Psychometrics Properties of Health Literacy Measurements in Diabetes Mellitus Patients: A Systematic Review

ABSTRACT

Background and Objectives: Diabetes mellitus is a global health challenge, and inadequate health literacy contributes to poor self-care, suboptimal glycemic control, and higher complication risks. Accurate measurement of health literacy is vital, yet the psychometric quality of existing tools for diabetes remains uncertain. To identify instruments with the strongest psychometric support to guide future research and clinical practice among patients with diabetes mellitus.

Materials and Methods: A systematic review was conducted in PubMed, Scopus, ScienceDirect, ProQuest, and Wiley Online Library from inception to September 2025. Eligible studies involved the development, translation, or validation of health literacy instruments in diabetes populations. Psychometric quality was assessed using the COSMIN checklist.

Results: Twelve studies describing 10 instruments were included, most of which were diabetes-specific. Internal consistency and construct validity were the most frequently evaluated properties, whereas measurement error, responsiveness, and test–retest reliability were seldom examined. The Diabetes Health Literacy Scale showed the strongest evidence, covering functional, communicative, and critical domains. Other instruments, such as the Functional, Communicative and critical Health literacy; Chinese Health Literacy scale for Diabetes; Korean Health Literacy scale for Diabetes Mellitus; and Health literacy related to adherence to drug treatment, demonstrated moderate evidence but lacked full validation. Domain-specific measures, including the Food Literacy Questionnaire and Oral Health Literacy tool, had limited psychometric support.

Conclusion: Ten instruments are available for assessing health literacy in diabetes, yet none has undergone comprehensive psychometric evaluation. The Diabetes Health Literacy Scale appears most suitable for practice and research, though further studies are needed to confirm its structural validity and adaptability across cultures. Continued instrument development and validation are essential for accurate measurement in diverse populations.

Paper Type: Research Article

Keywords: Diabetes mellitus, Health literacy, Measurement properties, Psychometrics, Reliability, Validity.

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Introduction

Diabetes mellitus (DM) is a chronic disease that is approaching an epidemic percentage around the world. Based on data from the World Health Organization, the global deaths increased quickly due to diabetes from 1.5 million to 1.6 million in 2012 and 2016, respectively. More recently, diabetes and its complication caused 4 million deaths by the end of 2017 (1).Poor glycemic control among patients with diabetes constitutes a major public health problem and a major risk factor for the development of diabetes complications. This need to increasing awareness and the capacity to control behaviors appropriate to the disease, which called health literacy.

World Health Organization (WHO) has identified health literacy as one of the greatest determinants of health, which defines it as “the cognitive and social capabilities that determine the motivation and ability of people to gain access, understand, and utilize information in such ways that enhance and maintain good health”. Low level of health literacy is common among people with diabetes, and they are associated with poor glycemic control, lower self-care activities, less knowledge about diabetes, lower self-efficacy, and worse communication with healthcare providers. By improving people's access to health information and their capacity to use it effectively, health literacy is critical to empowerment. It is necessary to measure the level of health literacy to develop educational intervention program for in diabetes population. There are various diabetic health literacy instruments, however, to choose the best instrument for the researchers or the health professionals, it is extremely important to explore the psychometric properties of health literacy instrument.

In this systematic review, health literacy component was based on Nutbeam (2) model of health literacy that including three dimensions (functional HL, interactive HL and critical HL). A systematic review of health literacy measurement is designed to provide a comprehensive overview to identify the best instrument that is currently available. To address these limitations, it has recently been suggested that a systematic review of instruments should use a standard guideline, such as the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist (3).

Health literacy (HL) plays a critical role in diabetes management, influencing self-care, glycemic control, and patient–provider communication. Several HL measurement instruments have been developed for people with diabetes, but their psychometric quality varies. Accurate measurement is essential for both research and clinical decision-making. Previous reviews have summarized HL instruments for people with diabetes, most notably the 2017 systematic review by Lee et al. (4), which identified 13 self-administered instruments and assessed their measurement properties using the COSMIN checklist. That review concluded that no instrument had been comprehensively evaluated and that gaps remained in reliability, responsiveness, and measurement error. Since 2017, several new diabetes specific HL instruments have been developed (e.g., Diabetes Health Literacy Scale [DHLS], Health Literacy related to Adherence to Drug

Treatment [ASAM D], Food Literacy Questionnaire [FLQ], Oral Health Literacy for People Living with Diabetes [OHLD]) and existing tools have been culturally adapted and validated in different populations (e.g., Korean, Persian, Portuguese versions). New psychometric data including additional structural validity, internal consistency, and cross cultural adaptation results are now available. However, no systematic review to date has integrated these newer instruments and evidence into a single comprehensive synthesis. This gap leaves researchers and clinicians without up-to-date guidance on the most appropriate health literacy measures for diabetes research and practice. Therefore, an up-to-date systematic review of the psychometric properties of health literacy instruments in patients with diabetes mellitus is necessary.

