Development of a Pharmacoeconomic Model to Demonstrate the Effect of Clinical Pharmacist Involvement in Diabetes Management

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ABSTRACT

BACKGROUND: A data collection tool was developed and nationally deployed to clinical pharmacists (CPs) working in advanced practice provider roles within the Department of Veterans Affairs to document interventions and associated clinical outcomes. Intervention and short-term clinical outcome data derived from the tool were used to populate a validated clinical outcomes modeling program to predict long-term clinical and economic effects.

OBJECTIVE: To predict the long-term effect of CP-provided pharmacotherapy management on outcomes and costs for patients with type 2 diabetes.

METHODS: Baseline patient demographics and biomarkers were extracted for type 2 diabetic patients having > 1 encounter with a CP using the tool between January 5, 2013, and November 20, 2014. Treatment biomarker values were extracted 12 months after the patient's initial visit with the CP. The number of visits with the CP was extracted from the electronic medical record, and duration of visit time was quantified by Current Procedural Terminology codes. Simulation modeling was performed on 3 patient cohorts—those with a baseline hemoglobin A1c of 8% to <9%, 9% to <10%, and ≥10%—to estimate long-term cost and clinical outcomes using modeling based on pivotal trial data (the Archimedes Model). A sensitivity analysis was conducted to assess the extent to which our results were dependent on assumptions related to program effectiveness and costs.

RESULTS: A total of 7,310 patients were included in the analysis. Analysis of costs and events on 2-, 3-, 5-, and 10-year time horizons demonstrated significant reductions in major adverse cardiovascular events (MACEs), myocardial infarctions (MIs), episodes of acute heart failure, foot ulcers, and foot amputations in comparison with a control group receiving usual guideline-directed medical care. In the cohort with a baseline A1c of ≥10%, the absolute risk reduction was 1.82% for MACE, 1.73% for MI, 2.43% for acute heart failure, 5.38% for foot ulcers, and 2.03% for foot amputations. The incremental cost-effectiveness ratios for cost per quality-adjusted life-year during the 2-, 3-, 5-, and 10-year time horizons were cost-effective for the cohorts of patients with a baseline A1c of 9% to <10% and ≥10%.

CONCLUSIONS: CPs acting as advanced practice providers reduced A1c from baseline for veterans with type 2 diabetes compared with modeled usual care. Archimedes modeling of the A1c reductions projects a decreased incidence of diabetes complications and overall health care spending when compared with modeled usual care.

J Manag Care Spec Pharm. 2018;24(5):449-57

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What is already known about this subject

- Studies have shown that a sustained reduction in hemoglobin A1c level in adults with diabetes is associated with significant cost savings within 1-2 years.
- Many studies have shown that clinical pharmacists (CPs) can be used to reduce A1c and effectively manage diabetes to goal.

What this study adds

- This study provides evidence that the use of CPs to manage diabetes provides a positive return on investment when compared with modeled usual care.
- Study results showed that CP management of diabetes is as effective or, in some cases, more effective in reducing microvascular and macrovascular outcomes and reducing overall costs than modeled usual care.

In the United States, 29.1 million people (9.3% of the population) have diabetes. Adults with diabetes are at increased risk of clinical complications compared with nondiabetics; cardiovascular death rates are 1.7 times higher, hospitalization rates for heart attack are 1.8 times higher, and hospitalization rates for stroke are 1.5 times higher in adults with diagnosed diabetes. In 2010, approximately 60% of the 73,000 nontraumatic lower-limb amputations in adults aged 20 or older were in diabetics.¹ The total economic cost for diagnosed diabetes was \$245 billion in 2012, of which \$176 billion were direct medical costs.²

Previous studies have shown that a sustained reduction in hemoglobin A1c level in adults with diabetes is associated with significant cost savings as soon as 1-2 years after the improvement.^{3,4} Diabetes is more prevalent in the veteran population than in the general population, affecting nearly 25% of the Veterans Health Administration (VHA) patient population.⁵ Diabetes is also a leading cause of blindness, end-stage renal disease, and nontraumatic limb amputation among adults in the United States.¹

