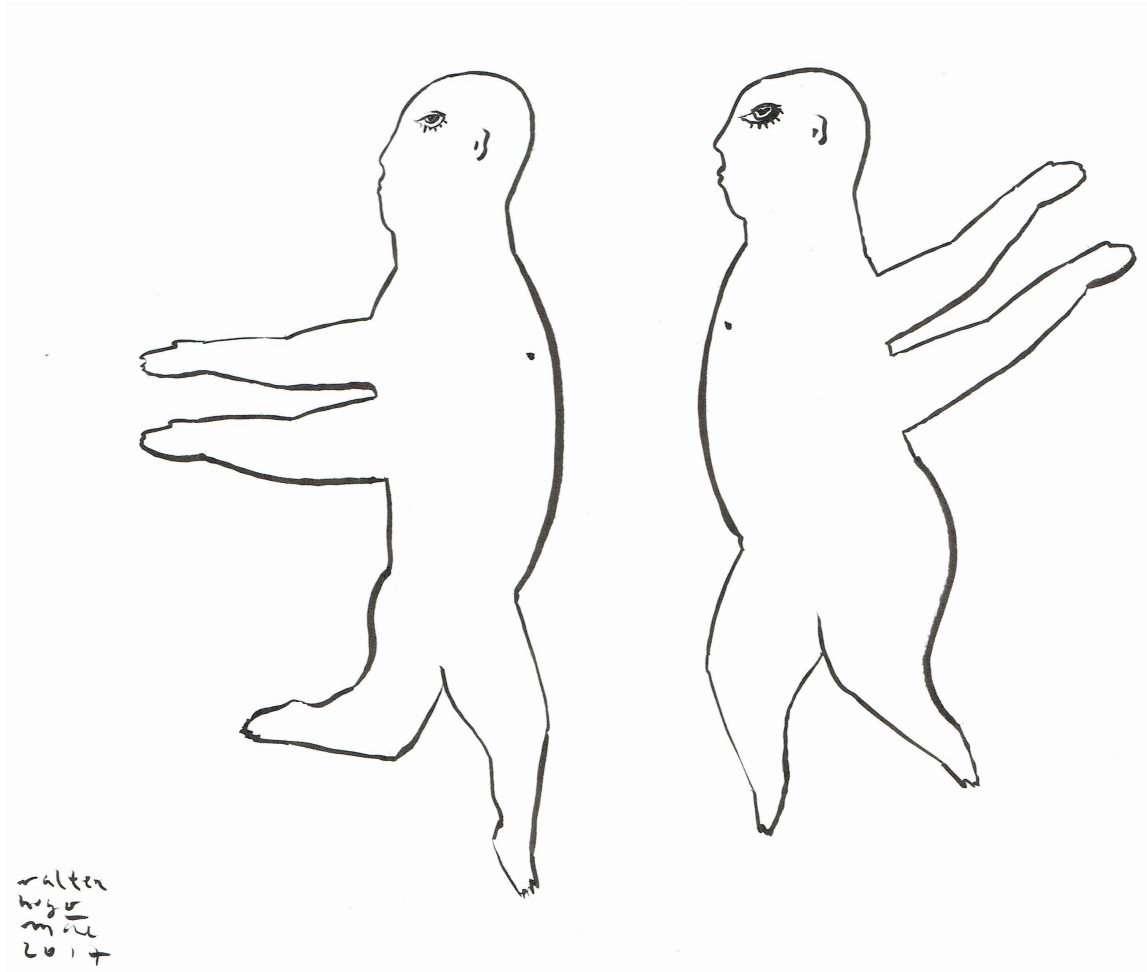


Lost in translation: health literacy in type 2 *diabetes mellitus* care

BY

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diabetes mellitus care



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ABSTRACT

Health literacy is usually defined as the set of individual skills allowing people to find, understand, assess, and use health information to make decisions. Limited health literacy has been linked to more difficult access to care, increased costs and poorer clinical outcomes. Because it is exacerbated by the mismatch between patient skills and the demands of health contexts, more recent conceptualisations of health literacy have expanded to encompass the skills and competencies of health professionals in communicating health information in ways that improve patients' understanding and ability to act. Type 2 diabetes presents as a particularly suitable framework to study the importance of health literacy, as it is heavily reliant on patient-centred communication to support the individual skills in successfully executing the complex recommendations associated with the disease.

The main goal of this thesis was to provide a basis for the assessment of health literacy and to provide recommendations for patient-centred communication in clinical encounters in type 2 *diabetes mellitus* in Portugal.

Using a multi-method design, this work includes two quantitative studies conducted in 2012 and a qualitative one conducted between 2012 and 2016. The first used a convenience sample of 249 participants to adapt, validate and compare three health literacy assessment tools in the Portuguese population: the Medical Term Recognition Test, the Short Assessment of Health Literacy for Portuguese-Speaking Adults, and the Newest Vital Sign. We concluded they could all be useful in assessing health literacy in different settings. The second study used a national representative sample of 1623 people to assess the prevalence of limited health literacy in Portugal with one of the instruments, the Newest Vital Sign, and documented that three in four people had limited health literacy. As neither of the instruments assesses the communication sub-dimension of health literacy, we explored perceptions on the constraining and facilitating factors to patient-centred communication of both patients and providers in the care of type 2 diabetes with a qualitative study of 7 focus groups. Findings from this last study suggested that communication skills of providers could improve considerably, especially in what concerns interpersonal and relational skills, while also suggesting that patients' participation and involvement in care could be claimed by patients and supported by providers and health systems.

Recent government investments in improving health literacy are not being matched by updates in diabetes care guidelines in Portugal. Results from this thesis could be used to inform care guidelines and interventions to lower the health literacy demands imposed on patients.

RESUMO

A literacia em saúde é habitualmente definida como o conjunto de competências individuais que permite às pessoas aceder, compreender, avaliar e usar informação sobre saúde para tomar decisões. A literacia em saúde inadequada tem sido associada a dificuldade de acesso a cuidados, custos mais elevados e piores resultados em saúde. Porque é agravada pela disparidade entre as competências dos pacientes e as exigências impostas pelos contextos de saúde, as conceitualizações mais recentes da literacia em saúde incluem as aptidões e competências dos profissionais de saúde em comunicar informação de forma a melhorar a compreensão e a capacidade de agir dos pacientes. A diabetes tipo 2 é o modelo ideal para estudar a importância da literacia em saúde, por ser muito dependente da comunicação centrada nos pacientes para sustentar as competências individuais em executar com êxito as recomendações complexas associadas à doença.

As normas de orientação clínica da diabetes mais recentes advogam um estilo de comunicação centrado no paciente e a avaliação da literacia, numeracia e das barreiras potenciais aos cuidados para otimizar resultados em saúde.

O objetivo principal desta tese foi produzir uma base para a avaliação da literacia em saúde e gerar recomendações para a comunicação centrada nos pacientes nas consultas de *diabetes mellitus* tipo 2 em Portugal.

Utilizando um desenho multi-método, este trabalho inclui dois estudos quantitativos realizados em 2012 e um estudo qualitativo realizado entre 2012 e 2016. O primeiro usou uma amostra de conveniência de 249 pessoas para adaptar, validar e comparar três instrumentos de avaliação da literacia em saúde na população portuguesa: o Medical Term Recognition Test, o Short Assessment of Health Literacy for Portuguese-Speaking Adults e o Newest Vital Sign. Concluímos que todos podiam ser úteis para avaliar literacia em saúde em diferentes contextos. O segundo estudo usou uma amostra representativa de 1623 pessoas para estimar a prevalência de literacia em saúde inadequada em Portugal com um dos instrumentos, o Newest Vital Sign, documentando que três em cada quatro pessoas possuíam literacia em saúde inadequada. Como nenhum dos instrumentos avalia a sub-dimensão da comunicação da literacia em saúde, exploramos as percepções dos factores constrangedores e facilitadores da comunicação centrada nos pacientes de pessoas com diabetes tipo 2 e de profissionais de saúde envolvidos nos seus cuidados, com um estudo qualitativo de 7 grupos focais. Os resultados deste último estudo apontam para um potencial considerável de melhoria das técnicas de comunicação dos profissionais de saúde, particularmente no que diz respeito às aptidões interpessoais e relacionais, sugerindo também que os pacientes poderão exigir uma maior participação e envolvimento nos cuidados de saúde, suportados pelos profissionais e sistemas de saúde.

Os investimentos governamentais recentes na promoção da literacia em saúde não têm sido acompanhados pela atualização das normas de orientação clínica da diabetes tipo 2 em Portugal. Os resultados desta tese podem ser usados para suportar diretrizes de cuidados em saúde e contribuir para desenhar intervenções que reduzam as exigências impostas aos pacientes em termos de literacia em saúde.

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Throughout the work presented in this thesis I have contributed to study design, data collection, data analysis and interpretation. I was also responsible for drafting the articles for publication and contributing to the final versions.

Contents

1	INTRODUCTION	I
1.1	Health literacy	I
1.1.1	Definition	I
1.1.2	Assessment	3
1.1.3	Epidemiology	4
1.2	Type 2 <i>diabetes mellitus</i>	5
1.2.1	Pathophysiology and risk factors	5
1.2.2	Epidemiology	8
1.2.3	Standards of care	9
1.3	Scope of health literacy in type 2 <i>diabetes mellitus</i> care	12
1.3.1	Study framework	13
1.3.2	Patient-centred communication	15
2	OBJECTIVES	17
3	PARTICIPANTS AND METHODS	18
3.1	Validation study	18
3.2	National survey	19
3.3	Qualitative study	19
4	PAPERS	21
4.1	Cross-cultural adaptation and validation of the health literacy assessment tool METER in the Portuguese adult population	21
4.2	SAHLPA validation in the Portuguese population: a useful instrument to assess health literacy in low-literate adults	29
4.3	Limited Health Literacy in Portugal Assessed with the Newest Vital Sign	46
4.4	Comparing health literacy instruments in the Portuguese population using structural equation modelling and calibration	56
4.5	Patient-centred communication in type 2 diabetes: the facilitating and constraining factors in clinical encounters	74
5	DISCUSSION	96
6	CONCLUSION	100
	REFERENCES	125

Listing of figures

1.1	Pathophysiology of type 2 diabetes	6
1.2	Elements involved in patient-centred care	10
1.3	Diabetes clinical course	12
1.4	Cumulative complexity model including health literacy	13
1.5	Basic communication models	15
3.1	Construct validity testing	18
3.2	Qualitative study methods	19

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Literacy is a bridge from misery to hope. It is a tool for daily life in modern society. It is a bulwark against poverty and a building block of development, an essential complement to investments in roads, dams, clinics and factories.

Kofi Annan. Message on occasion of International Literacy Day - 8 September (1997)

1

Introduction

The introduction is organised in three sections. The first covers issues related with the definition, assessment and epidemiology of health literacy. The following section describes the pathophysiology, risk factors, epidemiology and standards of care in type 2 *diabetes mellitus*. The final section describes the framework of the thesis, exploring patient-centred communication, a frequent missing link in health literacy assessment, and providing the rationale for the study of health literacy in type 2 diabetes care.

1.1 HEALTH LITERACY

1.1.1 DEFINITION

Health literacy has had multiple meanings throughout the last forty years.^{1,2} It was first coined in the '70s by Scott Simonds advocating for health education as a social policy in primary to secondary education curricula in the United States and was unrelated to following conceptualisations.³ Since then, over 250 different definitions have been identified in the literature, only agreeing on health literacy as a multidimensional construct.² The vast majority of definitions focus on health literacy as a set of individual patient skills, calling into play general literacy in a specific context.⁴⁻⁶ While the straightforward definition of literacy is the ability to read and write, the current definition of the United Nations Educational, Scientific and Cultural Organization (UNESCO) is *'the ability to identify, understand, interpret, create, communicate and compute, using printed and written materials, associated with varying contexts. Literacy involves a continuum of learning in enabling individuals to achieve his or her goals, develop his or her knowledge and potential, and participate fully in community and wider society.'*⁷

The World Health Organization defined health literacy in 1998 as representing *'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'*,⁸ and a year later the American Medical Association as *'the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment'*.⁹ Similarly in 2000, the U.S. National Library of Medicine construed health literacy 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'*,¹⁰ a definition later adopted by the Institute of Medicine and one of the most commonly used definitions up

to this date.^{2,4} This definition has been criticised for using the terms ‘basic’ and ‘appropriate’, potentially viewed as judgmental and autonomy conflicting.^{2,11}

In the same year, Nutbeam argued for health literacy as a strategy for empowerment, describing graded levels of individual health literacy skills, from functional/basic (read and understand numbers in everyday situations), to communicative/interactive (listening, speaking), and up to critical thinking skills (critically analyse and use information in different life situations). In that sense, previous definitions were viewed as restricted to the first level of health literacy skills.¹² This began to shift the focus of health literacy research as the concept moved from a deficit model to a system-wide asset model, i.e. from focusing on individual deficits to recognising the role of health systems and policies in improving health literacy at the individual, clinical and community levels.^{13–15}

Akin to the theory of New Literacy Studies which posits that literacy is not an autonomous skill set but only exists as a socially embedded practice,¹⁶ early on it was recognised that health literacy resulted from a balance between individual skills and the demands and expectations of health systems.^{4,17–19} This promoted a strand of research that focused on measuring the difficulty and complexity of printed and online health-related materials.^{20–25} It highlighted the mismatch between the high complexity of materials and the low literacy of people they were designed for.^{4,26,27}

In 2006, Kwan and colleagues explored existing health literacy definitions and proposed the following one: *‘The degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts to promote and maintain health across the life-course’*, reintegrating communication skills as a core competency of health literacy.²⁸ Three years later, Coleman and colleagues explicitly included people working in health contexts in the definition used by the Calgary Charter on Health Literacy.¹⁹ This document defined it as: *a set of skills (reading, writing, listening, speaking, numeracy, and critical analysis, as well as communication and interaction skills) allowing the public and personnel working in all health-related contexts to find, understand, evaluate, communicate, and use information in order to live healthier lives*. It went on describing that: *‘Health care professionals can be health literate by presenting information in ways that improve understanding and ability of people to act on the information.’*

Two years later, Sørensen and Van den Broucke⁶ *et al.* proposed a definition that aimed to capture the essence of the ones published up to the Spring of 2010, but not including the Calgary Charter’s: *‘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.’* At the same time it is commended by including a life course approach and attempting to bridge the individual-level factors with the societal-level ones, this and related conceptualisations have been criticised for incorporating motivation, thus neglecting the unique contribution of patient activation on health outcomes.^{29,30} Patient activation or having the motivation, knowledge, skills and confidence to make effective decisions to manage health has been advocated as related but distinct construct from health literacy.^{31–33}

In late 2010, Berkman *et al.* proposed a very similar definition to that of the Calgary Charter’s but without differentiating individuals based on their health-related occupation. They defined it as *‘the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions’*.¹¹

Kwan’s, Berkman’s, and the Calgary Charter’s definitions are more aligned with the current UNESCO definition of general literacy.⁷ The latter also explicitly includes the health literacy of health professionals, accompanying the shift in focus in health literacy research towards the communication skills of clini-

cians.^{14,19,34,35} For these reasons it is the working definition that will be adopted in this thesis.

1.1.2 ASSESSMENT

The lack of consensus on what represents health literacy was accompanied by the profuse development of assessment instruments.³⁶ Because of this, there is still no gold standard in health literacy assessment and the available instruments assess somewhat different sub-dimensions of health literacy.³⁷ In turn, this fosters the use of dissimilar instruments in different studies and challenges comparisons across studies and populations.^{36,38}

Instruments designed to evaluate individual health literacy have been broadly grouped based on the approach to measurement (subjective or self-reported vs. objective or directly testing skills), on specificity (general and disease-specific), and on the dimension of the health literacy construct they assess (word recognition, pronunciation, reading comprehension, numeracy or a combination of these).^{36,39,40}

Self-reported instruments ask people questions about their perceived difficulty performing health-related tasks and thus may be subject to response bias. Examples of these instruments are the European Health Literacy Questionnaire (HLS-EU-Q),⁴¹ the Health Literacy Questionnaire,⁴² the Subjective Numeracy Scale,⁴³ and the Health Literacy Management Scale (HeLMS).⁴⁴ Objective testing is performance based and is typically preferred for research purposes and in clinical settings.⁴⁵ Instruments in this category include the Rapid Estimate of Adult Literacy in Medicine (REALM),^{46,47} a medical word recognition test, the Test of Functional Health Literacy in Adults (TOFHLA),⁴⁸ the Medical Achievement Reading Test (MART),⁴⁹ the Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLA),⁵⁰ and the Newest Vital Sign (NVS)⁵¹. While subjective instruments may be more suitable to assess populations, objective ones may be more appropriate to assess individual skills.³⁷

The majority of health literacy instruments is not disease-specific, but a few have been developed to assess health literacy dimensions in patients with asthma,⁵² cancer,^{53,54} HIV,⁵⁵ heart failure,⁵⁶ and diabetes.^{57,58} Arguments against the use of disease-specific instruments are: reduction in generalisability, i.e. the comparison across different disorders, severities, interventions, which is called the bandwidth vs. fidelity dilemma,⁵⁹ and potential for overlooking the effects of an intervention that are important to patients.⁶⁰ Furthermore, in very prevalent diseases where it is likely that people have multiple co-morbidities, narrowing the focus to a single disease may be reductionist and ill-advised.

A more comprehensive list of health literacy instruments can be found at the Health Literacy Tool Shed, an online initiative funded by the U.S. National Institutes of Health's National Library of Medicine.*

The three most commonly used assessment instruments are objective and general ones: the REALM, the TOFHLA, and the NVS.⁴⁵ They have been paramount in the early health literacy field development because they linked limited health literacy to negative health outcomes.^{38,37} While they have been criticised for the disconnect with the broad construct of health literacy,^{61,62} the few instruments that have been developed directly based on models have yet to demonstrate association to health outcomes.³⁷

The assessment of the other side of the equation, the demand side, spurred the development and use of instruments to measure readability of health materials, including printed health education materials, patient consent forms, and websites.⁶³⁻⁶⁵ It also promoted the development of the *Health Literacy Universal Precautions Toolkit* commissioned by the U.S. Agency for Healthcare Research and Quality to aid health practices structure the delivery of care taking into account the possibility of every patient having limited health literacy.^{66,67}

*available at <http://healthliteracy.bu.edu>

The assessment of communication skills other than printed ones, has for the most part evolved independently from the health literacy field.⁶⁸ In health communication research, mainly in the context of physician training, some tools exist to assess the communication skills of physicians, most of them observer rated or coded, but a few based on self-assessments or self-reported by patients.^{68,69} And although a few health literacy instruments have been developed that also assess patients' listening skills, either objectively^{55,70} or subjectively,⁷¹⁻⁷³ there are still no health literacy instruments to rigorously assess the oral, numeracy, or writing skills of public health, health care, or private sector professionals.⁶² Furthermore, the assessment of the health literacy of graduating or working health professionals has either used health instruments designed for the lay public or focused on the knowledge they possess of health literacy barriers caused by patients' low literacy and of the strategies to minimise those barriers.⁷⁴⁻⁷⁸

1.1.3 EPIDEMIOLOGY

Limited health literacy has been linked to various adverse outcomes, including less knowledge about health and health care, decreased uptake of preventive services such as vaccination and cancer screening, greater use of emergency services, higher hospitalisation rates, higher financial costs, and increased mortality.⁷⁹⁻⁸⁸

Population estimates of general literacy are available for most countries,⁸⁹ but not for health literacy. The few population-based assessments of health literacy that are published have documented that between one and three in four people have limited health literacy worldwide.

The first estimates came from the United States with an instrument named the Health Activities Literacy Scale (HALS) derived from 191 health-related items and objective tasks previously used in general literacy population assessments, such as the National Assessment of Adult Literacy Survey (NAALS) and the International Adult Literacy Survey (IALS), which was not purposively designed to assess health literacy skills.⁹⁰ The policy report published in 2004 documented that 46% of American adults performed in the lower two levels out of five (corresponding to poor or very poor health literacy skills) of the HALS, 36% in the middle level, and 18% in the upper range of the scale.

Concurrently, the U.S. Department of Health and Human Services and the Department of Education collaboratively developed a purposive sample of materials and items related to health that was included in the 2003 NAALS. Health literacy was assessed by a 28-item scale of health related tasks designed to elicit respondents' skills for locating and understanding health-related information and services, for example 'determine a healthy weight range for a person of a specified height, based on a graph that relates height and weight to body mass index (BMI).'⁹¹ Results were reported by sub-scale (prose, document and quantitative literacy) using four literacy levels (for general literacy and health literacy): Below Basic, Basic, Intermediate, and Proficient. The distribution of health literacy was similar but not equal to the distribution among the levels of general literacy. Over half the participants had Intermediate health literacy, 35% had Basic or Below Basic and only 12% had Proficient health literacy.

In Europe as population data on health literacy were missing in 2011, the European health literacy survey (HLS-EU) was conducted to estimate health literacy levels in eight countries, Austria, Bulgaria, Germany, Greece, Ireland, the Netherlands, Poland and Spain.⁹² Health literacy was assessed with both a subjective and an objective instrument, the HLS-EU-Q supplemented with the NVS. Four levels of health literacy were considered in the HLS-EU-Q: insufficient, problematic, sufficient and excellent; and three levels in the NVS: high likelihood of limited literacy, possibility of limited literacy, and adequate literacy. Using the HLS-EU-Q, roughly half (47.6%) of the population was found to have limited (insufficient or problematic) health literacy, with substantial differences across countries, from 28.7% in the Nether-

lands to more than 62.1% in Bulgaria.⁹² With the NVS, 45% of respondents had a high likelihood or the possibility of limited health literacy; similarly, differences across countries were large, from 23.7% in the Netherlands to 63.1% in Spain.⁹³

Since the first HALS analysis was conducted, several other countries, including Canada, the Netherlands, Australia, and New Zealand, have used the same coding scheme to assess their population health literacy. In Canada it was estimated that 55% of adults scored below level 3 in the HALS in 2003,⁹⁴ and in 2006 49% of Australians aged 15 to 74 years achieved scores below level 3,⁹⁵ as did over 50% of non-Māori and Māori respondents in New Zealand,⁹⁶ and 54% in the Netherlands in the following year.⁹⁷

Likewise, the methodology of the European health literacy survey has been replicated in other Asian and European countries, revealing for example that the prevalence of limited health literacy in 2013 assessed with the HLS-EU was 44.5% in Taiwan,⁹⁸ 66.9% in Vietnam,⁹⁹ 85.4% in Japan,¹⁰⁰ and that in 2015 in Italy it was 54% as assessed with the HLS-EU-Q and 56% as assessed by the NVS.¹⁰¹

In Portugal, population surveys using the Newest Vital Sign in 2012 and the European Health Literacy Survey Questionnaire in 2014 place the estimate of limited health literacy at 73% and 49% of the population, respectively.^{102,103}

Limited health literacy is known to disproportionally affect the most vulnerable groups of the population: the elderly, migrants, those with lower education attainment, and those with chronic disease.^{91,92,104–106} Because it is more frequent among people who live in socioeconomically disadvantaged conditions it is now regarded as a key element in explaining and addressing health inequities.^{105,107} Because most of the research has been conducted in more economically developed countries, it is uncertain whether health literacy is a useful determinant of health outcomes in other regions of the World, adding value to measures of education or general literacy, and whether this same social gradient applies.

