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A Prospective Observational Study Assessing the Impacts of Health Literacy and Psychosocial Determinants of Health on 30-day Readmission Risk

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Abstract

Our objective was to assess the utility of an assessment battery capturing health literacy (HL) and biopsychosocial determinants of health in predicting 30-day readmission in comparison to a currently well-adopted readmission risk calculator. We also sought to capture the distribution of inpatient HL, with emphasis on inadequate and marginal HL (an intermediate HL level). A prospective observational study was conducted to obtain HL and biopsychosocial data on general medicine inpatients admitted to the UCLA health system. Five hundred thirty-seven subjects were tracked prospectively for 30-day readmission after index hospitalization. HL was significantly better at predicting readmission compared to LACE+ (Length, admission acuity, comorbidities, emergency room visits) alone (P = .013). A multivariate model including education, insurance, and language comfort was a strong predictor of adequate HL (P < .001). In conclusion, HL offered significant improvement in risk stratification in comparison to LACE+ alone. Patients with marginal HL were high-risk, albeit difficult to characterize. Incorporating robust HL and biopsychosocial determinant assessments may allow hospital systems to allocate educational resources towards at-risk patients, thereby mitigating readmission risk.

Kevwords

health literacy, 30-day readmission, observation, predictive analysis, health outcomes, social determinants, hospital medicine, marginal health literacy, LACE+, AURA, TOFHLA, patient education, healthcare language barriers.

Introduction

In response to national guidelines by the Center for Medicare and Medicaid Services to focus efforts on reducing hospital readmissions, healthcare systems seek to optimize transitions of care. Population-specific factors for poor care transitions have incorporated measures to predict 30-day readmission rates among hospitalized patients as a means to reduce unplanned readmissions (1). Metrics including the LACE+score (a standardized readmission risk tool including length of stay [L], acuity of admission [A], comorbidities [C], emergency room visits [E]) (2), have assisted providers in directing care towards high-risk patients for future readmission by utilizing clinical and nonclinical parameters (2,3). However, such tools are limited in specific populations. For example, the LACE+ score was demonstrated to be a poor predictor

of readmission when evaluating geriatric patients (4). It was also ineffective at predicting risk for hospitalized heart

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failure patients with limited health knowledge (5). Closer investigations of readmission risk stratification tools within various hospital populations are necessary to determine the appropriate allocation of resources.

Among other studied parameters, functional health literacy (used interchangeably with HL in this study) has been shown to correlate with length of stay (LOS) and readmission rates (6,7). As per the Institute of Medicine, HL is defined 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"(8). Recent studies have investigated HL's ability to predict readmissions for patients with specific disease states (9–13). In contrast to the LACE+, HL was shown to significantly predict mortality in patients with heart failure in a rural setting (11). Additionally, high HL was strongly associated with higher self-care confidence in hospitalized heart failure patients (9). Studies also suggest associations between HL and auxiliary risk factors for readmission, such as fall tendency in geriatric patients (14).

Multiple studies have utilized abbreviated tools such as the Rapid Estimate of Adult Literacy in Medicine and the Brief Health Literacy Screen (BHLS) to expediently assess patients, providing a binary output (High or Low) for HL with varying degrees of success (15-17). Jaffee et al. (18) demonstrated that the binary HL stratification tool, BHLS, could be used to elicit an association between LOS and HL. However, there is a paucity of studies utilizing validated tools that stratify HL beyond 2 functional categories, to assess HL's impacts with greater nuance and granularity. One such validated tool, the test of functional health literacy in adults (TOFHLA) includes a marginal HL category, defined as an intermediate level of HL between adequate and inadequate, with an objective range of scores that define its reproducibly. Statistical analyses in the literature depict marginal HL as equivalent to a 7th or 8th grade reading, comprehension level (19). However, due to a tendency to bifurcate functional HL level in creating shorter screening tools, the authors of this study theorize that patients with intermediate levels of HL remain uncharacterized. Thus, such patients are difficult to risk stratify. Moreover, few studies have investigated the impact of psychosocial determinants such as patient self-efficacy and language comfort on HL and readmission risk prediction (20–23).

