

Racial Disparities in HIV Antiretroviral Medication Management are Mediated by Health Literacy

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ABSTRACT

Background: Despite the availability of antiretroviral (ARV) therapy in the United States, only 30% of people living with HIV/AIDS (PLWH) in the US are virally suppressed. Nonadherence to ARVs remains the strongest correlate of viral suppression. African Americans (AA) living with HIV/AIDS remain disproportionately affected by this disease, and studies report a greater proportion of infections and deaths among this group. **Objective:** Earlier studies by this team and others have shown that health literacy (HL) may negatively influence disparities in health behaviors, including management of ARV prescriptions, between AA and non-AA PLWH. This current study expands these findings and tests whether HL may explain disparities in medication management among AA and non-AA PLWH and includes important covariates and measures of participants' actual medication regimens. **Methods:** PLWH were recruited from HIV care clinics in the greater metropolitan area of Atlanta, GA, and completed a face-to-face study visit. A total of 699 PLWH, 65% of whom were AA, completed this study visit. Assessment of knowledge and management of participants' actual medication regimens showed highly skewed responses, demonstrating accurate verbal descriptions of ARV prescription instructions. A measure of problem-solving (how to manage a mock ARV regimen) showed significantly different performance by race and that HL measures (both reading comprehension and numeracy) mediated this relationship. **Key Results:** Findings suggest that although PLWH may be able to verbally explain how they are supposed to take their ARV medication, challenges may arise with management issues (eg, determining need for a refill, counting pills to determine if a dose was missed) and that PLWH with low HL (who are disproportionately AA) may be at greater risk for mistakes. Other characteristics, such as cognitive impairment, were also shown to influence medication management. **Conclusion:** Attention to PLWH's potential for mismanagement of ARV and other medications is important to identify for educational interventions. [*Health Literacy Research and Practice*. 2018;2(4):e205-e213.]

Plain Language Summary: This study tested if problems with taking medicine to treat HIV may be caused by poor reading and math skills. Even though most people were able to correctly say how they should take their HIV pills, knowing if they had missed a pill or counting out a week's number of pills was harder for those with lower reading and math skills.

More than 1 million people in the United States were living with HIV/AIDS at the end of 2015, and there were an estimated 37,600 new HIV infections in 2014 (Centers for Disease Control and Prevention [CDC], 2015). Although the rates of new HIV infections in the US have decreased overall, this trend is not found across all subgroups. Men who have sex with men remain the largest subpopulation affected

by HIV in the US, and younger people (age 20-29 years) accounted for the greatest number of new infections in 2016 (CDC, 2015). Racial and ethnic groups are also disproportionately affected by HIV/AIDS. African Americans (AA) are the racial group most affected by HIV/AIDS in the US. In 2015, 48% of people diagnosed with AIDS living in the US were AA (CDC, 2015). In 2014, AAs accounted for 53% of the

HIV/AIDS-related deaths that year (CDC, 2015). Potentially contributing to these disparities are issues of socioeconomic status, access to health care, suboptimal health behaviors, and low health literacy (HL).

The poverty rate is higher among AAs than other racial/ethnic groups in the US (CDC, 2015). The socioeconomic challenges associated with poverty and marginalization (Oramasionwu, Brown, Ryan et al., 2009) can be directly and indirectly linked to reduced access to care, limited exposure to prevention education, and downstream consequences of health behaviors. AA patients living with HIV/AIDS are less likely to be retained in HIV care (Dasgupta, Oster, Li, & Hall, 2016), and these patterns persist over multiple years. Likewise, historical studies demonstrated that AAs may be less adherent to antiretroviral (ARV) treatment (Kalichman & Rompa, 2000; Kalichman et al., 2000), leading to increased HIV viral load, poorer health outcomes, and greater mortality among AAs living with HIV/AIDS.

