# Patient-Reported Medication Adherence Barriers Among Patients with Cardiovascular Risk Factors

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#### **ABSTRACT**

BACKGROUND: Many patients experience barriers that make it difficult to take cardiovascular disease (CVD)-related medications as prescribed. The Cardiovascular Intervention Improvement Telemedicine Study (CITIES) was a tailored behavioral pharmacist-administered and telephone-based intervention for reducing CVD risk.

OBJECTIVES: To (a) describe patient-reported barriers to taking their medication as prescribed and (b) evaluate patient-level characteristics associated with reporting medication barriers.

METHODS: We recruited patients receiving care at primary care clinics affiliated with Durham Veterans Affairs Medical Center. Eligible patients were diagnosed with hypertension and/or hyperlipidemia that were poorly controlled (blood pressure of > 150/100 mmHg and/or low-density lipoprotein value > 130 mg/dL). At the time of enrollment, patients completed an interview with 7 questions derived from a validated medication barriers measure. Patient characteristics and individual medication treatment barriers are described. Multivariable linear regression was used to examine the association between a medication barrier score and patient characteristics.

RESULTS: Most patients (n=428) were married or living with their partners (57%) and were men (85%) who were diagnosed with hypertension and hyperlipidemia (64%). The most commonly reported barriers were having too much medication to take (31%) and forgetting whether medication was taken at a particular time (24%). In adjusted analysis, those who were not employed (1.32, 95% CI=0.50-2.14) or did not have someone to help with tasks, if needed (1.66, 95% CI=0.42-2.89), reported higher medication barrier scores. Compared with those diagnosed with hypertension and hyperlipidemia, those with only hypertension (0.91, 95% CI=0.04-1.79) reported higher medication barrier scores.

**CONCLUSIONS:** Barriers to medication adherence are common. Evaluating and addressing barriers may increase medication adherence.

J Manag Care Spec Pharm. 2015;21(6):479-85

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## What is already known about this subject

- Medications are often required to control cardiovascular disease risk factors such as hypertension and hyperlipidemia. Over half of patients with chronic diseases are nonadherent with their prescribed medication regimens.
- Barriers to medication adherence include patient-related factors and drug-related factors, which include cost and regimen complexity.

# What this study adds

- This study provides a patient-reported perspective on common medication barriers among a unique veteran population.
- Findings of this analysis suggest that those who were not employed or did not have someone to help with tasks, if needed (i.e., lacked strong social support), experienced more barriers.

ardiovascular disease (CVD) is a leading cause of morbidity and mortality in the United States.¹ In addition to lifestyle changes, medications are often required to control CVD risk factors such as hypertension and hyperlipidemia. Despite the effectiveness of medication to reduce CVD risk, over half of patients with chronic diseases are not adherent with their prescribed medication regimen, which can have serious and negative health consequences.²-⁴ Factors associated with medication nonadherence are often complex and multifactorial. Sociodemographic risk factors, such as minority race, low health literacy, and lack of access, among others, are known to be associated with medication nonadherence.⁴-12

A systematic literature review conducted by Gellad et al. (2011) identified barriers to medication adherence, including patient-related factors (e.g., disease-related knowledge, health literacy, and cognitive function); drug-related factors (e.g., adverse effects and polypharmacy); and other factors such as the patent-provider relationships and various challenges to obtaining medications.<sup>13</sup> These barriers include the cost of medications and regimen complexity (i.e., the number of medications taken or the frequency of times per day).<sup>13</sup>

We evaluated baseline barriers to medication adherence among patients enrolled in a clinical trial and receiving care in the Veterans Affairs health care system who had poorly controlled CVD risk factors, specifically hypertension and/or hyperlipidemia. Because of their uncontrolled disease status, these patients are of particular importance and should provide a unique perspective on barriers to medication adherence. Using a patient-reported measure, our objectives were to (a) describe barriers to medication adherence and (b) evaluate clinical and sociodemographic characteristics associated with reporting medication barriers.

