Assessment of an Employee Wellness Clinic with the Clinical Pharmacist Practitioner Model

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Abstract

Objective: To assess outcomes of an employee Chronic Conditions Management Program (CCMP) with the clinical pharmacist practitioner (CPP) model in a Patient-Centered Medical Home (PCMH).

Methods: This IRB approved, cross-sectional, electronic chart review includes patients >18 years old enrolled in CCMP from June 2011 to January 2014 with >2 visits, and with diabetes, and/or hypertension, and/or dyslipidemia. Excluded patients had no biometrics 6 months before or during the study period. The primary outcome is percent of study patients meeting clinical goals vs. published historical rates from the mid to late 2000s from outside studies.

Results: There were 33 included patients. In the non-diabetes group, 67% (95% CI 47.8%-81.4%) met their low density lipoprotein (LDL) goal vs. 33% nationally, and 82% (95% CI 63.3%-91.8%) met their blood pressure (BP) goal vs. 48% nationally. In the diabetes group, as compared to data from the southwest, 80% (95% CI 58.4%-91.9%) met their Hemoglobin A1c (HbA1c) goal vs. 37%, 65% (95% CI 43.3%-81.9%) met their LDL goal vs. 23%, and 75% (95% CI 53.1%-88.8%) met their BP goals vs. 41%.

Conclusion: Patients enrolled in MAHEC's CCMP have well-controlled diabetes, and/or hypertension, and/or dyslipidemia. Additional research on the value of pharmacists as supervised prescribers in employee wellness programs should be considered.

Key words: Employee wellness, CPP, Clinical Pharmacist Practitioner, Collaborative practice agreement, Ambulatory care, PCMH, Chronic disease state management, Clinical pharmacy

Introduction

Over the last several decades, chronic diseases have shifted from the elderly to the younger, working population.[1] In 2007, 39% of Americans 18-64 years old had at least one chronic condition.[1] The majority of US healthcare costs are associated with chronic diseases.[1] In 2006, 84% of all healthcare spending was for 50% of the total population, all of whom had one or more chronic conditions.[1] The total estimated cost of diagnosed diabetes in 2012 was $245 billion, including $176 billion in direct medical costs and $69 billion in decreased productivity.[2] In 2010, the total estimated cost of heart disease and stroke (the results of uncontrolled hypertension and dyslipidemia) was estimated at $315.4 billion.[2] Because of these rising costs, many US employers have implemented employee wellness programs that focus on prevention and management of chronic conditions to prevent these expensive complications. According to a RAND Employer Survey in 2012, 51% of all employers with 50 or more employees offer a wellness program.[3] Of these wellness programs, 77% offer a lifestyle management component (primary prevention of

chronic disease), and 56% offer disease state management (secondary prevention of complications).[3]

The Asheville Project® began in 1996 as an effort by the City of Asheville, a self-insured government employer in North Carolina, to focus on education and management of diabetes among employees.[4] After success with the diabetes pilot, asthma and hypertension/dyslipidemia programs were added. Patients were provided with education through Mission Hospitals' Diabetes and Health Education Center, and community pharmacists monitored progress and attainment of goals.[4-6] In the diabetes arm, mean HbA1c decreased at all follow-ups, and 81.8% of patients improved at the last evaluation compared to baseline.[4] Mean LDL also decreased at every 6-month follow-up, with more than 50% of patients showing improvement at each visit.[4] At the end of the five-year study period, 64% of patients had an HbA1c of $<7.0\%$ and 44% had an LDL <100 mg/dl.[4] Pharmacist involvement in other chronic conditions such as asthma, hypertension, and dyslipidemia without diabetes resulted in similar improvement in biometrics.[5-6] This study series was the first to show the clinical and financial impact (a return on investment of 4 to 1) pharmacists can have on management of chronic conditions. This model has been replicated in other cities across the country.[7]