The ability to successfully carry out necessary health behaviors is an integral component of HL. Prior studies suggest that low HL is linked to several adverse health outcomes including intermediate disease markers, morbidity, general health status, and use of health resources (Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004). In a review characterizing HL, ethnicity was consistently related to low HL, with the number of AA study participants directly related to the prevalence of low literacy (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005). Sudore et al. (2006) found that AAs, people with less than a high school education, and people with low income had higher mortality and were much more likely to have low HL. Understanding of the effects

of low HL, which often also includes health numeracy (the ability to effectively use mathematical concepts with health-related information), on racial disparities is emerging. Low HL has explained lower medication-adherence rates among AAs compared to Whites (Osborn, Paasche-Orlow, Davis, & Wolf, 2007). Similarly, our earlier research demonstrated that numeracy explained racial disparities in medication concordance (ie, the match between prescription instructions and the patient's understanding of their ARV regimen) using a simulated regimen (Waldrop-Valverde et al., 2010). Whether this association holds true with patients' actual ARV medications is unknown.

ARV medications have significantly prolonged the lifespan of people living with HIV/AIDS; therefore, patients take their ARV medications for years and have likely received adherence education from providers. Additionally, contemporary ARV regimens are simpler than previous courses of therapy. These important real-world characteristics are essential to understand the impact of HL and numeracy on medication management among people living with HIV/AIDS and whether they may also serve to explain racial disparities in HIV/AIDS outcomes. Moreover, our earlier study (Waldrop-Valverde et al., 2010) did not account for important covariates, including neurocognitive status, which has been shown to be associated with medication discordance, adherence, and HL.

The purpose of the present study was to test the association of race with medication concordance and medication management—both with one's actual regimen and a simulated regimen—and whether HL and health numeracy are associated with and mediate any relationships.

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METHODS

Participants were recruited from four Atlanta-area urban HIV care sites. One site was associated with a large private health care system (A), one site was associated with a large public health care system (B), and the two others (C, D) were private primary care practices that care for persons living with HIV/AIDS. Recruitment was conducted via study flyers, referrals from clinic providers/staff, and through word of mouth. Inclusion criteria included being positive for HIV infection, being seen by a primary HIV care provider within the prior 9 months, prescribed ARVs for at least 6 months, and fluency in English. Verbal consent was obtained upon screening, and verification of information by medical record review was conducted. Written informed consent was obtained at baseline. The study included face-to-face visits at baseline and again 6 months post-baseline with three phone-monitoring phone calls between these face-to-face visits. Only baseline study visit data are used for the present analyses. Data were collected from September 2012 to July 2016. The study was approved by the Emory University Internal Review Board and the Research Oversight Committee of the Grady Health System.

Measures

Independent variables.

Demographic survey data and self-report questionnaires were administered using audio computer-assisted self-interviewing software in a private location at each recruiting clinic or on the Emory University campus. Performance-based measures, such as neurocognitive testing and the outcome measures, were administered face-to-face by a trained study interviewer.

Health literacy. The Short Test of Functional Health Literacy in Adults (S-TOFHLA) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999) measured HL and contains two prose passages and four numeracy items. Scores on the reading comprehension scale range from 0 to 36, and scores on the numeracy scale range from 0 to 4. Although these scales can be summed, for this analysis, reading comprehension and numeracy scores were analyzed separately. Cronbach's alphas were 0.943 for the reading comprehension subscale and 0.531 for the numeracy subscale.

Dependent variables.

Participants brought their ARV medications with them to the study visit. Two measures were used to assess concordance of a patient's knowledge with actual prescription instructions. The Drug Regimens Unassisted Grading scale (DRUGs) measures the ability to identify, open, dispense, and demonstrate timing of each current prescription

(Edelberg, Shallenberger, & Wei, 1999). For this study, only participants' current ARV medication prescriptions were used. Scores were totaled and converted to a percent correct that was based on the number of prescribed ARVs. The Columbia Medication Management Test (CMMT) uses a simulated ARV medication regimen comprised 5 medications (Albert et al., 1999). Sixteen items assess several types of medication management skills, including calculation of missed doses, calculation of when a new prescription is needed, and determination of which medicines should be taken with food and which would make one drowsy. The 16-items are answered by using a standardized set of prefilled medication bottles with mock prescription labels and a preset number of mock pills inside, along with a mock medication information sheet. Each of the 16-items were scored "correct/incorrect" and the total correct was summed. A low score on this measure has been associated with lower self-reported medication adherence, features of neuropsychological functioning, and estimated premorbid IQ (Patton et al., 2012).

