Evaluating the Impact of Health Literacy on Medication Adherence and Outcomes in Patients with Heart Failure

by Kristin Henry, PharmD, BCACP, Sara Griesbach, PharmD, BCPS, BCACP, and Po-Huang Chyou, PhD

Abstract

Introduction: Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions. The primary objectives of this study were to describe the relationship between different measures of health literacy among heart failure patients and medication adherence as well as the association with all-cause hospitalizations. Secondary outcomes include the association between health literacy and healthcare practitioner assessment of patient health literacy, health literacy and patient education level, and patient knowledge of target values for heart failure.

Methods: This prospective observational study enrolled new patients to the Marshfield Clinic Heart Failure Center. Health literacy was measured using the Rapid Estimate of Adult Literacy in Medicine (REALM-R), Short Test of Functional Health Literacy in Adults (STOFHLA), and the summed health literacy scale. Medication adherence was verified from pharmacy refill records, and all-cause hospitalizations were deduced from the electronic medical records.

Results: Forty-eight patients were enrolled into the study. The prevalence of low health literacy was 12.5% –33%, and non-adherence was measured at 23% –37%, depending on the clinical tool used. Lower health literacy level was associated with poorer medication adherence.

Conclusion: Health literacy is not often deliberately assessed in patients, even though low health literacy is prevalent in the heart failure population. Determining health literacy status may give clinicians insight into the patients' ability to adhere to medication regimens and to reach their health care goals. This study identified clinically useful questions that might provide an indication of a patient's health literacy and medication adherence.

One of the core concepts of the Patient Centered Medical Home (PCMH) is to facilitate a partnership between patients and practitioners to help ensure patients have the knowledge and feel empowered to actively participate in setting goals for their own health care.[1] An integral component to success of this partnership is understanding the barriers that prevent a patient from reaching specific treatment goals. One such barrier may include poor health literacy, which is defined by the Institute of Medicine 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."[2]

Health literacy is not regularly assessed by health care practitioners, even though low health literacy, including its effect on medication adherence, has a potential negative effect on health outcomes. For example, patients who have poorer understanding about disease processes and medications used to treat them have poorer adherence with prescribed medication regimens.[3] One method of assessing medication adherence is to analyze a patient's actual possession of medication as tracked through pharmacy refills. Patients who do not obtain a sufficient quantity of cardiovascular medications from pharmacies have an increased incidence of hospitalization for heart failure.[4] Furthermore, patients with heart failure and low health literacy have been shown to have higher rates of all-cause mortality in certain populations.[5] Pharmacists are generally the last members of the health care team with whom patients speak before taking their medications home, so it is crucial that pharmacists assess the health literacy level of their patients in order to communicate effectively with them.

The primary objectives of this study were to describe the relationship between different measures of health literacy among heart failure patients receiving care in an outpatient heart failure clinic and medication adherence as well as the association it has with all-cause hospitalizations. Secondary outcomes included reviewing the association between health literacy and healthcare practitioner assessment of patient health literacy, health literacy and patient education level, and patient knowledge of target values for heart failure.

Methods

Study Design

The study was designed as a prospective, observational project conducted at Marshfield Clinic (MC) Heart Failure Clinic (HFC) in Marshfield, Wisconsin. A multispecialty physician group practice in Wisconsin, MC has 56 regional sites and more than 780 physicians caring for more than 383,000 unique patients annually. In 2011, all 34 primary care sites in the MC system achieved Level 3 PCMH recognition from the National Committee on Quality Assurance.

Study methods were approved by MC's institutional review board in October 2011. Patients were identified for study

enrollment if they were at least 18 years of age and were completing one of their initial five visits in the HFC. Patients were eligible for referral to the HFC if they were recently diagnosed with heart failure or recently hospitalized due to a heart failure exacerbation. During the first five visits at the HFC, patients met with nurse practitioners and registered nurses in order to learn more about their disease state and ways to monitor and manage heart failure, including measuring daily weights and improving dietary choices. Patients also met with a pharmacist on their first visit to the HFC for a full medication profile review and additional counseling regarding the use of heart failure medications. Pharmacists communicated opportunities to improve drug therapy with the prescriber and documented in the electronic medical record as well as in the pharmacist intervention database.