In North Carolina, the medical and pharmacy boards may grant prescriptive authority and licensure as a Clinical Pharmacist Practitioner (CPP) to a clinical pharmacist under a collaborative practice agreement with a supervising physician. This allows CPPs to directly initiate, adjust, monitor, and discontinue medications that are listed on the collaborative practice agreement with the supervising provider. Although the Asheville Project® is well-known for demonstrating pharmacist impact on chronic conditions management through patient education and recommendations to providers, little is known about the potential added advantage of incorporating CPPs, or prescribing pharmacists, into this model. Studies have reported a wide range of acceptance rates of pharmacists' recommendations by physicians, from $<20\%$ to $>95\%$, depending on the practice setting, patient population and type of interaction the clinicians share.[8-12] This study is the first to investigate the clinical impact of incorporating the Asheville Project® model in a patient centered medical home (PCMH) with prescribing pharmacists, which may be more efficient and effective.

Methods

The MAHEC Family Health Center is a large, academic, Level 3 PCMH in Asheville, NC. Currently, five CPPs provide comprehensive medication management services for MAHEC patients. In 2011, MAHEC developed a Chronic Conditions Management Program (CCMP) for employees and beneficiaries. The CPP-run CCMP consists of monthly to quarterly 30-minute encounters with documentation of history of present illness, comprehensive medication management, vitals, assessment, and plan. The plan emphasizes healthy habits (nutrition, exercise, weight loss or maintenance), education, and optimization of pharmacotherapy for chronic disease states. CPPs can directly initiate, adjust, discontinue, and/or monitor medications listed in the CPP agreement, and then the documented encounter is reviewed and signed electronically by the supervising physician. The North Carolina CPP agreement can include any class of medication, including controlled substances as long as the CPP has a valid DEA number. Medications on the CPP agreement for the CCMP include any treatment for diabetes, hyperlipidemia, and hypertension. The MAHEC Human Resources Department markets the program as an additional employee benefit. Enrolled beneficiaries receive waived copays for pharmacist visits, health education classes, and waived or reduced copays for medications. Employees also receive free pedometers to encourage attainment of activity goals.

A list of patients enrolled in MAHEC's CCMP was provided by MAHEC's Human Resources Department, and informed consent to use protected health information was obtained for all currently enrolled employee participants. Once informed consent was obtained, patients were screened for inclusion in the study through information in their electronic health record. Eligible participants were at least 18 years old, enrolled in the program between June 2011 and January 2014, seen at least two times in the study period, with any one or a combination of the following: pre-diabetes, diabetes, hypertension, or dyslipidemia. Patients were excluded if he or she had no clinical measurements associated with the chronic condition six months before or during the study period.

The primary outcome measure was percent of patients achieving individualized clinical goals for BP, LDL, and/or HbA1c versus historical rates from published studies conducted at outside organizations. Patients with diabetes or pre-diabetes were evaluated separately from non-diabetes patients, since diabetic clinical goals (LDL and BP) were more stringent based on national guidelines in use during the study period (see Table 1).

Table 1. National standards for clinical goals in use during study period

Dyslipidemia	
Risk Category	**LDL Goal (mg/dl) based on ATP III Update**[13]
CHD Risk Equivalent*, or 10-year risk > 20%**	< 100 (optional < 70)
2+ Risk Factors*** (10-year risk ≤ 20%)	< 130
0-1 Risk Factor	< 160
Hypertension	
Risk Category	**BP Goal (mmHg) based on JNC7**[14]
Patients *without* diabetes or kidney disease	<140/90
Patients *with* diabetes or kidney disease	<130/80
Diabetes	
Risk Category	**HbA1c goal (%) based on ADA guidelines**[15-17]
Short duration, long life expectancy, and no significant cardiovascular disease	More stringent (<6.5)
Standard	<7.0
History of severe hypoglycemia, limited life expectancy, advanced complications, extensive comorbid conditions, longstanding diabetes that is difficult to control	Less stringent (<8.0)

Note. *CHD Risk Equivalents: symptomatic carotid artery disease, peripheral arterial disease, abdominal aortic aneurysm, diabetes.
**10-year risk evaluated by Framingham Risk Calculator.
***Risk Factors: cigarette smoking, hypertension, high-density lipoprotein (HDL) cholesterol < 40 mg/dl, family history of premature CHD (male first degree relative < 55 years; female first degree relative < 65 years), age (men ≥ 45 years; women ≥ 55 years). HDL cholesterol ≥ 60 mg/dl counts as negative risk factor.

