TBM

Evaluation of a self-management implementation intervention to improve hypertension control among patients in Medicaid

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Abstract

Elevated blood pressure can lead to serious patient morbidity and mortality. The aim of the study was to evaluate the implementation of a tailored multifaceted program, administered by care managers in a Medicaid setting to improve hypertension medication adherence. The program enrolled 558 Medicaid patients. Patients had at least one phone call by care managers. The individually tailored program focused on improving lifestyle and medication adherence. The primary outcome was the medication possession ratio (MPR), calculated using fill history from pharmacy claims. We observed an improvement of medication possession from 55% 9–12months prior to program enrollment to 77% 9–12months post initiation of the program. We demonstrated 12month sustainability and increased MPR. Personal interaction by phone allows the intervention to be tailored to participants' current concerns, health goals, and specific barriers to achieving these goals.

Keywords

Medication adherence, Hypertension, Medicaid, Health care disparities

Implications

Practice: A brief, tailored disease/self-management support for patients with increased CVD risk resulted in improvements of hypertension medication possession from 55% 9–12 months prior to starting the program to 77% 9–12 months after initiation of the program in a sample of Medicaid enrollees.

Policy: With enactment of the Patient Protection and Affordable Care Act, the current program may help ensure improve access to quality care among individuals with chronic diseases.

Research: Further research is needed to examine the long term sustainability of this program and its potential cost savings.

If not properly controlled, elevated blood pressure (BP) can lead to serious patient morbidity and mortality, including stroke, coronary heart disease, myocardial infarction, congestive heart failure, and death [1]. *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7) advocates the use of effective therapies that promote BP goals of <140/90 for patients without diabetes or renal disease [1, 2]. However, despite widespread guideline promotion, approximately 29% of the US population has hypertension, and only ≈50% of people in the USA with hypertension is controlled to this goal [3]. Inconsistent patient adherence to the prescribed treatment regimen is known to contribute to poor rates of BP control and improving medication adherence has been shown to be effective in improving BP [4–6].

The Health Decision Model (HDM), which combines decision analysis, behavioral decision theory, and health beliefs, is useful to identify patient characteristics related to treatment adherence and subsequent blood pressure control [7]. The HDM is useful for understanding the factors related to blood pressure control; however, it does not comprehensively explain poor blood pressure control in hypertensive patients. We have expanded upon this model by including patient characteristics such as memory, lifestyle behaviors, medication regimen, and experience of side effects associated with antihypertensive medication. We also considered the social and cultural environment (social support and trust in healthcare), medical environment (access to care), and physician characteristics (communication style) [7, 8].

Implementation of new modalities of care into routine healthcare delivery does not usually happen easily or completely [9]. Moreover, the effectiveness of a focused clinical intervention can be reduced after large-scale implementation. Successful implementation generally requires a comprehensive approach, in which barriers and facilitators to change in a specific setting are targeted [10]. It is important that interventions are simple and feasible to implement in busy clinical practices.

The aim of the present study was to evaluate the implementation of a multifaceted program, tailored to patients and administered by registered nurse care managers in a Medicaid setting to improve hypertension medication adherence as measured by prescription fill patterns. While in this quality initiative, only medication possession data were available, the program focused on adherence to treatment including medication. Focusing on medication adherence among a population of Medicaid is important because these individuals typically are sicker, have greater number of comorbidities, and are more likely to being struggling with other non-health stressors that result in barriers to receiving care relative to individuals with private insurance [11]. Further, the Institute of Medicine has noted the need to learn more about the impact of health behavior interventions on medication adherence [12]. The program implemented was based upon prior work indicating that improvements in medication adherence was a driving factor in demonstrating improvements in systolic blood pressure and blood pressure control in primary care clinics in the Veterans Health Administration [13] and university affiliated primary care clinics [14].

