Impact of Ambulatory Care Pharmacist-Led Diabetes Mellitus Management on Hemoglobin A1c Values Among Patients With Diabetes in a Primary Care Clinic Over Two Years

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ABSTRACT

Background: *Previous evaluation in the literature of ambulatory care pharmacist management on glycosylated hemoglobin (HgbA1c) has been positive, but often limited to 6 to 12 months of follow up.*

Objective: *The objective of this study is to evaluate the impact of an ambulatory care pharmacist on HgbA1c among patients with diabetes in a primary care clinic over two years.*

Methods: *Retrospective chart review was conducted on patients with type 2 diabetes managed by the ambulatory care pharmacist. Patients with at least one HgbA1c value ≥7% in the two-year pre-intervention period were included. The primary outcome was the change in mean HgbA1c from baseline to two years post-intervention. The secondary outcome was the change in mean of all HgbA1c values over two years pre-intervention compared to two years post-intervention.*

Results: *Data for 116 patients was analyzed two years prior to and two years after ambulatory care pharmacist service initiation. The mean HgbA1c at baseline pre-intervention was 8.8% compared to a mean HgbA1c of 7.8% two years post-intervention. A total of 12.9% of patients (n=15) had a baseline HgbA1c of less than 7% pre-intervention, compared to 42.2% of patients (n=49) two years post-intervention (p<0.001). The overall mean HgbA1c was 8.8% in the two-year pre-intervention period and 8.2% in the two-year post-intervention period (p<0.001). Among patients with an overall mean HgbA1c ≥8% in the pre-intervention period, the mean HgbA1c was 9.8% pre-intervention and 8.7% post-intervention.*

Conclusion: *Ambulatory care pharmacist interventions demonstrated a significant impact on HgbA1c reduction over two years of follow up.*

Keywords: diabetes, ambulatory care, pharmacist, pharmacy, interprofessional

INTRODUCTION

Diabetes mellitus is a pervasive chronic condition with a high degree of illness burden affecting 34.2 million individuals, or 10.5% of the US population.[1] Diabetes is associated with complications including microvascular and macrovascular disease, emergency department visits and hospitalizations, and death.[1] Suboptimal management of diabetes mellitus can lead to poor health outcomes and excessive healthcare costs, with estimated total costs up to $327 billion in 2017.[1–3] Poor glycemic control is linked to medication non-adherence, cost of medications, and treatment complexity.[4] Although there are differences in outcomes across the literature, reduction in glycosylated hemoglobin (HgbA1c) has been associated with microvascular and possibly macrovascular risk reduction.[5] Positive clinical, humanistic, and economic outcomes highlight the value of interprofessional care with a pharmacy team for diabetes management.[6]

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Multiple studies have demonstrated the benefit of pharmacist intervention on glycemic control in primary care settings.[7–9] A systematic review has shown the impact of pharmacists in a variety of ambulatory care practice settings on HgbA1c as compared to usual care.[7] This review found that HgbA1c was improved by approximately 1% across multiple studies when compared to usual care. In the review studies, pharmacist intervention involved team-based decision-making including therapeutic recommendations with or without collaborative practice agreements. A retrospective pre-post study in a military medical home where pharmacists conducted education and medication therapy management revealed a 1.1% HgbA1c reduction over 6 months.[8] A retrospective pre-post analysis of an employer-based ambulatory program where pharmacists made pharmacotherapeutic adjustments revealed a 0.7% HgbA1c reduction over up to 12 months.[9] Nevertheless, most studies were limited to 12 months of follow up. Literature has demonstrated that a 1% decrease in HgbA1c reduces risk of death related to diabetes by 21%, myocardial infarctions by 14%, microvascular complications by 37%, and diabetes-related healthcare costs by 13%.[10,11]

This study was conducted in an adult internal medicine clinic that is the outpatient training site for the internal medicine residency program. An ambulatory care pharmacist joined the