VHA clinical pharmacists (CPs) within a scope of practice are authorized as advanced practice providers with medication prescriptive authority and have been shown to be effective at reducing average A1c values in diabetic patients in the VHA system.⁶ There are numerous studies that have examined CPs

FIGURE 1 VHA PBM PhARMD Pharmacotherapy Reminder: Version 9 Disease State Goal Setting and Intervention Selection

Reminder Resolution: PBM PharmD Pharmacotherapy Rem V9

☒ Diabetes Mellitus, Type 2

Primary goal for patient (required to choose one):

☒ Patient's A1c goal is less than 7% Comment:

☐ Patient's A1c goal is less than 7.5%

☐ Patient's A1c goal is less than 8%

☐ Patient's A1c goal is less than 8.5%

☐ Patient's A1c goal is less than 9%

☐ Patient's goal is:

☒ Medication intervention

☒ Adjust dose or frequency of current medication

☐ Adjust dose or frequency of current medication due to hypoglycemia

☒ Adjust dose or frequency of current medication due to other reason

Plan:

☐ Discontinue and/or change to different medication

**If related to management of an adverse drug event or allergy, please document as well under additional pharmacotherapy intervention, manage adverse drug event or allergy

☐ Initiate new medication

☒ Nonpharmacologic intervention made

**Examples include, but are not limited to:

disease state education,
lifestyle counseling and education,
providing educational materials,
providing home monitoring devices,
making referrals for additional care

Plan:

☐ No change made

☐ Goals of therapy for condition achieved (guideline appropriate and/or patient established).

*If patient will no longer be seen by Clinical Pharmacist Specialist, please check "refer or transition back to provider".

Clear Clinical Maint Visit Info < Back Next > Finish Cancel

CLINICAL REMINDER ACTIVITY
PBM PharmD Pharmacotherapy Rem V9:

ASSESSMENT AND PLAN:

Health Factors: PBM PHARMD DM TYPE II ADJ DOSE FREQ MED, PBM PHARMD DM TYPE II GOAL OF <7%, PBM PHARMD DM TYPE II NONPHARM INTERV

* Indicates a Required Field

PBM=pharmacy benefits management; PhARMD=Pharmacists Achieve Results with Medications Documentation; VHA=Veterans Health Administration.

TABLE 1 Baseline Patient Demographics, Clinic Visit Information, and Clinical Parameters

Archimedes Inputs ^a	Baseline A1c 8% to <9%	Baseline A1c 9% to <10%	Baseline A1c ≥10%
Patients, n	2,850	2,000	2,460
Male (%)	96.4 (18.8)	95.5 (20.8)	95.5 (20.7)
Age (years)	65.4 (8.8)	64.2 (8.9)	61.6 (9.6)
Average number of visits	6.8 (4.3)	6.9 (4.1)	7.0 (4.7)
Average visit time (minutes)	27.9 (19.5)	27.9 (19.5)	27.9 (19.5)
Average achieved A1c (%)	8.2 (1.3)	8.6 (1.4)	9.3 (2.0)
Weight (kg)	106.4 (50.2)	106.2 (50.6)	103.8 (47.8)
BMI (kg/m ²)	34.0 (6.7)	34.1 (6.8)	33.3 (6.4)
Systolic blood pressure (mm Hg)	129.5 (15.2)	129.8 (15.6)	129.2 (16.0)
Diastolic blood pressure (mm Hg)	72.1 (10.6)	72.9 (10.2)	74.5 (10.9)
GFR (mL/min/1.73m ²)	73.3 (26.8)	74.5 (27.2)	80.9 (30.2)
Baseline A1c (%)	8.4 (0.3)	9.4 (0.3)	11.4 (1.4)
Average achieved A1c (%)	8.2 (1.3)	8.6 (1.4)	9.3 (2.0)
Total cholesterol (mg/dL)	155.0 (36.9)	158.0 (38.8)	173.9 (52.1)
HDL (mg/dL)	39.1 (11.1)	38.8 (10.3)	39.6 (11.6)
LDL (mg/dL)	80.8 (29.4)	83.0 (31.0)	92.3 (37.7)
Triglycerides (mg/dL)	193.7 (157.5)	198.7 (142.5)	239.5 (236.9)
Chronic obstructive pulmonary disease (%)	345 (12.1)	216 (10.8)	263 (10.7)
Chronic heart failure (%)	276 (9.7)	198 (9.9)	241 (9.8)
Chronic kidney disease, stages 3-5 (%)	262 (9.2)	166 (8.3)	172 (7.0)
Coronary artery disease (%)	812 (28.5)	588 (29.4)	667 (27.1)
History of stroke (%)	148 (5.2)	100 (5.0)	118 (4.8)
Hypertension (%)	2,423 (85.0)	1,706 (85.3)	2,022 (82.2)
Type 2 diabetes (%)	2,850 (100)	2,000 (100.0)	2,460 (100.0)