Covariates.

The Color Trails Test (D'Elia & Satz, 1989) and Hopkins Verbal Learning Test-Revised (Benedict, Schretlen, Groninger, & Brandt, 1998) were administered to assess executive functioning and verbal memory, respectively. Performance on each measure was scored and converted to *t* scores using each test's published norms. Neurocognitive impairment was defined as a score ≥ 2 standard deviations (*SDs*) below the normative mean on either test. Participants were divided into two groups reflecting cognitive impairment (≥ 2 *SDs*) or no cognitive impairment (≤ 2 *SDs*).

To test study aims, participants were classified as either AA or non-AA based on self-report of race. Ethnicity was not used as a classification. Gender was also classified based on self-report, and transgender participants ($n = 4$) were categorized according to their gender identity, not their biological sex at birth.

Statistical Methods

Summary statistics are provided for variables of interest including participants' relevant demographic and clinical characteristics, HL scores, and the outcomes. Descriptive statistics were compared between the AA group and non-AA group (which was comprised of several other races/ethnicities), and chi-square tests and two sample *t*-tests were applied for categorical variables and continuous variables, respectively.

Bivariate association analyses evaluated the relationship between each covariate of interest and the two outcome variables. For continuous covariates, the Pearson correlation coefficient was used to evaluate their association with the CMMT score, and the Spearman correlation coefficient

cient was used for DRUGs score, given the highly skewed distribution of scores on this measure. For categorical covariates, simple linear regression analysis and analysis of variance were conducted to evaluate outcome associations with binary and multilevel variables, respectively. Those associations significant at $p < .05$ were included in the final model. For multivariate analysis, multiple linear regressions (MLR) were performed to assess the association between the main independent variable (i.e., race) and each of the two outcomes while controlling for relevant clinical and demographic covariates.

Parallel multiple mediation analysis was performed to assess whether the effect of race on the outcome variables was mediated through the HL and numeracy skills while controlling for relevant factors including age, gender, neurocognitive impairment, education, and number of HIV medications. Parallel multiple mediation assumes that multiple mediators affect the relationship between race and medication adherence both simultaneously and independently of one another. The mediation macro PROCESS (Hayes, 2018) was applied to conduct the mediation analyses. The analyses use the distribution of the product method (MacKinnon, Lockwood, & Williams, 2004) to obtain estimates of both the direct and indirect effects of race on medication management via an ordinary least squares-based path analytic framework. This method produces estimates by first obtaining MLR coefficient estimates that represent the following: (1) the effect of the independent variable (race) on each mediator (numeracy, HL) adjusted for other factors and (2) the effect of each mediator on the outcome variable (medication management) adjusted for the independent variable and other factors (MacKinnon, Warsi, & Dwyer, 1995). For each mediator, the product of these two coefficients estimates the indirect effect of race on the outcome. For statistical inference, a bootstrap resampling approach (Bollen & Stine, 1990; MacKinnon et al., 2004; Preacher & Hayes, 2004) was implemented to estimate the confidence interval (CI) for the indirect effect, allowing for inference about the statistical significance of the mediated effects. A third MLR was performed to model the outcome variable in terms of the independent variable (i.e., race), and both mediator variables, adjusting for other factors. The direct effect of race on the outcome variable was estimated via the coefficient for race in the third MLR model and was used to assess whether the data show complete mediation or partial mediation. Results of our statistical analyses are presented in the next section. All statistical analyses were conducted using SAS software, version 9.4 (SAS Institute Inc., Cary, NC.) and assessed at the $\alpha = 0.05$ significance level.

