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

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Need for Study

Prevalence of Diabetes
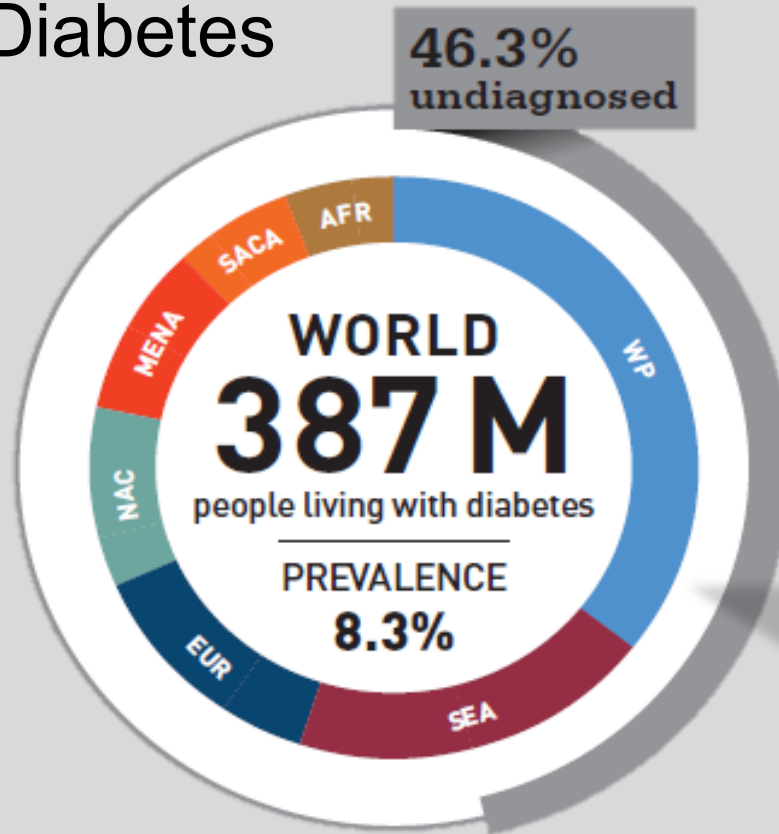
IDF Diabetes Atlas 6th edition
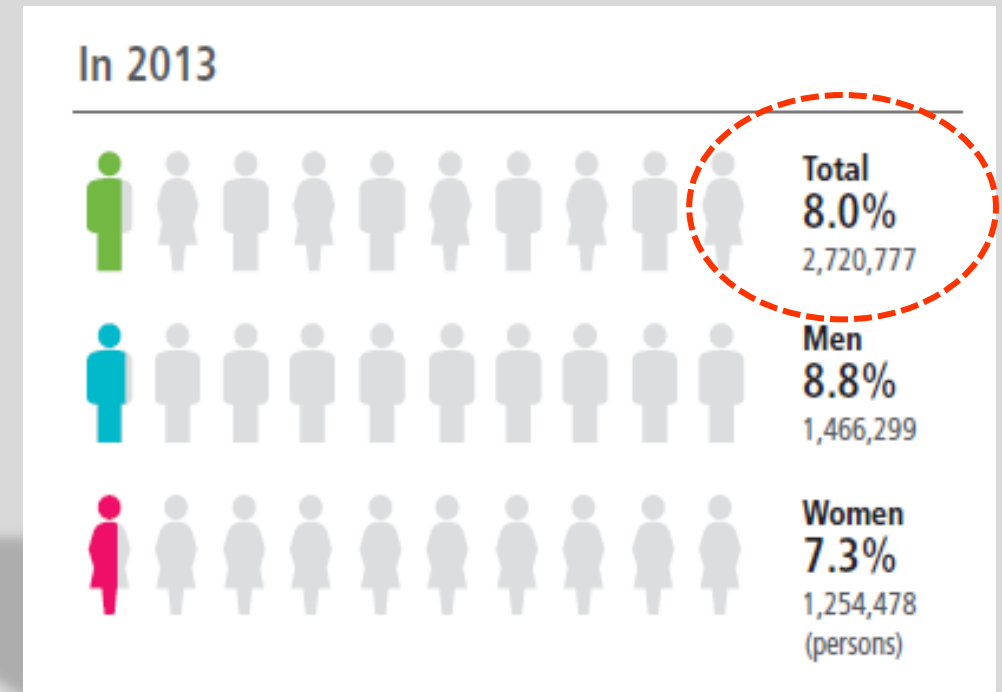
Diabetes Fact sheet 2015 in Korea

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	Instrument evaluation	Standard setting
• Constructs of diabetes health literacy • Item generation • Content validity	• Preliminary test • Survey (final test) • Item evaluation & revision	• 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 doctors) & 8 diabetes patients (type 2)
- Field observation (education setting)

