Predictors of Hemoglobin A$_{1c}$ Goal Attainment in Patients Treated With Insulin at a VA Pharmacist-Managed Insulin Clinic

Diane E. Hadley, PharmD, BCACP; Alice L. Scaletta, PharmD, BCACP;
Casmir I. Ogbonna, PharmD, MBA, BCPS, BCGP, USPHS;
Vincent J. Willey, PharmD, BCACP; and Tyan Thomas, PharmD, BCPS

Showing up to appointments and adherence to treatment recommendations correlated with glycemic goal attainment for patients.

About 30.3 million Americans (9.4%) have diabetes mellitus (DM).[1] Veterans are disproportionately affected—about 1 in 4 of those who receive US Department of Veterans Affairs (VA) care have DM.[2] The consequences of uncontrolled DM include microvascular complications (eg, retinopathy, neuropathy, and nephropathy) and macrovascular complications (eg, cardiovascular disease).

The American Diabetes Association (ADA) recommends achieving a goal hemoglobin A$_{1c}$ (HbA$_{1c}$) level of < 7% to prevent these complications. However, a goal of < 8% HbA$_{1c}$ may be more appropriate for certain patients when a more strict goal may be impractical or have the potential to cause harm.[3] Furthermore, guidelines developed by the VA and the US Department of Defense suggest a target HbA$_{1c}$ range of 7.0% to 8.5% for patients with established microvascular or macrovascular disease, comorbid conditions, or a life expectancy of 5 to 10 years.[4]

Despite the existence of evidence showing the importance of glycemic control in preventing morbidity and mortality associated with DM, many patients have inadequate glycemic control. Diabetes mellitus is the seventh leading cause of death in the US. Moreover, DM is a known risk factor for heart disease, stroke, and kidney disease, which are the first, fifth, and ninth leading causes of death in the US, respectively.[5]

Because DM management requires ongoing and comprehensive maintenance and monitoring, the ADA supports a collaborative, multidisciplinary, and patient-centered approach to delivery of care.[3] Collaborative teams involving pharmacists have been shown to improve outcomes and cost savings for chronic diseases, including DM.[6-12] In 1995, the VA launched a national policy providing clinical pharmacists with prescribing privileges that would aid in the provision of coordinated medication management for patients with chronic illnesses.[13] The policy created a framework for collaborative drug therapy management (CDTM) models, which grants pharmacists the ability to perform patient assessments, order laboratory tests, and modify medications within a scope of practice.

Since the initiation of these services, several examples of successful DM management services using clinical pharmacists within the VA exist in the literature.[14-16] However, even with intensive chronic disease and drug therapy management, not all patients who enroll in these services successfully reach clinical goals. Although these pharmacist-driven services seem to demonstrate overall benefit and cost savings to veteran patients and the VA system, little published data exist to help determine patient behaviors that are

Diane Hadley, Alice Scaletta, and Tyan Thomas are Ambulatory Care Clinical Pharmacy Specialists at Corporal Michael J. Crescenz VA Medical Center and are Associate Professors of Clinical Pharmacy, at the Philadelphia College of Pharmacy at the University of the Sciences in Pennsylvania. Casmir Ogbonna is a Commissioned Officer of the US Public Health Service and a Drug Safety Evaluator at the US Food and Drug Administration in Silver Spring, Maryland. Vincent Willey is a Principal Scientist at HealthCore, Inc, in Wilmington, Delaware.