Given the latent utility of HL assessment as an aid to risk stratify patients at risk for poor transitions of care, we evaluated the potential of using robust HL measurements in a risk assessment of our inpatient population. Within the scope of patient-centered readmissions work, our first objective was to assess the combined power of HL and psychosocial determinants in predicting 30-day readmission in general medicine inpatients. To fulfill this objective, we conducted a prospective observational study utilizing an assessment battery of psychosocial factors related to patient transitions of care and the validated assessment tool, TOFHLA, which measures HL with increased granularity by including a marginal subcategory. We also compared the assessment battery's risk-predictive capacity to that of the LACE+ score. Our second objective

was to better summarize the distribution of marginal and inadequate HL within our inpatient population, to better identify features of the population with marginal HL. Through this study, we hope to understand how an extensive assessment of HL and psychosocial determinants of health might fit into operational improvements in transitions of care workflows.

Methods

This prospective cohort study was conducted at 2 medical centers within the UCLA Health System: Ronald Reagan UCLA Medical Center (a tertiary care, academic teaching hospital) and UCLA Medical Center-Santa Monica (a teaching-affiliate community hospital). The study was conducted from February 16, 2018, to August 8, 2018. The protocol was submitted to the institutional review board (IRB) and was determined to be exempt from full IRB review.

As part of the protocol, trained quality improvement (Q.I.) personnel interviewed adult general medicine inpatients meeting inclusion criteria (Appendix Table 1a) at the bedside, utilizing the TOFHLA (Appendix Table 2). The TOFHLA evaluates functional HL, assessing numeracy and reading comprehension through a modified cloze procedure (24). For the purposes of this study, numeracy was defined as the ability to understand and use quantitative information, as per the definition within the administration manual of the TOFHLA tool (Appendix Figure 1). Correct response frequency was translated to one of the TOFHLA's 3 HL proficiencies: Inadequate (score: 0-16), Marginal (score: 17–22), and Adequate (score: 23–36). Descriptive criteria for each level of HL, as stated in the official administration manual, are provided in the Appendix. Patients unable to read or speak English or Spanish at any fluency were excluded from the study, as the TOFHLA tool is validated only in English and Spanish. Patients that could speak English or Spanish at any fluency, but preferred another language were asked whether they prefer a translator or preferred to interact with care providers in English or Spanish. Patients that preferred a translator were excluded from the study population. Patients that could speak English or Spanish at any fluency but preferred another language were also accounted for by the language preference question (Appendix Figure 2). Excluded patients were not given a HL status. Patients with permanent caregivers (for any medical purposes) that always needed to be present within the hospital room were also excluded from the study (see Appendix Table 1b for further details on exclusion criteria).

A cluster of psychosocial metrics: patient education level, self-rated health status, language comfort, native language, internet access to health content, ethnicity, gender, age, insurance status, and self-efficacy was included in the assessment battery. Self-efficacy was interpreted as the patient's belief in their abilities to interpret health information, perform health care tasks, and exercise control over their healthcare activities. We assessed this using a validated proxy measure termed the "Ask, Understand, Remember Assessment (AURA) tool." The AURA consists of 4 statements at a 6th-grade reading level and includes 4 tiers of agreement (25) (Appendix

Figure 3). Education level was measured using the International Standard Classification of Education (26) (Appendix Table 3). Patient self-rated health status was obtained using a 4-point scale (Appendix Table 4). Patients were subsequently asked to report their preferred language and their level of comfort with English using a validated 4-point scale (27) (Appendix Table 5). Patient access to internet health content was evaluated using a binary (yes/no) response (28). Patient ethnicity was self-reported and matched to a category in the US Census 6-category ethnicity table (29) (Appendix Table 6). Demographic data including patient gender, insurance provider, and age were elicited from the patient and confirmed utilizing the electronic medical record. LACE+ scores, as calculated at the time of index hospitalization discharge, were also recorded from the electronic medical record.

