



Clinical Utility of a Brief Screen for Health Literacy and Numeracy Among Adults With Diabetes Mellitus

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BACKGROUND AND OBJECTIVES: Our objectives were to (1) compare Newest Vital Sign (NVS) scores and administration characteristics with the short (S) version of the Test of Functional Health Literacy in Adults (S-TOFHLA) and Spoken Knowledge in Low-Literacy Diabetes (SKILLD) tool and (2) gather information from research assistants (RAs) regarding their perceptions of patient understanding of NVS items.

METHODS: Adults, age ≥ 18 years, with diabetes mellitus visiting a primary care clinic were recruited to participate. An RA orally administered a sociodemographic questionnaire. Patients completed, in random order, the NVS, S-TOFHLA, and SKILLD. Completion time for each tool was electronically recorded, while patients assessed tool difficulty using a 5-point Likert-type scale. RAs' comments regarding patients' understanding of individual NVS items were tallied.

RESULTS: A total of 226 patients (mean age=53.8 years, 31% male, 45.1% African American, 28.8% high school graduate) participated. African Americans were significantly less likely to score ≥ 4 on the NVS (adjusted OR=0.23, 95% CI=0.13, 0.42) as compared to Caucasians. NVS scores were highly correlated with S-TOFHLA scores, $\rho=0.62$, and moderately correlated with SKILLD scores, $\rho=0.39$. NVS scores were inversely correlated with completion time, $\rho=-0.25$ and difficulty rating, $\rho=-0.37$.

CONCLUSIONS: Related to the care of patients with diabetes, the most important feature of the NVS is that it can quickly provide a clinician with valuable insight regarding their patients' ability to complete a practical skill (ie, interpreting a food label) needed to achieve tight blood glucose control.

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Type 2 diabetes mellitus (DM) is the seventh leading cause of death in the United States¹ and affects nearly 26 million Americans, with more than one third of those individuals lacking a formal

diagnosis.² DM is not only a major cause of morbidity and diminished quality of life but also the leading cause of new blindness, end-stage renal disease, and non-traumatic lower limb amputations.³⁻⁵ Diabetes-related

mortality rates tend to be greater among those with less formal education.⁶ As patients with DM must acquire a significant degree of new knowledge and skills upon diagnosis, the combination of limited education and health literacy (HL) skills often pose major barriers to effective DM management.⁶⁻⁷

An important, but often overlooked, component of HL is numeracy skills.⁸ Using data from the 2003 National Assessment of Adult Literacy, nearly 110 million Americans have either basic or poor quantitative (numeracy) skills.⁹ Although numeracy skills have been defined in a variety of different ways,^{8,10,11} a common thread used to describe numeracy includes an individual's ability to understand and use numbers in everyday life.¹² Numeracy proficiency includes not only the capacity to solve basic mathematical skills but also the ability to understand time, currency, measurement, graphic representations, logic, hierarchies, and probability.¹³ While some studies have found that numeracy and literacy are highly correlated skills,^{14,15} other studies have shown that inadequate numeracy skills are common even among

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those with adequate literacy (document and prose) skills.^{10,16,17}

Cross-sectional studies have demonstrated a steep inverse relationship between limited numeracy skills and poor anticoagulation control,¹⁸ hospitalization in asthma patients,¹⁵ inconsistent interpretation of breast cancer risk,^{19,20} and poorer glycemic control in diabetics.²¹ On a daily basis, those with DM perform numeracy-related tasks such as blood glucose self-monitoring, counting carbohydrates, and determining insulin requirements. Unfortunately, many patients struggle to adequately manage their diabetes. For instance, Cavanaugh and colleagues found that individuals with DM who also have limited numeracy skills had not only less disease-related knowledge and perceived self-efficacy skills but also participated in fewer self-management behaviors.²²