#### **Theoretical Framework**

The Health Decision Model (HDM) guided this analysis.<sup>14</sup> The HDM combines concepts of decision analysis, behavioral decision theory, and health beliefs. It provides a framework for modifying patients' health beliefs and, in turn, improving adherence with recommended therapies.<sup>14</sup> Using this theoretical framework, we assert that a patient's perceptions of barriers will affect their health decisions; this assertion directed our measure selection.

#### Methods

### **Data Source**

This analysis evaluated barriers to medication adherence using survey data from patients enrolled in the Cardiovascular Intervention Improvement Telemedicine Study (CITIES; ClinicalTrials.gov Identifier NCT01142908), an ongoing randomized clinical trial. CITIES has been described in detail elsewhere. 15,16 In brief, CITIES was a tailored behavioral and educational pharmacist-administered and telephone-based intervention for reducing CVD risk. Patients were recruited from November 2011 until April 2014. Patients were eligible for the CITIES study if they were 40 years or older and received care from 1 of 3 primary care clinics affiliated with the Durham Veterans Affairs (VA) Medical Center and had active outpatient diagnostic codes from hypertension and/or hyperlipidemia that were poorly controlled over the 12 months prior to study enrollment (documentation in the electronic health record of an average outpatient blood pressure > 150/100mmHg and/or low-density lipoprotein value > 130 mg/dL over the year prior to the patient's study enrollment). Patients were randomized to a usual care or intervention arm. Patients randomized to the usual care group received print-based educational material. Those in the intervention arm engaged in home-based self-monitoring of their blood pressure and, for patients with diabetes, blood glucose. It was intended that interventiongroup patients receive approximately 12 monthly tailored telephone calls with a clinical pharmacist to review self-monitored values, make medication adjustments, and promote healthy lifestyle changes. Because our objective was to describe patientreported barriers without regard to the intervention effect, this analysis uses data from all enrolled CITIES patients (i.e., both usual care and intervention arms) from the baseline survey only. The Durham VA Institutional Review Board approved this study, and all patients provided informed consent.

#### **Outcome Measure**

To assess self-reported medication barriers, we used a multiitem scale that has been used among patients with human immunodeficiency virus (HIV)<sup>17</sup> and those with CVD risk factors.<sup>18-20</sup> In a previous study, individual barriers had been associated with medication adherence.<sup>17</sup> The multi-item scale addresses common barriers, including finding time to take

medications in the middle of the day and delaying taking pills to avoid having side effects at an inconvenient time. Patients in the original measure were presented with 7 items and were asked whether the items were true or false. Patients were not advised to consider a specific medication; rather, the measure holistically assessed barriers. The items were as follows: (1) "I delay taking medications to avoid having side effects at an inconvenient time"; (2) "I get confused about how much medication of each kind to take"; (3) "I have too much medication to take"; (4) "I have trouble remembering what my medications are for"; (5) "there is no one to help me keep track of when to take my medication"; (6) "I forget whether or not I have taken my medication at a particular time"; and (7) "the instructions for how to take my medications are too complicated to understand." Response options included "definitely false," "probably false," "probably true," and "definitely true" (coded 1 to 4). Summing responses to all items formed a summary score; higher scores correspond to more barriers.

We considered additional clinical and sociodemographic characteristics known to be associated with medication adherence. Clinical characteristics included diagnoses of hypertension, hyperlipidemia, or hypertension and hyperlipidemia, as well as diabetes (diagnosed vs. not diagnosed). Sociodemographic characteristics included age, race (non-Hispanic white vs. minority), gender (male vs. female), marital status (married or living with partner vs. all other statuses), education (high school graduate or less than high school vs. any college), and employment status (employed vs. not employed).

We also assessed health literacy, financial status, and social support. Health literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) test.<sup>21</sup> We created a binary measure for low health literacy that was equivalent to an eighth-grade reading level or lower (REALM score <60). Patients were asked about their subjective household financial status. Possible response options included the following: "after paying the bills, you still have enough money for special things that you want"; "you have enough money to pay the bills, but little spare money to buy extra or special things"; "you have money to pay the bills, but only because you have to cut back on things"; or "you are having difficulty paying the bills no matter what you do." This measure was dichotomized such that participants who reported the latter 2 categories (e.g., cutting back on things or difficulty paying bills) were considered to have inadequate financial status.<sup>22,23</sup> To determine social support, patients were asked whether there was someone to help with tasks, such as taking them to the doctor or fixing their lunch, if help was needed (has social support vs. lacks social support).