Patients were excluded from the study if they were legally blind, unable to communicate in English, unable to provide verbal consent for study participation, or if they resided in assisted living or nursing facilities. Information obtained from the patient's electronic medical record included the number of hospitalizations during the year prior to enrollment. Quantification of the number of drug related opportunities identified by a pharmacist at the patient's initial HFC appointment was collected from the pharmacist intervention database. Visits with patients were conducted face-to-face by the primary investigator with the use of a prepared script. Background information collected included race, gender, age, self-rated reading ability, and self-reported education level.

Health Literacy

Health literacy was measured using three tools: (1) the Rapid Estimate of Adult Literacy in Medicine (REALM-R)[6], (2) Short Test of Functional Health Literacy in Adults (STOFHLA)[7], and (3) the summed health literacy scale.[8] The REALM-R is a short exercise that requires a person to read and say several healthcare-related words, earning one point (up to a maximum of eight) for each word pronounced correctly.[6] The STOFHLA is a reading comprehension tool that requires a person to indicate the correct words to fill in the blanks (up to a maximum of 36) in a short healthcare-related script.[7] The summed health literacy scale was the combination of patient's scores on three clinical screening questions: (1) "How often do you have a family member or friend help you read health information like booklets on how to eat healthy or a handout from the pharmacy?"; (2) "How often do you have difficulty understanding health related information?"; and, (3) "How confident are you in filling out forms by yourself?"[8] Patients were asked to report their answers on a Likert scale with descriptions associated with the rankings 1 to 5, with 1 being "None of the time" and 5 being "Always." These were then combined to form the summed health literacy scale. Based on prior literature, low health literacy was classified as a score of 0–16 on the STOFHLA[7], 0–6 on the REALM-R[6], or >10 on the summed health literacy scale.[8] Finally, the nurse practitioner and pharmacist responsible for providing education to the patient were asked to estimate the patient's health literacy based on a scale proposed by Kelly & Haidet (Table 1).[9]

TABLE 1. Practitioner-Assessed Grade-Equivalent Health Literacy Levels

Level	Grade range	Description
1	High School	Will be able to read most patient education materials
2	7th-8th grade	Will struggle with most patient education materials
3	4th-6th grade	May not be able to read prescription labels
4	3rd grade and below	Will need repeated oral instructions, materials composed primarily of illustrations, or audio or video tapes

Medication Adherence

Medication adherence was estimated using the Medication Possession Ratio (MPR) after obtaining written authorization from the study subjects to collect refill records from patients' pharmacies for their angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta blockers, or other maintenance medication (e.g., HMG CoA reductase inhibitors, antidepressants, or other antihypertensives). The Morisky's Medication Adherence Scale (MMAS) was also utilized to gain an estimate of medication adherence, including possible barriers to medication use such as forgetfulness or underuse. The MMAS is an 8-item scale where the first seven items have "Yes/No" responses and the final question has a 5-point Likert response (i.e., How often do you have difficulty remembering to take all your blood pressure medication?). Medication adherence was defined based on prior literature,[10,11] with a MPR ≥0.8 or a MMAS score of 8 signifying adherence.

Statistical Analysis

Descriptive statistics such as the frequency (in percent) of low health literacy based on measurements from three defined instruments were described, with a corresponding 95% confidence interval (CI) derived from the exact binomial distribution. Spearman correlation coefficients and corresponding p-values were obtained and used to assess the relationships between each variable. A p-value of <0.05 was used to indicate that a significant relationship exists between two variables. All statistical analyses were completed using the commercially available Statistical Analysis System statistical software package.

