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## A Structural Equation Model of Relationships of Health Literacy, Illness and Medication Beliefs with Medication Adherence among Patients with Chronic Obstructive Pulmonary Disease

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### Abstract

**Objective:** To determine the relative contributions of health literacy (HL) and illness and medication beliefs to medication adherence among older COPD patients and determine the pathways through which they operate.

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**Conflict of Interest:** Juan P. Wisnivesky is a member of the research board of EHE International, has received consulting fees from Merck, UBS, and IMS Health, and was awarded a research grant from GlaxoSmithKline to conduct a COPD study. All remaining authors declare that they do not have a conflict of interest.

**Methods:** The study was conducted using data from a prospective cohort of COPD patients in New York City and Chicago. We used structural equation modeling to examine the pathways linking HL, through medications and illness beliefs, with COPD medication adherence.

**Results:** Out of 393 older adults with COPD, 123 (31%) had limited HL and 208 (53%) reported low adherence to daily COPD medications. Those with limited HL were more likely to have low medication adherence ( $p < 0.0001$ ). Medications concerns ( $p = 0.001$ ) and medication necessity ( $p = 0.003$ ) demonstrated a mediational role between HL and adherence. However, in the final multivariate model, HL did not have direct effect on medication adherence ( $p = 0.12$ ) and illness beliefs ( $p = 0.16$ ) did not demonstrate a mediational role between HL and adherence.

**Conclusion:** Our findings suggest that low HL is not a direct predictor of poor medication adherence among COPD patients.

**Practice Implications:** Addressing medication concerns and reinforcing the need for daily COPD medications may be a more effective strategy for increasing adherence in this population.

### Keywords

COPD; Health Literacy; Medication Beliefs and Adherence; Structural Equation Models; COPD illness

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### Background

Chronic Obstructive Pulmonary Disease (COPD) is a major health problem in the United States (US), affecting over 16 million adults and contributing to considerable morbidity and mortality [1, 2], including \$36 billion in direct and indirect costs [3] in 2010 and 149,050 deaths in 2017 [2]. Effective self-management by persons living with COPD is critical to reduce COPD exacerbations, excess healthcare services utilization, and mortality [4]. Therefore, it is crucial that patients with COPD manage this illness through adherence to daily medications, use of action plans, influenza and pneumonia vaccination, and routine physician monitoring.

For patients with COPD, one of the most important ways to prevent exacerbation and hospitalization is the daily use of prescribed medications such as inhaled corticosteroids, long-acting beta-agonists, long-acting anticholinergics, or combination medications. The regulation of lung function and reduction of COPD symptoms such as wheezing and shortness of breath relies on stringent adherence to a daily regimen of these medications. However, as few as 40% of patients with COPD adhere to their prescribed daily medications [5, 6].

There are several factors that have been shown to affect adherence to COPD medications. Contributors are dispersed among socioeconomic, medical, physical functioning, and neuro- and psycho-cognitive domains. Notably, COPD self-management behaviors are strongly associated with health literacy (HL) [7, 8] and illness and medication beliefs [9–15]. A challenge, however, to addressing these associations lies with the collinearity of these correlates of adherence since HL and beliefs are strongly associated with one another [16].

Indeed, in our previous studies we have found both limited HL and illness and medication beliefs to be associated with low medication adherence [13, 16, 17].

The Institute of Medicine defines HL as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” [18] Adults with limited HL have higher rates of morbidity and mortality, and limited HL may compromise patients’ understanding of the treatment regimen and interfere with timely acquisition of medications [7, 8]. Disparities in HL exist as COPD patients with limited HL are socioeconomically disadvantaged and are more likely to belong to a racial minority group [16]. Limited HL is associated with illness beliefs and medication concerns [16] that may influence medication adherence.

## Research Question

To our knowledge, the literature on potentially modifiable pathways that may help support medication adherence among COPD patients with low HL is limited. Therefore, the objective of this study was to determine the relative contributions of HL and illness and medication beliefs to medication adherence among COPD patients and determine the pathways through which they work. In order to test these interrelated factors, we employed a structured-equation modeling (SEM) approach.

