# Evaluation of Glycemic Control Maintenance in Veterans Discharged From a Pharmacist-Managed Diabetes Clinic

Charity Anicete, PharmD; Seema Kapadia, PharmD, BCACP; Mansi Patel, PharmD, BCPS; and Anthony Tardi, PharmD, BCACP

In January 2009, the Jesse Brown VAMC in Chicago, Illinois, started a pharmacist-managed diabetes clinic. The results showed that a pharmacist-managed diabetes clinic influences patients achieving an A1C reduction and maintaining glycemic control after discharge.

iabetes mellitus (DM) is a chronic disease that affects 25.8 million Americans or 8.3% of the U.S. population.<sup>1</sup> According to the 2011 National Diabetes Fact Sheet, an estimated 27% of Americans aged ≥ 65 years have been diagnosed with diabetes, and nearly 50% have prediabetes. The Centers for Disease Control and Prevention estimate 1 of 3 American adults could have diabetes by 2050.1 Due to its long-term complications and increased cardiovascular risk, diabetes is the seventh-leading cause of mortality in the U.S.1

To prevent numerous complications and overall mortality associated with diabetes, the American Diabetes Association recommends an A1C < 7% in most adults to achieve optimal glycemic control.<sup>2</sup> Individuals who have a history of severe hypoglycemia, limited life expectancy, or extensive comorbid conditions may have less stringent A1C goals. In general, every percent decrease in an A1C level can lead to a 21% decrease in diabetes-related deaths, 14% less

risk for myocardial infarction, and a 37% reduction in microvascular complications.<sup>3</sup>

Achieving target glycemic control, however, can be challenging for many patients with diabetes. According to the 2010 National Health and Nutrition Examination Survey from 2005 to 2008, 12.7% of American adults with diabetes aged ≥ 20 years had an A1C > 9%.4 Diabetes care is multifaceted and requires multiple interventions to achieve optimal glycemic control and to manage and prevent long-term complications. Since diabetes care requires complex medication therapy management, frequent monitoring, and lifestyle modifications, pharmacists play an integral role in its management. Several studies have evaluated the impact of clinical pharmacy interventions on diabetes-related outcomes.5,6

Rothman and colleagues evaluated a pharmacist-led, primary care-based diabetes management program for patients with type 2 diabetes mellitus (T2DM) and poor glycemic control.<sup>6</sup> The primary outcome was the

improvement in glucose control, as measured by the change in A1C level from baseline to 6-month follow-up. The study enrolled 159 subjects with an average baseline A1C of 10.8%. Clinical pharmacy intervention included a 1-hour initial pharmacy visit. At that visit, patients were educated on glucose control, glucose monitoring, hypoglycemic management, diet and exercise, foot and eye care, and medication management. Recommendations on diabetes medications, blood pressure, and lipid management were also made at the initial visit. The follow-up visits focused on diabetes medication management. The study showed that after a 6-month intervention, the mean reduction in A1C was 1.9%. which was statistically significant (P < .0001). The study concluded that a pharmacist-based diabetes program reduced A1C levels in patients with poorly controlled diabetes.

In January 2009, the Jesse Brown VAMC (JBVAMC) in Chicago, Illinois, started a pharmacist-managed diabetes clinic. Patients with diabetes who had an institution-specified critical A1C > 9% were eligible to enroll in the clinic. The goal of the clinic was to remove patients from

**Dr. Anicete** is as an outpatient clinical pharmacist, **Dr. Kapadia** and **Dr. Patel** are clinical pharmacy specialists in primary care, all at the Jesse Brown VAMC in Chicago, Illinois. **Dr. Tardi** is a clinical pharmacist in primary care at the Adam Benjamin Jr. VA Outpatient Clinic, a division of the Jesse Brown VAMC, in Crown Point, Indiana.