While the Rapid Estimate of Adult Literacy in Medicine (REALM)²³ and Test of Functional Health Literacy in Adults (TOFHLA)^{13,24} are frequently used HL assessment tools, both are generally too lengthy and labor intensive for routine use in busy clinical settings. In 2005, Weiss et al introduced the Newest Vital Sign (NVS), a quickly administered screening tool, that is highly sensitive in detecting inadequate HL and numeracy and available in both English and Spanish.²⁵ The primary purpose of this study was to examine the clinical utility of the NVS in a sample of adults with DM. Specifically, we sought to compare and contrast patients' scores and administration characteristics on the NVS, short(S)-TOFHLA²⁴ and Spoken Knowledge in Low-Literacy Diabetics (SKILLD)²⁶ tools. The secondary purpose of this study was to gather information from research assistants (RAs) regarding their perceptions of patient understanding of individual NVS items.

Methods

Setting and Sample

The Ohio State University (OSU) Biomedical Institutional Review

Board approved the research and informed consent procedures used in this study. This study was nested within a larger study designed to examine the association of HL, personal diabetes-related health behaviors, and outcomes. Patients carrying a diagnosis of DM who had made at least two visits each year in the previous 2 years to the OSU Rardin Family Practice Center (RFPC) composed the target population. At OSU RFPC, 11 faculty family physicians and 20 family medicine residents provide care to more than 9,100 individuals from the local community, the majority of who have limited financial resources. More than 700 patients in this practice have DM ($\approx 8\%$ of the total patient population). We excluded individuals who were younger than 18 years of age, pregnant, unable to speak English, legally blind, and/or with a known impairment that would interfere with their ability to complete the survey.

Structured Oral Interview

Medical students, trained as research assistants (RAs), recruited potential patients at OSU RFPC immediately before their appointment, by telephone shortly before their scheduled appointment, or randomly if an appointment was not scheduled during data collection. Immediately following scheduled appointments, RAs met with interested patients in a quiet, empty office void of distractions and explained the objectives of the study. First, the RA screened patients' visual acuity (VA) using a floating E eye chart, excluding those with a VA less than 20/50 corrected ($n=13$). Upon obtaining written and verbal informed consent of eligible patients, the RA orally administered a battery of questionnaires. Interviews took an average of 20 minutes to complete.

The interview began with the collection of four sociodemographic items (sex, age, race, and educational attainment). Next, the RA administered, in random order, the NVS, S-TOFHLA, and SKILLD to

each patient. The RA electronically recorded the time it took each patient to complete the NVS, S-TOFHLA, and SKILLD. Additionally, upon completing each tool, patients were asked to assess the difficulty of the NVS, S-TOFHLA, and SKILLD using a 5-point Likert-type scale ranging from "very easy" to "very difficult."

The NVS consists of a nutrition label from an ice cream carton (see Figure 1).²⁵ Subjects are asked six questions requiring the combination of both reading comprehension and ability to manipulate numerical data (eg, "If you ate the entire container, how many calories will you eat?"). The likelihood of limited literacy/numeracy is based on the number of correct answers on the NVS: 0–1 (likely), 2–3 (possible), 4–6 (unlikely). The complete NVS, including scoring directions, is available in electronic format: (<http://www.pfizerhealthliteracy.com/physicians-providers/NewestVitalSign.aspx>).

The S-TOFHLA is a 36-item timed reading comprehension test that uses a modified Cloze procedure, in which every fifth to seventh word in a passage of text about medical information is omitted and replaced with a blank space.²⁴ The individual must select a word to fit into the blank spaces from the four multiple-choice options provided for each space (eg, "Your doctor has sent you to have a ___ x-ray [stomach, diabetes, stitches, germs]."). Internal consistency of the S-TOFHLA, using Cronbach's alpha, is 0.97. The S-TOFHLA is scored on a scale of 0 to 36, with 36 representing the highest level of literacy. Using established convention, patients are categorized as having adequate literacy if the S-TOFHLA score was 23 to 36, marginal literacy if the score was 17 to 22, and inadequate literacy if the score was 0 to 16.

