Sustainability of Clinical Benefits Gained During a Multidisciplinary Diabetes Shared Medical Appointment After Patients Return to Usual Care

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IN BRIEF This study examined whether clinical benefits gained while participating in interdisciplinary diabetes shared medical appointments (SMAs) of finite duration (three to four monthly visits) are sustained after patients return to usual care. There are currently no publications confirming sustained clinical benefits beyond 9 months after SMA discharge without continued booster sessions to maintain benefits. At the end of the study, it was confirmed that both diabetes and cardiovascular benefits gained during multidisciplinary diabetes SMAs were sustained after patients were discharged to usual care without booster sessions for up to 3 years. The only exceptions were a statistically significant decrease in diastolic blood pressure at each yearly time point and a decrease in the percentage of patients meeting an A1C goal of <9% at year 2.

The Centers for Disease Control and Prevention reports that diabetes is one of the most common diseases in the United States, affecting 30.3 million Americans (9.4% of the total U.S. population) (1). In 2015 alone, 1.5 million American adults aged 18 years or older were diagnosed with diabetes. The estimated total cost of medical expenditures in 2012 was $245 billion dollars, which is an average of 2.3 times the costs of individuals without diabetes. When managing patients with diabetes, the American Diabetes Association (ADA) recommends the use of the Chronic Care Model, a proactive system of care delivery involving a patient-centered, team-based, multidisciplinary approach (2). This approach consists of six core elements for providing optimal care to patients with chronic disease and has been shown to be an effective framework for coordinated diabetes care delivery (3).

Coordinated delivery systems not only increase patient self-care through active participation in group learning that is not possible with individual appointments, but also ensure in-depth discussion of health topics relevant to diabetes that would take a great deal of time if practitioners repeated the topics to each patient individually. In response to this paradigm shift, the shared medical appointment (SMA) model was inspired by both encouragement from ADA to follow a patient-centered, team-based, multidisciplinary approach and the recognition of limitations in access to care. The differing SMA models in the literature vary in the makeup of clinicians participating, the duration and frequency of SMA interventions, and the outcomes measured.

In 1998, one of the earliest SMAs was documented by Trento et al. (4); quarterly SMA sessions were led with one to two physicians and a psycho-educator. Although diabetes control did not improve when measured during the initial study, the extended follow-up study, which included repetition of the quarterly

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sessions, found at year 2 a stabilization in diabetes control in the group subjects versus a worsening in diabetes control in the control group (5). This stabilization compared to an increase in A1C in the control group is clinically relevant because of a similar interruption in the steady decline in A1C control noted in the U.K. Prospective Diabetes Study and in a later SMA study by Trento et al. (6). The final publication by Trento et al. (6) examined the SMA intervention with quarterly sessions over a 4-year period. Physician involvement included at least 30 minutes before the SMA to review case notes and laboratory values, 60 minutes during the SMA, and up to 30 minutes after the SMA to provide individual consultations as clinically indicated. Diabetes control remained stable in the group patients but worsened in the control group, although a decrease in hypoglycemia was found in the control group (P <0.001) (6). Some later SMA studies also noted no change in A1C; however, these studies may have lacked a multidisciplinary team, had larger groups (14–20 patients per session) (7,8), or did not include medication changes (9).

An SMA design by Naik et al. (10) consisted of four group sessions occurring every 3 weeks over a 3-month period. These physician-led interventions demonstrated improvements in A1C (P = 0.03) and diabetes self-efficacy scores (P = 0.02) versus a comparator group. Nine months after the last intervention, a decline in diabetes self-efficacy scores (P = 0.17) and a reduced difference in A1C between groups (P = 0.05) were identified (6). This result led investigators to suggest booster sessions as a way to sustain clinical benefits. Around the same time, a Veterans Affairs (VA) study also supported the concern for unknown sustainability of diabetes benefits after participation in a 120-minute weekly multidisciplinary SMA 4-week series with a follow-up at 4 months (11). Subsequently, Cohen et al. (12) added five monthly booster sessions to this intervention and confirmed sustained diabetes benefits (P = 0.028) over a 6-month period. Interestingly, this was one of the few SMA study series noting a significant improvement in blood pressure control. This series was led by a nonphysician clinician, demonstrating that midlevel providers can successfully lead patients to improved metabolic markers in an efficacious SMA setting.

