Impact of a Physician-Led Point of Care Medication Delivery System on Medication Adherence

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ABSTRACT

Objectives: To evaluate the impact of a physician-led point of care medication delivery system (POCMDS) on adherence to glucose, blood pressure, and cholesterol-lowering medications.

Study Design: Prepost intervention observational study.

Methods: From December 15, 2010, to December 14, 2012, we conducted a prepost analyses of 800 Medicare Advantage members receiving care in a network of capitated clinics in south Florida serving a predominantly minority population. Eligibility criteria included a diagnosis of diabetes for at least 1 year, taking at least 1 of the 3 classes of medications, and having received care in the clinic network for at least for 12 months before and after the POCMDS implementation. Our primary outcome is the medication possession ratio (proportion of days covered [PDC]) for each class of medication.

Results: We found an absolute increase of 17 percentage points (95% CI, 13-20) in the PDC for oral antidiabetic agents, 29 (95% CI, 26-32) for cholesterol medications, and 21 (95% CI, 19-23) for blood pressure medications. Most of the subjects (80%) reported POCMDS was more convenient than using retail pharmacies. By having the POCMDS prioritize generic medications, the increases in adherence were not associated with increased pharmacy costs. At baseline, over half the patients were at goal for low-density lipoprotein cholesterol, glycated hemoglobin, and systolic blood pressure; thus, we did not detect any additional improvements in these intermediate clinical outcomes.

Conclusions: Among elderly minority patients with diabetes, a POCMDS improved adherence to various medications classes without increasing pharmacy costs. Thus, POCMDS may be of interest to policy makers, particularly in our current era of healthcare reform.

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Medication adherence is an important barrier to the delivery of quality health services, particularly among minority populations and the elderly.[1] Lack of medication adherence increases morbidity and mortality, resulting in up to $170 billion in additional health expenditures every year.[2,3] Twenty percent to 50% of patients with a complex illness, such as heart failure or type 2 diabetes, have inadequate adherence to medications known to improve clinical outcomes.[4-7] In spite of extensive documentation on the impact of adherence on outcomes and costs, we have not been able to identify sustainable solutions.[8] Successful interventions have been multi-modal, as well as difficult to implement and to sustain in real-world clinical practice settings dependent on clinical revenue streams for most of their funding.[9] The fact remains that medication adherence affects outcomes that will be used to measure physician performance, such as low-density lipoprotein cholesterol (LDL-C), glycated hemoglobin (A1C), or blood pressure.[10,11]

We examined the impact of allowing patients to receive medications directly from their healthcare provider in the context of a feasible financial model. The study intervention—an automated point of care medication delivery system (POCMDS)—was implemented as a pharmacy replacement service in a network of capitated clinics. We present a prepost evaluation of the impact of a POCMDS on medication adherence among a cohort of elderly patients with diabetes.

METHODS

Study Setting

The intervention was implemented and evaluated in 5 capitated clinics located in underserved areas across south Florida. The clinics belong to Chen Neighborhood Medical Centers (CNMC) network. Approximately 75% of the CNMC patient population is black and 25% white; 20% of the population is

of Hispanic descent. Patients are insured through Medicare Advantage plans. CNMC has a preventive model of care that mandates scheduling patients for primary care provider visits every 1 to 2 months.

Take-Away Points

Using a prepost design, this study evaluates the impact of a point of care medication delivery system (POCMDS) in a diabetic, mostly minority population from an at-risk clinic. We found that medication adherence measured with an objective method increases from 17 to 29 percentage points for hypertension, statins, and antidiabetic medications. The real-world impact of this study is:

- A simple and inexpensive POCMDS improves medication adherence by removing most of the barriers.
- The system does not increase costs, mostly because of the use of generics.
- The implementation of the system is feasible in at-risk practices.