The SKILLD, developed by Rothman and colleagues, is designed to screen diabetic patients for deficits in self-care knowledge and behaviors.²⁶ Administered orally, the SKILLD consists of 10 open-ended

Figure 1: Newest Vital Sign Food Label, Questions, and Answers

Nutrition Facts			
Serving Size			½ cup
Servings per container			4
Amount per serving			
Calories	250	Fat Cal	120
			%DV
Total Fat	13g		20%
Sat Fat	9g		40%
Cholesterol	28mg		12%
Sodium	55mg		2%
Total Carbohydrate	30g		12%
Dietary Fiber	2g		
Sugars	23g		
Protein	4g		8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT: This information is on the back of a container of a pint of ice cream.

- | | ANSWER CORRECT? | |
|--|-----------------|----|
| | yes | no |
| 1. If you eat the entire container, how many calories will you eat?
<i>Answer: 1,000 is the only correct answer</i> | | |
| 2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?
<i>Answer: Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you measure it into a bowl."</i> | | |
| 3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
<i>Answer: 33 is the only correct answer</i> | | |
| 4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
<i>Answer: 10% is the only correct answer</i> | | |

READ TO SUBJECT: Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings

- | | | |
|---|--|--|
| 5. Is it safe for you to eat this ice cream?
<i>Answer: No</i> | | |
| 6. (Ask only if the patient responds "no" to question 5): Why not?
<i>Answer: Because it has peanut oil.</i> | | |

Interpretation

Number of correct answers:

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.

items (eg, "How often should a person with diabetes check his or her feet?") addressing various aspects of diabetes management. Additionally, alternate wording for each of the 10 items is provided. Internal consistency of the SKILLD, using Cronbach's alpha, is 0.72. The SKILLD is scored from 0% to 100%, with scores <50% considered low knowledge.

Research Assistants' Assessment of the Newest Vital Sign (NVS)

Because the NVS is a relatively new instrument, we sought feedback from each of the RAs regarding their perceptions of patient understanding of individual NVS items. Eleven RAs conducted interviews throughout the data collection period. However, combined, five RAs conducted 182 (80.5%) interviews (ranging from 25–74 individual interviews). The other six RAs conducted 44 (19.5%) interviews combined. Therefore, to

address the second objective of the study, RAs conducting ≥25 interviews recorded general perceptions of patients' ability to complete the NVS. We summarized RAs' comments and recommendations for revisions, by individual NVS item.

Data Analysis

All analyses were performed using STATA SE Version 9.2 (Stata Corp, College Station, TX). *A priori*, statistical significance was set at $P < .05$. Descriptive statistics (mean±standard deviation, median, inter-quartile range, frequencies, percentages) were used to summarize patients' sociodemographic characteristics and NVS, S-TOFHLA, and SKILLD scores. RAs comments and recommendations regarding the NVS were tallied.

Adjusted odds ratios (ORs) and accompanying 95% confidence intervals (CIs) were calculated to assess

the association of NVS scores (≥4) and sociodemographic characteristics. Spearman's rank correlation (ρ) was used to examine the relationship of NVS scores with (1) both S-TOFHLA and SKILLD scores and (2) time taken to complete and difficulty rating of the NVS. Internal consistency of the NVS was assessed using Cronbach's alpha. The Wilcoxon signed-rank test was used to compare and contrast patient difficulty ratings of the NVS, S-TOFHLA, and SKILLD.

Results

Of 384 patients contacted to participate in this study, 40 were excluded (six were blind, 25 spoke inadequate English, nine had obvious cognitive deficits). Of the remaining 344 patients, 243 (68.0%) consented to participate. However, during the consent process, another 16 patients were also ineligible (one had a significant

language barrier, 13 had insufficient vision as measured by the floating E eye chart, one had a cognitive deficit, and one had gestational diabetes). Further, one patient started but refused to complete the interview in its entirety. Therefore, a total of 226 patients made up our final sample (corrected response rate=69.2% [227/328 patients]).

