VALIDITY AND RELIABILITY OF THE MALAY TRANSLATED VERSION OF THE DIABETES HEALTH LITERACY SCALE AMONG MALAYSIAN ADULTS WITH TYPE 2 DIABETES MELLITUS

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by

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LIST OF SYMBOLS

α	Alpha; level of significance
β	Beta; probability of type II error
df	Degree of freedom
n	Sample size; number of participants
p	Probability value
r	Rho; correlation coefficient
χ^2	Chi-square
%	Percent
=	Equal to
<	Less than
$\leq$	Less than or equal to
$\geq$	More than or equal to

LIST OF ABBREVIATIONS

AGFI	Adjusted goodness of fit index
AMA	American Medical Association
CFA	Confirmatory factor analysis
CFI	Comparative fit index
CHLSD	Chinese Health Literacy Scale for Diabetes
CHLSD-MC	Chinese Health Literacy Scale for Diabetes – multiple-choice version
CI	Confidence interval
CR	Composite reliability
DHLS	Diabetes Health Literacy Scale
DHLS-M	Malay translated version of the Diabetes Health Literacy Scale
DM	Diabetes mellitus
DNT	Diabetes Numeracy Test
EFA	Exploratory factor analysis
GFI	Goodness of fit index
HbA1c	Glycated hemoglobin
HL	Health literacy
HLS-EU-Q47	European Health Literacy Survey Questionnaire
HLS-M-Q18	Short form European Health Literacy Survey Questionnaire, Malay version
HLS-SF12	Short form Health Literacy Survey Questionnaire
ICF	Informed consent form
IPH	Institute for Public Health
IQR	Interquartile range
KR-20	Kuder-Richardson 20 coefficient
LAD	Literacy Assessment for Diabetes
MAR	Missing at random
MCAR	Missing completely at random
MDKT	Michigan Diabetes Knowledge Test
MI	Modification index
ML	Maximum likelihood
MNAR	Missing not at random
MOH	Ministry of Health Malaysia

NFI	Normed fit index
NHMS	National Health and Morbidity Survey
NVS	Newest Vital Sign
PIS	Participant information sheet
REALM	Rapid Estimate of Adult Literacy in Medicine
RMSEA	Root mean square error of approximation
SD	Standard deviation
SMBG	Self-monitoring of blood glucose
SPSS	Statistical Package for the Social Sciences
SRMR	Standardized root mean square residual
T2DM	Type 2 diabetes mellitus
TLI	Tucker–Lewis index
USA	United States of America
USD	United States dollar
USM	Universiti Sains Malaysia
WHO	World Health Organization
WRAT–3	Wide Range Achievement Test–Third Edition
WRMR	Weighted root mean square residual

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KESAHAN DAN KEBOLEHPERCAYAAN SKALA LITERASI KESIHATAN DIABETES VERSI BAHASA MELAYU DALAM KALANGAN ORANG DEWASA MALAYSIA DENGAN DIABETES JENIS DUA

ABSTRAK

Pengenalan: Instrumen untuk mengukur literasi kesihatan dalam kalangan orang dewasa Malaysia dengan diabetes jenis dua adalah terhad. Satu intrumen literasi kesihatan khusus untuk diabetes dalam versi Bahasa Melayu yang sah dan boleh dipercayai adalah diperlukan sebelum instrumen tersebut boleh digunakan untuk mengukur literasi kesihatan diabetes and menentukan hubungannya dengan pemboleh ubah lain. **Objektif:** Tujuan kajian ini adalah untuk menentukan kesahan dan kebolehpercayaan Skala Literasi Kesihatan Diabetes versi Bahasa Melayu (SLKD-M) dalam kalangan orang dewasa Malaysia dengan diabetes jenis dua. **Kaedah:** Skala Literasi Kesihatan Diabetes (SLKD) diterjemah ke Bahasa Melayu dan disesuaikan dengan budaya, diikuti dengan satu kajian keratan rentas yang dijalankan dengan menggunakan soal selidik kendiri dalam kalangan orang dewasa dengan diabetes jenis dua di Hospital Universiti Sains Malaysia (USM). Peserta kajian dipilih dengan menggunakan kaedah persampelan mudah. Analisis pengesahan faktor, ujian kebolehpercayaan dan analisis korelasi dijalankan. **Keputusan:** Sejumlah 250 orang dewasa dengan diabetes jenis dua mengambil bahagian dalam kajian ini. Umur median peserta adalah 63.0 tahun (julat antara kuartil = 12.3) dan kebanyakan peserta terdiri daripada lelaki (52.1%). Model pengukuran terakhir bagi SLKD-M dengan penyingkiran satu item yang bermasalah, memadankan data dengan baik berdasarkan beberapa indeks padanan: *Relative chi-square* (χ^2/df) = 3.858, *comparative fit index* (CFI) = 0.981, *Tucker–Lewis index* (TLI) = 0.976. Kebolehpercayaan komposit untuk

tiga subskala berdasarkan *Raykov's rho* adalah 0.962, 0.836 dan 0.828. Subskala SLKD-M mempunyai hubungan korelasi yang signifikan dengan Ujian Pengetahuan Diabetes Michigan versi Bahasa Melayu (r = 0.26 – 0.31) dan Soal Selidik Tinjauan Literasi Kesihatan bentuk ringkas versi Bahasa Melayu (r = 0.43 – 0.66). **Kesimpulan:** SLKD-M yang terdiri daripada tiga subskala dan 13 item adalah sah dan boleh dipercayai. SLKD-M boleh digunakan untuk mengukur literasi kesihatan diabetes dalam kalangan orang dewasa dengan diabetes jenis dua.