Materials and Methods

Study design

To compare and critically evaluate the content instruments and psychometric of the health literacy assessment, a systematic review was created. Developing a research question, searching the literature, establishing eligibility standards, choosing articles, assessing the methodological quality of the included studies, extracting data, comparing contents, synthesizing data, and coming to a general systematic review conclusion were all steps in the process.

Search methods

The Pubmed, Scopus, SienceDirect, ProQuest, Willey Online Library, electronic database was searched from their inception up to September 2025. The search terms were used in advance searching of Pubmed and ProQuest ((("Psychometrics"[MeSH] OR Validity AND Reliability [Text Word]) OR ("Cross-Cultural Comparison"[Mesh])) AND ("Health Literacy"[Mesh])) AND ("Diabetes Mellitus"[MeSH] OR diabetes [Text Word]). In Scopus, Willey Online Library and ScienceDirect (“psychometrics" OR “validity and reliability” OR "cross-cultural comparison" AND "health literacy" AND "diabetes mellitus" OR diabetes).

Eligibility criteria

The article had to meet three inclusion criteria. First, the article had to be published in a peer-reviewed journal. The second criterion for the selection of the papers was that the article had to be full-length and published in English. The final criterion was that the article had to be based on a theory and/or concept. In respect of this last criterion, it was not just enough for an article to mention a theory or concept in order to be selected, but, the theory and/or concept needed to be central to the research. The exclusion criteria include other publications, such as research notes, editors’ comments, readers’ comment, and book reviews.

Selection of studies

The selection method for the included studies is presented in Figure 1. PRISMA diagram. The researcher selected studies by following a Preferred Reporting Items for Systematic Review and Meta-Analyses. The EndNote version 21 was used to duplicate reports. The researcher screened all the articles based on the research titles and abstracts. After excluding irrelevant articles, the full texts were assessed for eligibility criteria.