Upon completion of bedside assessments, responses were securely stored in a database referred to as REDCap (Research Electronic Data Capture), a clinical research workflow-optimized, HIPAA compliant data storage platform (30). Following index discharge, enrolled patients placed in cohorts corresponding to their HL as defined by the TOFHLA were tracked prospectively, utilizing the electronic medical record to determine their 30-day readmission status within the UCLA Health hospital system. Patients readmitted for planned organ transplantation, maintenance chemotherapy, planned procedures, or obstetrical delivery were considered planned readmissions and excluded from the analysis.

Statistical Analysis

Two sample t-tests were used to compare continuous variables between groups, and Fisher's exact test was used to compare categorical variables. TOFHLA was analyzed as a variable (adequate vs inadequate/marginal). binary Unadjusted and multivariable logistic regression models were also used to analyze associations between patient characteristics and all 3 TOFHLA categories, as well as readmissions. Associations were summarized using odds ratios (ORs) and their 95% confidence intervals (CI). To evaluate whether TOFHLA adds predictive value to LACE + score predicting 30-day readmission (y/n), the area under the curve (AUC) from the receiver operating characteristic (ROC) curves of the 2 logistic models using LACE + score and combined LACE + score and TOFHLA, were compared using DeLong's test. All tests were 2-sided, and P-values <.05 were considered statistically significant. The data sets were assessed using completed case analysis, in which subject entries with incomplete or missing parameters were omitted from analysis, to ensure statistical uniformity. Analyses were performed using SAS, Copyright I 2002-2012 by SAS Institute Inc., Cary, NC, USA.

Results

Five hundred thirty-seven patients met the inclusion criteria and were subsequently evaluated by trained Q.I. personnel

Table 1. Univariate Statistics Summary of Patients' Demographics and TOFHLA Scores.

Variable	N = 537
Age	
MEAN (SD)	56.02 (18.43)
Ethnicity	
White	289 (54%)
Hispanic/Latino	107 (20%)
Black/African American	80 (15%)
Other	64 (12%)
Gender	
Female	269 (50%)
Male	268 (50%)
Education	
Less than HS	27 (5%)
HS or Some college	247 (46%)
College & post grad degree	263 (50%)
Preferred language English	
No	166 (31%)
Yes	370 (69%)
Insurance type	
MediCal	37 (7%)
Medicare	209 (39%)
PPO	37 (7%)
Other	247 (46%)
Missing	2 (0.003%)
TOFHLA score	
Adequate	339 (64%)
Marginal	134 (25%)
Inadequate	64 (12%)

to partake in our study. Table 1 is a summary of the descriptive statistics obtained for the patient cohorts.

Sample Characteristics

The median LOS was 7 days (IQR = 4-13 days), and the mean LACE+ score was 58.97 (SD = 14.7). As per the LACE+ score interpretation guidelines(2), LACE+ scores were defined as having low (score ≤ 28), medium (score between and including 29-58), and high (score ≥ 59) risk for readmission. This suggests that our patient population had several comorbidities, and at baseline, was on the border between medium and high risk for readmission. When tracking patients prospectively, it was determined that 107 (19.9%) patients had an unplanned readmission within the UCLA health system, 30-days after index discharge.

Parametric Associational Analysis

A ROC curve was used to assess the LACE+ score's ability to discriminate between 30-day unplanned readmitted and nonreadmitted patients. A second ROC curve was also generated by combining TOFHLA and LACE+ to evaluate any improvement in the discriminatory ability of the model. The AUC for LACE+ was 0.55, 95% CI:

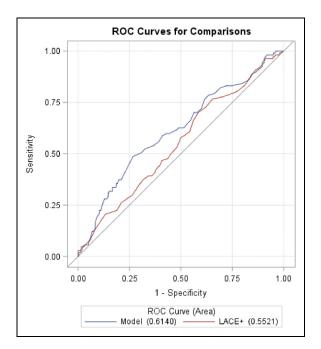


Figure 1. ROC curve comparison between TOFHLA and LACE+ scores in terms of readmission predictive power. LACE+ score alone (AUC=0.55, 95% CI: 0.49-0.61) with a model including LACE+ score and TOFHLA adequate score (y/n) (AUC=0.062; 95% CI: 0.013-0.111).