VALIDITY AND RELIABILITY OF THE MALAY TRANSLATED VERSION OF THE DIABETES HEALTH LITERACY SCALE AMONG MALAYSIAN ADULTS WITH TYPE 2 DIABETES MELLITUS

ABSTRACT

Introduction: The instrument for measuring health literacy among Malaysian adults with type 2 diabetes mellitus (T2DM) is limited. A valid and reliable diabetes-specific health literacy instrument in Malay is required before it can be used in measuring diabetes health literacy and determining its relationship with other variables. **Objective:** The aim of this study was to determine the validity and reliability of the Malay version of the Diabetes Health Literacy Scale (DHLS-M) among Malaysian adults with T2DM. **Method:** The Diabetes Health Literacy Scale (DHLS) was translated and culturally adapted into Malay, followed by a cross-sectional study which was conducted using a self-administered questionnaire among the adults with T2DM in Hospital Universiti Sains Malaysia (USM). The participants were recruited by convenience sampling. Confirmatory factor analysis (CFA), reliability testing and correlation analysis were performed. **Results:** A total of 250 adults with T2DM were participated in this study. The median age of the participants was 63.0 years old (interquartile range, IQR = 12.3) and most of the participants were male (51.2%). The final measurement model of DHLS-M with removal of one problematic item, fit the data well based on several fit indices: Relative chi-square (χ^2/df) = 3.858, comparative fit index (CFI) = 0.981, Tucker–Lewis index (TLI) = 0.976. The composite reliability of the three subscales based on Raykov's rho were 0.962, 0.836 and 0.828 respectively. The subscales of DHLS-M were significantly correlated with the Malay version of the Michigan Diabetes Knowledge Test (MDKT) (r = 0.26 – 0.31) and the Malay version

of the short form Health Literacy Survey Questionnaire (HLS-SF12) (r = 0.43 – 0.66). **Conclusion:** DHLS-M which consisted of three subscales and 13 items is valid and reliable. DHLS-M can be used to measure diabetes health literacy among Malaysian adults with T2DM.

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Globally, the prevalence of diabetes mellitus (DM) has increased over the years. In 2017, the estimated prevalence of diabetes (adults aged 20 to 79 years old) in the world was 8.8% (425 million people) (Cho et al., 2018). The number has increased to 10.5% (536 million) in 2021 and is expected to increase to 12.2% (783 million) in 2045 (Sun et al., 2022). In Malaysia, the prevalence of DM was 17.5% in 2015 and increased to 18.3% in 2019, then reduced to 15.6% in 2023 based on the findings from the National Health and Morbidity Survey (NHMS) (Institute for Public Health [IPH], 2015, 2020, 2024). The prevalence of DM in Kelantan was 18.5% in 2015 and increased to 19.5% in 2019 (IPH, 2015, 2020).

Diabetes mellitus is a chronic metabolic disorder presented with hyperglycemia or high blood sugar. Type 2 diabetes mellitus (T2DM) is the most common type of diabetes in adults (Ministry of Health Malaysia [MOH], 2020). Persistently high blood sugar over time can lead to microvascular complications (such as nervous system damage, renal damage and eye damage) and macrovascular complications (cardiovascular disease, stroke and peripheral vascular disease) (Deshpande et al., 2008). The estimated global health expenditure on diabetes increased from USD 850 billion in 2017 to USD 966 billion in 2021 and is expected to increase further to USD 1054 billion by 2045 (Cho et al., 2018; Sun et al., 2022).

Diabetes requires a lifelong regimen to control the disease and prevent or delay the disease progression and its complications. The management of T2DM involves the use of long-term medication and lifestyle changes. To obtain the optimal glycemic

control in T2DM, self-management including medication adherence, self-monitoring of blood glucose (SMBG), changes in diet and physical activity and appointments with healthcare providers, plays a vital role (Gonzalez et al., 2016). Self-management requires an individual to effectively use health information and health services (Marciano et al., 2019). Studies reported that DM patients with higher health literacy (HL) have better diabetes knowledge, self-management and glycemic control (Alsharit & Alhalal, 2022; Lee et al., 2021).

The World Health Organization (WHO) defines HL as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (Nutbeam, 1998, p. 357). For measuring HL, various instruments have been developed worldwide. The instruments commonly used among people with DM can be divided into general health literacy instruments and disease-specific (diabetes) health literacy instruments (Marciano et al., 2019).

The Diabetes Health Literacy Scale (DHLS) is a diabetes-specific health literacy instrument developed by Lee et al. in 2018 for measuring HL among DM patients. It is a valid and reliable instrument in Korean and the English version of the DHLS has been translated and culturally adapted to Persian version (Lee et al., 2018; Moshki et al., 2022).

1.2 Problem Statement

In Malaysia, one in six adults aged 18 and above have diabetes in 2023 (IPH, 2024). Local studies found that less than 20% of patients with T2DM who attended government healthcare facilities have optimal glycemic control (Hiong et al., 2020; Soffian et al., 2019). Although various types of medications were available for the

treatment of T2DM and diabetes education has been provided for the patients, the proportion of patients with controlled DM was still low (Soffian et al., 2019).