## Study Design and Methods

### Conceptual framework

The conceptual framework of our study is based on the Common Sense Model (CSM) of Self-Regulation [19]. According to the CSM, HL determines beliefs and attitudes surrounding one’s illness and medications, which in turn influence self-management behaviors [19]. The CSM posits that there are 5 domains of illness representations: identity (interpretation and labeling of symptoms), timelines (trajectory of disease), cause (etiology), consequences (perceived impact), and control (expectations for cure). These illness beliefs activate behavioral responses and guide coping procedures. Thus, COPD patients with low HL and limited knowledge of the purpose and mechanism of action of their COPD medications, may not recognize the medications’ long term impact on COPD symptoms and disease control, resulting in low adherence. Difficulties understanding medical information may render low HL patients more likely to adopt an acute disease model (disease is only present when patients have symptoms), a belief that has also been associated with low adherence to inhaled medications [12, 13, 16].

### Study participants and recruitment

This prospective cohort study was conducted in the primary care and pulmonary practices of the Mount Sinai Health System in New York City and Northwestern Medicine in Chicago, Illinois. We recruited community-dwelling, English or Spanish-speaking adults 55 years with physician-diagnosed COPD. Patients were excluded if they had asthma or another chronic respiratory illness, dementia, or other neurological and psychological conditions that would profoundly affect cognition (e.g., stroke, advanced Parkinson’s disease, schizophrenia). Potential study participants were identified by electronic medical record

review and screened for final study eligibility by telephone. Eligible participants were invited for an in-person interview. Interviews were conducted by a trained research coordinator in English or Spanish every 6 months for 2 years to assess changes in HL, illness and medication beliefs, and medication adherence.

Individuals were asked their preference for English vs. Spanish materials at initial contact, and from then on received materials in their language of choice. English comprehension was assessed through a self-report item in all participants. Interviews consisted of quantitative surveys administered by the research coordinator, who read items and response options aloud to the participant, as well as pencil and paper assessments. Interviews took place one-on-one in private research rooms at a medical center, and lasted approximately 1.5 hours at each visit.

The study was approved by the institutional review boards of the Icahn School of Medicine at Mount Sinai (# HS11-01325) and the Feinberg School of Medicine at Northwestern University (# STU00051862).

## Measures

All measures included have been validated in Spanish as well as English [20–23]. Adherence to COPD medications, the study outcome, was assessed with the 10-item Medication Adherence Rating Scale (MARS) [24]. The MARS is a validated measure that has been adapted for use with inhaled medications. It is composed of self-report questions about how often participants take or do not take their medications, which are assessed using a Likert scale with 5 options ranging from “always” to “never”. A mean MARS score between 1 and 5 was calculated from the response to each item and a higher score indicated better adherence. Participants with a mean MARS score  $\geq 4.5$  were coded as having good adherence [21].

HL was measured using the Short Test of Functional Health Literacy in Adults (S-TOFHLA), a 7-minute assessment including 36 items assessing reading comprehension and 4 items assessing numeracy [20, 25, 26]. S-TOFHLA assesses an individual’s ability to read and understand prose passages selected from commonly found healthcare-related instructions. Individual items were summed to obtain a score ranging from 0 to 36; patients who stated they could not read were scored 0. Scores are classified as inadequate HL (0–16; individuals will often misread the simplest of materials); marginal (17–22); and adequate (23–36; individuals can successfully navigate most materials in a healthcare setting). The S-TOFHLA was administered at the baseline, 1- and 2-year interviews. Due to the visual nature of the S-TOFHLA, a vision screening test was administered prior to the instrument. Those participants who failed the vision test were not given the S-TOFHLA and are excluded from the present analyses.

COPD-related beliefs were assessed using the Brief-Illness Perceptions Questionnaire (B-IPQ), a validated, 10-question instrument representing the five domains of the CSM [19, 22, 23, 27]. The B-IPQ score ranges from 0–100, with higher score indicating more negative or threatening perceptions about the illness. Medication beliefs were assessed with the Beliefs about Medicines Questionnaire (BMQ), a validated (English and Spanish) 10-item scale

composed of two subdomains: necessity and concern [28]. Higher scores on the concern subscale indicate greater concern about side effects and long-term dependence on COPD medications. Higher scores on the necessity subscale indicate greater belief in the necessity of COPD medications for preserving one's health.