1.2 TYPE 2 DIABETES MELLITUS

1.2.1 PATHOPHYSIOLOGY AND RISK FACTORS

The knowledge about disease pathophysiology and risk factors is important to understand lifestyle and management recommendations in type 2 *diabetes mellitus*.

Diabetes mellitus is a group of metabolic diseases that share the phenotype of elevated blood glucose or hyperglycaemia.¹⁰⁸ Type 2 diabetes is the most frequent form of *diabetes mellitus* (accounting for more than 90% of cases) and is believed to result from the interplay between genetic, epigenetic and environmental factors.¹⁰⁹ These factors interact and cause relative insulin deficiency via pancreatic β -cell dysfunction and insulin resistance (i.e. the decreased ability of insulin to act effectively on tissues) in target organs, disrupting normal insulin metabolism (Figure 1.1). In people without diabetes, when blood sugar rises (e.g. after a meal) pancreatic β -cells secrete insulin that reduces glucose production by the liver while increasing glucose uptake by adipose and skeletal muscle tissue, which aims to reduce blood sugar levels. Once β -cell dysfunction or insulin resistance (in the liver, adipose or muscle tissues) develops, an excessive amount of circulating glucose in the blood ensues (no longer counter-regulated effectively by insulin), resulting in hyperglycaemia and ultimately type 2 diabetes.¹⁰⁹

Chronic hyperglycaemia is an important etiological factor leading to disease complications.¹⁰⁸ Diabetes complications have been traditionally grouped into micro (retinopathy, neuropathy, nephropathy) and macrovascular complications (coronary heart disease, peripheral arterial disease, cerebrovascular disease), based on the caliber of the blood vessels they predominantly affect.¹⁰⁹

Several risk factors have been implicated in the onset of type 2 *diabetes mellitus*:

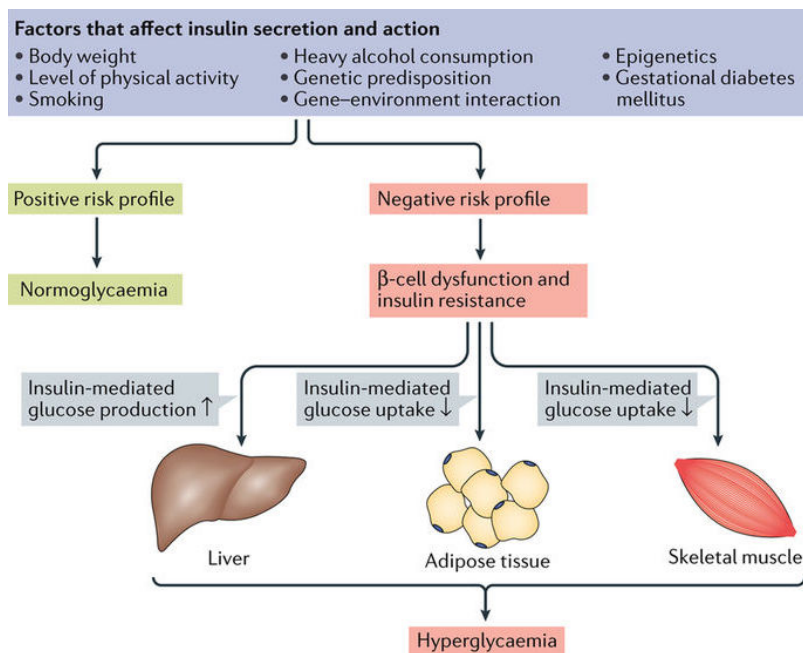


Figure 1.1: Pathophysiology of hyperglycaemia in type 2 diabetes mellitus (reproduced from Zheng Y. *et al.* ¹⁰⁹)

EXCESSIVE BODY WEIGHT AND ADIPOSITY A high body mass index (BMI) is associated with insulin resistance and is the strongest risk factor for type 2 diabetes. ^{110–112} Furthermore, even in people with normal BMI, weight gain has been associated with an increased risk of type 2 diabetes. ^{112,113} Abdominal obesity (measured by waist-to-hip ratio or waist circumference) and visceral obesity also seem to predict risk independently of BMI. ^{114–116}

UNHEALTHY DIET Several dietary factors have been implicated in the development of type 2 diabetes. Regular consumption of sugary beverages, which include soft drinks, fruit drinks, iced tea, and energy and vitamin water drinks was associated with increased risk of type 2 diabetes. ^{117,118} Frequent consumption of red meats ¹¹⁹ and low consumption of fibre rich foods (such as whole grains) ^{120,121} and leafy vegetables ^{122,123} have also been identified as risk factors. On the other hand, low-carbohydrate diets, including diets based on low glycaemic index and load foods have been shown to reduced the risk of developing type 2 diabetes in a updated meta-analysis including 3 large U.S. cohorts. ¹²⁴ Other dietary patterns have been found to reduce the incidence of type 2 diabetes in a more recent meta-analysis: the mediterranean diet (relative risks for comparing extreme quantiles: 0.87; 95% CI: 0.82, 0.93), Dietary Approaches to Stop Hypertension (DASH) (RR: 0.81; 95% CI: 0.72, 0.92), and Alternative Healthy Eating Index (AHEI) (RR: 0.79; 95% CI: 0.69, 0.90). ¹²⁵

SEDENTARY BEHAVIOUR More time spent in sedentary activities such as watching TV has been independently associated with an increased risk of type 2 diabetes, even after adjusting for physical activity. ^{126,127}

SMOKING A dose-response relationship between number of cigarettes smoked and risk of developing type 2 diabetes has been reported in a meta-analysis of 25 prospective cohort studies including 1.2 million participants: heavy smokers (≥ 20 cigarettes/day) had the highest relative risk (RR) for type 2 diabetes when compared with light smokers [pooled RR=1.61 (95% confidence interval: 1.43-1.80)].¹²⁸ Higher exposure to second-hand smoke has also been associated with the onset of type 2 diabetes.¹²⁹

EXCESSIVE ALCOHOL CONSUMPTION A meta-analysis described a U-dose relationship between alcohol consumption and the risk of developing type 2 diabetes for both men and women; the lowest risk was observed for alcohol consumption of about 2 drinks per day and the highest above 4 drinks per day.¹³⁰

GENETIC PREDISPOSITION Genome wide association studies have identified almost a hundred of common gene variants modestly linked with type 2 diabetes, explaining under 20% of the inherited risk overall.¹³¹ The search for lower-frequency variants has thus far proved unfruitful in explaining the remaining risk.¹³² As a consequence, presently genetic risk screening appears not to add value to traditional screening based on common clinical measurements (including age, BMI, waist circumference, increased blood pressure, fasting glucose and lipid serum levels).¹³³

GENE-ENVIRONMENT INTERACTIONS Type 2 diabetes is believed to result from the complex interaction between genes and the environmental context. Some examples of gene-environment interactions are:

- The abnormally high prevalence of type 2 diabetes in some indigenous populations, such as Pima indians, after transitioning to high calorie diets and physical inactivity.^{134,135} This has been called the ‘thrifty genotype hypothesis’¹³⁶ and says that genotypes favouring efficient metabolism and storage of energy (selectively advantageous in times of famine), become detrimental upon exposure to modern environments with excess food availability;¹³⁴
- Intrauterine exposure to famine causing fetal undernutrition presumably leads to fetal adaptation to scarce resources conferring a early selective advantage but is associated with higher rates of type 2 diabetes in adulthood. This was named the ‘thrifty phenotype hypothesis’ and is believed to result from epigenetic interactions, i.e mutations that in the presence of certain environmental exposures cause epigenetic changes that differentially affect gene transcription;^{137,138}
- Differential effects of lifestyle interventions, with carriers of specific alleles displaying dissimilar risks of developing type 2 diabetes in trials of dietary and exercise interventions;¹³⁴
- Inter-individual variability in response to anti-diabetic drugs, regarding efficacy (for metformin, sulfonylureas, thiazolidinediones and dipeptidyl peptidase-4 inhibitors) and adverse drug reactions (metformin-associated gastrointestinal disturbance, sulfonylurea-induced hypoglycaemia, and thiazolidinedione-associated oedema, hepatotoxicity, heart failure) has been reported in relation to genetic variants (pharmacogenomics).¹³⁹

GESTATIONAL DIABETES Gestational *diabetes mellitus*, i.e. diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation,¹⁴⁰ increases the risk of type 2 diabetes in exposed women and their offspring. In a meta-analysis of 20 studies that included 675 455 women, women with previous gestational diabetes had at least a seven-fold risk of developing type 2 diabetes in the future.¹⁴¹ Moreover, evidence shows that exposure to an hyperglycaemic uterine environment increases the risk of type 2 diabetes in the offspring.^{137,142}

OTHER FACTORS The composition and diversity of the gut microbiome, i.e the bacteria that reside in the human intestine, have been linked with type 2 diabetes, with people with type 2 diabetes presenting with reduced amounts of butyrate producing bacteria when compared to people without diabetes.^{143,144} Moreover, the use of some medications, such as statins, thiazides, and beta-blockers has been shown to raise blood glucose levels.¹⁴⁵

1.2.2 EPIDEMIOLOGY

Type 2 diabetes has been called the largest epidemic in human history.¹³⁷ According to the Non-Communicable Disease Risk Factor Collaboration, 422 million adults worldwide were estimated to have diabetes in 2014, and this number is expected to rise to 700 million people by 2025.¹⁴⁶ This is the prevalence estimate currently adopted by the World Health Organization¹⁴⁷ and is less optimistic than either that of the International Diabetes Federation¹⁴⁸ or of the Global Burden of Disease Group¹⁴⁹. Nonetheless, some authors have suggested that due to epidemiological misassumptions used to estimate values for countries without observed prevalence data, even this may grossly underestimate the global burden of disease.¹⁵⁰ The projected increase is primarily due to the growing prevalence of diabetes, accompanying population ageing, overweight, obesity, and unhealthy lifestyles.¹⁴⁶

Extrapolating from the only population-based study on national diabetes prevalence, PREVADIAB,¹⁵¹ in 2017 Portugal was estimated to have the highest comparative prevalence in adults aged 20-79 years of the European Union; its raw prevalence was estimated at 13.9%.¹⁴⁸ National prevalence was also documented to be increasing.¹⁵² As is the case with limited health literacy, diabetes is also more frequent among people of lower socioeconomic position,^{153,154} older people, minorities, and immigrants.¹³⁷

Over 1.5 million people die of diabetes each year, and diabetes ranks 6th as a cause of death globally and 5th nationally.^{155,156} By far the leading cause of death in people with type 2 diabetes is cardiovascular disease.¹⁵⁷ In a Swedish registry-based study, patients with type 2 diabetes were reported to have a 15% increased risk of all-cause mortality, when compared with people without diabetes.¹⁵⁸ Diabetes also represents one of the leading causes of disability, as a result of the chronic complications of acute myocardial infarction, stroke, blindness, renal failure, and lower limb amputations.¹⁴⁹ In the A₁chieve study, an international prospective study of people with type 2 diabetes from 28 countries starting insulin regimens, the overall prevalence of baseline complications was reported to occur in 27% of participants for macrovascular complications, and 53% for microvascular complications.¹⁵⁹

Until recently, it was believed that people with diabetes had a relative risk of microvascular complications 10–20 times higher than that of the people without diabetes, and 2–4 times higher of macrovascular complications.¹⁶⁰ More recent studies have begun to challenge this assumption, reporting large declines in the risk of diabetes complications.^{161,162} The excess mortality risk among people with diabetes when compared to people without has also been diminishing over the past two decades, ranging from a 15% to 40% reduction every 10 years.¹⁶⁰

1.2.3 STANDARDS OF CARE

Quality outcomes for people with type 2 diabetes are optimised by patient-centred care in the management of lifestyle, hyperglycaemia, and cardiovascular risk and disease, while supporting patients' self-management.¹⁶³ This section goes through each of these.

PATIENT-CENTRED CARE Models of chronic illness care, such as the Chronic Care Model¹⁶⁴ and the World Health Organization's Innovative Care for Chronic Conditions¹⁶⁵ highlight patient-centredness and self-management support. Patient-centred care, i.e. 'care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions', is widely acknowledged as a key indicator of quality of care.¹⁶⁶ Or as Epstein has put it 'healing relationships can be cultivated on the basis of who the patient is rather than who the physician would have him be'.¹⁶⁷ It has been slowly replacing the doctor-centred model of care, a paternalistic model, where the patient was seen as a passive recipient of care.^{168,169}

Although there is some variability in the description of the specific elements of patient-centred care, a 2013 review¹⁷⁰ found consensus on the following dimensions:

- centrality of the patient experience;
- respect and the expressions of values and beliefs;
- integrated approach to care;
- effective communication;
- shared decision-making.

Patient-centred care involves productive interactions between a prepared proactive care team and an informed activated patient (Figure 1.2).¹⁷¹ It is advocated by patients,^{172,173} patient organisations,¹⁷⁴ and health organisations alike.¹⁷⁵

Beyond the moral and ethical argument in support of patient-centred care, a 2015 Cochrane review showed that it was associated with better self-management, lower blood pressure and better glycaemic control in people with diabetes.¹⁷⁶ Furthermore, a 2017 meta-analysis examining the effect on cardiovascular risk factors of interventions to alter consultations between health professionals and people with type 2 diabetes towards patient-centredness found no overall effect on risk factors, but a subgroup analysis suggested benefit among studies in which interventions demonstrated impact on consultations with significant reductions in glycated hemoglobin levels (−0.53%).¹⁷⁷

Patient-centred care in the management of diabetes is advocated for by the American Diabetic Association, the European Association for the Study of Diabetes, the British National Institute for Health and Care Excellence and the International Diabetes Federation.^{178–181}

LIFESTYLE MANAGEMENT While predisposition to develop type 2 diabetes has a strong genetic basis, evidence suggests that a fair amount of cases can be delayed, prevented or reversed with lifestyle modification.¹⁸² Prevention and remission (return to "normal" measures of glucose metabolism of at least 1 year's duration in the absence of active pharmacologic therapy or ongoing procedures¹⁸³) of type 2 diabetes has been consistently documented after bariatric surgery,^{184–186} but a large longitudinal study published in

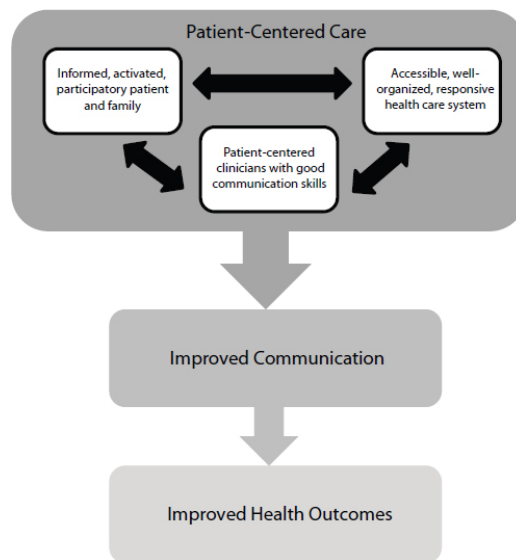


Figure 1.2: Elements involved in patient-centred care (reproduced from Epstein *et al.* ¹⁷¹)

2014 pointed to the possibility of type 2 diabetes remission without surgery.¹⁸⁷ Clinical trials of calorie restriction followed. In 2015, a small study with 29 participants with variable disease duration documented rates of restored normoglycaemia above 50% on a 8- week very-low-calorie diet.¹⁸⁸ In the recent Diabetes Remission Clinical Trial (DiRECT) delivered in the primary care setting, effective weight management through calorie restriction produced sustained remission (12 months) of type 2 diabetes in almost half of the participants in the intervention group that had been diagnosed in the previous 6 years.¹⁸⁹ Both in the short and the long term, a mediterranean diet was also shown to help people with type 2 diabetes achieve disease remission.¹⁹⁰ Trials testing intensive lifestyle interventions (including both diet and physical activity) have also shown optimistic results in reducing the risk and inducing remission of type 2 diabetes.^{191–195}

GLYCAEMIC MANAGEMENT Long term glycaemic control is one of the core components of diabetes management and is assessed by measuring the blood levels of glycated hemoglobin (HbA_{1c}), the sugar coated form of hemoglobin, which reflects average glycaemia over approximately 3 months.¹⁹⁶ There is ample evidence that a glycaemic target HbA_{1c} below 7% reduces microvascular complications.¹⁸² However, this is apparently not true for macrovascular complications or all-cause mortality, according to results from a 2017 meta-analysis.¹⁹⁷ It documented an U-shaped association between HbA_{1c} values and both cardiovascular mortality and death in people with diabetes, with higher risk below 6% and above 9% in HbA_{1c} values, establishing optimal HbA_{1c} targets from 6.0% to 8.0%.¹⁹⁷ Moreover, landmark randomised clinical trials in type 2 diabetes, such as the ADVANCE (Action in Diabetes and Vascular Disease: Preterax and Diamicon MR Controlled Evaluation),¹⁹⁸ the ACCORD (Action to Control Cardiovascular Risk in Diabetes),¹⁹⁹ and the VADT (Veterans Affairs Diabetes Trial)²⁰⁰ had already failed to demonstrate all-cause mortality reduction from intensive glycaemic treatment; the ACCORD trial actually reported increased mortality in the intensive glucose lowering arm. Contrastingly, long term follow-up data from the VADT and the United Kingdom Prospective Diabetes Study (UKPDS), provided evidence that more intensive treatment of glycaemia in newly diagnosed patients may reduce long-term cardiovascular disease rates (and overall mortality in the UKPDS), an effect described as glycaemic legacy or metabolic memory.^{201,202}

Furthermore, regarding drug therapy for glycaemic management, following the 2007 meta-analysis of rosiglitazone studies²⁰³ which raised concerns of adverse cardiovascular outcomes, both the European Medicine Agency²⁰⁴ and the U.S. Food and Drug Administration²⁰⁵ recommended the assessment of cardiovascular safety of all new glucose-lowering therapies, i.e, the exclusion that the new drug increases the risk of macrovascular complications. Since then, several large studies have been conducted that provided reassurance of the safety profile of these drugs.²⁰⁶ This also changed recommendations for add-on therapy after first-line therapy (lifestyle management and metformin) to include any drug proven to reduce major adverse cardiovascular events and cardiovascular mortality, after considering drug-specific and patient factors.²⁰⁷

CARDIOVASCULAR RISK AND DISEASE MANAGEMENT Primary and secondary prevention of adverse cardiovascular outcomes include lifestyle modification, including smoking cessation, weight management, blood pressure lowering, lipid management, and glycaemic reduction.²⁰⁸ Components not previously described will be explored herein.

Diabetes being called a coronary disease equivalent was challenged by a meta-analysis of 13 studies in 2009, reporting that people with diabetes had half the risk of coronary heart disease compared with patients with previous myocardial infarction.²⁰⁹ Nonetheless, the risk of atherosclerotic cardiovascular disease is higher in people with type 2 diabetes when compared with people without, and risk reduction strategies are recommended as they have been shown to improve outcomes.^{210,211}

The INTERHEART study, a large standardised international case-control study in 52 countries, reported current smoking as one of the strongest risk factors for atherosclerotic coronary heart disease, followed by psychosocial factors [a combined measure of psychosocial stress (home and work), life events, and depression], both ranking above diabetes.²¹² Similarly, the INTERSTROKE trial conducted in 32 countries documented that hypertension, waist-to-hip ratio, psychosocial factors (measured as in the INTERHEART study), current smoking and heavy alcohol consumption were all more important risk factors than diabetes.²¹³ These and other studies underscored the importance of management of cardiovascular risk factors other than hyperglycaemia.

There is evidence that addressing multiple atherosclerotic cardiovascular disease factors simultaneously is effective in reducing mortality in people with type 2 diabetes. A multifactorial intervention of cardiovascular risk reduction (behaviour modification, pharmacological therapy targeting hyperglycaemia, hypertension, dyslipidaemia, and microalbuminuria) was shown to reduce mortality after a prolonged follow-up of the Danish Steno-2 trial, resulting in a median survival gain of 7.9 years in the intensive treatment arm.²¹⁴

Findings from a 2018 meta-analysis of 141 cohort studies found that no safe level of smoking exists for cardiovascular disease, as smoking one cigarette per day carries a risk of developing coronary heart disease and stroke around half that for people who smoke 20 per day.²¹⁵ A prospective community-based cohort study using data from the Framingham Offspring Study found that among people with diabetes, those that had quit smoking for >4 years had a reduced risk of cardiovascular disease outcomes compared to those who had quit more recently, and either had a lower risk than current smokers.²¹⁶ The study also showed that the effect was not modified by the weight gain associated with smoking cessation.