**Table 1. Baseline characteristics** 

Variable	Characteristics	No. of patients
Age (y, mean $\pm$ SD)	63.8 ± 8.5	84
Gender	Male	84
	Female	0
Ethnicity	African American	70
	White	10
	Native Hawaiian or Pacific Islander	1
	Unknown	3

the critical hyperglycemic level by helping them achieve an A1C < 9%. The diabetes clinic pharmacist saw up to 12 patients a day. Clinical pharmacy interventions included 30 to 60 minutes of face-to-face appointments or 10 to 20 minutes of telephone appointments. The interval between each follow-up visit was dictated by the intensity of the diabetes management and intervention needed. Patients with complicated management issues were seen every 2 to 4 weeks. Patients were educated on glucose control, glucose monitoring, hypoglycemia management, medication compliance, and therapeutic lifestyle modifications. Medication reconciliation was performed at each visit to assess patients' medication compliance. Under a scope of practice and in accordance with up-to-date literature and guidelines, the clinical pharmacy specialist had the ability to order laboratory blood work before the patient visit and to prescribe medications (eg, antidiabetic agents, insulin, aspirin, antihypertensives, and lipidlowering agents) as necessary. No specific treatment algorithms were followed; instead, medication changes were made based on individualized response, patient medication history, and clinical judgment. Ophthalmol-

Table 2. Hemoglobin A1C and weight at baseline

Variable	Initial visit	Discharge	Change
		Mean $\pm$ SD	
A1C (%, N = 84)	10.3 ± 1.4	$7.9 \pm 0.8$	$-2.4 \pm 1.7$
Weight (kg, n = 63)	100.2 ± 19.4	101.2 ± 19.7	1.1 ± 3.4
SD = standard deviation.			

ogy and podiatry consults were placed, and a referral to a nutrition service was also suggested to the patient when appropriate. As patients achieved their acute

goal of < 9%, they were discharged from the diabetes clinic and transferred to primary care for further diabetes management.

Previous trials looking at the effect of clinical pharmacist interventions on the management of diabetes have demonstrated significant impact on achieving A1C goals. However, maintenance of these outcomes after patients are discharged from pharmacist-managed clinics has yet to be evaluated. The purpose of this study was to evaluate whether veterans discharged from the pharmacist-managed diabetes clinic were able to maintain glycemic control below the A1C value of 9%.

## **METHODS**

This study was approved by the Institutional Review Board and VA Research and Development Committee. It was a retrospective, electronic chart review of patients with an ICD-9 diagnosis of T2DM who were evaluated in the diabetes clinic from January 2009 through the end of data collection. Data were collected from January 1, 2008, through September 15, 2011, to allow for assessment of baseline and follow-up laboratory parameters. Patients aged > 18 years with a diagnosis of T2DM, a baseline A1C ≥ 9%, at least 2 documented diabe-

tes clinic visits, and a documented transfer of care from the diabetes clinic to primary care were included in the study. Patients who were lost to follow-up after 1 diabetes clinic visit and who did not have a follow-up A1C level after the initial diabetes clinic or within 12 months after discharge from the diabetes clinic or before September 15, 2011, were excluded from the study.

The primary endpoint was the number of patients who were able to maintain their A1C < 9% within 12 months after discharge from the diabetes clinic. Secondary endpoints included changes in A1C level and weight (kg) within 12 months after discharge from the diabetes clinic, follow-up visit with the primary care team, reenrollment to the diabetes clinic after the initial discharge, and medication and appointment adherence.

