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Outcomes of a pharmacist-managed clinic for underserved persons with unmanaged type 2 diabetes mellitus

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Abstract

Background: A multidisciplinary approach is recommended for the management of type 2 diabetes mellitus (DM).

Aim: To evaluate the impact of a pharmacist intervention on haemoglobin A1c (HbA_{1c}), systolic blood pressure (SBP), diastolic blood pressure (DBP), and diabetes-related hospitalisations in an underserved cohort with unmanaged type 2 DM.

Methods: This analysis was a retrospective cohort study. Criteria for inclusion were persons with unmanaged type 2 DM defined as HbA_{1c} values ≥8% at time of enrolment, ≥18 years old, and enrolment in a pharmacist-managed clinic for ≥12 months. Pre- and post-intervention differences in HbA_{1c}, SBP and DBP values were assessed using repeated measures analysis of variance (ANOVA). The risk of diabetes-related hospitalisations was estimated during the 12 months prior and during the 12 months post-intervention, and the relative risk (RR) was calculated.

Results: Mean HbA_{1c} values at 3, 6 and 12 months post-intervention were lower than baseline values ($p < 0.05$). There was no significant difference in mean HbA_{1c} values at 6 or 12 months compared to 3 months post intervention. Mean SBP values at 3, 6 and 12 months were lower than baseline ($p < 0.05$). Likewise, mean DBP values at 6 and 12 months were lower than baseline ($p < 0.05$). The estimated RR of diabetes-related hospitalisations was 0.40 (95% CI: 0.20–0.83; $p = 0.013$).

Conclusion: Enrolment in a pharmacist-managed diabetes program was associated with a significant reduction in HbA1c, SBP and DBP and reduction in risk of diabetes-related hospitalisations in an underserved cohort of patients with diabetes over a 12-month period.

Keywords

ambulatory care; pharmacist; diabetes mellitus; indigent care

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Conflict of interests statement

The authors declare that they have no conflicts of interest.

INTRODUCTION

Type 2 diabetes mellitus (DM) is a chronic condition with an estimated global prevalence of 9% among adults aged 18 years or older.[1] In 2014, an estimated 29.1 million people (9.3%) of the US population had type 2 DM.[2] Lack of glycaemic management is associated with increased risk of micro- and macrovascular complications, including cardiovascular disease, renal disease, stroke, blindness and lower-limb amputation.[3–5] In 2012, diabetes was directly responsible for 1.5 million deaths worldwide. The estimated cost of diabetes in the US was USD$245 billion dollars for the year 2012 for both direct and indirect healthcare costs. To address the growing burden of diabetes, management has shifted to a multidisciplinary approach involving non-physician healthcare professionals such as pharmacists.

Collaborative drug therapy management is defined as 'a formal partnership between a pharmacist and physician or group of physicians to allow the pharmacist(s) to manage a person's drug therapy'.[1,6–10] Under a collaborative drug therapy agreement (CDTA), a pharmacist may perform a number of tasks in addition to their professional responsibilities, including implementing or modifying drug therapy, ordering and evaluating laboratory tests related to drug therapy, and administration of immunisations. Using a CDTA for chronic conditions enhances the care of patients, frees up more time for physicians, and allows pharmacists to demonstrate their value as an integral part of the healthcare team.

The process of establishing a pharmacist-managed diabetes program has been well described in multiple reports.[7–12] Persons with DM who enrol in pharmacist-managed clinics show a significant reduction in haemoglobin A1c (HbA_{1c}), diabetes-related hospitalisations and emergency department (ED) visits.[13,14] Conversely, there is a lack of evidence of the impact of pharmacist care on diabetes management, diabetes-related hospitalisations and ED visits among underserved, non-Caucasian, non-English-speaking populations with unmanaged diabetes. The objective of this study was to evaluate the outcomes of a pharmacist intervention under a CDTA for the management of non-Caucasian, non-English-speaking persons with Community Free Service (hospital-provided financial assistance) and government-based insurance with unmanaged type 2 DM.