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internal medicine clinic in August 2017, at which time an interprofessional approach to the management of diabetes was implemented. The ambulatory care pharmacist serves as a faculty member in the internal medicine residency program and serves as a co-preceptor for the medical residents. Patients are identified for diabetes management by the pharmacist per provider referral and by pharmacist review of electronic medical record (EMR) reports that identify patients with uncontrolled diabetes. The pharmacy team, which is comprised of the ambulatory care pharmacist and pharmacy trainees (student pharmacists and/or pharmacy residents under pharmacist supervision), participates in interprofessional co-visits, one-on-one pharmacy visits, and telephonic visits. Interprofessional collaborative co-visits typically include a pharmacy team member, medical resident, and faculty attending physician seeing the patient together at the same time. After the patient is seen in a collaborative co-visit, pharmacy team recommendations for optimizing diabetes management are discussed with the team and implemented. In each of these visit types, the pharmacist can initiate, modify, or discontinue medications per an approved collaborative practice agreement (CPA). The CPA allows for pharmacist-management of diabetes and other chronic conditions and encounters are billed according to type of visit and time spent. The majority of patients seen with diabetes in the clinic have government-funded insurance. Telephonic visits are used to assess adherence to the treatment plan, medication access, and to allow for pharmacotherapeutic adjustments necessary to achieve treatment goals. Patients are seen in each of these visit types, with selection of face-to-face or telephonic visit based on factors such as the purpose of the encounter, expected duration of visit, and/or anticipated complexity of the encounter. The frequency of the face-to-face collaborative co-visits or pharmacy specific visits vary between every one to three months, while frequency of telephonic pharmacy calls vary between every one to four weeks depending on individual patient assessment. The duration of phone visits is typically 10 to 30 minutes, while face-to-face visits are typically 30 to 60 minutes. Pharmacotherapeutic changes follow the American Diabetes Association Standards of Medical Care in Diabetes guideline recommendations and are based on the pharmacist's clinical judgment.[12] During each encounter, the pharmacy team counsels the patient about dietary and lifestyle goals and modifications.

The objective of this study is to evaluate the impact of an ambulatory care pharmacist on HgbA1c values among patients with uncontrolled diabetes in a primary care clinic over a two-year period.

METHODS

This is a retrospective chart review evaluating the impact of an ambulatory care pharmacist on HgbA1c values two years prior to and two years after ambulatory care pharmacist service initiation. The pre-intervention period (August 2015 to July 2017) is defined as the period prior to the ambulatory care pharmacist joining the clinic. The post-intervention period is defined as the period during which the patients were receiving ambulatory care pharmacist care (August 2017 to August 2019). Patients served as their own control. The impact on glycemic control was measured by assessing change in HgbA1c from baseline over a two-year period. Automated EMR data query was used for data collection (no manual collection).

The primary outcome was the change in the mean HgbA1c of all patients at baseline pre-intervention compared to the mean HgbA1c of all patients at the end of the two-year intervention period (Figure 1). The secondary outcome was the change in the mean of all HgbA1c values of all patients over two years pre-intervention compared to the mean of all HgbA1c values of all patients over two years post-intervention (Figure 2), including the change in percentage of patients with overall mean HgbA1c less than 7%, 7 to 7.9%, 8 to 8.9%, 9 to 9.9%, or ≥10% pre-intervention compared to post-intervention.

Inclusion criteria consisted of adults at least 18 years of age with type 2 diabetes who had at least one face-to-face or telephonic encounter with the pharmacy team in the post-intervention period beginning in August 2017 and ending in August 2019. Patients were included if they had at least one pre-intervention HgbA1c value ≥7%. For the secondary outcome, patients were included if they had two or more HgbA1c values collected in the pre- and post-intervention period, but only one value was required to be ≥7% in the pre-intervention period. This study was reviewed by the Institutional Review Board and deemed to be exempt.

Statistical Analysis

For the primary outcome, the authors analyzed the change in HgbA1c from baseline to post-intervention using analysis of variance, adjusting for age, sex, race, and type of encounter (face-to-face and telephone encounters). For the secondary outcome, the authors analyzed mean HgbA1c in the two-year periods before and after August 2017 using a generalized linear model that accounts for multiple measurements per patient in each period. A p-value of less than 0.05 was considered significant. Paired t-test, mixed linear model, and logistic regression (SAS 9.4) were utilized for statistical analysis. A post-hoc power calculation was conducted to ensure that the sample size (determined by the number of patients managed by the pharmacist) was sufficient for the primary outcome. The sample size of 116 had 100% power to detect the 1-point HgbA1c decrease.