Social and demographic characteristics, including age, gender, race/ethnicity, income, and marital status, were collected through participant self-report. Number of comorbidities was also assessed by self-report and verified through review of the electronic medical record. All measures apart from social and demographic characteristics and S-TOFHLA were administered at baseline and repeated at all follow-up interviews.

### Statistical analysis

Descriptive statistics were used to assess distribution of all categorical and continuous variables. Chi-squared tests and Wilcoxon rank sum tests were conducted, as appropriate, to examine the association between HL and baseline sociodemographic characteristics, illness and medication beliefs and medication adherence, and for the unadjusted association between illness and medication beliefs with medication adherence.

SEM was conducted to determine the pathways through which HL and illness and medication beliefs affect medication adherence over time. The proportion of the total effect of HL on medication adherence that is attributable to the mediators was calculated by taking the ratio of the indirect effect through the mediated pathway, divided by the total effect. Illness beliefs were entered as a continuous variable based on the sum score of the B-IPQ. The subdomains of medication necessity and concerns were modeled separately as latent factors. The indirect effect for a pathway was calculated by multiplying the parameter estimates for each relationship in the pathway. Estimation for SEM was performed using maximum likelihood. The fit of the model was assessed using the root mean square error (RMSEA) of approximation and the comparative fit index (CFI). All models were adjusted for age, gender, race, income, marital status, number of comorbidities and time, and accounted for clustering due to repeated measures. SEM was performed using Mplus7 (Muthen & Muthen, Los Angeles, CA). All other analyses were conducted with SAS 9.3 (SAS Institute, Cary, NC).

### Results

A total of 1,132 patients with COPD were identified from medical records. Of these, 618 patients were eligible for participation and were contacted; the remaining 514 were excluded due to comorbid respiratory illnesses, cognitive impairment, and/or location. Telephone screening identified 482 eligible patients; of these 403 agreed to participate and 393 patients completed a baseline interview. Follow up rate in Year 1 was 85% and in Year 2 was 75%. The mean age was 68 years (standard deviation [SD]: 8.3 years). The majority of participants (59%) were female, 48% had monthly household incomes \$1,350, and 34% were married or partnered; 44% were Black, non-Hispanic and 16% were Hispanic. The median number of self-reported comorbidities in addition to COPD was 3 (range, 1 to 4). One hundred twenty-three participants (31%) had limited HL.

Those who had limited HL were more likely to be Black non-Hispanic (53% vs. 40%,  $p < 0.0001$ ) or Hispanic (29% vs. 11%,  $p < 0.0001$ ) than non-Hispanic whites, respectively. They were also older (69.7 vs. 67.2 years,  $p < 0.01$ ), had lower household incomes (71% vs. 37%,  $p < 0.0001$ ), and reported more comorbidities (4 [2, 5] vs. 2 [1, 3],  $p < 0.0001$ ) (Table 1). There were no differences in gender or marital status between those with limited versus adequate HL ( $p > 0.05$ ). As compared to non-Hispanic whites (40), Blacks (45), Hispanics (49) and other races (44) had significantly higher median B-IPQ score ( $p < .0001$ ) and significantly greater proportions among them had low medication adherence (43.9 vs. 69.7 vs. 70.4 vs. 80,  $p < .0001$ ).

### **Unadjusted Association of HL with Illness and Medication Beliefs, and Their Association with Medication Adherence**

At baseline, those with limited HL had higher median medication concern scores (14 [12, 18] vs. 12 [10, 15],  $p < 0.0001$ ) and lower medication necessity scores (12 [10, 16] vs. 16 [11, 18],  $p < 0.001$ ) (Table 2). No association was observed between HL and overall illness beliefs ( $p = 0.08$ ). However, there were differences among individual illness belief scores. Individuals with limited HL were more likely to report that COPD affected their life (7 [5, 9] vs. 6 [4, 8],  $p < 0.001$ ), they experience more symptoms from COPD (7 [5, 10] vs. 6 [4, 8],  $p < 0.001$ ), and they think that COPD affects them emotionally (7 [4, 10] vs. 6 [3, 9],  $p = 0.03$ ).