Hypertension is a frequent comorbidity in people with type 2 diabetes, that contributes to long-term disease complications. There is robust evidence from meta-analyses that treating hypertension to targets <140/90mmHg in people with diabetes reduces cardiovascular events and microvascular complications.^{217–219} Lower targets may provide additional benefit in some patients, but the evidence is not as strong.²¹¹

Dyslipidaemia is highly prevalent among people with type 2 diabetes,²²⁰ and statin-therapy is recommended in every person with type 2 diabetes.²¹⁰ There is unequivocal evidence that statins reduce mortality in people with diabetes as secondary prevention.²²¹ The benefit for mortality reduction in primary prevention is smaller.^{222,223}

SELF-MANAGEMENT SUPPORT Managing type 2 diabetes and changing behaviours is challenging and time-consuming for health professionals, patients, and caregivers. To prevent adverse outcomes throughout the clinical course (Figure 1.3), people with type 2 diabetes are expected to self-manage their health, by maintaining a healthy diet, engaging in physical activity, solving problems, coping with psychosocial issues and concerns, managing sometimes complex medication regimens, navigating the health system, performing regular laboratory health tests, and keeping appointments with multiple health professionals, while learning self-advocacy.^{224,225} All of this adds to the treatment burden experienced by people with type 2 diabetes and fosters suboptimal self-management, wasted resources and poor outcomes.²²⁶

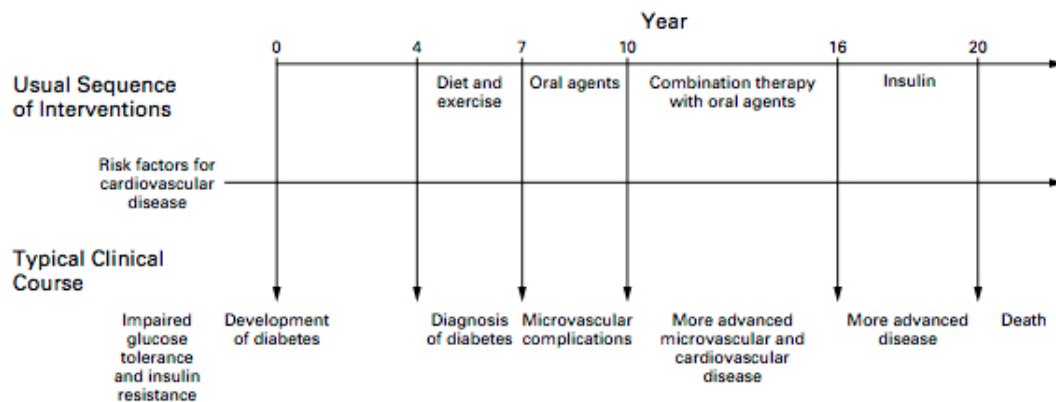


Figure 1.3: Diabetes clinical course (reproduced from Nathan D. M.²²⁷)

Self-management education and support provide the basis to aid people with diabetes to perform those activities and have been found to improve health outcomes.^{228–231} Diabetes self-management education refers to the approach of facilitating the knowledge, skill, and ability necessary for diabetes self-care, while diabetes self-management support is what is required to foster the development and support of coping skills and behaviours needed to self-manage on a continuous basis.²³² Both aim at helping patients overcome the barriers to self-management, by addressing the patient’s health beliefs, cultural needs, knowledge, physical limitations, emotional concerns, family support, financial status, medical history, health literacy and numeracy.²³²

From the above is clear that evidence-based diabetes care has changed significantly in the past decades, representing a challenge for providers in keeping up to date with the literature and in translating evidence-based care to patients.

1.3 SCOPE OF HEALTH LITERACY IN TYPE 2 *DIABETES MELLITUS* CARE

Taking into account the complexity in diabetes care for both patients and providers, type 2 diabetes presents an ideal framework to study health literacy. Furthermore, the assessment of health literacy in

the most traditional sense benefits from research on the other side of the equation, patient-centred communication, as effective communication between people with diabetes and the health professionals caring for them is paramount to patient-centred care.²³³

1.3.1 STUDY FRAMEWORK

Shippee *et al.* have argued that the complexity in chronic disease management results from a dynamic balance between the patient's workload of demands (the tasks and responsibilities people face in their daily lives) and patient capacity (their resources, skills and motivation to address demands).²³⁴ According to this patient-centred model, patient complexity is regarded as a dynamic state in which the personal, social, and clinical features of the patient's experience work as perturbing factors. These factors accumulate and interact, shaping access, utilisation, self-care, and health. Poor outcomes may cause providers to intensify treatment, creating a burden of treatment that leads care and outcomes back to increased demands. This may fuel overburden in patients whose workloads already exceed their capacity. Conversely, preventive care and provider support may restrain treatment burden. On the other hand, the burden of illness, i.e., the consequences of poor health that influence patients' functioning and quality of life, can give rise to decreased capacity from disease progression and impose further workloads. Thus, workload, capacity, and treatment and illness burdens are viewed as the major influencing factors of health outcomes.

Within this framework, the patient's health literacy would fit patient capacity and the health literacy of health professionals (specifically their communication skills), would influence disease-related demands (Figure 1.4).

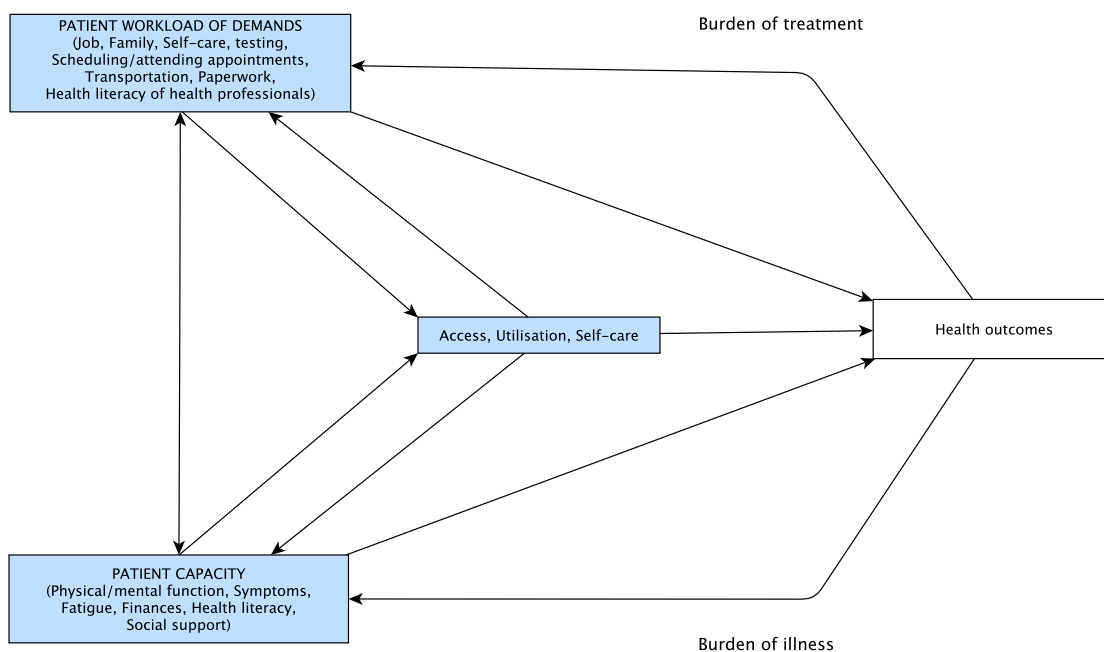


Figure 1.4: Cumulative complexity model including health literacy (adapted from Shippee *et al.*²³⁴)

There is already a lot of work on the association between health literacy and outcomes in people with type 2 diabetes. Milestone systematic reviews were published in 2004 by DeWalt *et al.*⁷⁹ and in 2011 by

Berkman *et al.*,⁸¹ but the scope was not limited to diabetes and included other chronic diseases. The 2004 review included studies that had used general literacy tests or health literacy tests. However, the results were also reported separately for diabetes and showed that in the included studies HbA_{1c} levels were somewhat higher among those with lower literacy than those with higher literacy, as were the rates of some diabetes complications. The updated 2011 review found there was insufficient evidence to conclude there was an association between health literacy and glycaemic control or diabetes complications.

In a systematic review published in 2012, Fransen *et al.* reported limited evidence for a positive association between health literacy and self-management behaviours in people with type 2 diabetes.²³⁵ In the same year, Loke *et al.* examined the consistency between adherence to cardiovascular or diabetes medication and health literacy in older adults and found no evidence of an association between health literacy assessed with either the REALM or the TOFHLA and medication adherence.²³⁶ In a 2013 systematic review published by Al Sayah *et al.*,²³⁷ authors reported a consistent positive association between higher health literacy and increased diabetes knowledge. There was a lack of consistent evidence on the relationship between health literacy or numeracy and clinical outcomes (HbA_{1c}, self-reported complications, achievement of clinical goals), behavioural outcomes (self-monitoring of blood glucose, self-efficacy), or patient-provider interactions (patient-physician communication, information exchange, decision-making, and trust). A narrative review published in 2014 by Bailey *et al.*, including only papers indexed in MEDLINE and conducted in the United States, also documented a consistent association between lower health literacy and numeracy and poorer diabetes-related knowledge.²³⁸ Some of the included studies in this review suggested literacy and numeracy were associated with intermediate outcomes, including self-efficacy, communication, and self-care (including adherence), but the relationship between literacy and glycaemic control was mixed. Not many studies had assessed diabetes-related complications, health care utilisation, safety, or quality of life, but they suggested that low literacy could be linked with increased risk of complications, including hypoglycaemia.²³⁸

Studies published since this last review have provided additional evidence on the association between limited health literacy and outcomes in people with type 2 diabetes. Franzen *et al.* found that in Switzerland, limited health literacy among people with type 2 diabetes was associated with more physician visits and consequently higher total and outpatient costs.²³⁹ In the same study, Mantwill *et al.* reported it was also associated with higher medication costs.²⁴⁰ Souza *et al.* found that limited health literacy was associated with poorer glycaemic control, as measured by HbA_{1c} in Brazil.²⁴¹ More recently, using a Japanese health literacy instrument that includes a communication component,⁷¹ a study concluded that health literacy might influence glycaemic control indirectly through self-efficacy and self-care behaviours in Taiwan.²⁴² In South Korea, Lee *et al.* reckoned that self-efficacy might also be a mediator in the relationship between health literacy and quality of life.²⁴³ Newer studies have also reinforced the link between limited health literacy and lower diabetes knowledge, both in people with type 2 diabetes^{244–246} and in the general population.²⁴⁷

Strategies to overcome the barriers caused by limited health literacy are called for to improve patient-centred care.^{248–250} Furthermore, this type of care has been equated with higher health literacy responsiveness of health organisations, i.e., the use of strategies to support low literate patients to navigate, understand, and use information and services to take care of their health.²⁵¹ Patient-centred care is underpinned by patient-centred communication,^{248,249} which is acknowledged a core dimension of that care.^{166,174,252} Specifically in the context of type 2 diabetes, patient-centred communication has been associated with higher disease knowledge,²⁵³ improved self-care,²⁵⁴ quality of life,²⁵⁵ and better measures of metabolic control.^{256–258}

Since 2012, the yearly Standards of Medical Care in Diabetes of the American Diabetes Association

have advocated for a patient-centred communication style and for the assessment of literacy, numeracy and potential barriers to care to optimise patient health outcomes.^{163,259–264} In the 2012 Global Guideline for Type 2 Diabetes, the International Diabetes Federation has also recommended communicating with a person with diabetes using a whole-person approach and respecting the person’s central role in their care.²⁶⁵ However, instruments to assess patients health literacy and numeracy are lacking in Portugal and patient-centred communication in type 2 diabetes is not yet an explicit cross-cutting recommendation in national^{266–268} or other international guidelines.^{148,179–181}

1.3.2 PATIENT-CENTRED COMMUNICATION

Patient-centred communication is a frequent missing link in the assessment of health literacy. Models from health communication studies can be outlined into three different communication models: the linear, the interactional, and the transactional model of communication (Figure 1.5).²⁶⁹ All three models have been used to explain health communication in different settings.

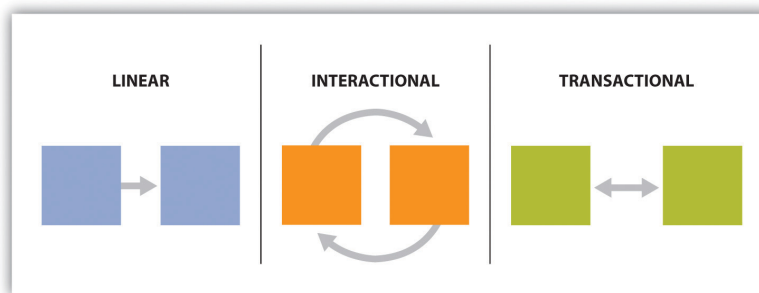


Figure 1.5: Basic communication models (reproduced from Wrench J. S. and Punyanunt-Carter N.²⁶⁹)

The linear model is the most basic illustration of the human communication process. It breaks down communication into four components: sender, message, channel, and receiver. It was adapted for interpersonal communication from the work of mathematician Claude Shannon²⁷⁰ in the ‘40s and is also referred to as the Shannon-Weaver model, the transmission or informational model, and the SMRC (sender-message-receiver-channel) model of communication. It postulates that a message travels straight from a person (the source), through a channel, to another person (the receiver), while also including the concepts of code (the system used to convey the information) and noise in the channel (barrier to communication).²⁷¹ When applied to interpersonal communication, it has been broadly criticised by its simplistic reduction of the communication process and by assuming that listeners are passive, but remains the best model to explain the communication components as well as unidirectional communication, such as what happens during public speaking and communication of public health messages.²⁶⁹ The interactional model developed by Wilbur Schramm a few years later holds that there is two-way feedback in message transmission and so both parties in turn become sender/receivers. It also added the notion of the fields of experience of both parties, necessary for encoding and decoding the messages.²⁷² It is the best model to explain clinical interactions using e-mail or text messages, as well as educational interactions.²⁷³ Contrastingly, the transactional model proposed by Dean Barnlund in the ‘70s reflects that sending and receiving occur simultaneously and that it is a social and relational process where fields of experience must overlap to build shared meaning.²⁷⁴

In health communication, healthcare professionals are consistently mentioned as one of the main sources of health information by the lay public and by people with chronic diseases.^{275–278} These findings are matched by results from Portuguese studies.^{103,279} In a population survey conducted in 2012, almost 85% of the respondents considered that health professionals were one of the two most important sources of health information.²⁷⁹ Consequently, although less explored, the communication dimension of health literacy in clinical encounters is of enormous relevance.²⁸⁰

Corresponding to a transactional model of communication, a patient-centred style has been advocated as the benchmark in clinical interactions that include people with chronic health conditions.²⁴⁸ Patient-centred communication has been defined as a communication style that serves the following functions: fostering the relationship, gathering information, providing information, decision-making, enabling treatment and disease-related behaviour and responding to emotions.^{281,282} For the United States Joint Commission it is intrinsically connected to health literacy and an essential strategy to increase patients' safety.²⁴⁸ It requires communication techniques known to enhance understanding by patients, overcoming the barriers caused by their limited health literacy, such as providing information in plain language and probing for understanding, as well as asking open-ended questions, active listening, maintaining eye contact, emphasising key messages, eliciting patients' concerns and goals, assessing and supporting readiness to change behaviours, and expressing empathy when responding to psychosocial distress.^{248,252,281–283}

Patient-centred communication practices have been linked to increased patient satisfaction,^{284,285} higher adherence to treatment,²⁸⁶ fewer diagnostic test expenditures,²⁸⁷ better health status and quality of life,^{288,289} and reduced levels of anxiety and depression.²⁹⁰

A patient-centred communication style is advocated by patients, teachers in clinical communication skills, and health professionals who take a biopsychosocial approach in health care.^{173,291,292} Unfortunately, patient-centred communication does not seem to occur in most clinical encounters, as patients continue to ask for more humane, empathic and supportive communication.^{173,293}

In sum, type 2 *diabetes mellitus* care relies heavily on patients' self-management to enable the adoption or maintenance of healthy lifestyles and other recommendations. Patient-centred communication is expected to provide self-management support and a central role to patients in the active management of their disease.

2

Objectives

The American Diabetes Association recommends assessing patients' health literacy and numeracy as well as providing patient-centred communication to improve outcomes for people with diabetes. Literacy and numeracy are critical skills to cope with the health literacy demands of diabetes care. In addition, because health professionals are a fundamental source of health information for patients, the communication dimension of health literacy in clinical encounters is of paramount importance.

We aimed to provide a basis for the assessment of health literacy and to provide recommendations for patient-centred communication in clinical encounters in type 2 *diabetes mellitus* in Portugal.

SPECIFIC OBJECTIVES

1. To validate health literacy instruments in the Portuguese population.
2. To compare the validity, precision and difficulty of health literacy instruments and to calibrate them.
3. To estimate the prevalence of limited health literacy in Portugal.
4. To explore the constraining and facilitating factors to patient-centred communication in clinical encounters of people with type 2 diabetes and the health professionals involved in their care.

3

Participants and methods

Papers included in this thesis are based on data from three different studies, two quantitative and one qualitative, that will be described herein.

3.1 VALIDATION STUDY

This study aimed to answer the first two specific objectives. We began by adapting and validating three existing individual health literacy instruments, the Medical Term Recognition Test (METER), the Newest Vital Sign (NVS) and the Brazilian Short Assessment of Health Literacy for Portuguese Adults (SAHLPA). Concerning construct validity testing, our strategy relied on examining known-groups validity, that is, administering the instrument to different groups that logically should have different levels of the construct to confirm whether the hypothesised difference was reflected in the scores of the groups. Thus, we assumed health literacy would decrease across groups with progressively lower familiarity obtaining and processing health information, in the following order: physicians, health researchers, engineering researchers, laypersons from the general population (fig. 3.1). We used convenience sampling from the four different settings, in a total of 249 people. We also tested associations with known health literacy determinants, namely age and education.

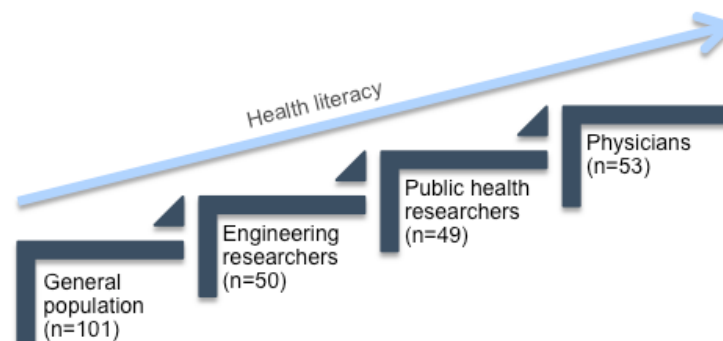


Figure 3.1: Main assumption in construct validity testing

We then compared their validity using structural equation modelling and compared their precision and difficulty and calibrated them using item response theory.

3.2 NATIONAL SURVEY

Tackling objective 3 involved analysis of data from a national survey conducted in 2012, aiming to assess health knowledge and health behaviours of the Portuguese population. The study evaluated a representative sample of Portuguese-speakers of any nationality in mainland Portugal. It used a multi-stage stratified probabilistic sampling procedure. A total of 1624 valid interviews were obtained (response rate: 70.8% of those invited).

Participants were evaluated through face-to-face interviews conducted using Computer Assisted Personal Interviewing with a structured questionnaire, including one of the aforementioned instruments, NVS, to assess health literacy. All estimates were weighted to be representative of the Portuguese population, using the variables considered in the design. To calculate the prevalence of limited health literacy and respective 95% confidence intervals, individuals unable to read or write (n=79) as well as one with missing education data were excluded, leaving a final sample of 1544.

3.3 QUALITATIVE STUDY

This study aimed to answer objective 4 and explore communication experiences of patients with type 2 diabetes and the health professionals caring for them, in Northern Portugal. Participants were selected using a purposive sampling strategy, based on the characteristics that we believed would represent the broadest variation in opinions. Figure 3.2 outlines the methodology used in this study.

Sample and recruitment	Purposive sampling Five focus groups with patients with type 2 diabetes: <ul style="list-style-type: none"> • Focus group 1 (n=7): without diabetes complications • Focus group 2 (n=7): diabetic retinopathy • Focus group 3 (n=5): diabetic nephropathy • Focus group 4 (n=7): diabetic foot • Focus group 5 (n=7): ischemic heart disease or cerebrovascular disease Two focus groups with health professionals: <ul style="list-style-type: none"> • Focus group 6 (n=6): primary care physician; nurse; nutritionist; pharmacist; ophthalmologist; vascular surgeon; • Focus group 7 (n=6): endocrinologist; nurse; nutritionist; pharmacist; psychologist, nephrologist
Data collection	Age and length of experience diversity (professional or disease experience) <ul style="list-style-type: none"> • <i>Patients</i> (2015-2016) • <i>Healthcare professionals</i> (2012) Semi-structured interview guide: factors that constrain and facilitate communication Audio-recorded and transcribed verbatim
Data analysis	Grounded theory (Bryant & Charmaz, 2007): Open coding (categories) → Axial coding (themes) → Selective coding (core themes loaded with patient-centred communication theory) - NVivo 10

Figure 3.2: Qualitative study methods

The sampling covered the standard range of areas of expertise involved in the care of type 2 diabetes patients in Portugal, and the typical range of diabetes micro and macrovascular complications. Within groups heterogeneity was pursued regarding age and professional experience/disease duration. We conducted two focus groups of health professionals in 2012 in a research institute and five focus groups of patients between 2015 and 2016 in a health center for the group without diabetes complications or a hospital for the remaining groups.

Focus groups followed a semi-structured set of questions aimed at understanding the experiences in communication between people living with type 2 diabetes and their healthcare professionals. Questions covered factors that constrain and facilitate communication, patients' information needs, and methods used for gathering and providing information. All the focus groups included a trained moderator and a co-moderator. Focus group discussions lasted from 56 to 93 minutes, with a median duration of 90 minutes. The audio of the focus groups was recorded, professionally transcribed verbatim and checked for accuracy.

Data were analysed independently by the first two authors using grounded theory, with NVivo 10 (QSR International, USA, 2013), and merged by consensus following continuous and iterative discussions, to strengthen coding consistency. This triangulation was further supported by the researchers' different backgrounds (medicine and sociology). In addition, classifications were always discussed and validated by the last author. Open coding, axial coding and selective coding were used. Quotations with similar meanings were synthesised into categories (open coding), which were then put together into themes (axial coding), and then into core themes (selective coding). During selective coding, inductive themes were loaded with interpersonal patient-centred communication theory in consultation with existing literature.

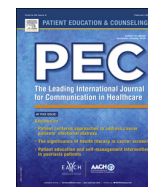
The great enemy of communication, we find, is the illusion of it. We have talked enough; but we have not listened. And by not listening we have failed to concede the immense complexity of our society – and thus the great gaps between ourselves and those with whom we seek understanding.

W. H. Whyte. “Is Anybody Listening?” (1952)

4

Papers

4.1 CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE HEALTH LITERACY ASSESSMENT TOOL METER IN THE PORTUGUESE ADULT POPULATION



Assessment

Cross-cultural adaptation and validation of the health literacy assessment tool METER in the Portuguese adult population



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ABSTRACT

Objective: We aimed to culturally adapt and validate METER in the Portuguese population, and to define cut-off values for adequate health literacy.