^aMean (SD), unless otherwise noted.

BMI=body mass index; GFR=glomerular filtration rate; HDL=high-density lipoprotein; LDL=low-density lipoprotein; SD=standard deviation.

providing direct care for patients with diabetes in the outpatient setting, and this practice has been shown to improve patient outcomes.⁷⁻¹⁰ To allow for the systematic documentation of CP workload and interventions, the VHA pharmacy benefits management (PBM) deployed a national data collection tool through the Pharmacists Achieve Results with Medications Documentation (PhARMD) Project. CPs use the tool to document disease state assessments, interventions, and outcomes (Figure 1).¹¹ The project data provide a means to identify patients receiving care from a CP, the disease states managed, and disease state interventions made by the CP. Once identified, patient demographics and biomarkers were extracted from the electronic medical record (EMR), which allowed for analysis of the interventions made by the CP.

The objective of this study was to evaluate PhARMD Project data for type 2 diabetes mellitus to determine whether treatment by a CP would result in a reduction in the 2-, 3-, 5-, and

10-year incidence of microvascular and macrovascular complication of diabetes, reduce overall medical costs, and increase quality-adjusted life-years (QALYs) compared with simulation-modeled usual care.

Methods

This quality improvement project was a retrospective review of patients treated by a CP with >1 type 2 diabetes-related encounter documented in the EMR using the PhARMD tool between January 5, 2013, and November 20, 2014. Patient data (Table 1) were pulled from the EMR in December 2014, with baseline defined as the time of the first visit where a type 2 diabetes-related PhARMD tool assessment was documented in the EMR. A1c values were extracted from the EMR again after at least 12 months had passed since the baseline visit. Patients were stratified by the baseline A1c level drawn on or immediately prior to the first visit where a diabetes-related PhARMD tool assessment was documented. The baseline visit with the CP was identified by the presence of a clinical reminder health factor. A health factor is an embedded discrete data element with standardized nomenclature that allows for easy data retrieval within a VHA central database. Group stratifications (those with baseline A1c values of 8% to <9%, 9% to <10%, and ≥10%) were chosen based on internal business logic for CP referral cut points at various VA facilities. Data from the EMR are available within the VHA's corporate data warehouse.¹² The number of visits with the CP related to diabetes was extracted from the EMR and duration of visit time was quantified using time-based medication therapy management Current Procedural Terminology codes (Appendix, available in online article).

The Archimedes Model was used to estimate long-term costs and consequences of diabetes complications based on the level of A1c lowering that was achieved in each subgroup. The Archimedes Model is a pharmacoeconomic tool that can accurately project long-term clinical and economic consequences of changes in patient biomarkers over time while adjusting for specific patient population demographics.^{13,14} The simulation model represents the average level of U.S. health care delivery for the control group and includes care processes representative of current national treatment guidelines.¹³ The diabetes portion of the model has been validated by simulating 18 different clinical trials.¹⁵ Simulated individuals have a unique physiology that is evolutionary over time and causes them to acquire diseases, have symptoms, and seek medical care, which may result in health-related outcomes, such as a myocardial infarction (MI) or foot amputation. The model tracks events that could affect health care utilization, costs, health outcomes, and quality of life. The full details of the model and associated specifics have been described fully elsewhere.¹³

Within the model, QALYs are calculated by multiplying the time a patient spends with a particular symptom or health