### **Medication Adherence Measure**

Medication adherence was evaluated using a validated, 4-item, self-reported measure developed by Morisky et al. (2008).<sup>24</sup> Participants were presented with 4 statements about CVD med-

TABLE 2

Individual Barriersa

Probably false

Definitely false

TABLE 1	Baseline	Characteristics	(N=428)	
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Characteristics	Total
Age in years, mean (SD)	61.2 (8.7)
Nonwhite race, n (%) <sup>a</sup>	231 (54.2)
Male, n (%)	363 (84.8)
Unmarried and not living with partner, n (%)	185 (43.2)
Highest level of education: high school graduate or less, n (%)	128 (29.9)
Low health literacy, n (%)	143 (33.4)
Unemployed, n (%)	300 (70.1)
Inadequate financial status, n (%)a	103 (24.2)
Not having someone to help with tasks if needed, n (%) <sup>a</sup>	42 (9.8)
Comorbid conditions	
Hypertension (but not hyperlipidemia), n (%)b	111 (25.9)
Hyperlipidemia (but not hypertension), n (%)b	42 (9.8)
Hypertension and hyperlipidemia, n (%)b	275 (64.3)
Diabetes diagnosis, n (%) <sup>c</sup>	171 (40.0)
Medication nonadherence, n (%)a	247 (58.7)

aMissing data: race (n=2); inadequate financial status (n=3: 1 responded "don't know" and 2 "refused"); someone to help with tasks (n=1: 1 responded "don't know"); medication nonadherence (n=7).

ication-taking behaviors. The statements were the following: (1) "when I feel better, I sometimes stop taking my medicine"; (2) "I am sometimes careless about taking my medicine"; (3) "when I feel better, I sometimes stop taking my medicine"; and (4) "if I feel worse when I take the medicine, sometimes I stop taking it." Patients were asked to reflect back over the previous 30-day period and indicate if the statements were true. Possible responses were a 4-point Likert scale ranging from "strongly agree" (1) to "strongly disagree" (4). Individuals were classified as nonadherent if they responded "strongly agree," "agree," "don't know," or "refused" for any of the 4 statements.

#### **Analyses**

Data were analyzed using SAS software version 9.2 (SAS Institute, Inc., Cary, NC). Descriptive statistics, including means and proportions, were used to summarize participants' baseline sociodemographic and clinical characteristics, as well as reported medication treatment barriers. Simple linear regression was used to compare scores of medication treatment barriers for patients who were classified as nonadherent versus adherent. Unadjusted and adjusted linear regression models were used to determine characteristics associated with experiencing an increased number of medication treatment barriers. The outcome variable for the regression models was a medication treatment barrier summary score (higher score means more barriers reported). In a post hoc analysis, chi-square

I delay taking medications to avoid having side effects at an inconvenient time.					
Definitely true	30 (7.0)				
Probably true	40 (9.4)				
Probably false	50 (11.7)				
Definitely false	307 (71.9)				
Missing/refused/don't know	1 (—)				
I get confused about how much medication of each kind to tak	e.				
Definitely true	8 (1.9)				
Probably true	19 (4.4)				
Probably false	35 (8.2)				
Definitely false	365 (85.5)				
Missing/refused/don't know	1 (—)				
I have too much medication to take.					
Definitely true	55 (12.9)				
Probably true	79 (18.5)				
Probably false	52 (12.2)				
Definitely false	241 (56.4)				
Missing/refused/don't know	1 (—)				
I have trouble remembering what my medications are for.					
Definitely true	23 (5.4)				
Probably true	38 (8.9)				
Probably false	37 (8.7)				
Definitely false	329 (77.0)				
Missing/refused/don't know	1 (—)				
There is no one to help me keep track of when to take my medication.					
Definitely true	73 (17.3)				
Probably true	22 (5.2)				

Medication Barriers (N=428)

Total, n (%)b

(9.0)

290 (68.6)

Missing/refused/don't know

I forget whether or not I have taken my medication at a particular time.