Two local studies reported that more than 60% of T2DM patients attended the government healthcare clinics have low HL. The HL among the patients was measured using the general health literacy instrument. The European Health Literacy Survey Questionnaire (HLS-EU-Q47) and the Newest Vital Sign (NVS) which have been translated into Malay and validated among Malaysian adults were used in the studies (Abdullah et al., 2020; Tan & Ismail, 2020). A local study reported that 75% of T2DM patients have diabetes-specific HL level equivalent to the secondary school level. Although the Malay and Mandarin versions of the diabetes-specific health literacy instrument, Literacy Assessment for Diabetes (LAD) were used in the study, the instrument was not validated in the Malay and Mandarin languages (Li et al., 2019).

1.3 Rationale and Significance of the Study

There is no available validated questionnaire in the Malay language to examine the HL related to diabetes among patients with T2DM. Malay language is the formal language and primary medium of communication in Malaysia. Therefore, a Malay translated version of the questionnaire is important for the researchers to explore the HL issue related to diabetes among the diabetes population. Upon identifying the factors associated with low HL, further action can be taken by healthcare providers to improve the communication between patients and healthcare providers, increase the ability of patients to understand their disease and be involved in the decision-making process related to the management of their condition.

1.4 Research Questions

1. Is the Malay translated version of the DHLS a valid and reliable questionnaire to measure diabetes HL among Malaysian adults with T2DM?
2. Is there any correlation between the Malay version of the Michigan Diabetes Knowledge Test (MDKT), the Malay version of the short form Health Literacy Survey Questionnaire (HLS-SF12) and the Malay translated version of the Diabetes Health Literacy Scale (DHLS-M)?

1.5 Research Objectives

1.5.1 General Objective

To determine the validity and reliability of the Malay translated version of the Diabetes Health Literacy Scale (DHLS-M) among Malaysian adults with T2DM.

1.5.2 Specific Objectives

1. To translate the English version of the DHLS into the Malay language.
2. To determine the construct validity of the DHLS-M by internal structure among Malaysian adults with T2DM using confirmatory factor analysis (CFA) and composite reliability based on Raykov's rho.
3. To determine the convergent validity by correlating the DHLS-M with other validated questionnaires (Malay version of MDKT and Malay version of HLS-SF12).

1.6 Research Hypothesis

1. The DHLS-M is valid and reliable in measuring diabetes health literacy among Malaysian adults with T2DM.

2. There is a significant correlation between the score of the Malay version of the MDKT, the Malay version of the HLS-SF12 and the DHLS-M.

CHAPTER 2

LITERATURE REVIEW

2.1 Search Terms and Databases

Google Scholar, ScienceDirect and Scopus were used in searching for literature. The literature search was conducted using the following keywords: diabetes health literacy, health literacy, diabetes, questionnaire, psychometric, confirmatory factor analysis, validation, translation, Malay. Alternative words for 'questionnaire' such as 'instrument' and 'tool' were also used. Boolean operator, 'AND' was used in combining the keywords. An example of the literature search strategy in this study is presented in Table 2.1.

Table 2.1 Literature Search Strategy

	Search Engine		
Example	**Google Scholar**	**ScienceDirect**	**Scopus**
"Diabetes health literacy"	718	40	172
"Diabetes health literacy" AND "psychometric"	212	6	49
"Diabetes health literacy" AND "Malay"	32	0	4
"Health literacy" AND "diabetes"	160000	7725	24557
"Health literacy" AND "diabetes" AND "questionnaire"	48700	3211	10004
"Health literacy" AND "diabetes" AND "tool"	60400	4234	9283
"Health literacy" AND "diabetes" AND "instrument"	33300	1927	5500
"Health literacy" AND "diabetes" AND "instrument" AND "validation"	15900	1274	3045
"Health literacy" AND "diabetes" AND "validation" AND "translation"	5020	568	711
"Health literacy" AND "diabetes" AND "Malay"	1820	75	384
"Health literacy" AND "diabetes" AND "validation" AND "Malay"	830	49	150

2.2 Health Literacy

The term ‘health literacy’ was first introduced in 1974 (Simonds, 1974). A systematic review conducted by Sørensen et al. (2012) reported that there were 17 definitions and 12 conceptual models of HL.

2.2.1 Definition of Health Literacy

The definition of HL is evolving and there is no consensus on the meaning of HL (Sørensen et al., 2012). WHO defines HL as ‘the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health’ (Nutbeam, 1998, p. 357). American Medical Association (AMA) defines HL as ‘the constellation of skills, including the ability to perform basic reading and numeral tasks required to function in the healthcare environment’ (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999, p. 553). Institute of Medicine (2004) defines HL as ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions’ (Ratzan & Parker, 2000, p. vi). These are the top three cited definitions in the literature.

After reviewing the 17 definitions in the literature, Sørensen et al. (2012) proposed a new comprehensive definition of HL: ‘Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course’ (p. 3). This definition covers the HL from public health perspective and the ‘health care, disease prevention and health promotion’ domains can be substituted with ‘being ill, being at risk and staying healthy’ for HL focusing on the individual level (Sørensen et al., 2012, p. 3).