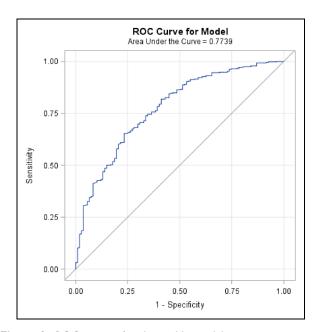


Figure 2. ROC curve of multivariable model investigation, a combination of demographic as TOFHLA predictors. AUC = 0.77, 95% CI (0.72-0.82).

(0.49-0.61) (Figure 1), while the combined TOFHLA and LACE+ score model had an AUC of 0.61; 95%CI: (0.55-0.68). Δ AUC was calculated by determining the difference between TOFHLA combined with LACE+ AUC and TOFHLA and LACE+ AUC alone. The *P*-value was

calculated using DeLong's test. The combined model performed significantly better than LACE+ alone, Δ AUC = 0.062, 95%CI (0.013, 0.111); P = .013 (Figure 1).

Predictors of TOFHLA

With the observed improvement in predictive performance by combining TOHFLA with LACE+ and given that the feasibility of administering the TOFHLA tool was not yet determined, we sought to ascertain whether a patient's TOHFLA score could be predicted in terms of commonly captured demographic and clinical characteristics. We first determined individual associations between HL and multiple psychosocial factors to help characterize patient HL Fisher's exact test revealed a significant association between adequate HL and high education level (P < .001). Fisher's exact test also demonstrated a significant association between inadequate HL and low education (less than high school P =.045). AURA scores were used to effectively assess a patient's self-efficacy. A Spearman correlation illustrated a significant correlation between HL and AURA score (rho = 0.12; P = .018) as well as HL and self-rated health status (rho = 0.09; P = .044). In multivariate analysis, the strongest predictors of Adequate TOHFLA (y/n) included: age (P< .001), gender (P = .03), education (Less than High School, High school and some college, and College and Postgraduate Degree) (P < .001), insurance (Medical, Medicare, PPO, and Other) (P = .05), and preferred language English (y/n) (P = .009) (Appendix Table 7). The selected metrics were designated as predictors of TOFHLA score based on their significant individual associations in comparison to other elicited metrics. Given their significant individual predictive power, we sought to determine the combined performance of these metrics in predicting HL. ROC analysis was conducted to achieve this and revealed that the AUC for the multivariable model was 0.77, 95%CI (0.72-0.82) (Figure 2). However, these combined characteristics (stated above) did not yield a significant correlation with readmission (AUC 0.18, 95%CI [0.10-0.27]).

Characterization of Marginal HL

In diving deeper into the granularity of the TOFHLA tool, we observed that marginal HL had a higher association with readmission, compared to inadequate HL (OR 3.28, 95% CI [1.85–5.38]), P<.001). Inadequate HL also had a higher association with readmission when compared to adequate HL (OR 1.94, 95% CI [1.048-3.603], P<.001). The mean education level for marginal HL was at the level of "some college coursework without a degree." However, identifying marginal HL using education as a proxy measure may not account for all marginal HL patients, due to variance in education levels (in contrast to adequate and inadequate HL, where the education level is significantly correlated, P<.001 and P=.045, respectively).

The language preference metric revealed that 31% of the total subject population had chosen a non-English primary language. Patients with marginal HL had a higher "non-English language" preference (39.9%). However, a majority (60.1%) of marginal HL patients were comfortable with English instructions, in contrast to the 71% of patients with inadequate HL choosing a non-English primary language.