Methods: We used the standard procedure for the adaptation of the words and surveyed health professionals to select the non-words. The instrument was administered to a total sample of 249 participants and retested in a sub-sample of 45 after three months. Cut-offs were defined using the modified Angoff procedure. Construct validity was assessed through association with educational attainment and health-related occupation.

Results: Exploratory factor analysis revealed two dimensions of the instrument, one for words and another for non-words. METER showed a high degree of internal consistency, and acceptable test–retest reliability. Adequate health literacy was defined as scoring at least 35/40 in words and 18/30 in non-words. Physicians scored higher than any other group, followed by health researchers, researchers from other areas and by people with progressively lower levels of education ($p < 0.001$).

Conclusion: We culturally adapted a brief and simple instrument for health literacy assessment, and showed it was valid and reliable.

Practice implications: The Portuguese version of METER can be used to assess health literacy in Portuguese adults and to explore associations with health outcomes.

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1. Introduction

Individual health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [1]. Inadequate health literacy is more prevalent among the elderly, those with lower levels of educational attainment [2] and with chronic disease [3]. It is associated with poorer self-management skills, less successful navigation of the healthcare system, higher morbidity and mortality [3–6].

The European Health Literacy Survey 2011 [7], conducted in eight European countries (Austria, Bulgaria, Germany, Greece, Ireland, the Netherlands, Poland, and Spain) found that only between 36.7% (in Spain) to 76.3% of the population (in the Netherlands) had adequate health literacy, as assessed by the Newest Vital Sign [8]. In Portugal, although health literacy has started to appear in the national political agenda [9], there are no published studies on the prevalence of adequate health literacy.

Health literacy is commonly measured using instruments based on word recognition or pronunciation: Medical Term Recognition Test (METER) [10], Rapid Estimate of Adult Literacy in Medicine (REALM) [11], Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA) [12], Medical Terminology Achievement Reading Test (MART) [13]; or reading comprehension and numeracy: Newest Vital Sign (NVS) [8], Test of Functional Health Literacy in Adults (TOFHLA) [14]. Most instruments were initially developed in English or Spanish and are being adapted worldwide

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[15–19]. Word pronunciation-based instruments perform well in English but have failed adaptation to languages with very high letter to sound correspondence (such as Spanish, Portuguese and Korean) because they are unable to discriminate between health literacy and ability to read [12,16,20]. METER is based on word/non-word recognition and is open-use, very brief, and self-administered, which means it can be added to a form or questionnaire without increasing participant burden considerably. We aimed to culturally adapt and validate METER in the Portuguese population, and to define cut-off values for adequate health literacy.

2. Methods

2.1. Original instrument

METER is an English language open use instrument based on REALM, consisting of a list of 40 medical words and 30 made-up non-words that intuitively sound like real medical terms. It is self-administered and it takes on average two minutes to complete. The participants are requested to mark only the words they are sure to be actual words. The score is calculated as the sum of all the correct words marked. The original METER performance cut-off points defined by the authors were 0–20 for low, 21–34 for marginal and 35–40 for functional health literacy levels [10].

2.2. Cross-cultural adaptation

We used the standard procedure for word adaptation [21]. An expert committee (with backgrounds in Family Medicine, Internal Medicine, Pharmacy, Psychology, and Sociology) ensured conceptual and item equivalence. Afterwards, two native Portuguese speakers proficiently fluent in English translated METER independently and merged the translations into a single Portuguese version. Next, two native English speakers, proficient in Portuguese, independently back-translated this version. They were unaware of the purpose of the instrument and had not seen the original version. The translators arrived at a consensus back-translated version, which was then revised and compared to the original by the committee, resolving any discrepancies between the two versions.

For the non-words, we surveyed 25 health professionals to identify common misspellings and build up constructions based on real medical terms, 30 of which were selected by the research team for inclusion in the instrument. The selection criteria were to avoid redundancy and to maximize diversity of conceptual areas.

This version was pre-tested in a small group of six lay people and the instructions wording was adjusted for the sake of clarity.

2.3. Sample and recruitment

The adapted version of the test was administered to a convenience sample of 249 people from several heterogeneous groups: physicians (from public hospitals and primary care health centers), health researchers (from a research institute), researchers from areas unrelated to health (from an engineering faculty), and general population (from a primary care health center). In the absence of prevalence data of inadequate health literacy in this population, the sample size was estimated based on other validation studies [8,11,12]. To assess construct validity we assumed that physicians would score highest on health literacy tests, followed by health researchers, people with a similar academic degree in areas unrelated to health, and by people with progressively lower levels of education attainment.

Eligibility criteria for the participants were age over 18 years and ability to speak and read Portuguese. Potential participants

with impaired vision were excluded. The instrument was re-administered to a convenience group (45 health researchers) after a three-month interval to assess test–retest reliability. This rather long test–retest interval of time aimed to reduce mnesic/learning bias.

The present investigation was carried out in accordance with the Code of Ethics of the Declaration of Helsinki and approved by the Ethics Committee of Centro Hospitalar de São João and the National Committee for Data Protection. Each participant provided written informed consent.

2.4. Cut-off definition

In the absence of a gold standard, cut-offs were defined using the modified Angoff procedure, a content-procedure method extensively applied for establishing absolute assessment criteria [22]. It is based on expert judgment of minimal competence of marginally competent individuals: a panel of judges trained in the use of the method discusses and agrees on the characteristics of a examinee scoring “borderline” for adequate health literacy and independently classifies each item according to the question “*Can a person with minimal competence answer the item correctly?*”, given a three-choice option of “yes”, “no” or “*don't know*”. An average of the scores of the judges is calculated to provide a passing score (the cut-off). The judges are allowed to review and discuss the initial scores and are given the option to independently alter their own classification if they wish to; this strategy usually does not change cut-offs meaningfully but reduces variability between judges [23]. The panel comprised six health literacy experts (with backgrounds in Family Medicine, Internal Medicine, Pharmacy, Psychology, and Sociology).

We used this method to dichotomize health literacy levels into adequate or inadequate in order to help guide decisions to tailor patient education and communication interventions to the patients' needs, both in future research and clinical practice.

2.5. Statistical analysis

Exploratory factor analysis was performed on the 70 items to evaluate homogeneity (i.e., to confirm there was a single latent variable measuring word recognition) and Cronbach's alpha was used to measure internal consistency. An item was considered to load in a determined factor when it showed an absolute factor loading higher than 0.4.

Physicians were excluded from these analyses, since they are not targets of the instrument. The global goodness of fit of the underlying model was evaluated using the comparative fit index (CFI), recommended for sample sizes below 250 [24].

Logistic regression was used to compare the prevalence of adequate health literacy across validation groups, adjusting for age.

Test–retest reliability was assessed using the standard error of measurement and respective two-way mixed intra-class correlation coefficient single-measure (ICC).

Exploratory factor analysis models were fitted using MPlus (V.5.2; Muthen & Muthen, Los Angeles, California, USA). All other statistical analyses were performed using Stata version 11.1 for Windows (StataCorp LP, College Station, TX).

3. Results

Demographic characteristics of the sample by validation group are summarized in Table 1. Women made up the majority of respondents in all validation groups (56.6%), except for the group of researchers in areas unrelated to health (12.0%). Less educated people were older.

Table 1
Demographic characteristics of the sample by validation group.

Validation group	n	Age in years, mean (SD)	Women, n (%)
Physicians	53	32.3 (7.1)	34 (64.2)
Health researchers	45	29.6 (5.6)	37 (82.2)
Other researchers	50	43.8 (13.0)	6 (12.0)
General population			
College education	18	41.6 (13.7)	11 (61.1)
12th grade	15	34.8 (11.1)	8 (53.3)
9th–11th grade	22	38.5 (12.4)	14 (63.6)
5th–8th grade	17	41.4 (14.0)	10 (58.8)
≤4th grade	29	61.1 (9.2)	21 (72.4)

SD—standard deviation.

3.1. Exploratory factor analysis

The scree plot curve inflected at the second component, revealing two underlying dimensions of the instrument (Fig. 1). Exploratory factor analysis confirmed these two dimensions, with almost all the items representing real words being included in the first dimension, and all the non-words in the second (Table 2). The CFI of the model improved from 0.83 in the uni-dimensional model to 0.93 with the two dimensions.

Fig. 2 depicts the plot of the percentage of correctly marked words against the percentage of non-words that were correctly not selected. The former ranged from 15 to 100%, whereas the latter from 45 to 100%. These two dimensions were poorly correlated ($r = 0.22$) and three patterns emerged, visually: a group of people scoring over two-thirds in both; a group scoring lower in the identification of real words and a group scoring lower in non-words. No one correctly identified less than two-thirds of both words and non-words.

3.2. Reliability

METER showed a high degree of reliability, with a Cronbach's alpha of 0.92 for the first dimension and 0.83 for the second. In the retest study after three months, the standard error of measurement was 1.54 for the words (ICC 0.49) and 0.82 for the non-words (ICC 0.61).

3.3. Cut-off definition

The final cut-offs defined by the judging panel using the Angoff method were 35 correct answers in the words subscale and 18 correct answers in the non-words subscale. The review, discussion and experts' independent adjustment of the initial scores kept cut-offs roughly unchanged (the cut-off for non-words increased by one point in the second round and the cut-off for words remained

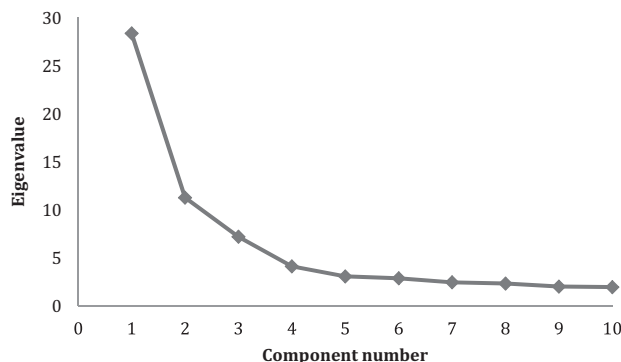


Fig. 1. Scree plot of eigenvalues after exploratory factor analysis.

constant) and reduced the variability between judges (the standard deviations decreased from 3.45 to 1.21 and from 2.71 to 1.50, for non-words and words, respectively).

We used these cut-offs to categorize health literacy as inadequate or adequate; adequate was defined as scoring at least the cut-off value in both words and non-words, i.e. $\geq 35/40$ and $\geq 18/30$, respectively.

3.4. Validity

Physicians scored higher than any other group, followed by health researchers, non-health researchers and by people with progressively lower levels of education (Fig. 3). The age-adjusted prevalence of adequate health literacy increased consistently across validation groups (OR = 2.79 for physicians, compared to people with education attainment below the fourth grade; p for trend <0.001).

4. Discussion and conclusion

4.1. Discussion

We culturally adapted a health literacy instrument that is brief and simple, and showed it was valid and reliable. This instrument can be used to assess health literacy levels and to sort between adequate and inadequate health literacy. We propose that words and non-words should be treated as different sub-scales with separate scoring.

Exploratory factor analysis revealed two dimensions of the instrument, one for words and another for non-words, implying that some individuals scored high in one dimension and low in the other. Because of the design of the original instrument, in which the participants are required to mark only the words they are sure to be actual words and not individually mark each item as true or false, the non-word items likely measure more than merely word recognition. The results suggest that this dimension also measures risk aversion, i.e. individuals more averse to error mark less words and non-words, thus scoring lower in the words sub-scale and higher in the non-word subscale; the opposite applies to less cautious individuals. The fact that no one scored very low in both dimensions supports this interpretation. With the original scoring instructions (total score as the sum of all the correct words marked), in the unlikely event that a participant marked all of the items, he/she would achieve the maximum score, even though that would not correspond to adequate health literacy. Therefore, scoring the two dimensions independently and then combining the performance on both sub-scales will reduce the misclassification of individuals with inadequate health literacy.

The rare exceptions to the perfect correspondence between words and non-words and each of the two dimensions were items 4 (a word that could fit in either dimension), item 37 (a non-word that could fit in either dimension), and item 47 (a word that does not fit in either dimension). Only one individual neglected to correctly mark item 4 as a word, and this might have misestimated the correlation due to ceiling effects, loading the item in both dimensions. Item 37 is one of the good examples of the effect of the small but significant correlation between the first and second dimensions - several items partially cross-loaded in both (as can be observed by the small factor loading differences between factors one and two). Item 47 is "impetigo", a contagious skin infection which causes sores and blisters, and relatively unfamiliar to lay people. Very few non-physicians correctly selected this word and this could explain why it does not fit in either dimension; it seems to be almost exclusively recognized by health professionals. Our finding is consistent with the word frequency effect in word

Table 2

Correct answers per item in words and non-words, and standardized factor loadings for one and two factors in exploratory factor analysis.

			Correct answers n (%)	Standardized factor loadings		
				One factor	Two factors	
					Factor 1	Factor 2
Words	Portuguese	English				
METER 2	Artrite	Arthritis	173 (88.3)	0.729	0.847	−0.104
METER 3	Obesidade	Obesity	183 (93.4)	0.849	0.952	−0.105
METER 4	Gripe	Flu	195 (99.5)	0.893	0.424	0.758
METER 6	Sífilis	Syphilis	148 (75.5)	0.668	0.885	−0.280
METER 7	Potássio	Potassium	161 (82.1)	0.746	0.861	−0.108
METER 8	Hormonas	Hormones	178 (90.8)	0.745	0.819	−0.015
METER 9	Nervos	Nerves	191 (97.4)	0.647	0.600	0.224
METER 14	Exercício	Exercise	176 (89.8)	0.650	0.745	−0.015
METER 15	Pústula	Pustule	63 (32.1)	0.187	0.587	−0.450
METER 17	Rim	Kidney	192 (98.0)	0.882	0.890	0.142
METER 18	Urgência	Emergency	185 (94.4)	0.617	0.633	0.115
METER 20	Menopausa	Menopause	192 (98.0)	0.769	0.794	0.146
METER 21	Diagnóstico	Diagnosis	182 (92.9)	0.906	0.947	−0.019
METER 23	Icterícia	Jaundice	110 (56.1)	0.466	0.769	−0.333
METER 24	Bexiga	Bladder	191 (97.4)	0.907	0.900	0.131
METER 25	Aborto	Miscarriage	192 (98.0)	0.888	0.870	0.175
METER 26	Hepatite	Hepatitis	189 (96.4)	0.927	0.945	0.047
METER 29	Asma	Asthma	192 (98.0)	0.898	0.897	0.151
METER 30	Inflamatório	Inflammatory	185 (94.4)	0.734	0.836	−0.019
METER 31	Anemia	Anemia	190 (96.9)	0.880	0.923	0.054
METER 34	Stress	Stress	186 (94.9)	0.848	0.906	−0.003
METER 39	Cancro	Cancer	192 (98.0)	0.902	0.878	0.145
METER 41	Antibióticos	Antibiotics	191 (97.4)	0.870	0.893	0.104
METER 43	Colite	Colitis	116 (59.2)	0.225	0.542	−0.306
METER 44	Diabetes	Diabetes	194 (99.0)	0.896	0.754	0.394
METER 47	Impetigo	Impetigo	10 (5.1)	−0.306	0.059	−0.561
METER 48	Menstrual	Menstrual	186 (94.9)	0.710	0.797	0.014
METER 50	Convulsão	Seizure	175 (89.3)	0.833	0.882	−0.007
METER 51	Apêndice	Appendix	184 (93.9)	0.866	0.938	−0.058
METER 54	Dose	Dose	166 (84.7)	0.754	0.895	−0.187
METER 55	Hemorroidas	Hemorrhoids	161 (82.1)	0.303	0.396	−0.017
METER 56	Testículo	Testicle	186 (94.9)	0.931	0.982	−0.065
METER 57	Olho	Eye	192 (98.0)	0.851	0.850	0.174
METER 61	Sexualmente	Sexually	179 (91.3)	0.596	0.674	0.018
METER 64	Medicação	Medication	191 (97.4)	0.731	0.759	0.131
METER 65	Micróbios	Germs	174 (88.8)	0.527	0.559	0.079
METER 66	Gonorreia	Gonorrhea	120 (61.2)	0.529	0.820	−0.342
METER 68	Fadiga	Fatigue	185 (94.4)	0.778	0.841	0.020
METER 69	Osteoporose	Osteoporosis	186 (94.9)	0.642	0.670	0.102
METER 70	Obstipação	Constipation	146 (74.4)	0.518	0.742	−0.184
Non-words						
METER 1	Imígdala	N/A	176 (89.8)	0.345	0.120	0.346
METER 5	Nervosite	N/A	173 (88.3)	0.665	0.312	0.551
METER 10	Anquia	N/A	195 (99.5)	0.868	0.426	0.759
METER 11	Cástula	N/A	195 (99.5)	0.889	0.426	0.757
METER 12	Ingesto	N/A	173 (88.3)	0.345	−0.081	0.581
METER 13	Intestigo	N/A	181 (92.3)	0.335	−0.023	0.520
METER 16	Cerpes	N/A	194 (99.0)	0.650	0.381	0.565
METER 19	Xirope	N/A	187 (95.4)	0.623	0.370	0.458
METER 22	Candíase	N/A	167 (85.2)	0.122	−0.298	0.540
METER 27	Enatoma	N/A	185 (94.4)	0.575	0.223	0.552
METER 28	Unhal	N/A	190 (96.9)	0.455	0.031	0.723
METER 32	Linsoma	N/A	182 (92.9)	0.328	−0.022	0.509
METER 33	Ceresiana	N/A	158 (80.6)	0.336	−0.014	0.472
METER 35	Algérico	N/A	173 (88.3)	0.295	0.067	0.337
METER 36	Jezum	N/A	166 (84.7)	0.393	0.174	0.345
METER 37	Súrgico	N/A	191 (97.4)	0.643	0.440	0.378
METER 38	Malorias	N/A	195 (99.5)	0.868	0.426	0.759
METER 40	Alcoolidade	N/A	160 (81.6)	0.294	−0.107	0.510
METER 42	Antidepressivo	N/A	170 (86.7)	0.395	−0.111	0.640
METER 45	Otorringologista	N/A	138 (70.4)	0.221	−0.096	0.374
METER 46	Nósea	N/A	189 (96.4)	0.491	0.116	0.635
METER 49	Gatarral	N/A	192 (98.0)	0.444	0.138	0.572
METER 52	Abdominável	N/A	151 (77.0)	0.352	−0.129	0.579
METER 53	Enxuteca	N/A	192 (98.0)	0.589	0.244	0.622
METER 58	Obstérico	N/A	183 (93.4)	0.382	−0.205	0.812
METER 59	Sonambulação	N/A	168 (85.7)	0.321	−0.211	0.664
METER 60	Drenação	N/A	153 (78.1)	0.136	−0.323	0.548

Table 2 (Continued)

			Correct answers <i>n</i> (%)	Standardized factor loadings		
				One factor	Two factors	
					Factor 1	Factor 2
METER 62	Purisia	N/A	193 (98.5)	0.594	0.161	0.762
METER 63	Fibrómico	N/A	184 (93.9)	0.421	−0.076	0.707
METER 67	Estómico	N/A	185 (94.4)	0.571	0.117	0.700
Cronbach's alpha				0.894	0.916	0.828

N/A: English not applicable for the non-words.

* Literal translation to English instead of the original version when Portuguese words were adjusted to maintain semantic and/or structural equivalence.

recognition, in which low frequency words are less often recognized as words [25].

The instrument had a high internal consistency (Cronbach's alpha ≥ 0.80) in both domains, similar to that of the original instrument (Cronbach's alpha = 0.93) [10] and of other health literacy tests [13,14].

The test–retest reliability was only reasonably acceptable as it is context-specific and depends on how much participants differ from each other. Even if the variability between the results in the two trials is negligible, the ICC will be small if the retest group is homogenous [26], as was the case in the group of health researchers, which is a limitation of this study.

The cut-off for the non-words could be underestimated by the Angoff method because the way it is done does not reflect the instrument's instructions, previously mentioned. It may have been hard for the judges to keep coming back to the concept that the test score default for non-words is inaction and that this corresponds to maximum score. Answering “yes/no/don't know” to the question of whether a minimally competent individual would answer the question correctly is more suitable to items with a true/false format. Despite the good performance of the final version of the instrument in discriminating the several validation groups, further studies comparing the performance of the non-word subscale with that of other health literacy tests are needed.

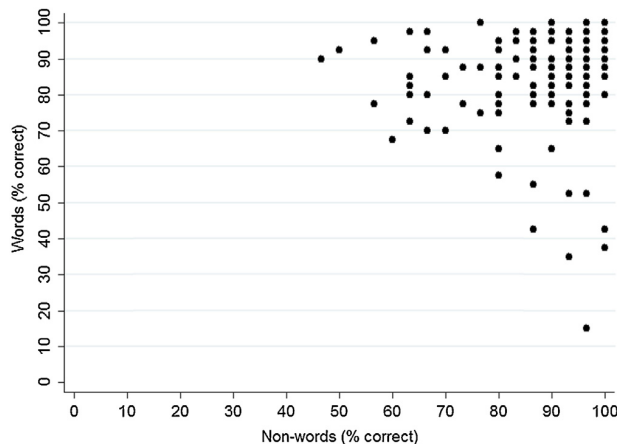
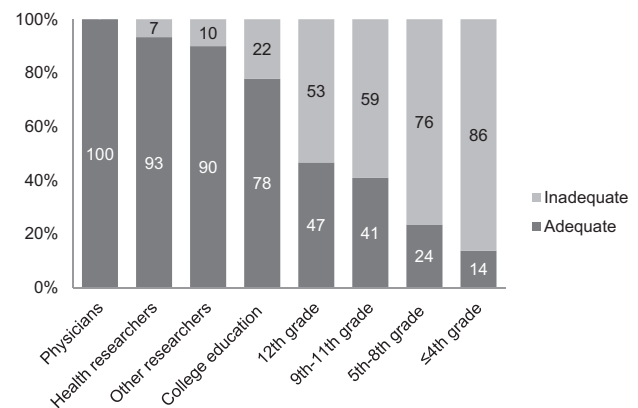
Different health literacy assessment instruments categorize health literacy scores into a variable number of categories in addition to providing a continuous score [27]. We decided to dichotomize the scores into adequate and inadequate instead of maintaining the three categories of the original instrument to simplify the decision-making regarding health education interventions for patients with inadequate health literacy, both in research and clinical settings.