2.2.2 Conceptual Model of Health Literacy

The conceptual models of HL are multidimensional and the dimensions of the models vary greatly (Sørensen et al., 2012). One of the widely accepted HL models is the one constructed by the Institute of Medicine (Liu et al., 2020) based on the definition by Ratzan and Parker (2000). It consists of four dimensions: cultural and conceptual knowledge, oral literacy, print literacy and numeracy. Cultural and conceptual knowledge includes the understanding of health and disease as well as the risks and benefits. Oral literacy includes the listening and speaking skills that are required for public health communication and interaction between practitioners and patients. Print literacy includes writing and reading skills that are required for reading health education materials and medication labels as well as filling in the informed consent documents. Numeracy includes the skills required to calculate nutrition labels and determine the proper dosage and timing of medicines (Institute of Medicine, 2004).

Another common HL model is the one constructed by Nutbeam (Liu et al., 2020) which derives from the literacy approaches proposed by Freebody and Luke (1990). It consists of three levels of HL: basic or functional HL, communicative or interactive HL and critical HL. Level one is functional HL which refers to the basic reading and writing skills that enable an individual to function in his daily life. Level two is interactive HL which refers to the more advanced skills that enable an individual to participate in activities, extract and use information. Level three is critical HL which refers to the more advanced skills that enable an individual to analyse information critically and use the information to exert control over life situation (Nutbeam, 2000).

After reviewing the 12 conceptual models in the literature, Sørensen et al. (2012) proposed a new comprehensive model of HL. It consists of four core dimensions of the competencies in health information processing (access, understand, appraise and apply)

in three levels of health continuum (healthcare, disease prevention and health promotion). The model yields a matrix of 12 dimensions. Access refers to 'the ability to seek, find and obtain health information', understand refers to 'the ability to comprehend the health information that is accessed', appraise refers to 'the ability to interpret, filter, judge and evaluate the health information that has been accessed' and apply refers to 'the ability to communicate and use the information to make a decision to maintain and improved health'. Healthcare refers to 'as a patient in the healthcare setting', disease prevention refers to 'as a person at risk of disease in the disease prevention system' and health promotion refers to 'as a citizen in relation to the health promotion efforts in the community, the workplace, the educational system, the political arena and the market place' (Sørensen et al., 2012, p. 9).

2.3 Health Literacy in Adults with Type 2 Diabetes Mellitus

A systematic review on the HL among adults with type 2 diabetes mellitus (T2DM) which was conducted by including 29 studies worldwide (Brazil, Canada, Marshall Islands, the Netherlands, South Korea, Switzerland, Taiwan, USA) reported that the prevalence of limited HL ranged from 7.3% to 76.3%. The study with the highest prevalence was conducted in Taiwan while the study with lowest prevalence was conducted in Switzerland (Abdullah et al., 2019a; Abdullah et al., 2022). A meta-analysis conducted by Pashaki et al. (2019) reported that the pooled prevalence of inadequate HL among Iranian adults with T2DM from 11 studies was 43.47% (95% CI: 31.00, 55.95). Two HL studies conducted among the adults with T2DM in Malaysia reported that the prevalence of limited HL was 64.4% and 65.3% respectively (Abdullah et al., 2020; Tan & Ismail, 2020).

Studies have been conducted to examine the relationship between diabetes knowledge, diabetes self-management, glycemic control and HL. Various studies reported that low HL was associated with poor diabetes knowledge (Al Sayah et al., 2013; Nugent et al., 2023; van der Heide et. al., 2014). The same results were also reported in a meta-analysis. Further subgroup analysis found that the strength of the correlation was affected by the types of HL instruments used in the study. Studies using performance-based HL instrument was more strongly correlated with diabetes knowledge compared to self-reported HL instrument (Marciano et al., 2019).

An association between lower HL and higher HbA1c level has been reported in several studies (Hashim et al., 2020; Marciano et al., 2019; van der Heide et. al., 2014) while Gomes et al. (2020) and Huang et al. (2018) found no correlation between HL and HbA1c level. A systematic review reported that several HL instruments were used in the study and the relationship between HL and glycemic control was mixed (Bailey, 2014).

Alsharit and Alhalal (2022), Nugent et al. (2023) and Robatsarpooshi et al. (2020) found that HL was positively related to diabetes self-management. In contrast, no relationship was reported between HL and diabetes self-management in a meta-analysis. Subgroup analysis was conducted and found that HL was correlated with diabetes self-management in studies using self-reported HL instruments (Marciano et al., 2019).

2.4 Instruments Used to Measure Health Literacy in Adults with Type 2 Diabetes Mellitus

Various instruments were used in measuring the health literacy in adults with T2DM. Al Sayah et al. (2012), Lee et al. (2017) and Levic et al. (2021) found that there were

nine, 13 and 11 different instruments used in studies measuring HL in adults with T2DM, respectively. The instruments can be classified into two groups based on the content: ‘general’ or ‘diabetes-specific (condition specific)’. ‘General’ HL instrument refers to an instrument measuring HL in general health context while ‘diabetes-specific’ HL instrument refers to an instrument measuring HL in diabetes context (O’Neill et al., 2014; Pleasant et al, 2011). Pleasant et al. (2011) proposed a comprehensive instrument should include a core module to assess general HL and an add-on module to assess the HL in specific context such as diabetes because different context may require different abilities and skills.