Low adherence to COPD medications was observed among 208 subjects (53%) at baseline. Participants with limited HL were more likely to have low medication adherence than those with adequate HL (67% vs. 49%,  $p < 0.0001$ ; Table 3). Those with low medication adherence had higher BIPQ illness score (45 [39, 51] vs. 42 [34, 50],  $p = 0.01$ ) and medication concern score (14 [10, 18] vs. 11 [10, 14],  $p < 0.0001$ ) as compared to those who were adherent to the medications. No statistically significant association was observed between medication necessity and medication adherence ( $p = 0.61$ ).

### **Mediation Analysis**

In the longitudinal, multivariate analysis, we found that medication beliefs were a partial mediator of the relationship between HL and medication adherence (RMSEA=0.040 and CFI=0.932, Figure 1). Specifically, lower HL was associated with greater medication concerns and greater medication concerns were associated with lower medication adherence. The total indirect effect of the pathway between HL and medication adherence (mediated by medication concerns) was significant ( $\beta = 0.005$ ,  $p = 0.001$ ). In addition, lower HL was associated with greater medication necessity and greater medication necessity was associated with higher medication adherence. The indirect effect of medication necessity mediating the relationship between HL and medication adherence was significant ( $\beta = -0.003$ ,  $p = 0.003$ ). No statistically significant direct association was observed between HL and medication adherence ( $\beta = 0.004$ ,  $p = 0.12$ ). The model did not demonstrate any direct association between illness beliefs and medication adherence or any mediational effect of illness beliefs between HL and medication adherence ( $\beta = < 0.001$ ,  $p = 0.16$ ).

## Discussion and Conclusion

### Discussion

In this study, we applied a SEM approach to examine how HL and illness and medication beliefs may affect medication adherence in patients with COPD. In the adjusted model, we did not find a direct association of HL with medication adherence. Rather, we observed that HL was associated with greater concerns about medications, which in turn, were associated with lower medication adherence. Our findings suggest that one way in which limited HL affects medication adherence is through the beliefs that patients develop regarding medication side effects. These results suggest that beliefs about COPD medications may be promising targets for self-management support interventions for those living with COPD that simultaneously address problems with limited HL.

The relationship between limited HL and poor medication adherence is already well-established [29]. However, past studies have found the direct relationship between HL and medication adherence in COPD to be weak, and suggested the exploration of possible mediators as a direction for future research [30]. Despite extensive research demonstrating self-management problems in COPD patients, little is known about the mediators of low adherence self-management. Our study is novel as it examines the mechanisms through which limited HL may lead to low medication adherence. Limited HL could affect the ability of COPD patients to understand new instructions and implement behaviors necessary to maintain control of the disease. This possibility has important implications for how health information is communicated to COPD patients and the degree to which other stakeholders should be involved in the care of COPD patients outside of formal practice settings and over the course of their illness.

To the best of our knowledge, our study is the first in the field of COPD research to utilize a SEM approach to study the pathway between medication adherence and HL. A previous application of SEM to this pathway in older patients with asthma similarly revealed a significant indirect path from poor HL to low medication adherence through medication concerns [31]. However, while in asthma patients there was also a significant direct path linking HL to medication adherence, the current study of COPD patients did not find such an effect, suggesting that medication concerns may be a more important mediator of HL and adherence among COPD patients than asthma patients.

In bivariate analysis, we found that racial disparities existed in HL, illness beliefs and medication adherence. In general, racial disparities are prevalent in the self-management of COPD. There is a greater shift towards self-management of health conditions [32] although diverse demographic composition of individuals with health conditions may impose some difficulties. Poor medication adherence is common among racial and ethnic minority groups. Patient beliefs due to diverse racial and ethnic backgrounds may impede medication adherence. Further work is required in this area to identify barriers and facilitators of medication adherence in racial and ethnic minority groups, and there is a need to better understand the reasons behind poor medication adherence that will enable healthcare providers and public health practitioners to provide appropriate support to at-risk patients.