Functional

Critical
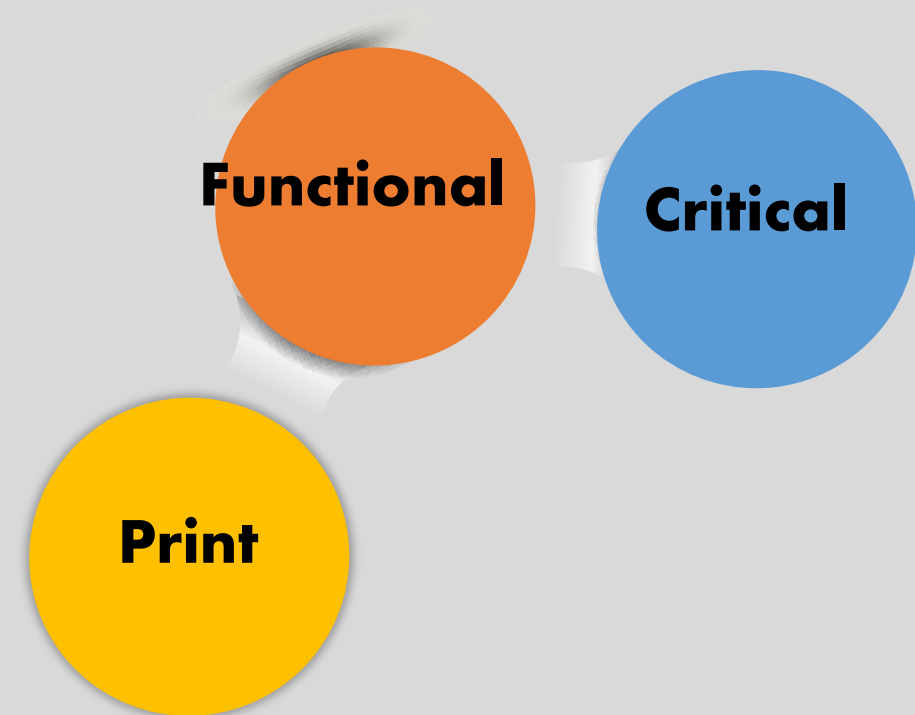
Print

Methods

2) Item generation

diabetes care standard & guideline, educational materials

American Association of Diabetes Educators (AADE) 7 Self-Care : 7 factors & 15 tasks
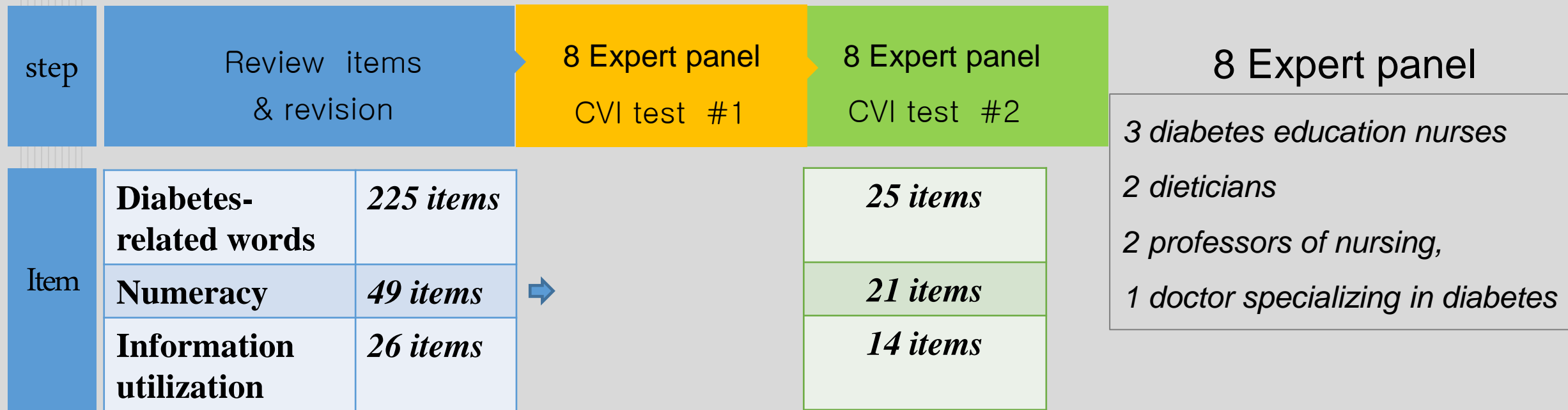
- Print : To understand meaning of the *diabetes-related words (225 item words)*

- 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

3) Content validity

step	Review items & revision	8 Expert panel CVI test #1	8 Expert panel CVI test #2

Item		
Diabetes-related words	*225 items*	*25 items*
Numeracy	*49 items*	*21 items*
Information utilization	*26 items*	*14 items*