RESULTS

Patient and Intervention Characteristics

Table 1 shows the patient and intervention characteristics for this study. One hundred and sixteen patients with type 2 diabetes who had at least one encounter with the pharmacy team and at least one pre-intervention HgbA1c value ≥7% were included; 88 of these patients were included in analysis of the secondary outcome as these patients had two or more HgbA1c

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values collected in the pre- and post-intervention period, with one HgbA1c ≥7% in the pre-intervention period. Fifty percent of the population was Caucasian and 48.3% of the population was African American; 50% of the population was female and 50% was male. The mean ± S.D. age was 54 ± 11.2 years. Pre-intervention, the mean number ± S.D. of HgbA1c measurements was 3.1 ± 2 compared to 4.8 ± 2 post-intervention. During the post-intervention period, the mean number ± S.D. of phone encounters was 6.8 ± 5.9, and mean number ± S.D. face-to-face encounters was 5.5 ± 3.8.

Primary Outcome Results

A total of 116 patients were included in the evaluation of the primary outcome. The mean HgbA1c at baseline pre-intervention was 8.8%, compared to a mean HgbA1c of 7.8% two years post-intervention, for a statistically significant 1-point decrease in HgbA1c (p<0.001). A total of 12.9% of patients (n=15) had a baseline HgbA1c of less than 7% pre-intervention, compared to 42.2% of patients (n=49) two years post-intervention (p<0.001). Proportion of patients achieving HgbA1c of less than 8% pre-intervention was 44.8% (n=52), compared to 64.7% (n=75) post-intervention (p<0.001) (Table 2). Results of an adjusted analysis of HgbA1c change post-intervention (adjusted for age, sex, race, and intervention type) are presented in Table 3. A statistically significant difference was found based on sex and race, but not based on age group or intervention type. The mean change in HgbA1c post-intervention was -1.3 among females compared to -0.4 among males (p=0.032), and -1.4 among Caucasians compared to -0.4 among African American patients (p=0.019).

Secondary Outcome Results

A total of 88 patients were included in the evaluation of the secondary outcome. The overall mean HgbA1c was 8.8% over two years pre-intervention vs 8.2% over two years post-intervention (p<0.001). Among patients with mean HgbA1c ≥8% during the pre-intervention period, the mean HgbA1c was 9.8% pre-intervention vs 8.7% post-intervention (change -1.1, p<0.001). Among patients with mean HgbA1c <8% during the pre-intervention period, the mean HgbA1c was 7.2% pre-intervention vs 7.4% post-intervention (change +0.2, p=0.128) (Table 4). Table 5 reveals statistically significant changes in overall mean HgbA1c in the pre- vs post-intervention periods after adjusting for age, sex, and race. These findings reveal that mean HgbA1c was 9.3% pre-intervention vs 8.6% post-intervention (change -0.6, p<0.001). The adjusted model demonstrated that for patients with mean pre-intervention HgbA1c ≥ 8.0%, mean HgbA1c was 9.7% pre-intervention vs 8.6% post-intervention for a statistically significant change of -1.1 (p<0.001). A statistically significant change in HgbA1c was not found among patients with pre-intervention HgbA1c <8%. Table 6 reveals the change in the percentage of patients in each HgbA1c category pre- compared to post-intervention (<7%, 7 to 7.9%, 8 to 8.9%, 9 to 9.9%, or ≥10%). Overall, 47.7% of patients changed to an improved HgbA1c category post-intervention.