Basic Feasibility Analysis

In a post-hoc feasibility analysis, we examined the time taken to administer the TOFHLA and capture other metrics to determine the feasibility of fitting this assessment battery into existing hospital system workflows. The total administration time for the TOFHLA assessment (mean time of 12.8 min per patient [SD: 2.82]) and psychosocial determinant assessments (mean total time of 3.0 min [SD: 1.1]) was 15.8 min. This time does not include pre-administration tasks to determine patient eligibility (using inclusion and exclusion criteria). Four printed pages of assessment battery administration-associated materials were required per patient. Data input into the REDCap database was conducted manually upon conclusion of assessments and took approximately 15 min for every 5 patients surveyed (mean input time: 15.3 min, SD: 3.6).

Discussion

Our first objective proposed a comparison between the combined predictive power of the TOFHLA and psychosocial parameters to that of the LACE + score regarding readmission risk. The ROC curve (Figure 1) for the TOFHLA and LACE+ model performed significantly better than the LACE + alone in predicting readmission (P = .013). A multivariable regression utilized education, ethnicity, preferred language (all cited as having an impact on HL) and other metrics including insurance status and language preference did not yield significant correlation with readmission risk (C-statistic 0.18) but had a strong ROC (C-statistic = 0.77) when estimating HL (23,26) (Figure 2). This indicates that the collection of disparate metrics may not capture the breadth of psychosocial influences tied to HL that affect readmission risk directly and indirectly. A cross-sectional analysis conducted by Fiscella et al. depicted direct, individual associations between variables such as ethnicity, income and relative risk of influenza infection (23), but further work is needed to appreciate how these variables portend marginal HL as a risk factor for readmission. The data validates that the LACE + tool alone may not sufficiently identify patients at high risk of readmission. The ROC analysis (Figure 2) also supports the position of utilizing the set of metrics including age, gender, education level, insurance, and preferred language as a proxy for TOFHLA score. However, the inability of this model to significantly predict readmission restricts us from incorporating these metrics solely into clinical care plans. Other models using pre-

Table 2. TOFHLA Categorization Levels Based on Health Literacy Fluency.

Level	TOFHLA score	Functional HL description
Inadequate HL	0-16	Unable to read and interpret health texts
Marginal HL	17-22	Has difficulty reading and interpreting health texts
Adequate HL	23-36	Can read and interpret most health texts

Table 3. International Standard Classification of Education. Eight Classifications.

International standard classification of education

Less than High School
High School Diploma or equivalent
Some College, no degree
Postsecondary non-degree award
Associate's degree
Bachelor's degree
Master's degree
Doctoral or Professional degree

Table 4. Self-Rated Health Status Using 5-Point Likert Scale Standardized Question.

Self-rated health status assessment scale

- 1. Very bad
- 2. Bad
- Good
- 4. Very Good
- 5. Excellent

existing social determinant parameters available in a patient's chart have been developed to eliminate the use of additional tools. For example, the area deprivation index (ADI), developed by the United States federal census office, was utilized by Hu et al. to appreciate the statistically significant influences of environment (such as a patient's neighborhood) on readmission likelihood (31). A promising body of research harnessing machine learning to titrate the weightage of individual social determinants on readmission risk is also underway (32,33).

Metrics such as the AURA reflect how social parameters such as self-efficacy have a quantifiable impact on the quality of life. The significant positive association between AURA score and HL (P=.018) indicates that inadequate HL and lower self-efficacy may increase barriers to communication and compliance. Metrics such as self-rated health status also remain unquantified, possibly due to the difficulty in data capture. However, the significant positive association between HL and self-rated health status (P=.044) suggests

that a patient's perception of health status may adversely affect their HL and may have impacts on readmission risk. Patients with low HL may invariably enter the hospital setting with a low self-efficacy and thus perceive their health condition as suboptimal due to their inability to

Table 5. Standardized 4-Point Scale to Assess English Language.