Aside from the study by Naik et al., only one other diabetes SMA study identified in the literature studied A1C changes beyond the last SMA intervention. In 1999, Sadur et al. (13) confirmed sustained benefits 6 months after the last SMA; however, there were intensive resources used during the intervention. During a 10-month period, the intervention consisted of a 120-minute SMA with a high-level multidisciplinary team that included a dietitian, behaviorist, and pharmacist and was led by a diabetes nurse educator, who was supported by two physicians. In addition to using the team during the SMA, more resources from the team were devoted to individual appointments between SMA sessions. Although the number of patients seen was higher than in other SMAs (10–18 per session), this high volume of clinician involvement may not be possible or sustainable in other clinic settings (13).

In 2009, the Phoenix VA Health Care System (PVAHCS), with clinical quality improvement in mind, developed a patient-centered, team-based, multidisciplinary approach to diabetes care. This high-intensity diabetes management (HIDM) clinic used a multidisciplinary approach and consisted of five 15-minute serial appointments with a nurse diabetes educator, clinical dietitian, clinical pharmacist, endocrinology nurse practitioner, and psychologist. Patients enrolled were 18–75 years of age, with a diagnosis of type 2 diabetes, and an A1C >9% (75 mmol/mol) who were taking insulin and seen by the endocrinology clinic or a diabetes nurse educator at least once. A retrospective chart review of the HIDM clinic, which excluded patients who were followed by a non-VA endocrinology clinic, were enrolled in an alternative diabetes research study, or had inadequate records was performed; it confirmed statistically significant reductions in outcome measures (A1C, diastolic blood pressure, percentage of patients meeting blood pressure goals, and number of patients on aspirin therapy) after four visits (14). Although the HIDM clinic was beneficial in achieving clinical outcomes, the resources used (clinician involvement and time) were significant enough for the team to examine other models of care.

In 2012, the PVAHCS explored other models that aimed to fulfill the ADA recommendations for a patient-centered, team-based, multidisciplinary approach to diabetes care, while minimizing clinician resources and associated costs. The diabetes SMA consisted of a group facilitator and one to two providers (nurse practitioner and/or clinical pharmacist). A team of diabetes specialists, including a clinical nutritionist, nurse diabetes educator, and psychologist, would alternate facilitating each 2-hour session. Each visit included some information sharing, group discussion, and education. Education topics covered during visits included the following: macronutrient identification, portion sizes, label reading, healthy snacking, hypoglycemia, sick days, foot care, exercise, complications, medication adherence, smoking cessation, behavior changes, barriers to change, and goal-setting. During these education sessions, a strong emphasis was placed on using motivational interviewing skills, and all facilitators received motivational interviewing training. Blood pressure and weight were taken at each clinic visit, and laboratory data (fasting lipid panel, comprehensive metabolic panel, and diabetic urinalysis) were taken before visits one and three. Based on the results of individual

blood pressure and laboratory data, patients were pulled from the group setting during sessions and seen in separate rooms for individual consultations with the nurse practitioner and the clinical pharmacist for diabetes and cardiovascular risk reduction interventions, respectively, if indicated. Similar to the HIDM clinic, the same inclusion/exclusion criteria and clinical outcomes assessment was used for patients enrolled in the diabetes SMA.

In the transition from the HIDM clinic to SMAs, the number of clinicians to operate the clinic was reduced from five to three, since the clinical nutritionist, nurse diabetes educator, and clinical psychologist rotated leading the sessions. Additionally, in a 3.5-hour clinic time, the HIDM team managed 10 patients, whereas the diabetes SMA treated up to 12 patients in a 2-hour period. In summary, resources and time were minimized while access was maximized, as evidenced by a 67% reduction in a full-time employee equivalent, 75% reduction in time administering the clinic, and increased access to the clinic by 17%.