Results

A total of 48 patients were enrolled in the study between October 2011 and April 2012. Baseline characteristics of participants are shown in Table 2. Nine patients who had been identified for participation in the study were not successfully enrolled due to various patient or systematic factors (Table 3).

Health Literacy Measurements

In the study population, low health literacy was assessed in 33% (95% CI 20-48%), 27% (95% CI 15-42%), and 12.5% (95% CI 5-25%) based on measurements

TABLE 2. Baseline Characteristics of Study Participants (n = 48)

Characteristic	No. (%)
Age (years), mean (SD)	70.9 (12.0)
Men	28 (58)
Race	
White	47 (98)
Other	1 (2)
Education level	
< 8th grade	2 (4)
Grade 8 to 11	11 (23)
Graduated high school/GED	15 (31)
Vocational/technical college	4 (8)
Some college	7 (15)
Graduated college	6 (13)
Post-graduate or professional degree	3 (6)
Self-rated reading ability	
Excellent or very good	28 (58)
Good	15 (31)
Okay	5 (11)
Poor	0 (0)
Terrible or very poor	0 (0)
All cause hospitalization, mean (SD)	1.6 (1.6)

SD, standard deviation; GED, general educational development

from the REALM-R[6] , STOFHLA[7] , and the summed health literacy scale[8], respectively. Primary outcomes are summarized in Table 4, and secondary outcomes are summarized in Table 5. Health literacy was not correlated with number of hospitalizations within the year before study enrollment (p=0.738, 0.163, 0.394 for REALM-R, STOFHLA, and summed health literacy scale, respectively). The summed health literacy scale was inversely correlated with the REALM-R (p=0.005) and the STOFHLA (p=0.054). The REALM-R was correlated with the STOFHLA (p=0.053). The summed health literacy scale was also inversely correlated with the MPR (p=0.025). The summed health literacy scale took on average 63 seconds to administer in completion to patients, whereas the STOFHLA took up to 7 minutes.

Health literacy was correlated with patient education level as measured by the summed health literacy scale (r=-0.33, p=0.02), but not per the REALM-R (r=0.26, p=0.08) or the STOFHLA (r=0.24, p=0.11). The final question of the summed health literacy scale demonstrated correlation with the MPR (r=-0.38, p=0.0085) and REALM-R (r=-0.36, p=0.0127) and was not correlated with the STOFHLA (r=-0.27, p=0.0619). Older age of the patient was correlated with lower health literacy based on the STOFHLA (r=0.52, p=0.0001) as well as with less knowledge of target values for heart failure (r=-0.42, p=0.0032). Patients who had higher health literacy as measured by the STOFHLA tended to have better knowledge of their clinical targets for heart failure (r=0.31, p=0.034). Nurse assessment of patient health literacy was significantly correlated with only STOFHLA (r=-0.48, p=0.0006) but not REALM-R or the summed health literacy scale. Pharmacist assessment of patient health literacy was not correlated with health literacy measurements.

Medication Adherence

Medication adherence as calculated by the MPR demonstrated that 77% (95% CI, 63-88%) of patients were adherent to their medications as previously specified, whereas 63% (95% CI, 47-76%) were adherent by MMAS. The final question of the MMAS ("How often do you have difficulty remembering to take all of your medication?"[11]) was significantly correlated with the MPR (r=-0.38, p=0.0093). While MMAS was correlated with number of hospitalizations (r=0.31, p=0.0326), MPR was not (r=-0.11, p=0.471). The MPR was correlated with the summed health literacy scale (p=0.0258), whereas the MMAS was not correlated with any of the measures of health literacy.

Discussion

Health Literacy

In this heart failure population, between one in three and one in eight patients were identified as having low health literacy, depending upon which health literacy assessment tool was being utilized. This is a large percentage of patients who were not previously identified as at risk for poor health outcomes due to problems understanding or comprehending basic health information. Lower health literacy was not correlated with increased number of all-cause hospitalizations, potentially due to the lack of long-term follow-up with the patients enrolled in the study. Only 17% of enrolled patients had been diagnosed with heart failure greater than 12 months prior to study enrollment. Analyzing all-cause hospitalizations might be more indicative of overall heart failure control and long-term outcomes in patients who have had heart failure for a longer period of time.

