Predictors of Medication Self-management Skill in a Low-literacy Population

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BACKGROUND: Patients' ability to manage medications is critical to chronic disease control. Also known as medication management capacity (MMC), it includes the ability to correctly identify medications and describe how they should be taken.

OBJECTIVE: To evaluate the effects of low literacy, medication regimen complexity, and sociodemographic characteristics on MMC.

DESIGN: Cross-sectional analysis of enrollment data from participants in a randomized trial.

PARTICIPANTS: Patients with coronary heart disease in an inner-city clinic.

MEASUREMENTS: Medication management capacity was measured with the Drug Regimen Unassisted Grading Scale (DRUGS), which scores subjects' ability to identify, open, describe the dose, and describe the timing of their medications. DRUGS overall and component scores were compared by literacy, Mini Mental State Exam score, regimen complexity (number of prescription medications), and socio-demographic characteristics.

RESULTS: Most of the 152 participants were elderly (mean age 65.4 years), women (54.6%), and African American (94.1%). Approximately half (50.7%) had inadequate literacy skills, and 28.9% had marginal skills. In univariate analysis, MMC was significantly associated with literacy ($P < .001$), and this effect was driven by the ability to identify medications. In multivariable models, patients with inadequate literacy skills had 10 to 18 times the odds of being unable to identify all of their medications, compared with those with adequate literacy skills ($P < .05$).

CONCLUSIONS: Adults with inadequate literacy skills have less ability to identify their medications. Techniques are needed to better educate low-literacy patients about their medications, as a potential strategy to enhance adherence.

KEY WORDS: health literacy; medication adherence; cardiovascular disease; patient education; underserved populations.

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A recent national survey found that during the previous 12 months, 30% of patients took prescription medications less often than prescribed, 26% delayed filling a prescription, 21% stopped taking a prescription sooner than prescribed, 18% never filled a prescription, and 14% took smaller doses than prescribed.¹ Prior research has shown that only 50% to 60% of patients are adherent with taking prescribed medications over a 1-year period.²⁻⁴ Nonadherence is an important public health issue, particularly in chronic disease management. It costs an estimated \$100 billion annually in the United States and accounts for 10% of hospital admissions.⁴

Medication management capacity (MMC) is an important aspect of adherence. It is defined as "the cognitive and functional ability to self-administer a medication regimen as it has been prescribed."⁵ Measures of MMC include functional skills such as correctly identifying medications, opening containers, and selecting the proper dose, and time of administration.⁶ Medication management capacity complements measures of adherence provided by self-report, pill count, or refill schedule. Whereas these indices generally focus on how often medications were taken or refilled, MMC provides information about the accuracy of medication use.⁷ The value of MMC as a construct is supported by literature demonstrating that low MMC predicts greater emergency department utilization, functional decline, and subsequent residence in assisted-living facilities.⁸

Factors known to be associated with MMC include socioeconomic status, cognitive function, certain activities of daily living, and in some studies, a more complex drug regimen.^{5,9-11} Although preliminary evidence suggests that low-literacy patients have lower MMC,¹²⁻¹⁵ no published reports have examined this relationship. Further, prior studies of MMC have been limited to the elderly, and most subjects were highly educated.^{5,9-11} We examined the independent association of literacy, cognitive function, regimen complexity, and sociodemographic characteristics with MMC in an inner-city medical clinic.

METHODS

Setting and Population

The study was conducted in the General Medical Clinic (GMC) of Grady Memorial Hospital, a large, urban, university-affiliated public hospital in Atlanta, Georgia, that serves a predominantly indigent population. The GMC is the main continuity care site for the Grady Health System, with over 50,000 outpatient visits per year. Patient enrollment took place in the clinic modules staffed by Emory University physicians and residents. Clinic patients are predominantly older (mean age 61), female (66%), African American (93%), and of low socioeconomic status (SES). Nearly half of patients at the hospital have poor literacy skills.^{16,17}

Data for the present analysis came from baseline interviews collected for a randomized, controlled trial—the Improving Medication Adherence through Graphically Enhanced interventions in Coronary Heart Disease study (IMAGE-CHD). Patients were eligible for the trial if they had a documented diagnosis of coronary heart disease (CHD), demonstrated by greater than 30% stenosis of 1 or more coronary vessels on cardiac catheterization, or a history of coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty, or myocardial infarction. Patients were ineligible if they were currently participating in another medication adherence study, were too ill to complete the enrollment interview, did not manage their own medications, were already using a medication pill card that graphically illustrated their

