Health Literacy in an Adult Dental Research Population: A Pilot Study

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Abstract

Objective: *The purpose of this investigation was to gather data concerning the level of health literacy in adults who frequently volunteer for our clinical research programs.* ***Methods:*** *A convenience sample of 99 adults was recruited from our database of subjects taking part in an ongoing series of investigations. Health literacy was measured using the Short Test of Functional Health Literacy in Adults (S-TOFHLA). Additional demographic and socioeconomic data were collected by means of a questionnaire.* ***Results:*** *The results indicated that 13 percent of the cohort of subjects scored in the "inadequate" or "marginal" categories as described by the criteria of the S-TOFHLA. Inadequate or marginal health literacy was associated with race, gender, and age. Unfortunately, the sample size was too small to determine the interaction of these variables.* ***Conclusions:*** *Dental faculty conducting clinical research investigations should be cognizant of the fact that a portion of adults, especially older adults, may have difficulty reading written instructions, informational letters of consent, prescriptions, and other documents. Researchers should make every effort to ensure that information provided in text form is provided in a manner that is easily understandable to the reader. Technical terminology and jargon should be avoided or if used, it should be explained in plain, simple language. If a potential subject is having difficulty, the investigator is obligated to take the additional time to educate the potential subject using alternative methods.*

Key Words: literacy, health literacy, adult, assessment, S-TOFHLA, informed consent statements

Introduction

At times, researchers are faced with the dilemmas in recruiting and retaining eligible panelists for clinical research or having a therapeutic product that shows great promise in the laboratory but is a failure when tested clinically. In many cases, the researcher is bewildered and concludes that the study design or product is flawed. However, it is possible that the subjects did not fully understand what is required of them or they did not comply with the product usage instructions, and this lack of understanding or compliance may be the result of poor literacy skills. However, little data are available concerning the prevalence of inadequate literacy skills in persons who volunteer to participate in clinical research. The purpose of this pilot investigation was to gather data concerning the level of health literacy in adults who frequently volunteer for our clinical research programs.

Health literacy has been 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" (1). The 2003 National Assessment of Adult Literacy was designed to assess the English literacy of adults in the United States and included items designed to measure health literacy (2). The respondents were rated as below-basic, basic, intermediate, or proficient based on the number of correct replies. The results indicated that many American adults have limited health literacy skills (14 percent were categorized as having below-basic skills). On average, females had higher skills than males, and Whites and Asian/Pacific Islanders had higher mean scores than did Blacks, Hispanics, or American Indians/Alaska Natives (2). Adults 65 years of age and older had lower literacy scores than younger age groups, as did those with lower self-reported educational attainment (2). Although it is agreed that low health literacy is consistently associated with gender, educational attainment, ethnicity, and age (3), low literacy levels have been found in all categories of American adults (4,5).

Studies have indicated that literacy and, specifically, health literacy are related to multiple aspects of health including knowledge, status, outcomes, and the use of services, especially preventive and health-promoting behaviors affecting medical and dental health (6,7). Although not corroborated, it is assumed this is true for oral health as well (8). Low health literacy may also be a factor in health disparities (9), particularly among the elderly (10).

In order to assess reading ability related to medicine, a number of reading assessment tools have been developed including the Wide Range Achievement Test (WRAT) and the Rapid Estimate of Adult Literacy in Medicine (REALM) (4) and the Test of Functional Health Literacy (TOFHLA) (11). Recently, efforts have been made to develop assessment tools

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that measure dental health literacy including the Rapid Estimate of Adult Literacy in Dentistry (REALD-99) (12), the REALD-30 (13), and the Test of Functional Health Literacy in Dentistry (TOFHLiD) (14). Preliminary studies appear promising, and these assessment tools show a great deal of promise for future use to assess literacy skills in a dental health setting.