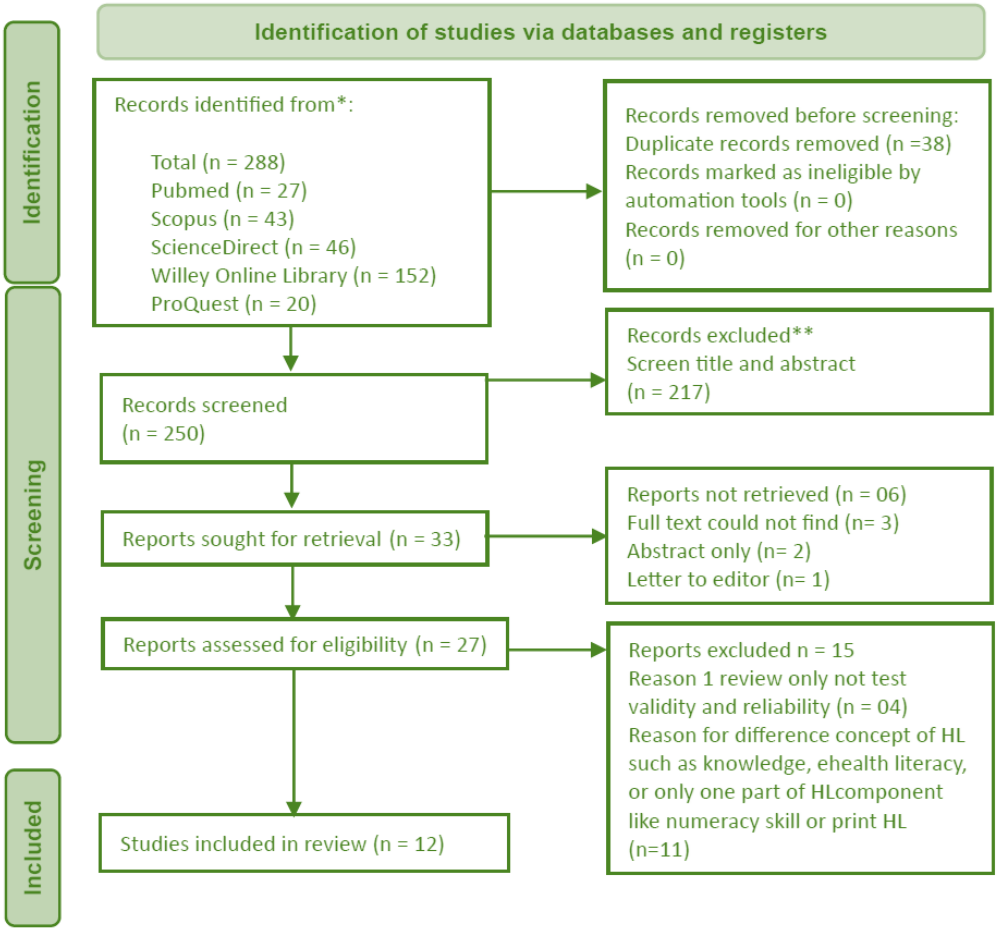
Search outcomes

In total, 250 records were identified after removing 38 duplicated from 288 records. These remaining records were screened for

eligibility based on their titles and abstracts, which resulted in the selection of 33 records. After finding full-text articles, 6 records were not retrieval due to do not find full text and just show abstract only or letter to editors. Total 27 articles were reported sought for retrieved. Assessment of their full texts led to 15 articles being excluded since they did not meet the inclusion criteria. Finally, 12 articles were included in this systematic review. The complete selection process is presented in the PRISMA flow diagram (Figure 1).

Quality appraisal

The COSMIN checklist was used to evaluate the included studies' methodological quality. Nine sections make up the check list: measurement error, internal consistency, reliability, content validity, structural validity, criterion validity, responsiveness, and cultural validity. A 4-point rating system is used for each item: poor, fair, good, or excellent. The lowest score of all the items for each measurement property is used to determine the overall score for that measurement property.



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Figure 1. Flowchart of studies based on PRISMA

Data extraction

The following data about the included studies were extracted: (a) the general characteristics of the included instruments (name of instrument, author, type of instrument, measurement approach, dimensions and number of items and response options); (b) the characteristics of the populations where the instrument properties were assessed (sample, age, setting and country) and (c) the measurement properties.

Results

12 studies were included in this systematic review, which included the following 10 instruments. There are five instruments of translation version including FCCHL (Functional, communicative, and critical HL- in Norwegian; HLS-K (Health literacy scale in Korean); CHLSD in Iran; HLQ (Health Literacy Questionnaire in English.

There are seven developments of instruments including CHLSD (Chinese Health Literacy Scale for Diabetes); MHLM-Medical Health Literacy Measurement; KHLS-DM (Korean Health Literacy Scale for Diabetes Mellitus); DHLS (Diabetes HL scale); ASAM-D (Health literacy related to adherence to drug treatment among diabetic patients); Food literacy questionnaire; OHLD- the oral health literacy among people living with diabetes. Total 10 instruments of health literacy because there are 2 instruments that were repeated including CHLSD (development and translation version); FCCHL (translation version in Dutch and Norwegian);

Study characteristics

The instrument characteristics are summarized in Table 1. There are eleven (91.67%) diabetic specific instruments. The language version of instruments are nine English version, others from China, Iran, Persian, and Norwegian. Also, there are various countries conduct cross-cultural adaptations of health literacy measurements such as Korea, Brazil, Iran, China, Portugal, Norwegian, and Pennsylvania. The number of dimensions of the instruments varied from two to nine. The item-response options were either dichotomous or scales. Almost studies set sample of 100 % of diabetes mellitus patients and only one study conduct with 64% of this population in Pennsylvania.

Content comparisons of the included studies

The content of health literacy measurement instruments was indicated in Table 2, in which, the instruments of functional, communicative, and critical health literacy (FCCHL), Diabetes Health Literacy scale (DHLS) that are covered all dimensions of health literacy according to health literacy theory of Nut beam, 2000.

Besides, Table 2 presents content comparisons of two instruments that are DHLS and HLS-K, however HLS-K is translation version of DHLS and is same contents of the original instrument.

Methodological quality and measurement properties

The Table 3 showed data extractions from all the included instruments to measure health literacy. Almost studies frequently assessed characteristics of the construct validity, internal consistency.