On completion of at least three of four monthly SMA sessions with 8–12 patients per session, enrolled patients had a significant reduction in metabolic markers such as A1C, and an increased percentage reached blood pressure and lipid Healthcare Effectiveness Data and Information Set (HEDIS) measures. After participation in up to four SMA sessions, patients returned to usual care (primary care clinics) within the PVAHCS. Initial results confirming equivalent clinical outcomes between HIDM to SMA models were presented at the American College of Clinical Pharmacy 2014 annual meeting (15). The current study investigates whether the clinical benefits realized during this short intervention of up to four monthly SMA sessions, led by a multidisciplinary group of midlevel providers, would have a sustained clinical benefit without additional booster sessions used in prior SMA study models. If confirmed, this result would support the investment of time and resources in creating and sustaining diabetes SMA programs within clinical practices.

Research Design and Methods

This study is a retrospective chart review of patients previously enrolled in the diabetes SMA at the PVAHCS. The protocol was approved by the PVAHCS institutional review board. Participants were contacted to obtain verbal consent for study continuation beyond the initial prospective diabetes SMA study, which measured changes from start to end of diabetes SMA sessions. Participants were excluded if verbal consent was not obtained or they did not have at least one post-discharge A1C measurement. Objectives were evaluated from the time of diabetes SMA discharge and during subsequent yearly increments through September 2015. Data collected during these yearly increments included any values for that time point plus or minus 6 months. The primary objectives evaluated included A1C, systolic blood pressure (SBP), and diastolic blood pressure (DBP). Secondary objectives evaluated the percentage of patients meeting a goal A1C of <9% (75 mmol/mol), the percentage of patients meeting a goal A1C of <7% (53 mmol/mol), the percentage of patients meeting the ADA blood pressure goal of <140/90 mmHg, mean LDL levels (mg/dL), the percentage of patients meeting the HEDIS measure of LDL cholesterol of <100 mg/dL (2.6 mmol/L), the percentage meeting the 2013 American College of Cardiology/American Heart Association goals of moderate- to high-intensity statin therapy, and mean insulin dosages. Lastly, the number of diabetes-related emergency room (ER) visits or hospitalizations since discharge was also gathered. Continuous variables were analyzed using a paired Student *t* test, and categorical variables were analyzed using the McNemar test. Statistics were determined to be significant if α was calculated as <0.05.

TABLE 1. Demographic Data*

Included (*n* =71)	
Male sex [*n* (%)]	69 (97.2)
Mean age (range)	60.8 (39–73)
Ethnicity [*n* (%)]	
White	44 (62.0)
Black	12 (16.9)
Hispanic	11 (15.5)
Declined to answer	4 (5.6)
Asian	0 (0.0)
Excluded (*n* = 24)	
Reason supporting exclusion [*n* (%)]	
Unable to reach	12 (50.0)
Deceased	6 (25.0)
Declined participation	5 (20.8)
No follow-up A1C	1 (4.2)

*n = 95.

Results

A total of 95 subjects met the inclusion criteria; however, investigators obtained verbal consent from 71 subjects (Table 1). The most common reason for exclusion was investigators not being able obtain verbal consent from subjects (n = 12). The average time elapsed since SMA discharge was 29.1 months, with a range of 20–37 months.

Based on clinic discharge date, all eligible patients (n = 71) had follow-up data available and collected post-discharge at 2 years, with the exception of LDL (n = 64). Analysis was extended to a 3-year follow-up for eligible patients (n = 24–33). Evaluation of the primary outcomes (Table 2) revealed no significant difference in mean A1C at any time point (P = 0.43, 0.12, and 0.164, respectively). At year 3, there was a significant 6.78 mmHg reduction in SBP (P = 0.03). Additionally, compared to SMA discharge, there was a statistically significant reduction in DBP at years 1, 2, and 3 (P = 0.01, 0.04, and 0.01, respectively).