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regimen, had no mailing address or telephone number, routinely filled prescriptions outside of the Grady pharmacy system, were unable to communicate in English, or had visual acuity worse than 20/60, significant psychiatric illnesses (physician diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder), overt delirium, or dementia. Of the 968 patients with CHD screened for the trial, approximately 490 were deemed eligible, and 440 enrolled in the study (5 of these enrollees later withdrew consent). The most common reasons for ineligibility were not filling prescriptions in the Grady pharmacy system (215), refusal to complete the screening process (approximately 120), having a caregiver who managed the patient's medications (78), and having overt dementia or delirium (13).

Study Protocol

Research staff screened patient charts 1 business day before routinely scheduled appointments and called all patients with a diagnosis of CHD to remind them to bring their medications with them to the clinic. On the day of the appointment, consenting patients who met the full eligibility criteria completed a 45-minute interviewer-assisted questionnaire and were enrolled in the trial. The questionnaire contained scales assessing various aspects of medication use, including beliefs, self-efficacy, and adherence. Patients who brought their medications to the appointment completed a measure of MMC and are the subject of the present analysis. Interviewers measured MMC before literacy, education, or cognitive function and were therefore effectively blinded to these assessments. Data collection took place in a private examination room, immediately before or after the scheduled physician appointment. Upon completion of the interview, patients received \$5 compensation and were randomized to receive 1 of the adherence interventions or usual care for a period of 1 year. The study materials and protocol were approved by the Emory Institutional Review Board and Grady Research Oversight Committee.

Measures

Sociodemographic characteristics including age, gender, race, marital status, employment status, and years of education were collected at enrollment. The 30-item Mini-Mental State Examination (MMSE) provided a measure of cognitive function.¹⁸

Literacy skills were assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM).¹⁹ This instrument provides a valid and reliable measure of literacy in the health care setting by testing patients' ability to read and pronounce 66 common health terms. Scores on the REALM can be grouped into 3 categories of literacy—inadequate (0 to 44, representing a reading level of $\leq$ sixth grade), marginal (45 to 60, a reading level of seventh to eighth grade), and adequate (61 to 66, indicating $\geq$ ninth-grade reading level).

Medication management capacity for chronic, oral medications was assessed with the Drug Regimen Unassisted Grading Scale (DRUGS).^{8,9} This tool requires subjects to perform the following 4 tasks with each of their medications: identify the appropriate medication, open the container, select the correct dose, and report the appropriate timing of doses. Thus, the instrument not only provides a measure of management capacity but also indicates specific areas of difficulty. Scores

on the DRUGS can range from 0 to 100, weighting each of the 4 tasks equally. To administer the test, the name, dosage, and dosing instructions from each medication bottle first were recorded into a data chart. After lining up the bottles in a random order on a table, the interviewer started by stating the name of a medication (generic and brand name when appropriate), and asked the patient to identify the correct medication. Patients were given credit for correctly identifying the medicine whether they did so by looking at the bottle, label, or pills themselves. They were encouraged to use any of these approaches, and the method of identification was noted. The patient was then asked to open the bottle and state the timing and dosage of the medication. If the patient was unable to complete a step, it was scored as incorrect and then performed by the interviewer, so the patient could attempt the subsequent step. After each medication was tested, the bottle was removed from the table.

Data Analysis

Patients' age, gender, marital status, employment status, years of schooling, literacy, cognitive function, and medication regimen complexity were summarized with descriptive statistics and frequency tables. Regimen complexity was represented as the number of prescription medications. Owing to the lack of consensus in the literature about how to define this construct, regimen complexity was also examined as the number of prescription doses required each day (i.e., a drug that is taken as 2 pills 3 times a day would count as 3 doses) and total number of medications (i.e., over-the-counter products plus prescription medications). Scores on the DRUGS and its components (ability to identify medication, open container, indicate dose, and report timing) were also analyzed with descriptive statistics and frequency tables.