TABLE 2 ICER Calculations (Cost per QALY)

	Discounted Medical Costs + Program Costs – Control (\$)	Discounted Medical Costs + Program Costs – PhARMD (\$)	Discounted QALYs – Control	Discounted QALYs – PhARMD	ICER (\$)
Baseline A1c ≥ 10%					
2-year TH	146,336,346	144,008,876	16,080	16,151	-32,781.27
3-year TH	216,698,576	211,908,246	23,403	23,545	-33,734.72
5-year TH	349,881,839	338,721,564	36,740	37,060	-34,875.86
10-year TH	640,203,982	613,367,403	63,511	64,323	-33,049.97
Baseline A1c 9% to < 10%					
2-year TH	152,653,060	153,374,680	16,035	16,068	21,867.27
3-year TH	226,783,198	226,085,152	23,337	23,400	-11,080.10
5-year TH	368,008,663	364,521,043	36,611	36,738	-27,461.57
10-year TH	670,615,746	661,170,019	63,065	63,354	-32,684.18
Baseline A1c 8% to < 9%					
2-year TH	155,539,390	157,908,403	15,843	15,852	263,223.67
3-year TH	230,246,997	232,077,673	23,060	23,075	122,045.07
5-year TH	373,694,873	374,541,509	36,130	36,161	27,310.84
10-year TH	672,057,311	670,636,929	61,830	61,906	-18,689.24
80% Program Effectiveness					
Baseline A1c ≥ 10%					
2-year TH	146,336,346	145,041,370	16,080	16,136	-23,124.57
3-year TH	216,698,576	213,433,312	23,403	23,517	-28,642.67
5-year TH	349,881,839	341,520,619	36,740	36,996	-32,661.02
10-year TH	640,203,982	619,301,719	63,511	64,160	-32,206.88
Baseline A1c 9% to < 10%					
2-year TH	152,653,060	153,797,356	16,035	16,061	44,011.38
3-year TH	226,783,198	226,791,761	23,337	23,388	167.90
5-year TH	368,008,663	365,785,567	36,611	36,712	-22,010.85
10-year TH	670,615,746	663,626,165	63,065	63,296	-30,257.93
Baseline A1c 8% to < 9%					
2-year TH	155,539,390	158,001,600	15,843	15,850	351,744.29
3-year TH	230,246,997	232,278,538	23,060	23,072	169,295.08
5-year TH	373,694,873	374,939,182	36,130	36,155	49,772.36
10-year TH	672,057,311	671,488,006	61,830	61,891	-9,332.87
75% Program Effectiveness					
Baseline A1c ≥ 10%					
2-year TH	146,336,346	145,299,494	16,080	16,133	-19,563.25
3-year TH	216,698,576	213,814,579	23,403	23,510	-26,953.24
5-year TH	349,881,839	340,220,383	36,740	36,980	-40,256.07
10-year TH	640,203,982	620,785,298	63,511	64,120	-31,886.18
Baseline A1c 9% to < 10%					
2-year TH	152,653,060	153,903,025	16,035	16,059	52,081.88
3-year TH	226,783,198	226,968,413	23,337	23,384	3,940.74
5-year TH	368,008,663	366,101,698	36,611	36,706	-20,073.32
10-year TH	670,615,746	664,240,201	63,065	63,282	-29,380.39
Baseline A1c 8% to < 9%					
2-year TH	155,539,390	158,024,900	15,843	15,850	355,072.86
3-year TH	230,246,997	232,328,754	23,060	23,071	189,250.64
5-year TH	373,694,873	375,038,600	36,130	36,154	55,988.63
10-year TH	672,057,311	671,700,775	61,830	61,887	-6,255.02
70% Program Effectiveness					
Baseline A1c ≥ 10%					
2-year TH	146,336,346	145,557,617	16,080	16,129	-15,892.43
3-year TH	216,698,576	214,195,845	23,403	23,503	-25,027.31
5-year TH	349,881,839	342,920,146	36,740	36,964	-31,078.99
10-year TH	640,203,982	622,268,877	63,511	64,079	-31,575.89

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TABLE 2 ICER Calculations (Cost per QALY) (continued)