Sociodemographic characteristics of the study sample are depicted in Table 1. As compared to those identifying as Caucasian, African-Americans were significantly less likely to score ≥ 4 on the NVS (adjusted OR=0.23, 95% CI=0.13, 0.42). Participants without a high school diploma were less likely to score ≥ 4 on the NVS (adjusted OR=0.27, 95% CI=0.09, 0.78), while those with a college degree or higher were more likely to score ≥ 4 on the NVS (adjusted OR=7.90, 95% CI=3.16, 19.73) as compared to those with a high school education.

Distribution of NVS, S-TOFHLA, and SKILLD scores are presented in Figure 2. Distribution of NVS scores were bimodal as compared to S-TOFHLA and SKILLD scores, which were negatively skewed. NVS scores were highly correlated with S-TOFHLA scores, $\rho=0.62$, $P=.01$ and moderately correlated with SKILLD scores, $\rho=0.39$, $P=.01$. Internal consistency, using Cronbach's alpha, of the NVS was .80.

Patients completed the NVS more quickly than either the S-TOFHLA

Table 1: Sociodemographic Characteristics of the Study Sample and Adjusted ORs, With 95% CIs, of Scoring ≥ 4 on the NVS

Sociodemographic Characteristic	Mean (SD) or %	Adjusted* OR (95% CI) of Scoring ≥ 4 on the NVS
Age (years)	53.8 (12.8)	0.97 (0.95, 0.99) per year
Male	31.0	0.92 (0.52, 1.61)
Race		
Caucasian	44.7	Reference
African-American	45.1	0.23 (0.13, 0.42)
Other	10.2	0.47 (0.19, 1.16)
Educational attainment		
Less than high school	16.4	0.27 (0.09, 0.78)
High school graduate	28.8	Reference
Some college	34.9	1.77 (0.86, 3.65)
College graduate or greater	19.9	7.90 (3.16, 19.73)

n=226

* Adjusted for all other sociodemographic characteristics

OR—odds ratio

CI—confidence interval

NVS—Newest Vital Sign

or SKILLD (see Table 2). Using the signed-rank test, patients ranked the NVS as more “difficult” than the S-TOFHLA and SKILLD, $P=.01$. NVS scores were inversely related to the time taken to complete the instrument, $\rho=-0.25$, $P=.01$ and difficulty rating, $\rho=-0.37$, $P=.01$.

Overall, RA comments regarding NVS items addressed issues related to ambiguities, relevance of material, wording, clarity, thought processes

required, and scoring procedures. Specific RA comments and recommendations for revisions, by individual NVS item, are presented in Table 3.