Clinical utility of different patient assessment tools depends upon a number of factors including ease of use and time to complete the tool. The summed health literacy scale took on average only 63 seconds to complete and it does not require special training to administer, so this may be a tool that can be incorporated with relative ease into clinical practice. If time constraints further reduce the ability of a clinician to use these questions in clinical practice, we suggest that the third question from the summed health literacy scale ("How confident are you in filling out forms by yourself?") be utilized, as it was significantly correlated with measures of health literacy.

Previous literature suggests education level and age are not adequate indicators of health literacy in patients by themselves.[12] However, this study demonstrated that older age was correlated with lower health literacy based on the STOFHLA and the patient's education level was correlated with

TABLE 3. Reasons for Lack of Enrollment (n = 9)

Reason for lack of enrollment	No. (%)
Patient concern about participating	2 (22)
Patient "forgot glasses"	2 (22)
Patient un-enrolled in HFC	1 (11)
Patient did not show for appointment	3 (33)
System factors: scheduling conflicts	1 (11)

HFC, Heart Failure Clinic

TABLE 4. Primary Objective Results

HL Measurement	M2	Correlation Between HL and M2, r	p-value
REALM-R	Hospitalizations	0.05	0.738
	STOFHLA	0.28	0.053
	Summed Scale	-0.4	0.005[a]
	MPR	0.2	0.188
	MMAS 8	-0.14	0.328
STOFHLA	Hospitalizations	-0.2	0.163
	Summed Scale	-0.28	0.054
	MPR	0.07	0.632
	MMAS 8	-0.13	0.394
Summed Health Literacy Scale	Hospitalizations	-0.13	0.394
	MPR	-0.32	0.025[a]
	MMAS 8	0.12	0.405

HL, Health Literacy; M2, Measurement 2; REALM-R, Rapid Estimate of Adult Literacy in Medicine–Revised[7]; STOFHLA, Short Test of Functional Health Literacy in Adults[6]; MPR, Medication Possession Ratio; MMAS, Morisky's Medication Adherence Scale
[a] Significant at P<0.05.

the summed health literacy scale. Therefore, although they do not predict health literacy on their own, age and education level may still be contributors to health literacy levels.

Medication Adherence Rates

Adherence to medications in this study was better than 50%, which is the average rate of adherence to chronic medications in developed countries according to the World Health Organization.[13] Self-reported adherence to medications was correlated with all-cause hospitalizations, supporting the link between lower medication adherence and increased hospitalization described by previous studies.[14] A lack of correlation between measures of adherence and health literacy does not discount a possible relationship, but it is possible that this relationship was not observed due to the small sample size and the complexity of the relationship between medication adherence and health literacy.

When comparing the clinical utility of different measurements of medication adherence, the MPR requires considerably more effort by the healthcare provider to collect information about refill histories needed to perform the calculation. This is complicated when patients do not use the same pharmacies to fill their medications each month or if their regimen is frequently being modified, which commonly occurs in heart failure patients as they start new medications and titrate towards goal doses. Greater clinical utility could be found in a method that accurately measures medication adherence and relies upon verbal confirmation from a patient rather

TABLE 5. Secondary Objective Results

HL Measurement	M2	Correlation Between HL and M2, r	p-value
REALM-R	Nurse assessment	0.09	0.561
	Pharmacist assessment	-0.03	0.830
	Patient education level	0.26	0.080
	Patient knowledge of target heart failure values	0.12	0.415
	Nurse assessment	-0.48	0.0006[a]
STOFHLA	Pharmacist assessment	-0.28	0.052
	Patient education level	0.24	0.105
	Patient knowledge of target heart failure values	0.31	0.034
	Nurse assessment	-0.11	0.474
Summed Health Literacy Scale	Pharmacist assessment	0.17	0.261
	Patient education level	-0.33	0.023[a]
	Patient knowledge of target heart failure values	0.09	0.554