	Discounted Medical Costs + Program Costs – Control (\$)	Discounted Medical Costs + Program Costs – PhARMD (\$)	Discounted QALYs – Control	Discounted QALYs – PhARMD	ICER (\$)
70% Program Effectiveness					
Baseline A1c 9% to <10%					
2-year TH	152,653,060	154,008,694	16,035	16,058	58,940.61
3-year TH	226,783,198	227,145,065	23,337	23,381	8,224.25
5-year TH	368,008,663	366,417,829	36,611	36,700	-17,874.54
10-year TH	670,615,746	664,854,237	63,065	63,267	-28,522.32
Baseline A1c 8% to <9%					
2-year TH	155,539,390	158,048,199	15,843	15,849	418,134.83
3-year TH	230,246,997	232,378,971	23,060	23,070	213,197.40
5-year TH	373,694,873	375,138,018	36,130	36,152	65,597.50
10-year TH	672,057,311	671,913,544	61,830	61,883	-2,712.58
25% Higher Program Costs					
Baseline A1c ≥ 10%					
2-year TH	146,336,346	144,717,626	16,080	16,151	-22,798.87
3-year TH	216,698,576	212,616,996	23,403	23,545	-28,743.52
5-year TH	349,881,839	339,430,314	36,740	37,060	-32,661.02
10-year TH	640,203,982	614,076,153	63,511	64,323	-32,177.13
Baseline A1c 9% to <10%					
2-year TH	152,653,060	154,155,430	16,035	16,068	45,526.36
3-year TH	226,783,198	226,793,902	23,337	23,400	169.90
5-year TH	368,008,663	365,229,793	36,611	36,738	-21,880.87
10-year TH	670,615,746	661,878,769	63,065	63,354	-30,231.75
Baseline A1c 8% to <9%					
2-year TH	155,539,390	158,617,153	15,843	15,852	341,973.67
3-year TH	230,246,997	232,786,423	23,060	23,075	169,295.07
5-year TH	373,694,873	375,250,259	36,130	36,161	50,173.74
10-year TH	672,057,311	671,345,679	61,830	61,906	-9,363.58
50% Higher Program Costs					
Baseline A1c ≥ 10%					
2-year TH	146,336,346	145,426,376	16,080	16,151	-12,816.48
3-year TH	216,698,576	213,325,746	23,403	23,545	-23,752.32
5-year TH	349,881,839	340,139,064	36,740	37,060	-30,446.17
10-year TH	640,203,982	614,784,903	63,511	64,323	-31,304.28
Baseline A1c 9% to <10%					
2-year TH	152,653,060	154,792,180	16,035	16,068	64,821.82
3-year TH	226,783,198	227,502,652	23,337	23,400	11,419.90
5-year TH	368,008,663	365,938,543	36,611	36,738	-16,300.16
10-year TH	670,615,746	662,587,519	63,065	63,354	-27,779.33
Baseline A1c 8% to <9%					
2-year TH	155,539,390	159,325,903	15,843	15,852	420,723.67
3-year TH	230,246,997	233,495,173	23,060	23,075	216,545.07
5-year TH	373,694,873	375,959,009	36,130	36,161	73,036.65
10-year TH	672,057,311	672,054,429	61,830	61,906	-37.92

A1c = hemoglobin A1c; ICER = incremental cost-effectiveness ratio; PhARMD = Pharmacists Achieve Results with Medications Documentation data tool; QALY = quality-adjusted life-year; TH = time horizon.

outcome by a factor representing the associated decrease in quality of life.¹⁴ Patient parameters used in Archimedes Model simulations included sex, age, weight, body mass index, blood pressure, glomerular filtration rate, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides,

total cholesterol, and A1c. Comorbid medical conditions included chronic obstructive pulmonary disease, congestive heart failure, chronic kidney disease, coronary artery disease, history of stroke, and hypertension. Baseline patient data used for the PhARMD group simulations are outlined in Table 1.

