic Characteristics of Clinic Patients[a] (*n* = 95)

Characteristic	No. (%) Pts
Women	50 (53)
Ethnicity	
African American	49 (52)
Caucasian	42 (44)
Hispanic	4 (4)
Medication	
Antiplatelet	27 (28)
ACE inhibitor or ARB	63 (66)
Insulin	36 (38)
Metformin	76 (80)
Sulfonylurea	39 (41)
HMG-CoA inhibitor	49 (52)
Thiazolidinedione	7 (7)
Medical history	
Coronary artery disease	12 (13)
Hypertension	77 (81)
Dyslipidemia	71 (75)
Amputation	3 (3)
Retinopathy	6 (6)

[a] ACE = angiotensin converting enzyme, ARB = angiotensin-receptor blocker, HMG-CoA = hydroxymethylglutaryl–coenzyme A.

provided a savings of $74,906 per year.

Discussion

This observational study had several limitations. Due to the paucity of published information describing the expected cost savings associated with improved HbA_{1c} control, the cost savings estimates calculated in this study were extrapolated from a previous study by Wagner et al.[18] There are a number of differences between the Wagner et al. study and this observational analysis. The Wagner et al. study occurred over five years in the closed system of a health maintenance organization, while this study was conducted over two years in a free clinic population of a small, rural community. Given the difference in health care systems, patient populations, and patient demographics, it is likely that differences also existed in patient utilization of health care resources as well as the cost to care for each patient. The Wagner et al. study did not evaluate disease management conducted by pharmacists. Cost savings in the current study represent hypothetical dollars saved through improved HbA_{1c} control. Savings in this study represent costs avoided to the overall health care community, including the local hospital and those who would assume responsibility for unpaid medical expenses. In addition, all services provided in this study arose solely from donated community resources. For these reasons, the estimated cost savings reported in the current study must be considered carefully.

A prominent limitation was the lack of a comparator group. Given the growing evidence that demonstrates the positive impact of pharmacist interventions in other settings, it would be unethical to deny treatment to an underserved individual who requires diabetes care. The sample size for this study was small, which was expected given the newness of the pharmacy service being evaluated. Despite this, significant improvements in numerous clinical outcomes were documented. CPT coding information used in the evaluation of pharmacist time spent was available only for the second year of the study period, when the electronic medical record was initiated. Generalizability of the results from this study is limited by the patient population studied and the fact that medications were provided to patients without cost.

The impact of pharmacist care on a rural uninsured population has not previously been described in the literature. Despite the additional social challenges encountered in this patient population, significant improvements in HbA_{1c} values, SBP, DBP, LDL cholesterol levels, and triglyceride levels were achieved. Outcomes were similar to those improvements previously described in other patient populations[6-17] and comparable or better than those achieved in insured and indigent populations as described by the State of Health Care Quality 2011 report (Table 3).[19] Because patients referred for pharmacist care were managed solely

Table 2.
Clinical Outcomes of Clinic Patients[a] (*n* = 95)

Variable	Mean ± S.D. Baseline Value	Mean ± S.D. Follow-up Value	*p*
HbA_{1c}, %	10.7 ± 2.4	8.1 ± 1.9	<0.0001
SBP, mm Hg	130.9 ± 21.7	123.6 ± 16.2	0.0011
DBP, mm Hg	77.9 ± 11.0	74.1 ± 9.9	0.0015
LDL cholesterol, mg/dL[b]	103.5 ± 33.2	81.5 ± 25.8	<0.0001
Triglyceride, mg/dL[b]	251.7 ± 258.7	156.5 ± 87.9	0.0001
HDL cholesterol, mg/dL[b]	41.7 ± 14.4	41.5 ± 12.5	0.7504

[a] HbA_{1c} = glycosylated hemoglobin, SBP = systolic blood pressure, DBP = diastolic blood pressure, LDL = low-density lipoprotein, HDL = high-density lipoprotein.
[b] *n* = 82.