The comparison group for BP was taken from the National Center for Health Statistics that showed 48.4% of adults with hypertension were considered controlled in 2007-2008.[18] The comparison group for LDL was taken from the 2005-2008 National Health and Nutrition Examination Survey (NHANES) survey in U.S. adults aged ≥ 20 years, which found that 33.2% of

Americans treated for high cholesterol were at their LDL goal.[19] The comparison group for diabetes patients was taken from a retrospective study of diabetes patients in a large managed care organization in New Mexico, which found that the percent of patients meeting their HbA1c, LDL, and systolic BP goals were 37%, 23%, and 41%, respectively.[20] This study was chosen due to lack of national data about percent of diabetes patients meeting these goals. Secondary endpoints included changes over time in biometric indicators at 6, 12, and 18 months each compared to baseline measurements, and median number and type of direct medication interventions made by the CPP.

Descriptive statistics, including frequency, percent, and 95% confidence intervals were calculated using SAS® software (Cary, NC) at Mission Hospital's Research Institute. Comparison rates falling outside MAHEC CCMP 95% confidence intervals were considered statistically significant differences at $p < 0.05$.

This study was approved by Mission Hospital's Institutional Review Board and MAHEC's Center for Research.

Results

Of the 52 enrolled participants, 33 were included in the study. Major reasons for exclusion were less than two encounters in the study period, no qualifying chronic condition, and age < 18 years old. The majority of patients were female, and hypertension and hyperlipidemia were the most common disease states. Baseline characteristics are summarized in Table 2.

Table 2. Demographics of included participants (n = 33)

Characteristics	**N (%)**
Female	27 (81)
Diabetes or Pre-Diabetes	20 (61)
Hypertension	27 (82)
Hyperlipidemia	27 (82)
	M ± SD
Mean age at enrollment, years	50 ± 12
Median number of visits	4 ± 3

Patients without Diabetes or Pre-Diabetes

Larger percentages of MAHEC patients without diabetes or pre-diabetes met their individualized goals for LDL and blood pressure compared to national data (see Figure 1).[18]

Patients with Diabetes or Pre-diabetes

More MAHEC patients with diabetes or pre-diabetes met their individualized targets for LDL, blood pressure, and A1c compared to the percentages reported in a large outside study conducted in New Mexico (see Figure 2).[20]

Figure 1. Percent of Patients without Diabetes or Pre-diabetes at Individualized Goals