8 Expert panel

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.
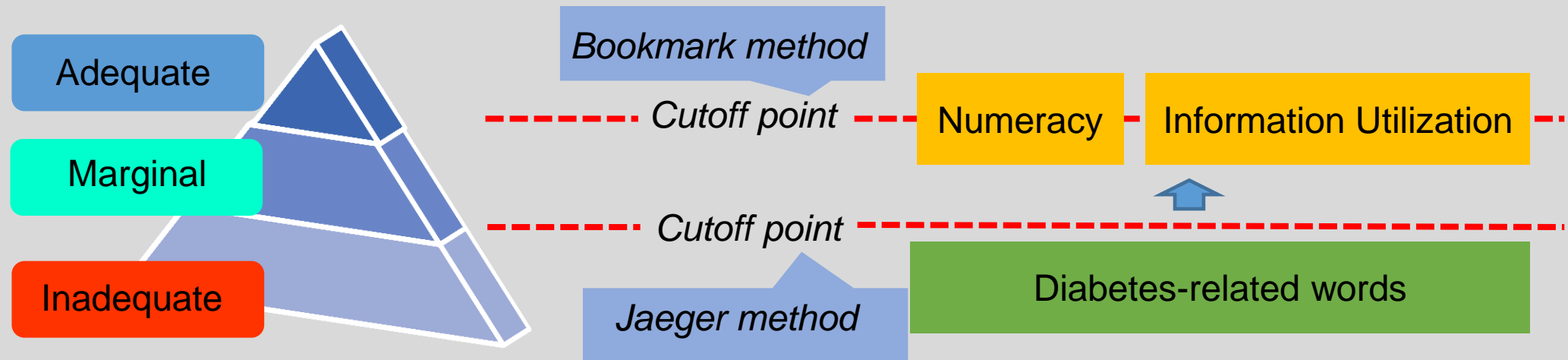
Methods

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.
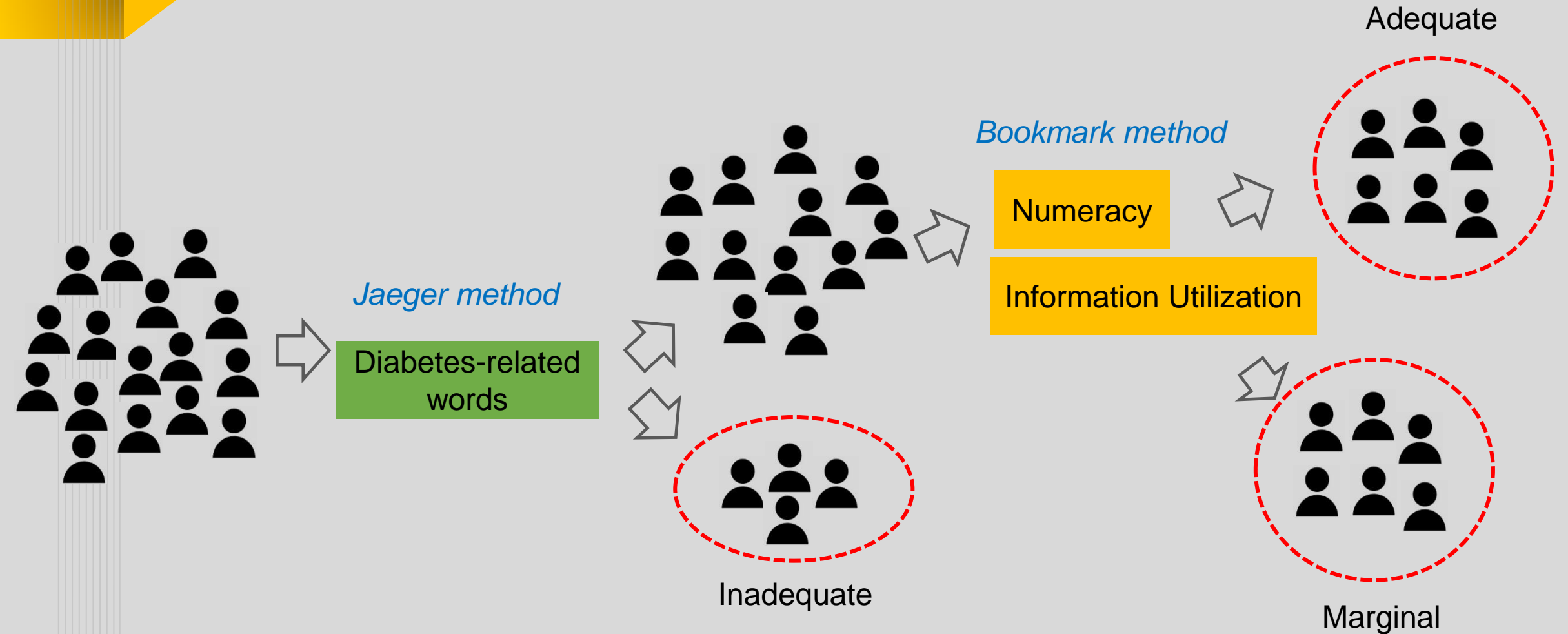
Methods

- 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.