DISCUSSION

This retrospective chart review demonstrated significantly improved glycemic control among patients with HgbA1c ≥7% in the two years post-implementation of ambulatory care pharmacist diabetes management services. We demonstrated an approximate 1-point reduction in HgbA1c among our patients. These findings are consistent with other studies of pharmacist services demonstrating improved glycemic control.[7] Reduction of HgbA1c by 1% has been associated with reductions in microvascular and macrovascular complications as well as healthcare costs.[10,11] Furthermore, one study revealed that ambulatory pharmacist management of diabetes resulted in an expected savings of $1,118 per patient among patients with HgbA1c reduction of ≥1%.[13] One important difference of our study is the longer duration of follow up of two years, compared to other literature which typically evaluated HgbA1c at the 3, 6, or 12 month period.[7,14] Therefore, this study demonstrates the longer-term impact of pharmacist-managed care on HgbA1c.

In our primary outcome adjusted analysis, we found a statistically significant improvement in baseline pre-intervention vs post-intervention HgbA1c. It was found that the number of each intervention type (face-to-face vs telephonic) did not have a statistically significant impact on change in HgbA1c for the primary outcome, although a numerically larger change in HgbA1c was found for patients with 4 to 9 encounters during the intervention period. These findings warrant further research into the number of encounters that may lead to HgbA1c improvement. Additional hypothesis-generating results include the HgbA1c difference found based on female sex and Caucasian race.

Hypothesis-generating findings from the subgroup analysis of the secondary outcome show that among patients with uncontrolled pre-intervention mean HgbA1c ≥8%, there was a statistically significant decrease in mean HgbA1c. Whereas, patients whose pre-intervention mean HgbA1c was more controlled (<8%), a slight non-statistically significant increase in mean HgbA1c from pre- to post-intervention was observed. This may be due to more pharmacist encounters devoted to patients with worse glycemic control compared to patients with better HgbA1c control. However, the finding for patients with mean HgbA1c <8% was not statistically significant and thus inferences of this type are flawed.

In this study, we included patients with HgbA1c ≥ 7% at any time point in the two-year pre-intervention period regardless of their goal, while most prior literature included patients with baseline HgbA1c ≥ 8%. We did this to better capture patients who had uncontrolled diabetes at any point in the pre-intervention period and therefore may have had higher risk of poor diabetes control in the future. Our adjusted analyses demonstrated more benefit in HgbA1c reduction among patients with more uncontrolled diabetes (i.e. HgbA1c ≥8%).

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Lastly, the majority of patients in this study moved to an improved HgbA1c category post-intervention, demonstrating the value of pharmacist management.

This study has many strengths. A post-hoc power calculation was conducted and found that the sample size of 116 was sufficient for the primary outcome. The sample size is comparable to other studies evaluating impact of pharmacist intervention on HgbA1c. Our findings also demonstrate the value of interprofessional co-visits whereby the pharmacy team member conducts visits jointly with the medical team member. Many of the face-to-face visits in our clinic are performed in this manner. While other literature has demonstrated the value of physician-pharmacist co-visits on HgbA1c whereby pharmacist visits occur on the same day as the physician visit, our visits are unique in that the visits were conducted with all team members present in the room simultaneously with the patient.[15] This promotes interprofessional collaborative practice and education for pharmacy trainees and demonstrates the value of such a model. Lastly, our study demonstrates the value of pharmacist intervention not only by comparing mean HgbA1c at two distinct time points as revealed by the primary outcome, but also by comparing mean HgbA1c over the span of two time periods as revealed by the secondary outcome (Figures 1 and 2).

Despite the improvements demonstrated to HgbA1c, some limitations to our study do exist. This study was retrospective in nature and therefore casual inferences are limited. The sample size was determined based on the number of patients who were managed by the pharmacist and patients served as their own control. Furthermore, there is a risk for selection bias given that pharmacist management of patients is based on provider referrals and EMR reports revealing patients with uncontrolled diabetes which are sometimes incomplete; therefore, there may be a small number of clinic patients with uncontrolled diabetes who are not managed by the pharmacist and thus not included in this analysis. It is also important to note that this study included patients who had at least one HgbA1c value ≥7% anytime during the two-year period pre-intervention; as such, ~13% of patients had a HgbA1c <7% at baseline prior to the intervention period but had an elevated HgbA1c at some point during the pre-intervention period. This was accounted for by also reporting the change in HgbA1c category post-intervention, with almost half of all patients moving to a better HgbA1c category. For the secondary outcome, only 88 of the 116 total patients were evaluated given that evaluation for this outcome required two or more HgbA1c values collected in the pre- and post-intervention period. We are unable to account for interventions made by other members of the interprofessional team, and it is possible that pharmacist presence in the clinic influences prescribing practices across physicians in the office even when the patient was not directly seen by the pharmacist.[16] Lastly, we did not evaluate patient medications, renal function, body mass index, incidence of hypoglycemia, acute care visits, or precise timing of the pharmacist encounter; in the future, these may be components to evaluate for stratification purposes.