Statistical Results

A total of 699 participants enrolled in the study and 65% ($n = 424$) self-reported their race as AA; non-AA participants in the sample were mostly White ($n = 223$), with Asian ($n = 4$), Native American ($n = 4$), and other ($n = 27$) accounting for the remaining categories. Only 2.4% ($n = 17$) self-reported Hispanic ethnicity. On average, participants had been taking their current ARV regimen for 3.75 years ($SD 4.28$). CMMT total scores were available for 674 of the participants (**Table 1**). Compared to non-AAs, the AA group had a significantly higher proportion of men, lower level of education, higher percentage of neurocognitive impairment, lower scores for the S-TOFHLA numeracy and comprehension test, and a lower CMMT score. We note that about 87.5% of study participants achieved a summary score of 100 for the DRUGs test, showing no errors on this measure. Scores on the reading comprehension and numeracy subtests suggested that most participants' HL levels were not low and that, although AA and non-AA participants had significantly different HL and numeracy scores, the overall average scores (33.5 and 3.45, respectively) were close to the maximum score possible (36 on reading comprehension and 4 on numeracy), suggesting a possible ceiling effect.

Results from bivariate association analyses indicate statistically significant associations between each covariate and the CMMT total score with the exception of age, which approached significance ($p = .07$). The DRUGs test was found to have significant associations with each covariate except race, gender, and recruitment site. The Spearman correlation coefficient between CMMT and DRUGs was 0.16 ($p < .0001$). Although statistically significant, the magnitude of the correlation coefficient was small, implying that these measures of medication management may not capture the same concept for the population represented by our sample.

Prior to mediation analysis, we first performed MLR to evaluate whether there was a connection between the independent variable, race, and each measure of medication management while controlling for demographic and clinical factors. Results in **Table 2** show that, when controlling for other factors, race was significantly associated with CMMT score ($p < .0001$) but not the DRUGs score. Due to the lack of association between race and DRUGs, we performed the mediation analysis for the CMMT score only.

Mediation analyses were performed to evaluate whether the effect of race on the CMMT score was mediated by HL and numeracy skills, while adjusting for potential confounding factors. **Figure 1** shows the results of our mediation analysis model that considered both HL and numeracy as simultaneous, independent mediators, measured here

TABLE 1
Demographic and Clinical Characteristics for Study Participants and Comparison Between Race Groups

Characteristic	Total (N = 698)		African American (n = 275)		Non-African American (n = 423)		p Value
	n	%	n	%	n	%	
Gender							
Male	495	70.9	221	80.4	274	64.8	< .001
Female	203	29.1	54	19.6	149	35.2	
Recruitment site ^a							.009
Clinic A	185	26.6	61	29.4	124	22.3	
Clinic B	250	36.0	102	35.1	148	37.4	
Clinic C	229	32.9	90	32.9	139	32.9	
Clinic D	31	4.5	20	2.6	11	7.3	
Neurocognitive impairment							< .001
<2 SD	325	46.6	179	65.1	146	34.5	
≥2 SD	373	53.4	96	34.9	277	65.5	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
Number of school years completed	13.3	3.08	12.59	3.03	13.96	2.97	< .001
Median income in last month	\$986	3.14	\$890	2.97	\$1,200	3.34	.052
Age	48.07	9.76	47.92	9.55	48.29	9.55	.625
Total number of ARV medications	2.33	1.06	2.35	1.05	2.29	1.07	.467
S-TOFHLA numeracy	3.45	1	3.27	1.1	3.73	0.73	< .001
S-TOFHLA reading	33.55	3.67	32.98	4.22	34.42	2.35	< .001
DRUGs	97.38	8.6	97.04	8.43	97.92	8.85	.188
CMMT	11.57	3.60	10.48	3.6	13.19	2.93	< .001

Note. Bold p values indicate statistical significance. ARV = antiretroviral; CMMT = Columbia Medication Management Test; DRUGs = Drug Regimens Unassisted Grading scale; S-TOFHLA = Short Test of Functional Health Literacy in Adults.