METHODS

Study Setting and Care Delivery Model

This was a retrospective cohort study of patients with diabetes seen by the pharmacist at the Rhode Island Hospital Center for Primary Care and Specialty Medicine (RIH CPC) from 1 January, 2012 to 31 December, 2013. Patients were initially seen by a healthcare provider (doctor, nurse or nurse practitioner) and then referred to the pharmacist-managed diabetes care program for further help with attaining glycaemic targets. Pharmacists practised under a CDTA that included diabetes and diabetes-related conditions (hypertension and hyperlipidaemia). The CDTA was based on the 2012–2013 practice guidelines recommended by the American Diabetes Association (ADA).[15–17]

Pharmacists who provided diabetes education in the clinic had received disease state management training in diabetes and were certified diabetes outpatient educators (CDOE).[18] The CDOE certification course offers extensive training in diabetes self-management education and related conditions such as hypertension, hyperlipidaemia and obesity. They were also certified in medication therapy management (MTM) by the American PharmacistS Association (APhA); MTM involves a comprehensive review of all medications (prescription, over-the-counter medications and herbal supplements) that a patient is taking with the goal of optimising medication therapy to improve outcomes. Responsibilities of the pharmacists included: diabetes education; initiating and modifying doses, monitoring, and discontinuing medications for diabetes and diabetes-related conditions; ordering and interpreting laboratory tests in accordance with current guidelines; administration of vaccinations; scheduling follow-up visits with the pharmacist; and coordinating referrals to other healthcare providers (including primary care physicians, social workers, ophthalmologists, podiatrists, dentists, dieticians, diabetes/smoking cessation group classes, and same day sick appointments). Interpreters were available in person or via telephone for persons who required language services. All non-English speaking persons had an interpreter present in person or via telephone at their visit with the pharmacist. Physicians were available for consultation if questions arose. All changes made were documented in the electronic medical record for communication to other healthcare providers at the end of each office visit. The process workflow is depicted in Figure 1. Medication information was ascertained for all persons via medication reconciliation review by the pharmacist at each office visit.

Study Population and Measures

The study cohort included persons with diabetes who were seen by the pharmacist for their initial diabetes management at the Rhode Island Hospital Center for Primary Care and Specialty Medicine (RIH CPC) between 1 January, 2012 to 31 December, 2013. The RIH CPC is a clinic that provides coordinated primary care services and a number of specialty services to patients referred by their physician. Referrals to the pharmacist included those who were unable to obtain their HbA_{1c} goal after seeing the physician, have severe unmanaged diabetes (HbA_{1c} 10% or greater), or need additional education regarding their diabetes. Persons referred to the pharmacist-managed diabetes care service had been seen previously by a physician, were diagnosed with type 2 DM, were at least 18 years old, and had a HbA_{1c} at the time of enrolment of ≥8%. Changes to antihyperglycaemic and other diabetes-related medications of persons seen in the clinic were made according to a collaborative practice agreement with specific titration parameters. Examples of medication changes made by the pharmacist included: initiating and modifying doses of antihypertensive medications such as angiotensin converting enzyme inhibitors; initiating and intensifying cholesterol medications such as statins; and initiating insulin and titrating insulin based on self-monitoring of blood glucose values.

The inclusion criteria for persons in this study were unmanaged type 2 DM, defined as HbA_{1c} values ≥8% at baseline, age ≥18 years at time of enrolment and enrolment in the pharmacist-managed clinic for ≥12 months.

The outcomes of this study were changes in mean HbA_{1c}, systolic blood pressure (SBP), and diastolic blood pressure (DBP) from the 12 months prior to enrolment in the pharmacist-managed diabetes clinic to 3, 6 and 12 months post enrolment. We assessed the risk of diabetes-related ED visits and hospitalisations before and after clinic enrolment. Diabetes-related ED visits and hospitalisations were defined as hyperglycaemia, hypoglycaemia, diabetic foot and other soft tissue infections, gastroparesis and diabetic ketoacidosis. Elevated SBP was defined as SBP values >120 mmHg and elevated DBP was defined as DBP values >80 mmHg.