For this investigation, the Short TOFHLA (S-TOFHLA) was chosen because it offered a number of advantages. The original TOFHLA was designed with the assumption that more than classroom reading ability is necessary to understand and negotiate the modern health care setting (15), and it has been found to have good correlation to both the WRAT and the REALM (15). The TOFHLA and the S-TOFHLA are designed to measure a patient's ability to read and comprehend the items commonly encountered as part of the health care environment (11,15). In both assessments, subjects read passages from which every fifth to seventh word is removed. Lists of possible choices of words are provided and the patient must determine which of the words provided best fits (15). The S-TOFHLA consists of two sections totaling 36 questions of these exercises. The first section is based on patient instructions that might be given preoperatively, and the second is based on the rights and responsibilities of applying for Medicaid. The first section has a readability level of approximately 4.3-grade level and the second has a readability level of grade 10.4 using the Gunning Fog Index (15). Inadequate health literacy is defined as 0 to 16 correct responses; marginal literacy is defined as 17 to 22 correct responses, and adequate health literacy as 23 to 36 correct responses (15,16). For this investigation, the S-TOFHLA was chosen as opposed to the TOFHLA because of its good correlation to the TOFHLA (0.91), its shorter duration of administration (7 versus 20 minutes), the ability to test multiple panelists simultaneously, the availability of validated versions in both English and Spanish, and the elimination of the visual acuity test required in the TOFHLA (15,16).

Materials and Methods

Subject Identification and Procedures. This study was a single-visit study performed at the Oral Health Research Institute of the Indiana University School of Dentistry. The subjects were recruited from an established panel of approximately 100 adults who routinely participate in our ongoing research projects. These were ambulatory adults who are in good medical and dental health. The sample size was based purely on the number of likely affirmative responses the invitation to participate was likely to generate. Subjects were asked to complete an informational letter of consent form, an authorization for the release of health information for research form, and to answer an inclusion/exclusion criteria questionnaire. Prior to the initiation of the investigation, all documents were approved by the IUPUI/Clarian Institutional Review Board (IRB).

Administration of the S-TOFHLA. The S-TOFHLA was administered by study personnel using the narrative provided in the examination packet (15). Subjects were asked if they could see the questions and reading sections and had to self-report affirmatively with either regular or corrected vision. A private writing area was provided with adequate lighting. Pens and other necessary writing supplies were also provided. Each test was timed using stopwatches. Subject identification information on the test was limited to a preprinted subject identification number, which was attached to the test. The necessary demographic information (age, gender, race, etc.) was added by the study coordinator, who was unaware of the test results. Similarly, the principal investigator scored all the tests but had no knowledge of the identity of the participants. Approximately 10 percent of the subjects were asked at random at the conclusion of the S-TOFHLA examination to attend an additional appointment 24 hours after the first. The S-TOFHLA was administered a second time in a manner identical to the first to determine the repeatability of the test in this population.

Following initial analyses of the data, the subjects were asked to complete an additional questionnaire by mail. Additional demographic and health and health perceptions data were collected. The questionnaire and informational letter of consent were reviewed and approved by the IRB as an amendment to the original protocol.

Data Management and Analyses. All data were reviewed by the data manager and processed through multiple verification and edit checking programs. Questionable responses were investigated and resolved prior to their addition to the database. The Kuder–Richardson 20 (KR-20) reliability measure was computed to measure the internal consistency of the S-TOFHLA scale total score. Repeatability of the total score was evaluated using a paired *t*-test and an intraclass correlation coefficient (ICC). Repeatability of the functional health literacy level was evaluated using a two-way contingency table and percentage agreement. Linear regression models were used to evaluate age, gender, and race as predictors of the total score; interactions between predictors were examined but were not found to be significant. Logistic regression models were used to evaluate age, gender, and race as predictors of the functional health literacy level, and interactions between predictors were again examined and not found to be significant. Associations of the items from the questionnaire with categorized health literacy were evaluated using Mantel–Haenszel Chi-square tests for ordered categorical data. All analyses of the total score were performed after using a transformation commonly used for proportions: $\sin^{-1}(\text{total score}/36)^{1/2}$.

Results

Of the 100 possible adults in this study cohort who were invited to

Table 1
Total Score Results by Race and Gender

Race	Gender	*n*	Mean	Standard deviation	Standard error	Min	Max	Median
All	All	99	30.8	5.6	0.6	13	36	33
All	F	59	31.7	4.3	0.6	18	36	33
All	M	39	29.9	6.5	1.0	13	36	33
B	All	37	29.4	5.7	0.9	13	36	31
W	All	58	31.9	5.0	0.7	15	36	34
B	F	31	30.6	4.6	0.8	20	36	32
B	M	6	22.7	6.7	2.7	13	32	22.5
W	F	26	32.8	3.9	0.8	18	36	34
W	M	32	31.1	5.7	1.0	15	36	34

W, White; B, Black; M, male; F, female.

