

Development of a health literacy assessment instrument related to drinking habit*

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Objective: to develop and verify the validity, reliability, and interpretability of an instrument to assess Health Literacy regarding Drinking Habits (HLDH). **Method:** a methodological study conducted among people with diabetes enrolled in the Family Health Strategy and consisting of the following steps: development of the HLDH; verification of content validity by a committee of judges; pre-test (n=20); reliability estimation (n=62): Cronbach's alpha (CA), Cohen's kappa (K) and Intraclass Correlation Coefficient (ICC), satisfactory results (≥ 0.60); estimate of concurrent validity (n=212); interpretability of scores (n=212): range from 0 to 18, with the cut-off point being ≤ 14 (HLDH inadequate). The SPSS program was used for statistical analyses. **Results:** HLDH presented dynamic and adequate application, showing relevance to its content and the proposed construct. The 18 words presented $K > 0.60$, $CA=0.82$ and $ICC=0.91$. There was a correction of the HLDH with education ($rs=0.537$; $p=0.000$). Interpretability: 31.6% (n=67) presented inadequate HLDH. **Conclusion:** HLDH was considered validated, reliable, and with good interpretability.

Descriptors: Health Literacy; Diabetes Mellitus; Reproducibility of Results; Alcoholism.

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Desenvolvimento de um instrumento de avaliação do letramento em saúde relacionado com o hábito etilista

Objetivo: desenvolver e verificar a validade, confiabilidade e interpretabilidade de um instrumento que se propõe a avaliar o Letramento em Saúde quanto ao Hábito Etilista (LSHE). **Método:** estudo metodológico realizado entre pessoas com diabetes cadastradas na Estratégia de Saúde da Família e constituído pelas seguintes etapas: desenvolvimento do LSHE; verificação da validade de conteúdo por um comitê de juízes; pré-teste (n=20); estimativa da confiabilidade (n=62): Alfa de Cronbach (AC), kappa de Cohen (K) e Coeficiente de Correlação Intraclasse (CCI), resultados satisfatórios ($\geq 0,60$); estimativa da validade concorrente (n=212); interpretabilidade dos escores (n=212): variam de 0 a 18, sendo o ponto de corte ≤ 14 (LSHE inadequada). Utilizou-se o programa SPSS para as análises estatísticas. **Resultados:** o LSHE apresentou aplicação dinâmica e adequada, mostrando-se relevante quanto ao seu conteúdo e ao construto propostos. As 18 palavras apresentaram $K > 0,60$, $AC=0,82$ e $CCI=0,91$. Houve correção do LSHE com a escolaridade ($r_s=0,537$; $p=0,000$). Interpretabilidade: 31,6% (n=67) apresentaram LSHE inadequada. **Conclusão:** o LSHE foi considerado validado, confiável e com boa interpretabilidade.

Descritores: Letramento em Saúde; Diabetes Mellitus; Reprodutibilidade dos Testes; Alcoolismo.

Desarrollo de un instrumento para evaluar la alfabetización sanitaria relacionada con el hábito del alcohol

Objetivo: desarrollar y verificar la validez, confiabilidad e interpretabilidad de un instrumento que se propone evaluar el Letramento en Salud respecto al Hábito Etilista (LSHE). **Método:** estudio metodológico realizado entre personas con diabetes censadas en la Estrategia de Salud de la Familia y constituído por las siguientes etapas: desarrollo de la LSHE; verificación de la validez del conteo por un comité de jueces; prueba previa (n=20); estimación de la confiabilidad (n=62): Alfa de Cronbach (CA), kappa de Cohen (K) y coeficiente de correlación intraclase (CCI), resultados satisfactorios ($\geq 0,60$); estimación de la validez concurrente (n=212); interpretabilidad de las puntuaciones (n=212): rango de 0 a 18, siendo el punto de corte ≤ 14 (LSHE inadecuada). Para los análisis estadísticos se utilizó el programa SPSS. **Resultados:** el LSHE presentó una aplicación dinámica y adecuada, mostrándose relevante en cuanto a su contenido y a la construcción de propuestas. Las 18 palabras presentaron $K > 0,60$, $AC=0,82$ e $ICC=0,91$. Hubo correlación de la LSHE con la escolaridad ($r_s=0,537$; $p=0,000$). Interpretabilidad: el 31,6% (n=67) presentó una LSHE inadecuada. **Conclusión:** la LSHE se consideró validada, fiable y con buena interpretabilidad.