^aTotals do not always equal the full sample size due to missing data.

by the S-TOFHLA reading comprehension and numeracy subtest scores. **Figure 1** shows the indirect effect of race as mediated by HL reading comprehension skills is -0.19 (95% CI $[-0.337, -0.064]$) that does not include zero; therefore, the mediation effect is statistically significant. Given that the effect of race on CMMT was still significant after adjusting for the mediator ($\beta_3 = 1.69, p < .0001$), the effect of race is partially mediated by health numeracy skills. **Figure 1** also shows that we have similar findings regarding health numeracy skills. Namely, the indirect effect of race as mediated by numeracy skills is -21 (95% CI $[-0.367, -0.085]$); therefore, the mediation effect of numeracy skills

was significant in partially mediating the effect of race on medication adherence.

DISCUSSION

Earlier studies from this team and others have demonstrated that HL, measured in terms of reading comprehension and numeracy skills, may partially explain differences by race in management of ARVs. The purpose of the present study was to further test this finding with a larger sample with greater diversity in socioeconomic status and using their actual ARV medications. Findings support earlier reports that HL, both reading comprehension and numeracy

TABLE 2
Results from Multiple Linear Regression Models for CMMT and DRUGs

Covariate	CMMT			DRUGs		
	Parameter Estimate	t Statistic	p Value	Parameter Estimate	t Statistic	p Value
Race (African American)	-1.64	-6.30	< .001	-0.50	-0.70	.482
Gender ^a	-0.53	-1.98	.049	-0.28	-0.38	.704
Neurocognitive impairment	-1.89	-7.30	< .001	-0.70	-0.98	.328
Recruitment site ^b	-	-	.547 ^c	-	-	.763 ^c
Clinic A	-0.13	-0.24	.826	-0.88	-0.52	.604
Clinic B	0.1	0.17	.874	-0.64	-0.38	.704
Clinic C	0.29	0.50	.631	-1.34	-0.80	.426
Age	0.02	-1.32	.186	-0.09	-2.54	.011
Number of school years completed	0.26	6.3	< .001	0.01	-0.04	.965
Median income in last month	0.03	0.78	.438	0.07	0.64	.519
Total number of ARV medications	-0.2	-1.81	.071	-0.91	-2.90	.004

Note. Bold p values indicate statistical significance. ARV = antiretroviral; CMMT = Columbia Medication Management Test; DRUGs = Drug Regimens Unassisted Grading scale.
^aWomen versus men. ^bClinic D is the reference. ^cp value for the type III test for the overall effect of recruitment site.

skills, partially mediates the association between race and management of the simulated HIV regimen, such that the worse performance on the CMMT among AAs in our sample was partially explained by lower reading comprehension and numeracy skills. The distribution of data on the DRUGs was highly left-skewed, indicating that most participants, regardless of race, were able to verbally articulate and physically demonstrate knowledge of their personal HIV prescriptions. This ceiling effect with limited range of scores may have limited our ability to demonstrate a relation between race and this variable.

Results from mediation analysis support and expand upon our earlier studies where we found that numeracy skills were significantly lower among AA study participants and that these lower skills explained the poorer performance on the measure of managing a simulated HIV regimen (Waldrop-Valverde et al., 2010). Although a different measure of numeracy was used in the current study than that used in our prior research, both studies support the important role of numeracy in medication management. Unlike our prior studies, the current study demonstrated that reading comprehension was also significantly associated

with poorer medication management skills. These findings suggest that medication management requires verbal inferences and understanding of the contextual information in addition to mathematical facts and problem solving. Clearly, medication management is a multifaceted skill set that may have several contributors.

