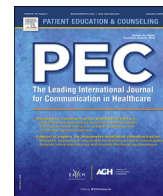




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# Validation of the health literacy scale for diabetes as a criterion-referenced test with standard setting procedures

Soo Jin Kang<sup>a</sup>, Kang Hee Sim<sup>b</sup>, Bok Rye Song<sup>c</sup>, Jeong-Eun Park<sup>d</sup>, Soo Jung Chang<sup>e</sup>,  
Chanho Park<sup>f</sup>, Mi Sook Lee<sup>g,\*</sup>

<sup>a</sup> Department of Nursing, Daegu University, Daegu, Republic of Korea

<sup>b</sup> Department of Diabetes Education, Samsung Medical Center, Seoul, Republic of Korea

<sup>c</sup> Department of Diabetes Education, Seoul St. Mary's Hospital, Seoul, Republic of Korea

<sup>d</sup> Department of Nursing, Cheil General Hospital & Women's Healthcare Center, Dankook University College of Medicine, Seoul, Republic of Korea

<sup>e</sup> Department of Nursing, Woosuk University, Jeollabuk-do, Republic of Korea

<sup>f</sup> Department of Education, Keimyung University, Daegu, Republic of Korea

<sup>g</sup> Department of Psychology, Daegu University, Daegu, Republic of Korea

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### ABSTRACT

**Objective:** To develop and examine the psychometric properties of the Korean Health Literacy Scale for Diabetes Mellitus (KHLS-DM), and to establish reasonable cutoff scores.

**Methods:** Initially, 299 items were generated to measure diabetes-related words, numeracy, and information utilization. Content validity assessment and preliminary tests were conducted. After exploratory factor analysis (EFA) and Rasch analysis, the remaining 65 items were administered to a quota sample of 500 diabetic patients aged 40–74 years. The items were narrowed down to 58 items based on an item fit index. To obtain cutoff scores, Jaeger's method and the Bookmark method were employed.

**Results:** A confirmatory factor analysis (CFA) was performed, and a three-factor model was supported ( $\chi^2/df = 3.891$ , CFI = 0.92, TLI = 0.91, RMSEA = 0.04). The overall scores ranged from 0 to 58, and two cutoff points were established. The scale exhibited good internal consistency (Cronbach's  $\alpha = 0.83$ ).

**Conclusions:** The KHLS-DM is a reliable and valid measure with cutoff points to classify individuals into three groups (adequate, marginal, and inadequate).

**Practice implications:** The standard setting may be useful for researchers to validate health literacy measures in other countries and populations.

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## 1. Introduction

### 1.1. Background

Diabetes is one of the most common chronic diseases affecting quality of life. The prevalence of type 2 diabetes is approximately 8.8%, with 387 million patients worldwide [1]. In Korea, more than 13.7% of adults have been diagnosed with diabetes [2]. Although diabetes is the fifth-leading cause of death in Korea [3] and its complications are a major cause of morbidity and mortality, the proportion of controlled diabetes has been reported to be 23.3% (HbA1C < 6.5) [4].

Health literacy is reportedly associated with decreased risk of adverse diabetes-related outcomes [5–7]. Although some researchers have shown that low literacy is not directly associated with HbA1c level [8,9], Yamashita and Kart [10] suggest that this could be due to the differences between general and disease-specific health literacy measures used in previous studies. It is not clear that these general and disease-specific measures of health literacy can be used interchangeably.

The most commonly used health literacy instruments [11–13] are not designed to measure numeracy ability and the specific skills needed to care for patients with diabetes. Based on a systematic review [14], and a few diabetes health literacy instruments [15–17], we identified that diabetes patients required the skills of interpretation of glucose level, adjustment of insulin, carbohydrate counting, and making decisions needed in their diabetes care. Due to differences in both language and health care systems, direct translation of measurements for the assessment of health literacy is inappropriate [18,19].

\* Corresponding author at: Department of Psychology, Daegu University, Zip 42400, 33, Seongdang-ro 50-gil, Nam-gu, Daegu, Republic of Korea.

E-mail addresses: [kangsj@daegu.ac.kr](mailto:kangsj@daegu.ac.kr) (S.J. Kang), [Lee-ms5131@daegu.ac.kr](mailto:Lee-ms5131@daegu.ac.kr) (M.S. Lee).

Although health literacy measures in diabetes care are important, research on this topic is limited in Korea owing to the lack of a reliable, valid, and skill-based health literacy instrument. Moreover, although Korean health literacy studies had been developed using solid psychometric techniques [18,20–22], these measures do not provide proper cutoff scores.

The measures without optimal cutoff values may not be of much use in practice; for example, they cannot provide information needed to tailor patient education or interventions based on one's health literacy level. New measures of health literacy have been reported as being able to detect limited health literacy in patients using Receiver Operative Characteristic (ROC) analysis with the TOFHLA or the REALM as a gold standard [13,23,24]. To develop a skills-based health literacy measure with appropriate cutoff scores, we defined the properties of diabetes health literacy skills and applied standard setting methods such as Jaeger's method and the Bookmark method.