Intervention

From 2008 to 2009, CNMC deployed the POCMDS in 5 practices. The intervention was developed through a process of stakeholder engagement and consists of delivering medications at the time of clinical encounters to improve medication adherence. The system is an electronic controlled-access medication storage cabinet that automatically dispenses medications when ordered. During the encounter, providers place prescription orders through the electronic health record (EHR), which interfaces with the POCMDS. The system then releases a pre-sealed labeled medication bottle, and staff takes the medications to the ordering provider, who gives at least a 90-day supply of medications to the patient along with printed instructions. An outsourced company assists in completing regulatory issues, setting up the required hardware and software, establishing processes for adjudication of claims, and stocking and restocking inventory. The POCMDS formulary consists mostly of generic medications that require no co-payments. In the pre-POCMDS period, physicians could prescribe any brand or generic medication and co-payments would vary accordingly.

Study Design and Study Population

In 2010, with support from the Robert Wood Johnson Foundation, investigators from the University of Miami conducted an independent evaluation of the POCMDS. As the system had already been implemented in all sites, we performed a prepost intervention observational study.

For our analysis, we focused on subjects with diabetes (*International Classification of Diseases, Ninth Revision, Clinical Modification* code 250.xx). We included subjects who had a diagnosis of diabetes in the preintervention period who used medications for at least 1 of 3 indications (oral antidiabetic, blood pressure, or LDL-C–lowering medications) for 12 months before and after enrolling in the POCMDS. The purpose of this strategy was to compare adherence to medications for the same indication before and after the intervention.

Primary Outcome

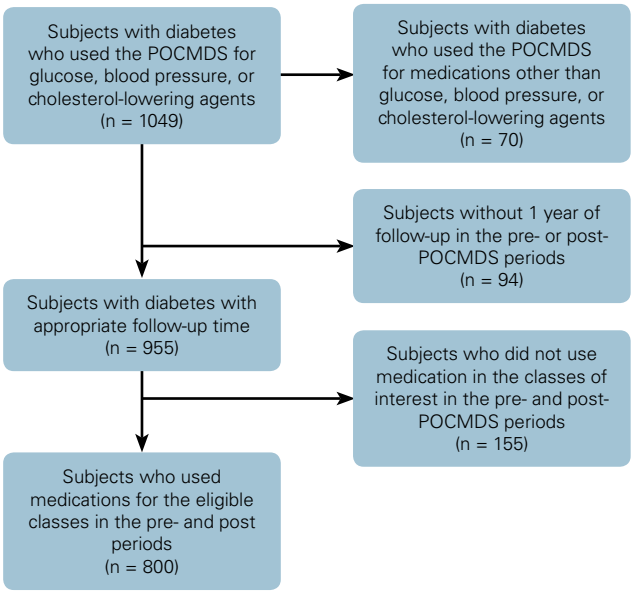
Our primary outcome was the proportion of days covered (PDC), a validated objective measure particularly useful for calculating adherence to multiple concurrent chronic medications.[12-14] PDC is defined as the sum of the days each patient has availability to at least 1 medication for each class or indication during the pre- and post periods divided by the duration of each follow-up period. Data on medication supply were obtained using pharmacy claims files—which include National Drug Codes (NDCs)—as well as the date a medication was obtained, and number of pills dispensed.[15] The NDCs were manually reviewed and each relevant medication was classified as an oral antidiabetic (OAD), blood pressure, or cholesterol-lowering agent. We will refer to these 3 categories as medication classes. For the few medications with multiple possibilities of daily dosing, such as metformin, we manually retrieved the dose and frequency from the EHR. We calculated the PDC for each medication class—hence, each subject could have up to 3 PDCs.

For each PDC, the index date was the first date in which a subject used the POCMDS to refill a medication in that class. For subjects who were taking more than 1 medication within the same class, we calculated the overall PDC across each class without accounting for terminal gaps in use.[16] For example, if a subject used a beta-blocker for 7 months and a calcium channel blocker for 5 months with 2 months of overlap, the numerator included the days the subject was covered by either medication. Our PDC was interval-based and used 365 days as the denominator to avoid overestimation of adherence. In addition to PDC measured as a continuous outcome, we also reported PDC as a dichotomous variable with adequate adherence defined as a PDC of 0.80 or above.[7,12,14,17] The strategy was nondifferential, as it was similarly used for the pre- and post periods.