TABLE 1. Definition of Measures

Measures	Definition
Optimal frequency of glucose monitoring	• Once daily for basal insulin only regimen • Twice daily for basal-prandial regimen • Twice daily for fixed-mixed insulin regimens (ie, Novolog 70/30 insulin)
Adherence to pharmacist's recommendations	• Each pharmacist's progress note during the review period included an explicit statement verifying that the patient followed directions or did not follow directions; this statement was used to determine adherence. • Adherence was assessed by asking patient to state his/her insulin regimen—discrepancies between the patient's stated dose and the dose documented in the previous pharmacist's progress note was considered nonadherence. For example, a patient who had no documented discrepancies between his/her stated dose and the prescribed dose at 7 of the 10 scheduled visits would be documented as having 70% adherence rate. Adherence to other regimens was not factored into this definition.
Adherence to bringing glucose meter or glucose log to appointments	• Each pharmacist's progress note during the review period included an explicit statement verifying whether the patient brought glucose meter and/or glucose log to appointment. For example, a patient who had no documented discrepancies between his/her stated dose and the prescribed dose at 7 of the 10 scheduled visits would be documented as having 70% adherence rate.
Percentage of visits attended	• Computerized Patient Record System was reviewed to determine the number of appointments each patient missed during the review period. For example, if the patient showed for 7 of the 10 scheduled visits during the review period, he was considered to have attended 70% of his scheduled appointments.

associated with glycemic goal attainment when using these services.

At the Corporal Michael J. Crescenz VA Medical Center in (CMCVAMC) Philadelphia, Pennsylvania, where this study was performed, primary care providers may refer patients with uncontrolled DM to the pharmacist disease state management (DSM) clinic. The clinic is a form of a CDTM and receives numerous referrals per year, with many patients discharged for successfully meeting glycemic targets.

However, a percentage of patients fail to attain glycemic goals despite involvement in this clinic. We observed specific patient behaviors that delayed glycemic goal attainment. This study examined whether these behaviors correlated with prolonged glycemic goal attainment. The purpose of this study was to identify patient behaviors that led to glycemic goal attainment in insulin-treated patients referred to this pharmacist DSM clinic.

METHODS

This study was performed as a single-center retrospective chart review. The protocol and data collection documents were approved by the CMCVAMC Institutional Review Board. It included patients referred to a pharmacist-led DSM clinic for insulin titration/optimization from January 1, 2011 through December 31, 2012. Data were collected through June 30, 2013, to allow for 6 months after the last referral date of December 31, 2012.

This study included patients who were on insulin therapy at the time of pharmacy consult, who attended at least 3 consecutive pharmacy DSM clinic visits, and had an HbA$_{1c}$ ≥ 8% at the time of initial clinic consult. Patients who failed to have 3 consecutive pharmacy DSM clinic visits, were insulin-naïve at the time of referral, aged ≥ 90, lacked at least 1 follow-up HbA$_{1c}$ result while enrolled in the clinic, or had HbA$_{1c}$ < 8% were excluded.

Among the patients who met eligibility criteria, charts within the Computerized Patient Record System (CPRS) were reviewed in a chronologic order within the respective study time frame. A convenience sample of 100 patients were enrolled in each treatment arm: the goal-attained arm or the goal-not-attained arm.

The primary study variable was HbA$_{1c}$ goal attainment, which was defined in this investigation as at least 1 HbA$_{1c}$ reading of < 8% while enrolled in the DSM clinic during the review period. Secondary variables included specific patient factors such as optimal frequency of self-monitoring of blood glucose (SMBG) testing, adherence to pharmacist's instructions for changes to glucose-lowering medications, adherence to bringing glucose meter/glucose log book to clinic appointments, and percentage of visits attended. Definitions for each variable are provided in Table 1. Data were collected for the 4 months prior to the date of at goal HbA$_{1c}$. For patients in the goal-not-attained group, the secondary variables were collected for the 4-month period prior to the end of

TABLE 2. Summary of Baseline (Preclinic Enrollment) Demographics and Clinical Characteristics

Characteristics	Goal Not Attained (n = 105)	Goal Attained (n = 102)
Age, mean (SD), y	61.4 (8.6)	61.4 (7.3)
Male participants, No.	104	100
Female participants, No.	1	2
Race or ethnic group, No.		
American Indian/Alaskan Native	1	0
Black	78	70
Multiracial	1	2
Native Hawaiian/Pacific Islander	1	2
White	24	28
Medications, mean, No.	12.9	13.5
Medical conditions, mean, No.	8.7	8.6
Duration of diabetes mellitus, mean, y	11.2	10.8
Baseline HbA$_{1c}$ value, %	10.7	10.2
Insulin regimens, %		
Basal only	33.3	29.4
Basal + prandial	53.3	56.9
Fixed-mixed[a]	13.3	13.7

[a]Fixed-mixed includes prepared mixed combination of intermediate-acting insulin and short- or rapid-acting insulin (eg, NPH-Regular 70-30).
Abbreviation: HbA$_{1c}$, hemoglobin A$_{1c}$.

follow date. This final date was determined as either the last pharmacy visit date due to loss of follow-up or end of data collection time frame of June 30, 2013.