For univariate analyses, we categorized age (<65 vs ≥ 65), years of education (<12 vs ≥ 12), REALM (inadequate, marginal, or adequate), MMSE (<24 vs ≥ 24), and number of medications (<7 vs ≥ 7). Marital status was used as a proxy for social support and coded as married or living with someone, versus all others. Employment provided an indication of socioeconomic status and was coded as working full- or part-time, versus unemployed, retired, or disabled. We compared values for the DRUGS score and its 4 components across categories of patient characteristics and regimen size using Mann-Whitney and Kruskal-Wallis tests for nonparametric data. We also dichotomized DRUGS and its component scores and compared them across patient and regimen characteristics using Pearson's χ^2 test, or Fisher's exact test where appropriate.

Significant factors from the univariate analyses were entered into multivariable logistic regression models. The full models were reduced using a backward elimination approach with likelihood ratio tests. Two alternate modeling strategies were also performed. In one, years of schooling was excluded from the list of potential predictors. Some note that education is causally associated with literacy and that controlling for education may therefore constitute overadjustment and falsely attenuate the observed effect between literacy and the outcome of interest.²⁰ The second alternate approach treated continuous covariates as such, to ensure that categorization of these predictors had no meaningful effect on the observed association between literacy and MMC. Analyses

were performed with SPSS (Version 13.0 for Windows). Tests of significance were 2-sided, and α was set at 0.05.

RESULTS

Of the 435 patients who remained in the randomized trial, 152 (35%) brought their medications to the clinic on their day of enrollment and completed the DRUGS measure for inclusion in this analysis. (See Table 1 for patient characteristics.) Compared with patients who did not bring their medications, subjects in the current analysis were older (mean age=65.4 vs 62.9 years, $P=.02$) and had slightly lower scores on the MMSE (mean=24.1 vs 25.0, $P=.008$), but did not differ on other measured characteristics. Among subjects who brought their medicines, the mean number of prescriptions was 6.2, only slightly lower than the mean number of prescribed daily doses (7.4), indicating that the majority of prescribed medicines were dosed once daily.

Scores on the DRUGS tool were high overall (mean=94.4, SD=7.4, range 68.8 to 100). Total DRUGS scores increased with literacy level ($P=.001$), as did the ability to identify medications correctly ($P<.001$, see Table 2). Patients with inadequate literacy specifically struggled with identifying their medications by viewing the bottle exterior or label ($P<.001$, compared with higher literacy patients). Interestingly, subjects with inadequate and adequate literacy were equally likely to open the bottle and view the pills as a means of trying to identify them. Scores on the other 3 DRUGS component items (open container, indicate dose, and report timing) demonstrated little change by literacy level.

Because medication identification accounted for nearly all the variability in DRUGS scores, subsequent analyses focused on the identification component of MMC. Overall, 57 of 152 patients (38%) were unable to identify all of their medications, despite being able to look at the bottle, label, or pills themselves. Relationships between medication identification and patient characteristics are shown in Table 3. Patients had greater difficulty identifying all of their medications if they were age 65 or older ($P=.02$), had not completed high school ($P<.001$), or were cognitively impaired ($P=.001$). Over half (57%) of patients with inadequate literacy skills were unable to identify all of their medications, compared with 25% of those with marginal literacy and 7% of those with adequate literacy skills ($P<.001$). Gender, race, marital status, and employment were not significantly associated with medication identification, nor was regimen complexity, whether defined as number of prescription medications, prescription doses per day, or total number of medications.

In logistic regression models, which treated inability to identify all medications as the outcome of interest, literacy remained a strong independent predictor (Table 4). In the first modeling strategy, which allowed years of schooling as a predictor, patients with inadequate literacy were significantly less likely to identify all of their medications, compared with those with adequate literacy skills (odds ratio [OR]=12.00%, 95% confidence interval [95% CI] 2.57 to 56.08). In the second modeling approach, which excluded years of schooling, the odds of incomplete medication identification for patients with inadequate literacy were higher (OR=18.04%, 95% CI 3.99 to 81.56). The third strategy, which treated age, years of schooling, and cognitive function as continuous variables, demonstrated a similar effect of literacy on the inability to identify