Secondary Outcomes

Intermediate clinical outcomes. Laboratory data on A1C and LDL-C were abstracted from the EHR. For the pre-POCMDS analyses, we used the laboratory values measured immediately before enrolling in the POCMDS for that particular class. For the post-POCMDS analyses, we used all the values within a year after the implementation to be able to conduct a repeated measures analysis. We used the EHR to obtain blood

Figure 1. Flowchart of Patient Recruitment



POCMDS indicates point of care medication delivery system.

pressure data for all subjects who used blood pressure medications in the pre- and post periods. We collected all blood pressure values present in the EHR for an average of 10 blood pressure recordings per patient in each of the 2 study periods. We calculated the mean and median LDL-C, A1C, and blood pressure before and after using the POCMDS.

Pharmacy costs. We used CNMC claim data to collect the per-patient cost of prescription medications for each medication class. These values represent the payments made per prescription to retail pharmacies in the preintervention period or to the outsourced POCMDS company in the postintervention period (this cost includes a per-prescription dispensing fee). We added all the values in the cost field for each class. In our analysis, we report the mean difference in cost for the 3 classes of medications the year before and after enrolling in the POCMDS.

Patient satisfaction. As part of the evaluation, we also conducted a patient satisfaction survey in a sample of 270 patients in 4 of the implementation sites. In this report, we present data on the proportion of patients who agree or strongly agree that the implementation of the POCMDS had a positive impact on: 1) convenience, 2) patient–physician communication, 3) medication adherence, and 4) the quality of care they are receiving.

Statistical Analyses

To test prepost intervention differences in PDC, A1C, LDL-C, and blood pressure, we used a paired *t* test. To account for the within-subject correlation of our measures and the effect of time, we used linear mixed regression models, which also included categorical classification variables to index time intervals pre- and post intervention. The regression parameters from this model were examined to determine the statistical significance of our continuous outcomes pre- and post intervention at $P < .05$. As this was a prepost comparison on the same subjects, we did not adjust for traditional covariates, such as gender or race. Models that adjusted for small changes in age and comorbidity during the time period had nearly identical results as our reported findings. Lastly, to examine PDC as a dichotomous variable, we used the McNemar test. Because of the distribution of the costs data, we used the Wilcoxon Signed Rank test to compare pharmacy costs in the pre- and post periods.

The fitness of the data was assessed using the deviance ratio. Analyses were performed using SAS version 9.0 (SAS Institute, Cary, North Carolina), and all significance tests were 2-tailed. The University of Miami Institutional Review Board approved the study.

RESULTS

Baseline Characteristics

Figure 1 shows the process for inclusion and exclusion into the study. We identified 800 eligible subjects, and of them, 84% used blood pressure medications and 48% used a cholesterol-lowering medication in both the pre- and postintervention periods. Interestingly, only 43% of the sample was on OAD agents during pre- and post periods, as many patients were treated only with insulin and/or with lifestyle interventions. However, during the post period, 80 patients started blood pressure medications, 175 started cholesterol medications, and 162 started antidiabetic medications. Table 1 depicts the baseline characteristics of the entire cohort and by medication class.

Medication Adherence and Clinical Outcomes

As shown in Figure 2, we found statistically significant improvements in prepost PDC comparisons in all 3 classes of medications. We found an absolute increase in PDC of 17 percentage points for OAD (95% CI, 13-20), 29 (95% CI, 26-32) for cholesterol medication, and 21 (95% CI, 19-23) for blood pressure medications. Using the dichotomous PDC, the proportion of subjects with medication availability at least 80% of the time increased from 33% to 48% for OAD ($P < .01$), 14% to 40% for cholesterol-lowering medications, and 46% to 78% for blood pressure medications ($P < .01$). Our linear mixed regression models