METHODS

Setting

The program occurred in three of 14 community-based networks that are part of the statewide Community Care of North Carolina (CCNC) program, an outgrowth of a two-decade effort in North Carolina to better manage the care of Medicaid patients through enhanced patient-centered medical homes. This public–private partnership has five primary components: (1) linkage of Medicaid recipients to a primary care medical home, (2) linkage of primary practices to one of 14 local Medicaid-supported networks that provide shared accountability for the quality care provided to enrolled Medicaid patients; (3) population-based health tools (e.g., evidence-based guidelines, monitoring pharmacy utilization for the population of patients); (4) care management programs that include care coordination, patient self-management support, and targeted care management for high-risk individuals; and (5) the implementation of evidence-based best practice guidelines and the use of extensive chart abstraction and administrative data to provide feedback to providers on the quality of care [15–17]. These features were developed to mirror the components of the Wagner Chronic Care Model for the organization of primary care [18, 19].

At a statewide level, CCNC is operated by North Carolina Community Care Networks, Inc. (NCCCN), a non-profit, tax-exempt organization that facilitates statewide contracting between the 14 CCNC networks and healthcare payers, including Medicaid and Medicare, and allows the participating regional networks to share information technology and other centralized resources. NCCCN also serves as a centralized resource for quality improvement, reporting, web-based case management system, practice support, and provider and member education [15, 16, 20].

This was not a research project. Rather, it was a quality improvement program of CCNC in three of its provider networks. The Duke IRB reviewed the project and subsequently determined that it is not research.

Patient eligibility

Potentially eligible study patients were identified through weekly data extractions from Medicaid eligibility and claims administrative databases. Initial inclusion criteria were: (1) having a diagnosis of hypertension during the previous year (hypertension ICD9 code of 401.0, 401.1, or 401.9); (2) North Carolina Medicaid eligibility for at least 12 months prior to data extraction; (3) enrollment with a primary care provider who is part of a participating CCNC network; and (4) having received a hypertensive medication prescription (ACE inhibitors, beta blockers, calcium channel blockers, diuretics, alpha$_1$ blockers, and/or central alpha$_2$ agonists) in the previous year. Medication adherence analyses were limited to participants who remained Medicaid enrolled, without dual Medicare coverage, throughout the study period (Table 1).

Procedures

Between September 2008 and May 2010, all Medicaid patients meeting program eligibility criteria were identified to the care management staff of three participating CCNC provider networks. The eligible patient lists were updated weekly, were used to identify comorbid conditions such as diabetes or ischemic vascular disease, and determine patient's historical medication possession ratio for blood pressure medications. These factors influenced the prioritization of eligible patients for outreach by the care manager. For example, during the course of the intervention, one care manager found that patients with comorbid diabetes were less likely to want to participate in the program, and focused her outreach efforts toward those without diabetes. Others prioritized outreach to patients with recent emergency department visits or hospitalizations, or to eligible patients who actively responded to a mailed invitation to participate in the program. Care managers contacted patients by mail or phone to invite them to participate in the program. The program aimed at calling patients ten times over the course of 6 months, at approximately 3-week intervals, with a tailored schedule of educational and behavioral support modules.

Table 1 | Baseline sample characteristics

Baseline characteristics[a]	Non-participants (n=3,992)		Participants≥1 Contact (n=558)	
Demographics				
Age (mean age (SD))[b]	46.8 (13.0)		51.1 (9.7)	
Ethnicity				
Non-hispanic	2,521	63.2%	340	60.9%
Hispanic	80	2.0%	11	2.0%
Unreported	1,391	34.8%	207	37.1%
Race				
White	1,497	37.5%	201	36.0%
American Indian/Alaskan Native	164	4.1%	9	1.6%
Asian	9	0.2%	3	0.5%
Black or African American	2,053	51.4%	296	53.1%
Pacific Islander	2	0.1%	0	0.0%
Unreported	267	6.7%	49	8.8%
Gender				
Male	1,185	29.7%	138	24.7%
Female	2,807	70.3%	420	75.3%
Dual status				
Non-dual	3,673	92.0%	492	88.2%
Dual	319	8.0%	66	11.8%
Medication adherence (Avg Index)[c]	0.58		0.65	
Health characteristics				
Body mass index (mean BMI (SD))[d]	N/A		35.12 (9.62)	
Current tobacco user (n=168)[e]	N/A	N/A	55	32.7%
Exercise never or <1 hr/week (n=237)[f]	N/A	N/A	115	48.5%
Medical history				
Diabetic[g]	1,744	43.7%	380	68.1%
AMI[h]	162	4.1%	44	7.9%
IVD[i]	369	9.2%	127	22.8%