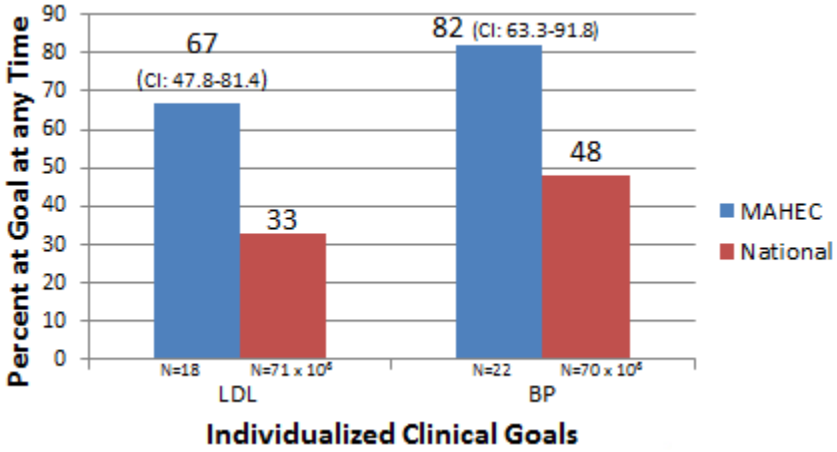
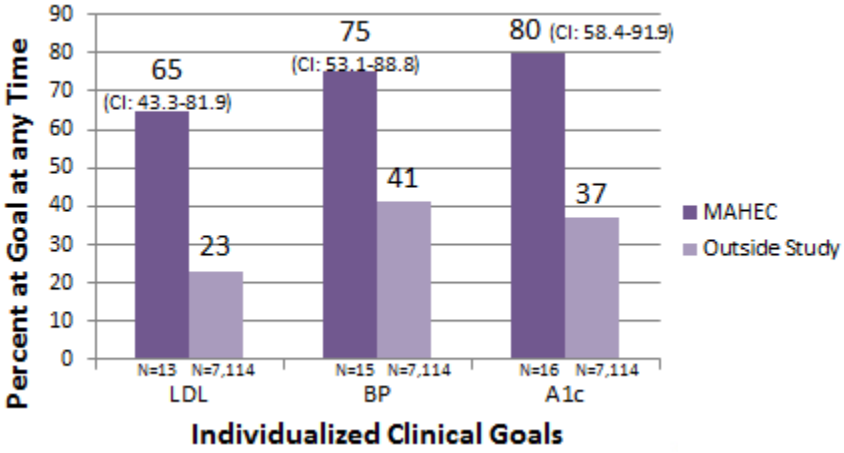


Figure 2: Percent of Patients with Diabetes or Pre-diabetes at Individualized Goals



Change in BP, LDL and HbA1c over Time

Average baseline systolic BP was 130 mmHg, which decreased significantly to 122 mmHg at 6 months ($p = 0.02$), but changes were not statistically significant for the remainder of the study period. Average baseline diastolic BP was 79 mmHg, which remained stable (see Figure 3). Average LDL at baseline was 117 mg/dl, which continued to decrease throughout the study period (see Figure 4). Average baseline HbA1c was 6.2%, which did not change significantly over time (see Figure 5).

