Advanced Practice Pharmacists: cost of medications prescribed by ClinicaL Pharmacist PractitionErs compared to Primary Care Providers in North Carolina (APPLE-NC)

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Abstract

Introduction: There is a need to discover new methods of cost-effective care as the healthcare system transitions to a model emphasizing quality outcomes. Medication prices continue to rise and must be considered when evaluating the cost of new approaches to treatment. Increased utilization of advanced practice pharmacists represents one solution to appropriate medication use in chronic disease state management. However, the effect on the cost of prescribed pharmacotherapy is unknown.

Objective: To determine the cost of medications prescribed to patients receiving care from both Clinical Pharmacist Practitioners (CPPs) and Primary Care Providers (PCP: physician, family nurse practitioner, and physician assistant) compared to those just receiving care from PCPs.

Methods: This was a retrospective matched cohort analysis. Each cohort was matched by gender, age, and disease states of interest. There were 130 patients total, 65 in each cohort, seen at the University of North Carolina outpatient clinics between November 2008 and November 2011. The primary endpoint was average medication cost per day per patient determined by the average wholesale price (AWP) of prescribed medications. The secondary endpoint was average number of therapy changes per year per patient.

Results: There was no statistical difference in the average medication cost per day per patient in the CPP cohort versus PCP cohort ($38.52 vs. $38.23, respectively; p = 0.97). Patients managed by CPPs experienced a higher average number of therapy changes per year compared to patients only managed by PCPs (21.1 vs. 15.5, respectively; p = 0.032).

Conclusions: CPPs utilized within the healthcare team did not result in an increased medication cost despite being correlated with more therapy changes.

Introduction

The introduction of the Affordable Care Act (ACA) in 2010 catalyzed a reform within healthcare. Once founded on fee for service, healthcare is progressing to a model that incentivizes efficient and high-quality care. Hospitals not meeting performance standards, such as target readmission rates, will be subject to financial penalties with respect to Medicare reimbursements.[1] Similarly, incentives were created to reduce hospital-acquired conditions and those within the lowest quartile can also lose 1% of Medicare reimbursements.[1] Changes to the medical landscape, such as Accountable Care Organizations (ACO), bundled payments for care improvement, and the patient centered medical home are a few strategies already utilized to increase coordination of care, achieve these standards, and reduce spending.[1,2]

Despite these efforts, total spending on healthcare continues to rise. In 2013, healthcare costs were $2.9 trillion with retail prescription drugs contributing $271.1 billion nationally.[3] Medication spending increased by 12.6% in 2014, and the Centers for Medicare and Medicaid Services (CMS) expect a growth of 6.3% annually from 2015-2024 partly due to the increase in newly insured patients under the ACA.[3,4] Pharmacists are medication experts and expanding their clinical services can reduce overall healthcare spending. The Asheville Project found consultations with community-based pharmacists reduced the average amount paid per patient year from the insurer's perspective for both cardiovascular and diabetes related medical costs.[5,6] However, medication expenditures increased in both studies by as much as 290%.

Collaborative drug therapy management (CDTM), defined as a collaborative practice agreement between a physician and pharmacist that allows pharmacists to initiate, monitor, and adjust drug regimens, is permitted to varying degrees in 48 states.[7] However, four states, which include California, Montana, New Mexico, and North Carolina, enable expanded scopes of practice and prescribing authority.[8,9] North Carolina passed the Clinical Pharmacist Practitioner Act on July 1, 2000 enabling pharmacists meeting specific post-graduate training to provide drug therapy management under a protocol of a supervising physician.[10,11] Drug therapy management includes initiating or modifying drug therapies, which may include controlled substances, and ordering lab tests**.** There is a lack of literature examining the effects advanced practice pharmacists, such as CPPs, have on patient outcomes and cost of care. The medication arm of the APPLE-NC study aims to explore the effect of CPPs on medication costs for Medicare beneficiaries.