The instruments can be further classified into two categories based on the approach used to assess the HL: ‘direct’ or ‘indirect’ (Al Sayah et al., 2012). ‘Direct’ instrument, also known as ‘objective’ or ‘performance-based’ instrument refers to an instrument which assesses an individual’s HL directly. On the other hand, ‘indirect’ instrument, also called ‘subjective’ or ‘self-reported’ instrument refers to an instrument which assesses an individual’s HL indirectly (Al Sayah et al., 2012; Haun et al., 2014). For a ‘direct’ instrument, an individual may feel shame and embarrass especially if he has low HL and the assessment was based on the word recognition (Wolf et al., 2007). Good visual acuity (for word recognition assessment), good writing abilities (for open-ended question) and high concentrations are also required for ‘direct’ instrument. Besides that, for word recognition test, it needs to be administered by a researcher or clinician. In contrast, an ‘indirect’ instrument assesses the confidence level or the ability of an individual in performing a health-related task (Al Sayah et al., 2012).

The various types of instruments used in measuring the HL in adults with T2DM (Al Sayah et al., 2012; Lee et al., 2017; Levic et al., 2021) are listed in Table 2.2.

Table 2.2 Examples of Various Types of Health Literacy Instrument

Type of Instrument	Examples
General Health Literacy	
Performance-based	Short form of Test of Functional Health Literacy in Adult, s-TOFHLA (Baker, et al., 1999) Rapid Estimate of Adult Literacy in Medicine, REALM (Davis et al, 1991) Revised form of Rapid Estimate of Adult Literacy in Medicine, REALM-R (Bass III et al., 2003) Newest Vital Sign, NVS (Weiss et al., 2005)
Self-reported	3 brief Screening Questions, 3-brief SQ (Chew et al., 2008) Functional, Communicative, and Critical Health Literacy Scale, FCCHL (Ishikawa et al., 2008) European Health Literacy Survey Questionnaire, HLS-EU-47 (Sørensen et al., 2013)
Diabetes-specific Health Literacy	
Performance-based	Literacy Assessment for Diabetes, LAD (Nath et *al.*,2001) Diabetes Numeracy Test, DNT (Huizinga et al., 2008)

2.5 Malay Version of the Health Literacy Instruments

Several general HL instruments have been used in measuring HL in adults with T2DM in Malaysia (Abdullah et al., 2019b; Abdullah et al, 2020; Tan & Ismail, 2020). The instruments were translated from English into Malay. The validated Malay version of the instruments used were NVS and HLS-EU-Q47.

The NVS was translated into Malay and tested among 35 adults in Malaysia. The Cronbach's alpha was 0.76 (Chan et al., 2015). It is a performance-based instrument which consists of an ice cream nutrition label and six questions. The participants need to read the label and use the information to answer the questions. The administration time is three minutes, thus suitable for use as a HL screening instrument in health care setting (Chan et al., 2015; Weiss et al., 2005).

The HLS-EU-Q47 was translated into Malay and validated among 462 adults in Malaysia. The Malay version of the instrument was valid and reliable (Duong et al., 2017). It is a self-reported instrument which consists of 47 items with 4-point Likert scale of perceived difficulty as the response option. For each item, the participants need to choose one option that best describes his difficulty level. The administration time is 20 to 30 minutes (Duong et al., 2017; Sørensen et al., 2013). There were also two Malay versions of short form HLS-EU-Q47, HLS-M-Q18 and HLS-SF12. HLS-M-Q18, which consists of 18 items, was validated among 866 adults in Malaysia (Mohamad et al., 2020). HLS-SF12, which consists of 12 items, was validated among 462 adults in Malaysia (Duong et al., 2019). Both instruments were valid and reliable (Duong et al., 2019; Mohamad et al., 2020).

There was only one Malay version of diabetes-specific HL instrument used in a local study to measure the HL in adults with diabetes. However, the Malay version of the instrument was not validated (Li et al., 2019). Therefore, there is no available validated diabetes-specific HL instrument in Malay.

2.6 Diabetes-Specific Health Literacy Instruments

A systematic review conducted by Tavousi et al. (2022) found that there were at least nine diabetes-specific HL instruments. The details of the instruments are described below.

2.6.1 Literacy Assessment for Diabetes

Literacy Assessment for Diabetes (LAD) was developed by Nath et al. (2001) in the United States of America (USA) to measure literacy among adults with DM in the healthcare setting. It consists of 60 words which are commonly found in education materials and encountered by the DM patients during outpatient visits. The words are

divided into three lists and the lists are arranged in ascending difficulty. It is a word recognition test and the participants are required to read the words aloud during assessment. One score is given to a correctly pronounced word. Zero score is given to a mispronounced word or an unrecognized word. The total score is in the range of 0 to 60 and is further categorized into three HL levels. The administration time of LAD is about three minutes (Nath et al., 2001).

LAD was tested on 203 participants. LAD was correlated with Wide Range Achievement Test–Third Edition (WRAT–3) and Rapid Estimate of Adult Literacy in Medicine (REALM). Thus, LAD was valid in measuring literacy in adults with diabetes (Nath et al., 2001).

2.6.2 Diabetes Numeracy Test

Diabetes Numeracy Test (DNT) was developed by Huizinga et al. (2008) in the USA to measure diabetes-related numeracy skills among adults with DM. It consists of 43 mathematical questions (addition, subtraction, multiplication, division, fractions or decimals, numerical hierarchy and multi-step calculations) covering five diabetes self-management areas (nutrition, exercise, blood glucose monitoring, oral medication and insulin use). It is a self-administered test and the participants are required to write the answer in the column provided. One score is given to a correctly answered question while zero score is given to an incorrect answer. The total score is converted into percent correct (in the range of 0% to 100%). The average administration time of DNT is 33 minutes (Huizinga et al., 2008).