Some validation studies of health literacy instruments have used concurrent validation, that is, through the comparison with

an existing instrument. This is a controversial option given the multiple proposed definitions of the underlying construct [28] and the diverse and restrictive scope of the instruments [27]. There is just no way to tell which one better represents health literacy. Our strategy assumed that health literacy should be higher in physicians, followed by health researchers, people with a similar academic degree in areas non-related to health and by people with progressively lower levels of education attainment. The data confirm this hypothesis and this suggests that the instrument measures more than educational attainment, but we cannot exclude the possibility of it not measuring more than the ability to recognize medical jargon—only one of the aspects of health literacy. Furthermore, METER and other word recognition tests do not directly address the individual ability of accessing, understanding, processing and communicating information that is included in the health literacy construct; vocabulary knowledge plays only a small part in these competencies. However, the score in these instruments is associated with other clinically relevant health measures and may be used to screen for individuals who could use more help in understanding and acting on health information. The comparison with the performance of other health literacy instruments may shed some light on this issue by exploring the need to use multiple instruments simultaneously to assess health literacy.

4.2. Conclusion

We culturally adapted and validated METER in the Portuguese population and defined cut-off values for adequate health literacy. This instrument distinctly differentiates individuals based on educational attainment and health-related occupation, in spite of measuring only vocabulary knowledge—a small part of the health literacy construct. Future studies should reveal how it performs when used together with health literacy instruments not based on word recognition.

**Fig. 2.** Percent correct answers in words and non-words in METER.**Fig. 3.** Health literacy by validation group.

4.3. Practice implications

The Portuguese version of METER can be used to assess health literacy in Portuguese adults and to explore associations with health outcomes. Further studies are needed to determine the usefulness of this instrument as a screening tool and decision-aid in clinical settings, either used on its own or in combination with other health literacy assessment tests.

Measuring the health literacy of Portuguese adults can highlight the issue of inadequate health literacy in the national political agenda, and raise awareness by the general population. In turn, this could indirectly promote system changes to improve the communication of health information, namely by encouraging strategies that enhance comprehension by health consumers. These strategies will benefit not only those with inadequate health literacy but potentially everybody.

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Appendix A

Validated version of the instrument

A lista seguinte inclui alguns termos que existem na linguagem médica. Alguns desses termos estão relacionados com partes ou funções do corpo, com tipos de doenças ou com coisas que podem melhorar ou piorar a saúde. A lista também contém algumas palavras que podem parecer ou soar como termos reais, mas que não existem.

À medida que for lendo esta lista, coloque uma cruz "X" ao lado das palavras que são termos reais. Não tente adivinhar. Coloque uma cruz "X" ao lado das palavras só quando tiver a certeza que existem mesmo.

<input type="checkbox"/> Imígdala	<input type="checkbox"/> Jezum
<input type="checkbox"/> Artrite	<input type="checkbox"/> Súrgeo
<input type="checkbox"/> Obesidade	<input type="checkbox"/> Malórias
<input type="checkbox"/> Gripe	<input type="checkbox"/> Cancro
<input type="checkbox"/> Nervosite	<input type="checkbox"/> Alcoolidade
<input type="checkbox"/> Sífilis	<input type="checkbox"/> Antibióticos
<input type="checkbox"/> Potássio	<input type="checkbox"/> Antidepressivo
<input type="checkbox"/> Hormonas	<input type="checkbox"/> Colite
<input type="checkbox"/> Nervos	<input type="checkbox"/> Diabetes
<input type="checkbox"/> Anquia	<input type="checkbox"/> Otorringologista
<input type="checkbox"/> Cástula	<input type="checkbox"/> Nósea
<input type="checkbox"/> Ingesto	<input type="checkbox"/> Impetigo
<input type="checkbox"/> Intestigo	<input type="checkbox"/> Menstrual
<input type="checkbox"/> Exercício	<input type="checkbox"/> Gatarral
<input type="checkbox"/> Pústula	<input type="checkbox"/> Convulsão
<input type="checkbox"/> Cerpes	<input type="checkbox"/> Apêndice
<input type="checkbox"/> Rim	<input type="checkbox"/> Abdominável
<input type="checkbox"/> Urgência	<input type="checkbox"/> Enxutea
<input type="checkbox"/> Xirope	<input type="checkbox"/> Dose
<input type="checkbox"/> Menopausa	<input type="checkbox"/> Hemorroidas
<input type="checkbox"/> Diagnóstico	<input type="checkbox"/> Testículo
<input type="checkbox"/> Candiase	<input type="checkbox"/> Olho
<input type="checkbox"/> Icterícia	<input type="checkbox"/> Obstérico
<input type="checkbox"/> Bexiga	<input type="checkbox"/> Sonambulação
<input type="checkbox"/> Aborto	<input type="checkbox"/> Drenação
<input type="checkbox"/> Hepatite	<input type="checkbox"/> Sexualmente
<input type="checkbox"/> Enatoma	<input type="checkbox"/> Purisia
<input type="checkbox"/> Unhal	<input type="checkbox"/> Fibrômico

<input type="checkbox"/> Asma	<input type="checkbox"/> Medicação
<input type="checkbox"/> Inflamatório	<input type="checkbox"/> Micróbios
<input type="checkbox"/> Anemia	<input type="checkbox"/> Gonorreia
<input type="checkbox"/> Linsoma	<input type="checkbox"/> Estômico
<input type="checkbox"/> Ceresiana	<input type="checkbox"/> Fadiga
<input type="checkbox"/> Stress	<input type="checkbox"/> Osteoporose
<input type="checkbox"/> Algérico	<input type="checkbox"/> Obstipação

Correct answers in boldface.

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4.2 SAHLPA VALIDATION IN THE PORTUGUESE POPULATION: A USEFUL INSTRUMENT TO ASSESS HEALTH LITERACY IN LOW-LITERATE ADULTS

SAHLPA validation in the Portuguese population: a useful instrument to assess health literacy in low-literate adults

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Abstract

The Brazilian version of the Short Assessment of Health Literacy in Portuguese-speaking Adults (SAHLPA), a 50-item reading ability and comprehension test, has been proposed as a particularly helpful instrument to assess health literacy in people with limited skills. We aimed to validate it in the Portuguese population.

We used the standard procedure for cultural adaptation and administered the instrument to 249 participants. We examined construct validity using groups with expectedly increasing levels of health literacy (laypersons from the general population, engineering researchers, health researchers, and physicians), and through association with age and educational attainment, dichotomising scores at the median of the layperson's group.

Exploratory factor analysis revealed the instrument was one-dimensional and justified reduction to 33 items. SAHLPA-33 displayed adequate reliability (Cronbach's $\alpha=0.73$). The frequency of limited health literacy was highest among laypersons and lowest among physicians ($p<0.001$; p for trend <0.001). The proportion of participants with limited health literacy decreased with increasing education attainment (age- and sex-adjusted p for trend <0.001). Limited health literacy also tended to decrease with age, although the association was non-significant (sex- and education-adjusted p for trend $=0.067$).

We culturally adapted a brief and simple instrument for health literacy assessment, and showed it was valid and fairly reliable. In Portuguese low-literate adults, SAHLPA-33 fills the gap in health literacy assessment instruments, and may be used to guide communication strategies with vulnerable patients and communities.

Keywords: health literacy; SAHLSA; SAHLPA; validation studies; Portugal.

Introduction

Individual health literacy has been defined as the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts to promote and maintain health across the life-course'.¹ Limited health literacy has been linked to various adverse outcomes, including higher mortality, and is more common among the elderly, immigrants, and those with lower levels of education.²⁻⁵

In the past three decades, numerous instruments have been developed to screen for limited individual health literacy in research or clinical settings.⁶ The most widely used include the 66-item Rapid Estimate of Adult Literacy in Medicine (REALM),⁷ and the full and short versions of the Test of Functional Health Literacy in Adults (TOFHLA⁸ and STOFHLA⁹).³ Most of them were originally developed in English and are being adapted to other languages and populations.⁶ The REALM¹⁰ is a 125-item instrument developed as a fast screening tool to identify patients with limited abilities to read common medical and lay terms for body parts and illnesses. It presents words in ascending order of difficulty and is based on the idea that patients having trouble reading and pronouncing words probably will have issues with reading comprehension. The most commonly used is the reduced 66-item version⁷ that is frequently used to estimate patient reading levels (converting raw scores into grade equivalents) and tailor communication with patients accordingly.

In languages with very high letter to sound (phoneme-grapheme) correspondence, such as Spanish and Portuguese, the adaptation of health literacy assessment instruments based on word recognition and pronunciation, such as the REALM, is hindered by their inability to discriminate between health literacy and ability to read.^{11;12} The Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA)¹³ was designed to overcome this issue by incorporating word comprehension. It has been adapted to Portuguese and validated in the Brazilian population as the Short Assessment of Health Literacy for Portuguese-speaking Adults (SAHLPA).¹⁴ These instruments have been proposed as less intimidating alternatives to assess health literacy in a clinical setting, and particularly helpful in assessing health literacy in the population groups most vulnerable to limited health literacy.¹³ In Portugal, limited health literacy has been estimated to affect between 49¹⁵ and 73%¹⁶ of the population. There is a lack of health literacy instruments designed specifically for low-literate populations that can be used to tailor health education interventions, as well as to study the impact of this social determinant of health.¹⁷ Because of these characteristics, its brevity and ease of administration, we aimed to culturally adapt and validate SAHLPA in the Portuguese population.

Methods

Original instrument

The SAHLPA is the Brazilian adapted version of the SAHLSA. SAHLSA is based on the 66-item REALM¹⁰ supplemented by a simple comprehension test. An expert panel

using the Delphi method developed two simple terms to match each REALM medical term: a key (a word with similar meaning) and a distractor (a word unrelated to the medical term). The resulting instrument consists of 50 medical terms the participants are requested to read aloud and associate with one of two word options. Participants are shown 50 laminated flash cards, each with a medical term in boldface on top and a key and distractor at the bottom. Because the key and distractor are used to test comprehension, participants are asked not to guess and to answer “Don’t know” if they don’t know the correct association. To answer correctly, the participants must both correctly pronounce the medical term and match it to the key. The score is calculated as the sum of all correct answers and varies between 0 and 50. It was validated in a convenience sample of 201 Spanish-speaking adults living in the United States. It takes 3-6 minutes to complete.¹³

SAHLPA was validated in a convenience sample of 226 Brazilian adults over the age of 60. Construct validity was assessed through correlation with formal education, self-reported functional literacy and global cognitive testing. The cut-off point for inadequate health literacy was defined by the inability to fully understand a medical prescription by a sub-sample of the participants and was 42 for the 50-item version and 14 for the short version (SAHLPA-18). Both the full (50-items) and reduced versions (18-items) showed good psychometric properties (Cronbach’s $\alpha=0.93$ and 0.90 , respectively) and high correlation (>0.60) with the variables used for construct validity testing. The full version takes 3-6 minutes to administer and the short one 1-2 minutes.¹⁴

Cross-cultural adaptation of SAHLPA to European Portuguese

An expert committee (with backgrounds in Family Medicine, Internal Medicine, Pharmacy, Psychology, and Sociology) cross-culturally adapted SAHLPA into European Portuguese, ensuring semantic and item equivalence. To preserve semantic equivalence, some words were altered: “recreação” was replaced by “lazer”, “similar” by “semelhante”, “matrimônio” by “casamento”, “coceira” by “coçar”, “tranquilo” by “calmo”. Other words were changed to match the correct spelling used in Portugal and accommodate spelling differences between Brazil and the other Portuguese speaking countries: “estresse” was replaced by “stress”, “Papanicolaou” by “Papanicolau”, “dolorido” by “dorido” and “contraceptivo” by “contracetivo” (Table 1). Because of word pronunciation differences between regions in Portugal, all but overtly inappropriate accents (e.g. ignoring written accents) were accepted as correct.

A pilot version was administered to a sample of six people and the instructions wording was adjusted for clarity.

Sample and recruitment

The adapted version of the instrument was administered to a convenience sample of 249 people, as part of a validation study of individual health literacy instruments in the Portuguese population.¹² Participants were recruited from four different groups: physicians from public hospitals and primary care health centres ($n=53$), health researchers from

Table 1: Correct answers per item and standardised factor loadings in exploratory factor analysis

Item	Medical Term	Key/Distractor		Correct answers n(%) N=196	Standardised factor loadings
SAHLPA 1	Anemia	Nervo	<i>Sangue</i>	192(98.0)	0.65
SAHLPA 2	Menopausa	<i>Senhoras</i>	Meninas	195(99.5)	0.95
SAHLPA 3	Comida	<i>Jantar</i>	Passeio	195(99.5)	0.95
SAHLPA 4	Medicamento	Instrumento	<i>Tratamento</i>	194(99.0)	0.8
SAHLPA 5	Olho	Ouvir	Ver	196(100)	-
SAHLPA 6	Asma	<i>Respiração</i>	Pele	193(98.5)	0.72
SAHLPA 7	Gravidez	Parto	Infância	196(100)	-
SAHLPA 8	Intestino	Suor	<i>Digestão</i>	194(99.0)	0.88
SAHLPA 9	Alcoolismo	<i>Vício</i>	Lazer*	194(99.0)	0.81
SAHLPA 10	Depressão	Apetite	<i>Sentimentos</i>	185(94.4)	0.56
SAHLPA 11	Emprego	<i>Trabalho</i>	Educação	192(98.0)	0.68
SAHLPA 12	Pílula	<i>Comprimido</i>	Bolacha	195(99.5)	0.95
SAHLPA 13	Diabetes	<i>Açúcar</i>	Sal	194(99.0)	0.8
SAHLPA 14	Rim	<i>Urina</i>	Febre	193(98.5)	0.75
SAHLPA 15	Gordura	Laranja	<i>Manteiga</i>	194(99.0)	0.82
SAHLPA 16	Stress*	<i>Preocupação</i>	Feliz	195(99.5)	0.95
SAHLPA 17	Gripe	Saudável	<i>Doente</i>	193(98.5)	0.75
SAHLPA 18	Inflamatório	<i>Inchaço</i>	Suor	190(96.9)	0.6
SAHLPA 19	Avisar	Medir	<i>Dizer</i>	190(96.9)	0.68
SAHLPA 20	Obesidade	<i>Peso</i>	Altura	195(99.5)	0.95
SAHLPA 21	Hepatite	Pulmão	<i>Fígado</i>	185(94.4)	0.51
SAHLPA 22	Nutrição	Refrigerante	Saudável	162(82.7)	0.33
SAHLPA 23	Osteoporose	<i>Osso</i>	Músculo	194(99.0)	0.88
SAHLPA 24	Papanicolau*	<i>Teste</i>	Vacina	194(99.0)	0.79
SAHLPA 25	Aborto	Casamento*	<i>Perda</i>	194(99.0)	0.8
SAHLPA 26	Hemorroida	<i>Veias</i>	Coração	188(95.9)	0.61
SAHLPA 27	Anormal	Semelhante*	<i>Diferente</i>	193(98.5)	0.74
SAHLPA 28	Menstrual	<i>Mensal</i>	Diário	195(99.5)	0.95
SAHLPA 29	Ataque	Ferida	Saudável	181(92.4)	0.48
SAHLPA 30	Calorias	Vitaminas	<i>Alimentos</i>	183(93.4)	0.59
SAHLPA 31	Comportamento	Pensamento	Conduta	164(83.7)	0.45
SAHLPA 32	Convulsão	Tonto	Calmo*	181(92.4)	0.48
SAHLPA 33	Retal	Regador	<i>Supositório</i>	186(94.9)	0.54
SAHLPA 34	Alérgico	Resistência	<i>Reação</i>	194(99.0)	0.84
SAHLPA 35	Apêndice	Coçar*	<i>Dor</i>	194(99.0)	0.79
SAHLPA 36	Artrite	Estômago	<i>Articulação</i>	176(89.9)	0.57
SAHLPA 37	Cafeína	<i>Energia</i>	Água	184(93.9)	0.51
SAHLPA 38	Colite	Intestino	Bexiga	168(85.7)	0.29
SAHLPA 39	Vesícula biliar	Artéria	Órgão	180(91.8)	0.47
SAHLPA 40	Icterícia	Amarelo	Branco	151(77.0)	0.37
SAHLPA 41	Próstata	Circulação	<i>Glândula</i>	172(87.8)	0.53
SAHLPA 42	Potássio	Mineral	Proteína	154(78.6)	0.34
SAHLPA 43	Recomendado	Instrução	Decisão	167(85.2)	0.37
SAHLPA 44	Incesto	Família	Vizinhos	158(80.6)	0.41
SAHLPA 45	Irritação	Rígido	Dorido*	169(86.2)	0.35
SAHLPA 46	Sífilis	Contracetivo*	Preservativo	126(64.3)	0.28
SAHLPA 47	Testículo	Óvulo	<i>Esperma</i>	179(91.3)	0.55
SAHLPA 48	Herpes	Ar	Sexo	139(70.9)	0.28
SAHLPA 49	Impetigo	Cabelo	Pele	63(32.1)	-0.12
SAHLPA 50	Obstipação	Preso	Solto	160(81.6)	0.38

Cronbach's alpha: 0.73 (excluding the 17 removed items)

Removed items in boldface; * adjusted words from the Brazilian version to maintain semantic equivalence and/or correct spelling in European Portuguese; physicians were excluded from this analysis.

a research institute in Public Health (n=45), researchers from areas unrelated to health from an Engineering faculty (n=50), and laypersons from the general population users of a primary care health centre (n=101). Eligibility criteria for the participants were age over 18 years and ability to speak and read Portuguese. Potential participants with impaired vision were excluded.

Statistical analysis

Participant characteristics are described using frequencies and median [25th-75th percentiles (P25-P75)] as appropriate, by validation group, for sex and age, and compared across the groups using the χ^2 test for sex and the Kruskal-Wallis for age.

Exploratory factor analysis was performed on the 50 items and visual analysis of the scree plot was used to evaluate homogeneity (i.e., to verify there was a single latent factor measuring reading skills and comprehension). An item was considered to load in a certain factor when it showed an absolute factor loading higher than 0.5. Items with clear ceiling effects (100% participants answering correctly) and items with loadings <0.5 were removed from the instrument.

Cronbach's α was used to measure internal consistency. Physicians were excluded from these analyses, since they are not part of the target population of the instrument. The global goodness of fit of the underlying model was evaluated using the comparative fit index (CFI) recommended for sample sizes below 250.¹⁸

To assess construct validity we assumed that physicians would score highest on the health literacy test, followed by health researchers, people with a similar academic degree in areas unrelated to health, and finally by laypersons from the general population. Raw scores were compared across these validation groups with the Kruskal-Wallis test, complemented by pairwise comparisons, with a Bonferroni correction to adjust p-values for multiple comparisons. SAHLPA scores were also dichotomised at the median of the laypersons subsample into adequate health literacy (scores at or above the median) and limited health literacy. Fisher's exact test was used to compare proportions of limited health literacy across validation groups, with a test for linear trend. Logistic regression was used to calculate odds ratios (OR) and 95% confidence intervals (95%CI) to compare the odds of limited health literacy across age and education groups. Physicians were excluded from the regression analyses, since the instrument was not developed to assess them. A sensitivity analysis was performed restricting the regression analysis to the laypersons subsample. Two-sided p values less than 0.05 were considered to define a statistically significant result.

Exploratory factor analysis models were fitted using MPlus (V.5.2; Muthen & Muthen, Los Angeles, California, USA). All other statistical analyses were performed using STATA11®.

Ethics review and consent

The present investigation was carried out in accordance with the Code of Ethics of the Declaration of Helsinki and approved by the Ethics Committee of Centro Hospitalar

de São João and the National Committee for Data Protection. Both the authors of SAHLSA and SAHLPA authorised the adaptation and validation of the instrument in the Portuguese population. Each participant provided written informed consent.

Results

Characteristics of the sample are summarised in Table 2. Women made up the majority of respondents in all validation groups except for the group of engineering researchers, $p < 0.001$. Engineering researchers and laypersons from the general population were older ($p < 0.001$).

Table 2: Characteristics of the sample by validation group

	Physicians (n=53)	Health researchers (n=45)	Engineering researchers (n=50)	General population (n=101)	<i>p</i>
Women, n (%)	34 (64.2)	37 (82.2)	6 (12.0)	64 (63.4)	< 0.001
Age in years, median (P25-P75)	30.0 (27.0-34.0)	28.0 (26.0-31.0)	48.5 (31.0-53.0)	42.0 (34.0-58.0)	< 0.001

The scree plot curve inflected at the first component, revealing a single dimension of the instrument (Figure 1). The global fit of the underlying model was good (CFI 0.97). Two items (SAHLPA 5 e 7) were removed because of a ceiling effect and 15 items because they had factor loadings below 0.5 (Table 1). The final version contained 33 items (SAHLPA-33; Appendix). SAHLPA-33 showed an adequate degree of reliability, with a Cronbach's α of 0.73.

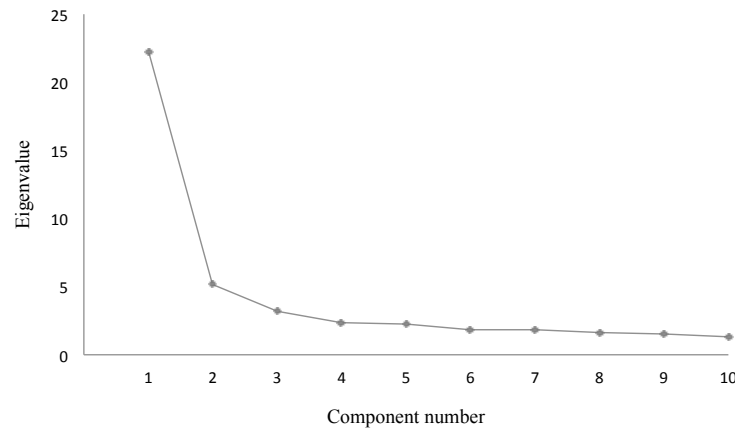


Figure 1: Scree plot of eigenvalues after exploratory factor analysis

The distributions of SAHLPA-33 scores were left skewed and with positive kurtosis

Table 3: Odds ratios and 95% confidence intervals (95%CI) for the association between sample characteristics and limited health literacy

	N (%)	Odds ratio (95% CI)	<i>p</i> for trend	Adjusted odds ratio* (95% CI)	<i>p</i> for trend
Age			0.257		0.067
18-30	59 (30.1)	Ref.		Ref.	
31-48	69 (35.2)	1.14 (0.46-2.82)		0.54 (0.18-1.58)	
49-86	68 (34.7)	1.63 (0.68-3.91)		0.37 (0.11-1.21)	
Sex					
Women	107 (54.6)	Ref.		Ref.	
Men	89 (45.4)	0.86 (0.43-1.74)		1.41 (0.62-3.19)	
Education attainment					<0.001
<9th grade	46 (23.5)	Ref.		Ref.	
9-12th grade	22 (11.2)	0.27 (0.09-0.85)		0.20 (0.06-0.70)	
>12th grade	128 (65.3)	0.09 (0.04-0.20)		0.05 (0.02-0.15)	

*Adjusted for all variables in the table

in all validation groups, but with different distribution shapes (Figure 2). The scores ranged from 24 to 33 in the general population subsample, 31 to 33 for researchers and 32 to 33 for physicians.