[a] Data is displayed as counts and percentages (of 'n') unless noted otherwise

[b] Age is calculated as of May 31, 2010

[c] Average medication adherence index for antihypertensive agents

[d] BMI values were reported by 251 of the 558 participants completing at least one encounter. BMI values were reported by 136 of the 305 participants completing at least four encounters

[e] Participants were first asked about their smoking status during encounter 7. So the denominator for this characteristic=number of participants completing at least seven encounters (n=168)

[f] Participants were asked about their exercise habits during Encounter 5. So the denominator for this characteristic=number of participants completing at least five encounters (n=237)

[g] Diabetes diagnosis defined by claims with primary through sixth ICD-9 diagnosis codes of 250.XX, 357.2X, 362.0X, 366.41 or DRG codes of 294, 295 (version≤24.0) or DRG codes of 294, 295, 637, 638, 639 (version≥25.1)

[h] *AMI* acute myocardial infarction. AMI diagnosis defined by claims with primary through sixth ICD-9 diagnosis codes of 410.XX or DRG codes of 121, 122, 516, 526 (version≤24.0)

[i] *IVD* ischemic vascular disease. IVD diagnosis defined by claims with primary through sixth ICD-9 diagnosis codes of 411.XX, 413.XX, 414.0X, 414.8X, 414.9X, 429.2X, 433.XX, 434.XX, 440.1X, 440.2X, 444.XX, 445.XX or ICD-9 procedure codes of 00.66, 36.01, 36.02, 36.05, 36.06, 36.07, 36.09, 36.1X, 36.2X or DRG codes of 106, 107, 109, 140, 516, 517, 526, 527, 547, 548, 549, 550, 555, 556, 557, 558, 559 (version≤24.0) or DRG codes of 231, 232, 233, 234, 235, 236, 247, 248, 249, 280, 281, 282 (version≥25.1)

Interventions

Tailored behavior self-management intervention

The behavioral intervention was tailored to individuals' circumstances and needs [21]. Patient factors targeted in the tailored intervention included perceived risk of hypertension, memory, literacy, social support, patients' relationship with their healthcare provider, and adherence and side effects of hypertension medication therapy [22]. In addition, the intervention focused on improving adherence to the following five hypertension recommendations: the DASH dietary pattern [23–26], weight loss in the overweight [27, 28], reduced sodium intake [28, 29], regular moderate-intensity physical activity [30, 31], and moderation of alcohol intake [32]. These encounters included a core group of modules potentially implemented during each call (e.g., medication and side effects) plus additional modules activated at specific intervals (e.g., diet, hypertension knowledge, social support) [33]. All information was presented in an easily understood format with a Flesch–Kincaid readability [34] score of <9th grade.

We used the HDM [35] as the theoretical model for identifying factors to focus on in the tailored behavioral intervention. We expanded upon this model by including patient character-

istics such as memory, lifestyle behaviors, and experience of side effects associated with antihypertensive medication [7]. We also used behavior change theories to provide a framework for understanding change in behaviors related to blood pressure control [36].