Descriptorios: Alfabetización en Salud; Diabetes Mellitus; Reproducibilidad de los Resultados; Alcoholismo.

Introduction

Alcohol abuse is recognized as a major public health problem worldwide. Alcohol use, abuse, and dependence are among the major risk factors for disease, disability, and death⁽¹⁾. Furthermore, it may be associated with several situations and complications found in the following morbidities: heart and cerebrovascular diseases⁽²⁾, psychiatric disorders⁽³⁻⁴⁾, traffic injuries⁽⁵⁾, neoplasms⁽⁶⁾, sexually transmitted diseases⁽⁷⁾, liver cirrhosis⁽⁸⁾, among others. The drinking habit, at least in the social domain, is widespread among people with and without Diabetes Mellitus (DM). However, there are important effects of alcohol on the progression and complications of DM, such as impaired glycemic control, increased risk of impotence, peripheral neuropathy, strokes, and a likelihood of retinopathy⁽⁹⁻¹⁰⁾. Complications can be prevented by keeping a healthy lifestyle and acquiring self-care habits, such as medication adherence, adequate diet, regular physical activity, and abstinence from tobacco and ethanol⁽¹¹⁾.

Self-care depends on the understanding of information that translates into guidelines for daily life⁽¹²⁾, acquired through printed educational materials, verbal instructions, and lectures/courses of education to the individual⁽¹³⁾. It is observed that low levels of Health Literacy regarding drinking habit may favor the development of complications related to DM, such as uncontrolled glycemic control. On the other hand, adequate levels may produce a protective effect or delay complications due to self-care and the ability to understand health guidelines. In this sense, there is a need to incorporate Health Literacy into the routine of people with DM, especially regarding the habit of drinking⁽¹⁴⁾.

Health Literacy refers to the personal, cognitive, and social skills necessary for people to access, understand, evaluate and make use of information essential for health maintenance⁽¹⁵⁾. Thus, it becomes mandatory to find ways to measure Health Literacy in this public⁽¹⁶⁻¹⁷⁾ through valid and reliable instruments, to contribute to the acknowledgment by patients who need a special approach to communication by health professionals⁽¹⁸⁻²⁰⁾.

The creation of instruments for the assessment of health conditions has increased⁽²⁰⁾; however, not all of them present acceptable methodological qualities⁽¹⁶⁻¹⁷⁾. A Delphi study presents the COSMIN-checklist (Consensus-Based Standards for the Selection of Health Measurement Instruments) that proposes standards to define the methodological quality of surveys that assess health-related events. This is composed of 4 domains: 3 domains to estimate the evaluation of instruments (reliability, validity and responsiveness); and 1 for the evaluation of interpretability⁽¹⁶⁻¹⁷⁾.

An instrument that assesses knowledge and behavior regarding drinking habit among people with DM was

identified. However, the study does not report results concerning the assessment of the quality of the instrument used⁽²¹⁾. Tools that assess knowledge and behavior, i.e., questions related to Health Literacy, may offer professionals, especially those working in primary health care, enough information to map the territory of action of the Family Health Strategy (FHS), increasing assistance and reducing or minimizing complications related to DM.

In this way, the study aimed to develop and verify the validity, reliability, and interpretability of an instrument to assess Health Literacy regarding drinking habits among people with DM.

Method

This is an investigation in the form of a literature review that aimed to identify studies on Health Literacy regarding drinking habit, as well as measurement instruments used to assess Health Literacy levels. The scientific databases PubMed, Scientific Electronic Library Online, and Virtual Health Library were considered. For the searches, the descriptors "Health Literacy", "Drinking Habit" and "Alcoholism" were used, applying the Boolean operator "and". The selection process considered original investigations published in English, Portuguese and Spanish, without a time cut⁽²²⁾.