Definitely true

Probably true

Probably false

Definitely false

Definitely false

Missing/refused/don't know

The instructions for how to take my medications are

too complicated to understand.		
Definitely true	4	(0.9)
Probably true	8	(1.9)
Probably false	35	(8.2)
Definitely false	379	(89.0)
Missing/refused/don't know	2	(—)

Note: Median medication adherence barrier score was 10.0 (minimum = 7.0, maximum = 28.0). Mean medication adherence barrier score was 10.5 (standard deviation = 3.9). One patient had missing data for the barrier score as all 7 medication barriers had missing data.

 $^{a}$ At least 1 barrier was reported (response of definitely true or probably true) by 56.9% of patients (n=243).

statistics were used to more closely examine characteristics associated with the overall summary score and the individual medication barriers.

<sup>&</sup>lt;sup>b</sup>Classification of disease was based on administrative review of diagnosis codes and/or having a relevant prescription (e.g., antihypertensive medication would indicate a hypertension diagnosis).

<sup>&</sup>lt;sup>c</sup>Diabetes diagnosis was based on patient self-report and/or documentation in the electronic health record.

mg/dL=milligram per deciliter; mmHg=millimeter of mercury; SD=standard deviation.

<sup>&</sup>lt;sup>b</sup>Percentage calculations exclude missing/refused/don't know responses from the respective denominator.

TABLE 3 Regression Results Describing Factors Associated with Medication Barriers (N=428)

	Unadjusted			Adjusted <sup>a</sup>		
	Parameter Estimate (95% CI)				P Value	
Age	-0.05	(-0.09, -0.01)	0.020 <sup>b</sup>	-0.04 (-0.09, 0.005)	0.076	
Nonwhite race	1.35	(0.62, 2.09)	<0.001b	0.51 (-0.29, 1.32)	0.210	
Male	-0.55	(-1.58, 0.48)	0.294	0.002 (-1.10, 1.10)	0.998	
Unmarried	1.04	(0.30, 1.79)	0.006 <sup>b</sup>	0.66 (-0.10, 1.42)	0.087	
Highest level of education: high school graduate or less	0.08	(-0.73, 0.90)	0.837	-0.37 (-1.23, 0.48)	0.389	
Low health literacy	0.90	(0.12, 1.68)	0.024 <sup>b</sup>	0.83 (-0.03, 1.69)	0.059	
Not employed	1.50	(0.70, 2.29)	<0.001b	1.32 (0.50, 2.14)	0.002b	
Inadequate financial status	1.26	(0.40, 2.12)	0.004 <sup>b</sup>	0.43 (-0.45, 1.30)	0.336	
Not having someone to help with tasks if needed	2.27	(1.04, 3.49)	<0.001b	1.66 (0.42, 2.89)	0.009 <sup>b</sup>	
Diabetes	0.73	(-0.02, 1.48)	0.058	0.61 (-0.16, 1.39)	0.122	
Hypertension only <sup>c</sup>	0.73	(-0.13, 1.58)	0.095	0.91 (0.04, 1.79)	0.042b	
Hyperlipidemia only <sup>c</sup>	-1.08	(-2.34, 0.18)	0.094	-0.59 (-1.91, 0.72)	0.377	

aNumber of observations used in adjusted model: 421 out of 428 (7 not included due to missing data on medication barriers (n = 1), race (n = 2), financial status (n = 3), and help with tasks (n = 1)). R-square = 0.12.

#### Results

Baseline data were collected for 428 patients with poorly controlled CVD risk factors. Patient mean age was 61 years, and 54% were nonwhite. Approximately 43% were unmarried, and most were men (85%). A minority (10%) lacked someone to help with tasks if needed. Over half (64%) of patients were diagnosed with both hypertension and hyperlipidemia; 40% were diagnosed with diabetes. Table 1 provides additional detail regarding patients' sociodemographic characteristics.