The Level of Diabetes Health Literacy Skill

Methods

Adequate

Bookmark method

Numeracy

Information Utilization

Jaeger method

Diabetes-related words

Inadequate

Marginal

15

Methods

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 the 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

Example) Jaeger method

Diabetes-related words (30 items)

| Items	Panel							mean	Median
	A	B	C	D	E	F	G		
1. 공복 (empty stomach)	0	1	1	1	1	1	1		
2. 망막 (Retina)	1	1	1	1	1	0	1		
3. 포도당(glucose)	0	0	1	0	1	0	1		
4. 나트륨(Sodium)	1	1	1	1	1	1	1		
5. 단순당질 (simple carbohydrate)	1	1	1	0	1	1	1		
28. 합병증 (complication)	1	1	0	0	1	1	0		
29. 콜레스테롤 (cholesterol)	0	0	0	1	0	0	1		
30. 식품교환표 (food exchange table)	1	0	1	1	1	0	0		
합계	8	9	15	10	10	11	14	11	10

< 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

A B C D E F G

17
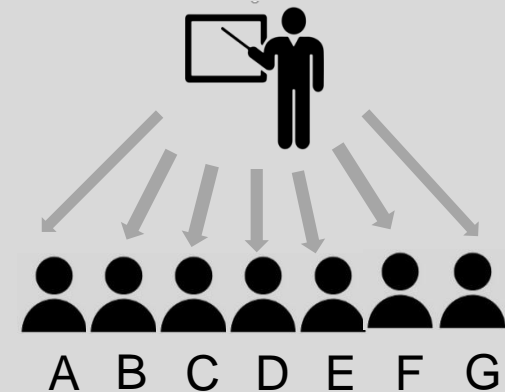
Methods

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

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

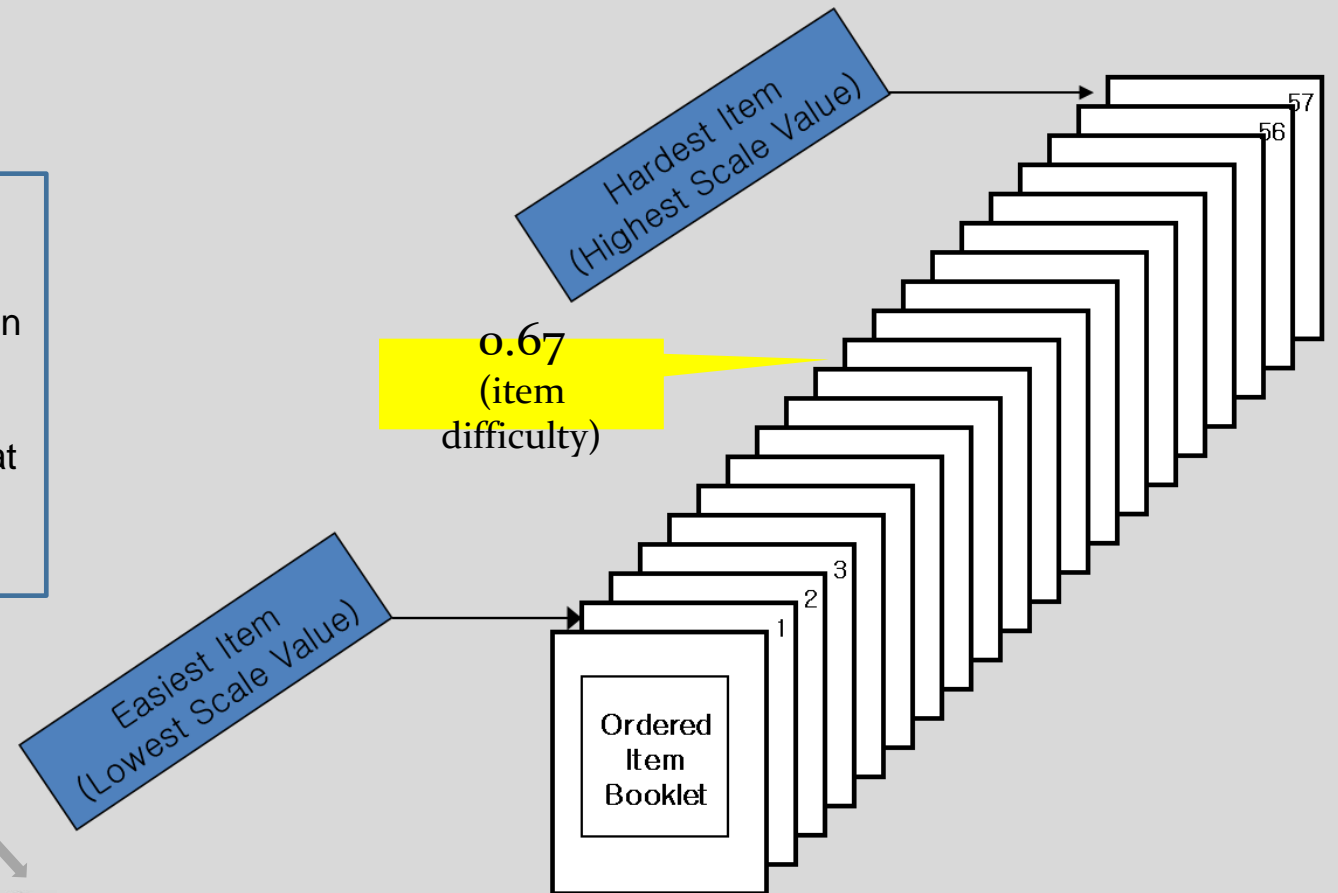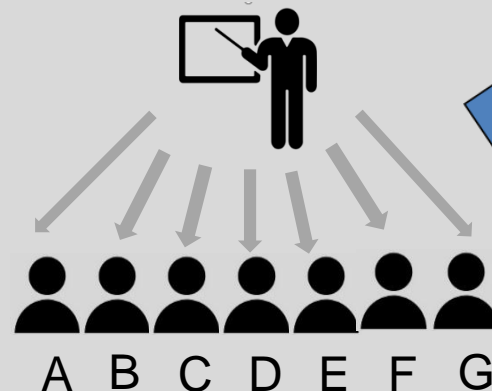| Skill level	Performance Level Description
Adequate	• Has a solid understanding of numeracy related to diabetes and is able to perform calculation accurately • Has the ability to understand and evaluate diabetes-related information (medication, meal) and self-care methods
Marginal	• Has a lacks understanding 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