TABLE 3 Absolute Risk Reduction of Diabetes Complications: PhARMD Versus Control

Event	Baseline A1c (%)	2 Years	3 Years	5 Years	10 Years
Myocardial infarction, % (95% CI)	≥ 10	0.49 (0.12, 0.87)	0.68 (0.22, 1.14)	0.79 (0.21, 1.37)	1.73 (0.92, 2.54)
	9 to <10	0.11 (-0.27, 0.49)	0.20 (-0.25, 0.65)	0.24 (-0.34, 0.82)	0.62 (-0.21, 1.45)
	8 to <9	0.02 (-0.38, 0.42)	0.08 (-0.41, 0.57)	0.12 (-0.49, 0.73)	0.22 (-0.62, 1.05)
Acute heart failure, % (95% CI)	≥ 10	0.63 (0.12, 1.14)	1.03 (0.44, 1.62)	1.28 (0.57, 1.99)	2.43 (1.51, 3.30)
	9 to <10	0.16 (-0.39, 0.71)	0.17 (-0.45, 0.79)	0.31 (-0.44, 1.06)	0.58 (-0.40, 1.56)
	8 to <9	0.05 (-0.49, 0.59)	0.06 (-0.56, 0.68)	0.11 (-0.64, 0.86)	0.23 (-0.75, 1.21)
Foot ulcer, % (95% CI)	≥ 10	1.84 (1.26, 2.42)	2.50 (1.81, 3.19)	3.64 (2.79, 4.49)	5.38 (4.28, 6.48)
	9 to <10	0.68 (0.07, 1.29)	1.06 (0.33, 1.79)	1.38 (0.49, 2.27)	2.03 (0.89, 3.17)
	8 to <9	0.18 (-0.46, 0.78)	0.39 (-0.32, 1.10)	0.38 (-0.49, 1.25)	0.73 (-0.39, 1.85)
Foot amputation, % (95% CI)	≥ 10	0.58 (0.26, 0.90)	0.61 (0.22, 1.00)	0.91 (0.41, 1.41)	2.03 (1.35, 2.72)
	9 to <10	0.20 (-0.15, 0.55)	0.23 (-0.19, 0.65)	0.28 (-0.25, 0.81)	0.74 (0.02, 1.48)
	8 to <9	0.04 (-0.31, 0.39)	0.07 (-0.35, 0.49)	0.10 (-0.45, 0.65)	0.34 (-0.41, 1.09)
Major adverse cardiovascular event, % (95% CI)	≥ 10	0.56 (0.06, 1.06)	0.73 (0.12, 1.34)	0.81 (0.06, 1.57)	1.82 (0.80, 2.84)
	9 to <10	0.12 (-0.38, 0.62)	0.25 (-0.34, 0.84)	0.30 (-0.46, 1.06)	0.57 (0.80, 2.84)
	8 to <9	0.06 (-0.46, 0.58)	0.13 (-0.50, 0.76)	0.12 (-0.67, 0.91)	0.22 (-0.83, 1.27)

Note: Archimedes Model results derived from VA data inputs.

A1c = hemoglobin A1c; CI = confidence interval; PhARMD = Pharmacists Achieve Results with Medications Documentation; VA = Veterans Administration.

The discount rate used to convert medical costs and QALYs over time to present values was 3%.¹⁴ Intervention costs were based on average CP salary and benefits cost per visit and are presented along with all other costs and incremental cost-effectiveness ratios (ICERs) in Table 2.

Reductions in the 2-, 3-, 5-, and 10-year incidence of microvascular and macrovascular diabetic complications, resulting medical costs, and QALYs were estimated using the Archimedes Model.¹² These modeled absolute risk reduction results are reported in Table 3. Sensitivity analyses were conducted to assess the extent to which our results for the ICERs were dependent on assumptions related to program effectiveness and costs (Table 4). Intervention costs for the PhARMD group only were increased by 25% and 50% to test the influence of geographic pharmacist salary differences. Program effectiveness was decreased to 80%, 75%, and 70% of original effectiveness to test differences in individual pharmacist effectiveness.