DNT has been tested on 398 DM patients and showed good internal reliability. The reported Kuder-Richardson 20 coefficient (KR-20) was 0.95. For validity testing, the DNT was significantly correlated with education, income, REALM, WRAT–3 and

Brief Diabetes Knowledge Test with reported Spearman's correlation (rho) between 0.51 to 0.71 (Huizinga et al., 2008).

A short version of DNT or DNT15 was also derived from DNT. It consists of 15 items from DNT covering the five self-management areas. The administration time of DNT15 is approximately 10 to 15 minutes. The DNT15 showed good internal consistency (KR-20 was 0.89) and highly correlated with DNT (rho was 0.97) (Huizinga et al., 2008).

2.6.3 Chinese Health Literacy Scale for Diabetes

Chinese Health Literacy Scale for Diabetes (CHLSD) was developed by Leung et al. (2013) in Hong Kong to measure diabetes-specific health literacy among adults with DM. The conceptualization of CHLSD was based on the revised Bloom's taxonomy model where cognitive processes in learning are divided into six levels: remembering, understanding, applying, analysing, evaluating and creating (Anderson et al., 2001). CHLSD consists of 34 items and four subscales which cover four levels of cognitive processes (remembering, understanding, applying and analysing). The remembering subscale is a word recognition test where the participants need to read aloud 18 terms (words or phrases) commonly found in education materials for DM patients. Two scores are given for a correctly pronounced term, one score is given for a correctly pronounced term but with hesitation and zero score is given for a wrongly pronounced or unrecognized term. The remaining 16 items are open-ended questions (seven items for understanding subscale, five items for applying subscale and four items for analysing subscale) covering diabetes care (such as administration of oral drugs and insulin, blood glucose monitoring, instructions on medical follow-up and examination, and financial assistance) and health-related decision making. The participants need to write the answer in the column provided. Two scores are given for a correctly answered question.

The total score of CHLSD is ranging from zero to 68. Total score less than 48 indicates inadequate health literacy. The average administration time of CHLSD is seven minutes (Leung et al., 2013).

The content validity of CHLSD was performed using five experts. CHLSD has been tested on 137 T2DM patients and showed acceptable internal reliability. Cronbach's alpha for remembering, understanding, applying and analysing subscale were 0.89, 0.67, 0.65 and 0.72 respectively. For validity testing, all the subscales were significantly correlated with Diabetes Knowledge Scale (rho were 0.27, 0.39, 0.38 and 0.20), while only remembering and understanding subscales were significantly correlated with Diabetes Management Self-Efficacy Scale (rho were 0.25 and 0.26) (Leung et al., 2013).

A multiple-choice version, CHLSD-MC was derived from CHLSD by Leung et al. (2015). The 16 open-ended questions from the three subscales (understanding, applying and analysing) were modified to multiple choice questions. CHLSD-MC is a self-administered instrument. It was tested on 64 DM patients. All items in CHLSD-MC showed either intermediate to good agreement or excellent agreement with the open-ended questions in CHLSD (Leung et al., 2015).

2.6.4 Diabetes Health Literacy Scale

Diabetes Health Literacy Scale (DHLS) was developed by Lee et al. (2018) in South Korea to measure diabetes-specific HL among adults with DM. The conceptualization of DHLS was based on the HL model by Sørensen et al. (2012), which consisted of the ability of an individual to access, understand, appraise and apply health-related information. DHLS also included health numeracy, which defined as the ability of an individual to access, process, interpret, communicate and act on quantitative health

information by Golbeck et al. (2005). The definition of diabetes-specific HL was 'the degree to which patients with diabetes think they have the necessary skills and abilities to seek, comprehend, interpret, communicate, and enumerate diabetes-related information both in a medical environment and in their daily lives for treating and self-managing their own condition' (Lee et al., 2018, p. 3). DHLS consists of 14 items and three subscales which are informational HL, numerate HL and communicative HL. It is a self-administered instrument. Participants' responses are self-rated as the level of agreement with a 5-point Likert scale, ranging from zero for 'not really', one for 'slightly' through four for 'very much'. Higher score indicated better diabetes-specific health literacy (Lee et al., 2018).

The content validity of DHLS was performed using five experts. The Korean version of DHLS has been tested on 462 DM patients. It has been proven to be valid, with acceptable goodness of fit [χ^2/df ratio = 2.41 (χ^2 = 179.63, df = 74, p <0.001); RMSEA = 0.07 (90% CI: 0.06–0.09); SRMR = 0.04; GFI = 0.91; CFI = 0.95] and reliable (Cronbach's alpha for the three subscales were 0.90, 0.80 and 0.85 respectively). Furthermore, DHLS was moderately correlated with Diabetes Knowledge Test (r = 0.42, p < 0.001), Diabetes Management Self-Efficacy Scale (r = 0.56, p < 0.001) and Screening Question of Health Literacy-3 (r = 0.42, p < 0.001) (Lee et al., 2018).