Our findings can inform the development of targeted interventions to support medication adherence among those living with COPD. Interventions seeking to promote medication adherence could identify and address patients' concerns about their COPD medications as a way of potentially reducing low adherence among low-HL individuals. We included such a strategy in a multi-component, complex self-management support intervention for older adults with asthma that resulted in improved adherence to controller medications and better clinical outcomes [33].

Findings of this study should be interpreted in light of its strengths and limitations. Strengths include the large sample size (n=393), prospective design, racial and ethnic diversity, and rigorous assessment of HL, and use of SEM to determine association between HL, and illness and medication beliefs with medication adherence. Limitations include recruitment of patients from two, urban health systems, which may affect generalizability, and reliance on a self-reported measures for beliefs and medication adherence, which may be subject to social desirability bias [21]. Moreover, the S-TOFHLA requires a minimum level of visual acuity, and therefore our analyses excluded individuals with significant visual impairment, which may affect the generalizability of the findings to the older COPD patient population.

## Conclusion

In summary, we found that the relationship between limited HL and low medication adherence among those living with COPD was partially mediated by increased concerns about medications.

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All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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**Highlights:**

- Health literacy does not have direct effect on medication adherence. Medication beliefs are a partial mediator of the relationship between health literacy and medication adherence.
- Addressing medication concerns and reinforcing the need for daily COPD medications may lead to improved adherence among COPD patients with limited health literacy.

**Practice Implications**

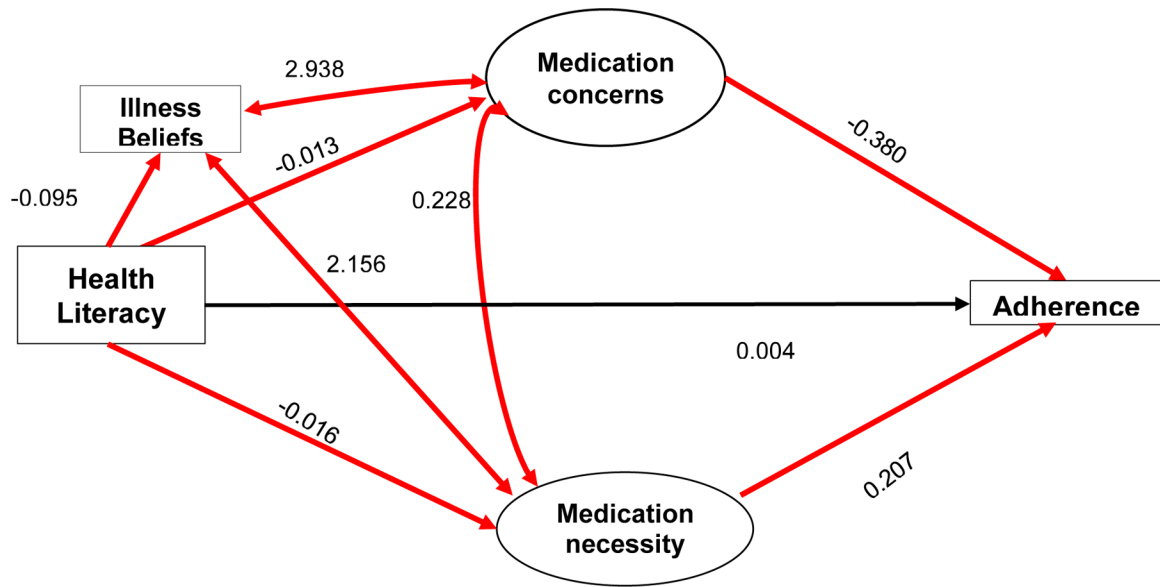
In light of these findings and the widespread problem of low medication adherence among COPD patients, interventions that target concerns about controller medications, especially for those at risk of low HL, should be developed and tested.