Nevertheless, the measurement error and responsiveness were not evaluated for any of the instruments.

Table 1. Characteristics of instrument and study samples

No	Author, year	Type (Development or translation version)	Name of instruments	Type (diabetes specific or nonspecific)	Language version	Dimensions (No of items)	Response options	Study sample	Mean age in years	Setting	Country
1	(Leung et al., 2013)	Development	Chinese Health Literacy Scale for Diabetes (CHLSD)	Specific	China English	4 (34)	Rating sale	137 diabetes	72.3 ± 5.4	community centers	China
2	(Ahmadi, Niknami, & Ghaffari, 2022)	Translation	Iranian version of CHLSD-Translation (CHLD-I)	Specific	Persian	3(34 item)	Rating sale	283 (100% T2DM)	52.4 ± 11.5	clinic	Iran
3	(Reisi et al., 2017)	Cross-cultural addaptation	Functional, communicative and critical HL (FCCHL)	Specific	English	3 (14)	4-point scale	187 (100% T2DM)	57.4 ± 11.07	Clinic	Iran
4	(Finbråten et al., 2018)	Translation	Functional, communicative and critical HL (FCCHL)	Specific	Norwegian	3(12)	6-poit rating scale	386 (100% T2DM)		Community	Norwegian
5	(Stilley et al., 2014)	Development	Medical Health Literacy Measurement (MHLM)	not specific	English	3(6)	Rating sale	89 (64% diabetes)	55.6 ± 9.0	Community sites	Pennsylvania
6	(Kang et al., 2018)	Development	Korean Health Literacy Scale for Diabetes Mellitus (KHLS-DM)	Specific	English	2 (58)	4-point scale	500 (100% T2DM)	73.5	Clinic and community health care center	Korea
7	(Lee & Lee, 2018)	Translation	Health Literacy Scale translation verson (HLS-K)	Specific	English	3(14)	5-point scale	459 diabetes	59.6 ± 10.57	Clinic	South Korea
8	(Lee et al., 2018)	Development	Diabetes Health Literacy scale (DHLS)	Specific	English	3 (14) information, numeray, communicative Health literacy	5-point Likert scale	462 diabetes	54.52 ± 11.06	Clinic	Korea
9	(Cardoso et al., 2019)	Development	Health literacy related to adherence to drug treatment among diabetic patients (ASAM-D)	Specific	English	(18 item)	Dichotomous	62 diabetes	54.9 ± 9.97	Community	Brazil
10	(Bastami, Mardani, & Rezapour, 2022)	Development	Food literacy questionnaire(FLQ)	Specific	Iran	5(33)	Likert-type scale	300 diabetes	-	Community	Iran

No	Author, year	Type (Development or translation version)	Name of instruments	Type (diabetes specific or nonspecific)	Language version	Dimensions (No of items)	Response options	Study sample	Mean age in years	Setting	Country
11	(Do Ó et al., 2022)	Cross-cultural addaptation	Health Literacy Questionnaire (HLQ)	Specific	English	9 (44)	4-point scale and 5-point scale	453 diabetes	61 ± 18	Clinic	Portugal
12	(Martins et al., 2023)	Development	the oral health literacy among people living with diabetes (OHLD)	Specific	English	3(10 item)	A Likert-type scale	239 diabetes	-	Community	Portugal

Table 2. Contents of health literacy instruments

Study	Instrument	Health literacy						
		Functional HL			Interactive HL		Critical HL	
		Reading	Writing	Numeracy	Social skill	Cognitive skill	Analyze information	Use information
(6)	CHLSD	yes	yes	yes	-	yes	yes	yes
(7)	CHLSD	yes	yes	yes	-	yes	yes	yes
(8)	FCCHL	yes	yes	yes	yes	yes	yes	yes
(9)	FCCHL	yes	yes	yes	yes	yes	yes	yes
(10)	MHLM	yes	yes	yes	-	-	yes	yes
(11)	KHLS-DM	yes	yes	yes	-	-	yes	yes
(12)	HLS-K	yes	yes	yes	yes	yes	yes	yes
(13)	DHLS	yes	yes	yes	yes	yes	yes	yes
(14)	ASAM-D	yes	yes	yes	-		yes	yes
(15)	FLQ	yes	yes	yes	-	yes	yes	yes
(16)	HLQ	yes	yes	yes	-	yes	yes	yes
(17)	OHLD	yes	yes	yes	-	yes	yes	yes