Statistical Analysis

Descriptive statistics were calculated for all variables at baseline to describe the study cohort. Means with standard deviations (SD) were used for continuous variables and percentages for binary and categorical variables. Pre- and post-intervention differences in blood pressure and HbA_{1c} were assessed using repeated measures analysis of variance (ANOVA). Mean reductions in HbA_{1c}, SBP and DBP values, following pharmacist intervention, are reported along with 95% confidence intervals (CI).

The effect of pharmacist-managed ambulatory services on diabetes-related hospitalisations and diabetes-related ED visits was estimated using a Poisson regression with robust error variance to calculate the relative risk of outcomes after receipt of pharmacist services versus before. A multivariate regression model was then estimated to account for potential confounding variables, including age, sex and race. Covariates (age, sex and race) were selected based on *a priori* knowledge. Statistical significance for all analyses was set *a priori* at the alpha = 0.05 level. All analyses were performed using Sigma Plot (version 13, Systat Software, Inc., San Jose, CA, USA) or SAS (version 9.4; SAS Institute Inc., Cary, NC, USA). This study was approved by the Rhode Island Hospital Institutional Review Board.

RESULTS

Study Population

A total of 60 subjects met the inclusion criteria over a 2-year period. Out of 60 total patients, 47 patients had complete data at 12 months (21.7% were lost to followup). The baseline characteristics of the cohort are presented in Table 1. Approximately 35% of patients had baseline HbA_{1c} values ≥ 12%, while 65% of patients had baseline HbA_{1c} values ≥10%. At baseline, a total of 46 patients had elevated SBP while 15 patients had elevated DBP. A total of 38 patients received angiotensin converting enzyme inhibitors or angiotensin receptor blockers to control their blood pressure at baseline. A total of 35 patients in our cohort were on RIH or state-sponsored healthcare programs, compared with 22 patients who were on a federal government-sponsored program.

Impact of Pharmacist Intervention on HbA_{1c} Values

Mean HbA_{1c} values (±SD) of the cohort prior to and following referral to a pharmacist-managed clinic are presented in Figure 2A. There were no significant differences among mean HbA_{1c} values at 3, 6 and 12 months pre-pharmacist intervention and baseline values. In contrast, mean HbA_{1c} values at 3, 6 and 12 months following the intervention were

significantly lower than baseline values ($p < 0.05$). The mean reduction in HbA_{1c} values at 3 months following pharmacist intervention was 2.3% (95% CI: −2.9 to −1.7; $p < 0.05$) compared to baseline. The mean reduction in HbA_{1c} values at 6 months following pharmacist intervention was 2.1% (95% CI: −2.76 to −1.44; $p < 0.05$) compared to baseline. The mean reduction in HbA_{1c} values at 12 months was 2.05% (95% CI: −2.65 to −1.45; $p < 0.05$) compared to baseline. There was no significant difference in mean HbA_{1c} values at 6 months compared to 3 months following pharmacist intervention (Figure 2B). Likewise, there was no significant difference in mean HbA_{1c} values at 12 months compared to 6 months following pharmacist intervention (Figure 2B).

Impact of Pharmacist Intervention on SBP and DBP Values

Changes in SBP and DBP of persons with SBP values >120 mmHg at baseline ($n = 46$) at 3, 6 and 12 months following pharmacist intervention is presented in Figure 2C. There was a significant reduction in mean SBP values at 3, 6 and 12 months following pharmacist intervention compared to baseline ($p < 0.05$). Likewise, there was a significant reduction in mean DBP values at 6 and 12 months following pharmacist intervention compared to baseline ($p < 0.05$). The mean reduction in SBP at 3 months was 5.8 mmHg (95% CI: −10.3 to −1.3; $p < 0.05$) compared to baseline. The mean reduction in SBP at 6 months was 7.0 mmHg (95% CI: −14.0 to −0.4; $p < 0.05$) compared to baseline. The mean reduction in SBP at 12 months was 6.0 mmHg (95% CI: −12.0 to −0.2; $p < 0.05$) compared to baseline. The mean reduction in DBP at 6 months was 3.4 mmHg (95% CI: −5.7 to −1.0; $p < 0.05$) compared to baseline. The mean reduction in DBP at 12 months was 5.4 mmHg (95% CI: −7.5 to −3.3; $p < 0.05$) compared to baseline.