TABLE 2. Primary and Secondary End Points

	SMA Discharge	Year 1	*P*	Year 2	*P*	Year 3	*P*
A1C							
Patients evaluated (*n*)	71	69		71		31	
Mean A1C (% [mmol/mol] ± SD)	8.50 (69) ± 1.36	8.65 (71) ± 1.61	0.43*	8.87 (73) ± 1.88	0.12*	8.92 (74) ± 2.12	0.64*
Patients meeting A1C goal <9% (% [*n*])	66.2 (47)	58.0 (40)	0.41†	60.6 (43)	0.00†	48.4 (15)	1.00†
Patients meeting A1C goal <7% (% [*n*])	12.7 (9)	15.9 (11)	0.75†	12.7 (9)	1.00†	16.1 (5)	0.38†
Blood pressure							
Patients evaluated (*n*)	71	70		71		33	
Mean SBP ± SD (mmHg)	135.75 ± 17.49	133.16 ± 16.03	0.22*	136.70 ± 18.29	0.64*	128.97 ± 12.63	0.03*
Mean DBP ± SD (mmHg)	79.62 ± 11.90	76.03 ± 10.53	0.01*	76.79 ± 11.84	0.04*	75.42 ± 9.23	0.01*
Patients meeting blood pressure goal <140/90 mmHg (% [*n*])	57.7 (41)	70.0 (49)	0.17†	60.6 (43)	0.85†	69.7 (23)	0.27†
Cholesterol							
Patients evaluated (*n*)	71	67		64		24	
Mean LDL in mg/dL (mmol/L) ± SD	79.73 (2.07) ± 24.22	81.96 (2.12) ± 27.86	0.56*	85.30 (2.21) ± 3.75	0.22*	88.58 (2.29) ± 35.89	0.82*
Patients meeting LDL goal <100 mg/dL (% [*n*])	78.9 (56)	74.6 (50)	0.77†	64.1 (46)	0.06†	70.8 (17)	1.00†
Patients on moderate- or high-intensity statin (% [*n*])	73.2 (52)	74.6 (50)	1.00†	76.6 (49)	0.58†	83.3 (20)	0.45†

**Continuous variables were evaluated using the Student t test for paired samples, based on clinic discharge versus yearly follow-up data.*

†P values were derived from the McNemar test, based on clinic discharge versus yearly follow-up data.

Evaluation of secondary outcomes (Table 2) demonstrated no significant differences in percentage of patients meeting an A1C goal <7% (53 mmol/mol) at years 1, 2, and 3 compared to clinic discharge (P = 0.75, 1.00, and 0.38, respectively). A significant difference was detected for the number of patients meeting an A1C goal <9% (75 mmol/mol) at year 2 compared to clinic discharge (P = 0.00). All other markers demonstrated a nonsignificant change from time of clinic discharge to yearly follow-up evaluations. The mean total daily insulin dosage at SMA discharge was 99.2 units. There was a nonsignificant increase to 104.8, 107.2, and 129.2 units at years 1, 2, and 3, respectively. Lastly, 13 participants had at least one diabetes-related ER visit or hospitalization, with a total number of 21 ER visits or hospitalizations. The most common reason for hospitalization was hyperglycemia or hypoglycemia.

Discussion

The results of this study confirm the majority of clinical benefits of the diabetes SMA at the PVAHCS were sustained after patients returned to usual care for up to 3 years plus or minus 6 months after SMA discharge. Although there was a slight upward trend in A1C and insulin dose during the follow-up period, neither increase was significant. Additionally, secondary outcomes such as change in percentage of patients meeting ADA A1C goal <7% (53 mmol/mol) remained nonsignificant, while a slight decrease in percentage of patients meeting HEDIS A1C goal <9% (75 mmol/mol) at year 2 indicates that, over time, the potential for fluctuation/worsening in diabetes control does exist. Cardiovascular outcomes also showed sustained improvements, with an interesting statistically significant slight decrease in SBP at year 3 and DBP at years 1, 2, and 3 for unknown reasons.

As supported by prior studies, possible combined factors contributing to this SMA clinic's positive outcomes include multidisciplinary clinician involvement (2,11,13,16–18), ability to adjust medications (4–6,10–13,16–18), limited number (range 4–10) of patient participants per SMA group (4–6,10–13,16–18), and minimum number of sessions for clinical benefit (16). The minimum

number of SMA sessions for clinical benefits was noted to be four in another SMA study (16) by a similar multidisciplinary team held within a VA clinic setting. In that study, individuals with four of more SMA sessions noted an average decrease in A1C of 0.4% compared to those with fewer sessions. However, the present study demonstrated that clinical benefits can also be sustained with a minimum of just three visits. It is also promising that the sustained clinical benefits were noted after a relatively short intervention time of 120 days. Prior studies without noted A1C improvements despite longer durations of intervention cited the possible need to follow patients longer to note clinical benefits (7,8).

