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MEDICATION HEALTH LITERACY MEASURE: DEVELOPMENT AND PSYCHOMETRIC PROPERTIES

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Abstract

Background & Purpose—Low levels of health literacy are prevalent world-wide. This report details development and psychometric properties of a health literacy measure for oral medications based on design of the Newest Vital Signs.

Methods—The measure was completed during the baseline interview. A Principal Components Analysis evaluated dimensionality of the measure. Cronbach's Alpha assessed subscale internal consistencies.

Results—Internal consistencies and reliability for the subscales were acceptable for a new instrument ($\alpha = .661$), ($\alpha = .686$), ($\alpha = .400$). A three-factor structure explained 65.34% of the total variance. Divergent validity with the REALM was established.

Conclusions—Our data indicates that the medication health literacy tool is multi-dimensional, valid, and reliable. This information is important in light of emerging evidence of the impact of health literacy on medication adherence and health.

Keywords

Health; Literacy; Medication; Validity; Reliability

INTRODUCTION

Health outcomes and costs of health care are clearly related to the degree that patients follow their treatment regimens (Dunbar-Jacob, 2005). There is compelling evidence that patients

with chronic illness are not adhering to treatment regimens as prescribed in the United States and around the world (National Council, 2007). Non-adherence has been a persistent problem over the past 25 years despite numerous informational, educational and behavioral interventions to promote better patient compliance, particularly with medications (Burke & Dunbar-Jacob, 1995). Our aging population, with increasing numbers of comorbid chronic illnesses and comparably complex medication regimens, is at risk of poor physical and emotional health outcomes resulting in marginal quality of life due to difficulty with adherence to medication regimens (McElnay, McCallion, al-Diagi, & Scott, 1997). An increasing amount of data based evidence demonstrates that being able to understand basic information about prescriptions impacts significantly on ability to adhere to a medication regimen (Gazmararian et al., 2006; Davis et al., 2006).

BACKGROUND

Health literacy is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (U.S. Department of Health and Human Services, 2012). Medical and pharmaceutical researchers have increasingly focused on health literacy over the past decade, particularly as it relates to adherence with varied treatment regimens (Ngoh, 2009). Low levels of health literacy are prevalent world-wide (Jovic-Vranes, Bjegovic-Mikanovic, Marinkovic, & Kocev, 2011); inadequate health literacy is associated with poorer health outcomes, medication non-adherence, increased hospitalizations and health care costs (Eichler, Wieser, & Brugger, 2009).

A study of relationships between health literacy, cognitive ability, education, health and demographic variables among community dwelling adults diagnosed with chronic heart failure determined that older African American males scored lower on a test of health literacy and that education and cognitive ability explained age differences in health literacy (Morrow et al, 2006). Distribution of patient targeted print education materials at pharmacies was not related to patient awareness of risk of nonsteroidal antiinflammatory drugs suggesting that more effective strategies to deliver medication information is needed (Miller et al., 2010). Oncology patients are expected to follow complex treatment regimens delivered by multiple providers over time; information is often delivered to patients and families at highly stressful times. Much of the material is written at reading levels above those of most patients' ability; there is clearly a need to improve how needs of patients with low levels of health literacy are met (Garcia et al., 2009). Correct use of medications is particularly crucial for older adults who are prescribed, on average, triple the number of prescriptions written for younger adults. Co-morbid conditions such as diabetes, hypertension, arthritis are treated with multiple medications taken several times each day. This situation is compounded by difficulties with comprehension and working memory more prevalent among the elderly; clarity and brevity of instructions are important (Park & Morrell, 1991). Glaucoma patients with poor health literacy demonstrated poorer compliance, worse disease understanding, and greater disease progression compared to those with adequate health literacy (Juzych, et al., 2008). Limited literacy is a significant risk factor for misunderstanding dosage instructions for liquid medications commonly prescribed for children (Bailey et al., 2009).

Health literacy is a complex construct but the most often used tests: Rapid Estimate of Adult Literacy in Medicine (REALM) and Test of Functional Health Literacy in Adults (TOFHLA) focus on pronunciation, reading, and word comprehension. Administration of the REALM is brief but available only in English; TOFHLA is available in English and Spanish but administration takes 22 minutes. These measures are limited in that they provide no information about ability to process, understand, and use information; relevance and application to clinical care is limited. A recently published systematic review of 7 studies that investigated relationships between health literacy measured with either TOFHLA or REALM found no definite association between health literacy and medication adherence among older adults (Loke, Hinz, Wang, and Salter, 2012).

The Newest Vital Sign (NVS), a brief, valid health literacy tool available in English and Spanish, was developed with support from Pfizer Corporation's Health Literacy/Clear Health Communication Initiative. NVS was developed by a panel of health literacy experts based on scenarios and questions from over 1000 patients. The final version consists of an ice cream label with facts about nutrition and six questions that target the ability to understand and use the information in various ways: prose, the ability to understand and apply words; numeracy, the ability to use numbers and mathematical concepts in everyday life; and documentation, the ability to interpret what is on the label (Weiss, 2005). The measure assesses prose, numeracy and documentation and yields a total score.