Table 1. Patient and Regimen Characteristics

Characteristic (N=152)	
Age, mean (SD), y	65.4 (10.3)
Women, No. (%)	83 (54.6)
Race, No. (%)	
Caucasian	6 (3.9)
African American (non-Hispanic)	143 (94.1)
Asian	0 (0.0)
Hispanic/Latino	2 (1.3)
Other	1 (0.7)
Marital status, No. (%)	
Married	25 (16.4)
Separated	18 (11.8)
Divorced	36 (23.7)
Widowed	47 (30.9)
Single/never married	25 (16.4)
Living with someone	1 (0.7)
Employment, No. (%)	
Unemployed	26 (17.1)
Full-time	1 (0.7)
Part-time	9 (5.9)
Retired or disabled	116 (76.3)
Years of education, mean (SD)	10.7 (3.6)
	Range 0 to 20
Literacy, No. (%)	
Inadequate	77 (50.7)
Marginal	44 (28.9)
Adequate	31 (20.4)
MMSE, mean (SD)	24.1 (3.3)
Prescription medications, mean (SD)*	6.2 (2.3)
	Range 1 to 14
Daily doses, mean (SD)*	7.4 (3.2)
	Range 2 to 17
Total medications, mean (SD)*	7.4 (2.6)
	Range 2 to 15

*Prescription medications refers to number of prescribed medications. Daily doses takes into account the number of times per day each prescription medication is to be taken. Total medications is the number of prescription and over-the-counter products.

MMSE, Mini-Mental State Exam.

medications (OR for inadequate literacy=10.39%, 95% CI 2.09 to 51.54). In all 3 modeling approaches, marginal literacy was associated with 4 to 5 times the odds of incomplete medication identification, but this effect was not statistically significant.

DISCUSSION

Our analysis shows that inadequate literacy skills are significantly associated with reduced MMC, and in particular, an in-

Table 2. DRUGS Score and Components for Overall Sample and by Literacy Level

DRUGS Performance, Mean (SD)	Total (n=152)	Literacy Level		
		Inadequate (n=77)	Marginal (n=44)	Adequate (n=31)
Overall score*	94.4 (7.4)	92.1 (8.7)	96.3 (4.9)	97.7 (4.3)
Components:				
Identify**	85.8 (24.1)	76.9 (28.4)	92.0 (17.0)	99.2 (2.9)
Open	99.7 (2.3)	99.7 (1.7)	100 (0)	99.2 (4.5)
Dose	97.0 (8.9)	96.1 (10.2)	97.6 (7.3)	98.3 (7.5)
Timing	95.2 (9.1)	95.6 (8.3)	95.4 (8.1)	94.0 (12.0)

* $P=.001$ for comparison across literacy level.

** $P<.001$ for comparison across literacy level.

DRUGS, Drug Regimen Unassisted Grading Scale.

Table 3. Association of Patient and Regimen Characteristics with the Inability to Identify All Medications

Characteristic	Unable to Identify All Medications, N (%)	P Value
Age		
< 65	18 (27%)	.02
≥ 65	39 (46%)	
Gender		
Female	28 (34%)	.29
Male	29 (42%)	
Race		
African American	55 (38%)	.71
Other	2 (25%)	
Marital status		
Married or living with someone	10 (39%)	.91
Other	47 (37%)	
Employment		
Working full-time or part-time	5 (50%)	.50
Unemployed, retired, or disabled	52 (37%)	
Education		
< 12 y	41 (58%)	< .001
≥ 12 y	16 (20%)	
Literacy		
Inadequate	44 (57%)	< .001
Marginal	11 (25%)	
Adequate	2 (7%)	
MMSE		
< 24	34 (53%)	.001
≥ 24	23 (26%)	
Medications		
< 7	28 (35%)	.50
≥ 7	29 (40%)	

MMSE, Mini-Mental State Exam.

ability to identify medications. Depending on the modeling strategy, patients with inadequate literacy had 10 to 18 times the odds of being unable to identify all of their medications, compared with those with adequate literacy skills. Individuals with marginal literacy skills also appeared less able to identify medications, although this effect was not statistically significant.

Summary scores on the DRUGS were similar to those seen in other reports.^{8,9} Unfortunately, the 2 published manuscripts and several abstracts reporting DRUGS performance did not describe relative ability on each of the component tasks,^{8,9,12–15,21–25} so we are unable to compare our findings on the identification domain with other studies. Nevertheless,

given the present results, it is possible that a reasonable estimate of MMC could be obtained only by asking patients to identify their medications. This would be a welcome methodological refinement as the full DRUGS test takes 5 to 15 minutes to administer. Such an approach is most likely to be useful when the patients lack physical limitations (and can therefore open pill bottles without difficulty), and when they are primarily prescribed medications to be taken as 1 pill per day, as was the case in the present investigation. Under these circumstances, scores on the opening, dosing, and timing components of the DRUGS are likely to be high and demonstrate little variability, as was observed here.