Table 1. Baseline Characteristics of the Entire Cohort

	Entire Cohort, N = 800	Diabetes Only, n = 350	Dyslipidemia and Diabetes, n = 387	Hypertension and Diabetes, n = 666
Age, years (SD)	76.24 (7.96)	75.35 (8.24)	76.40 (7.76)	76.44 (7.79)
Female gender, n (%)	460 (58)	196 (56)	224 (58)	392 (59)
Black race, n (%)	611 (76)	275 (79)	291 (75)	521 (78)
Charlson Comorbidity Index score, mean (SD)	4.23 (2.43)	4.61 (2.16)	4.58 (2.37)	4.31 (2.47)
Mean number of pills/daily (SD)	2.52 (2.37)	2.86 (2.65)	2.72 (2.60)	2.62 (2.44)
Median A1C, (IQR)	6.77 (6.28- 7.68)	6.98 (6.40-8.00)	6.87 (6.40-7.78)	6.77 (6.30-7.60)
Median LDL-C, (IQR)	94.00 (78-115)	92.67 (77.67- 115)	93.00 (75-113)	93.00 (74.67-114)
Mean SBP, mm Hg (SD)	N/A	N/A	N/A	136.5 (13)
Median SBP, mm Hg (IQR)	N/A	N/A	N/A	135.6 (127-144)
Mean DBP, mm Hg (SD)	N/A	N/A	N/A	75.9 (7.6)
Median DBP, mm Hg (IQR)	N/A	N/A	N/A	75.4 (69.9-79.4)
Median number of visits before POCMDS (IQR)	5 (2-10)	N/A	N/A	N/A
Median number of visits after POCMDS (IQR)	5 (2-10)	N/A	N/A	N/A

A1C indicates glycated hemoglobin; DBP, diastolic blood pressure; LDL-C, low-density lipoprotein cholesterol; N/A, not applicable; IQR, interquartile range; POCMDS, point of care medication delivery system; SBP, systolic blood pressure; SD, standard deviation.

found very similar results, with the increase in continuous PDC from the pre- to the post periods being 21 percentage points for OAD and blood pressure medications and 28% for cholesterol-lowering medications (P <.001). We did not detect clinically significant improvements in any of our clinical outcomes (P >.05).

Costs and Patient Satisfaction

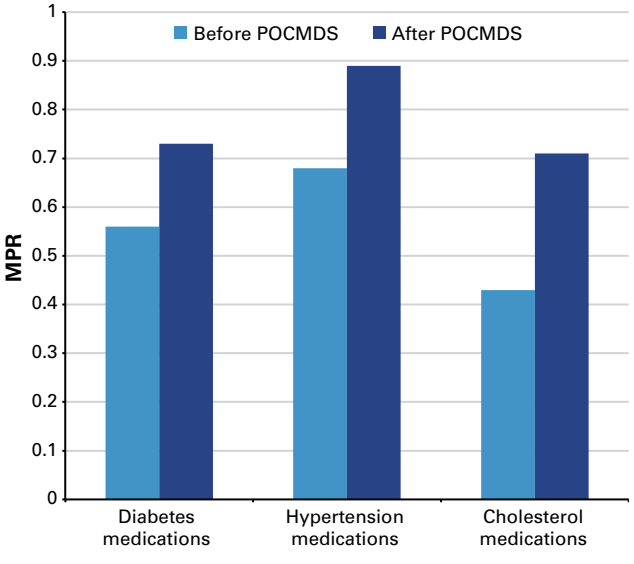
For all 3-drug classes, there was a trend toward decreasing medications costs, but this trend only achieved statistical significance for cholesterol-lowering medications (Table 2). Our survey revealed that the POCMDS was more convenient than filling prescriptions at retail pharmacies for 76% of subjects and that improved the ability to take medications for 87%, patient physician communication for 76%, and perceived quality of care for 80% of elderly individuals with diabetes.

DISCUSSION

We found that in a cohort of predominantly black elderly individuals with diabetes, the delivery of medications by physicians at the time of a clinical encounter improved medication adherence by 20 to 30 percentage points, depending on the medication class. The intervention was well received by patients, most of whom reported high degrees of satisfaction and improvements in their ability to take their medications. The marked increase in medication availability was not associated with increased pharmacy costs.