There are no known instruments available that assess health literacy related to understanding and using information on prescription medication labels. This report details development and psychometric properties of a health literacy measure for oral medications based on data from two studies conducted at the University of Pittsburgh (NR00978) and (P01NR0110949).

METHODS AND MATERIALS

Instrument Development

The medication health literacy screen was developed as a measure of use and understanding of information on prescription labels. In the current investigation, two labels were utilized: one for immunosuppressant medication and one for diabetes medication. Both are formatted like the NVS, consisting of a label for the immunosuppressant drug (Prograf©) and diabetes medication (Metformin©). The labels, developed in consultation with a practicing registered pharmacist (RGS), are printed and laminated. Six questions to assess prose, numeracy, and documentation follow the content and format of the NVS. Unlike the NVS, we chose to use subscale scores (prose, numeracy, documentation) to inform clinicians about specific literacy abilities in addition to the total score. (Prograf label and questions are attached) The questions were developed in consultation with 2 health literacy experts (CN, AC). The advice and contribution of these experts during development of the screening measure establishes content and face validity for the tool.

Study Setting and Sample

First time, English speaking, adult liver transplant recipients were recruited from the Starzl Transplant Institute (STI) at the University of Pittsburgh Medical Center (UPMC) prior to discharge from the hospital or at an early clinic visit. Diabetics with co-morbid conditions (hypertension and/or hyperlipidemia) on complex medication regimens (more than 2 medications, at least one of which is taken twice a day) were recruited from community sites in Allegheny and Fayette counties in Pennsylvania. Approval from the University of Pittsburgh's IRB was obtained prior to recruitment in both studies; informed consent was obtained from all subjects at the time of enrollment. This report focuses on a subset of 50 liver transplant recipients who were transplanted between May, 2007 and April, 2010 and 89 subjects with diabetes and co-morbid conditions recruited between February 2010 and January 2012. Education levels, the only socio-demographic characteristic likely to impact on health literacy, are comparable in both samples.

Description, Administration, Scoring of the Instrument

All subjects completed the health literacy measure in person during the baseline assessment shortly after enrollment. Participants in both studies were handed the medication label (Prograf label for liver transplant recipients, Metformin label for diabetics) and given time to read it. The interviewer then asked the six questions (2 prose, 2 numeracy, 2 documentation); answers were noted and scored. Each question is scored 0 for incorrect and 1 for correct yielding a possible subscale score of 2 and a total score of 6. Totals for each section and the total were recorded. Each questionnaire was reviewed separately by 3 members of the research team to determine inter-rater agreement; disparate opinions were discussed and resolved. Liver transplant recipients also completed the REALM to assess convergent or divergent validity with the medication health literacy measure.

Analytic Strategies for Validity and Reliability Assessment

All analyses were performed using SPSS v. 20 (SPSS, Inc). Significance was set at .05. Items were examined to determine issues such as redundancy (inter-item correlations greater than .8) or floor and ceiling effects. Item feasibility was also assessed; items with more than 5% missing data were considered problematic. Internal consistency reliability was assessed using Cronbach's alpha for each subscale; total reliability was not calculated given the multidimensional structure of the instrument. According to Nunnally and Bernstein (1994), an acceptable internal consistency coefficient for a new instrument would be considered satisfactory at around the $\alpha=.7$ level. However, alpha fluctuates based on the number of items per scale and the size of the sample (Charter, 2003). Because each of the subscales of the health literacy tool contains only two items and the sample size was less than 400, internal consistency estimates were expected to be slightly less than the recommended cut-off (Charter, 2003). There was no data from a gold standard measure of medication health literacy; therefore, two *a priori* hypotheses were tested in order to establish evidence of validity.

Hypothesis 1: The factor structure of the health literacy tool will be multi-dimensional, with two items loading on each of three subscales.

In order to test hypothesis 1, a Principal Components Analysis (PCA) with Varimax rotation was performed. Several details were considered prior to conducting the PCA including sample size and the factorability of the item correlation matrix. Streiner (1994) suggested that an adequate PCA solution can be obtained with five participants per variable as long as the sample size surpasses 100. The KNO statistic (Kaiser, 1974) and Bartlett's Test of Sphericity were both examined to determine the factorability of the data. Factor retention was based on the scree plot, eigenvalues greater than 1, and amount of total variance explained by the factor. Loadings greater than .32 were considered acceptable (Tabachnik & Fidell, 2006). Items with factor loadings greater than .32 on two or more factors were considered cross-loaders. Cross-loading items were investigated further by checking internal consistency of the subscale with and without the item.

Hypothesis 2: The REALM is a test of pronunciation whereas the medication health literacy screen assesses the ability to understand and use information on prescription labels; therefore these instruments will represent different constructs. Each subscale score of the health literacy tool will have a weak relationship with the REALM score, indicating that the construct measured by the health literacy tool is distinct from the construct measured by the REALM. This would provide divergent validity evidence. In order to test hypothesis 2, correlations between the health literacy subscale scores and REALM scores were computed. REALM scores were available for the sample of 50 liver transplant recipients; therefore, the investigation of hypothesis 2 focused on the liver transplant subgroup.