We hypothesized that patients who were more adherent to treatment plans, regularly attend clinic visits, and appropriately monitor their glucose levels were more likely to meet their glycemic goals.

Statistical Analysis

Univariate descriptive statistics described the individual variables/predictors of HbA$_{1c}$ goal attainment. As the study's purpose was to identify patient factors and characteristics associated with HbA$_{1c}$ goal attainment, a logistic regression model framework was used for all covariates to evaluate each measured variable's independent association with HbA$_{1c}$. The univariate tests were used to compare patient characteristics between the 2 study groups: Pearson chi-square test was used for nominal data, and a paired t test (for normally distributed data) or Wilcoxon rank sum test (for non-

normally distributed data) was used for continuous variables. Variables having a P value < .2 underwent a multivariate analysis stepwise logistic regression model to identify patient factors and characteristics associated with HbA$_{1c}$ goal attainment. A Fisher exact test was used to determine gender effect on HbA$_{1c}$ goal attainment, categoric variables were analyzed using Pearson chi-square test, and an unpaired t test was used for continuous data. The backward elimination approach to inclusion of variables in the model was used to build the most parsimonious and best-fitting model, and the Hosmer-Lemeshow goodness-of-fit tests was used to assess model fit. Data analyses were performed using IBM SPSS, version 18.0 (Armonk, NY).

RESULTS

Five hundred eighty-four patient records were reviewed, and 207 patients met inclusion criteria: 102 patient records were reviewed for the goal-attained arm, and 105 patient records for the goal-not-attained arm. Most patients were excluded from the analysis due to not having 3 consecutive visits during the specified period or having an HbA$_{1c}$ of < 8% at the time of referral to the pharmacist DSM clinic.

The patients in this study had type 2 diabetes for about 11 years, were overwhelmingly male (99%), were aged about 61 years, and were taking on average 13 medications at the time of referral to the pharmacist DSM clinic. Mean HbA$_{1c}$ at time of enrollment was slightly higher in the goal-not-attained arm vs goal-attained arm (10.7% vs 10.2%, respectively), but the difference was not statistically significant (P = .066). A little more than half the patients in both study arms were on basal + prandial insulin regimens (Table 2).

Patients who attained their goal HbA$_{1c}$ were more likely to bring their glucose meter/glucose log book to at least 80% of their appointments (P < .001). Additionally, this same cohort followed insulin dosing instructions at least 80% of the time (P < .001). Frequency of glucose testing was not significantly different between goal-attained and goal-not-attained groups (P = .375). Moreover, our analysis showed that, on average, patients who met goal did so within 6 months of referral to the pharmacist-managed clinic (P < .001) (Table 3).

Five variables were included in the multivariate analysis because they had a P value ≤ .2 in univariate analyses: (1) patient adherence to instructions (P < .001); (2) duration in clinic (P < .001); (3) patient bringing glucose meter or glucose log to appointments (P < .001); (4) percentage of scheduled appointments

patient attended (P = .015); and (5) baseline HbA$_{1c}$ (P = .066). Following instructions at least 80% of the time and duration in clinic were the only significant contributing factors when entered into the multivariate analysis. Longer duration in the pharmacist-managed clinic was inversely related to goal attainment; in other words, patients in clinic for longer periods were less likely to attain glycemic goals (odds ratio [OR] = 0.895, 95% CI: 0.830-0.964). Following instructions at least 80% of the time increased the likelihood of glycemic goal achievement (OR 17.3; 95% CI: 8.0-37.4).