Demographic information, such as age, gender, and ethnicity were collected. Other data assessed were A1C level and weight at least 1 year prior to initial diabetes clinic visit and at discharge, number of diabetes clinic visits, and duration of enrollment. Changes in baseline A1C level and weight were obtained by comparing the baseline value at the initial visit with the last value documented on discharge. Medication information obtained included the following: documentation of antidiabetic medications at least 6 months before the initial visit and documentation of oral antidiabetic medications, insulin

Table 3. Clinic follow-up at baseline (N = 84)

Variable	Mean ± SD	
No. of diabetes mellitus clinic visits	5.0 ± 3.4	
Duration of enrollment (mo)	4.4 ± 3.3	
No. of visits (mo)	$1.4 \pm 0.6$	
SD = standard deviation.		

and other injectable diabetes medications started before the initial diabetes clinic visit, during enrollment, and after discharge. Documentation of A1C level, weight, primary care appointments, and placement of follow-up reminders within 3, 6, 9, and 12 months after discharge were collected. Medication and appointment adherence were also assessed.

Statistical analysis was performed using a paired *t* test, a Student *t* test, and a chi-square test. An alpha level of 0.05 was used to determine statistical significance.

## **RESULTS**

Four hundred ninety-eight charts were reviewed, and 84 patients who met the inclusion criteria were enrolled in the study. Four hundred fourteen patients were excluded due to the following reasons: 169 were lost to follow-up, 132 had an A1C < 9%, 76 were still actively enrolled in the clinic, and 37 did not have a follow-up A1C test after discharge. The study population was 100% male and 83% African American; mean age 64 years (Table 1).

Other baseline information evaluated included the mean A1C level and weight at initial visit and discharge, number of clinic visits, duration of enrollment, and medication use. The mean average A1C (%) was

Table 4. Medication at baseline (N = 84)

Medication	Initial visit, No. of patients (%)	Discharge, No. of patients (%)
Oral medications only	26 (31)	19 (23)
Insulin only	32 (38)	25 (30)
Other injectable medications only	0 (0)	0 (0)
Combination (oral + insulin)	26 (31)	39 (46)
Combination (oral + other injectables)	0 (0)	1 (1)

 $10.3 \pm 1.4$  and  $7.9 \pm 0.8$  at initial visit and discharge, respectively. This resulted in a mean difference of 2.4%  $\pm 1.7$ % decrease in A1C. The mean average weights (kg) were 100.2  $\pm 19.4$  and  $101.2 \pm 19.7$  at initial visit and discharge, respectively. This resulted in a mean difference of 1.1  $\pm 3.4$  kg increase in weight. Only 63 patient weights were analyzed, because not everyone enrolled had weight documented at the initial visit and on discharge (Table 2).

During the course of the diabetes clinic follow-up, patients enrolled in the study had an average of  $5.0 \pm 3.4$ clinic visits for a mean duration of  $4.4 \pm 3.3$  months, which was equivalent to  $1.4 \pm 0.6$  visits per month (Table 3). Of the total study population, 89% were on diabetes medications at least 6 months before the initial diabetes clinic visit. All patients were on diabetes medications at the time of enrollment. The number of patients who were on oral antidiabetic medications or insulin alone decreased, whereas those started on combination of oral medications and insulin increased from 31% to 46% from initial visit to discharge

When evaluating the primary endpoint, 64% of the study population maintained their A1C < 9% while 36% had an A1C level that increased to > 9% within

12 months after discharge. Hemoglobin A1C levels and weight at the initial visit and on discharge were compared in order to analyze baseline characteristics between the 2 groups. Both groups had a significant decrease in A1C levels from initial visit to discharge (P < .001), but there was no significant difference between the 2 groups (A1C < 9%:  $-2.6 \pm 1.8\%$ ; A1C > 9%:  $-2.0 \pm 1.3\%$ ; P = .16) (Figure 1). The mean change in weight was significant in patients who maintained their A1C levels (P = .02), but not for patients who had an elevated A1C level (P = .3). There was no significant difference between the 2 groups (A1C < 9%: 1.2 ± 3.4 kg; A1C > 9%: 0.75  $\pm$  3.2 kg; P = .60) (Figure 2). In addition, there was no difference in the number of average clinic visits and duration of enrollment between the 2 groups. Both groups had an average of 1.4 visits per month.