CONCLUSION

Ambulatory care pharmacist management in an adult internal medicine clinic demonstrated a significant impact on HgbA1c reduction among patients with diabetes over two years of follow up. A 1-point decrease in HgbA1c from baseline pre-intervention (8.8%) to two years post-intervention (7.8%) was demonstrated. Future studies are needed to compare outcomes among patients who were not managed by the ambulatory care pharmacist.

Conflicts of Interest: We declare no conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents, and royalties.

Treatment of Human Subjects: IRB exemption granted

The opinions expressed in this paper are those of the authors.

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Table 1. Baseline Patient and Intervention Characteristics	
n	116
Age (yrs)	
Mean ± SD	54.4 ± 11.2
Gender (n, %)	
Female	58 (50)
Patient-Identified Race (n, %)	
African American	56 (48.3)
Caucasian	58 (50)
Asian	1 (0.9)
Other	1 (0.9)
Number of HgbA1c measurements	
Pre-Intervention	
Mean ± SD	3.1 ± 2.0
Post-Intervention	
Mean ± SD	4.8 ± 2.0
Encounter type	
Phone encounters	
Mean ± SD	6.8 ± 5.9
Face-to-face encounters	
Mean ± SD	5.5 ± 3.8

Table 1. Baseline characteristics including demographics, number of HgbA1c measurements, and type of encounter

Table 2. Patients with HgbA1c <7% and <8% at Baseline Compared to Post-Intervention		
Patients with HgbA1c <7%		*P* Value
Baseline (n, %)	15 (12.9)	<0.001
Post-Intervention (n, %)	49 (42.2)	
Patients with HgbA1c <8%		
Baseline (n, %)	52 (44.8)	<0.001
Post-Intervention (n, %)	75 (64.7)	

Table 2. Comparison of patients with HgbA1c <7% and <8% at baseline compared to post-intervention

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Table 3. Adjusted Analysis of Change in Mean HgbA1c at Baseline Compared to Post-Intervention by Subgroup			
	n	**Mean Change in HgbA1c**	*p-value*
Age Group			
Under 50	38	-1.3	*0.311*
50 - 64	58	-0.8	
65 or older	20	-0.5	
Sex			
Female	58	-1.3	*0.032*
Male	58	-0.4	
Race			
African American	56	-0.4	*0.019*
Caucasian or Other	60	-1.4	
Intervention Type			
Face-to-face encounters			
0 - 3	46	-0.5	*0.222*
4 - 9	49	-1.3	
10 or more	21	-0.8	
Phone encounters			
0 - 3	39	-0.9	*0.766*
4 - 9	49	-1.1	
10 or more	28	-0.7	

Table 3. Change in mean HgbA1c at baseline compared to post-intervention adjusted for age, sex, race, and intervention type (face-to-face or phone encounters)

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Table 4. Mean of Overall HgbA1c Values in the Pre- and Post-Intervention Periods				
	n	**HgbA1c (%) Pre-Intervention**	**HgbA1c (%) Post-Intervention**	*p-value*
Overall	88	8.8	8.2	*<0.001*
Patients with mean pre-intervention HgbA1c < 8.0%	52	7.2	7.4	*0.128*
Patients with mean pre-intervention HgbA1c ≥ 8.0%	36	9.8	8.7	*<0.001*
Age Group				
Under 50	24	9.6	8.9	*0.005*
50 - 64	45	8.7	8.0	*<0.001*
65 or older	19	8.4	8.1	*0.162*
Sex				
Female	42	8.9	8.2	*<0.001*
Male	46	8.8	8.3	*0.001*
Race				
African American	43	9.0	8.3	*<0.001*
Caucasian or Other	45	8.6	8.1	*<0.001*