English language assessment scale

- I. Not at all
- 2. Not well
- 3. Well
- 4. Very well

Table 6. U.S. Census 6-Category Ethnicity Categorization.

Ethnicity categorization

American Indian/Alaska native Asian Black/African American Pacific Islander White Hispanic/Latino effectively utilize health resources and navigate the healthcare environment (Figure 1). This is consistent with the literature for specific patient populations. Taal et al. (34) demonstrated an association between self-efficacy and health status amongst patients with rheumatoid arthritis, concluding that patient education should focus on strengthening self-efficacy to improve self-management. Furthermore, Salbach et al. (35) observed a positive association between self-efficacy and health status in post-stroke patients in a randomized trial.

The complexity in identifying marginal HL patients, as noted in the results, may force care teams to default marginal HL patients to the adequate category, as such patients may have some competency that masks any limitations without a deeper investigation. However, the data suggests that marginal HL patients should be defaulted to the inadequate HL category, due to the greater similitude in population profiles and higher readmission risk. Specifically, as it pertains to discharge teaching, it is plausible that the marginally health literate patient will understand some post-discharge instructions but misunderstand details that are necessary for complex medication administration.

The analysis also revealed that the optimal period for assessment battery administration was well before patient discharge, to effectively organize educational interventions delivery around the patient's predicted LOS. Additionally, incorporation of the assessment battery into a clinical care

Table 7. Univariate (Unadjusted) and Logistic Regression Model (Adjusted) Model Using TOFHLA Proficiencies as Outcome Variables. Two Sample *t*-Tests Were Used to Compare Continuous Variables Between Groups, and Fisher's Exact Test was Used to Compare Categorical Variables.

Effect	Unadjusted-odds ratio (95%CI)	P-value	Adjusted-odds ratio (w/ transplant)	P-value	Adjusted-odds ratio (w/ o transplant)	<i>P</i> -value
Age	0.98 (0.97, 0.99)	.0048	0.96 (0.95, 0.98)	<.001	0.96 (0.95, 0.98)	<.001
Gender male	0.73 (0.48, 1.12)	.1541	0.79 (0.49, 1.28)	.336	0.8 (0.49, 1.29)	.361
Ethnicity		<.001		.006		.006
Hispanic/Latino versus White	0.26 (0.15, 0.44)	<.001	0.41 (0.2, 0.83)	.0139	0.41 (0.2, 0.85)	.016
Black/African American versus White	0.44 (0.24, 0.81)	.0088	0.35 (0.18, 0.68)	.002	0.35 (0.18, 0.68)	.002
Other versus White	0.63 (0.31, 1.3)	.2133	0.7 (0.3, 1.66)	.4186	0.71 (0.3, 1.68)	.437
Education	,	<.001	,	<.001	,	<.001
HS or Some college versus Less than HS	6.41 (2.61, 15.75)	<.001	5.23 (1.85, 14.78)	.002	5.43 (1.94, 15.21)	.001
College degree and Post graduate versus Less than HS	13.94 (5.53, 35.11)	<.001	10.72 (3.64, 31.58)	<.001	11.16 (3.83, 0.57)	<.001
Insurance		.003		.061		.058
Medicare versus MediCal	2.49 (1.21, 5.11)	.0139	2.74 (1.17, 6.43)	.021	2.76 (1.18, 6.48)	.020
PPO versus MediCal	2.32 (0.87, 6.18)	.0938	1.53 (0.5, 4.65)	.455	1.53 (0.5, 4.65)	.456
Other versus MediCal	3.95 (l.91, 8.17)	<.001	2.8 (l.24, 6.37)	.014	2.82 (I.24, 6.4I)	.013
Preferred language English versus Other	2.84 (1.83, 4.39)	<.001	2.23 (1.22, 4.08)	.010	2.25 (1.23, 4.11)	.009
Transplant yes versus no	1.58 (0.84, 2.97)	.1568	1.21 (0.61, 2.43)	.583		
Internet access yes versus no	2.99 (1.65, 5.44)	<.001	, ,			
Good self-health yes versus no	1.31 (0.85, 2.02)	.2189				
Aura high versus low	2.34 (1.52, 3.61)	<.001				