Among those who demonstrated a reduction in SBP at 12 months compared to baseline ($n = 37$; 80%), the mean reduction in SBP was 10.0% from baseline (95% CI: −12.4 to −7.6; $p < 0.001$). Where there was a reduction in DBP at 12 months compared to baseline ($n = 33$; 72%), the mean reduction was 9.3% from baseline (95% CI: −10.8 to −7.8; $p < 0.001$).

Impact of Pharmacist Intervention on Diabetes-related Hospitalisation and ED Visits

The risk of diabetes-related ED visits and hospitalisation during the pre and post-pharmacist intervention periods are presented in Table 2. The risk of diabetes-related ED visits in the pre-intervention period was 30.0% compared with 23.3% in the post-intervention period. The estimated relative risk (RR) of ED visits was 0.71 (95% CI: 0.36–1.39). There was no significant change in the risk of diabetes-related ED visits between the pre- and post-intervention periods ($p = 0.32$).

The risk of diabetes-related hospitalisations in the pre-intervention period was 18.3% compared with 8.3% in the post-intervention period. The estimated RR of hospitalisation in the post- versus pre-intervention period was 0.40 (95% CI: 0.20–0.83; $p = 0.013$).

DISCUSSION

Pharmacological treatment is central to type 2 DM management, especially among persons who present with inadequately managed disease and co-morbid conditions like hypertension. As drug experts, pharmacists are uniquely situated to optimise drug therapy, identify

potential drug-related side effects, encourage medication adherence and provide education on appropriate medication use. In our institution, clinical pharmacy services are engaged in multiple interdisciplinary approaches to optimise drug therapy outcomes in various practice areas. The incorporation of pharmacist services in the diabetes clinic allowed the provision of pharmaceutical care to patients with unmanaged diabetes. The provision of pharmaceutical care, via a defined CDTA model, was associated with a significant early and persistent reduction in HbA_{1c} values, indicative of better diabetes management. In our cohort, we observed a mean reduction in HbA_{1c} of 2% that was sustained over a 1-year period. Chung *et al.* have observed a similar magnitude of reduction in HbA_{1c} values (−1.90% ± 2.44) among a Hispanic population with low-income state-provided insurance or federal insurance and type 2 DM who were exposed to a clinical pharmacy diabetes care program.[14]

Our work adds to a growing body of evidence supporting the benefit of pharmacy-based diabetes management programs incorporating a CDTA.[7–14,19–21] McAdam-Marx *et al.* found that a pharmacist-led diabetes collaborative care management program was associated with a reduction in HbA_{1c} values versus the control group (0.44%; 95% CI: −0.64 to −0.25; $p < 0.001$).[21] Other studies have found an even more substantial effect with pharmacist involvement in diabetes care. Kiel *et al.* saw a 1.6% reduction in HbA_{1c} with pharmacist-led diabetes care from baseline to follow-up ($p < 0.001$). In persons with an initial HbA_{1c} ≥ 8.5%, the mean reduction was even greater at 2.7% ($p < 0.001$).[22] A review of 23 studies evaluating pharmacist intervention in diabetes care reported the effect of pharmacist intervention on HbA_{1c} to be a mean reduction of 1.5% (SD ± 0.8%).[23] In the United Kingdom Prospective Diabetes Study (UKPDS), a reduction of 1% (7.0 (6.2–8.2) *vs* 7.9% (6.9–8.8), $p < 0.0001$) in the HbA_{1c} was associated with a 30% decrease in diabetes-related deaths ($p = 0.01$, 95% CI: 0.53–0.92), a 15% reduction in combined fatal and nonfatal myocardial infarction ($p = 0.014$, 95% CI: 0.74–0.97), and a 21% reduction in risk of complications ($p = 0.01$, 95% CI: 0.66–0.95).[24] Over a 12-month period, we have observed a 2% mean reduction in HbA_{1c} from baseline which might translate to an overall reduction in risk of diabetes complications.