A primary goal of this current study was to understand if the potential discordance in understanding how to manage a simulated medication regimen translated into problems with one's actual medication regimen. As demonstrated by the highly left-skewed scores on the DRUGs, most participants were able to describe and demonstrate their ARV prescription instructions. Eligible participants had been taking their current regimen for at least 9 months, ensuring that new prescription information did not influence study outcomes. The DRUGs measure itself requires that a participant's actual prescription bottles are used and may have provided a reminder of the prescription information to the participant. However, this is what would also be expected to occur in the real world. The lack of variation in DRUGs scores would suggest that for patients who have been taking an ARV regimen for at least 9 months, most are able to verbally describe and demonstrate

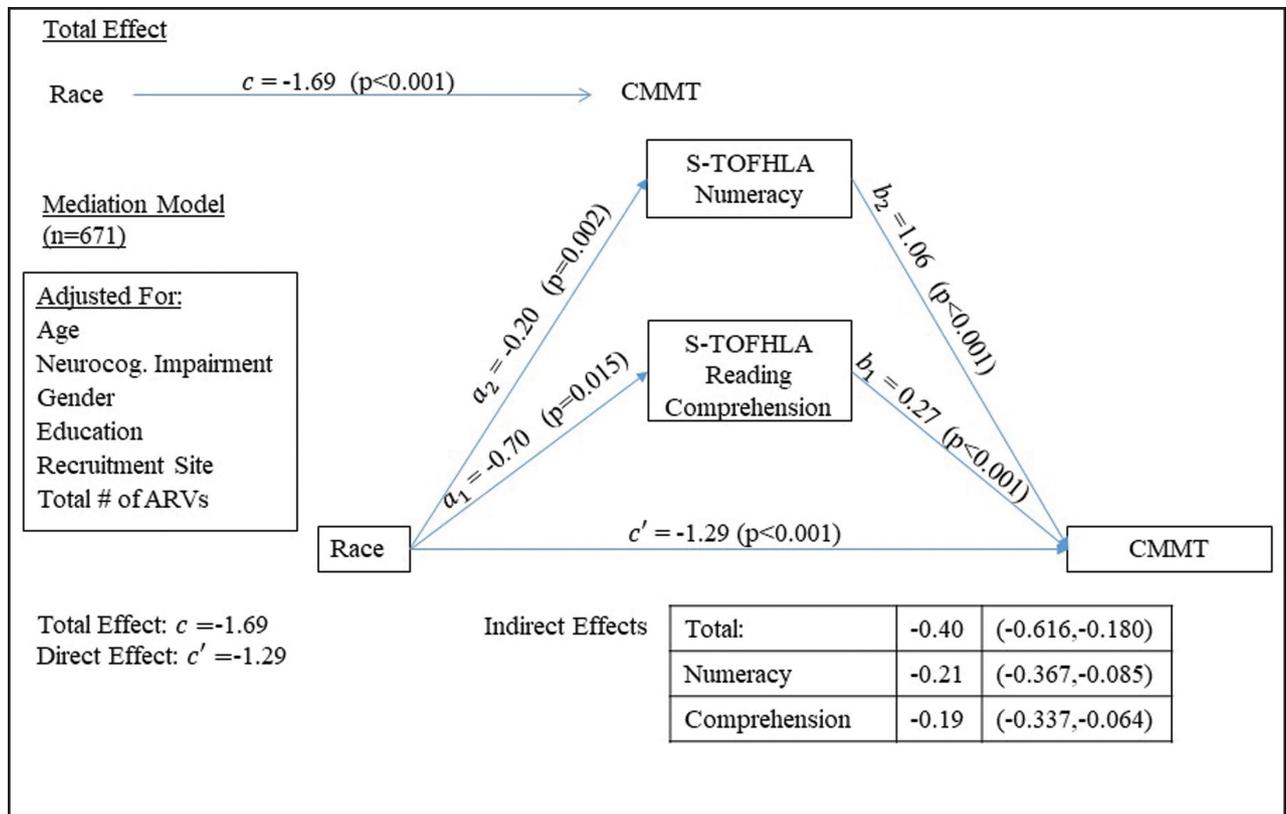


Figure 1. Parallel mediation analysis. ARV = antiretroviral medication; CMMT = Columbia Medication Management Test; Neurocog = neurocognitive; S-TOFHLA = Short Test of Functional Health Literacy in Adults.