HL, Health Literacy; M2, Measurement 2; REALM-R, Rapid Estimate of Adult Literacy in Medicine–Revised[7]; STOFHLA, Short Test of Functional Health Literacy in Adults[6]
[a] Significant at P<0.05.

than upon external data collection. The final question of the MMAS ("How often do you have difficulty remembering to take all of your medication?") was significantly correlated with the MPR, suggesting that asking this question at a patient visit may serve as a clinically useful indication of a patient's medication adherence.

Clinician Assessment

Health literacy is not regularly assessed in patients, but clinicians may be able to deduce it through their interactions and conversations with patients. In the MC HFC, nurses had an opportunity to meet with patients on at least two separate occasions, whereas pharmacists only had one scheduled 30-minute appointment with the patient before they were asked to evaluate health literacy of the study participant. This is a possible explanation for why nurses were more accurately able to predict health literacy of patients than were pharmacists (according to the STOFHLA, p=0.0006, but not the REALM-R or summed health literacy scale) (Table 5).

Limitations

There are a few considerations that limit the interpretation of the results of this study. First, the study investigated only the patient's health literacy. Heart failure patients may rely upon family members or friends for information about their health and their medications or for motivation to remember to take their medications. Only patients who were residing in assisted living or nursing facilities were excluded from the study, but patients who might rely heavily upon family members for help with managing their disease state were included. This may deemphasize the relationship between health literacy of the patient and medication adherence or even hospitalizations. Future studies might consider investigating the impact that a caregiver's health literacy has on a patient's medication adherence or risk of hospitalization.

Additionally, this study enrolled a small number of patients. Several patients had been identified for potential enrollment but were unable to be enrolled due to various reasons. Some patients decided not to participate stating reasons such as forgetting their glasses. Interestingly, forgetting one's glasses at home has been suggested to be an indicator of lower health literacy on its own.[14] It is therefore likely that the results of this study underestimated the actual rates of low health literacy in this heart failure study population, hence, the interpretation of our findings should be taken carefully.

Finally, the population in this study was from a single center in a rural community. The majority of the patients described themselves as white, and over half of the patients had a high school or lower education. Although education level and literacy level are not adequate indicators of health literacy alone, they may be contributors.[14] Therefore, the same rates of low health literacy and medication adherence may not be observed in a more heterogeneous, urban-based population.

Conclusion

Approximately 30% of newly enrolled patients in the MC HFC have low health literacy. Several tools that may be useful in clinical practice have been identified to help clinicians gain a quick estimate of health literacy and medication adherence. This study identified that the clinical question, "How confident are you in filling out forms by yourself?" might provide an indication of a patient's health literacy, and the MMAS question "How often do you have difficulty remembering to take all of your medications?" provides an indication of a patient's medication adherence. Once clinicians are able to identify patients with lower health literacy or low medication adherence, they may better be able to target their interventions and tailor their communication to effectively reach their patients. Future direction for research includes development and investigation of tools that can be utilized with patients who are identified to have low health literacy or low medication adherence in order to improve these measures. Furthermore, in order to promote the goals of the PCMH by improving communication of health information between providers, it may be possible to develop a "Low Health Literacy" indicator in a patient's electronic medical record problem list. Identifying potential barriers to effective communication such as low health literacy will help equip clinicians with the tools they need to help communicate more effectively with patients about their medications and disease states. With this foundation, patients then may be able to make greater strides towards their health care goals. •

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Author contributions: K.H. wrote the manuscript, designed the research, and performed the research. S.G. wrote the manuscript, and designed the research. S.K. designed the research. P.H.C. wrote the manuscript, and analyzed the data.