Conclusions

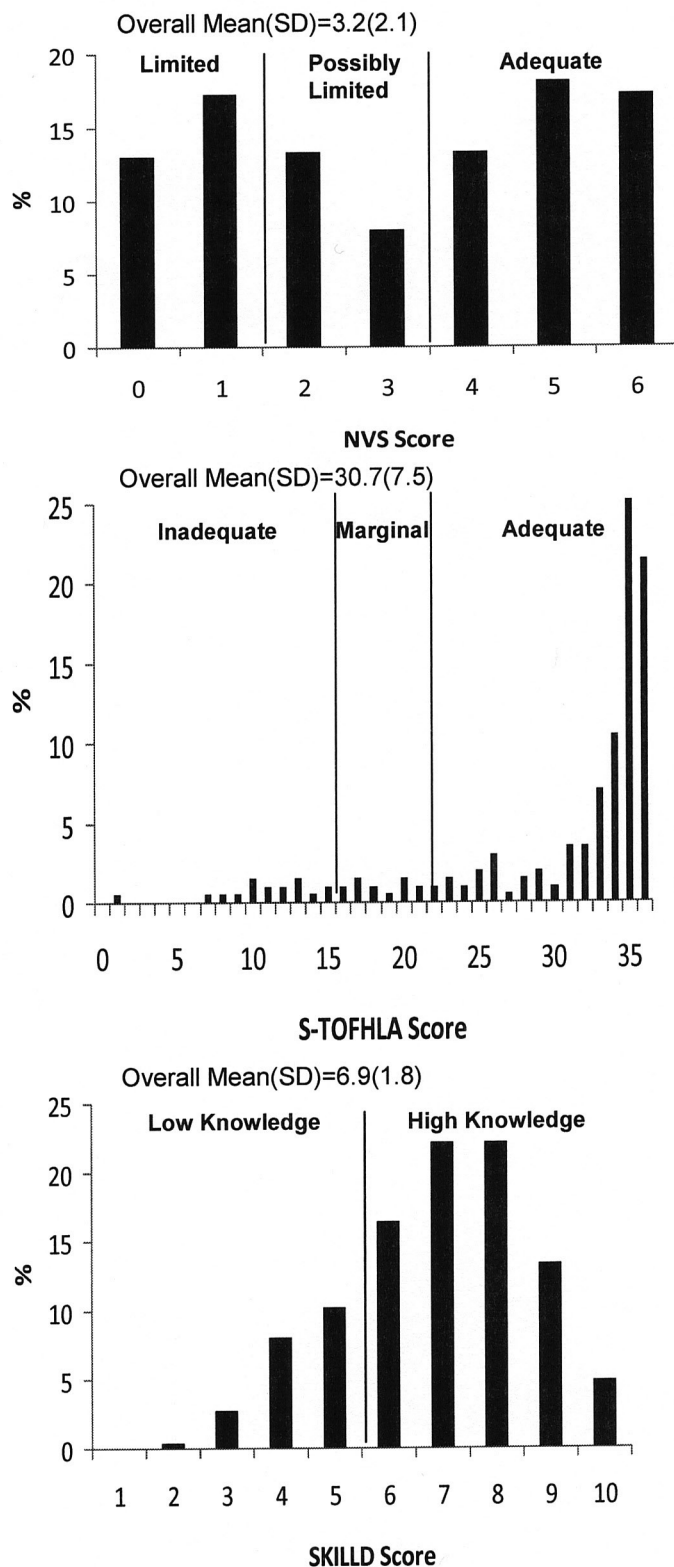
Among our sample of predominantly underserved diabetics, nearly one fifth of whom did not have a high school diploma, receiving care in a primary care setting in the

Table 2: Time to Complete and Ease of Administration of NVS, S-TOFHLA, and SKILLD Scale

Variable	Health Literacy/Numeracy Tool		
	NVS	S-TOFHLA	SKILLD
	Median (IQR) or %	Median (IQR) or %	Median (IQR) or %
Time to complete assessment in seconds	181 (138, 237)	340 (278, 424)	225 (182, 273)
Ease of administration			
Very easy/Easy	46.9	75.2	68.4
Okay	28.8	21.2	25.4
Hard/Very hard	24.3	3.6	6.2

IQR=interquartile range

Figure 2: Distribution of NVS, S-TOFHLA, and SKILLD Scale Scores



NVS—Newest Vital Sign, S-TOFHLA—Short Test of Functional Health Literacy in Adults, SKILLD—Spoken Knowledge in Low Literacy Diabetes

Midwestern US, NVS scores were strongly correlated with S-TOFHLA scores and moderately correlated with SKILLD scores. These findings are important because the S-TOFHLA and SKILLD assess different skill sets. The S-TOFHLA assesses reading comprehension within the context of general health issues, while the SKILLD includes items specifically related to knowledge of diabetes-related management.

