Approaches for the Development and Validation of Criterion-referenced Standards in the Korean Health Literacy Scale for Diabetes Mellitus (KHLS-DM)

Kang Soo-Jin, RN, PhD, Assistant Professor Daegu University, Republic of Korea

This research was supported by Basic Science Research Program though the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT & Future Planning (No. 2013R1A1A3007607).
Contents

1. Need for study

2. Method
   1) Instrument Development
      • Conceptual Framework & Item Generation
   2) Instrument Evaluation
      • Preliminary Test & Final Test
   3) Standard settings
      • Jaeger and Bookmark methods

3. Results (Final test)
   1) General characteristics of the Sample
   2) Validity
   3) Reliability

4. Conclusion and limitations
Prevalence of Diabetes

IDF Diabetes Atlas 6th edition

Diabetes Fact Sheet 2015 in Korea
Need for Study

- Health literacy is associated with the *decreased* risk of adverse diabetes-related outcomes, however, *this relationship is not consistent*.

- General and disease-specific health literacy instruments may be complementary, however, it is not clear that these measures can be used interchangeable.
Need for Study

- Currently used health literacy instruments are limited on measuring skills which needed in diabetes care, because of numeracy skills which are not included. The numeracy items of the TOFHLA is not sufficient to measure ability to engage in diabetes care.

- Although health literacy measures in diabetes care are important, the research on this topic is limited in Korea because of the lack of a reliable, valid, and comprehensive skills-based diabetes health literacy instrument for Korean.
Need for Study

- Health literacy studies for Korean such as KHLS (Korean Health Literacy Scale), KHLI (Korean Health Literacy Instrument), and Health Literacy Index for Female Marriage Immigrants (HLI-FMI) were developed using robust psychometric method.

- However, Korean health literacy instruments does not suggest cutoff point for screening limited health literacy group.
Purpose

1. 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.

2. To validate the scale’s psychometric properties.

3. To establish the reasonable cutoff scores using criterion-referenced methods.
Methods

Instrument development
- Constructs of diabetes health literacy
- Item generation
- Content validity

Instrument evaluation
- Preliminary test
- Survey (final test)
- Item evaluation & revision

Standard setting
- Construction of panel
- Performance Level Description
- Jaeger and Bookmark methods
Methods

1) Constructs of diabetes health literacy

- Literature review (HL definition, conceptual framework)
- In-depth interview with 11 diabetes educators; (10 nurses, 2 dietarians and 1 doctor) & 8 diabetes patients (type 2)
- Field observation (education setting)
Methods

2) Item generation

diabetes care standard & guideline, educational materials
American Association of Diabetes Educators (AADE) 7 Self-Care : 7 factors & 15 tasks

• Print : To understand meaning of the diabetes-related words (225 item words)

• Functional : To apply arithmetic operation and use numerical information (49 items)

• Critical : To interpret health information and decide in problem solving situation. (26 items)
## Methods

### Phase 1: Instrument development

### 3) Content validity

<table>
<thead>
<tr>
<th>Step</th>
<th>Review items &amp; revision</th>
<th>8 Expert panel CVI test #1</th>
<th>8 Expert panel CVI test #2</th>
<th>8 Expert panel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes-related words</td>
<td>225 items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numeracy</td>
<td>49 items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information utilization</td>
<td>26 items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>With rating 4-point scale</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 diabetes education nurses
2 dieticians
2 professors of nursing,
1 doctor specializing in diabetes

With rating 4-point scale
(from 1 = not relevant to 4 = very relevant)
Methods

1) Preliminary test

- The preliminary test was conducted in a convenience sample of 200 adult diabetes patients at community in Seoul, Korea (March 2 - 18, 2016)
- The questionnaires were administered via face-to-face interview by Gallup, one of the famous Korean Research Institute.
- EFA and Rasch model was applied, then 10 items were modified. Also, 5 diabetes-related words were added.
Methods

2) Final test

- The survey was conducted in a (quota) sample of 500 adult type 2 diabetes patients (40-74 age) at community and clinic in Seoul and Gyeonggi area, Korea (March 12 - May 12, 2016).

- The questionnaires (diabetes-related words 30 items, numeracy 26 items, and information utilization 9 items) were administered via face-to-face interview by Gallup, one of the famous Korean Research Institute.
Methods

- Standard setting refers to establish cutoff scores to distinguish different levels of performance and each cutoff score function to divide into two or more performance categories.