The study by Watts et al. (16), an extension of the original publication of SMA benefits by Kirsh et al. (17), demonstrated the long-term sustainability of SMA clinics themselves (>4 years) within a VA Health Care System; however, their sustainability outside of a VA Health Care System is of concern. Clancy et al. (7) cited cost as a limitation of SMA implementation, which was associated with a greater cost of care compared to standard care. The sustainability of clinical benefits seen after discharge back to usual care without the need for booster sessions suggested or used in other studies supports the short-term investment of potentially increased resources to implement and integrate multidisciplinary diabetes SMAs into the care of patients with type 2 diabetes (10,12). Use of midlevel practitioners may also reduce total costs compared to physician involvement, which may also be more difficult to integrate in the future, with the increasing scarcity of access to primary care providers.

Unique aspects of the diabetes SMA at the PVAHCS included use of midlevel practitioners; limitation of a maximum of four sessions within a 4- to 6-month duration compared to prior SMAs, which often used either a greater number/frequency of sessions or quarterly participation with an extended duration of up to several years; decreased time of 2 hours, with individual consultation occurring simultaneously to improve time efficiency for involved clinicians as opposed to additional time before or after the SMA; and rotating clinicians for group discussions to minimize clinician involvement for each session. It should be noted that because all facilitators received training on motivational interviewing and goal-setting, a strong emphasis was placed on using these techniques during the group sessions. Additionally, the SMA focused on patients with higher A1C levels compared to other SMA studies. Instead of patients being referred from primary care clinics, they were recruited through the nurse diabetes educator or endocrinology clinic provider, indicating that the patients may have been more complex, having been already referred to diabetes specialists for care.

Limitations of this study include its retrospective design, small population size, homogenous population, and lack of comparator group. As noted by Kirsh et al. (17), a VA population may have at baseline a higher degree of camaraderie, which may increase the openness and supportive interactions between patients, compared with a non-VA patient population. As a retrospective chart review, the quality of study data is also reliant on the completeness of chart documentation. The authors of this study took steps to improve internal validity by primarily assessing laboratory values or vital signs; however, secondary measures such as total daily insulin dose and diabetes-related ER visits or hospitalizations were based on the quality of clinical documentation. Study results may not be generalizable to all patients with type 2 diabetes, since this study population primarily consisted of older, white males with poorly controlled diabetes who were taking insulin. As a retrospective chart review, there is also possible selection bias. It is possible that subjects noting better diabetes and cardiovascular risk control were more likely to provide informed consent to be included in the study. It is also possible that those subjects who met inclusion criteria but had worse glycemic and cardiovascular control were more likely to have died and thus were not included in the study. While there was a lack of a comparator group, prior SMA studies with a similar clinic setup (clinician participation) and patient population (veterans, A1C >9% [75 mmol/mol]) have confirmed that benefits noted were beyond regression to the mean, and these benefits were subsequently associated with the SMA intervention (16,17). Additionally, despite being a closed health care system, there is still variability in what constitutes "usual care." Usual care may entail more than follow-up with a primary care provider. Additional providers or resources may include clinical pharmacists, endocrinology clinics, or participation in other group classes. Lastly, most medication changes were not tracked; however, the nonsignificant increase in insulin dose associated with maintaining similar diabetes control further supports considering SMAs for improving diabetes care.

Conclusion

To our knowledge, this study demonstrated the longest sustainability of clinical benefits after return to usual care from a diabetes SMA. Future areas of research include a longer fully retrospective evaluation of the diabetes SMA clinic, including all patients who participated in the diabetes SMA. Investigating various factors of the diabetes SMA clinic (e.g., visit frequency, clinic duration) may also provide a clearer picture of the optimal clinic structure. This may also aid in development of booster sessions, given the trend of slow increase in A1C. Lastly, further investigation of diabetes-related ER visits and/or hospitalizations may help identi-

fy which patients may benefit from continued follow-up after SMA discharge. Additional follow-up may also be provided by midlevel providers to continue access to safe and timely diabetes care.

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Duality of Interest

No potential conflicts of interest relevant to this article were reported.

Author Contributions

A.K.L. researched data, contributed to discussion, and wrote the manuscript. K.B. researched data, contributed to discussion, and reviewed and edited the manuscript. J.K. researched data, contributed to discussion, and reviewed and edited the manuscript. A.K.L. is the guarantor of this work and, as such, had full access to all the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis.

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