Methods

Design and participants

This was a 36-month retrospective matched cohort study. The study population consisted of every Medicare beneficiary seen by a PCP or CPP at the University of North Carolina at Chapel Hill Healthcare System (UNC) for chronic disease management. The outpatient clinics included: Internal Medicine, Endocrine, Family Medicine, Outpatient Oncology, Solid Organ Transplant, Geriatrics, and Anesthesia Spine Center. The North Carolina Translational and Clinical Sciences Institute collected claims data on every patient seen by either a CPP as a referral from the patient's PCP or managed by a PCP alone at the clinics. All eligible patients were separated into either a CPP or PCP cohort and matched by age, gender, and ICD-9 codes for chronic disease states of interest using SAS software, version 9.2 (SAS Institute, Inc., Cary, NC (2008)) and randomly selected for inclusion using Microsoft Excel®.

Inclusion and Exclusion Criteria

Medicare patients were included if they were seen between 11/01/08 through 11/01/11. All patients required an ICD-9 code for one of the following chronic disease states of interest: hypertension, type 2 diabetes mellitus, or peripheral neuropathy. These disease states were selected because of their prevalence and associated complexity of pharmacotherapy management. Patients in the CPP cohort were included in the analysis if they had at least two CPP visits in addition to two PCP visits during the study period. This requirement was to demonstrate continuity of care between the CPP and PCP. Patients in the PCP cohort were included if they were seen at least twice by a PCP during the study period and were not managed by a CPP. Dual eligible Medicare and Medicaid patients were excluded.

Outcomes

The primary endpoint was the difference in average medication cost per day per patient. The secondary endpoint was average number of therapy changes per year per patient defined as a dose increase or decrease, or drug initiation or discontinuation.

Medication History

Medications were tracked using WebCIS, an electronic medical record (EMR) utilized by UNC during the study period. Only prescription medications were included in the cost analysis. Herbal supplements, vitamins, minerals, and medications only available over-the-counter were excluded. These products were not always initiated by the practitioner and therefore were not accurately recorded in the EMR.

Cost and Therapy Change Calculation

All medications were priced according to the 2009 AWP listed within the 2010 edition of Redbook.[12] The manufacturer with the lowest AWP was used for each medication, excluding repackagers, to maintain consistency. All medications were assumed to be generic unless only brand was available during 2009. Boxed medications, such as topical preparations and inhalers, as well as oral medications prescribed, "as needed" (PRN) were priced as a one-month supply unless the prescription directions recorded in the EMR indicated exact quantities. If oral PRN medications did not indicate quantities, they were excluded from pricing and were only evaluated for therapy changes.

Medication cost was calculated by multiplying the number of drug units used during the treatment duration by the AWP. Drug unit was defined as a tablet, milliliter of solution, or box of medication (e.g., inhaler, topical). Treatment duration was defined as time from first to last recorded medical visit. Adherence was assumed to be 100% to maintain consistency between cohorts. Total cost was divided by the number of days seen by a provider to generate cost per day. Total therapy changes was divided by the number of days and multiplied by 365 to standardize by year. Standardizing cost and therapy changes by time allows for direct comparison of patients managed for different durations at UNC.

Statistical analysis

Assuming a medium Cohen's effect size of 0.5 standard deviations, a sample size of 130 subjects was needed to achieve an 80% power using a two-tailed t-test and alpha of 0.05. Total cost and therapy changes were analyzed using two-tailed matched pairs t-tests.

Results

Baseline demographics are listed in Table 1. The average age was 64 years and 61.5% of all patients were female. Baseline clinical variables are shown in Table 2. Mean HbA1c was significantly higher in the CPP cohort compared to the PCP cohort (7.5 vs. 6.8, respectively; p = 0.023).

Table 1. Baseline demographics.

	CPP (n=65)	PCP (n=65)
Female – no. (%)	40 (61.5)	40 (61.5)
Male – no. (%)	25 (38.5)	25 (38.5)
Age, Average – year	64	64
Age < 65 years – no. (%)	27 (41.5)	27 (41.5)
Age ≥ 65 years – no. (%)	38 (58.5)	38 (58.5)
Caucasian – no. (%)	41 (63.1)	38 (58.5)
African American – no. (%)	22 (33.8)	26 (40.0)
Hispanic – no. (%)	1 (1.5)	1 (1.5)
Asian – no. (%)	1 (1.5)	0 (0.0)
Hypertension – no. (%)	63 (96.9)	63 (96.9)
Diabetes, Type 2 – no. (%)	28 (43.1)	36 (55.4)
Peripheral Neuropathy – no. (%)	34 (52.3)	31 (47.7)
Hypertension only – no. (%)	16 (24.6)	14 (21.5)
Diabetes only – no. (%)	0 (0.0)	0 (0.0)
Peripheral Neuropathy only – no. (%)	2 (3.1)	2 (3.1)
Hypertension and Diabetes – no. (%)	15 (23.1)	20 (30.8)
Hypertension and Peripheral Neuropathy – no. (%)	19 (29.2)	13 (20.0)
Diabetes and Peripheral Neuropathy – no. (%)	0 (0.0)	0 (0.0)
All Disease States of Interest – no. (%)	13 (20.0)	16 (24.6)
Smoker – no. (%)	11 (16.9)	11 (16.9)
Non-smoker – no. (%)	54 (83.1)	54 (83.1)
Treatment for Hypertension – no. (%)	59 (90.8)	57 (87.7)