Hypertension is commonly associated with diabetes and is an independent risk factor of cardiovascular complications among persons with type 2 DM.[25,26] Aggressive management of blood pressure is recommended for persons with type 2 DM. Under the CDTA agreement, pharmacists are authorised to initiate and modify antihypertensive therapies for patients enrolled in the diabetes clinic. In our cohort, the majority of patients had a diagnosis of hypertension and were on antihypertensive regimens, and at baseline approximately 80% of the cohort had above-goal SBP values. These patients required more aggressive drug therapy management by pharmacists. A majority of this subset of our cohort experienced a statistically and clinically significant reduction in SBP and DBP with a mean reduction at 12 months approximating 10% from baseline values.

It is estimated that health resource utilisation attributed to hospitalisations constitutes 15.7% of all direct costs of diabetes management compared with 5.7% for ED visits. We aimed to examine the impact of a pharmacist intervention on health resource utilisation in our cohort. In order to evaluate the risk of ED visits and hospitalisations, we identified

specific diabetes-related diagnoses including hyperglycaemia, hypoglycaemia, diabetic foot and other soft tissue infections, gastroparesis and diabetic ketoacidosis. We observed a significant reduction in diabetes-related hospitalisations for these diagnoses and a trend toward a reduction in diabetes-related ED visits.

There were some limitations to our study. The retrospective nature of this study limited our ability to collect additional covariates (e.g. duration of DM at enrolment and baseline fasting plasma glucose levels) and adjust our estimates for those covariates. Our small sample size reduced the precision of our estimates; however, despite this, we were able to detect a meaningful difference in the outcomes. A considerable proportion of subjects (21.7%) were lost to follow-up in our study; this may induce a potential selection bias and should be addressed in future work. Future work should emphasise incident hypoglycaemic episodes, which we were unable to do in our study, but are important, especially for older individuals. Future studies should be conducted prospectively and with a greater number of subjects. Considerations should be given to collecting additional data regarding hypoglycaemia and elderly/frail populations.

In conclusion, we present evidence supporting the role of the pharmacist in improving disease control and reducing health resource utilisation in underserved patients with inadequately managed type 2 DM.