Table 3.
Comparison of Goal Attainment Between Clinic Patients and National Report[a]

Goal	% Clinic Pts Attaining Goal	% Pts Attaining Goal in National Committee for Quality Assurance Report[19]				
		Commercial HMO	Commercial PPO	Medicare HMO	Medicare PPO	Medicaid HMO
HbA_{1c} < 7%	35.8	42.5	28.2	NR	NR	34.7
BP < 130/80 mm Hg	62.1	33.9	23.6	33.3	26.7	32.2
LDL cholesterol < 100 mg/dL	82.9	47.7	37.3	52.1	45.9	34.6
HbA_{1c} > 9%	27.4	27.3	46.6	25.9	35.2	44.0

[a] HbA_{1c} = glycosylated hemoglobin, HMO = health maintenance organization, PPO = preferred provider organization, NR = not reported, BP = blood pressure, LDL = low-density lipoprotein.

by a pharmacist for their diabetes, blood pressure, and cholesterol, with very few if any exceptions, the results can be attributed directly to pharmacist interventions. In addition to improved guideline adherence, as measured by an increased rate in goal attainment, pharmacist intervention was also found to result in more appropriate use of therapeutic agents currently recommended for patients with diabetes.

Conclusion

Pharmacist management of patients with type 2 diabetes significantly influenced clinical and economic outcomes in an uninsured population living in a rural area with few health care resources.

References

1. Centers for Disease Control and Prevention. National diabetes fact sheet, 2011. www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf (accessed 2011 Jul 18).
2. American Diabetes Association. Standards of medical care in diabetes—2009. *Diabetes Care.* 2009; 32(suppl 1):S13-61.
3. Gaede P, Lund-Andersen H, Parving HH et al. Effect of a multifactorial intervention on mortality in type 2 diabetes. *N Engl J Med.* 2008; 358:580-91.
4. Wilper AP, Woolhandler S, Lasser KE et al. Hypertension, diabetes, and elevated cholesterol among insured and uninsured U.S. adults. *Health Aff.* 2009; 28:w1151-9.
5. Pizer SD, Frakt AB, Iezzoni LI. Uninsured adults with chronic conditions or disabilities: gaps in public insurance programs. *Health Aff.* 2009; 28:w1141-50.
6. Davidson MB, Karlan VJ, Hair TL. Effect of a pharmacist-managed diabetes care program in a free medical clinic. *Am J Med Qual.* 2000; 15:137-42.
7. Scott DM, Boyd ST, Stephan M et al. Outcomes of pharmacist-managed diabetes care services in a community health center. *Am J Health-Syst Pharm.* 2006; 63:2116-22.
8. Jameson JP, Baty PJ. Pharmacist collaborative management of poorly controlled diabetes mellitus: a randomized controlled trial. *Am J Manag Care.* 2010; 16:250-5.
9. Rothman RL, Malone R, Bryant B et al. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *Am J Med.* 2005; 118:276-84.
10. Odegard PS, Goo A, Hummel J et al. Caring for poorly controlled diabetes mellitus: a randomized pharmacist intervention. *Ann Pharmacother.* 2005; 39:433-40.
11. Choe HM, Mitovich S, Dubay D et al. Proactive case management of high-risk patients with type 2 diabetes mellitus by a clinical pharmacist: a randomized controlled trial. *Am J Manag Care.* 2005; 11:253-60.
12. Ragucci KR, Fermo JD, Wessell AM et al. Effectiveness of pharmacist-administered diabetes mellitus education and management services. *Pharmacotherapy.* 2005; 25:1809-16.
13. Cioffi ST, Caron MF, Kalus JS et al. Glycosylated hemoglobin, cardiovascular, and renal outcomes in a pharmacist-managed clinic. *Ann Pharmacother.* 2004; 28:771-5.
14. Hogue VW, Babamoto KS, Jackson TB et al. Pooled results of community pharmacy-based diabetes education programs in underserved communities. *Diabetes Spectrum.* 2003; 16:129-33.
15. Goyette D, Disco ME, Leal S et al. The pharmacist as a primary care provider for the medically underserved. *J Am Pharm Assoc.* 2003; 43:S52-3.
16. Andrus MR, Clark DB. Provision of pharmacotherapy services in a rural nurse practitioner clinic. *Am J Health-Syst Pharm.* 2007; 64:294-7.
17. Shane-McWhorter L, Oderda GM. Providing diabetes education and care to underserved patients in a collaborative practice at a Utah community health center. *Pharmacotherapy.* 2005; 25:96-109.
18. Wagner EH, Sandhu N, Newton KM et al. Effect of improved glycemic control on health care costs and utilization. *JAMA.* 2001; 285:182-9.
19. National Committee for Quality Assurance. The state of health care quality, 2011. www.ncqa.org/LinkClick.aspx?fileticket=FpMqqpADPo8%3d&tabid=836 (accessed 2012 Jan 30).