Table 2. Baseline clinical variables.

	CPP (n=65)		PCP (n=65)		
	Mean	**95% CI**	**Mean**	**95% CI**	**p-value**
Body Mass Index – kg/m²	31.2	29.4 - 33.0	31.0	29.3 - 32.6	0.4878
10 year CVD risk – %	23.3	18.1 - 28.5	22.7	17.8 – 27.7	0.802
Systolic Blood Pressure – mmHg	132.4	127.3 - 137.5	136.6	131.2 - 142.0	0.267
Total Cholesterol – mg/dL	184.2	169.4 – 199.0	182.4	168.0 - 196.8	0.859
High Density Lipoprotein – mg/dL	51.2	46.6 – 55.8	53.3	48.2 - 58.3	0.536
Hemoglobin A1c – %	7.5	6.8 – 8.2	6.8	6.2 – 7.3	0.023
Brief Pain Score	7.2	6.2 – 8.2	6.5	8.0 – 5.0	0.368

There was no statistical difference in the primary endpoint of average medication cost per day per patient. The medications prescribed to the CPP cohort cost on average $38.52 per day per patient and $38.23 per day per patient in the PCP cohort (mean difference $0.29; p = 0.97) (Table 3). Patients in the CPP cohort required more average therapy changes per year than patients in the PCP cohort (21.1 vs. 15.1, respectively; p=0.032).

Table 3: Average difference in medication cost per day and therapy changes per year.

	CPP	PCP	Mean Difference	P-Value
Medication Cost, Average – $/day	$38.52	$38.23	$0.29	0.97
Therapy Changes, Average – changes/year	21.1	15.5	5.6	0.032

Discussion

Medication cost is an important factor when assessing overall healthcare efficiency. The medication arm of the APPLE-NC study provided an estimate of the total cost of medications prescribed to Medicare patients managed only by PCPs compared to those also managed by CPPs. A matched cohort design was utilized to reduce variability in disease state complexity while still enabling enough eligible patients for inclusion in the analysis. Age, gender, and three disease states of interest were identified for this purpose. Hypertension and type 2 diabetes mellitus were selected because of their known prevalence within the UNC outpatient clinics and ease of monitoring disease state management. In addition to total cost of care, the overall APPLE-NC study analyzed efficacy of treatment. Hypertension and diabetes mellitus have target clinical biomarkers (blood pressure and glycosylated hemoglobin, respectively) recommended by national guidelines that allowed for objective comparison between cohorts. Peripheral neuropathy is a subjective measure and therefor not as easily comparable, however, it was selected because of its complexity in pharmacotherapy management and presumed interrelatedness with diabetes mellitus at UNC clinics. After randomization, it was discovered that some patients had disease states of interest that were not linked with the appropriate ICD-9 codes. For example, some patients carrying only the ICD-9 code for hypertension also had diabetes. Therefore, cohorts were accurately matched on gender and age only. The accurate diagnoses per the EMR are reflected in table 2.

Baseline characteristics were similar between both cohorts except for mean Hemoglobin A1c, which was significantly higher in the CPP cohort. It was hypothesized that that the utilization of advanced practice pharmacists would be associated with a higher cost of medications because patients managed by pharmacists generally have multiple comorbidities, complex drug regimens, or are refractory to standard therapies.[13,14] However, there was no significant difference in medication costs despite more therapy changes in the CPP cohort. This may be caused by a few reasons that were not directly measured within this study: 1) CPPs utilize more, low cost medications to optimize therapy 2) The adjustments made by CPPs were primarily for dose optimization, not addition of new therapies 3) Number of therapy changes does not drive overall cost of medications. Additionally, a confounding variable is that CPPs participated in an anticoagulation clinic included in the study. This clinic may have contributed to the large number of therapy changes per year, as CPPs were influential in adjusting warfarin doses.