Table 4. Comparison of mean of overall HgbA1c values in the pre- and post-intervention periods based on mean pre-intervention HgbA1c, age, sex, and race

Table 5. Adjusted Analysis Change in Mean of Overall HgbA1c Values in the Pre-Intervention Compared to Post-Intervention Period (n=88)			
	Adjusted HgbA1c (%), mean	Change in HgbA1c	*p-value*
Pre-Intervention	9.3	-0.6	*<0.001*
Post-Intervention	8.6		
Patients with pre-intervention overall mean HgbA1c < 8.0% (n=52)			
Pre-Intervention	7.2	0.20	*0.253*
Post-Intervention	7.4		
Patients with pre-intervention overall mean HgbA1c ≥ 8.0% (n=36)			
Pre-Intervention	9.7	-1.1	*<0.001*
Post-Intervention	8.6		

Table 5. Change in mean of overall HgbA1c values in the pre-intervention compared to post-intervention period adjusted for age, sex, and race

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Table 6. Change in Overall Mean HgbA1c Category in Pre- Compared to Post-Intervention Periods (n=88)		
Mean HgbA1c %	**Pre-intervention HgbA1c (n, %)**	**Post-Intervention HgbA1c (n, %)**
Less than 7.0	11 (12.5)	15 (17)
7.0 - 7.9	21 (23.9)	34 (38.6)
8.0 - 8.9	17 (19.3)	16 (18.2)
9.0 - 9.9	19 (21.6)	13 (14.8)
10.0 or higher	20 (22.7)	10 (11.4)
Description of Patient HgbA1c Category Change in Post-Intervention Period		
Improved HgbA1c Category (n, %)	42 (47.7)	
Same HgbA1c Category (n, %)	29 (33)	
Worse HgbA1c Category (n, %)	17 (19.3)	

Table 6. Change in overall mean HgbA1c category in pre- compared to post-intervention periods with description of HgbA1c category change

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Figure 1. Primary Outcome Illustration