how their medicines are to be taken. Kripalani et al. (2006) used the DRUGs and also found minimal variation in overall test performance. In their sample of mostly elderly patients, HL was significantly associated with identifying (naming) medications. In investigating the impact of medication concordance, Schillinger, Wang, Rodriguez, Bindman, & Machtinger (2006) found no correlation between missed doses and concordance between patient and provider's medication instructions. As described in a comprehensive review of available tests of medication management ability (Farris & Phillips, 2008), there is currently no single measure that adequately evaluates all aspects necessary for accurate medication management. The present study found few problems with knowledge of one's prescription but demonstrated significant challenges in the potential to mismanage a new prescription that was highly associated with HL and numeracy and more likely to occur among AAs living with HIV/AIDS in this sample.

Because the tested model resulted in partial but not full mediation, other factors not included in this analysis likely contribute to medication management. The skills needed to perform HL assessments overlap considerably with those

measured in neuropsychological testing (Waldrop-Valverde, Jones, Gould, Kumar, & Ownby, 2010). In fact, the current study found a significant relationship between impairment on measures of verbal memory, speed of information processing, and mental flexibility. Their association with medication management indicates that these skills have a direct relationship with one's ability to manage a prescription regimen and likely also map onto the skills underlying the HL measures. Other studies have also shown that although HL has a significant association with medication adherence, the relationship, as measured in a meta-analysis, was small (Zhang, Terry, & McHorney, 2014). Variables in addition to HL, including older age, less education, lower income, and more ARVs, in the current study were associated with less skill in medication management and may reflect a sociodemographic risk profile for poor medication management.

Participants in this study were mostly men and the sample's performance on study measures of HL and medication management should be interpreted with this demographic in mind. Historical research has generally shown that women perform better on tests of verbal/verbal comprehension skills and men perform better on tests of math skills (al-

though many confounding factors may not be adequately addressed in these studies). Our earlier work (Ownby, Acevedo, Waldrop-Valverde, Jacobs, & Caballero, 2014) has shown that women have higher reading comprehension scores, as measured by the TOFHLA, when a host of other covariates are controlled in analyses. Likewise, we also demonstrated (Ownby et al., 2014) that women performed less well than men on a numeracy measure. The current study sample was comprised of 70% men, and more than one-half of these were AA. The gender and racial makeup of study samples in prior studies, showing gender differences in HL, may not reflect the makeup of the current study. The current findings, therefore, add to the body of literature on both race and gender associations with HL, and point to the need for more research to tease out shared effects within and across gender and race.

STUDY LIMITATIONS

The findings of this study should be considered in terms of their limitations. The cross-sectional nature of the study precludes any statements on causality and merely provides associations. The lack of real-time measurement of medication management that captures the moment-to-moment decision-making process prevents understanding of whether the potential mismanagement noted herein translates to real-world challenges. The CMMT does not offer clinically relevant indicators of medication adherence or other associations with health outcomes, thereby making interpretation of scores on this measure difficult clinically. It is also a hypothetical assessment and may make it particularly difficult for people with low HL to complete due to its reliance on hypothetical scenarios that are not necessarily reflective of their medication management skills. Additionally, people who may have medication management or adherence challenges are likely to have their regimen changed; this study did not include a measure of lifetime experience with ARVs to account for the historical influence of ARV exposure. Despite these shortcomings, the present study adds to our understanding of HL and medication management and its influence in racial disparities among persons living with HIV/AIDS.

CONCLUSIONS

Improved measurement of actual day-to-day medication management behaviors would complement those of medication adherence and better inform the effects of HL and medication mismanagement on health outcomes. Such an understanding could benefit interventions to improve medication-taking behaviors among those most likely to mismanage their regimens. Given that many adults living with HIV/AIDS are also treated for other comorbid condi-

tions, the relationships noted herein among those prescribed medications for other comorbid conditions would also be an important focus.

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