Data collected in this study were included in the overall APPLE-NC study, which found patients managed by PCPs in conjunction with CPPs were as likely to reach their disease state goals as patients only managed by PCPs. Additionally, there was no difference in medical charges, defined as the cost of inpatient admissions, emergency department visits, and outpatient visits identified using Medicare claims data.[15]

Limitations

There are limitations that should be considered when assessing the impact of the medication arm of the APPLE-NC study. It has a very small sample size of 130 patients. However, many more patients qualified for inclusion and could be utilized for subsequent research. Although the cohorts were correctly matched by age and gender, there were inconsistencies with the claims data and diagnoses recorded in the EMR. This may partially be due to a limited search method for disease states. Another limitation is the use of AWP for medication prices. Pharmacies and healthcare systems may obtain medications at prices lower than AWP, depending on contractual agreements, and the true cost would be more accurately reflected in Medicare claims data. AWP was also limited to one year. However, this was done to reduce the effect of AWP variability that may not accurately correlate with medication price fluctuations. Additionally, the data set only captured medical visits within the UNC Healthcare system. Medications prescribed at visits to outside hospitals, such as an urgent care facility, would not be included in the total costs. As previously stated, there is an outpatient anticoagulation clinic that CPPs participate in, which could confound the results of total therapy changes. As a retrospective study, there are limitations to extracting information from the EMR. There may be differences in documentation styles between CPPs and PCPs affecting the quality of data utilized to generate medication histories.

Implications

Although CPPs appear to contribute expertise without increasing overall medication spending, there are barriers to implementing similar models ubiquitously. Pharmacists working collaboratively with physicians are not reimbursed directly for their services, and must use an "incident to" billing method.[16] CPT codes range from 99211 to 99215, often referred to as levels 1-5, with increasing complexity and fees respectively. Many CPPs are required to bill as a Level 1 visit, which is described as requiring five minutes typically to manage minimal problems without the need of a physician (Table 4).[17] Scott et al. found CPPs billed on average $51,322 during 1,658 patient encounters per year from 2007-2011 in anticoagulation and pharmacotherapy clinics at the Mountain Area Health Education Center Family Health Center.[16] They estimated these charges would increase to an average of $110,854 per year and $164,565 per year if CPPs could bill at levels 3 and 4, respectively. Lack of provider status and ability to bill for services align with the perceived barriers of CPPs. It was the most common challenge to clinical practice noted by 55.2% of active and inactive CPPs responding to a survey conducted in 2011.[18] Currently, there is legislation within congress, H.R. 592 and S. 314, that amends title XVIII of the Social Security Act. If passed, pharmacists will receive "80 percent of the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848 if such services had been furnished by a physician."[19] Increasing the compensation to match the services pharmacists are already providing will magnify their ability to deliver cost-efficient healthcare.

Conclusion

This study demonstrated that the involvement of advanced practice pharmacists in chronic disease state management did not result in a difference in total medication costs despite an increased number of therapy changes. The overall APPLE-NC trial can serve as the foundation for other health systems to evaluate the care delivered by pharmacists on a larger scale and advocate for their recognition as providers.

Table 4: CPT/HCPCS code descriptions.*

Code	Code Description	Problems	Time Involved (minutes)	Comments
99211	No documentation requirements; may not require the presence of a physician	Minimal	5	"Level 1" visit
99212	At least two of the following: problem-focused history, problem-focused examination, straightforward decision making	Self-limited or minor	10	"Level 2" visit
99213	At least two of the following: expanded problem-focused history, expanded problem-focused examination, medical decision making of low complexity	Low to moderate severity	15	"Level 3" visit
99214	At least two of the following: detailed history, detailed examination, medical decision making of moderate complexity	Moderate to high severity	25	"Level 4" visit
99215	At least two of the following: comprehensive history, comprehensive examination, medical decision making of high complexity	Moderate to high severity	40	"Level 5" visit, typically involves a complete physical examination

*Adapted from references 16 and 17.

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