RESULTS

Socio-demographics

The sample was predominantly male (64.7%), white (94.1%), age ranged from 37–73 (mean 55.6, sd 9.0). Nearly half of the sample (47.1%) had completed education beyond the high school level; 19.6% completed 4 years of college or graduate school. These statistics are comparable to data in the larger samples.

Analyses

Table 1 reports the inter-item correlations for each subscale item of the health literacy scale, along with the response distributions. Correlations among the prose and numeracy items were moderate; however, correlations among the documentation items and prose/numeracy items tended to be weak. There were no ceiling or floor effects noted in the item distributions, and there were no missing data. Internal consistency for the prose and numeracy subscales were acceptable for a new instrument ($\alpha = .661$) and ($\alpha = .686$), respectively; however, the reliability of the documentation subscale was slightly lower than expected ($\alpha = .400$). The KMO statistic was .6 and Bartlett's Test of Sphericity was significant at ($\chi^2_{(15)}=61.5, p < .001$) indicating that the PCA was appropriate for the data. The PCA yielded three factors that explained 65.34 % of the total variance (see Table 2). PCA component loadings are reported in Table 2. The two prose items loaded together to form one factor, and the two numeracy items loaded on a different factor. One documentation item loaded strongly on the third factor, while the second documentation item cross-loaded onto two separate factors (numeracy and documentation). In order to

clarify where the second documentation item best fit, Cronbach's alpha was computed for the numeracy subscale with and without the item. When the second documentation item was added to the numeracy subscale, reliability dropped from $\alpha = .686$ to $\alpha = .593$; therefore, it was determined that the item best fit on the documentation subscale.

Correlations between the 3 health literacy subscales and the REALM were weak and non-significant, indicating diverse measures. Correlations ranged from $r = .004$ (documentation and REALM) to $r = .139$ (numeracy and REALM).

DISCUSSION

Our data indicates that the medication health literacy tool is multidimensional, measuring the constructs of prose, numeracy and documentation as does the Newest Vital Signs instrument. Statistical analyses also document internal consistency and reliability within acceptable limits. Divergent validity with the REALM demonstrates that this measure assesses ability to understand and use information to make decisions about medication taking rather than ability to read and pronounce health related words.

While the internal consistency reliability of the subscales did not achieve the exact .7 level recommended by Nunnally and Bernstein, the prose and numeracy scales were very close. It is expected that with a larger sample size, all three reliability coefficients will increase and meet expectations. Although it can be argued that the low internal consistency coefficient produced by the documentation subscale indicates that an item or both items should be eliminated from the overall scale, the content measured by these items is necessary to maintain the conceptual framework, based on the NVS, of the instrument. Both documentation items were correctly answered by the majority of the participants, indicating that the items are feasible to include on the instrument. Further analyses at the item level with larger samples should be undertaken before a final decision is made on item inclusion. Results of the PCA reveal that the health literacy tool maintained the conceptual structure of the measurement of three separate concepts: numeracy, prose, and documentation. The measurement of these three concepts together represents the person's understanding of information on prescription labels, which can help clinicians assess if patients will correctly use the prescription.

This information is important to clinicians and researchers in light of the emerging evidence of the impact of health literacy on medication adherence and health outcomes. Being able to assess an individual's ability to use information on a pharmaceutical label to make decisions about medications can lead to discussions and interventions that improve the individual's, and ultimately, society's health status and outcomes.

The current investigation details the first steps in scale development. Items were developed in conjunction with content experts, establishing face validity for the tool. Additionally, the PCA analysis provided an initial, exploratory look at the underlying factor structure of the tool. The strengths of the current study are a diagnostically diverse sample and consistent administration of the health literacy screen across samples. Limitations include relatively small, socio-demographically similar and well educated groups of subjects. Further analyses

at the item level and confirmatory factor analysis should be conducted with larger samples to establish stable internal consistency coefficients and confirm the internal structure.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Inter-item correlations and % correct

Item	Prose 1	Prose 2	Num 1	Num 2	Doc 1	Doc 2	%correct
Prose 1	—						86.5
Prose 2	.361**	—					82.3
Numeracy 1	.232**	.117	—				60.3
Numeracy 2	.161	.093	.392**	—			29.1
Documentation 1	−.037	−.066	.034	−.105	—		74.5
Documentation 2	−.041	.026	.057	.196*	.072	—	92.2

**
 $p < .01$

*
 $p < .05$

Table 2

Factor Loadings

Item	Factor 1	Factor 2	Factor 3
Prose 1	.194	.818	-.065
Prose 2	.089	.813	-.065
Numeracy 1	.691	.344	.010
Numeracy 2	.821	.158	-.218
Documentation 1	-.026	.059	.951
Documentation 2	.549	-.219	.321
% Variance Explained (65.34)	28.51	19.88	16.95