Table 3. Data extraction of methodology and psychometric measurement of the Health Literacy instruments

Psychometric measurement	Leung et al., 2013	(7)	(8)	(9)	Stilley et al., 2014	(11)	(12)	(13)	(14)	(15)	(16)	(17)
	CHLSD	CHLSD	FCCHL	FCCHL	MHLM	KHLS-DM	HLS-K	DHLS	ASAM-D	FLQ	HLQ	OHLD
Content Validity	-	Quali: no change Quanti keep itemts have: CVR >= 0.54 CVI > 0.79	Modified some itemts. CVI 0.82	CVI > 0.79	-	-	CVI >0.79	CVI >0.79	-	-	-	-
Item analysis and item selection	-	-	-	-	--	Good fit		Good	-	-	-	-
Face validity	-	Quanti: Impact score > 1.5 Quali: replaced some medical terns	-	-	-	-	-	-	-	-	-	-
Convergent Validity	-	-	Pearson's correlation coefficient (r = 0.45; P < 0.01. A moderate correlation (r = 0.30; P < 0.01)	-	-	-	-	The DHLS was moderately correlated withknowledge (r=0.42, p < 0.001) and self-efficacy (r = 0.56, p < 0.001)	-	-	-	AVE for the Access, Understand /appraise, and Apply subscales were 0.831, 0.981, and 0.954
Construct Validity	Cronbach's alpha: 0.884 RMSEA = 0.008,	Factor loading value > 0.4. The results of	CFI = 0.92 TLI = 0.93 RMSEA =0.077	normed X2 = 3.32, SRMR = .078,	A three-factor structure explained	CFI = 0.92 TLI = 0.91 RMSEA = 0.04	X2 / df = 3.891, SRMR = 0.042, GFI = 0.924,	(X2 = 1837.58, p < 0.001), and the KMO	validity of content was completed and	KMO) was 0.836 (p< 0.001) Bartlett sphericity	the fit was quite satisfactory [X2wlsmv = 2147.3 (df =	quality parameters (X2 /df = 2.459; CFI = 0.988; TLI =

Psychometric measurement	Leung et al., 2013	(7)	(8)	(9)	Stilley et al., 2014	(11)	(12)	(13)	(14)	(15)	(16)	(17)
	CHLSD	CHLSD	FCCHL	FCCHL	MHLM	KHLS-DM	HLS-K	DHLS	ASAM-D	FLQ	HLQ	OHLD
	CFI = 0.997	convergent validity: Cronbach's alpha > 0.7 Good fit model	Factor loading (range from 0.443-0.899) Eigenvalue (1.1; 3.73; 4.45) > 1	RMSEA = .132, CFI = .854, NNFI = .821	65.34% of the total Variance.	x2 = 2785.72, df = 1592, p < .001	RMSEA = 0.079 (90% CI = 0.069–0.090), and CFI = 0.962.	value (0.88) was good. PCA with varimax rotation extracted a three-factor solution (eigenvalues > 1) that accounted for 68.40% of the total variance	presented alpha=0.77	test was also significant (P<0.001: 4212.142) A five-pronged structure accounted for 52.745% of food literacy variance	866), p = 0.001; CFI = 0.931, TLI = 0.925, RMSEA = 0.057 (90% C.I. 0.054–0.060), and WRMR = 1.528] Factor loadings were satisfactory, with 37 of the 44 items showing factor loadings above 0.60 (range 0.60–0.80).	0.981) and poor RMSEA (0.078).
Internal Consistency (Cronbach's alpha coefficient)	-	K-R coefficients 0.8, 0.71, 0.73, 0.87, and 0.89,	(0.82) in which Functional (0.91) communicat ive (0.80), and critical items (0.76)	0.75 in which the highest (.866)	0.661 (prose) and 0.686 (numeracy) <0.4 (document)	0.83for the overall scale 0.92 (the diabetes-related words, and 0.83 the numeracy & information utilization)	Cron- bach's alpha for the total scale was 0.90.	0.91subscal es ranged from 0.80 to 0.90	0.773 Alpha Cronbach Scale dimension was 0.610–0.951		Composite reliability ranged from 0.74 to 0.83.	the composite reliability CR for these subscales were 0.893, 0.962, and 0.822, good (CR>0.7)
Criterion validity	-	-	-	-	-	significant moderate	-	The DHLS was also correlated	-	-	-	-