DISCUSSION

The development and constant modification of clinical practicing guidelines has made DM treatment a focus and priority.[3,4] Additionally, the collaborative approach to health care and creation of VA pharmacist-driven services have demonstrated successful patient outcomes.[6-16] Despite these efforts, further insight is needed to improve the management of DM. Our study identified specific behavioral factors that correlated to veteran patients to attaining their HbA$_{1c}$ goal of < 8% within a VA pharmacist DSM clinic. Additionally, it highlighted factors that contributed to patients not achieving their glycemic goals.

Our univariate analysis showed behaviors such as showing up for appointments and following directions regimens to correlate with glycemic goal attainment. However, following directions was the only behavioral factor that correlated to glycemic goal attainment in our multivariate analysis. Additionally, our findings indicated that factors for HbA$_{1c}$ goal attainment included patients who brought their glucose meter/glucose log book and attended clinic appointments at least 80% of the time, respectively.

These findings can help further refine the process for identifying patients who are most likely to achieve glycemic goals when referred to pharmacist DSM clinics or to any DM treatment program. Assessment of a patient's motivation and ability to attend clinic appointments, bring their glucose meter/glucose log book, and to follow instructions provided at these appointments are reasonable screening questions to ask before referring that patient to a diabetes care program or service. Currently, this is not performed during the consult process to the pharmacist DSM clinic at the respective VA.

Additionally, our findings show that patients who met goal did so, on average, within 6 months of referral to the pharmacist DSM clinic. This finding may have occurred because patients who successfully reach HbA$_{1c}$ goal in

TABLE 3. Summary of Goals

Variables	Goal Not Attained (n = 105)	Goal Attained (n = 102)	P
Frequency of self-monitored glucose testing, No. (%)			
At least once daily	18 (17.7)	13 (12.7)	.375
At least twice daily	87 (82.9)	89 (87.3)	
Follows instructions provided at appointment, No. (%)			
> 80% of the time	11 (10.5)	69 (67.6)	< .001
< 80% of the time	94 (89.5)	33 (32.4)	
Brings glucose meter or glucose log book to appointment, No. (%)			
> 80% of the time	24 (22.9)	51 (50)	< .001
< 80% of the time	81 (77.1)	51 (50)	
Group appointments attended, mean, %	88.4	92.6	.015
Duration in clinic, mean, mo	9.0	6.4	< .001

2 consecutive checks are discharged from the clinic. Patients who do not meet this goal continue with the clinic, thus increasing their duration of enrollment in this service. This finding could help clinical pharmacists estimate how long patients will be followed by the service, thus allowing for a more accurate estimation of workload and clinic capacity. Additionally, this finding provides insight if the patient should remain in clinic or be transferred to another program. Our findings aligned with previous studies showing the link between patient behaviors and glycemic goal attainment.[17-19]

Limitations

This study has a few notable limitations. First, it is limited to 1 VA medical center, so our findings may not be extrapolated easily to other institutions of the Veterans Health Administration. Ideally, future studies centered on identifying factors that lead to successful glycemic goal attainment would be helpful from multiple VA institutions. This would encourage more factors to be identified and trends to be strengthened. Ultimately, this would allow for more global changes to the consult process from primary care to pharmacist DSM clinics nationally vs at a local VA institution. Additionally, this study was limited to a specific retrospective time frame, therefore limiting its ability to identify trends. This study also relied on some subjective factors, such as the patient's self-report of properly following the clinic instructions. Another limitation was that our

investigation was not designed to characterize the specific pharmacist's interventions that improved glycemic control. Future studies would benefit from the inclusion of specific interventions and their effect on glycemic goal attainment.

CONCLUSION

This retrospective study offers insight to specific patient behavioral factors that correlate with glycemic goal attainment in a VA pharmacist DSM clinic. Behavioral factors linked to HbA$_{1c}$ goal attainment of < 8% included appointment keeping, bringing glucose meter/glucose log book at least 80% of the time to these appointments, and following clinic instructions. This investigation also found that patients who attain glycemic goals generally do so within 6 months of enrollment. Furthermore, this study provided insight that following the clinic instructions a majority of the time strongly contributes to glycemic goal attainment. We believe that an assessment of patients' behaviors prior to referrals to diabetes management programs will yield useful information about possible barriers to glycemic goal attainment.