Figure 3. BP Change from Baseline

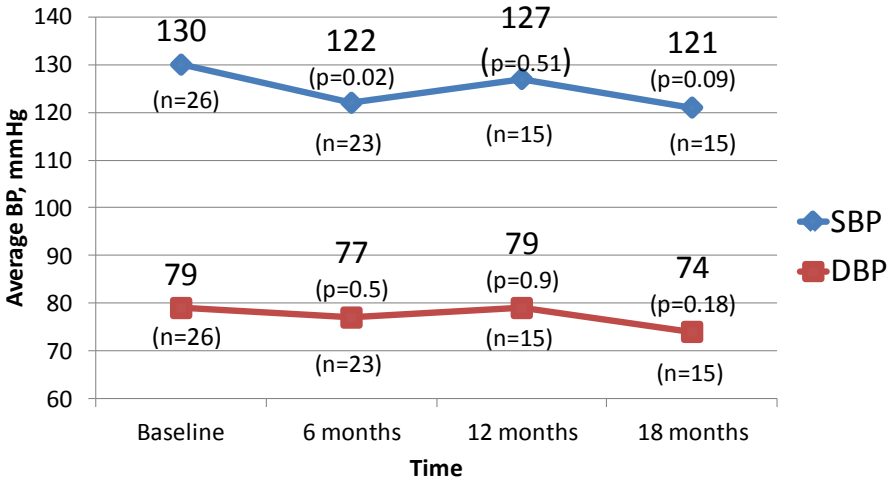


Figure 4. LDL Change from Baseline

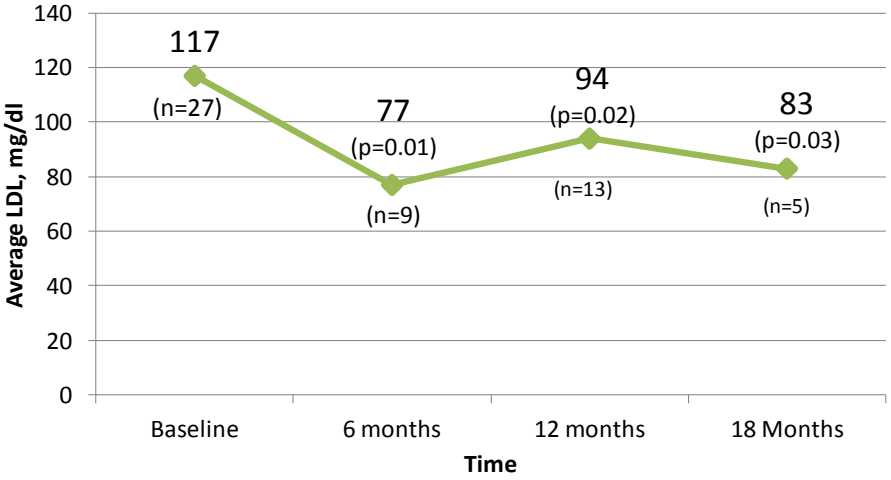
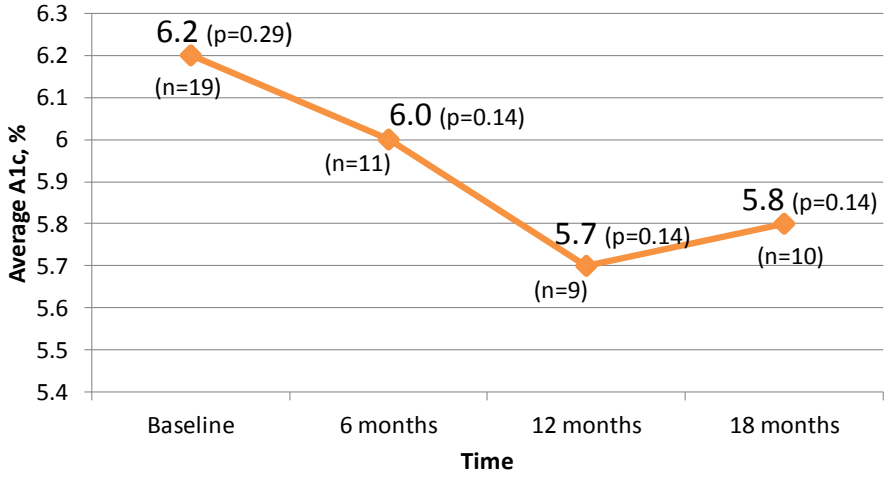


Figure 5. HbA1c Change from Baseline



CPP Pharmacotherapy Changes over Time

Median number of total CPP changes to pharmacotherapies was 0 (range 0-4) at 6 months, 0 (0-2) at 12 months, and 0 (0-6) at 18 months. Median number of dose changes was 0 (0-2) at 6 months, 0 (0-2) at 12 months, and 0 (0-5) at 18 months. Median number of medications added was 0 (0-2) at 6 months, 0 (0-1) at 12 months, and 0 (0-2) at 18 months. Median number of medications stopped was 0 (0-1) at 6 months, 0 (0-0) at 12 months, and 0 (0-1) at 18 months.

Discussion

As mentioned previously, the Asheville Project® model is an evidence-based and replicable strategy to improve the health of employees with chronic conditions. Other studies have demonstrated how clinical pharmacists with collaborative practice agreements can also improve the control of chronic conditions. A 2010 meta-analysis of 224 studies evaluating therapeutic outcomes in pharmacist intervention groups vs. comparison groups found a mean difference of -1.8% (95% CI -2.7 to -0.9) in A1c, -6.3 mg/dl (95% CI -6.5 to -6.0) in LDL, -7.8 mmHg (95% CI -9.7 to -5.8) in systolic BP and -2.9 mmHg (95% CI -3.8 to -2.0) in diastolic BP.[26]

This study is the first to evaluate the impact of prescribing pharmacists on the health of employees. Although this study did not have a true comparator group, a high percentage of patients in MAHEC's CCMP met individualized clinical goals, compared to lower percentages from outside studies.