Psychometric measurement	Leung et al., 2013	(7)	(8)	(9)	Stilley et al., 2014	(11)	(12)	(13)	(14)	(15)	(16)	(17)
	CHLSD	CHLSD	FCCHL	FCCHL	MHLM	KHLS-DM	HLS-K	DHLS	ASAM-D	FLQ	HLQ	OHLD
						correlation (r = 0.45)		with the Screening Questions of Health Literacy-3 (r = 0.42, p < 0.001), thereby also satisfying criterion validity				
Test-retest reliability	Good (r = 0.898, p < 0.001)	-	0.85 (P < 0.01)	-	-	Good	-	Excellent	-	-	-	-
Inter-item correlations	-	-	-	-	% correct range from 29.1% - 92.2 %	-	-	Excellent	-	-	inter-factor correlations in the nine-factor model range from 0.283 (scales 3 and 8) to 0.891 (6 and 7)	-
ICC	-	>= 0.8	-	-	-	-	-	ICC for the total scale was 0.89, and those for the subscales ranged from 0.80 to 0.85	Kappa values ranged from 0.31 to 1.00.	-	-	-

- No informations

Table 4. Methodological quality and measurement properties

Study	Instrument	Internal consistency		Reliability (test-retest)		Measurement error		Content validity		Construct validity		Criterion validity		Responsiveness		Cross-cultural validity (translation process)
		MQ	QM	MQ	QM	MQ	QM	MQ	QM	MQ	QM	MQ	QM	MQ	QM	MQ
(6)	CHLSD		0	Good	+		0		0	Good	+		0		0	NA
(7)	CHLSD-I	Fair	+		0		0		+	Fair	+		0		0	Good
(8)	FCCHL	Fair	+	Good	+		0	Good	+	Good	+		0		0	Good
(9)	FCCHL	Fair	+		0		0		+	Good	+		0		0	Good
(10)	MHLM	Poor	+		0		0		0	Fair	+		0		0	NA
(11)	KHLS-DM	Good	+	Good	+		0		0	Good	+	Fair	+		0	NA
(12)	HLS-K	Fair	+		0		0		0	Fair	+		0		0	Fair
(13)	DHLS	Excellent	+	Excellent	+		0	Good	+	Good	+	Fair	+		0	NA
(14)	ASAM-D	Fair	+	Good	+		0		+	Fair	+	Fair	+		0	NA
(15)	FLQ		0		0		0		0	Good	+		0		0	NA
(16)	HLQ	Fair	+		0		0		0	Fair	+		0		0	Fair
(17)	OHLD	Good	+		0		0		0	Fair	+		0		0	NA

CHLSD (Chinese Health Literacy Scale for Diabetes); MHLM (Medical Health Literacy Measurement); FCCHL (Functional, communicative and critical HL); KHLS-DM (Korean Health Literacy Scale for Diabetes Mellitus); HLS-K (Health literacy scale in Korean); DHLS (Diabetes HL scale); ASAM-D (Health literacy related to adherence to drug treatment among diabetic patients); CHLSD-I (Iranian version of CHLSD Translation); FLQ (Food literacy questionnaire); HLQ (Health Literacy Questionnaire); OHLD- the oral health literacy among people living with diabetes.

MQ, methodological; QM, quality of measurement properties; NA, not applicable; Hypothesis test validity, convergent, discriminant, and known-groups validity.

+, positive; "?", indeterminate; -, negative; 0, no information

The results for measurement properties of each study are presented in table 4 for all translation version instruments, the methodological quality was assessed as being "fair" according the translation process (5).