Our results compare favorably with data from other adherence interventions, which had shown smaller effect sizes.[18] The Agency for Healthcare Research and Qual-

Figure 2. Mean Medication Possession Ratio Before and After POCMDS



MPR indicates medication possession ratio; POCMDS, point of care medication delivery system.

Table 2. Mean Costs by Class in the Same Cohort of Patients With Diabetes Before and After POCMDS

Medication Class	Number of Subjects	Mean Cost in Pre-POCMDS, $ (SD)	Mean Cost in Post-POCMDS, $ (SD)	*P*
Oral diabetes medications	350	214 (432)	167 (392)	.8
Blood pressure medications	665	248 (313)	234 (307)	.4
Cholesterol-lowering agents	387	116 (185)	99 (207)	<.01

POCMDS indicates point of care medication delivery system; SD, standard deviation.

ity concluded that, at present, there is only low strength of evidence to support most medication adherence intervention programs.[19] Successful examples are pharmacist-led approaches, simplified dosing and packaging, disease management programs, motivational interviewing, and most commonly, a combination of these strategies.[9,10,20,21] However, most of these initiatives require start-up and maintenance costs, which limit the ability to translate these interventions into practice without additional funding.

The strengths of the POCMDS are: 1) ability to address multiple known barriers to adherence,[22] such as access, out-of-pocket costs, communication, and medication reconciliation; 2) sustainability achieved by switching to a generic heavy formulary; 3) effective use of time and resources, as providers and staff redirected time previously used for communicating with pharmacies and insurance companies regarding prescriptions toward discussing prescribed medications with patients[22]; and 4) increased accountability in monitoring appropriate medication delivery and use. This model of care fulfills 3 of 4 strategies recommended to improve adherence: reduction of co-payments, use of data infrastructure to support interventions, and using a financial model that rewards the practice for improved clinical outcomes.[23]

Although the relationship between medication refills and intermediate clinical outcomes has been well-established,[15,24-26] our study did not detect improvements in clinical outcomes. This finding has also been noted in other adherence intervention studies.[9,20,27] We speculate multiple reasons for this lack of correlation. First, the majority of patients we evaluated were already at their clinical targets for LDL-C, A1C, and blood pressure. Second, CNMC clinicians report that the POCMDS was implemented at a time when results of randomized studies were dampening their enthusiasm for very tight glycemic and blood pressure control among elderly individuals with diabetes.[28] Lastly, the POCMDS formulary prioritized generic statins. At the time of the implementation, the more potent statins (atorvastatin and rosuvastatin) were not yet available in generic formulation and less potent statins were dispensed instead.

Strengths and Limitations

The strengths of our study are: the inclusion of all subjects with diabetes with comparable data in the pre- and post periods, a rigorous analyses plan, and the availability of a strong information technology infrastructure that allowed us to collect reliable raw data from a variety of sources.

Our study has several limitations. The prepost design limits our ability to establish causality and control for confounders; nevertheless, we used very rigorous inclusion criteria to reduce the likelihood of bias and performed sensitivity analyses adjusting for all available covariates. Also, CNMC baseline intermediate measures were better than those reported for patients in other capitated health systems serving vulnerable populations.[29,30] The impact on intermediate outcomes may be higher among less optimally controlled subjects. Generalizability can be limited as all clinics belong to the same capitated network. However, the POCMDS has been implemented in 23 more clinics across 4 states since we began our evaluation. Pharmacy claims data do not provide a direct measure of medication use and can be influenced by social desirability factors, although this is mitigated, in part, by the requirement of bringing bottles that need refills to the clinic visit. Lastly, the calculation of PDC by class does not capture adherence to individual medications and could overestimate adherence; however, the same approach was used to analyze the pre- and post-POCMDS adherence.

CONCLUSIONS

The implementation of the POCMDS led to large improvements in medication adherence. The intervention had high levels of acceptability and did not result in greater pharmacy costs to the capitated health system. Future studies with larger samples should evaluate the impact of the POCMDS on clinical outcomes among diverse populations, as well as its impact on healthcare utilization and overall costs.

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