There was a statistically significant difference in mean ranks of SAHLPA-33 scores between the four validation groups ($p < 0.001$), with the group of laypersons from the general population exhibiting a lower mean rank of scores than the other groups (all $p < 0.001$), and the group of engineering researchers showing a lower rank of scores than physicians ($p = 0.042$).

Using health literacy as a binary variable, our data revealed evidence of an association between limited health literacy and validation group (Fisher's test $p < 0.001$; p for trend of the original hypothesis < 0.001). In regression analyses, limited health literacy was less common with increasing age, although not significantly (Table 3). There was a negative association between limited health literacy and education attainment (p for trend < 0.001). The strongest association was observed for people with education attainment above the twelfth grade; they were significantly less likely to have limited health literacy when compared to people with education attainment below the ninth grade (sex and age-adjusted OR=0.05, 95%CI 0.02-0.15).

When considering only the subsample of laypersons, results were similar: there was a significant negative association between limited health literacy and education attainment (p for trend=0.001) and no significant association with age, although the direction of the association was the same.

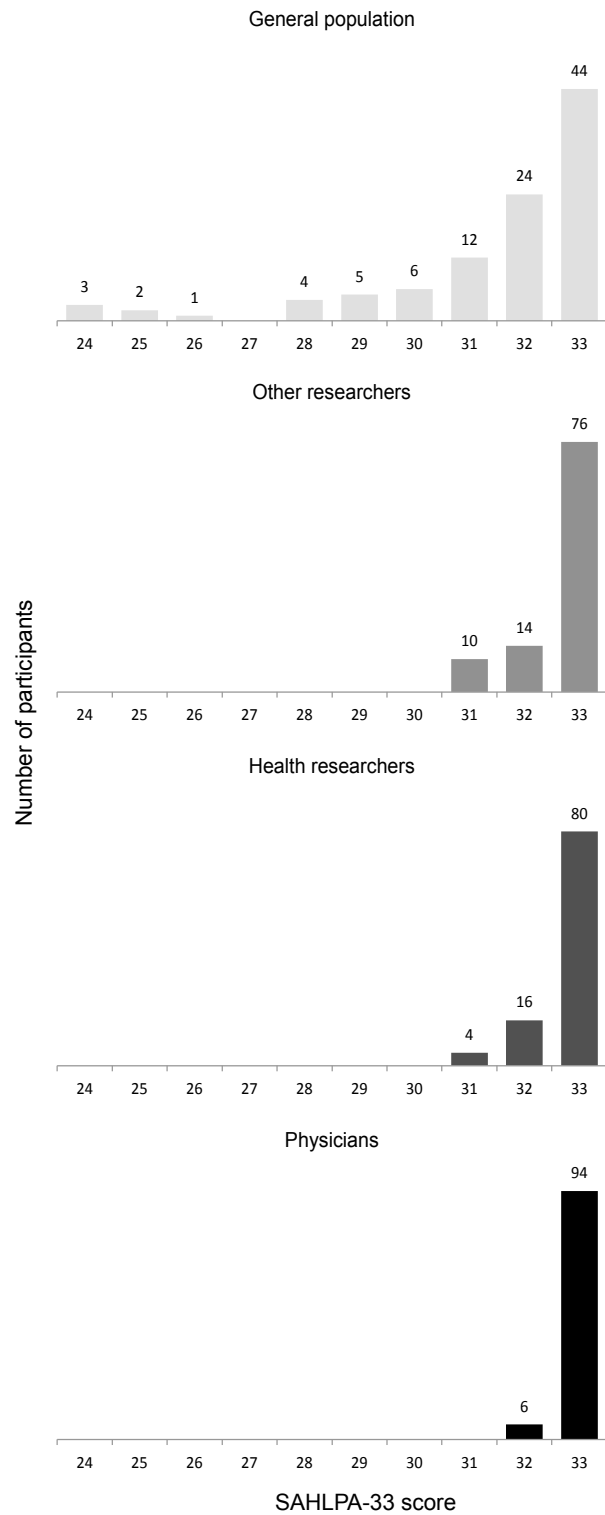


Figure 2: SAHLPA-33 score distribution by validation group

Discussion

We adapted a brief and simple health literacy instrument to European Portuguese, and showed that it was valid and fairly reliable in the Portuguese population. Regarding construct validity, health literacy was significantly associated with health occupation and higher education attainment.

Our results revealed an evident left skew and positive kurtosis in the SAHLPA scores. This asymmetry in scores distribution was more pronounced in our study than in the Brazilian one, which may be explained by the use of a more diverse and literate sample: the average score of the 50-item SAHLPA in our sample was 6 points higher than that found in the Brazilian study, even when considering only the laypersons subsample (43.8, standard deviation (SD)=4.4 vs. 37.7, SD=9.0), and 9 points higher when considering the whole sample (46.7, SD=3.8).¹⁴ Furthermore, validation of SAHLPA in the Brazilian population was restricted to patients over 60 years old (mean 74.4 years) and a quarter of the sample (25.7%) had less than 4 years of schooling.¹⁴ In contrast, our sample included participants between 18 and 86 years (median 38.5 years), and only 14.8% had less than 4 years of schooling. Hence, our study design oversampled people with higher health literacy, pushing scores to the upper end of the scale.

Our findings show that SAHLPA-33 is fairly reliable. The lower internal consistency (Cronbach's $\alpha=0.73$), when compared to that of the Brazilian SAHLPA-18 version (Cronbach's $\alpha=0.90$), could be explained by the lower variability in score distributions, that is known to underestimate the reliability.¹⁹

Although two different screening instruments previously validated in the Portuguese population were available,^{12;16} we decided not to test concurrent validity, because neither of them is considered a gold standard in health literacy assessment. Instead, our strategy relied on examining known-groups validity, that is, administering the instrument to different groups that logically should have different levels of the construct to confirm whether the hypothesised difference was reflected in the scores of the groups.²⁰ Thus, we assumed health literacy would decrease across groups with progressively lower familiarity obtaining and processing health information, in the following order: physicians, health researchers, engineering researchers, laypersons from the general population. Although our data showed a significant trend ($p<0.001$), the instrument was better at discriminating people in the lower range of the health literacy spectrum, as it was designed to do.^{10;13}

Less educated people tended to have lower health literacy, in accordance with results from previous studies.²¹

We were not able to find a significant association between limited health literacy and age. The magnitude and direction of this association appears to vary according to the type of assessment instrument used. A recent systematic review found that limited health literacy, when assessed using instruments based on medical vocabulary, such as the REALM (the precursor of SAHLPA), only weakly associates with older age.²² Instruments based on reading comprehension, reasoning, and numeracy skills, such as the NVS or the TOFHLA, in contrast, usually reveal positive associations between limited

health literacy and age. The authors argue that crystallised cognitive abilities, such as the ones involved in word recognition and pronunciation, are not affected by ageing-related decline, as opposed to those requiring fluid cognitive abilities, more related to reasoning and problem solving. In addition, it is also plausible that as people age and become more exposed to healthcare, their medical vocabulary increases, altering the traditional direction of the association between limited health literacy and age.²³ Arguably, our study was underpowered to detect this association.

Some limitations are worth pointing out. SAHLPA is based on the REALM, a test popularly used to assess health literacy, but centred on reading skills. In fact, the REALM was not designed to assess health literacy but to estimate patient reading levels.⁷ Some authors have suggested that REALM scores should be treated as a correlate or predictor of health literacy and not as a measure of health literacy per se, because the instrument lacks coverage on three primary content areas of health literacy: comprehension, numeracy, and information seeking/navigation.²⁴ SAHLPA and SAHLPA on the other hand, include comprehension of written health materials and thus have better content validity than the REALM. We did not examine test-retest reliability and future studies using SAHLPA in less literate samples should determine it.

An instrument based on the Brazilian SAHLPA-18 has been recently validated in the Portuguese population, adding five items to the shortened instrument, all of them drug-related.²⁵ It is undetermined if the addition of these items significantly increased the difficulty of the instrument, rendering it less appropriate for less literate samples. SAHLPA-33 on the other hand, when compared with two other health literacy measurement instruments (the Newest Vital Sign¹⁶ and METER¹²) using item response theory has shown to have better discrimination and precision at lower levels of respondent ability (unpublished data).

SAHLPA-33 fills the gap in health literacy assessment instruments for Portuguese low-literate adults. In contrast to instruments based on self-assessment questions and more vulnerable to non-response bias,¹⁷ it offers an objective way to assess health literacy in this vulnerable group. National and international policies now recognise health literacy as a crucial determinant of health and are focusing on strategies to improve it.²⁶⁻²⁸ We hope that the SAHLPA-33 can help support policy makers and clinicians in providing more effective health education, specifically targeted to low health literacy adults.

Conclusion

We have adapted a brief and simple instrument to assess health literacy in the Portuguese population. SAHLPA-33 can be used to explore associations with health outcomes and to guide health interventions, especially in less literate populations.

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Appendix

SAHLPA – Versão para a população portuguesa

O Short Assessment of Health Literacy for Portuguese-speaking Adults (SAHLPA) é um instrumento breve e de fácil aplicação, desenvolvido para avaliar literacia em saúde. Pode ser utilizado na prática clínica ou em contexto de investigação.

A administração deve ser realizada com cartões contendo um termo médico (em destaque), acompanhado por duas palavras de associação. Prevendo a possibilidade de défice visual, o material é impresso em fonte Times New Roman, tamanho 34 a 40.

Instruções para Administração do SAHLPA

SHORT ASSESSMENT OF HEALTH LITERACY IN PORTUGUESE-SPEAKING ADULTS (SAHLPA-33)

Instruções para o Entrevistador

Instruções para o Entrevistador:

1. Antes de iniciar o teste, certifique-se de que tem consigo os cartões de aplicação e a folha de respostas.
2. Antes de iniciar o teste, diga ao entrevistado:
“Vou mostrar-lhe uns cartões, cada um deles com 3 palavras escritas. Primeiro, gostava que lesse a primeira palavra em voz alta. Depois, eu vou ler-lhe as duas palavras seguintes e gostava que me dissesse qual das duas está mais relacionada com a primeira. Se não sabe a resposta, por favor, diga ‘não sei’. Não tente adivinhar.”
3. Mostre o primeiro cartão e diga:
“Por favor, leia agora a primeira palavra em voz alta.”
4. Leia as duas palavras de associação e diga:
“Qual das duas palavras está mais relacionada com a primeira palavra? Se não sabe, por favor diga ‘não sei’.”
5. As instruções devem ser repetidas, caso seja necessário.
6. Continue o teste com os restantes cartões.
7. O item deve ser pontuado como correto apenas quando a pronúncia da palavra chave e a associação estiverem ambas corretas. Cada item vale um ponto. O score final obtém-se pela soma simples das pontuações de todos os itens.

CHAVE	ASSOCIAÇÃO		
1. ANEMIA	<input type="checkbox"/> nervo	<input type="checkbox"/> SANGUE	<input type="checkbox"/> não sei
2. MENOPAUSA	<input type="checkbox"/> SENHORAS	<input type="checkbox"/> meninas	<input type="checkbox"/> não sei
3. COMIDA	<input type="checkbox"/> JANTAR	<input type="checkbox"/> passeio	<input type="checkbox"/> não sei
4. MEDICAMENTO	<input type="checkbox"/> instrumento	<input type="checkbox"/> TRATAMENTO	<input type="checkbox"/> não sei
5. ASMA	<input type="checkbox"/> RESPIRAÇÃO	<input type="checkbox"/> pele	<input type="checkbox"/> não sei
6. INTESTINO	<input type="checkbox"/> suor	<input type="checkbox"/> DIGESTÃO	<input type="checkbox"/> não sei
7. ALCOOLISMO	<input type="checkbox"/> VÍCIO	<input type="checkbox"/> lazer	<input type="checkbox"/> não sei
8. DEPRESSÃO	<input type="checkbox"/> apetite	<input type="checkbox"/> SENTIMENTOS	<input type="checkbox"/> não sei
9. EMPREGO	<input type="checkbox"/> TRABALHO	<input type="checkbox"/> educação	<input type="checkbox"/> não sei
10. PÍLULA	<input type="checkbox"/> COMPRIMIDO	<input type="checkbox"/> bolacha	<input type="checkbox"/> não sei
11. DIABETES	<input type="checkbox"/> AÇÚCAR	<input type="checkbox"/> sal	<input type="checkbox"/> não sei
12. RIM	<input type="checkbox"/> URINA	<input type="checkbox"/> febre	<input type="checkbox"/> não sei
13. GORDURA	<input type="checkbox"/> laranja	<input type="checkbox"/> MANTEIGA	<input type="checkbox"/> não sei
14. STRESS	<input type="checkbox"/> PREOCUPAÇÃO	<input type="checkbox"/> feliz	<input type="checkbox"/> não sei
15. GRIPE	<input type="checkbox"/> saudável	<input type="checkbox"/> DOENTE	<input type="checkbox"/> não sei
16. INFLAMATÓRIO	<input type="checkbox"/> INCHAÇO	<input type="checkbox"/> suor	<input type="checkbox"/> não sei
17. AVISAR	<input type="checkbox"/> medir	<input type="checkbox"/> DIZER	<input type="checkbox"/> não sei
18. OBESIDADE	<input type="checkbox"/> PESO	<input type="checkbox"/> altura	<input type="checkbox"/> não sei
19. HEPATITE	<input type="checkbox"/> pulmão	<input type="checkbox"/> FÍGADO	<input type="checkbox"/> não sei
20. OSTEOPOROSE	<input type="checkbox"/> OSSO	<input type="checkbox"/> músculo	<input type="checkbox"/> não sei
21. PAPANICOLAU	<input type="checkbox"/> TESTE	<input type="checkbox"/> vacina	<input type="checkbox"/> não sei
22. ABORTO	<input type="checkbox"/> casamento	<input type="checkbox"/> PERDA	<input type="checkbox"/> não sei
23. HEMORROIDA	<input type="checkbox"/> VEIAS	<input type="checkbox"/> coração	<input type="checkbox"/> não sei
24. ANORMAL	<input type="checkbox"/> semelhante	<input type="checkbox"/> DIFERENTE	<input type="checkbox"/> não sei
25. MENSTRUAL	<input type="checkbox"/> MENSAL	<input type="checkbox"/> diário	<input type="checkbox"/> não sei
26. CALORIAS	<input type="checkbox"/> vitaminas	<input type="checkbox"/> ALIMENTOS	<input type="checkbox"/> não sei
27. RETAL	<input type="checkbox"/> regador	<input type="checkbox"/> SUPOSITÓRIO	<input type="checkbox"/> não sei
28. ALÉRGICO	<input type="checkbox"/> resistência	<input type="checkbox"/> REAÇÃO	<input type="checkbox"/> não sei
29. APÊNDICE	<input type="checkbox"/> coçar	<input type="checkbox"/> DOR	<input type="checkbox"/> não sei
30. ARTRITE	<input type="checkbox"/> estômago	<input type="checkbox"/> ARTICULAÇÃO	<input type="checkbox"/> não sei
31. CAFEÍNA	<input type="checkbox"/> ENERGIA	<input type="checkbox"/> água	<input type="checkbox"/> não sei
32. PRÓSTATA	<input type="checkbox"/> circulação	<input type="checkbox"/> GLÂNDULA	<input type="checkbox"/> não sei
33. TESTÍCULO	<input type="checkbox"/> óvulo	<input type="checkbox"/> ESPERMA	<input type="checkbox"/> não sei

Score Total SAHLPA-33:

4.3 LIMITED HEALTH LITERACY IN PORTUGAL ASSESSED WITH THE NEWEST VITAL SIGN

Limited Health Literacy in Portugal Assessed with the Newest Vital Sign

Prevalência de Literacia em Saúde Inadequada em Portugal Medida com o *Newest Vital Sign*



ARTIGO ORIGINAL

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ABSTRACT

Introduction: In Portugal, health literacy has started to be addressed through national policies, but research on the topic is still scarce. We aimed to estimate the prevalence and sociodemographic correlates of limited health literacy in Portugal using an existing health literacy instrument, the Newest Vital Sign.

Material and Methods: Following cross-cultural adaptation of the instrument, a sample of 249 participants was evaluated to assess reliability and construct validity of the Newest Vital Sign; the latter was tested assuming physicians would score highest, followed by health researchers, then by engineering researchers and finally by laypersons from the general population. We applied this validated version in a representative sample of 1544 Portuguese-speaking residents in Portugal aged between 16 and 79 years and quantified the associations between limited health literacy and sociodemographic characteristics.

Results: The instrument showed high reliability (Cronbach's $\alpha = 0.85$). Health-related occupation showed association with higher scores in the Newest Vital Sign (p trend < 0.001). The prevalence of limited health literacy in the Portuguese population was 72.9% (95% CI: 69.4 - 76.4). We found no differences between men and women, but persons with limited health literacy were significantly older ($p < 0.001$) and less educated ($p < 0.001$).

Discussion: The burden of limited health literacy in Portugal is higher than that in other European countries. It should drive a universal precautions approach to health communication at all levels of the health system.

Conclusion: We validated a brief and simple instrument and estimated the prevalence of limited health literacy in the literate Portuguese population at roughly three out of four people.

Keywords: Health Literacy; Portugal; Prevalence; Validation Studies

RESUMO

Introdução: A literacia em saúde começa a ser alvo de políticas de saúde em Portugal, mas a investigação neste tema ainda é escassa. Pretendemos estimar a prevalência de literacia em saúde inadequada e os fatores sociodemográficos associados em Portugal, utilizando um instrumento de avaliação da literacia em saúde já existente, o *Newest Vital Sign*.

Material e Métodos: Após adaptação transcultural do instrumento, avaliámos uma amostra de 249 participantes para examinar fiabilidade e validade de construto do *Newest Vital Sign*; esta última foi testada assumindo que os médicos teriam pontuação máxima, seguidos por investigadores na área da saúde, investigadores na área da engenharia e finalmente por leigos da população geral. Em seguida, aplicámos a versão validada numa amostra representativa de 1544 pessoas, residentes em Portugal, entre os 16 e os 79 anos, e quantificámos as associações entre literacia em saúde inadequada e características sociodemográficas.

Resultados: O instrumento revelou elevada fiabilidade (α de Cronbach = 0,85). A profissão ligada à saúde associou-se a pontuações mais elevadas no *Newest Vital Sign* (p para a tendência $< 0,001$). A prevalência de literacia em saúde inadequada na população portuguesa foi de 72,9% (IC 95%: 69,4 - 76,4). Não encontramos diferenças entre homens e mulheres, mas as pessoas com literacia em saúde inadequada eram significativamente mais velhas ($p < 0,001$) e com menor escolaridade ($p < 0,001$).

Discussão: A carga de literacia em saúde inadequada em Portugal é mais alta do que a observada noutros países europeus. Esta deve conduzir a medidas de precaução universais no âmbito da comunicação em saúde, a todos os níveis de cuidados.

Conclusão: Adaptámos um instrumento breve e simples e estimámos que, na população portuguesa alfabetizada, três em cada quatro pessoas possuem literacia em saúde inadequada.

Palavras-chave: Estudos de Validação; Literacia em Saúde; Portugal; Prevalência

INTRODUCTION

Health literacy has been defined as people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions concerning healthcare, disease prevention and health promotion to maintain or improve quality of life.¹ It is commonly measured using instruments based on word recognition or pronunciation, such as the Rapid Estimate of Adult Literacy in Medicine (REALM),²

the Medical Term Recognition Test (METER),³ or the Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLISA),⁴ as well as with instruments that assess reading comprehension and numeracy, such as the Test of Functional Health Literacy in Adults (TOFHLA)⁵ or the Newest Vital Sign™ (NVS).⁶ Most instruments were originally developed in English and are being adapted worldwide.⁷

Limited health literacy is more prevalent among the

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elderly, those with lower levels of education⁸ and with chronic disease.⁹ It is associated with less successful navigation of the healthcare system, poorer self-management skills, greater costs, higher morbidity and mortality.⁹⁻¹² Improving health literacy is regarded as a critical factor for enabling healthier choices and is becoming increasingly common in political health agendas worldwide.^{13,14}

The prevalence of limited health literacy has been estimated to be 60% in Canada,¹⁵ 59% in Australia,¹⁶ over 50% in New Zealand¹⁷ and around 26% in the United States.¹⁸ The diversity of instruments used may partially explain differences between these countries. The European Health Literacy Survey, conducted in eight European countries (Austria, Bulgaria, Germany, Greece, Ireland, Netherlands, Poland, and Spain) in 2011, found that half of the population had limited health literacy.¹⁹ This survey used the same instrument (HLS-EU-Q86 supplemented with the Newest Vital Sign) in all countries, with prevalence ranging from 28.7% in the Netherlands to 62.1% in Bulgaria.

In Portugal, health literacy has started being addressed through national policies, but research on the topic is still scarce.²⁰ It is a central part of the current Portuguese Health Plan,^{21,22} and is targeted in a specific Health Programme, the Health Education, Literacy and Self-Management Programme.²³ The aims of this government initiative, subsequently merged with the Prevention and Management of Chronic Disease Programme and renamed Health Literacy and Integrated Care,²⁴ are to prepare and support informal caregivers in home-based care, preventing diabetes, obesity and promoting mental health and healthy aging, as well as the rational and safe use of medicines. The two-year associated pilot project approved in July 2017,²⁵ Literacy for the Safety of Healthcare, additionally aims to increase patient, family, caregivers and healthcare institutions' involvement in the improvement of the quality and safety of healthcare delivery, as well as to increase patient literacy in that area.

Given this recent investment, it is essential to validate measurement instruments that are fast, easy to administer, and can be used in clinical settings and in survey questionnaires without greatly increasing participant burden. We aimed to estimate the prevalence and sociodemographic correlates of limited health literacy in Portugal after adapting and validating the NVS in the Portuguese population.