### 1.2. Standard setting method

Health literacy instruments are often used as criterion-referenced tests; that is, these measures are used to provide researchers or health care providers a score range and an interpretation of what a patient is expected to be able to do. In order to do so, we need cutoff values for differentiating health literacy levels that can identify individuals with limited health literacy. The methods used to set the cutoff scores are called standard setting methods [25]. Standard setting methods can be categorized as item-centered methods, which are more widely used, and person-centered methods. Item-centered standard setting procedures are based on evaluation of items by subject matter experts (SMEs). Usually 5 to 15 SMEs participate in a standard setting procedure as panelists. They start the procedure from a performance level description (PLD), which is a description of what people belonging to a specific level can do. They then evaluate each item by assuming how a minimally competent person (MCP) [25] for each level would perform on each item.

For Jaeger's method, the SME's duty is to make a judgment on whether an MCP would answer each item correctly or not [26]. Sum of 1 (i.e., correct answers) would function as the cutoff score for each SME, and their sums are aggregated for the final cutoff score. For the Bookmark method, an ordered item booklet (OIB), which is the set of items ordered by their difficulty levels, is used [27]. The panelists start evaluating from the easiest item to the hardest one and place a bookmark when the correct response probability of an MCP falls behind the preset level, which is generally 0.67 [28]. The Bookmark method is relatively simple, but it requires all items be analyzed by an item response theory (IRT) model.

Diabetes health literacy is a specific, task-oriented skill; therefore, standard setting methods are necessary for obtaining the cutoff scores in distinguishing different diabetes health literacy levels. Jaeger's method is less preferred for a test of multiple choice items; however, it may be an inevitable choice when the probability of the correct answer is hard to estimate. Therefore, it is appropriate for a test asking whether a patient knows some vocabulary or not. The Bookmark method is a popular standard setting method, especially for a measure consisting of multiple choice items analyzed with IRT.

### 1.3. Aims

The aims of this study were: (a) to develop the Korean Health Literacy Scale for Diabetes Mellitus (KHLS-DM), which can be used to assess the health literacy level of diabetes patients; (b) to validate the KHLS-DM; and (c) to establish reasonable cutoff scores using a standard setting method.

## 2. Methods

### 2.1. Phase 1: instrument development

#### 2.1.1. Construction of the KHLS-DM

Through relevant literature reviews [14,17,29–33] and in-depth interviews [34], we defined diabetes health literacy as a personal skill that determines the ability to understand information, apply numeric skills, and make a diabetes-related decision to manage one's condition in daily life. We constructed three types of literacy skills of the KHLS-DM: print, numeracy, and critical literacy.

First, print literacy refers to having skills related to reading, writing, and understanding texts [32]. The KHLS-DM is designed to measure the ability of patients to comprehend diabetes-related words. Second, numeracy is essential in diabetes self-care for understanding medication dosage, blood test results, adjusting insulin, interpreting food labels, food change systems, etc. [6,14,16]. Finally, critical literacy is the ability to critically analyze and utilize diabetes-related information to manage one's health [33,35].

#### 2.1.2. Diabetes-specific item generation

To generate items, we adapted the framework of the AADE 7 Self-Care Behaviors™ [36]. The framework consists of seven factors that are essential for self-management: healthy eating, physical activity, taking medication, monitoring, problem solving related to diabetes self-care, reducing the risk of complications, and psychosocial aspects of living with diabetes. Based on this framework, we derived the tasks and skills necessary to care for diabetes. Moreover, we reviewed diabetes care standards and guidelines [37,38] and educational materials for diabetes management.

In the "diabetes-related words" section, 28,578 words were extracted from the educational materials (pamphlets, websites, and brochures, etc.). Among them, a list of 2661 diabetes-related words was created, and then 225 words were selected by two nursing professors and a diabetes education nurse based on the frequency of use, difficulty grade [39], and importance [34]. This section is a modified version of the REALM, in that participants provide their subjective assessment using a four-point Likert scale (1 = I know nothing, 2 = I don't know, 3 = I know a little, and 4 = I exactly know).

"Numeracy and information utilization" is a combined section that is useful to diabetes educators in understanding the patient's ability and functioning, and to provide patient-centered instruction in the context of diabetes management. The numeracy items were presented as multiple choice and open-ended short-answer questions. The items have to do with understanding numeric information, arithmetic skills, and rough estimations questionnaires in which the amount of food is determined based on experience, such as portion size and the diabetes plate method, rather than precise measurement. Items for information utilization consisted of a multiple-choice format for understanding or evaluating newspaper, guidelines, medical examination results, and nutritional labels. Each item of the numeracy and information utilization section was dichotomously scored (correct = 1, incorrect or no response = 0), and no partial credit was given. There was no time limit for the administration of the scale. Based on the 15 tasks, 75 initial items of numeracy (49 items) and information utilization (26 items) were generated. Fig. 1 presents the process for instrument development.

#### 2.1.3. Content validity

To examine the content validity of the 229 preliminary items, we asked nurses, dietitians, and physicians specializing in diabetes to review and modify the items as necessary. Next, a

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