Research phases

Seven phases were applied for the development⁽¹⁷⁾ of the instrument named Health Literacy regarding Drinking Habits (HLDH): I) Definition of participants; II) HLDH development (conceptual structure, definition of construct objectives, construction of items/response scale, selection, and organization of items and HLDH structuring)^(17,22-23); III) Content validity; IV) Pre-test; V) Reliability estimation: Cronbach's alpha (CA), Cohen's kappa (K) and Intraclass Correlation Coefficient (ICC); VI) Concurrent validity (correlation test) and; VII) Interpretability⁽²²⁾.

Definition of the participants

Representatives of the Municipal Health Department of a medium-sized population municipality were made aware of the importance of the study. On that occasion, lists were requested with the enumeration of the *Unidades Polos* (UPs) (Headquarters) of the FHS teams. A simple random drawing was used to select the UPs, and the data collection for the research was composed of three phases: 1st collection (pre-test); 2nd collection (reliability and concurrent validity) and 3rd collection (interpretability).

Three UPs were randomly selected for the investigation. The first UP was considered for the pre-test (20 participants) and the second for reliability estimation using a sample of 62 participants - populations consisting of 50 to 100 participants are sufficient⁽²⁴⁾. A third was considered for the concurrent

validity and interpretability phases of the instrument (212 participants) in an infinite population [$Z=1.96/\text{confidence level } (1-\alpha)$; $p=0.50$ proportion of individuals without the condition; $1-p=\text{proportion of individuals without the condition}$; $d=\text{tolerable error of } 0.07+8\% \text{ loss} / n=196+16$ (possible loss = 212)]^(22,25). This is because the construct generated by the scale "Health Literacy regarding Drinking Habits" after the adopted cutoff point, which may be interpreted as a dichotomous variable. A sample of 10 to 20 people is indicated for each item of the scale to assess concurrent validity and interpretability⁽²⁶⁾. The HLDH has 18 items, requiring 180 participants to compose the sample; in this sense, we chose to seek a larger number of participants due to the possibility of loss and the risk of not reaching the idealized number.

Each FHS provided a list with the names of people diagnosed with DM. According to each step of the investigation, people with DM were included until the pre-established number was obtained by convenience sampling and sample calculation⁽²²⁾.

Participants were people aged 18 years or older enrolled at the FHS and diagnosed with DM provided by the FHS. We excluded people with three or more comorbidities, those who did not have Portuguese as their native language and those with vision/hearing problems (reported or perceived) or intoxication by drugs or alcohol at the time of the interview⁽²²⁾. The cognitive condition was considered as an exclusion criterion, evaluated through the Mini-Mental State Examination (MMSE) among participants aged 60 years or older because this age group was at high risk of developing mental confusion associated with the lack of obtaining an accurate diagnosis^(22,27).

Development of Health Literacy regarding Drinking Habits (HLDH)

The selection of words used in the Health Literacy regarding drinking habits (HLDH) instrument was defined by a scientific literature search, for which expressions were chosen that reflected the central theme of the study - drinking habit, alcoholism, alcohol dependence or abuse and that were repeated in the investigations, besides the classic expressions. Also considered in the development of the instrument was the theoretical model proposed by Sorensen⁽¹⁵⁾ that addresses factors related to Health Literacy: personal, cognitive, and social skills to access, understand, evaluate and apply health-related information. The theoretical model displays proximal and distal factors that determine or are determined by Health Literacy in which the influence of previous knowledge, skills, and motivation in the process of accessing, understanding, evaluating, and applying health-related information is considered⁽¹⁵⁾.

To structure the HLDH, we used the SAHLPA (Short Assessment of Health Literacy for Portuguese-speaking Adults)⁽¹⁸⁾ instrument, consisting of 18 trios of words referring to access and understanding of factors associated with general health. This instrument requires that, in each trio of words, the main expression be associated with one of the other two to define the Health Literacy level. For each correct answer, one point is added, and the final score can vary from 0 to 18. The cut-off point was defined as a value equal to or below 14, which suggests problems in Health Literacy⁽¹⁸⁾.