management plan upon admission would have allowed for timely delivery of assessments, reducing interference with transition of care procedures. Volunteer Q.I. personnel also reduced the burden on nursing and clerical staff by administering the assessment battery during their standard volunteer shift hours. Given that physicians and allied health care providers could utilize collected data to make educational resource allocation decisions in real time, the intended user base for the assessment battery data was determined to be care-team constituents responsible for choosing, and delivering educational interventions to patients during discharge planning.

As part of the next steps to inform change, the results were presented to health system leadership focused on readmission reduction as well as nursing leadership focused on patient education. Further pilots utilizing the study results are in development to help administer patient education to at risk populations at integral times to improve patient outcome and experience.

Limitations

This study should be interpreted in view of its limitations. While we were able to enroll patients at 2 study sites, our results may not be generalizable to other patient populations. Additionally, paper administration of the assessment battery might be cumbersome without dedicated Q.I. personnel due to burdening health systems with resource constraints. Utilizing an electronic medium may augment administration time and ease, and reducing data upload time. Moreover, readmissions of patients within other departments were not captured, potentially affecting the predictive capacity of the metrics discussed. Future iterations will include piloting this assessment battery in other service lines.

Conclusion

The superior predictive capacity of HL demonstrates its value in readmission risk assessment. Known psychosocial determinants such as ethnicity, language preference, and education level fail to characterize marginal HL effectively, highlighting the latent need to increase the granularity of HL assessment tools used in stratifying readmission risk. However, these determinants, along with others such as AURA score and self-rated health status, associate significantly with adequate HL, underscoring the multifactorial composition of HL as a socio-clinical marker of patient health. Further interventions may focus on optimizing HL tool administration and integration into operational workflows for discharge planning in general medicine and stepdown unit patients. Additionally, broadening the linguistic scope of the TOFHLA may capture HL in high readmission risk patients with no English or Spanish fluency.

Finally, the utilization of trained volunteer Q.I. personnel and electronic assessment mediums could augment prospective data collection. The data on psychosocial determinants presented here could act as a nidus for the assembly of larger datasets that more accurately capture marginal HL. Through the assessment of HL and the collection of significantly associated psychosocial determinants, hospital systems may allocate educational resources towards marginal HL patients and reduce the risk of unplanned readmissions in this patient population.

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Informed Consent

Verbal informed consent was obtained from the patients for their anonymized information to be published in this article.

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Appendix

Descriptive criteria for each category of health literacy according to TOFHLA administration protocol:

directions for their healthcare." They are likely to "take their medication incorrectly, or fail to follow prescribed diets or treatment regiments."

Table 1a. Study Inclusion Criteria.

Inclusion criteria	Reasoning
Age >18 Patient primary care team: internal medicine only (all patients within the purview of internal medicine hospitalists in general medicine wards) Ability to read English or Spanish language at any fluency	 Per TOFHLA, AURA administration instructions. Access to patients in other service lines was limited, and most patients in these service lines did not meet mental and visual acuity criteria during the study period.
Do not require access to translator and prefer to speak in the chosen language (English or Spanish) with the care provider.	 English OR Spanish fluency at any level meant that patients could be provided the TOFHLA (English) or TOFHLA (Spanish) as a valid measure of health literacy. Patients with other language preferences that did not want a translator (preferred to communicate in English or Spanish) were still valid candidates for the TOFHLA, as they preferred either English or Spanish over their primary language, during all patient-provider interactions.
Ability to speak English or Spanish language at any fluency	 English OR Spanish fluency at any level meant that patients could be provided the TOFHLA (English) or TOFHLA (Spanish) as a valid measure of health literacy.
 Patients with other language preferences that did not want a translator (preferred to communicate in English or Spanish) were still valid candidates for the TOFHLA, as they preferred either English or Spanish over their primary language, during all patient-provider interactions. Ability to comprehend and respond to prompts provided by research assistants: Negative assessment of altered mental status by nurse assessment and medical history 	
Negative assessment of oculomotor or visual function impairment by nurse assessment and medical history	 Patient visual acuity and mental status were assessed by the providing nurse, to ensure that patient evaluation via TOFHLA was effectively assessing health literacy.
Ability to provide informed consent to Q.I. personnel at all segments of assessment battery administration	 Q.I. personnel would ensure that collected data was given with fully informed consent, and patient consent status did not change throughout the assessment period.
Subject must be located within a private hospital room	 Subjects in hospital rooms with significant background noise or interaction with others were excluded, to minimize interruptions and distractions during the assessment.
Subject may be bilingual, but must select a preferred language	 Patients were required to select the preferred language for interactions with all care providers. This was confirmed with the nurse in charge of care.
Patients with caregivers for specific physical needs only.	 Caregivers were required to leave the room during assessment battery administration, to ensure that their prompts or responses did not affect the patient's responses.