Nearly 57% of the sample endorsed at least 1 barrier (responding "definitely true" or "probably true"). The most commonly reported medication barrier was having too much medication to take (31%), followed by forgetting whether or not medication had been taken at a particular time (24%) and not having anyone to help keep track of when to take medications (23%). Few patients (3%) reported that instructions for how to take their medications were too complicated to understand. The median medication barrier score was 10 (minimum=7, maximum=28); mean medication adherence barrier score was 10.5 (standard deviation=3.9). Those who were non-adherent had a higher medication barrier score than those who were adherent (n=420, P<0.01). Complete information about patient-reported medication barriers is presented in Table 2.

In unadjusted regression analyses, being younger at enrollment, nonwhite race, unmarried, having low health literacy, not currently being employed, reporting inadequate financial status, and not having someone to help with tasks if needed were each significantly associated with reporting a higher barrier score. In adjusted analysis, those who were not employed (1.32, 95% confidence interval [CI] = 0.50-2.14) or did not have someone to help

with tasks if needed (1.66, 95% CI=0.42-2.89) reported higher medication barrier scores. Compared with those diagnosed with hypertension and hyperlipidemia, those with only hypertension (0.91, 95% CI=0.04-1.79) reported higher medication barrier scores. Unadjusted and adjusted regression results are presented in Table 3. Associations between social support and individual medication barriers, as well employment status and individual medication barriers, are presented in Table 4.

#### **Discussion**

This analysis contributes to our understanding of patientreported barriers to medication treatment adherence among those with poorly controlled CVD risk factors. Medication adherence barriers are common;13 we observed that over half of the sample reported having problems with at least 1 barrier. In addition, patients who reported medication nonadherence experienced higher medication barrier scores. Obtaining information about medication barriers from the patient's perspective is critical in order to know where and how to intervene to improve medication adherence. Findings of this analysis suggest that those who were not employed or did not have someone to help with tasks if needed (i.e., lacked strong social support) experienced higher medication barrier scores. Additionally, compared with patients diagnosed with both hypertension and hyperlipidemia, patients with only hypertension reported higher medication barrier scores.

Social support is known to positively impact chronic disease outcomes.<sup>25</sup> The relationship between social support and medication barriers adds to our understanding of the impact of poor social support and health outcomes. In fact, perceived

<sup>&</sup>lt;sup>b</sup>Indicates a P value of < 0.05.

<sup>&</sup>lt;sup>c</sup>Compared with having both a hypertension and a hyperlipidemia diagnosis.

CI = confidence interval.

TABLE 4 Post Hoc Analysis of Individual Barriers

Individual Barriers <sup>a</sup>	Employed n=128 n (%)	Not Employed n=300 n (%)	P Value <sup>b</sup>	Adequate Social Support n=385 n (%)	Inadequate Social Support n = 42 n (%)	P Value <sup>b</sup>
I delay taking medications to avoid having side effects at an inconvenient time.	16 (12.5)	54 (18.1)	0.199	62 (16.1)	7 (16.7)	1.000
I get confused about how much medication of each kind to take.	6 (4.7)	21 (7.0)	0.398	21 (5.5)	5 (11.9)	0.162
I have too much medication to take.	28 (21.9)	106 (35.5)	0.006	116 (30.2)	18 (42.9)	0.115
I have trouble remembering what my medications are for.	11 (8.6)	50 (16.7)	0.034	51 (13.3)	10 (23.8)	0.100
There is no one to help me keep track of when to take my medication.	22 (17.2)	73 (24.7)	0.100	72 (18.9)	23 (54.8)	< 0.001
I forget whether or not I have taken my medication at a particular time.	19 (14.8)	83 (27.8)	0.004	82 (21.4)	20 (47.6)	< 0.001
The instructions for how to take my medications are too complicated to understand.	3 (2.3)	9 (3.0)	0.765	9 (2.3)	2 (4.8)	0.611

<sup>&</sup>lt;sup>a</sup>Missing data on individual barriers range from 1-5.

social support may be more important than functional social support, particularly in the context of cardiovascular outcomes. Family support has been shown to be significantly associated with medication adherence in the context of hypertension. The measure of social support used here assesses for instrumental support, a specific subtype of social support that involves tangible aid. Other types of social support, such as informational, appraisal, or emotional, may have additional or alternate impacts on medication adherence. Ea