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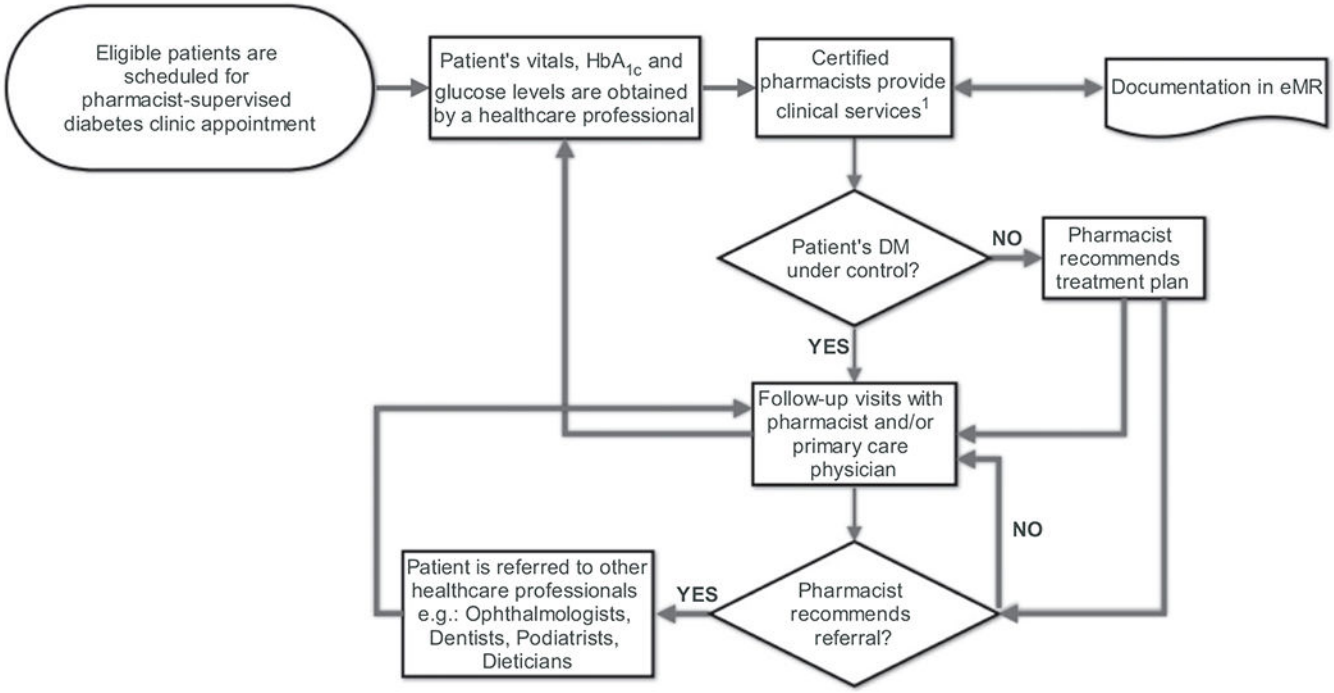

Figure 1.

Process flowchart of the multidisciplinary coordinated care model for persons with treatment-resistant/unmanaged type 2 diabetes. eMR = Electronic Medical Record, DM = diabetes mellitus. [1] Certified pharmacists conduct medication therapy management (MTM), disease state education, administer immunisations and recommend preventive care.