Analyses were conducted using Microsoft Excel (Microsoft Corp., Redlands, WA), Minitab 16 (Minitab, Inc., State College, PA), and ARChES Outcomes Analyzer (Evidera, Bethesda, MD). The study was reviewed by the institutional review board for Edward Hines, Jr. VA Hospital, Hines, Illinois, and James A. Lovell Federal Health Care Center, North Chicago, Illinois, and determined to be a quality improvement project, not human research.

Results

A total of 7,310 patients were included in the analysis. Analysis of costs and events for 2-, 3-, 5-, and 10-year time horizons demonstrated that patients receiving care by CP would have fewer major adverse cardiovascular events (MACEs), MIs, episodes of acute heart failure, foot ulcers, and foot

amputations in comparison with a simulated control group receiving usual medical care. The percentage of absolute risk reduction for diabetes-related complications over all 4 time horizons in the CP-managed patients is outlined in Table 3. Estimated medical costs, including intervention costs, were lower and QALYs gained were greater in the CP-managed group for those with a baseline A1c ≥10% over the 2-, 3-, 5-, and 10-year time frames. For those with a baseline A1c 9% to <10%, estimated medical costs were lower and QALYs gained were greater in the CP-managed group over the 3-, 5-, and 10-year time frames. In the group with a baseline A1c 8% to <9%, estimated medical costs were higher in the CP-managed group over the 2-, 3-, and 5-year time frames, but they were lower at the 10-year time frame. QALYs gained were greater in the CP-managed group over the 2-, 3-, 5-, and 10-year time frames. The corresponding ICER for cost per QALY was negative (cost saving) for CP-managed patients with a baseline A1c of 9% to <10% and ≥10% according to the time horizon trends at 2, 3, 5, and 10 years for each group. The ICER was negative for CP-managed patients with a baseline A1c of 8% to <9% only at the 10-year time horizon. The resulting negative ICERs at those time points indicate that the CP-managed group was more effective, with a lower total cost than usual care (Table 2).

Sensitivity Analysis

Intervention costs for the PhARMD group were increased by 25% and 50% to test the influence of geographic variance in pharmacist salary. Program effectiveness was decreased to 80%, 75%, and 70% of original effectiveness to test differences in individual pharmacist effectiveness. The results of the sensitivity analysis are detailed in Table 4. For the group with a baseline A1c ≥10%, the PhARMD group demonstrated higher

TABLE 4 Sensitivity Analysis: ICER (Cost per QALY)

	Baseline A1c (%)	2 Years (\$)	3 Years (\$)	5 Years (\$)	10 Years (\$)
Reference scenario	≥ 10	-32,781.27	-33,734.72	-34,875.86	-33,049.97
Discount rate: 3%	9 to < 10	21,867.27	-11,080.10	-27,461.57	-32,684.18
Program effectiveness: 100%	8 to < 9	263,223.67	122,045.07	27,310.84	-18,689.24
Program cost: \$2,835,000					
Program effectiveness					
80%	≥ 10	-23,124.57	-28,642.67	-32,661.02	-32,206.88
	9 to < 10	44,011.38	167.90	-22,010.85	-30,257.93
	8 to < 9	351,744.29	169,295.08	49,772.36	-9,332.87
75%	≥ 10	-19,563.25	-26,953.24	-40,256.07	-31,886.18
	9 to < 10	52,081.88	3,940.74	-20,073.32	-29,380.39
	8 to < 9	355,072.86	189,250.64	55,988.63	-6,255.02
70%	≥ 10	-15,892.43	-25,027.31	-31,078.99	-31,575.89
	9 to < 10	58,940.61	8,224.25	-17,874.54	-28,522.32
	8 to < 9	418,134.83	213,197.40	65,597.50	-2,712.58
Program costs					
25% increase	≥ 10	-22,798.87	-28,743.52	-32,661.02	-32,177.13
	9 to < 10	45,526.36	169.90	-21,880.87	-30,231.75
	8 to < 9	341,973.67	169,295.07	50,173.74	-9,363.58
50% increase	≥ 10	-12,816.48	-23,752.32	-30,446.17	-31,304.28
	9 to < 10	64,821.82	11,419.90	-16,300.16	-27,779.33
	8 to < 9	420,723.67	216,545.07	73,036.65	-37.92

A1c = hemoglobin A1c; ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life-year.