Subsequently, the HLDH instrument was given a physical character through the structural organization of its items: Title, Instructions, and Response Scale.

HLDH content validation

Content validation was applied to analyze the adequacy and coherence of the HLDH items. For this purpose, an expert committee selected by convenience and composed of 10 judges with different degrees and wide experience (Dental Surgeon, Physical Educator, Nurse, Pharmacist, Physiotherapist, Psychologist, Nutritionist, Clinical Physician, Endocrinologist and Health Technician) examined the quality of the items of the instrument especially if they were representative of the construct that was intended to be assessed⁽²⁸⁾. There is no consensus in the literature regarding the number of experts needed to compose a committee, which may vary from 3 to 20 professionals. The expert committee had scientific publications related to alcoholism, methodological and technical knowledge regarding the creation of instruments to assess health conditions, and professional experience in preventive care, treatment and recovery of patients with alcohol dependence or abuse⁽²⁸⁻³⁰⁾. All were invited 10 days in advance through a letter containing guidelines about the objective of the activity (to evaluate the representativeness of the items of the instrument concerning Health Literacy regarding drinking habits among people with DM). A focus group was conducted to promote a discussion about the items of the HLDH and the team was guided to suggest changes, insertions and/or eliminations of items to better adapt the instrument.

The completion and adequacy of the instrument were conducted based on suggestions made in the committee's final review of the HLDH, after pre-testing of a nonprobability sample of 20 people. The final version was approved and released for reliability estimation and concurrent validity⁽²⁸⁾ (Figure 1).

Keyword	Words of Association			Got it right?
Anxious	<input type="radio"/> Cracked	<input type="radio"/> Dumped	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Alcoholism	<input type="radio"/> Addiction	<input type="radio"/> Sportsman	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Dose	<input type="radio"/> Date	<input type="radio"/> Amount	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
“Cachaça”	<input type="radio"/> Water	<input type="radio"/> Distilled spirits	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Cirrhosis	<input type="radio"/> Liver	<input type="radio"/> Stomach	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Destiled	<input type="radio"/> “Pinga”	<input type="radio"/> Beer	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Drink	<input type="radio"/> Beverage	<input type="radio"/> Earring	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Inebriate	<input type="radio"/> Lucid	<input type="radio"/> Drunk	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Alembic	<input type="radio"/> Distillation	<input type="radio"/> Cheating	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Hangover	<input type="radio"/> Tranquility	<input type="radio"/> Nuisance	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Abstinence	<input type="radio"/> Absence	<input type="radio"/> Happiness	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Dependent	<input type="radio"/> Imprisoned	<input type="radio"/> Free	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Agony	<input type="radio"/> Formation	<input type="radio"/> Affliction	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Unruly	<input type="radio"/> Illusion	<input type="radio"/> Excess	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Relapse	<input type="radio"/> Weakness	<input type="radio"/> Farewell	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Content	<input type="radio"/> Heat	<input type="radio"/> Percentage	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Risk	<input type="radio"/> Wealth	<input type="radio"/> Danger	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No
Alcoholic	<input type="radio"/> Consumption	<input type="radio"/> Place	<input type="radio"/> I do not know	<input type="radio"/> Yes <input type="radio"/> No

Figure 1 - Final version of the Drinking Habit Health Literacy Tool (HLDH). Montes Claros, MG, Brazil, 2016

Reliability estimation

Reliability was assessed using internal consistency and test-retest/reproducibility. In the test-retest, the capacity of the test to generate identical results was verified, measuring the event in the same people at different times. The aim is to correlate the two measurements obtained on different occasions⁽³¹⁾. The HLDH reliability estimation was performed using a sample composed of 62 participants.