2.6.5 Diabetes-Specific Health Literacy

Diabetes-specific health literacy (DSHL) was developed by Yeh et al. (2018) in Taiwan to measure the diabetes-specific HL among T2DM patients. The conceptualization of DSHL was based on the HL model by Nutbeam (2000) where HL divided into three levels: functional HL, communicative HL and critical HL. DSHL consists of 11 items and three subscales which are functional, communicative and critical HL. Functional

HL subscale (two items) assesses the ability in reading and understanding instruction and brochure received at the hospital. Communicative HL subscale (four items) assesses the ability in extracting, comprehending, communicating and applying the information related to DM. Critical HL subscale (five items) assesses the ability in processing and use quantitative information in making health decision. All the items are multiple-choice questions. One point is given to a correctly answered question and zero point is given to a wrong answer (Yeh et al., 2018).

The face validity of DSHL was performed using 14 experts. The Taiwan version of DSHL was tested on 1059 T2DM patients. It has been proven to be reliable (KR-20 = 0.89) (Yeh et al., 2018).

2.6.6 Korean Health Literacy Scale for Diabetes Mellitus

Korean Health Literacy Scale for diabetes mellitus (KHLS-DM) was developed by Kang et al. (2018) in South Korea to measure the diabetes-specific HL among T2DM patients. Diabetes HL was defined as an individual's ability to understand information, apply numeric skills, and make diabetes-related decisions to manage his disease condition. The conceptualization of KHLS-DM was based on three types of literacy skills: print, numeracy, and critical literacy. KHLS-DM consists of 58 items and three subscales which are diabetes-related words, numeracy and information utilization. Diabetes-related words or print literacy assesses the ability of an individual to recognise diabetes-related words. Numeracy assesses the ability of an individual to understand and apply quantitative information in insulin and oral medication dosage, blood test results and nutrition label in food packaging. Information utilization or critical literacy assesses the ability of an individual to analyse and use diabetes-related information to manage his health. KHLS-DM was divided into two sections which are diabetes-related words section and numeracy and information utilization section. Diabetes-related words

section consists of 30 words. The response is a 4-point Likert scale, ranging from 1 (I don't know) to 4 (I exactly know). The numeracy and information utilization section consists of six open-ended questions and 22 multiple-choice questions. One score is given to a correct answer and zero score is given for a wrongly answered or unanswered question. A higher score indicates higher diabetes HL. The average administration time of KHLS-DM was 24.5 minutes (Kang et al., 2018).

The face validity of KHLS-DM was performed using seven experts. The Korean version of KHLS-DM was tested on 50 T2DM patients. It has been proven to be valid with acceptable goodness of fit (χ^2 = 2785.72, *df* = 1592, *p* <0.001; RMSEA = 0.04; GFI = 0.91; CFI = 0.92). Cronbach's alpha was 0.92 for the diabetes-related words section, and 0.83 for the numeracy and information utilization section. The diabetes-related words section (*r* = 0.31) and numeracy and information utilization section (*r* = 0.46) were significantly correlated with the 3-Brief SQ (Kang et al., 2018).

2.6.7 Diabetes-Specific Rapid Estimate of Adult Literacy in Medicine

Diabetes-Specific Rapid Estimate of Adult Literacy in Medicine (DM-REALM) was developed by Kim et al. (2020) in the USA to measure the diabetes-specific HL focusing on print HL among DM patients. The conceptualization was based on the Rapid Estimate of Adult Literacy in Medicine (REALM) model. It consists of 82 words related to understanding or managing DM which are commonly found in practice guidelines, education materials and patient counselling data. The 82 words are divided into three lists according to the difficulty level (29 low, 28 medium and 25 high) and the lists are arranged in ascending difficulty level. It is a word recognition test and the participants are required to read the words aloud during assessment. One score is given to a correctly pronounced word. Zero score is given to a mispronounced word or an unrecognized word.

The content validation of the DM-REALM was performed using an expert panel of patients, family members, community, health workers, nurses, physicians and dieticians. The English version of the DM-REALM has been tested on 261 adults with T2DM and it showed good reliability (Cronbach alpha was 0.99). Two shorter versions of DM-REALM, 20-item and 40-item versions were derived from 82-item DM-REALM. Both 20 item and 40-item versions showed good reliability (Cronbach alpha were 0.97 and 0.95 respectively) (Kim et al., 2020).

2.6.8 Diabetes Health Numeracy Test

Diabetes Health Numeracy Test (DHNT) was developed by Lee et al. (2020) in the South Korea to measure the health numeracy among adults with DM. It consists of seven multiple-choice questions assessing the numeric skills (basic, computational, analytical, and statistical) required in understanding and interpreting diabetes information as well as performing self-management. It is a self-administered test and the participants are required to choose one answer out of the five choices provided, including a 'I do not know' option. One score is given to a correctly answered question while zero score is given to an incorrect answer.

The content validation of the DHNT was performed using six experts. Rasch analysis confirmed that all items were fit. DHNT was significantly correlated with diabetes knowledge (r = 0.40) and subjective diabetes numeracy (r = 0.47). It also showed good consistency, with KR-20 of 0.81 (Lee et al., 2020).