The intervention was telephone administered for several reasons. First, non-physician delivered interventions has been found to significantly improve patient outcomes for multiple diseases [13, 14, 37–41]. Furthermore, telephone reminders are quite effective in changing patient behavior including improving medication adherence [42], physical activity [43], and enhancing diet adherence [44]. Telephone interventions also provide an opportunity to reach more patients and these interventions may be more acceptable and convenient than in-person interventions [45]. Delivering an intervention by telephone may enhance the intervention's cost-effectiveness [46, 47], primarily due to reduced visit rates. This factor is particularly relevant for our sample because many patients have difficulties traveling to the clinic. In addition, most US homes have phones (>94%) [48] making it potentially useful tool to deliver an intervention.

Institutional support and care manager training

The three locations that implemented the program were the three most enthusiastic regarding the program. Before the program was implemented, the three sites identified hypertension as a problem in their organizations and were supportive of the program. Feedback was solicited both before and during implementation from participating care managers and administrators.

The three care manager interventionists had a panel of their own patients and contacted patients on their own. One care manager at each site was responsible for calling patients. The hypertension program was the primary focus of these individuals during the course of the intervention. The most common challenges the care managers experienced were locating and tracking down patients, particularly given their other responsibilities.

In terms of training, the program was provided to care managers before contacting patients and they spent a few hours reviewing the program. Because the program provides computerized tailored self-management support scripts that are triggered based on patient answers to questions, the program requires minimum training.

Study measures

Baseline

Patient information including age, race, ethnicity, diagnoses, and prescription fill history were obtained from North Carolina Medicaid administrative data.

Study outcomes–antihypertensive adherence

The primary outcome of the study was the medication possession ratio (MPR). MPR is calculated by summing the number of days supply for each prescription fill, which is calculated by the dispensing pharmacist based in the instructions for use (numerator), divided by the number of days in the therapeutic window (denominator) for a given time period. We first calculated the numerator and denominator for each participant by drug class (i.e., participants with claims from multiple drug classes had a numerator and denominator calculated for each drug class). MPR was calculated at the patient level by: (1) summing the numerators for the participant–drug class level for a given patient; (2) summing the denominators from the participant–drug class level of a given patient; and (3) dividing the overall patient numerator by the overall patient denominator. Participants with a MPR ≤0.6 were categorized as having "very poor" adherence, those with a MPR between 0.6 and 0.8 were categorized as having "poor" adherence, and those with a MPR ≥0.8 were categorized as having "good" adherence. Graphs display, for each time period based on the index date of first intervention encounter, the percentage of participants (within the program or network) with very poor, poor, and good medication adherence for antihypertensive agents are presented [49–52].

MPR is an excellent measure in QI programs within systems such as CCNC where all medication data is available. Although precise calculations have varied among studies, MPR is the most commonly used measure for adherence studies that utilize automated pharmacy records. The calculation of MPR used here is the most common [53].

RESULTS

There were 4,550 individuals who met inclusion criteria of which 558 individuals were contacted and received at least a phone contact. For the 558 individuals, the mean age was 51 years, 53% were African-American, and 75% were female. Body mass index at baseline was 35.1% and 48.5% reported none or less than 1 h of exercise per week. Non-participants (n=3,992) were similar to study participants (n=558) in race and ethnicity, but non-participants were slightly younger (47 vs. 51 years) and were more likely to be males 30% vs. 25%.

On average, individuals received 4.5 phone contacts over the 6-month intervention period. During the 90 days prior to the first intervention encounter (index date), 35% of patients were >80% adherent to hypertension medication. By the period of 90–179 days following the first encounter, 54% had >80% adherence for hypertension medication. The proportion increased to 57% for participants out to 270–359 days post first encounter. As indicated in Fig. 1, the average MPR for individuals who received one or more contacts from the care

manager ranged from 55% to 60% from 91 to 720 days prior to initial encounter, the MPR improved slightly from 91 to 180 days to 0–90 days prior to first encounter from 60% to 65%. Within the first 89 days of contact, MPR increased from 65% to 69%. The trend continued to improve such that by 270–359 days out after initial encounter, MPR continued to improve and average 77% (Fig. 1a). Among the 3,992 individuals not contacted for the intervention, MPR ranged from 58% to 61% percent prior to the introduction of the program and increased to 64% by year 1 after the introduction of the program (Fig. 1b).