The internal consistency of the instrument was tested by calculating the Cronbach’s Alpha statistical test. This can assume values between 0 and 1, and the closer to 1, the more reliable is the assessment instrument, with values equal to or greater than 0.7 is considered acceptable⁽³¹⁻³²⁾. In the study of reproducibility, the test-retest method was used (interval of 3 to 7 days) to measure the degree of agreement between two independent evaluations of the instrument. Cohen’s Kappa coefficient (K), simple Kappa coefficient, indicated for nominal categorical variables, was applied to each of the HLDH items, since its response-assertions are binary. Agreement was performed as described in specialized literature, comprising $K < 0.00$ = almost nonexistent; $0-0.19$ = small; $0-0.39$ = unsatisfactory; $0.40-0.59$ = moderate; $0.60-0.79$ = substantial; $0.80-1.00$ = almost perfect⁽³²⁾. Test-retest reliability or reproducibility for total scores was assessed using the Intraclass Correlation Coefficient (ICC), indicated for quantitative variables (values found in the HLDH scale) that considers the same interpretation adopted for the K coefficient^(23,31,33).

Concurrent validity

The concurrent validity occurred through the similarity between the scores obtained in the HLDH and the education of people with DM. After the results of the statistical normality test to verify the sample distribution (Kolmogorov-Smirnov Tests) and identify the appropriate Pearson or Spearman Correlation test, analyzing the association between the HLDH and education, a significance level of 5% was admitted, a method used in other studies⁽²²⁻²³⁾.

Application form

Physical boards were used to apply the HLDH. These boards had main terms that were located on the top and typed in bold, highlighted with equal font and size, offering two possibilities of association. The researcher would loudly read the main word, and then ask the respondent which word was correctly associated with the main term. For each word correctly associated, one point is added, and the score can vary from 0 to 18. At the beginning of each application, participants were told not to risk guessing the word association; in these cases, the guidance was to say, “I do not know”⁽²²⁾.

Interpretability of HLDH

The cutoff point of the HLDH instrument was determined using the Confidence Interval (CI). Thus, participants who obtained results like or lower than the lower limit of the CI of the mean (cutoff ≤ 14)

were considered with inadequate HLDH⁽²²⁾. Also, the SAHLPA instrument, used in this study as a basis for structuring the HLDH, presented the same cutoff point in its validation process (scores ≤ 14 suggest inadequate HLDH)⁽¹⁸⁾.

We recruited 212 people with DM, registered in two FHS units from an infinite probabilistic sample randomly selected, disregarding the participants in the pre-test (n=20) and test-retest (n=62). Statistical analyses were performed using the Windows (Statistical Package for the Social Sciences) software SPSS, version 20.0, and Excel.

Results

Characterization of the participants

The test-retest had the participation of 62 individuals with DM. Most were women (n=52; 83.9%), with mean age of 54.9 years (SD=9.97; minimum value=29; maximum value=77) and mean education of 5.63 (SD=3.99). In the Concurrent Validity and Interpretability phases, 212 individuals with DM participated. Most were female (n=136; 64.2%), mean age 60.20 years (SD=10.86; minimum value=22; maximum value=92) and mean family income of R\$ 820.60 (SD=746.38; minimum value=R\$ 0.00; maximum value=R\$ 4,000.00). The mean education level found was 7.66 years (SD=4.34; minimum value=0; maximum value=28).

Validity of content

After performing the word analysis and applicability of the instrument, it was verified by the expert committee that the HLDH has an adequate application method for the DM population. Likewise, it was considered valid regarding its content and the construct it proposes to assess. The judges participated in discussions with the expert committee and reported their perceptions regarding the applicability of the HLDH. The results were discussed again among the committee, judges, and HLDH creators, who considered the instrument adequate. The final version of the HLDH is as shown in Figure 1, and this format is recommended for the exclusive use of the evaluator. Another version was developed to be presented to the participants: 18 boards were made for each word association.

Reliability estimation

The internal consistency or AC was 0.82 (p=0.000) demonstrating good reliability. Regarding reproducibility, the 18 words of the Health Literacy regarding drinking habits (HLDH) obtained K equal to or greater than 0.69 (Table 1). The ICC was 0.91 (p=0.000).