- This research used the Jaeger (1978) and Bookmark method.
Methods

Phase 3 Standard setting

Jaeger method

Bookmark method

Inadequate

Diabetes-related words

Numeracy

Information Utilization

Adequate

Marginal
Methods

Phase 3 Standard setting

Jaeger method:

- The sum of estimated answer for each item becomes the cutoff scores of the subjects.
- For example, it is assumed that the answer is 1 if the subjects knows the answer, but 0 if they do not know the answer and the sum of these numbers becomes the cutoff score for the judge.
- Therefore, the average of each panel’s cutoff score or the median value becomes the final cutoff score. This study used mean score.
Methods

Phase 3 Standard setting

Example) Jaeger method

<table>
<thead>
<tr>
<th>Items</th>
<th>Panel</th>
<th>mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>1. 공복 (empty stomach)</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2. 양막 (Retina)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3. 포도당(glucose)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4. 나트륨(Sodium)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5. 단순당질 (simple carbohydrate)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>28. 합병증 (complication)</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>29. 콜레스테롤 (cholesterol)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>30. 식품교환표 (food exchange table)</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>합계</td>
<td>8</td>
<td>9</td>
<td>15</td>
</tr>
</tbody>
</table>

Example:

Jaeger method

Diabetes-related words (30 items)

< Round 1 >

- 7 panel members were asked about the minimum competence person (MCP) for each of the 30 words.
- They answered 1 if the MCP should know the term and 0 if they don’t.
- After test, there was a chance for the judge to explain about the results.

< Round 2 > Repeat

< Round 3 > Repeat
Methods

Phase 3 Standard setting

Bookmark method:

- Bookmark method is that it calculates items score based on the Ordered Item Booklet (OIB), a booklet that organizes items according to their difficulty (item difficulty) as determined by an Item Response Theory (IRT).

- Each panel bookmarks the last item that subjects in a group boundary are expected to answer based on the Performance Level Description (PLD) required by each numeracy and information utilization.
Methods

**Phase 3 Standard setting**

PLDs are statements that describe the specific knowledge and skills diabetes patients typically demonstrate at each performance level.

<table>
<thead>
<tr>
<th>Skill level</th>
<th>Performance Level Description</th>
</tr>
</thead>
</table>
| Adequate    | • Has a solid understanding of numeracy related to diabetes and is able to perform calculation accurately  
              • Has the ability to understand and evaluate diabetes-related information (medication, meal) and self-care methods |
| Marginal    | • Has a lacks understanding of numeracy related to diabetes and could make errors when performing calculation  
              • Has limited ability to understand and evaluate diabetes-related information (medication, meal) and self-care methods |
Methods

Phase 3 Standard setting

Bookmark method:

< Round 1 >

• Panel who has a full understanding of PLD were given OIB (Ordered Item Booklet) and those who are in the boundary of two groups bookmarked the question that subjects have 0.67 chance of answering correctly.

< Round 2 > Repeat

< Round 3 > Repeat

Numeracy Information Utilization

0.67 (item difficulty)

Easiest Item (Lowest Scale Value)

Hardest Item (Highest Scale Value)

Ordered Item Booklet
Descriptive analysis was computed for participants’ demographics and health literacy scores using the SPSS 21.0 (SPSS Inc. Chicago, IL).

EFA for preliminary test and CFA for survey were performed using the M-plus 2.1 program.

Rasch model was applied to estimate item difficulties and the goodness-of-fit indices of the items using the WINSTEP 3.64.2 program (Linacre, 2008).