In terms of categorizing individuals <60%, 60–80%, >80% MPR, Fig. 2 shows similar patterns. Prior to the intervention, 42–54% of individuals were less than 60% adherent with their medications. By 9–12 months after program initiation, however, only 24% of participants were less than 60% adherent. Similarly, the proportion of individuals who were >80% adherent with their antihypertensive medications ranged from 25% to 35% prior to the intervention. After the initiation of the intervention, the proportion of individuals adherent at least 80% of the time improved to 57%.

DISCUSSION

Among a sample of Medicaid enrollees with hypertension receiving a tailored telephone hypertension self-management support intervention, we observed an improvement of hypertension medication possession from 55% 9–12 months prior to starting the program to 77% 9–12 months after initiation of the program. These rates were greater than the approximate 4,000 individuals who also met inclusion criteria, but were not contacted (MPR 64% at 12 months post introduction of the program). These findings were obtained in a low income, Medicaid population using an easy to use nurse care manager, telephone-administered intervention. A majority of the effects observed were obtained with two phone contacts.

In our prior work that is mostly characterized as being efficacy/effectiveness, we were concerned with showing the intervention works and focusing a greater attention to internal validity such as intervention fidelity and inclusion criteria [13, 14, 54, 55]. In this quality improvement/implementation project, the care managers used the program to identify and administer the intervention alongside existing activities and in concert with traditional care delivery with the hope of reflecting how the program would be used in the community, outside of a research environment.

Rates of refill adherence in our study population were in line with other prior studies; up to 80% of patients who are prescribed medications fail to adhere to them at some point [56, 57]. As many as 60% of hypertensive patients discontinue their treatment within the first year of care [58–60], and fewer than 65% remain in therapy after 3 years [60, 61]. Of those remaining in treatment, antihypertensive medication adherence varies from 40% to 70% [62–64].

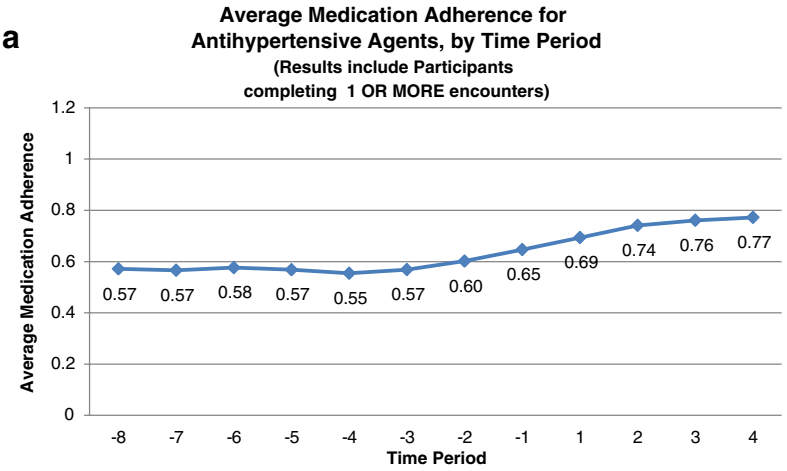
Interventions aimed at improving medication have shown mixed results. In a recent systematic review of the literature, 36 of 81 interventions reported in 69 randomized clinical trials were associated with improvements in adherence, but only 25 interventions led to improvement in at least one treatment outcome. Almost all of the interventions that were effective for long-term care were complex, including combinations of more convenient care, information, reminders, self-monitoring, reinforcement, counseling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care [65]. By contrast, the current intervention was relatively less complex and easier to administer, and was successful within the context of a quality improvement initiative for a Medicaid population.