Table 2
Relationship of Age with the Level of Functional Health Literacy

	Literacy level					
	n	Mean	Standard deviation	Standard error	Min	Max
Inadequate	2	80.0	7.1	5.0	75	85
Marginal	10	74.2	4.3	1.4	65	79
Adequate	86	70.4	5.8	0.6	59	85

Table 3
Level of Functional Health Literacy by Race and Gender

		Inadequate		Marginal		Adequate	
Race	Gender	No.	%	No.	%	No.	%
All	All	3	3	10	10	86	87
All	F	0	0	5	8	54	92
All	M	2	5	5	13	32	82
B	All	1	3	6	16	30	81
W	All	1	2	4	7	53	91
B	F	0	0	4	13	27	87
B	M	1	17	2	33	3	50
W	F	0	0	1	4	25	96
W	M	1	3	3	9	28	88

W, White; B, Black; M, male; F, female.

participate in the investigation, 99 provided written consent and 98 completed the investigation. One panelist had to leave because of a scheduling conflict and did not take the S-TOFHLA. The mean age of the subjects was 71.0 years (±5.9 years), with a range of 59 to 85 years of age. Females comprised 60 percent of the panel ($n = 59$), and males 40 percent ($n = 39$). One subject did not provide gender information. Thirty-seven panelists self-identified as Black, and the rest as White ($n = 58$). Three subjects did not self-identify their race. The mean score for all participants was 30.8 (±5.6), indicating an adequate level of health literacy. Females and Whites scored higher than males and Blacks. Tables 1 and 2 summarize the level of health literacy of the subjects by their reported age and by the reported gender and race. The level of health literacy was defined as inadequate, marginal, or adequate based on the scoring criteria used with the S-TOFHLA (15). As can be seen in Table 3, a lower level of reported functional health literacy was associated with a higher mean age.

In accordance with the S-TOFHLA scoring instructions, missing responses were considered as incorrect responses. None of the 13 subjects with inadequate or marginal levels of health literacy completed the 36 questions provided in the allotted time, and all 13 did not provide responses to questions 33 to 36. Of the 10 with marginal literacy skills, nine did not complete questions 28 to 36. Next, missing responses were excluded from the analyses to determine which of the questions tended to be answered incorrectly more often by the subjects who did not have adequate health literacy. While the limited sample size makes it difficult to make strong conclusions, items 3, 4, and 19 were found to be more difficult for these subjects to answer. Of significance is the fact that items 3 and 4 are in section 1 of the S-TOFHLA, with a readability index of grade 4.3.

Using multiple-variable linear regression to predict the total score from age, race, and gender, the R^2 for the model was 0.23, indicating that the three demographic variables explain 23 percent of the variation in total score. Whites had significantly higher total scores than Blacks ($P < 0.01$), females had significantly higher total scores than males ($P = 0.02$), and total score decreased significantly with age ($P < 0.01$). Similar results were obtained using multiple-variable logistic regression to predict adequate versus marginal or inadequate health literacy level.

Table 4
Associations of Functional Health Literacy Level with Survey Responses*

	All		Inadequate		Marginal		Adequate	
	No.	%	No.	%	No.	%	No.	%
Rate your dental health								
Excellent	3	3	0	0	0	0	3	100
Very good	20	22	1	5	1	5	18	90
Good	53	58	1	2	6	11	46	87
Fair	14	15	1	7	1	7	12	86
Poor	1	1	0	0	0	0	1	100
Rate how well you take care of your teeth and gums								
Excellent	5	5	0	0	0	0	5	100
Very good	28	30	0	0	2	7	26	93
Good	51	55	3	6	7	14	41	80
Fair	8	9	0	0	0	0	8	100
Is it sometimes hard for you to understand the things told to you by your doctor or dentist?								
Yes	17	19	1	6	1	6	15	88
No	73	81	2	3	8	11	63	86
What is the highest grade you completed?								
9	2	2	0	0	1	50	1	50
10	3	3	0	0	1	33	2	67
11	2	2	0	0	2	100	0	0
12	21	23	0	0	1	5	20	95
Some college	42	46	2	5	2	5	38	90
Completed college	13	14	0	0	2	15	11	85
Completed graduate school	8	9	1	13	0	0	7	88
Do you have dental insurance?								
Yes	44	48	1	2	4	9	39	89
No	48	52	2	4	5	10	41	85
Which best shows the total family income for all people living in your house over the past year?								
Less than $5,000	1	1	0	0	0	0	1	100
$5,000-9,999	8	9	0	0	0	0	8	100
$10,000-19,999	11	13	0	0	1	9	10	91
$20,000-29,999	18	20	2	11	2	11	14	78
$30,000-39,999	21	24	0	0	5	24	16	76
$40,000-49,999	7	8	0	0	0	0	7	100
$50,000-79,999	15	17	1	7	1	7	13	87
$80,000-99,999	5	6	0	0	0	0	5	100
$100,000 or more	2	2	0	0	0	0	2	100
What is the normal time you spend reading each week?								
<1 hour/week	8	9	0	0	0	0	8	100
1-5 hours/week	25	27	1	4	4	16	20	80
5-10 hours/week	30	33	1	3	3	10	26	87
10+ hours/week	28	31	1	4	2	7	25	89