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

A B C D E F G

Hardest Item (Highest Scale Value)

0.67 (item difficulty)

Easiest Item (Lowest Scale Value)

Ordered Item Booklet

Numeracy   Information Utilization

Statistical analysis

- 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.

Results

| Table 1 . General characteristics of participants | | | N= 500 |

Characteristics	Category	N	% or Mean (SD)
Gender	Male	250	50.0
	Female	250	50.0
Age (yr)	40-49 yr	70	14.0
	50-59 yr	180	36.0
	60-69 yr	180	36.0
	70 yr	70	14.0
	Min-Max	40-74	
Education	≤ Elementary school	50	10.1
	Middle school	76	15.4
	High school	263	53.1
	University or College	106	21.4
Duration of DM	≤ 5 yr	235	47.1
	6-10 yr	162	32.5
	11-20 yr	89	8.7
	21-30 yr	13	2.6

Results

Table 1 . General characteristics of participants

Characteristics	Category	N	% or Mean (SD)
Tx of DM	Oral	350	70.0
	Insulin	95	19.0
	Oral + Insulin	55	11.0
Health Insurance	National health insurance (건강보험)	451	90.2
	Medical benefit (의료급여)	49	9.8

Results

Outfit 1.5 < 11, 13, 14

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

ID	MEASURE	Infit		Outfit	
		Mnsq	Zstd	Mnsq	Zstd
QNI1	-0.01	0.81	-5.20	0.75	-4.80
QNI2	0.46	1.05	1.40	1.05	1.20
QNI3	0.48	1.24	6.40	1.30	6.00
QNI4	-1.23	0.99	-0.10	0.92	-0.70
QNI5	0.79	0.85	-4.30	0.83	-4.00
QNI6	0.94	0.87	-3.60	0.82	-3.90
QNI7	-0.01	0.90	-2.60	0.86	-2.50
QNI8	0.36	1.05	1.50	1.07	1.40
QNI9	-0.09	0.82	-4.80	0.74	-4.70
QNI10	0.71	0.93	-2.00	0.91	-2.00
QNI11	2.40	1.30	3.80	1.73	5.00
QNI12	0.40	1.09	2.40	1.09	2.00
QNI13	0.10	1.35	8.40	1.58	9.30
QNI14	0.26	1.32	8.10	1.42	7.50
QNI15	-1.63	0.94	-0.70	0.72	-2.00
QNI16	0.07	1.08	2.10	1.09	1.50

Results

ID	MEASURE	Infit		Outfit	
		Mnsq	Zstd	Mnsq	Zstd
QNI17	-1.96	0.92	-0.70	0.65	-2.20
QNI18	-1.84	1.00	0.00	0.96	-0.20
QNI19	0.20	0.88	-3.50	0.83	-3.70
QNI20	1.09	1.07	1.70	1.11	2.00
QNI21	-1.43	0.92	-1.00	0.91	-0.70
QNI22	-0.11	0.77	-6.30	0.69	-5.80
QNI23	0.99	0.86	-3.90	0.82	-3.80
QNI24	-1.15	0.90	-1.50	0.79	-1.90
QNI25	-0.91	0.88	-2.10	0.77	-2.50
QNI26	-0.39	0.96	-0.90	0.94	-0.80
QNI27	-0.14	1.17	3.90	1.32	4.80
QNI28	0.15	1.18	4.50	1.20	3.60
QNI29	0.88	0.95	-1.50	0.95	-1.10
QNI30	0.46	1.00	0.00	0.98	-0.40
QNI31	-0.50	0.84	-3.40	0.73	-3.90
QNI32	-0.84	0.98	-0.30	1.06	0.60
QNI33	-1.02	0.97	-0.40	0.85	-1.50
QNI34	1.44	1.08	1.70	1.19	2.70
QNI35	1.09	1.00	0.00	0.99	-0.20