Even though surrogate markers of cardiovascular health (systolic BP and LDL) improved during the study period, the magnitude of the changes was small likely since baseline averages were already close to goal. Importantly, previous studies have demonstrated the clinical benefit of small changes in clinical markers. For example, each 20 mmHg increase in systolic BP over 115 mmHg doubles the risk of stroke,[21] each 10 mg/dl increase in LDL increases risk of heart attack by 20%,[22] and each 1% drop in HbA1c reduces risk of microvascular complications by ~33%.[23] While not all of these specific changes were achieved in this study, it suggests that small changes in clinical markers may still have significant clinical impacts.

This study had several limitations. The sample size was small, due to a low number of enrolled participants in the CCMP, with only 36% of eligible beneficiaries participating. Since the sample size was based on availability alone, the study may not have been adequately powered. Since its inception in 2011, the MAHEC Human Resources Department has been marketing the program to employees with chronic conditions as an added health insurance benefit. However, perhaps due to low incentive for those who can afford their medications, participation has remained low. After this study was completed, pre-diabetes, asthma, and smoking cessation were added as eligible conditions for enrollment, information about the program is now given at new employee orientation, and it is now advertised at the annual employee health fair to encourage more participation.

Since the study was retrospective, selection bias may have been present. Patients who chose to participate may have been more health-conscious, as evidenced by baseline measurements that were likely close to clinical goals. Therefore, the potential impact of a pharmacist in an uncontrolled population may be more significant. Median interventions made by the CPP remained low throughout the study, likely due to enrollment of healthy patients at baseline who were on appropriate pharmacotherapy. This is in contrast to the Asheville Project®, in which the medication costs increased due to new prescriptions, but with overall decreased health care costs due to reduced inpatient care.[4-6]

During data collection, two significant guideline changes occurred that altered the management of cholesterol and blood pressure.[24-25] However, most patient encounters occurred

before November 2013, and before these guideline changes were implemented. Although meeting specific LDL targets and stringent BP goals may not apply to future management of cholesterol and blood pressure, this type of chronic conditions management was standard practice for both groups (those with and without diabetes) during this time period.

It was not feasible to perform a cost analysis, because MAHEC switched insurance providers at the time of initiation of the CCMP, so historical financial data was no longer available for CCMP participants and non-participants. As more beneficiaries enroll in the program, it will be valuable to know if CPPs have the same financial impact as pharmacists involved in the Asheville Project®.

Due to protocols preventing the release of information about employee health information, a control group of eligible employees not enrolled in the program was unavailable. This led to a potentially inappropriate comparison to historical data since these results were published between 2004 and 2008 and they may not accurately represent current control of chronic conditions in Western North Carolina. Non-national data had to be used for the diabetes population due to paucity of research in this area at the time. It was also not feasible to compare clinical and financial outcomes with the CCMP using the CPP model compared to a non-CPP model, but this would be an interesting future direction for this study.

Individualized clinical goals were used due to the wide variability of patient circumstances in a small patient population. This may limit external validity of this study, in addition to the limitations inherent when data is collected from a single site. Also, it is a clinician specific and site-specific philosophy to treat pre-diabetes and diabetes with similar clinical goals. This may not represent the clinical strategies at other institutions.

Conclusion

Involvement of pharmacists in the health care team continues to be associated with meeting clinical goals for chronic conditions. This is the first study to evaluate the use of a CPP in a PCMH employee wellness program, and it provides a foundation for future research of the value of pharmacists as supervised prescribers in this setting.

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