To apply Jaeger and bookmark method, the median values were computed by excel program.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Category</th>
<th>N</th>
<th>%  or Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>250</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>250</td>
<td>50.0</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>40-49 yr</td>
<td>70</td>
<td>14.0</td>
</tr>
<tr>
<td></td>
<td>50-59 yr</td>
<td>180</td>
<td>36.0</td>
</tr>
<tr>
<td></td>
<td>60-69 yr</td>
<td>180</td>
<td>36.0</td>
</tr>
<tr>
<td></td>
<td>70 yr</td>
<td>70</td>
<td>14.0</td>
</tr>
<tr>
<td></td>
<td>Min-Max</td>
<td>40-74</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>≤ Elementary school</td>
<td>50</td>
<td>10.1</td>
</tr>
<tr>
<td></td>
<td>Middle school</td>
<td>76</td>
<td>15.4</td>
</tr>
<tr>
<td></td>
<td>High school</td>
<td>263</td>
<td>53.1</td>
</tr>
<tr>
<td></td>
<td>University or College</td>
<td>106</td>
<td>21.4</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>≤ 5 yr</td>
<td>235</td>
<td>47.1</td>
</tr>
<tr>
<td></td>
<td>6-10 yr</td>
<td>162</td>
<td>32.5</td>
</tr>
<tr>
<td></td>
<td>11-20 yr</td>
<td>89</td>
<td>8.7</td>
</tr>
<tr>
<td></td>
<td>21-30 yr</td>
<td>13</td>
<td>2.6</td>
</tr>
</tbody>
</table>
### Table 1. General characteristics of participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Category</th>
<th>N</th>
<th>%</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx of DM</td>
<td>Oral</td>
<td>350</td>
<td>70.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insulin</td>
<td>95</td>
<td>19.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral + Insulin</td>
<td>55</td>
<td>11.0</td>
<td></td>
</tr>
<tr>
<td>Health Insurance</td>
<td>National health insurance</td>
<td>451</td>
<td>90.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical benefit</td>
<td>49</td>
<td>9.8</td>
<td></td>
</tr>
</tbody>
</table>
### Results

**Table 2.** Item difficulty and the Goodness-of-fit according to Numeracy and Information

<table>
<thead>
<tr>
<th>ID</th>
<th>MEASURE</th>
<th>Infit</th>
<th>Outfit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mnsq</td>
<td>Zstd</td>
</tr>
<tr>
<td>QNI1</td>
<td>-0.01</td>
<td>0.81</td>
<td>-5.20</td>
</tr>
<tr>
<td>QNI2</td>
<td>0.46</td>
<td>1.05</td>
<td>1.40</td>
</tr>
<tr>
<td>QNI3</td>
<td>0.48</td>
<td>1.24</td>
<td>6.40</td>
</tr>
<tr>
<td>QNI4</td>
<td>-1.23</td>
<td>0.99</td>
<td>-0.10</td>
</tr>
<tr>
<td>QNI5</td>
<td>0.79</td>
<td>0.85</td>
<td>-4.30</td>
</tr>
<tr>
<td>QNI6</td>
<td>0.94</td>
<td>0.87</td>
<td>-3.60</td>
</tr>
<tr>
<td>QNI7</td>
<td>-0.01</td>
<td>0.90</td>
<td>-2.60</td>
</tr>
<tr>
<td>QNI8</td>
<td>0.36</td>
<td>1.05</td>
<td>1.50</td>
</tr>
<tr>
<td>QNI9</td>
<td>-0.09</td>
<td>0.82</td>
<td>-4.80</td>
</tr>
<tr>
<td>QNI10</td>
<td>0.71</td>
<td>0.93</td>
<td>-2.00</td>
</tr>
<tr>
<td>QNI11</td>
<td>2.40</td>
<td>1.30</td>
<td>3.80</td>
</tr>
<tr>
<td>QNI12</td>
<td>0.40</td>
<td>1.09</td>
<td>2.40</td>
</tr>
<tr>
<td>QNI13</td>
<td>0.10</td>
<td>1.35</td>
<td>8.40</td>
</tr>
<tr>
<td>QNI14</td>
<td>0.26</td>
<td>1.32</td>
<td>8.10</td>
</tr>
<tr>
<td>QNI15</td>
<td>-1.63</td>
<td>0.94</td>
<td>-0.70</td>
</tr>
<tr>
<td>QNI16</td>
<td>0.07</td>
<td>1.08</td>
<td>2.10</td>
</tr>
</tbody>
</table>