Results
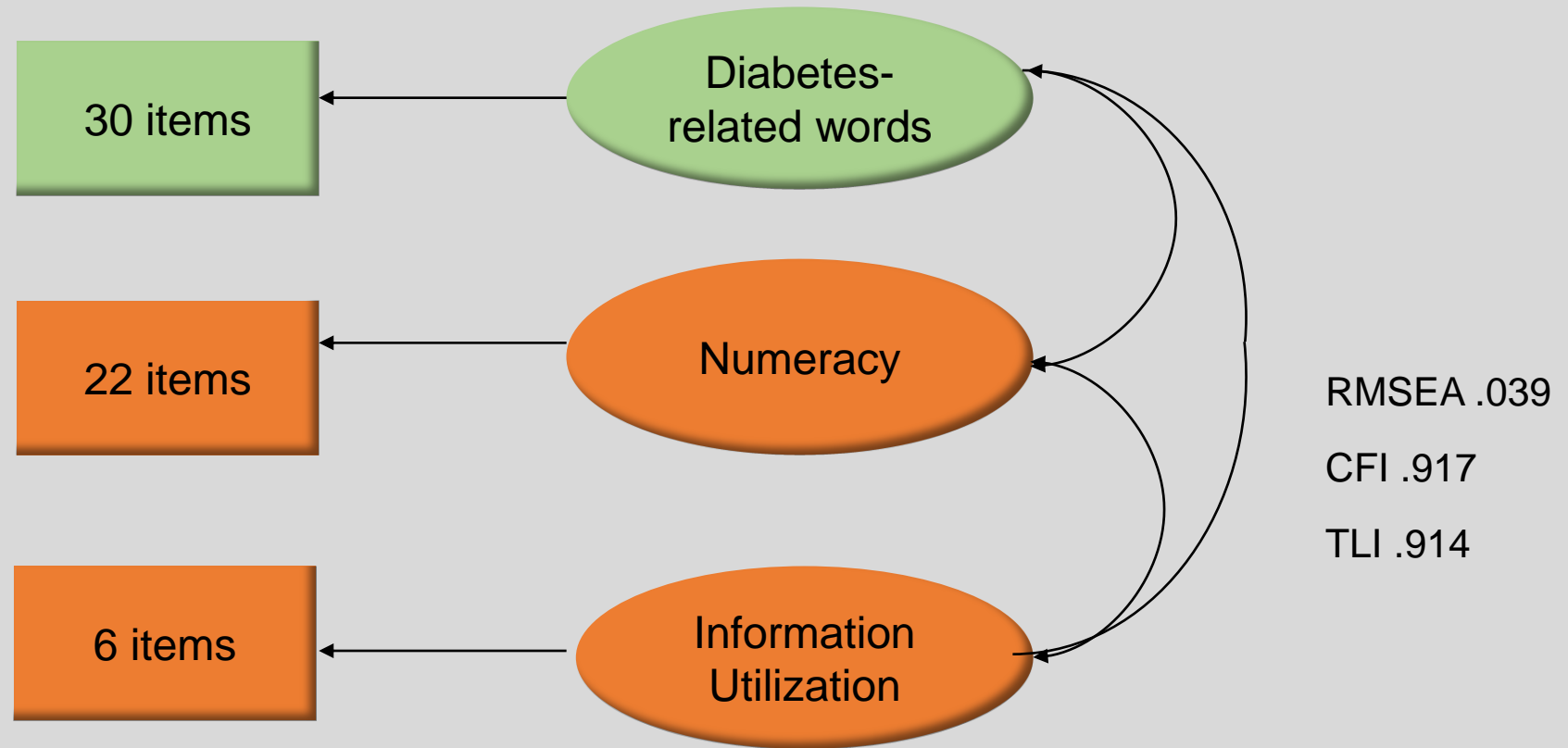
Confirmatory Factor Analysis of KHLS-DM

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

RMSEA .039

CFI .917

TLI .914

Results

Diabetes-related words (30 items)