2.6.9 Summary of the Reviewed Diabetes-Specific Health Literacy Instruments

The characteristics of the diabetes-specific HL instruments are summarised in Table 2.3. In this study, the English version of the DHLS was chosen to be translated into Malay because DHLS allows the assessment of the informational HL, numerate HL and

communicative HL in adults with T2DM. Most of the instruments only cover either the numeracy skills or the information processing skills (remembering, understanding, applying, analysing). Although DSHL covers the functional HL, communicative HL and critical HL, numeracy skill is not assessed. Numeracy skill is important for adults with DM especially in self-management such as blood glucose monitoring and adjustment of insulin's dose (Osborn et al., 2010). KHLS-DM assesses print literacy, numeracy and critical literacy, but it consists of 58 items which requires longer administration time as compared with DHLS which consists of 14 items. Word recognition test is unsuitable for the Malay language as the word in Malay can be pronounced correctly based on the spelling although the word is unfamiliar. DHLS is a self-reported instrument which does not require as high concentration as performance-based instrument (Al Sayah et al., 2012). Thus, it is easy and suitable to use in clinical setting.

Table 2.3 Characteristics of Diabetes-Specific Health Literacy Instruments

Instrument	Performance-based or self-reported	Number of Items and Subscales/ Dimension	Mode of Administration	Validation of Instrument	Country
LAD	Performance-based (word recognition test)	60 items; diabetes related word	Clinician or researcher administered	Validity: correlated with WRAT–3 & REALM	USA
DNT	Performance-based (open-ended question)	43 items; numeracy	Self-administered	Validity: correlated with education, income, REALM, WRAT–3 and diabetes knowledge (r = 0.51 – 0.71) Reliability: KR-20 = 0.95	USA
DNT-15	Performance-based (open-ended question)	15 items; numeracy	Self-administered	Validity: correlated with DNT (r = 0.97) Reliability: KR-20 = 0.89	USA
CHLSD	Performance-based (word recognition test & open-ended question)	34 items; 4 subscales (remembering, understanding, applying, analysing)	Clinician or researcher administered	Validity: significantly correlated with diabetes knowledge (r = 0.27, 0.39, 0.38, 0.20) Reliability: Cronbach's alpha = 0.89; 0.67, 0.65, 0.72	Hong Kong
CHLSD-MC	Performance-based (multiple-choice question)	16 items; 3 subscales (understanding, applying, analysing)	Self-administered	All items in CHLSD-MC showed intermediate to excellent agreement with CHLSD	Hong Kong
DHLS	Self-reported (5-point Likert scale)	14 items; 3 subscales (informational HL, numerate HL, communicative HL)	Self-administered	Validity: χ^2/df ratio = 2.41; RMSEA = 0.07 (90% CI: 0.06–0.09); SRMR = 0.04; GFI = 0.91; CFI = 0.95; correlated with diabetes knowledge (r = 0.42), Diabetes Management Self-Efficacy Scale (r = 0.56) and Screening Question of Health Literacy-3 (r = 0.42) Reliability: Cronbach's alpha = 0.90, 0.80, 0.85	South Korea

Table 2.3 (continued)

Instrument	Performance-based or self-reported	Number of Items and Subscales/ Dimension	Mode of Administration	Validation of Instrument	Country
DSHL	Performance-based (multiple-choice question)	11 items; 3 subscales (functional HL, communicative HL, critical HL)	Self-administered	Reliability: KR-20 = 0.89	Taiwan
KHLS-DM	Self-reported (4-point Likert scale) and performance-based (open-ended question & multiple-choice question)	58 items; 3 subscales (diabetes-related words/print literacy, numeracy, information utilization/critical literacy)	Self-administered	Validity: χ^2 = 2785.72, *df* = 1592, *p* <0.001; RMSEA = 0.04; GFI = 0.91; CFI = 0.92; correlated with 3-Brief SQ (*r* = 0.31; 0.46) Reliability: Cronbach's alpha = 0.92; 0.83	South Korea
DM-REALM	Performance-based (word recognition test)	82 items; diabetes related words	Clinician or researcher administered	Reliability: Cronbach alpha = 0.99	USA
40-item DM-REALM	Performance-based (word recognition test)	40 items; diabetes related words	Clinician or researcher administered	Reliability: Cronbach alpha = 0.97	USA
20-item DM-REALM	Performance-based (word recognition test)	20 items; diabetes related words	Clinician or researcher administered	Reliability: Cronbach alpha = 0.95	USA
DHNT	Performance-based (multiple-choice question)	7 items; numeracy	Self-administered	Validity: Rasch analysis confirmed all items fit; correlated with diabetes knowledge (*r* = 0.40) and subjective diabetes numeracy (*r* = 0.47) Reliability: KR-20 = 0.81	South Korea

2.7 Validation of an Instrument

Validation of an instrument is the process to verify the validity and reliability of the instrument.

2.7.1 Validity of an Instrument

Validity of an instrument refers to how accurate or how well an instrument measures what it is designed to measure (Fletcher et al., 1996). The validity of an instrument can be assessed using subjective judgement and statistical analysis (Tsang et al, 2017). In this study, the content validity, cognitive debriefing and construct validity were examined.

2.7.1(a) Content Validity

Content validity is a subjective assessment of an instrument by a group of experts. The purpose of content validity is to determine whether the items are adequately and sufficiently measuring the theoretical concept an instrument is designed to measure. The selection of the right experts to evaluate the instrument is important for content validation (Tsang et al., 2017).

2.7.1(b) Cognitive Debriefing

Cognitive debriefing is a subjective assessment of an instrument by a group of 5 to 8 participants (target population). The purpose of cognitive debriefing is to determine whether the participants can understand all the items, interpret the items correctly and assess if items are relevant to them. Cognitive debriefing is preferably performed by a researcher with experience in qualitative interviewing or cognitive debriefing (Wild et al., 2005).