MATERIAL AND METHODS

The present article reports two complementary studies. Firstly, we validated an existing health literacy measure, the Newest Vital Sign™,⁶ in the Portuguese population. Then, we applied the validated instrument to estimate the prevalence of limited health literacy in Portugal.

Validation of the Newest Vital Sign in the Portuguese population

Original instrument

The Newest Vital Sign™ is a health literacy assessment tool available in English and Spanish, in which an ice cream nutrition label is given to review and six questions asked

about it. Scores range from 0 to 6 (1 point for each correct answer): a score of 0 - 1 suggests high likelihood (50% or more) of limited literacy; 2 - 3 indicates the possibility of limited literacy; and 4 - 6 almost always indicates adequate literacy.⁶ These three categories were based on the stratum-specific likelihood ratios for the two cut-off scores, stratified by dichotomised TOFHLA score.⁶

Cross-cultural adaptation

We used the standard procedure for the cross-cultural adaptation of health instruments.²⁶ Briefly, two native Portuguese speakers proficiently fluent in English translated the Newest Vital Sign™ independently and merged the translations into a single Portuguese version. Afterwards, two native English speakers, proficient in Portuguese, independently back-translated this version, blinded to the original version. The translators arrived at a consensus back-translated version, which was then revised and compared to the original by a multidisciplinary and bilingual expert committee (with backgrounds in Internal Medicine, Pharmaceutical Sciences, Psychology, Sociology, Nutrition and Epidemiology), resolving any discrepancies. This committee also ensured item and conceptual equivalence of the original and final versions. The final version was pre-tested in a small group of six lay people.

Sample and recruitment

The Portuguese adapted version of the instrument (NVS-PT) was administered to a convenience sample of 249 people in 2012, as part of a validation study of individual health literacy instruments in the Portuguese population.²⁷ Participants were recruited from four different groups: physicians from public hospitals and primary care health centres ($n = 53$), health researchers from a research institute in Public Health ($n = 45$), researchers from areas unrelated to health from an Engineering faculty ($n = 50$), and laypersons from the general population attending a primary care health centre ($n = 101$). To assess construct validity we assumed that physicians would score highest on health literacy tests followed by public health researchers, engineering researchers, and finally by the general population. To detect a medium effect size difference (30%) between these groups using the χ^2 test and three categories of health literacy with a significance level of 5% and 80% power, the total sample size was estimated at 151 participants.²⁸

Eligibility criteria for the participants were age over 18 years and ability to speak and read Portuguese. People with impaired vision were excluded.

Statistical analysis

Psychometric testing of the NVS-PT excluded physicians, since the instrument was not designed to assess them, resulting in more than 32 persons per item. Items 5 and 6 were considered together, as in the original instrument question 6 is only asked if question 5 is answered correctly. Cronbach's alpha was used to measure internal consistency, exploratory factor analysis was performed on

the five items (1, 2, 3, 4 and 5-6), and visual analysis of the scree plot was used to evaluate homogeneity (i.e., to verify there was a single latent factor measuring reading comprehension and numeracy). All items showing absolute factor loadings higher than 0.4 were considered part of the factor. The global goodness of fit of the underlying model was evaluated using the comparative fit index (CFI), recommended for sample sizes below 250.²⁹

Participant characteristics were described using frequencies, median and 25th - 75th percentiles (P25 - P75), as appropriate, by validation group, for sex, age and health literacy category, and compared across the groups using the χ^2 test for sex, the Kruskal-Wallis test for age and Fisher's exact test for health literacy, with a test for linear trend. Two-sided p values less than 0.05 were considered to define a statistically significant result.

Exploratory factor analysis models were fitted using MPlus (V.5.2; Muthen & Muthen, Los Angeles, California, USA). All other analyses were performed using Stata version 11.2 for Windows (StataCorp LP, College Station, TX).

Prevalence of limited health literacy

Sample and recruitment

This analysis was based on a national survey conducted in 2012, aiming to assess knowledge about obesity, diabetes, cardiovascular diseases and cancer, as well as health behaviours of the Portuguese population, and has been previously described.³⁰ The study evaluated a representative sample of Portuguese-speakers of any nationality in mainland Portugal, with respect to sex, age, education, marital status, and residence. A stratified probabilistic sampling procedure by residence according to nomenclature of territorial units for statistics II region (Norte, Centro, Lisboa e Vale do Tejo, Alentejo and Algarve) and number of inhabitants in geographical units with at least 10 dwellings (< 2000, 2000 - 9999, 10 000 - 19 999, 20 000 - 100 000 and > 100 000 inhabitants) was used to identify 150 geographical units. In these units, a total of 585 starting points were designated for the selection of households through standard random route procedures. Potentially eligible participants were identified in each household and the individual with the most recent birthday date was invited to participate; a total of 1624 valid interviews were obtained (response rate: 70.8% of those invited). Participants were evaluated through face-to-face interviews conducted using Computer Assisted Personal Interviewing with a structured question-

naire, including the validated instrument, NVS-PT, to assess health literacy.

Statistical analysis

For the purpose of this analysis, individuals unable to read or write (n = 79) as well as one with missing education data were excluded, leaving a final sample of 1544.

All estimates were weighted to be representative of the Portuguese population, using the variables considered in the design. Demographic characteristics of the weighted sample were similar to those of the Portuguese population.³¹ For a comparison between unweighted and weighted study sample characteristics, please refer to Appendix 1 (<https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/9135/5253>).

Health literacy was classified into the recommended categories,⁶ as well as dichotomized into adequate and limited health literacy (for scoring purposes, questions that were answered as "do not know" or "no answer" were coded as wrong answers).

We calculated prevalence with 95% confidence intervals (95% CI) for the three categories of health literacy, stratified by sample characteristics and used the χ^2 test to test for comparisons between categories. We performed a sensitivity analysis including individuals unable to read or write in the lowest health literacy category. We computed adjusted prevalence ratios (PR) and 95% confidence intervals using Poisson regression with the dependent variable as the prevalence of having limited health literacy and sex, age and education as independent variables. Two-sided p values less than 0.05 were considered significant. All statistical analyses were carried out using STATA, version 11.2 (Stata Corp LP, College Station, Texas, USA).

RESULTS

The first part of this section presents the results of the validation of the Newest Vital Sign in a convenience sample. Afterwards, the prevalence and sociodemographic associations of limited health literacy in a representative sample of the Portuguese population are shown.

Validation of the Newest Vital Sign in the Portuguese population

Cross-cultural adaptation

To ensure conceptual equivalence, the expert committee transformed '(serving size) ½ cup' in the original

Table 1 - Characteristics of the validation sample by group

	Physicians (n = 53)	Health researchers (n = 45)	Other researchers (n = 50)	General population (n = 101)
Women, n (%)	34 (64.2)	37 (82.2)	6 (12.0)	64 (63.4)
Age in years, median (P25 - P75)	30.0 (27.0 - 34.0)	28.0 (26.0 - 31.0)	48.5 (31.0 - 53.0)	42.0 (34.0 - 58.0)
NVS-PT scores, n (%)				
0 - 1: high likelihood of limited HL	0 (0.0)	0 (0.0)	0 (0.0)	58 (57.4)
2 - 3: possibility of limited HL	0 (0.0)	5 (11.1)	4 (8.0)	24 (23.8)
4 - 6: adequate HL	53 (100)	40 (88.9)	46 (92.0)	19 (18.8)

NVS-PT: Portuguese version of the Newest Vital Sign; HL: Health literacy

version into '125 mL', as cups are not a common measurement unit in Portugal. Similarly, abbreviations 'sat' and 'cal' in the original version were replaced by full words, because they are not routinely abbreviated in Portuguese nutrition labels and the sentence "This information is on the bottom of an ice cream container" was added. The Portuguese adapted version of the instrument (NVS-PT) is presented in Appendix 2 (<https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/9135/5254>).

Validation in a convenience sample of the Portuguese population

Demographic characteristics of the sample by validation group are summarized in Table 1. Women made up the majority of respondents in all validation groups except for the group of non-health researchers (12.0%), $p < 0.001$. Engineering researchers and laypersons from the general population were older ($p < 0.001$).

The scree plot curve inflected at the first component, revealing one underlying dimension of the instrument (Fig. 1) and exploratory factor analysis confirmed it (Table 2). The CFI of the model was 1.00. NVS-PT showed high internal consistency, with a Cronbach's alpha of 0.85.

Physicians scored highest in health literacy, followed by

non-health researchers, health researchers and finally by the general population (p for trend of the original hypothesis < 0.001 ; Table 1).

Prevalence of limited health literacy

The proportion of women was 50%, the median age was 41.0 years (P25 - P75: 27.0 - 55.0 years), and nearly 40% had 4th grade or less schooling (Table 3). There were 0.3% of respondents (95% CI: 0.0 - 0.6) not answering any of the NVS-PT questions. An additional 16.2% (95% CI: 13.4 - 19.1) reported not to know how to answer all of the questions (data not shown). The latter proportion declined with increasing education from 47.8% (95% CI: 34.0 - 61.5) for persons with less than four years of formal education to 3.4% (95% CI: 0.4 - 6.5) for persons with complete college (sex and age-adjusted PR = 0.12 for persons with complete college when compared to people with $< 4^{\text{th}}$ grade; p for trend < 0.001).

The prevalence of limited health literacy in the literate Portuguese population aged between 16 and 79 years was 72.9% (95% CI: 69.4 - 76.4). A total of 30.4% (95% CI: 26.9 - 33.9) were classified in the intermediate category "possibility of limited health literacy" and 42.5% (95% CI: 38.3 - 46.6) in the lowest category "high likelihood of limited health

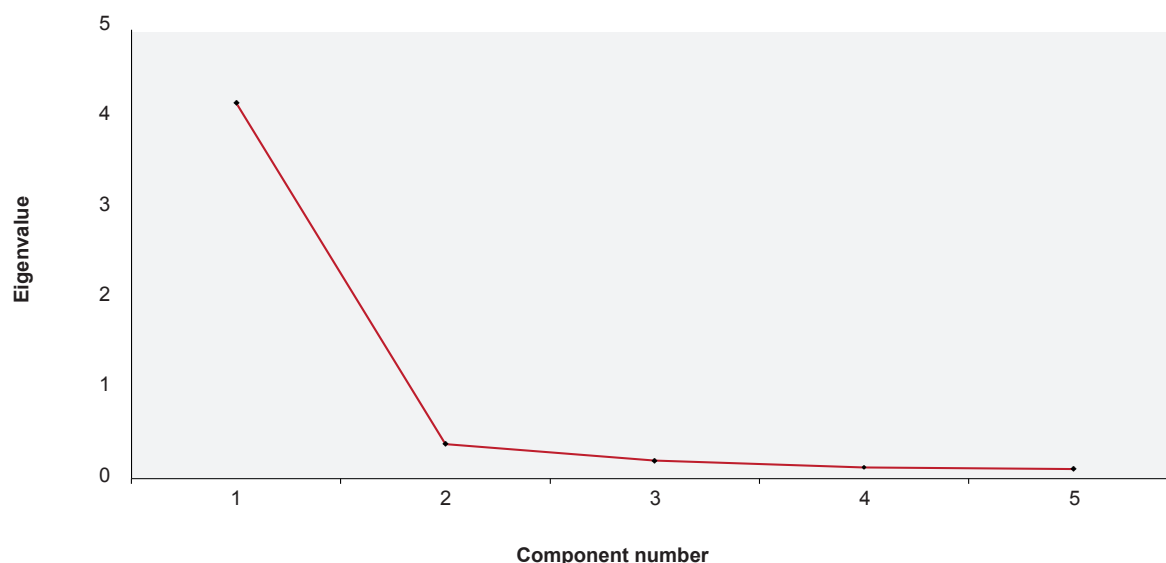


Figure 1 - Scree plot of eigenvalues from exploratory factor analysis

Table 2 - Correct answers per item, and standardised factor loadings in exploratory factor analysis

Item	Correct answers n (%)	Standardised factor loadings (one factor)
NVS-PT 1	116 (59.18)	0.949
NVS-PT 2	119 (60.71)	0.888
NVS-PT 3	114 (58.16)	0.917
NVS-PT 4	105 (53.57)	0.928
NVS-PT 5 6*	143 (72.96)	0.788
	102 (52.04)	

NVS-PT: Portuguese version of the Newest Vital Sign

* Items 5 and 6 analysed together (NVS 6 only asked if NVS 5 was answered correctly)

Table 3 - Survey sample characteristics by health literacy category

	Total	Adequate HL	Possibility of limited HL	High likelihood of limited HL
	Weighted % (95% CI)			
Sex				
Women	50.0 (46.4 - 53.5)	25.0 (20.6 - 29.3)	34.6 (29.8 - 39.5)	40.4 (35.3 - 45.5)
Men	50.0 (46.5 - 53.6)	29.3 (24.0 - 34.5)	26.2 (21.6 - 30.8)	44.5 (38.7 - 50.3)
<i>p</i> value	0.045			
Age (years)				
16 - 24	18.6 (15.2 - 22.0)	38.3 (28.7 - 47.9)	29.5 (21.0 - 38.1)	32.2 (21.2 - 43.2)
25 - 34	18.1 (14.9 - 21.3)	36.5 (27.0 - 46.0)	32.0 (22.6 - 41.4)	31.5 (22.0 - 41.1)
35 - 44	19.5 (16.8 - 22.3)	35.2 (27.2 - 43.2)	25.3 (19.0 - 31.6)	39.5 (31.5 - 47.5)
45 - 54	18.4 (15.6 - 21.2)	19.4 (12.9 - 26.0)	36.4 (28.8 - 44.0)	44.2 (35.9 - 52.4)
55 - 64	14.9 (12.8 - 16.9)	15.4 (10.9 - 19.9)	31.7 (25.1 - 38.4)	52.9 (45.9 - 59.8)
65 - 79	10.5 (8.8 - 12.2)	6.3 (3.2 - 9.3)	26.4 (18.1 - 34.6)	67.4 (59.1 - 75.7)
<i>p</i> value	< 0.001			
Education				
< 4 th grade	11.1 (8.3 - 13.8)	2.5 (-0.7 - 5.7)	23.5 (12.0 - 35.0)	74.0 (62.2 - 85.7)
4 th grade	28.0 (24.4 - 31.5)	14.9 (9.5 - 20.4)	28.6 (23.1 - 34.0)	56.5 (49.2 - 63.9)
5 th - 9 th grade	19.5 (16.6 - 22.4)	25.9 (18.2 - 33.6)	30.8 (23.5 - 38.0)	43.4 (35.3 - 51.5)
10 th - 11 th grade	13.8 (11.2 - 16.5)	24.4 (15.2 - 33.5)	39.3 (28.3 - 50.3)	36.3 (25.2 - 47.4)
12 th grade	17.0 (14.1 - 19.8)	49.0 (39.4 - 58.7)	30.8 (22.0 - 39.6)	20.2 (13.3 - 27.1)
Complete college	10.7 (8.5 - 12.9)	55.5 (45.1 - 66.0)	29.6 (19.8 - 39.4)	14.9 (7.8 - 22.0)
<i>p</i> value	< 0.001			

HL: Health literacy; Weighted: % of 1544 participants; CI: Confidence interval

literacy", whereas 27.1% (95% CI: 23.6 - 30.6) were classified as having adequate health literacy.

If individuals unable to read or write ($n = 79$) were included in the lowest health literacy category, the weighted prevalence of limited health literacy would rise to 74.5% (95% CI: 71.1 - 77.8), 28.6% (95% CI: 25.4 - 31.9) would have the possibility of limited health literacy, and 45.8% (95% CI: 41.9 - 49.8) would have a high likelihood of limited health literacy, whereas the prevalence of adequate health literacy would drop to 25.5% (95% CI: 22.2 - 28.9).

Limited health literacy increased gradually with age ($p < 0.001$) and decreased with education ($p < 0.001$). Slightly more women were in the intermediate category of health literacy ($p = 0.045$) (Table 3).

In the multivariable model, limited health literacy remained positively associated with age and inversely associated with education (Fig. 2). Persons over 64 years old were 21% more likely to have limited health literacy when compared to persons under 25 (sex- and education-adjusted p for trend = 0.006) and persons with complete college education were 50% less likely to have limited health literacy when compared to persons with less than the 4th grade (sex- and age-adjusted p for trend < 0.001). We found no significant differences between men and women (age- and education-adjusted $p = 0.282$).

DISCUSSION

We validated the NVS in the Portuguese population,

used it to estimate a prevalence of limited health literacy in Portugal of almost three out of four people, and showed that limited health literacy was positively associated with age and inversely associated with education.

Validation of the Newest Vital Sign in the Portuguese population

We culturally adapted a brief and simple instrument and showed it was valid and reliable. The NVS-PT can be used to assess health literacy and to sort the Portuguese population according to adequate and limited health literacy.

Some validation studies of health literacy instruments have used concurrent validation, that is, through the comparison with an existing instrument.⁷ This is a controversial option given the multiple proposed definitions of the underlying construct¹ and the diverse and restrictive scope of the instruments.³² Additionally, the NVS has been shown to provide higher prevalence estimates of limited health literacy when compared to health literacy instruments without a numeracy component.³³ It cannot be presumed, however, that either estimate is more valid than the other.

Our strategy assumed that health literacy would be higher in physicians, followed by health researchers, people with a similar academic degree in areas non-related to health and by people with progressively lower levels of education. In our sample, however, non-health researchers scored higher than health researchers, although the difference between them was non-significant. This might

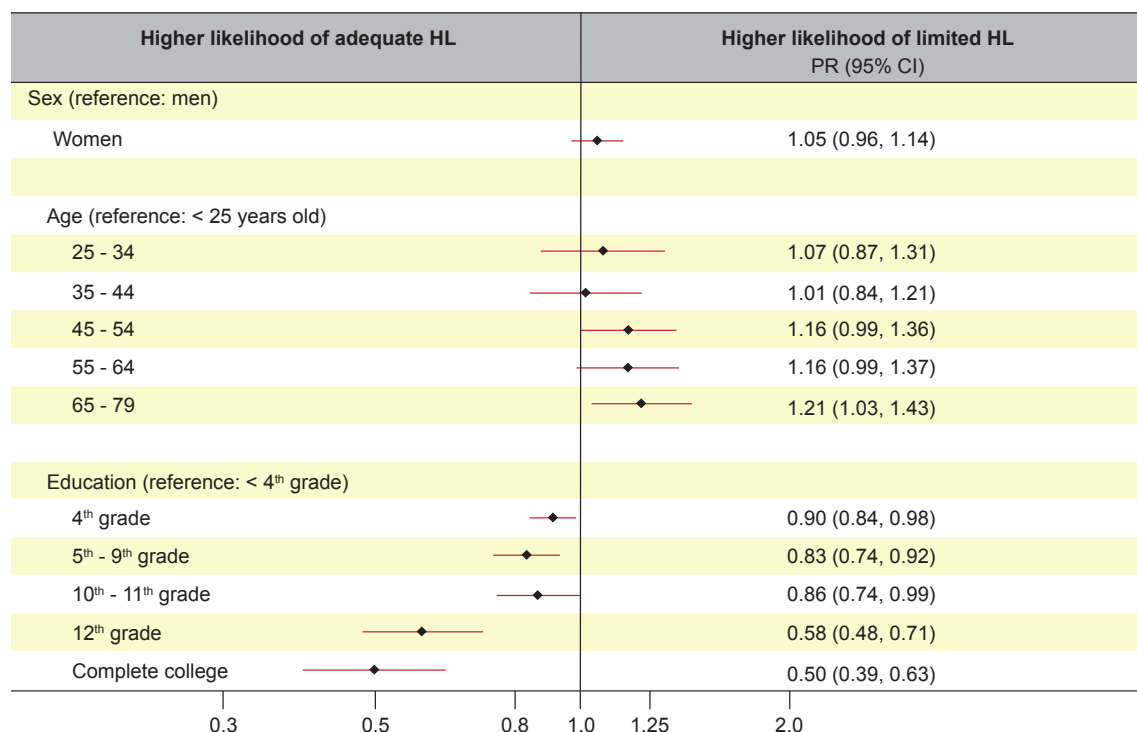


Figure 2 - Prevalence ratios and 95% confidence intervals [PR (95% CI)] for the association between limited health literacy (HL) and sample characteristics (adjusted for sex, age and education)

be related with the strong numeracy component of the instrument. Yet, physicians scored higher than either of the groups, suggesting the instrument is measuring more than numeracy. The NVS was designed to assess individual reading comprehension and numeracy skills, a small part in the health literacy construct. Nonetheless, assessment of patients' numeracy skills may have a critical role in improving appropriate use of medicines and avoiding dosing errors, aligning with the goals of the national Health Literacy and Integrated Care Programme.²⁴ Assessing health literacy as a cognitive capacity also disregards how people rely on their social network for support with health literacy-related tasks.³⁴ Notwithstanding, it has been used in multiple settings,³⁵ correlates well with more complex instruments such as the TOFHLA,⁶ and NVS scores have been associated with health knowledge^{36,37} and clinically relevant health outcomes.^{38,39} Additionally, the patients find the instrument acceptable⁴⁰ and it can be used for international comparisons of the prevalence of limited health literacy. To study the role of individual health literacy in the management of complex chronic conditions or health literacy associations with the perception of risk communication, we suggest assessing health literacy with this instrument complemented with a word recognition instrument such as the METER²⁷ to provide a more comprehensive assessment of health literacy. As a limitation, we did not examine consistency of scores over time. Further research is needed to examine test-retest reliability and to explore if the NVS-PT can also be used as a quick screening tool in clinical settings in Portugal.

Prevalence of limited health literacy

We estimated a prevalence of limited HL in a representative sample of the literate Portuguese population aged between 16 and 79 years of almost three in four people. This prevalence is higher than the observed for other countries using the same measurement tool in the European Health Literacy Survey 2011. The Netherlands had the highest NVS scores, with only 23.7% of the respondents showing limited health literacy. The country with the lowest NVS scores was Spain, in which 63.1% of the population exhibited limited health literacy.⁴¹ Given the close association between education and the numeracy component of health literacy, our findings could be explained by differences in education between countries. The average years of completed education over the age of 25 in Portugal was 8.2 in 2012, whereas in Spain it was 9.6.⁴² As for the other seven countries included in the European Survey, average education was also higher than in Portugal.⁴³ Prevalence comparisons of limited health literacy with other countries are harder because of the diversity of instruments used.¹⁵⁻¹⁸

The choice of a health literacy instrument with relatively limited scope to calculate a prevalence of limited health literacy could be regarded as a limitation of this study. Our prevalence estimates are higher than the 49% found to have problematic or inadequate levels by Espanha *et al.*²⁰ However, in contrast with the latter, numeracy is assessed objectively and this health literacy component is a crucial competency to deal with the complex demands of chronic illness.⁴⁴ It also takes considerably less time to administer,⁷ which makes it a better option in the context of longer surveys.