< Round 1 >
용어 Jaeger 결과 R1
Median = 10
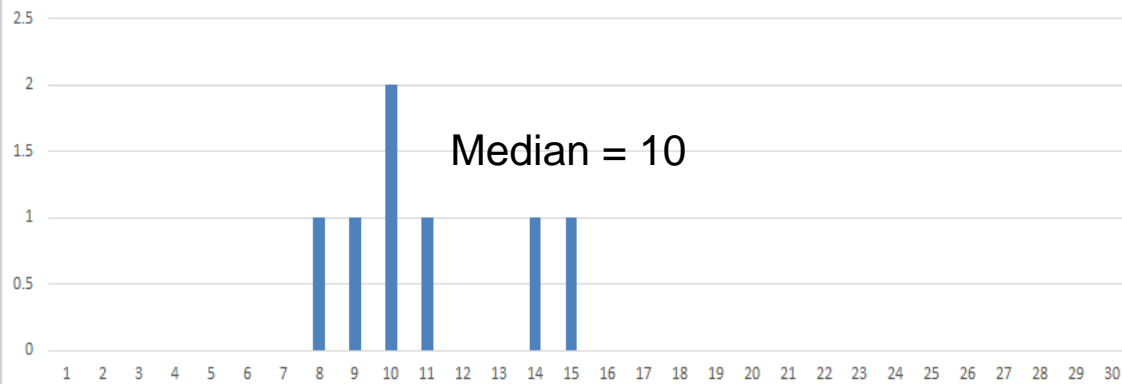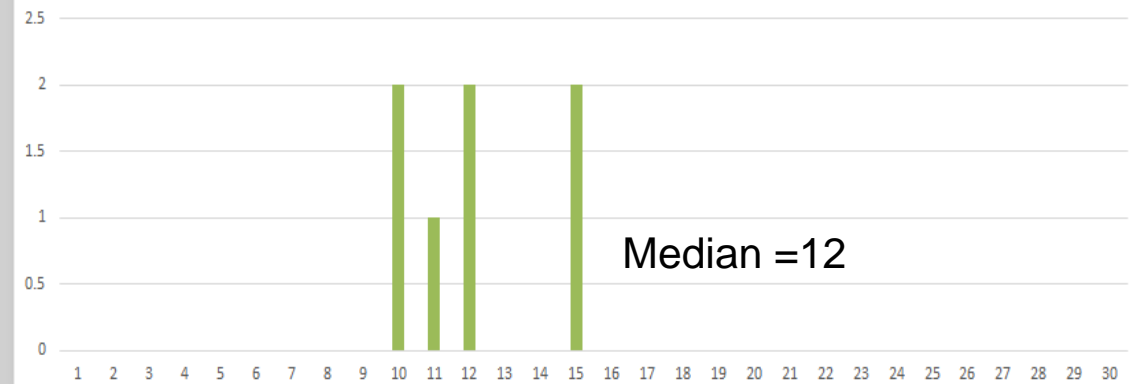
< Round 2 >
용어 Jaeger 결과 R2
Median = 12

< Round 3 >
용어 Jaeger 결과 R3
Median = 12
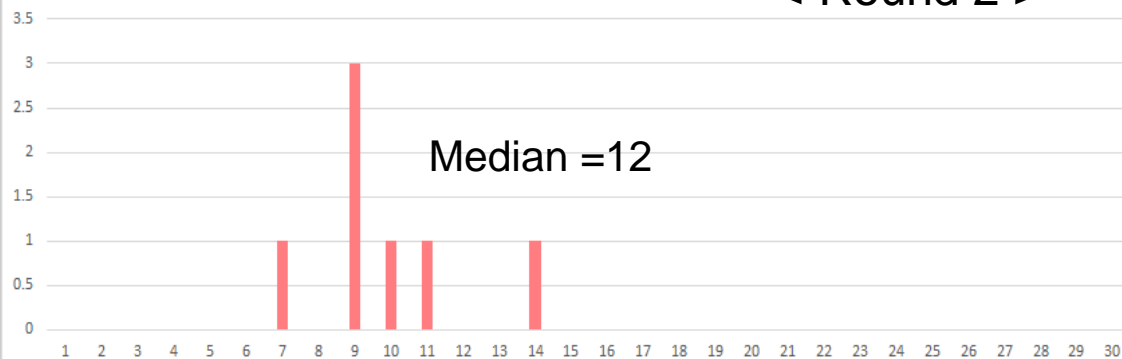
N= 500

Adequate		87.6%
Marginal	Jaeger method	
Inadequate	Cutoff point (12)	12.4%

Results

Numeracy & Information utilization (28 items)

정보이해 A/B Bookmark 결과 1R

< Round 1 >

Median = 24

정보이해 A/B Bookmark 결과 3R

< Round 3 >

Median =16
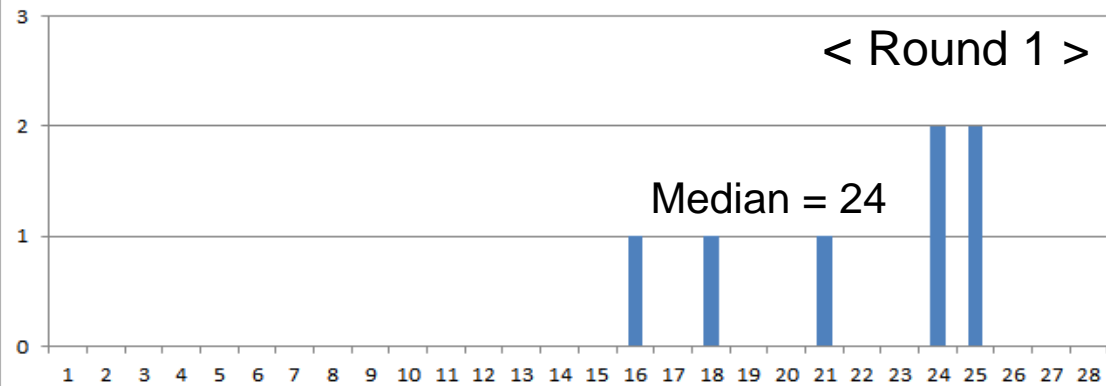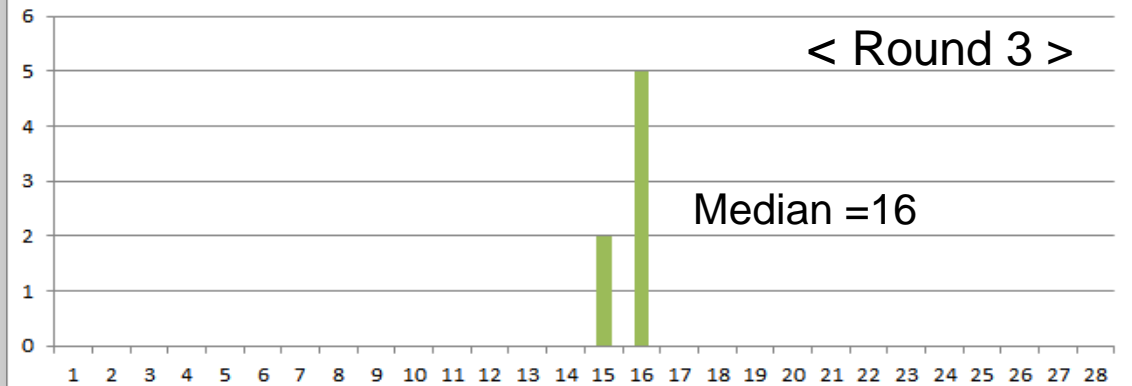
정보이해 A/B Bookmark 결과 2R