In reviewing prior work, a number of findings stand out in the current study. First, our project was a quality improvement initiative, examining an intervention in a 'real world setting' and using existing infrastructure which required interventionists incorporating the program into their already busy schedules. While barriers and facilitators to implementation were not explicitly evaluated, there were multiple factors that may have contributed to success. These include implementation sites volunteering to participate, active feedback being requested from care managers, primary responsibility for the program resting with the care mangers who had a specific panel of patients, and the step-by-step guidance provided by the computer program.

Second, unlike most studies, we demonstrated 12 month sustainability and potentially improvement in medication adherence. Third, the impact of our results–77% adherence at 12 months–is among some of the larger effects observed, which is particularly relevant given the ease of administering the intervention. The intervention was telephone based and prior work suggests that these contacts for hypertension-related self management take approximately 18 min [66].

Potential explanations for our findings may be attributed to the care managers being able to identify individuals lacking adequate hypertension adherence at baseline. In previous studies, electronic monitoring of adherence to antihypertensive drug treatment resulted in improvement of blood pressure [67] with a reduced need for treatment intensification [68]. A second explanation is that these individuals receiving healthcare via Medicaid may have lacked adequate access to healthcare and attention and subsequently a telephone administered intervention may be a way to alleviate these access barriers. Addressing these access barriers through the development of patient-centered medical homes is a primary goal of CCNC. A third explanation may be the use of telephone to admin-

a



Time Period Key	
-8	631 to 720 days prior to Date Completed 1st Encounter
-7	541 to 630 days prior to Date Completed 1st Encounter
-6	451 to 540 days prior to Date Completed 1st Encounter
-5	361 to 450 days prior to Date Completed 1st Encounter
-4	271 to 360 days prior to Date Completed 1st Encounter
-3	181 to 270 days prior to Date Completed 1st Encounter
-2	91 to 180 days prior to Date Completed 1st Encounter
-1	1 to 90 days prior to Date Completed 1st Encounter
1	Date Completed 1st Encounter + 89 days subsequent to Date Completed 1st Encounter
2	90 to 179 days subsequent to Date Completed 1st Encounter
3	180 to 269 days subsequent to Date Completed 1st Encounter
4	270 to 359 days subsequent to Date Completed 1st Encounter

b

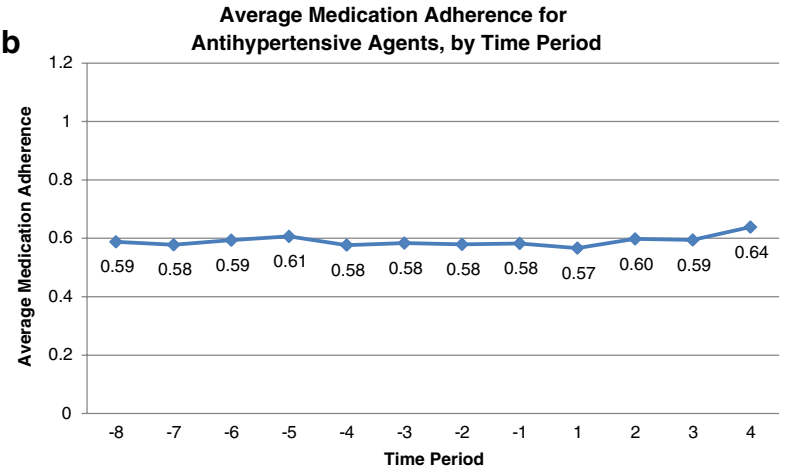


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Fig 1 | a Average medication adherence for antihypertensive agents, by time period among participants. b Average medication adherence for antihypertensive agents, by time period among non-participants