It is possible that being employed might increase a patient's access to affordable medications, perhaps through employeesponsored health or pharmacy benefits, which might improve medication adherence. Our study sample was composed of patients seeking care through the VA health care system. Most veteran patients are able to receive their medications for a copayment of approximately \$7. For veterans with a serviceconnected health problem, related medications are often free. Despite this, employment status was still related to increased reporting of medication barriers. Our finding that patients reporting that they had someone to help them reported lower medication barrier scores is expected. Generally, patients without adequate social support do poorly and have worse medication adherence. 17,29 Having someone to assist with obtaining and taking medications may make a meaningful impact in reducing barriers and improving adherence, particularly for patients who may have difficulty fulfilling these roles themselves. Also important to note is that relatively few patients (n=12, 2.8%) reported that it was definitely or probably true that their medications were too complicated to understand. This has been a historically well-documented issue in other disease contexts, such as with HIV.<sup>17</sup> Because taking multiple drugs (i.e., polypharmacy) has been negatively associated with adherence, 30,31 we anticipated that patients diagnosed with both hypertension and hyperlipidemia would report higher

medication barrier scores. However, we found that patients with hypertension reported higher medication barrier scores than those with hyperlipidemia alone or with both conditions. The reason behind this is unclear.

Because we do not have a precise prediction tool to determine which patients experience problems with adherence, it may be important to screen patients for the presence of common medication adherence barriers. For common barriers such as having too much medicine to take or forgetting to take medications, there are myriad existing electronic tools available. From the health care system perspective, these tools might include electronic health record systems that already inform medication reconciliation. From the patient perspective, available tools include self-monitoring and medication reminders in the form of smartphone applications and web-based software. Linking patients with existing resources of relevance to their specific barriers is critical to address problems and subsequently improve medication adherence.

#### **Limitations**

This analysis had several limitations. First, this was a predominately male population seeking care at a single site in the VA health care system. It is possible that there are gender differences with regard to barriers and that the VA patient population may not be broadly generalizable to the U.S. population. For example, medication costs may be reduced for many patients filling prescriptions in the VA, and a prescription mailing service is available for many patients. These programs may address logistical issues experienced by patients receiving care in nonfederal health care systems, which could influence barriers reported in our patient cohort. Second, it is possible that medication treatment barriers mediate medication adherence. A mediation analysis would enable us to address questions about a causal pathway. To do that, the variables would need to

bExact P value from Pearson chi square test.

be collected over time. However, reliance on baseline data (i.e., a single time point of data collection) precludes our ability to address causality. This analysis used data from patients enrolled in a clinical trial, which may result in selection bias. Despite these limitations, our analysis provides important information about the patient-reported barriers to medication treatment.

#### Conclusions

Despite access to low-cost or free medications, barriers to medication adherence were common in this sample of veterans at high risk for cardiovascular disease. Screening for medication barriers, including an evaluation of sociodemographic characteristics such as employment status and lack of adequate social support, may help identify patients at risk for potential adherence problems. Personalized, tailored, and scalable interventions that address medication barriers are likely to be essential to continue the decrease of cardiovascular disease in this population. Identifying and subsequently addressing barriers faced by a specific patient may be critical to make a meaningful improvement in medication adherence, which could result in improved patient outcomes and ultimately reduce health care spending.

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#### **DISCLOSURES**

This study was funded by a VA Health Services Research and Development (HSR&D) grant (VA HSR&D IIR 08-297) awarded to Bosworth. Bosworth was supported by a research career scientist award, also from VA HSR&D (VA HSR&D 08-027). The research reported here was supported by the Department of Veterans Affairs, Veterans Health Administration, and Health Services Research and Development Service. Zullig (CDA 13-025) and Crowley (CDA 13-261) were supported by VA HSR&D Career Development Awards. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Study concept and design were primarily contributed by Zullig and Bosworth, assisted by the rest of the authors. Data were collected by Zullig, McCant, Danus, and Bosworth and analyzed by Zullig and Stechuchak, along with Goldstein, Olsen, Crowley, Oddone, and Bosworth and assisted by McCant and Danus. The manuscript was written by Zullig and Stechuchak, along with Goldstein, McCant, Danus, Crowley, and Bosworth and assisted by Olsen and Oddone. All authors contributed to manuscript revision.

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