References

1. Hurtado MP, Swift EK, Corrigan J. Envisioning the National Health Care Quality Report. Washington, DC: National Academy Press; 2001.
2. Ratzan SC, Parker RM. Introduction. In: Selden CR, Zorn M, Ratzan SC, & Parker RM, eds. National Library of Medicine Current Bibliographies in Medicine: Health Literacy. NLM Pub. No. CBM 2000-1. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services; 2000.
3. Hobbs FD. Concordance with heart failure medications: what do patients think? *Fam Pract.* 2006;23(6):607-608.
4. Murray MD, Tu W, Wu J, Morrow D, Smith F, Brater DC. Factors associated with exacerbation of heart failure include treatment adherence and health literacy skills. *Clin Pharmacol Ther.* 2009;85(6):651-658.
5. DeWalt DA, Malone RM, Bryant ME, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. *BMC Health Serv Res.* 2006;6:30.

6. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. *Patient Educ Couns.* 1999;38(1):33-42.
7. Bass PF 3rd, Wilson JF, Griffith CH. A shortened instrument for literacy screening. *J Gen Intern Med.* 2003;18(12):1036-1038.
8. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam Med.* 2004;36(8):588-594.
9. Kelly PA, Haidet P. Physician overestimation of patient literacy: a potential source of health care disparities. *Patient Educ Couns.* 2007;66(1):119-122.
10. Valenstein M, Blow FC, Copeland LA, et al. Poor antipsychotic adherence among patients with schizophrenia: medication and patient factors. *Schizophr Bull.* 2004;30(2):255-264.
11. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich).* 2008;10(5):348-354.
12. De Geest S, Sabaté E. Adherence to long-term therapies: evidence for action. *Eur J Cardiovasc Nurs.* 2003;2(4):323.
13. Peterson PN, Shetterly SM, Clarke CL, et al. Health literacy and outcomes among patients with heart failure. *JAMA.* 2011;305(16):1695-1701.
14. MacLaughlin EJ, Raehl C, Treadway AK, Sterling TL, Zoller DP, Bond CA. Assessing medication adherence in the elderly: which tools to use in clinical practice? *Drugs Aging.* 2005;22(3):231-255.

Summary from the APhA Annual Meeting

by Alicia Ritscher 2019 PharmD Candidate, Heather Stoner 2019 PharmD Candidate, Jing Wu 2018 PharmD Candidate

Editors Note:

This article recaps several presentations of PSW members at the American Pharmacist Association 2017 Annual Meeting in San Francisco, CA.

Betty Chewning

As the healthcare system is evolving to become more patient-centered, Professor Betty Chewning exemplifies how researchers in the UW-Madison School of Pharmacy Social and Administrative Sciences program are able to stay on the front-line of innovative research practices. She used community-based participatory research (CBPR) to invite community members to provide guidance in research design, implementation, and dissemination. Dr. Chewning was able to show how these engaging methods fostered mutual trust and desired outcomes in each population studied, a promising foundation for possible future explorations in improving public health.

Kevin Look

Medications are an important part of care for older adults, especially as the population continues to grow, and medication regimens become more complex as people age. Professor Kevin Look, also from the UW-Madison School of Pharmacy Social and Administrative Sciences Program, investigated the importance of patient characteristics (i.e. their health, independence, living situation, etc.) on medication management by caregivers. After conducting focus groups with caregivers in a rural Wisconsin County, Dr. Look found that several factors including the patient's health, independence, living situation, and beliefs, make managing medications easier or harder for the caregiver. He also discovered that caregivers were frustrated that their concerns were overlooked when communicating with health care providers. By supporting the caregivers through addressing concerns and providing education, Dr. Look identified this area as an opportunity for pharmacists to have a positive impact on patient care.

Alicia Ritscher and Heather Stoner are 3rd Year Doctor of Pharmacy Candidates and Jing Wu is a 4th year Doctor of Pharmacy Candidate at the University of Wisconsin-Madison School of Pharmacy, Madison, WI.