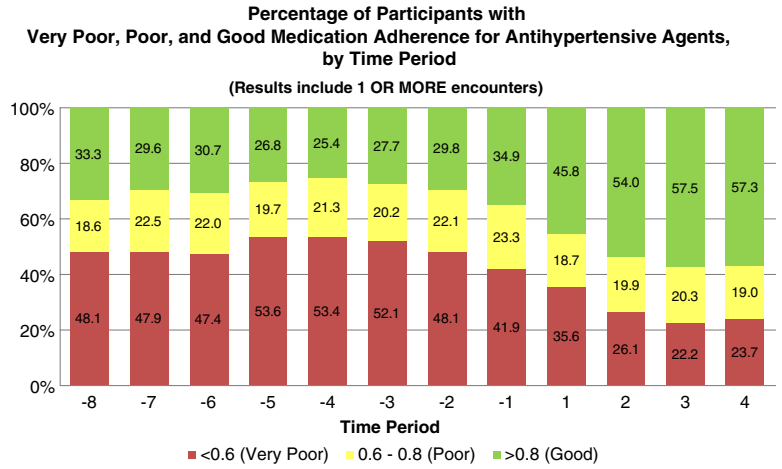

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Fig 2 | Percentage of participants with very poor, poor, and good medication adherence for antihypertensive agents, by time period

ister the tailored intervention. The use of telephones to implement the intervention allows individualized, personal interaction at minimal cost and without the time and transportation barriers that accompany in-person programs. In addition, the use of land lines or cell phones allows individuals to receive the intervention at their convenience and enhances access to the program and potentially reduces healthcare costs. Prior work by our group suggest that telephone-based interventions at a minimum do not increase costs and healthcare use and potentially may actually be cost effective [66, 69].

The results of the study need to be considered in light of a few limitations. First, there was no control group and it cannot be ruled out that a Hawthorne effect has occurred. It is possible that simply receiving attention form a care manager could change behavior regardless of the intervention content. Additionally, not having a case-mix-adjusted control group may contribute to the possibility of favorable selection with regard to adherence. Notably however, minimal improvements in medication adherence were observed among the approximate 4,000 non-participants over 12 months, and these effects were not comparable to those found in the intervention group.

Second, we are unable to determine the relationship between pill refill and clinical outcomes like improvements in BP. However, high medication adherence is associated with better blood pressure control [5, 6, 70]. Further, medication adherence, in and of itself, is a critical indicator of whether efforts on the part of payers (e.g., Medicaid) to improve care for cardiovascular risk factors are successful. This is because blood pressure readings are typically not readily available to payers outside of integrated healthcare systems. In addition, the Institute of Medicine has identified multiple comparative effectiveness research priorities related to treatment adherence [12]. An additional issue is that while the program was multicomponent and included diet, exercise, smoking, alcohol use, because it was a quality initiative program, we did not have outcomes to assess changes in these specific behaviors. Related, we did not formally evaluate the intervention fidelity. However, the number of monthly phone calls was tracked. Finally, it is unknown how generalizable our findings are outside of this Medicaid population. Moreover, the context is one where the impact of the patient's ability to pay for care is minimized. Thus, in the current US health care system, the program may be difficult to sustain without revisions to the reimbursement structure. However, in integrated health care environments (e.g., Veterans Health Administration, Kaiser, Geisinger, and some Medicaid and Medicare programs), the current program may be sustained and may be beneficial. With enactment of the

Patient Protection and Affordable Care Act, interest in these types of programs is likely to expand. Just as private companies and for-profit health insurance programs have emphasized disease management, there is likely to be greater focus on prevention and disease management programs such as this one examined here.

We implemented an intervention with components that have been extensively tested in clinical trials within diverse populations. While these efficacy trials have shown a positive impact of tailored disease/self-management support for patients with increased CVD risk, the current study adds to our understanding of implementing the intervention within complex healthcare settings. Community Care of North Carolina is at the vanguard of making care management services available as part of efforts to establish Medicaid patient-centered medical homes (PCMHs) for patients served by a wide variety of provider organizations. The further development of the PCMH model has the potential to expand implementation of programs such as the one described here into a greater variety of healthcare systems, which may in turn lead to improved patient medication adherence.

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