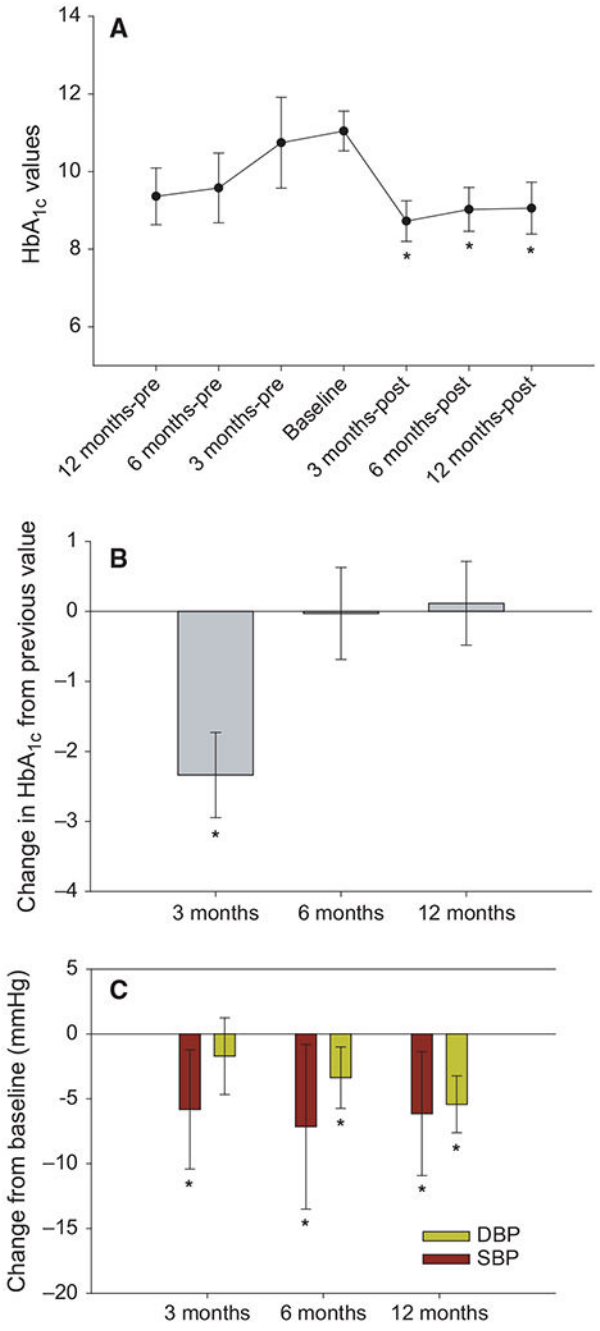

Figure 2.

(A) Trend of mean haemoglobin A1c (HbA_{1c}) values (± standard deviation) prior to and following enrolment in the pharmacist-managed diabetes clinic ($n = 60$). *Indicates that mean HbA_{1c} values at 3, 6 and 12 months following enrolment in the pharmacist-run program were significantly lower than baseline values ($p < 0.05$). **(B)** Change in haemoglobin A1c (HbA_{1c}) values from previous recorded values following enrolment in the pharmacist-run medical clinic. Data is presented as mean change with 95% confidence intervals (CI). *Indicates that the reduction in HbA_{1c} at 3 months following enrolment is

significantly different from 0 ($p < 0.05$). The change in mean HbA_{1c} values at 6 months from corresponding values at 3 months was not different from 0. Similarly, the change in mean HbA_{1c} values at 12 months from corresponding values at 6 months was not different from 0. **(C)** Impact of pharmacist-managed diabetes clinic on systolic blood pressure (SBP) and diastolic blood pressure (DBP) values of newly admitted treatment-resistant persons with Type II diabetes ($n = 46$) at baseline and at 3, 6 and 12 months following admission. Bar represents mean change in BP compared to baseline values and error bars represent 95% confidence intervals (CI). *Significantly different from 0 ($p < 0.05$).

Table 1

Baseline characteristics of the pharmacist-managed type II diabetes mellitus cohort

Patient characteristic	Pharmacist-managed cohort (*n* = 60)
Age, years	
Mean (±SD)	54 (13)
Median (range)	53 (25–81)
Sex, no. (%)	
Male	30 (50)
Female	30 (50)
Race, no. (%)	
Caucasian	24 (40)
African American	18 (30)
Asian	2 (3%)
Unidentified or other[a]	16 (27)
Baseline HbA_{1c}, no. (%)	
<8	0 (0)
8–9.9	21 (35)
10–11.9	18 (30)
12–13.9	17 (28)
>14	4 (7)
Mean (± SD)	11 (2)
Median (range)	11 (8–17.5)
Baseline blood pressure (mmHg)	
SBP: mean ± SD	132 ± 15
SBP: median (range)	134 (100–166)
SBP > 120 mmHg, no. (%)	46 (77)
DBP: mean ± SD	74 ± 9
DBP: median (range)	74 (57–94)
DBP > 80 mmHg, no. (%)	15 (25)
Insurance status	
Hospital-based financial aid (%)	27 (45)
Medicare (%)	22 (37)
State Medicaid (%)	8 (13)
Private insurance (%)	3 (5)

SBP = systolic blood pressure; DBP = diastolic blood pressure; LDL = low-density lipoprotein; TG = triglycerides; HDL = high-density lipoprotein; HbA_{1c} = hemoglobin A1c.

[a]Includes Hispanic patients.

Table 2

Impact of pharmacist-managed diabetes care on risk of diabetes-related ED visits and hospitalisations among persons with unmanaged diabetes ($n = 60$) in the 12 months post-enrolment in the clinic versus the 12 months before

	Pre-intervention (%)	Post-intervention (%)	RR (95% CI)	p-Value
Diabetes-related ED visits	30.0	23.3	0.71 (0.36–1.39)	0.32
Diabetes-related hospitalisations	18.3	8.3	0.40 (0.20–0.83)	0.01

CI = confidence interval; ED = emergency department; RR = relative risk.