< Round 2 >

Median =16

N= 438

Cutoff point (16)

Adequate

Bookmark method

45.6%
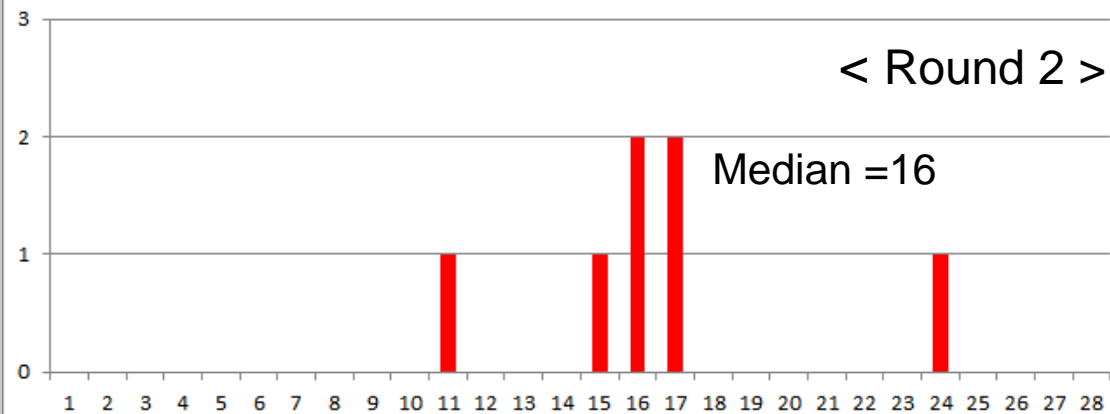
Marginal
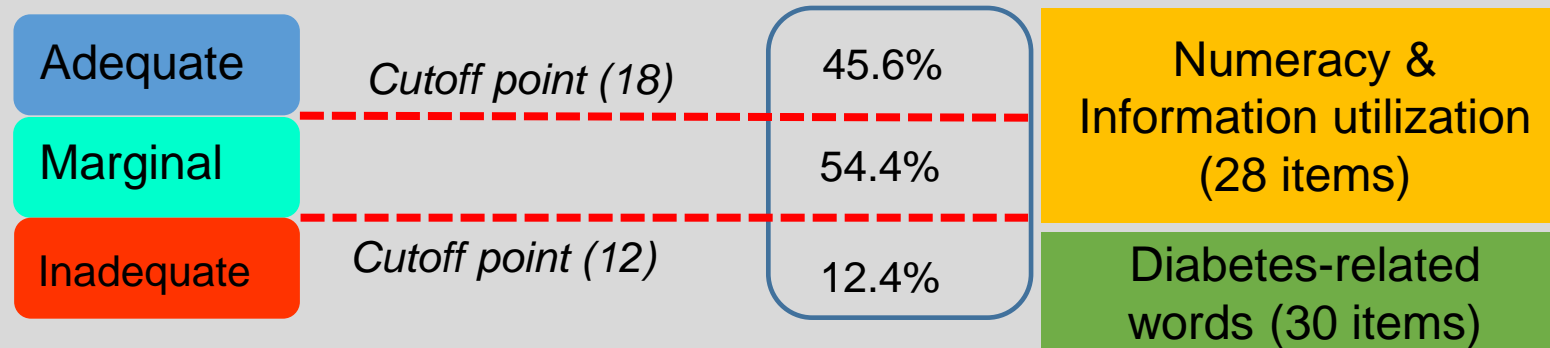
54.4%

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		45.6%	Numeracy & Information utilization (28 items)
Marginal	Cutoff point (18)	54.4%	
Inadequate	Cutoff point (12)	12.4%	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.