- Adequate HL → Patients are able "to read, understand and interpret most health text."
- Marginal HL → Patients have "difficulty reading and interpreting health text," and "struggle to understand
- Inadequate HL →Patient are "unable to read and interpret health texts."

Table 1b. Study exclusion criteria

Exclusion criteria	Reasoning
Age <18 years	Per TOFHLA and AURA administration guidelines
Altered mental or visual/ oculomotor impaired status as determined by nurse assessment	 Inability to perform tasks required to assess health literacy and other metrics, per the print material administered in the assessment battery
No fluency in English or Spanish language	 Patients that required translator services during interactions with care providers and could not speak English or Spanish in any fluency could not be tested with the TOFHLA.
Patients with permanent caregivers for any medical purpose that require assisting the patient with tasks beyond the daily living activities, and any assistance in mental tasks.	 Patient mental ability and thus health literacy is likely to be influenced by the caregiver in any interactions with the healthcare system. Additionally, such caregivers were unable leave the room, introducing opportunity for error.

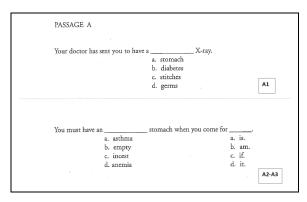


Figure 1. TOFHLA sample passage as given to subject.

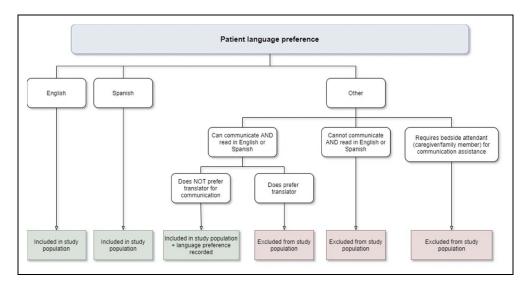


Figure 2. Study design—Patient language preferences were subclassified and utilized to determine the study population using the schematic above.

	AU	RA	
	ou just a few questior DISAGREE with the fo	ns about your visits wit ollowing statements.	h your doctor. Tell
INTERVIEWER: After or 'A Lot' to the sta		ask if they AGREE or	DISAGREE 'A Little
DISA	GREE	AGREE	
1. It is easy for me t	o <u>ask</u> my doctor que	stions.	
1	2	3	4
(A Lot)	(A Little)	(A Little)	(A Lot)
2. It is easy for me t	o <u>ask</u> for help if I don	't understand someth	
1	2	3	4
(A Lot)	(A Little)	(A Little)	(A Lot)
3. It is easy for me t	o <u>understand</u> my doc	ctor's instructions.	
1	2	3	4
(A Lot)	(A Little)	(A Little)	(A Lot)
	o <u>remember</u> my doc		
4. It is easy for file i			
1	2	3	4

Figure 3. Ask, Understand, Remember Assessment (AURA) tool scoring and interpretation index. Source: Clayman et al., 2010.