Outfit 1.5 < 11, 13, 14
<table>
<thead>
<tr>
<th>ID</th>
<th>MEASURE</th>
<th>Infit</th>
<th>Outfit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mnsq</td>
<td>Zstd</td>
</tr>
<tr>
<td>QNI17</td>
<td>-1.96</td>
<td>0.92</td>
<td>-0.70</td>
</tr>
<tr>
<td>QNI18</td>
<td>-1.84</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>QNI19</td>
<td>0.20</td>
<td>0.88</td>
<td>-3.50</td>
</tr>
<tr>
<td>QNI20</td>
<td>1.09</td>
<td>1.07</td>
<td>1.70</td>
</tr>
<tr>
<td>QNI21</td>
<td>-1.43</td>
<td>0.92</td>
<td>-1.00</td>
</tr>
<tr>
<td>QNI22</td>
<td>-0.11</td>
<td>0.77</td>
<td>-6.30</td>
</tr>
<tr>
<td>QNI23</td>
<td>0.99</td>
<td>0.86</td>
<td>-3.90</td>
</tr>
<tr>
<td>QNI24</td>
<td>-1.15</td>
<td>0.90</td>
<td>-1.50</td>
</tr>
<tr>
<td>QNI25</td>
<td>-0.91</td>
<td>0.88</td>
<td>-2.10</td>
</tr>
<tr>
<td>QNI26</td>
<td>-0.39</td>
<td>0.96</td>
<td>-0.90</td>
</tr>
<tr>
<td>QNI27</td>
<td>-0.14</td>
<td>1.17</td>
<td>3.90</td>
</tr>
<tr>
<td>QNI28</td>
<td>0.15</td>
<td>1.18</td>
<td>4.50</td>
</tr>
<tr>
<td>QNI29</td>
<td>0.88</td>
<td>0.95</td>
<td>-1.50</td>
</tr>
<tr>
<td>QNI30</td>
<td>0.46</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>QNI31</td>
<td>-0.50</td>
<td>0.84</td>
<td>-3.40</td>
</tr>
<tr>
<td>QNI32</td>
<td>-0.84</td>
<td>0.98</td>
<td>-0.30</td>
</tr>
<tr>
<td>QNI33</td>
<td>-1.02</td>
<td>0.97</td>
<td>-0.40</td>
</tr>
<tr>
<td>QNI34</td>
<td>1.44</td>
<td>1.08</td>
<td>1.70</td>
</tr>
<tr>
<td>QNI35</td>
<td>1.09</td>
<td>1.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Results

Confirmatory Factor Analysis of KHLS-DM

- Diabetes-related words: 30 items
- Numeracy: 22 items
- Information Utilization: 6 items

Model fit indices:
- RMSEA = 0.039
- CFI = 0.917
- TLI = 0.914
Results

Diabetes-related words (30 items)

< Round 1 >
Median = 10

< Round 2 >
Median = 12

< Round 3 >
Median = 12

Median = 10

Median = 12

Adequate
Marginal
Inadequate

Jaeger method
Cutoff point
(12)

N = 500

87.6%
12.4%
Results

Numeracy & Information utilization (28 items)

- **Round 1**
  - Median = 24

- **Round 2**
  - Median = 16

- **Round 3**
  - Median = 16

**Adequate**

- Bookmark method
  - Cutoff point (16)
  - N = 438
  - 45.6%

**Marginal**

- 54.4%
Results

Considering the difficulty for each questionnaire, questions with 16 points and questions with 18 points had similar difficulty and therefore, final cut-off score has been decided to be 18.

- Adequate (Cutoff point 18): 45.6%
- Marginal (Cutoff point 18): 54.4%
- Inadequate (Cutoff point 12): 12.4%

Numeracy & Information utilization (28 items)
Diabetes-related words (30 items)
Conclusion and limitations

1. The Korean Health Literacy Scale (KHLS)-DM consists of three parts:
   (30-item diabetes-related words, 22-item Numeracy, and 6-item Information utilization).

2. The cutoff point of the KHLS- DM
   A: diabetes-related words part : below 12 (Inadequate)
   B: numeracy and information utilization part : below 18 (Marginal), above 19 (Adequate)

3. Total reliability Cronbach’s alpha .918
   (diabetes-related words .914, numeracy and information utilization .833)

4. Test-retest reliability .89
Conclusion and limitations

• The KHLS-DM is a reliable and valid instrument for Korean.

• The bookmark and Jaeger method are new and scientific approach to decide to level of skills for diabetes patients.

• When health literacy measures translated into other countries and cultures, it is a useful and scientific approach to modify a scoring system and cutoff scores.

- It seems to be necessary to conduct further research on how the standard setting and cutoff –points developed in this study can be used in practice, and to increase validity of a study that monitors their self-care activities and glucose level.
Thank You.