Table 1 - Levels of agreement (Simple Kappa Coefficient) and Cronbach's alpha for the word associations of the Health Literacy instrument regarding drinking habit (HLDH). Montes Claros, MG, Brazil, 2016 (n=62)

Keyword/associated words	Kappa reproducibility*	Cronbach's Alpha
Anxious / Cracked; Dumped	1.00	0.819
Alcoholism / Addiction; Sportsman	1.00	0.812
Dose / Date; Amount	0.69	0.813
"Cachaça" / Water; Distilled spirits	1.00	0.811
Cirrhosis / Liver; Stomach	1.00	0.818
Destiled / "Pinga"; Beer	0.95	0.814
Drink / Drink; Earring	1.00	0.811
Inebriate / Lucid; Drunk	1.00	0.811
Alembic / Distillation; Cheating	0.89	0.816
Hangover / Tranquility; Nuisance	1.00	0.815
Abstinence / Absence; Happiness	0.80	0.808
Dependent / Imprisoned; Free	1.00	0.809
Agony / Formation; Affliction	1.00	0.812
Unruly / Illusion; Excess	0.93	0.819
Relapse / Weakness; Farewell	1.00	0.819
Content / Heat; Percentage	0.95	0.817
Risk / Wealth / Danger	1.00	0.814
Alcoholist / Consumption; Place	0.89	0.822

*p<0.05 for all items

Competing validity

We opted for the Spearman/non-parametric correction coefficient since the normality tests (Kolmogorov-Smirnov Test) showed p=0.000. The result obtained was statistically significant (rs= 0.537; p=0.000).

Interpretability

The mean HLDH score was 15.10 (SD=3.14; 95%CI=14.67-15.54; minimum value=0 and maximum value=18). Among the 212 people with DM, inadequate HLDH level was recorded among 67 (31.6%) participants. The main word "Hangover" had the highest number of hits in the association 202 (95.3%). In contrast, the word "content" was the one with the lowest proportion of correct answers: 113 (53.3%) (Table 2).

Table 2 - Frequency of correct answers and errors/does not know in the application of the Health Literacy instrument regarding drinking habit (HLDH). Montes Claros, MG, Brazil, 2016 (n=212)

Keyword / Right association word	n	%
Anxious / Cracked	Right	163 76.9
	Error/Not sure	49 23.1
Alcoholism/ Addiction	Right	194 91.5
	Error/Not sure	18 8.5
Dose / Amount	Right	193 91.0
	Error/Not sure	19 9.0
"Cachaça" / Distilled spirits	Right	186 87.7
	Error/Not sure	26 12.3
Cirrhosis / Liver	Right	199 93.9
	Error/Not sure	13 6.1
Destiled/ "Pinga"	Right	158 74.5
	Error/Not sure	54 25.5
Drink/ Beverage	Right	192 90.6
	Error/Not sure	20 9.4
Inebriate / Drunk	Right	197 92.9
	Error/Not sure	15 7.1
Alembic / Distillation	Right	187 88.2
	Error/Not sure	25 11.8
Hangover / Nuisance	Right	202 95.3
	Error/Not sure	10 4.7
Abstinence / Absence	Right	184 86.8
	Error/Not sure	28 13.2
Dependent / Imprisoned	Right	147 69.3
	Error/Not sure	65 30.7
Agony / Affliction	Right	195 92.0
	Error/Not sure	17 8.0
Unruly / Excess	Right	154 72.6
	Error/Not sure	58 27.4
Relapse / Weakness	Right	199 93.9
	Error/Not sure	13 6.1
Content / Percentage	Right	113 53.3
	Error/Not sure	99 46.7
Risk / Danger	Right	197 92.9
	Error/Not sure	15 7.1
Alcoholist / Consumption	Right	141 66.5
	Error/Not sure	71 33.5

Discussion

The multidimensionality of HL refers to individual factors, sociodemographic characteristics, access to and use of health services, patient-professional interaction and self-care. Thus, such literacy depends on a complex network of interaction between the health system and the educational system with the social and cultural factors in which people are immersed⁽¹⁴⁾. Therefore, the importance of the instruments proposed to evaluate HL is confirmed. However, these instruments must follow methodological and scientific parameters and be valid and

reliable so that the results of the investigations can be useful in decisions regarding clinical practice and in the feasibility of public policies to combat the complications of DM. In this context, there is the need to consider the population, related factors, objective and design of the investigation⁽³⁴⁻³⁵⁾.