Synthesis of results

Table 5 presents the level of evidence for measurement properties in each instrument. There were moderate positive results for CHLSD's construct validity and reliability, however unknow evidence for the content validity, criterion validity and internal consistency. The FCCHL is a translation version in two countries that measure the functional, communicative, and critical health literacy in people with diabetes, based on the model of HL reported by Nutbeam (2000). Two study indicated that assessed its psychometric measurement. There was moderate positive evidence for its reliability (test-retest), content validity, and construct validity. In addition, there was moderate positive result for internal consistency, however limited unknow for criterion validity of this instrument. The MHLM is only not diabetes specific instrument in this systematic review. There was almost unknown evidence for internal consistency, reliability (test-retest), content validity, criterion validity and only indicated the evidence with moderate positive results of construct validity. The KHLS-DM was original development in Korea. There were moderate positive results in its validity and reliability but only limited positive evidence for criterion validity. The HLS-K is translation version of DHLS. DHLS is showed better results than others instrument. In particularly, there was strong positive evidence for the internal consistency and reliability (test-retest) of DHLS. Moreover, its content validity and construct validity are evidence with moderate positive results. In another way, there was unknown about results of test-retest and criterion validity of HLS-K, only shown moderate positive results of its internal consistency and construct validity. The ASAM-D is one of three instrument indicated evidence with limited positive results for its criterion validity. The ASAM-D was original developed for diabetes in community in Brazil. In a population of diabetes mellitus patients, there was moderate evidence for construct validity and limited positive results for its internal consistency, and unknown reliability (test-retest) of this instrument. In this systematic review, there are mentioned various fields to measure health literacy so besides ASAM-D the FLQ and OHLD are also developed in English version such as in food from Iran (FLQ), in medication adherence (ASAM-D) from Brazil as well as in an oral health literacy measurement (OHLD) from Portugal. OHLD is a short version that measures oral health literacy in Portugal. There were moderate positive results for its internal consistency and limited positive evidence for its construct validity. There was unknown evidence for its reliability (test-retest) for both FLQ and OHLD. The HLQ contains 44 items in 9 subscales, which was developed for Portugal patients with diabetes mellitus disease. There were limited positive results for its internal consistency and construct validity. In addition, there was unknown evidence for its reliability (test-retest), content validity, criterion validity.

Table 5. Level of evidence for the measurement properties in each instrument

No	Instrument	Internal consistency	Reliability (test-retest)	Measurement error	Content validity	Construct validity	Criterion validity	Responsiveness
1	CHLSD		+			+		
2	FCCHL	+	++		++	++		
3	MHLM	?				+		
4	KHLS-DM	++	++			++	+	
5	HLS-K	++				++		
6	DHLS	+++	+++		++	++	+	
7	ASAM-D	+			+	++	+	
8	FLQ					++		
9	HLQ	+				+		
10	OHLD	++				+		

+++/---, Evidence with strong positive/negative results (findings of good methodological quality in multiple studies or of excellent methodological quality in one study).

++/--, Evidence with moderate positive/negative results (findings of fair methodological quality in multiple studies or of good methodological quality in one study).

+/-, Evidence with limited positive/negative results (consistent findings of fair methodological quality in one study). ± Conflicting evidence (conflicting findings).

? Unknown (only findings of poor methodological quality).

Discussion

In the population with diabetes mellitus, 10 health literacy instruments measuring both diabetes-specific and diabetes non-specific types of HL instruments were identified by this systematic review. Which of these two types is better to apply to individuals with diabetes in practice is an important question to think about. The results of this study indicate that the majority of the instruments used to measure health literacy cover nearly all aspects of the field, including functional, interactive, and critical health literacy. Specifically, the comprehensive constructs of health literacy by Nutbeam (2000) are measured by the DHLS, which has strong evidence in psychometric measurement results.

Several issues with the measurement characteristics of health literacy instruments were found by this systematic review. First, it was not always clear whether the structural validity of the instruments was empirically satisfied because there was insufficient factor analysis done of the underlying structure of the included instruments. Additionally, the evidence supporting the instruments' internal consistency was diminished by this absence of structural support. Another problem is the absence of assessments for some measurement properties, such as reliability, measurement error and responsiveness. It is crucial results of this systematic review regarding the criterion validity of the included instruments, the frequently used criterion (i.e. gold standard) instruments were DHLS, KHLS-DM, and ASAM-D which measure a wide range of health literacy.

All things considered, the DHLS can be regarded as the most suitable instrument currently available for use with individuals who have diabetes mellitus because: (a) it is a model-based, comprehensive measure; (b) its

items may be more sensitive in a clinical setting aimed at diabetes because it is a diabetes-specific type of instrument; and (c) there is stronger evidence supporting the measurement properties of the HLS than there is for the other instruments included in this study. However, there was little evidence to refute the DHLS's hypothesis testing validity, necessitating further analysis based on actual data.