Some clinicians may presume that patients who identify their medications on the basis of the pills' color and shape are more likely to have inadequate literacy skills. Our results do not support this relationship. When presented with their own medication bottles, patients with inadequate literacy skills were no more likely to look at the pills in order to identify the medications. Future research should seek to validate this observation, perhaps framing the identification task in a different manner.

Our findings may shed some light on the larger issue of medication adherence. Despite decades of research on medication use, the reasons behind nonadherence remain unclear.^{2–4} Recent evidence points to poor literacy as a risk factor, likely through its effect on patients' ability to understand how to follow the medication regimen. Kalichman et al.²⁶ demonstrated that patients with lower literacy skills were less adherent to antiretroviral therapy, and this effect persisted after controlling for other variables. Low-literacy patients in that study often cited confusion about the regimen as a reason for nonadherence.²⁶ Other studies have shown that low-literacy patients struggle to understand medication instructions. In a survey of Medicare managed care enrollees, Gazmararian et al.²⁷ found that 47.5% of adults with inadequate literacy skills incorrectly described the timing of medication doses when looking at a pill bottle, compared with 24.4% of those with marginal, and 11.5% of those with adequate literacy skills. Similarly, 54.3% of respondents with inadequate literacy skills could not describe how to take medication on an empty stomach, compared with 33.7% and 15.6% of those with marginal and adequate literacy skills, respectively.²⁷ These published findings, combined with results of the present investigation, suggest that inadequate literacy skills significantly impact patients' ability to manage medications. Because understanding how to take medications could be considered a prerequisite for taking them correctly, we expect literacy to be connected to adherence and even with rates of medication errors, but the current evidence is limited. Additional research is needed to investigate the relationship between literacy and medication use, with attention to mediating and moderating factors.

There are several limitations to this study. First, it was conducted in a single institution, which serves a predominately low-literacy, African-American population with a large burden of chronic disease. However, this high-risk group warrants study, as it is more likely to benefit from future interventions to improve medication self-management and adherence. Further, our results were consistent with several preliminary reports of literacy and MMC in different settings.^{12–15}

Second, the DRUGS measure could only be performed among patients who brought their medications to the clinic. While there were no important clinical differences between

Table 4. Multivariable Models Showing Factors Associated with Inability to Identify All Medications

Variable	OR (95% CI)	
	Strategy 1	Strategy 2
Age < 65 y	—	1.95 (0.92 to 4.16)
Schooling < 12 y	3.22 (1.44 to 7.21)	NA*
MMSE < 24	—	—
Literacy [†]		
Marginal	4.75 (0.95 to 23.75)	4.78 (0.97 to 23.53)
Inadequate	12.00 (2.57 to 56.08)	18.04 (3.99 to 81.56)

*Modeling strategy 2 excluded years of schooling as a potential covariate.

[†]Reference group: adequate literacy.

—Indicates variable was dropped during model reduction.

MMSE, Mini-Mental State Exam; CI, confidence ratio; OR, odds ratio; NA, not applicable.

patients who brought and did not bring their medicines, it is possible that unmeasured factors (e.g., number of medications, actual understanding of the medication regimen, or adherence rates) were different among the subjects in this analysis who brought their medications to their clinic visit when prompted to do so by a phone call versus those who did not adhere to such instruction.

Third, scores on the DRUGS were high overall and distributed nonparametrically. Although similar score distributions have been observed in prior research and we applied appropriate statistical techniques, the clinical relevance of deficits in MMC is uncertain. DRUGS scores have been associated with some clinical outcomes, such as functional decline and emergency department use, but the instrument is relatively new, and further investigation is required to establish its predictive value.⁸

In summary, we found a large independent association between literacy and MMC, primarily in patients' ability to identify their medications. The present investigation adds to the growing body of evidence, suggesting that inadequate literacy skills may be an important risk factor for poor comprehension and medication mismanagement. Physicians and pharmacists should strive to educate low-literacy patients more fully about proper medication use. Additional research is also needed into strategies that may facilitate such education, such as improved packaging, labeling, and dispensing practices.

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