Regarding reliability, the HLDH instrument showed adequate values: AC=0.82⁽³⁶⁾. All words obtained a satisfactory K, and the instrument presented an ICC of 0.91. Identical results can be observed in investigations that evaluated different health-related events^(18,37). The word association that presented the lowest K was "Dose versus date/quantity". This result can be explained by the association of words with distilled beverages since these are served considering a previously defined measure. This situation is not observed when consuming fermented beverages such as beer and wine. Between the test and retest, there is the probability of errors related to natural changes that may arise during the interval^(24,31). We tried to reduce this effect since the interval adopted in data collection is from 3 to 7 days⁽¹⁹⁾.

In the concurrent validity, it was observed that higher levels of HLDH are related to higher levels of education (Pearson's Correlation=0.537; p=0.000). This correlation was also evidenced in other studies on HL^(18,20,38-41) using other instruments, such as: SAHLPA; Health Literacy Questionnaire; Europe-Asia Health Literacy Survey Questionnaire; and Health Literacy Scale. School education can help individuals better understand their health condition and, consequently, apply healthy practices in their routine. However, the dialogue between health professionals and patients remains necessary to stimulate and warn about the problems of DM, encourage habits and attitudes in a language appropriate to their socioeconomic, cultural, and educational situation⁽⁴²⁾. It also highlights the importance of Primary Health Care in performing a positive approach in embracing people with problems involving alcoholism⁽⁴³⁾.

Regarding interpretability, the HLDH proved to be satisfactory, since the instrument can discriminate people as to the HL regarding the drinking habit; most participants showed adequate HLDH (n=145; 68.4%). It is suggested that this result may be due to the access, understanding, evaluation and application of health-related information, especially in health education campaigns conducted by the ESF programs. It is noteworthy that the results do not allow the inference that access, understanding, evaluation and application of this information have an impact on lifestyle habits⁽²²⁾, especially continuously. Therefore, longitudinal studies that consider these issues in delimited ways are needed to elucidate these issues.

The construct validity process consists of Structural Validity, Cross-Cultural Validity and Hypothesis Test, whereas Criterion Validity is composed of Concurrent

and Predictive Validity⁽¹⁶⁻¹⁷⁾. Structural Validity was not applied since it is an instrument with binary variables. Cross-Cultural Validity does not apply to the HLDH, since it is an instrument created in the language of origin of the target audience (Brazilian Portuguese). Hypothesis Testing will be considered in another manuscript. The Predictive Validity was not applied due to the inexistence of a gold standard⁽¹⁶⁾. Thus, only the application of Concurrent Validity is justified.

The impossibility of the HLDH investigating the assessment and application of information regarding the drinking habit according to the four dimensions proposed by Sorensen⁽¹⁵⁾ is considered a limitation of this study, since the instrument was developed based on the structure and application method of the SAHLPA⁽¹⁸⁾. However, we consider as a strong point the possibility of the instrument to distinguish different levels of HL regarding the drinking habit; besides being short, its application method is dynamic, favoring to have more reliable answers (reducing response bias) without generating discomfort for the participants. Future applications are necessary to reinforce or identify limitations in this instrument, especially in larger samples and from other locations⁽²⁴⁾, a situation that may lead to adaptations in the instrument.

Conclusion

The HLDH was considered valid, reliable, and easy to interpret. It was presented as a quick-to-apply and easy-to-understand instrument, and it can be an efficient tool to assess the HLDH regarding the drinking habit among people with DM. The DM patients evaluated showed adequate levels of HLDH. Health professionals and researchers may use this instrument to detect people with communication impairments, and it may also be useful to guide the implementation of health education groups related to alcohol abuse.

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