This review builds upon and extends earlier work by Lee at al., (2017) (4) by incorporating studies published between 2017 and Sepember 2025 and identifying four newly developed diabetes specific HL instruments (DHLS, ASAM D, FLQ, OHLD) and multiple culturally adapted versions not included in the earlier synthesis. Our review also updates psychometric evidence for previously reported tools such as FCCHL and HLQ, including structural validity and internal consistency data from newer validation studies. Compared with the 2017 review, our findings confirm persistent gaps in responsiveness and measurement error assessment but reveal improvements in reporting of internal consistency, construct validity, and cross cultural validity. The DHLS, developed in Korea and since adapted into other languages, now demonstrates strong positive evidence for internal consistency and test–retest reliability, positioning it as a leading candidate for use in diabetes specific HL assessment. The ASAM D, FLQ, and OHLD provide domain specific HL measures (medication adherence, food literacy, oral health literacy) that expand the range of available tools for targeted interventions. This updated synthesis enables more informed instrument selection. For comprehensive HL assessment in diabetes, the DHLS appears most suitable, particularly in settings where a diabetes specific measure is warranted. For domain focused assessments, FLQ and OHLD may be considered where nutrition or oral health literacy is of primary interest. Cross cultural adaptations, such as the Persian CHLSD and Portuguese HLQ, should be prioritized when working in corresponding language populations, though additional validation is recommended. Although several instruments have been translated and adapted into different languages, the cultural adaptation processes were often insufficiently described or evaluated. The lack of detailed evidence on cross-cultural validity may reduce the accuracy and applicability of these instruments in diverse populations. Future studies should conduct rigorous translation and cultural validation procedures to ensure the conceptual and measurement equivalence of health literacy instruments across settings.

Many instruments included in this review lacked strong and precise factor analyses to confirm their conceptual structure. This shortcoming restricts confidence in the dimensional validity of these tools and may affect the accurate interpretation of health literacy outcomes. Future research should employ more rigorous exploratory and confirmatory factor analyses to strengthen the theoretical and structural validity of health literacy instruments. In addtion, several included studies did not provide complete or transparent reporting of their statistical methods, particularly regarding structural analysis, content validation, and assessments of instrument validity. The lack

of detailed methodological reporting limits the ability to evaluate the robustness and reproducibility of their findings. Future psychometric research should ensure comprehensive and transparent reporting following COSMIN standards to enhance the interpretability and comparability of results.

According to the COSMIN standards, several key measurement properties, such as measurement error, responsiveness, and test–retest reliability, were rarely assessed among the included instruments. The absence of these evaluations limits the ability to fully establish the reliability and validity of current health literacy measures. Future psychometric research should therefore include comprehensive testing of these properties to enhance the methodological quality and interpretability of health literacy instruments used in diabetes research and practice.

Beyond psychometric evaluation, the findings of this review have important implications for diabetes health education and health promotion. Validated health literacy instruments can support healthcare providers in identifying patients with limited health literacy, tailoring educational materials to individual needs, and enhancing patient engagement in self-care. The Diabetes Health Literacy Scale (DHLS), in particular, can be applied in both clinical and community settings to assess patients' understanding, communication, and critical appraisal skills related to diabetes care. Incorporating such instruments into health promotion programs allows educators to evaluate the effectiveness of interventions, monitor improvements in patients' health literacy, and design strategies that promote empowerment and better glycemic control. Future research should further explore how the use of validated health literacy tools can optimize patient education and improve clinical outcomes

Study Limitations and Strengths: Additionally, this study had certain restrictions. The selection process may have introduced bias as only peer-reviewed journal articles published in English were included. Some of the instruments used in this study had their psychometric qualities evaluated in individuals with diabetes only once, therefore the evidence supporting the measurement qualities of each instrument may not be strong enough to be considered pooled evidence. Further psychometric research involving individuals with diabetes using these tools is required. Although many instruments assessed in this review measure specific components such as functional or communicative health literacy, few comprehensively and psychometrically evaluate all three dimensions, including critical health literacy. This gap may lead to an incomplete understanding of patients' overall health literacy and limits the ability of researchers and clinicians to capture its full impact on diabetes self-management. Future research should focus on developing or refining multidimensional instruments that integrate all core components of health literacy.

Conclusions

Ten tools were found in this systematic review to assess the health literacy of diabetics. Furthermore, no instrument's responsiveness, measurement error, or reliability were evaluated. None of the instruments' measurement properties were

evaluated in its entirety. The DHLS may be the most appropriate tool to use with diabetics in practice and research, according to the available data. Functional, interactive, and critical health literacy are all covered by the comprehensive model-based measure known as the DHLS. But more research is necessary to confirm the HLS's structural validity, especially for multilingual versions of the test.

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