Changes in A1C levels and weight within 12 months after discharge were assessed as secondary endpoints. The change in A1C level from discharge to 12 months postdischarge was significant for both groups (P < .001). Patients who maintained glycemic control had an additional  $0.4 \pm 0.7\%$  mean A1C reduction, whereas patients who lost glycemic control had a  $1.8 \pm 1.5\%$  mean A1C

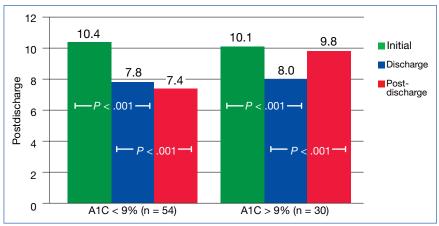


Figure 1. Change in A1C (%) from baseline to 12 months postdischarge.

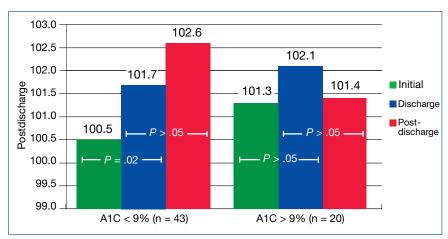


Figure 2. Change in weight (kg) from baseline to 12 months postdischarge.

increase (P < .001) (Figure 1). On the other hand, the change in weight within 12 months after discharge was not significant for both groups. Patients who maintained A1Cs < 9% had a  $0.8 \pm 4.8$  kg mean weight increase, while patients who lost glycemic control had  $0.7 \pm 5.7$  kg mean weight reduction (P = .26) (Figure 2).

In order to ensure patients were appropriately transferred back to their primary care physician (PCP), appointment scheduling and follow-up reminder placements were assessed. Of the total study population, 82% of patients had a PCP appointment scheduled and 43% had a PCP follow-up reminder placed on dis-

charge from the diabetes clinic. All patients had either an appointment or follow-up reminder scheduled. However, the number of patients that had follow-up visits with PCPs decreased throughout the 12 months after discharge. Ninety-one percent of the total patient population had follow-up visits with their PCPs within the first quarter, whereas only 49% followed up during the last quarter after discharge. In addition, of the 30 patients who lost glycemic control, 43% were reenrolled in the diabetes clinic within 12 months after the initial discharge.

Forty-two percent of the total study population was at least 80%

adherent with their diabetes medications after discharge from the diabetes clinic. There was no significant difference between the 2 groups. Forty-three percent of patients who maintained their A1C levels vs 40% of patients who lost glycemic control were at least 80% adherent with medications (P = .82). Similarly, 64% of the total study population was at least 80% adherent with PCP visits within 12 months after discharge. Again, there was no significant difference between the 2 groups. Sixty-seven percent of patients who maintained their A1C levels vs 60% of patients who lost glycemic control were at least 80% adherent with PCP visits (P = .54).

## **DISCUSSION**

Achieving and maintaining the target A1C goal is essential in preventing long-term complications and overall mortality associated with diabetes. Previous studies have demonstrated that pharmacist involvement in diabetes management led to significant reduction in A1C levels and helped patients achieve their target A1C goal.5,6 However, the long-term maintenance of the target A1C goal was not addressed in these studies. To our knowledge, no study involving pharmacist-managed diabetes clinics has evaluated the maintenance of glycemic outcomes once patients are discharged from the clinic.

At the JBVAMC, patients with an A1C > 9% are enrolled in the pharmacist-managed diabetes clinic and discharged to their PCPs once they achieve an A1C < 9%. On average, patients discharged from the clinic achieved a mean A1C reduction of 2.4%, with an average A1C of 7.9% on discharge. This study demonstrated that about two-thirds of the patients were able to maintain their A1C < 9% within 12 months

after discharge from the diabetes clinic. All patients were appropriately discharged and transferred from the diabetes clinic to their primary care team for continued follow-up. This is important as continuity of care plays an essential role in helping patients maintain optimal glycemic control. This study also evaluated patients' weight, average number of clinic visits, and medication and appointment adherence to help determine any influencing factors on the maintenance of glycemic control. Even though patients who maintained their A1C < 9% had slightly better medication and appointment adherence than did the patients who had elevated A1C levels, this study did not find any significant differences between the 2 groups.