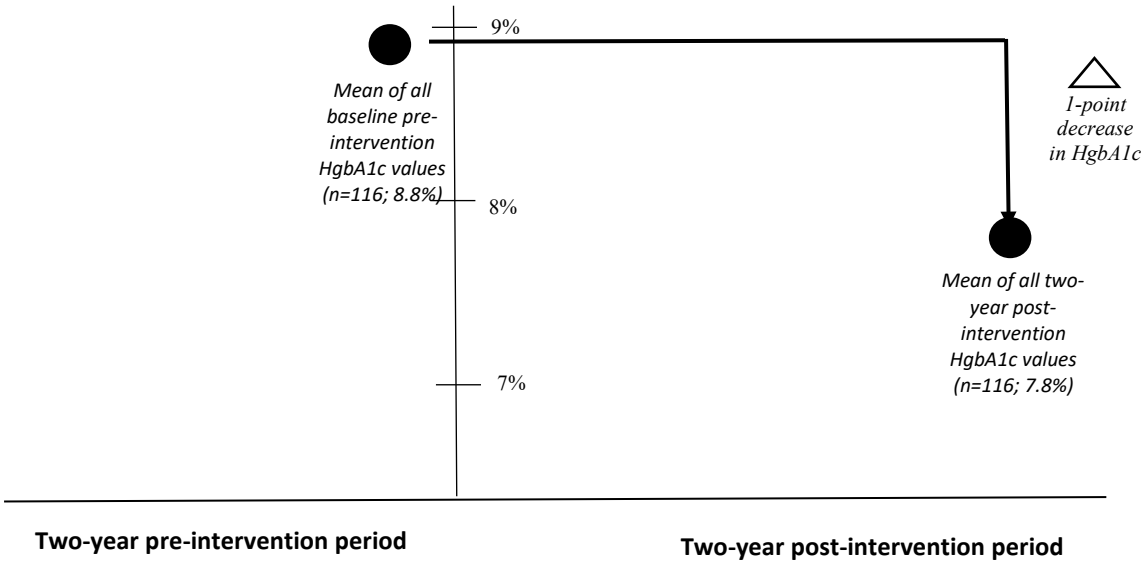
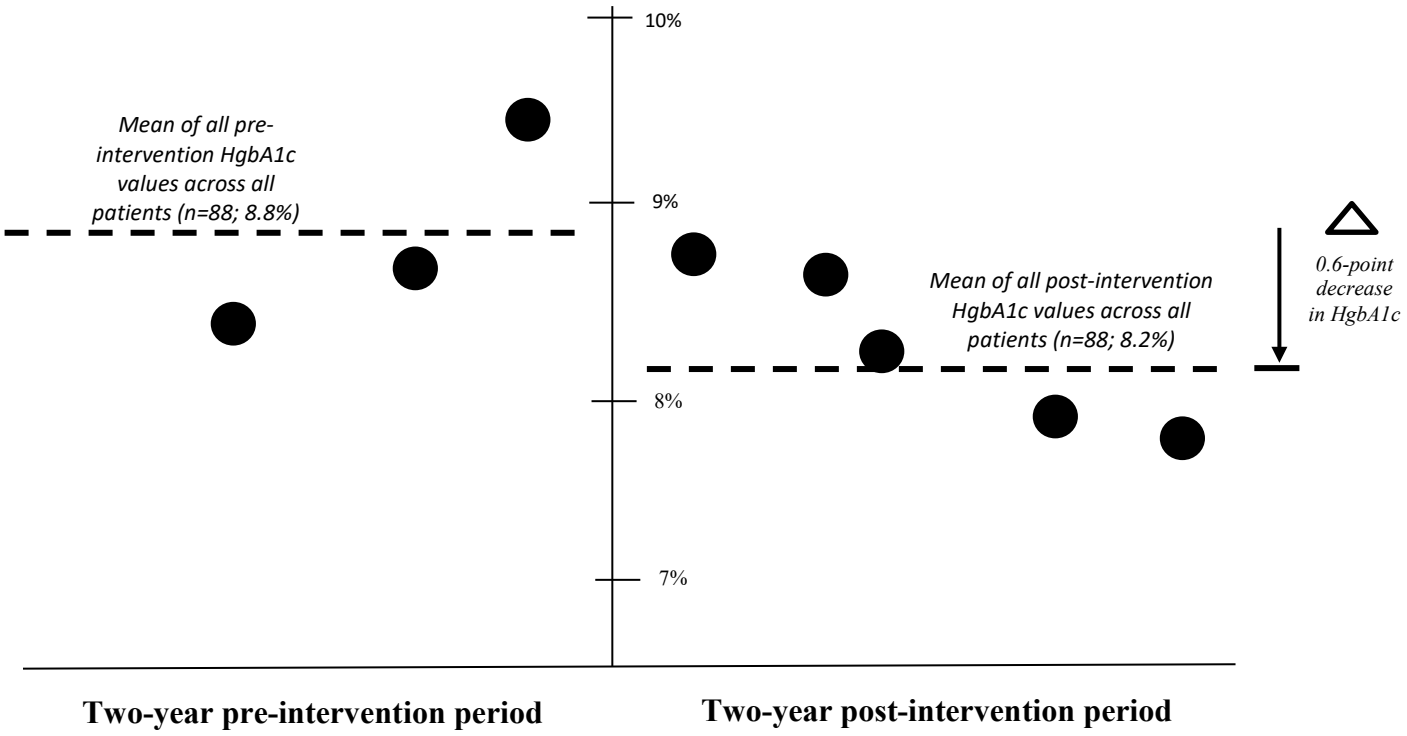


Figure 1. Illustration of change in the mean HgbA1c of all patients at baseline pre-intervention compared to the mean HgbA1c of all patients at the end of the two-year intervention period

Figure 2. Secondary Outcome Illustration*



* HgbA1c values as portrayed in the figure are used for illustrative purposes and are not all to scale with the results of this study.

Figure 2. Illustration of change in the mean of all HgbA1c values of all patients over two years pre-intervention compared to the mean of all HgbA1c values of all patients over two years post-intervention