* *P*-values for all variables >0.05.

The *c*-statistic for the logistic model was 0.80, with race ($P = 0.03$) and age ($P = 0.01$) significant and gender marginally significant ($P = 0.09$). With the small number of marginal and inadequate scores, there may be some overfitting for the logistic model; however, because the results are similar to the linear regression, age, race, and gender should be considered to be important predictors of health literacy level.

In analyzing the repeatability data, the KR-20 for the total score was 0.89, indicating acceptable internal consistency reliability for the scale. Although the total score improved by an average of 1 point from the first to the second test, the difference was not statistically significant ($P = 0.37$). The ICC for repeatability was 0.88. Functional health literacy levels were repeated for 9 of the 10 subjects. One subject who was classified as having inadequate functional health literacy for the first test improved to marginal health literacy for the second test.

Of the original 99 subjects who participated in the investigation, 92 completed and returned the questionnaire. Analyses of the data indicated that the self-reported grade level attained was significantly associated ($r = 0.28$, $P = 0.01$) with their measured literacy level (Table 4). None of the other questionnaire items were found to be statistically significant.

Discussion

This investigation was a small pilot study using a convenience sample of older adults taking part in our dental research projects. Therefore, the results cannot be used to make general statements concerning the health literacy of all adults, older adults, or all adults taking part in clinical research investigations. However, of interest, the data do support available findings that a significant proportion of Americans, in particular males, members of racial/ethnic minority groups, and older Americans, may have difficulty in reading and understanding health care information (2).

Poor literacy skills may directly affect whether a person decides to participate as a research subject. Reluctance to read lengthy informed consent statements may limit the opportunities the potential subject has to be included in research and limit their access to new procedures (17). Informed consent statements are frequently lengthy, complex, and filled with unfamiliar medical and legal terminology, and efforts must be made to enhance potential subject understanding (18,19). While IRBs require that informed consent statements be written at a sixth-grade reading level, many are frequently found to be written at a much higher level of reading ability (20), and

informed consents reviewed and approved by IRBs have been found to fall short of their own written standards (20). This is also true of educational brochures commonly distributed by dentists as a means to inform their patients (21,22). Therefore, the investigator should determine the reading level of all written materials prior to their dissemination. A Web site allowing investigators to determine the readability of documents they may distribute is available at http://www.harrymclaughlin.com/SMOG.htm (23).

Health care professionals/researchers routinely assume that potential subjects possess adequate literacy skills although they may not. Should the researcher determine the literacy level of potential subjects prior to their acceptance into an investigation and exclude those persons with limited skills? It seems less than ethical that these individuals be excluded from taking part in research, especially if there is the possibility they could derive a direct benefit from their participation. It can be argued that if people with low literacy skills become involved in a research investigation, they may have difficulty taking responsibility for the tasks they may have to perform or that they may not fully understand their rights and responsibilities and as such may pose a risk to themselves and the investigation. However, steps can be taken by the investigator to protect the individual and at the same time allow them to participate. Efforts to overcome some of the difficulties those with poor literacy skills may have and allow them to make more informed decisions concerning their participation are currently underway (24,25). It is suggested that before beginning a research investigation, potential subjects should undergo some assessment of literacy skills using a standard testing methodology. For those identified with limited literacy skills, especially the elderly, educational efforts should then be tailored to the potential subject to increase their level of comprehension and understanding. As a result of this preliminary investigation, it is apparent that we, as researchers, must develop more skill-level-appropriate educational materials or provide chairside assistance to adults participating in our research investigations, who are identified as having low health literacy skills. It is our responsibility to effectively educate this population in understanding our informed consent statements, medical history forms, product use instructions, and other documents that we commonly use in our research investigations.

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