# **LIMITATIONS**

There were several limitations to this study, including its retrospective design and small sample size. As consistent with the JBVAMC patient population, all patients included in this study were primarily African American males, which limits the study's external validity. When documenting a patient's postdischarge A1C level, the last A1C level closest to the 12-month period was documented. However, not all patients had their A1C level checked quarterly after discharge. Therefore, some patients only had their A1C levels checked within the first quarter of the 12-month period. This inconsistency is a limitation to the study as the authors were unable to ascertain whether these patients were able to further maintain or lose glycemic control if their A1C level was checked 1 year after discharge from the clinic. Another major limitation to the study was the difficulty to accurately assess medication and appointment adherence. Medication adherence was assessed based on the patients' refill history. However, the authors were not able to determine whether patients actually took their medication after it was filled. Eighty percent was used as the benchmark for determining medication and appointment adherence. For future studies, calculating and documenting the actual percentage based on medication refill history and appointment show-rates may provide a better picture of patients' adherence.

Finally, perhaps the biggest limitations were confounding factors not accounted for in this study. Patients' behavior and attitude as well as other external factors, such as family support and socioeconomic status, may play a role in shaping patients' motivation and accountability in controlling their diabetes. These factors could potentially be assessed through the use of a patient survey; however, due to the retrospective nature of this study, these factors were not evaluated. In addition, this study did not assess whether patients who lost glycemic control were initiated on concomitant medications. such as corticosteroids and antipsychotic medications, which could potentially increase blood glucose levels. Also, intensification and discontinuation of an antidiabetic regimen after being discharged from the clinic were not evaluated.

### CONCLUSION

Overall, this study supported the use of a clinical pharmacy specialist in diabetes management. The pharmacistmanaged diabetes clinic at JBVAMC has been beneficial in achieving A1C level reductions. Moreover, this study demonstrated that the pharmacist role in the diabetes clinic may have helped to promote the maintenance of glycemic control after discharge. Future studies may be warranted to

assess specific characteristics of patients who lost glycemic control after discharge from the clinic. This will be necessary to help target the specific patient population that may need a longer duration of care in the diabetes clinic.

#### Author disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

#### Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of Federal Practitioner, Quadrant HealthCom Inc., a division of Frontline Medical Communications Inc., the U.S. Government, or any of its agencies. This article may discuss unlabeled or investigational use of certain drugs. Please review complete prescribing information for specific drugs or drug combinations—including indications, contraindications, warnings, and adverse effects—before administering pharmacologic therapy to patients.

# **REFERENCES**

- Centers for Disease Control and Prevention. National diabetes fact sheet: National estimates and general information on diabetes and prediabetes in the Unites States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.
- American Diabetes Association. Standards of medical care in diabetes—2012. *Diabetes Care*. 2012;35(suppl 1):S11-S63.
- Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ. 2000;321(7258):405-412.
- Centers for Disease Control and Prevention National Center for Health Statistics. National Health and Nutrition Examination Survey: Analytic Guidelines, 1999-2010. Centers for Disease Control and Prevention Website. http://www.cdc.gov/nchs/data/series/sr\_02/sr02\_161.pdf. Accessed November 1, 2013.
- Stading J, Herrmann J, Walters R, Destache C, Chock A. Impact of pharmacist intervention on diabetes patients in an ambulatory setting. *Diabetes Spectrum*. 2009;22(4):241-246.
- Rothman R, Malone R, Bryant B, Horlen C, Pignone M. Pharmacist-led, primary care-based disease management improves hemoglobin A1C in high-risk patients with diabetes. Am J Med Qual. 2003;18(2):51-58.