QALYs and lower cost than the usual care group in all cases when the intervention cost and program effectiveness were varied. In the group with a baseline A1c 9% to < 10%, the PhARMD group demonstrated higher QALYs and lower cost than usual care over 5- and 10-year time periods when the intervention cost and program effectiveness were varied. The group with a baseline A1c 8% to < 9% demonstrated higher QALYs and lower cost than usual care only at the 10-year time period.

Discussion

To our knowledge, this is the first study to track interventions and assign cost-effectiveness ratios to a large national cohort of CP-managed patients. In this project, patients in the PhARMD group were predicted by the Archimedes Model to have a lower risk of MACE, MI, acute heart failure, foot ulcer, and foot amputation compared with usual care. More pronounced outcomes were modeled in patients with a higher baseline A1c and those with higher absolute reductions in A1c. Cardiovascular outcomes were statistically significant when the reduction in A1c was > 1% from baseline. These outcomes were deemed to have significantly positive cost effects on the health care system. In addition, ICER analysis demonstrates negative cost per QALY outcomes after 3 years in nearly all groups, even after deeply discounting for hypothetical productivity variations. The results suggest that it is cost effective to incorporate CPs into patient care teams for diabetic patients, especially for patients with higher baseline A1c levels.

Limitations

There are several limitations to consider regarding this project and its applicability to other patient populations or practice settings. The demographics of the VA population analyzed in this project are likely different from the general population of diabetic patients who may be treated elsewhere. The simulated control group was a model of usual care by the Archimedes Model and, although the model was able to simulate 18 diabetes clinical trials, this does diminish the applicability of the findings. The usual care group of the Archimedes Model represents the average level of guideline-directed U.S. health care and may not be reflective of usual care at the VHA. Given the design of this project, we were unable to identify if other members of the health care team (dietitians, social workers, etc.) provided diabetes care in addition to the CP. The costs of CP-provided care in different settings will vary, although the sensitivity analysis attempted to account for this variability.

Conclusions

We have demonstrated that interventions made by a CP in the care of patients with type 2 diabetes, when compared with validated modeling of usual care, resulted in reductions in A1c and decreased downstream diabetes-related events. The model showed that these interventions were cost effective in all 3 groups of patients over a 10-year time period. Factors associated with more robust outcomes include higher baseline A1c and larger A1c reductions from baseline. Additionally, we

have demonstrated that using the Archimedes Model to project future effects of CP interventions and improvements in surrogate markers can yield important information that might better inform payers of the value of the CPs in diabetes management. Data analyzed in this fashion can be utilized to predict clinical outcomes, incurred health care costs, QALYs, ICERs, and cost-benefits related to CP interventions in diabetes. This information is important in guiding management decisions about the best use of CPs in the provision of direct patient care and medication management services. CPs, working as advanced practice providers treating veterans with type 2 diabetes, improve patient outcomes, lower overall health care costs, and are cost effective when compared to a simulated control group.

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DISCLOSURES

There was no outside funding source or sponsor for this project. None of the authors report any conflicts of interest. The views expressed in this article are those of the authors and do not necessarily reflect the views or policies of the U.S. Department of Veterans Affairs.

Preliminary data from this project were previously presented in abstract form at the Academy of Managed Care Pharmacy 27th Annual Meeting and Expo; April 8-10, 2015; in San Diego, California.

ACKNOWLEDGMENTS

The authors thank Samantha Wright for data management support and the Department of Veterans Affairs Pharmacy Benefit Management, Clinical Pharmacy Practice Office, Pharmacoeconomic Modeling Work Group for input on this project. The authors also recognize the work of the PBM PhARMd Steering Committee and those clinical pharmacists who documented their interventions using the PhARMd tool for their contributions to these data.

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APPENDIX

**Medication Therapy Management
Current Procedural Terminology Codes**

Code	Care Modality	Associated Time
99605	Face-to-face	15 minutes
99606	Face-to-face	15 minutes
99607	Face-to-face	15 minutes
98966	Telephone	5-10 minutes
98967	Telephone	11-20 minutes
98968	Telephone	21-30 minutes