The correlation between HL and DM knowledge has been previously observed and intuitively makes sense as one would expect a person with greater HL to also have a more comprehensive understanding of how to best manage his/her disease.^{27,28} Our finding that NVS scores strongly correlated with S-TOFHLA scores is consistent with a study of hypertensive adults.²⁹ Further, the distribution of both NVS and S-TOFHLA scores in our patient population mirrored that of Weiss et al.²⁵ Similarly, in our sample, the NVS took approximately 3 minutes to administer, which is consistent with Weiss et al's original sample²⁵ and another sample of primary care patients as well.³⁰

While the NVS was correlated with both the S-TOFHLA and SKILLD, interestingly, patients' rated the NVS as the most challenging of the three tools. To our knowledge, patient self-reported difficulty of the NVS, S-TOFHLA, and SKILLD have not been examined previously.

Also, unique to our study, RAs provided feedback regarding the experiences of patients completing the NVS. Of note, one of the most interesting RA comments related to the ordering of NVS items. Specifically, RAs observed that many patients found the immediate use of arithmetic to be intimidating. For example, the first NVS item, "If you eat the entire container, how many calories will you eat?" is perhaps the most demanding of the six NVS items. As suggested by the RAs, moving the fifth and sixth NVS items ("Is it safe for you to eat this ice cream?" and "Why not?") to the beginning of

Table 3: Research Assistants' Summative Comments and Recommendations Regarding Administration of the NVS

NVS Item	Comment	Recommended Revisions
1	Many patients found the immediate use of arithmetic to be intimidating.	Move questions #5 and #6 to the beginning.
1	"Entire container" possibly confusing without seeing a container physically present.	Change to "entire container of this ice cream."
2	Expected form of answer is unclear to some participants.	Ask "How many cups of ice cream?"
2	"How much ice cream should you have?" may be perceived as a trick question. Patients with diabetes probably should not have any ice cream.	Change to "How much ice cream could you have?"
3	Long, complicated question with an unnecessary first sentence.	Omit first sentence.
3	"Consuming" is a complex word.	Change "consuming" to "eating."
3	Unclear question due to verb tense.	Change to "If you stopped eating ice cream, how many grams of saturated fat would you then be..."
4	Many patients were uncomfortable with percentages.	Accept "one tenth" as a correct answer.
5	"Substances" is a complex word.	Change "substances" to "things."
5/6	Can be answered using simple logic, because only one allergen is food related.	Add "wheat products" or some other food allergy to the list as a distracter.
6	Unclear grading if reply is "because it has peanuts."	Clarify whether "because it has peanuts" is an acceptable answer.

NVS—Newest Vital Sign

the NVS should be explored in future studies. This strategy was used by Bass and colleagues³¹ in the development of the REALM-Revised (R). The REALM-R is composed of 11 medical-related words; however, the first three words ("fat," "flu," and "pill") are not scored but were placed at the beginning to decrease test anxiety and bolster patient confidence. Improving ease of NVS administration could ultimately affect its utility for both clinical and research purposes.

Study results should be considered in the context of several limitations. First, the generalizability of these findings may be limited by the fact that participants were recruited from a single family medicine practice in the Midwestern United States. Second, nearly one third of those approached to participate in the study refused to do so.

Third, the study sample was limited to English-speaking participants exclusively. Fourth, we did not assess NVS test-retest reliability (stability) in our sample; however, consistent with the findings of Weiss et al,²⁵ the NVS demonstrated good internal consistency using Cronbach's alpha in our study as well.

Practice Implications

The NVS has many desirable characteristics as an HL/numeracy screening tool. However, related to the care of patients with diabetes specifically, perhaps the most important feature of the NVS is that it can quickly provide the clinician with valuable insight into the underlying issues (eg, struggles to interpret food labels) often associated with poor disease control. Based on our findings, numeracy is an important metric to consider in the care of diabetic

patients; however, this issue needs to be addressed in greater depth in future studies.

Assessing patients' ability to interpret a nutritional label, such as the NVS, is appropriate in diabetic patients as this is a practical skill needed to achieve tight control of blood glucose. Our suggestions for revising the NVS are not likely to change its advantageous qualities. We maintain that any tool that can enable clinicians to more effectively manage patients with chronic diseases should be developed and continually refined to improve quality of care and disease outcomes.

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