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**Figure 1: Mediation analysis to determine the pathways linking health literacy and illness and medication beliefs with medication adherence**

Indirect effect of medication concerns (from Health Literacy to Adherence): 0.005 (p=0.001)

Indirect effect of medication necessity (from Health Literacy to Adherence): -0.003 (p=0.003)

Indirect effect of Illness belief (from Health Literacy to Adherence): 0.000 (p=0.160)

Values indicate  $\beta$ s

Circles indicate latent variables

Rectangles indicate exogenous variables

RMSEA=0.040; CFI=0.932

**Table 1:**

Association of Health Literacy with Baseline Patient Characteristics

Characteristics	All Patients (n = 393)	Health Literacy Level <sup>§</sup>		P-value
		Adequate (n = 265)	Limited (n=123)	
Age, years, Mean $\pm$ SD	68.07 $\pm$ 8.26	67.23 $\pm$ 8.06	69.74 $\pm$ 8.54	0.006
Female, No. (%)	230 (59)	151 (57)	75 (61)	0.46
Race/Ethnicity, No. (%)				
White	144 (37)	126 (48)	18 (15)	<.0001
Black	173 (44)	105 (40)	65 (53)	
Hispanic	64 (16)	29 (11)	35 (29)	
Other	12 (3)	5 (2)	5 (4)	
Household Income, No. (%)				<.0001
US\$>1,350/month	199 (52)	162 (63)	35 (29)	
Marital Status, No. (%)				0.13
Married/living with partner	132 (34)	96 (36)	35 (29)	
Comorbidities, Median (IQR)	3 (1,4)	2 (1,3)	4 (2,5)	<.0001

<sup>§</sup>Health literacy scores were missing for n = 5 subjects.

**Table 2:**

Association of Health Literacy with COPD Health Beliefs at Baseline

Characteristics	All Patients (n = 393)	Health Literacy		P-value
		Adequate (n = 265)	Limited (n= 123)	
<b>Illness Beliefs</b>				
B-IPQ, median (IQR)	44 (37, 51)	44 (37, 50)	45 (38, 52)	0.08
How much does COPD affect your life?	6 (4,9)	6 (4,8)	7 (5,9)	0.00
How long do you think COPD will continue?	10 (9,10)	10 (10,10)	10 (7,10)	0.00
How much control you have over your COPD?	6 (5,8)	6 (5,8)	7 (4,9)	0.71
How much do you think your treatment can help?	8 (6,10)	8 (6,10)	9 (6,10)	0.16
How much do you experience COPD symptoms?	6 (4,9)	6 (4,8)	7 (5,10)	0.00
How concerned are you about COPD?	10 (7,10)	10 (7,10)	10 (8,10)	0.01
How well do you feel you understand your COPD?	9 (7,10)	9 (7,10)	9 (6, 10)	0.59
How much does COPD affect you emotionally?	7 (3,9)	6 (3,9)	7 (4,10)	0.03
<b>Medication Beliefs, median <math>\pm</math> SD</b>				
Necessity score	14 (10, 18)	16 (11, 18)	12 (10, 16)	0.0001
Concern score	12 (10, 16)	12 (10, 15)	14 (12, 18)	<.0001

B-IPQ: Brief Illness Beliefs Questionnaire, COPD: chronic obstructive pulmonary disease

Results of unadjusted Wilcoxon Rank Sum tests

**Table 3:**

Association of Health Literacy and Beliefs with Medication Adherence at Baseline

Characteristic	All Patients (n = 393 )	Adherence		P-value
		Good (n =134)	Low (n=208)	
<b>Limited Health Literacy</b> , No. (%)	123 (31.7)	25 (19.1)	82 (39.8)	<.0001
<b>Illness Beliefs</b> : B-IPQ, median (IQR)	44 (37, 51)	42 (34, 50)	45 (39, 51)	0.01
<b>BMQ scores, mean <math>\pm</math> SD</b>				
Necessity score, median (IQR)	14 (10, 18)	14 (11, 18)	14 (10, 18)	0.61
Concern score, median (IQR)	12 (10, 16)	11 (10, 14)	14 (10, 18)	<.0001

B-IPQ: Brief Illness Beliefs Questionnaire

Results of unadjusted Wilcoxon Rank Sum Tests