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, Frontline Medical Communications Inc., *the US Government, or any of its agencies. This article may discuss unlabeled or investigational use of certain drugs. Please review the complete prescribing information for specific drugs or drug combinations—including indications, contraindications, warnings, and adverse effects—before administering pharmacologic therapy to patients.*

REFERENCES

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Published 2017. Accessed September 25, 2018.
2. Gaspar JL, Dahlke ME, Kasper B. Efficacy of patient aligned care team pharmacist service in reaching diabetes and hyperlipidemia treatment goals. *Fed Pract.* 2015;32(11):42-47.
3. American Diabetes Association. Standards of medical care in diabetes—2017. *Diabetes Care.* 2017;40(suppl 1):S6-S135.
4. US Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. https://www.healthquality.va.gov/guidelines/CD/diabetes/VADoDDMCPGFinal508.pdf. Published April 2017. Accessed September 7, 2018.
5. Centers for Disease Control and Prevention. Deaths: leading causes for 2014. *Natl Vital Stat Rep.* 2016;65(5):1-96.
6. Nigro SC, Garwood CL, Berlie H, et al. Clinical pharmacists as key members of the patient-centered medical home: an opinion statement of the Ambulatory Care Practice and Research Network of the American College of Clinical Pharmacy. *Pharmacotherapy.* 2014;34(1):96-108.
7. Smith M, Bates DW, Bodenheimer T, et al. Why pharmacists belong in the medical home. *Health Aff (Millwood).* 2010;29(5):906-913.
8. Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US Pharmacists' effect as team members on patient care. *Med Care.* 2010;48(10):923-933.
9. Wubben DP, Vivian EM. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: a systematic review. *Pharmacotherapy.* 2008;28(4):421-436.
10. Touchette DR, Doloresco F, Suda KJ, et al. Economic evaluations of clinical pharmacy services: 2006-2010. *Pharmacotherapy.* 2014;34(8):771-793.
11. Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report of the U.S. Surgeon General. American College of Clinical Pharmacy. https://www.accp.com/docs/positions/misc/Improving_Patient_and_Health_System_Outcomes.pdf. Published December 2011. Accessed September 10, 2018.
12. Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. *J Am Pharm Assoc (2003).* 2008;48(2):203-211.
13. Ourth H, Groppi J, Morreale AP, Quicci-Roberts K. Clinical pharmacist prescribing activities in the Veterans Health Administration. *Am J Health Syst Pharm.* 2016;73(18):1406-1415.
14. Taveira TH, Friedmann PD, Cohen LB, et al. Pharmacist-led group medical appointment model in type 2 diabetes. *Diabetes Educ.* 2010;36(1):109-117.
15. Edwards KL, Hadley RL, Baby N, Yeary JC, Chastain LM, Brown CD. Utilizing clinical pharmacy specialists to address access to care barriers in the veteran population for the management of diabetes. *J Pharm Pract.* 2017;30(4):412-418.
16. Cripps RJ, Gourley ES, Johnson W, et al. An evaluation of diabetes-related measures of control after 6 months of clinical pharmacy specialist intervention. *J Pharm Prac.* 2011;24(3):332-338.
17. Jones H, Edwards L, Vallis TM, et al; Diabetes Stages of Change (DiSC) Study. Changes in diabetes self-care behaviors make a difference in glycemic control. *Diabetes Care.* 2003;26(3):732-737.
18. Schetman JM, Schorling JB, Voss JD. Appointment adherence and disparities in outcomes among patients with diabetes. *J Gen Intern Med.* 2008;23(10):1685-1687.
19. Rhee, MK, Slocum W, Zeimer DC, et al. Patient adherence improves glycemic control. *Diabetes Educ.* 2005;31(2):240-250.