The sensitivity analysis based on the inclusion of illiterate people aimed to avoid underestimating health literacy, considering that Portugal has one of the highest illiteracy rates in Europe.⁴³ This approach increased our prevalence estimates by 1.9% representing approximately 67 000 additional persons with limited health literacy in Portugal.

A considerable proportion of participants reported not to know how to answer any of the NVS-PT questions. Although this is not commonly reported in other studies, we find it relevant as a potential proxy of acceptability of the instrument. Participants could have been afraid of answering incorrectly and thus decided not to answer.⁴⁵ It is likely, however, that if the instrument had been administered in a clinical setting, as intended by the developers, this proportion would be lower, as reported by Ryan *et al.*⁴⁶ The positive association we found between non-response and education is in accordance with the results from Griffin *et al.*, which compared characteristics between interview participants and non-respondents in health literacy tests and found that non-responders were more likely to have lower education.⁴⁷

The associations we observed between limited health literacy and older age are consistent with those found by the European Health Literacy Survey¹⁹ and with studies conducted in other countries.^{8,15,18} Education is consistently one of the main predictors of health literacy and our results confirm the association between limited health literacy and lower educational attainment.^{8,15,17-20} These associations are worrisome, as the elderly and less educated are known to experience higher chronic disease burden and worse health outcomes.²⁰

Future research in Portugal should focus on the association between health literacy and outcomes such as health status, health behaviour and healthcare use.

The high burden of limited health literacy in the Portuguese population advocates for a universal precautions approach to health communication by health professionals and the health care system in general, by lowering the health literacy demands placed on individuals. This means assuming most patients will have difficulties understanding health information and using the clearest health messages possible with all patients. Universal precautions by health professionals to improve communication include using plain, non-medical language, limiting content, repeating key information, using illustrations, videos and demonstrations, as well as designing easy to read educational material that patients can take home to complement spoken instructions. They also include fostering patient participation with the 'teach-back method' by asking patients to repeat in their own words what has been explained, promoting the National Patient Safety Foundation "Ask Me 3"⁴⁸ programme by encouraging patients and families to ask three simple but essential questions of their providers in every health care encounter (1. What is my main problem? 2. What do I need to do? 3. Why is it important for me to do this?), and by asking for direct patient feedback.⁴⁹

Health institutions can employ additional strategies to reduce health literacy barriers that include training all staff in health literacy techniques, systematically offering assistance filling out forms, linking patients to non-medical support and resources, and creating a welcoming environment easy to navigate, with clear physical signage and direction instructions.⁵⁰ The universal precautions approach also translates into increasing communications skills and empathy of health professionals, in the involvement of patients' families and social networks, and in not assuming that communication has been achieved until demonstrated. Finally, these strategies and initiatives should be evaluated in the framework of the national project Literacy for the Safety of Healthcare.²⁵

CONCLUSION

The Newest Vital Sign was successfully validated in the Portuguese population and used to estimate a prevalence of limited health literacy of almost three in four people.

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PROTECTION OF HUMANS AND DATA CONFIDENTIALITY

The Ethics Committee of Centro Hospitalar de São João approved the validation study and the Ethics Committee of the University of Porto approved the survey. All participants provided written informed consent.

CONFLICTS OF INTEREST

None declared.

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4.4 COMPARING HEALTH LITERACY INSTRUMENTS IN THE PORTUGUESE POPULATION USING STRUCTURAL EQUATION MODELLING AND CALIBRATION

Comparing health literacy instruments in the Portuguese population using structural equation modelling and calibration

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Abstract

We compared and calibrated three previously validated health literacy instruments, the METER, the NVS and the SAHLPA, administered to the same Portuguese sample, using modern test theory methods. Confirmatory factor analysis from structural equation modelling supported the calculation of correlation coefficients (r) between each instrument and an underlying latent factor for validity comparisons, and the one-parameter logistic model from item response theory enabled the comparison of their reliability and discriminative power, as well as calibration among them. Although one of the instruments emerged as the best measuring the latent factor ($r_{METERwordsubscale}=0.923$, $r_{NVS}=0.562$, $r_{SAHLPA}=0.758$), all of them appear to have value in specific contexts. Implications for use in clinical and research settings are discussed.

Keywords: health literacy; comparative study; calibration; educational measurement; models, statistical; psychometrics; Portugal

Introduction

Individual health literacy has been defined as ‘the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions’ (Berkman, Davis, & McCormack, 2010). In the last few decades, numerous instruments have been developed to assess general individual health literacy, both as screening tools and as more comprehensive assessments (Haun, Valerio, McCormack, Sorensen, & Paasche-Orlow, 2014). Performance based measures are usually based on word pronunciation or recognition, such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis *et al.*, 1993), the Medical Term Recognition Test (METER) (Rawson *et al.*, 2010), the Short Assessment of Health Literacy for Portuguese-speaking Adults (SAHLPA) (Apolinario *et al.*, 2012), or reading comprehension and numeracy, such as the Test of Functional Health Literacy in Adults (TOFHLA) (Parker, Baker, Williams, & Nurss, 1995), the Newest Vital SignTM (NVS) (Weiss *et al.*, 2005), and the Numeracy Understanding in Medicine Instrument (NUMI) (Schapira *et al.*, 2012). The choice of an instrument is limited by the difficulty in establishing which one best represents the health literacy construct. In addition, the tools available measure health literacy somewhat differently and display dissimilar number and source of items, varying levels of difficulty and psychometric properties, all of which compromise comparisons among them. We propose two strategies to overcome these issues: the application of structural equation modelling and calibration between instruments.

In structural equation modelling, multiple instruments can be used as manifest variables or indicators of an underlying construct of health literacy reflecting a continuum that is not directly observable (Kline, 2011). It is used when there is no gold standard or reference instrument available. By determining the strength of association of each instrument with this latent construct (through the estimation of correlation coefficients), they allow direct comparisons of validity between tests.

To enable direct comparisons between instrument scores, calibration is used to adjust the scores of instruments with unequal reliability, taking into account the level of difficulty of each instrument.

We aimed to directly compare the previously validated Portuguese versions of METER (Paiva *et al.*, 2014), NVS (Paiva *et al.*, 2017), and SAHLPA (Paiva *et al.*), according to the strength of the association with an underlying latent construct of individual health literacy as well as to provide equivalent score values between the instruments.

Methods

This study is based on secondary data from the application of a battery of three individual health literacy instruments on a convenience sample of 196 adults. This sample was obtained from three different settings: health researchers, from a research institute in Public Health (n=45), engineering researchers, from an Engineering faculty (n=50), and laypersons from the general population, users of a primary care health centre (n=101). Engineering researchers were mostly male (88.0%), while health researchers were both

younger and most often female than the other three groups. The laypersons group had lower health literacy scores in all four instruments (Paiva *et al.*; Paiva *et al.*, 2014; Paiva *et al.*, 2017).

The instruments were applied in the following fixed order: firstly the METER, then the NVS and finally the SAHLPA, aiming to minimise discomfort of participants by placing the most difficult instrument in the middle and the easiest in the end.

Health literacy instruments

METER The METER is an English language open use instrument based on the REALM, consisting of a list of 40 medical words and 30 made-up non-words that intuitively sound like real medical terms. It is self-administered and the participants are requested to mark only the words they are sure to be actual words (Rawson *et al.*, 2010). This instrument has been previously validated in the Portuguese population and exploratory factor analysis revealed two dimensions to the instrument, one for words and another for non-words (Paiva *et al.*, 2014). It showed a high degree of internal consistency (Cronbach's alpha of 0.92 for the word subscale and 0.83 for the non-word subscale) (Paiva *et al.*, 2014). For the purpose of this study, because each subscale represented a different health literacy sub-dimension, they were treated as two separate instruments.

NVS The NVS is a health literacy assessment tool available in English and Spanish, in which a patient is given an ice cream nutrition label to review and is asked six questions about it. Scores range from 0 to 6 (1 point for each correct answer) (Weiss *et al.*, 2005). The NVS has been successfully validated in the Portuguese population (Paiva *et al.*, 2017). Psychometric analysis revealed one underlying dimension of the instrument, related to reading comprehension and numeracy. It showed high internal consistency (Cronbach's alpha of 0.85) and exhibited construct validity.

SAHLPA The SAHLPA is the Brazilian Portuguese version of the Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA) (Lee, Bender, Ruiz, & Cho, 2006), a word recognition and comprehension instrument that has been adapted to European Portuguese and validated in the Portuguese population (Apolinario *et al.*, 2012; Paiva *et al.*). It consists of 33 (in the European Portuguese version) medical terms adapted from REALM (Davis *et al.*, 1993) that the participants are requested to read aloud and associate with one of two word options; the word options for each term consist of a key (a word with similar meaning) and a distractor (a word unrelated to the medical term). Participants are shown laminated flash cards, each with a medical term in boldface and the key and distractor at the bottom. To answer correctly, the participants must both correctly pronounce the medical term and match it to the key. It showed a fair degree of reliability, with a Cronbach's alpha of 0.73.

Structural equation modelling

In the absence of a reference method, structural equation models allow us to compare health literacy assessments using three or more instruments with a latent (unobservable) health literacy factor. Within structural equation modelling, we used one factor confirmatory factor analysis (only one latent factor considered) to estimate this latent factor by calculating correlation coefficients between it and the four health literacy instruments validated in the Portuguese population (METER word subscale, METER non-word subscale, Newest Vital Sign, and SAHLPA). This method assumes that the scores of the tests are independent within any level of the latent factor. As the distributions of scores were highly non-normal (Table 1), the number of items in each instrument was higher than five, and data had no missing values), we used maximum likelihood estimation with robust standard errors and a Satorra-Bentler scaled test statistic (MLM) (Rhemtulla, Brosseau-Liard, & Savalei, 2012). We used it to calculate the unstandardised (β) and standardised correlation coefficients (r) and to assess model fit with this scaled Chi-square statistic (χ^2), presented with the respective degrees of freedom (df) and p value, that adjusts for the kurtosis of the distributions minimising type I error rates (Jiang & Yuan, 2017). The robust comparative fit index (CFI) and the robust root mean square error of approximation (RMSEA) with 90% confidence interval (CI) are also reported. Standard errors (SE) of the unstandardised coefficients were calculated using bootstrapping to avoid underestimation caused by non-normality (Yuan & Hayashi, 2006). We considered the model had good fit if the χ^2 yielded a p value higher than 0.05, the CFI was higher than 0.95 and the RMSEA was lower than 0.06 (Hu & Bentler, 1999). When any instrument displayed correlations below 0.30 with the latent factor and if there was a theoretical rationale, we removed instruments from the analyses. To assess if the instruments were equivalently measuring the latent factor we constrained unstandardised slopes to be equal for all the instruments. If this model with constrained slopes did not display good fit, we rejected the hypothesis of measurement equivalence.

We performed three sensitivity analyses to support the conclusions: one not including public health researchers, another not including engineering researchers, and a third including only the sample of laypersons from the general population.

Calibration

Concurrent calibration involves estimating item and ability parameters in all scales simultaneously by combining data from all items. Given the binary nature of the items (answers could only be correct or incorrect for each item) and the small relative sample size when compared to the number of items, we used the one-parameter logistic model (1PL) from Item Response Theory (Embretson & Reise, 2000). This method models the probability of a particular respondent answering a specific item correctly, as a function of the additive combination of the person's ability and the item's difficulty level. Based on this calibration, we calculated the information and response functions of each instrument, treating the latent variable as continuous. The test information function models the precision that can be achieved with each instrument at any value of respondent abi-

lity (in the latent variable) and is inversely related to the measurement variance. It is used to compare reliability between instruments: instruments with higher information at a specific level of ability are more precise at that level. It also allows comparisons of discrimination between instruments. The test response function models the expected score as a function of ability; it aligns the instruments along the scale of the continuous latent factor, based on the difficulty of each item, thus allowing direct comparisons between scores obtained using different instruments in different samples.

All statistics were calculated using R software, version 3.3.1. Skewness and kurtosis of the distributions were computed using the e1071 package 1.6-8, structural equation modelling was performed using the lavaan package version 0.5-23.1097, and calibration was performed using the equate package 2.0-4.

Ethics review and consent

The present investigation was carried out in accordance with the Code of Ethics of the Declaration of Helsinki. The Ethics Committee of Centro Hospitalar de São João and the National Committee for Data Protection approved the validation studies of all health literacy instruments used in this analysis.

Results

Sample characteristics

Scores varied between 6 and 40 for the METER word subscale, 14 and 30 for the METER non-word subscale, 24 and 33 for the SAHLPA, and 0 and 6 for the NVS (Table 1).

Structural equation modelling

Table 2 shows the correlation matrix between the four instruments. The METER non-word subscale stands out because of lower correlations with the other instruments ($r=0.137$ with the METER word subscale, $r=0.227$ with the SAHLPA and $r=0.555$ with the NVS).

In the first model (Figure 1; Model 1), the instrument exhibiting higher correlation with the latent construct was the METER word subscale ($r=0.859$), followed by the SAHLPA ($r=0.795$), the NVS ($r=0.605$) and finally by the METER non-word subscale ($r=0.287$). The model had a low comparative fit index (CFI=0.735) and a high root mean square error of approximation (RMSEA=0.427; 90%CI: 0.333-0.529). Because there was also a theoretical rationale for the low correlation of the METER non-word subscale, we removed it from the analysis and constrained unstandardised slopes to be equal across the remaining three instruments (Figure 1; Model 2). We also rejected this second model as it displayed a low CFI (0.550) and a high RMSEA [0.462 (90%CI: 0.301-0.645)]. The next model (Figure 1; Model 3) was a saturated one, i.e. the number parameters to be estimated exactly equalled the number of observed variables, leaving zero degrees of freedom and hindering calculation of model fit. In this model, the correlation coefficients

between the instruments and the latent construct dropped for all the instruments except the METER word subscale, whose correlation coefficient rose to 0.923; the correlation coefficient between the latent construct and the NVS fell to 0.562, the one of the SAHLPA to 0.758. Thus, in this final model the instrument that best measured the latent construct was the METER word subscale, followed by the SAHLPA and finally by the NVS.

In the sensitivity analysis, when we first excluded health researchers and then engineering researchers from the models (leaving $n=146$ and $n=151$, respectively), results showed the same ranking in correlation coefficients in all models and similar fit indices (Table 3). In contrast, when we repeated the analysis with only the laypersons sample (leaving $n=101$), correlation coefficients changed in Model 1, inverting the order in rankings between the METER word subscale and the SAHLPA (now $r=0.775$ and $r=0.863$), reducing the correlation of the NVS to 0.334 and rendering the correlation of the METER non-word subscale negative ($r=-0.010$). Additionally, some of the p-values of the estimates become non-significant, namely the ones associated with the estimates for the METER non-word subscale ($p=0.924$) and SAHLPA ($p=0.106$) in the first model, and for the SAHLPA ($p=0.133$) in the third and last model.

Calibration

The correlation coefficient between the METER non-word subscale and the latent construct was weak ($r=0.287$), so it was excluded from calibration analysis as well.

The peak precision values for each instrument in the test information function curve were at -2.25 standard deviation of respondent ability for the METER word subscale, -0.25 for the NVS, and -3 for the SAHLPA (Figure 2; Test information function). METER was more precise i.e., had higher information function than the other instruments at almost every level of respondent ability, except for values under -2.75 standard deviations, when SAHLPA was more precise. Above -0.75 standard deviations, the NVS was more precise than the SAHLPA.

The METER displayed good discrimination throughout the whole range (-4 to 4) of respondent ability, as evidenced by the lack of plateaus on the curve (Figure 2; Test response function), whereas the NVS showed better discrimination in the middle range of ability (between -2 and 2 standard deviations), and the SAHLPA at the lower range, up to 0.5 standard deviations. The test response function graph in Figure 2 also permits direct comparisons of point estimates between the three instruments across different studies, by drawing a vertical line in the graph intersecting the values one wishes to compare with. For example, a sample with median health literacy score of 34 (read in the Y axis) using the METER would transect the x-axis at -0.5 standard deviations of ability, which corresponds to an expected median score of approximately 2.5 using the NVS, and 32 using the SAHLPA (read in the Y axis). Given a score in one of the three instruments, this method can also be used to predict individual scores in the other two.

Discussion

The Portuguese versions of METER, NVS, and SAHLPA were compared according to the strength of the association with an underlying latent construct of individual health literacy. In addition, it was possible to compare precision and discrimination of the instruments as well as to calibrate them, i.e., provide equivalent expected score values. The instrument with stronger correlation with the latent factor was the METER word subscale, followed by the SAHLPA, and lastly by the NVS.

The model that included the METER non-word subscale was undoubtedly misspecified. The authors of the Portuguese version suggested that it measured risk aversion and not so much health literacy (Paiva *et al.*, 2014). This instrument does not measure word recognition and comprehension but pseudoword recognition, which in psycholinguistic literature are based on different skills. Pseudowords or pseudohomophones are non-words very similar to actual words both orthographically and phonetically (Chateau & Jared, 2000). When a word is presented, orthographically and phonetically similar words are activated in memory, through access to the person's lexicon or vocabulary (the words a person knows). Pseudoword recognition involves accessing a greater extent of the lexicon, and checking whether the word could exist by also accessing the meaning of similar words (Barca & Pezzulo, 2015). The METER non-word subscale requires the recognition of pseudowords as such and their rejection as words, what is commonly called a lexical decision task (Norris, 2013). In contrast with word recognition, this relies heavily on working memory i.e., the cognitive system that is responsible for temporarily holding information available for processing (Baddeley, Eysenck, & Anderson, 2015). The instruments used to estimate the latent factor assess primarily word recognition and reading comprehension and this is why the correlation of the METER non-word subscale with the latent factor was so low. We are not suggesting that pseudoword recognition is not a sub-dimension of the health literacy construct but merely that its relative validity could not be assessed without resorting to additional instruments.

The reliance on working memory could also explain the lower correlation found between this latent factor and the NVS. The NVS likely measures both word comprehension (understanding mathematical questions) and numeracy, another sub-dimension of the health literacy construct. Numeracy, seen as the ability to deal with numbers and perform arithmetic calculations, has also been linked to reading abilities and working memory (Aiken, 2016; DeStefano & LeFevre, 2004). Furthermore some authors have suggested different pathways for literacy and numeracy, which also explains the lower correlations between the NVS and the latent factor (Carreiras, Monahan, Lizarazu, Dunabeitia, & Molinaro, 2015). Nevertheless, when assessing individual health literacy as a social determinant of health, numeracy is increasingly valued as a patients' competency in managing chronic conditions and the NVS may be preferred as an assessment tool (Abdel-Kader *et al.*, 2010; Apter *et al.*, 2008; Hanoch, Miron-Shatz, Rolison, Omer, & Ozanne, 2015; McNaughton *et al.*, 2013).

The first and second sensitivity analyses produced equivalent results and confirmed the ranking of strength of association with the latent factor. The results from the third sensitivity analysis reflected less sample heterogeneity (due mainly to lower scores

in the NVS) and an insufficient sample size for reliable confirmatory factor analysis (Kline, 2011). Albeit possible, it is therefore unlikely that results using a sample with lower health literacy would have altered our conclusions. Findings from calibration analysis suggest that the METER word subscale is simultaneously the best instrument in reliability and discrimination throughout the whole range of respondent ability, except at lower values, when SAHLPA is favoured. This is consistent with the original design intention of the latter instrument to centre assessment on less literate populations (Lee *et al.*, 2006). Partially because of the lower number of items when compared with the other two instruments, the NVS displayed less precision and less discriminative power. However, in the middle range of ability the precision of the NVS and the METER word subscale was similar. Thus, in this range, taking into consideration the number of items of each instrument, the most informative instrument per item was the NVS. As the three instruments take roughly the same time to administer (2-5 minutes) this becomes irrelevant in the choice of instrument. In addition, because of their reduced administration time, any of them can be easily added to health questionnaires in research or clinical settings without increasing respondent burden.

Outside of the scope of the validation of new instruments, in which new instruments are compared to existing ones, studies comparing health literacy instruments are rare (Kiechle *et al.*, 2015; Osborn *et al.*, 2007). Also rare is the application of modern test methods such as structural equation modelling and item response theory to health literacy instrument development, in spite of having been proposed as a way to strengthen the field of health literacy measurement (Nguyen, Paasche-Orlow, Kim, Han, & Chan, 2015). We took the proposal a step further and showed they can also be a good option to compare health literacy assessment instruments. To our knowledge, no other studies have done this before.

Conclusions

The previously validated Portuguese versions of METER, NVS and SAHLPA were compared according to the strength of the association with an underlying latent construct of individual health literacy and we have provided correspondence of values between the scores of each of the instruments. When aiming to assess individual health literacy with one of these three instruments, our findings suggest using the METER word subscale when the estimated health literacy of a sample is expected to be normally distributed or when a continuous measure is needed, the SAHLPA in samples with expected very low health literacy, and the NVS when assessment of the numeracy component of health literacy is required.

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Table 1: Scores on health literacy instruments, by subsample

	METER	Health researchers (n=45)	Engineering researchers (n=50)	General population (n=101)	<i>p</i> -value
Women, n (%)	107 (54.6)	37 (82.2)	6 (12.0)	64 (63.4)	$< 0.001^a$
Age in years, mean (SD)	41.4 (14.7)	29.6 (5.6)	43.8 (13.0)	45.5 (15.5)	0.003^b
Mean scores (SD)					
METER word subscale [6-40] ^c	34.6 (5.5)	37.2 (1.8)	37.5 (1.8)	32.1 (6.4)	$< 0.001^b$
METER non-word subscale [14-30] ^c	27.2 (3.4)	29.3 (1.3)	28.8 (1.6)	25.6 (3.9)	$< 0.001^b$
NVS [0-6] ^c	3.6 (2.3)	5.3 (1.2)	5.5 (1.1)	1.8 (1.8)	$< 0.001^b$
SAHLPA [24-33] ^c	32.1 (1.7)	32.8 (0.5)	32.7 (0.7)	31.5 (2.2)	$< 0.001^b$

SD, standard deviation; ^a Chi-square test; ^b Kruskal-Wallis test; ^c observed range (higher scores correspond to higher health literacy)

Note: possible range of instruments' scores: METER word subscale: 0-40, non word subscale: 0-30, NVS: 0-6, SAHLPA: 0-33

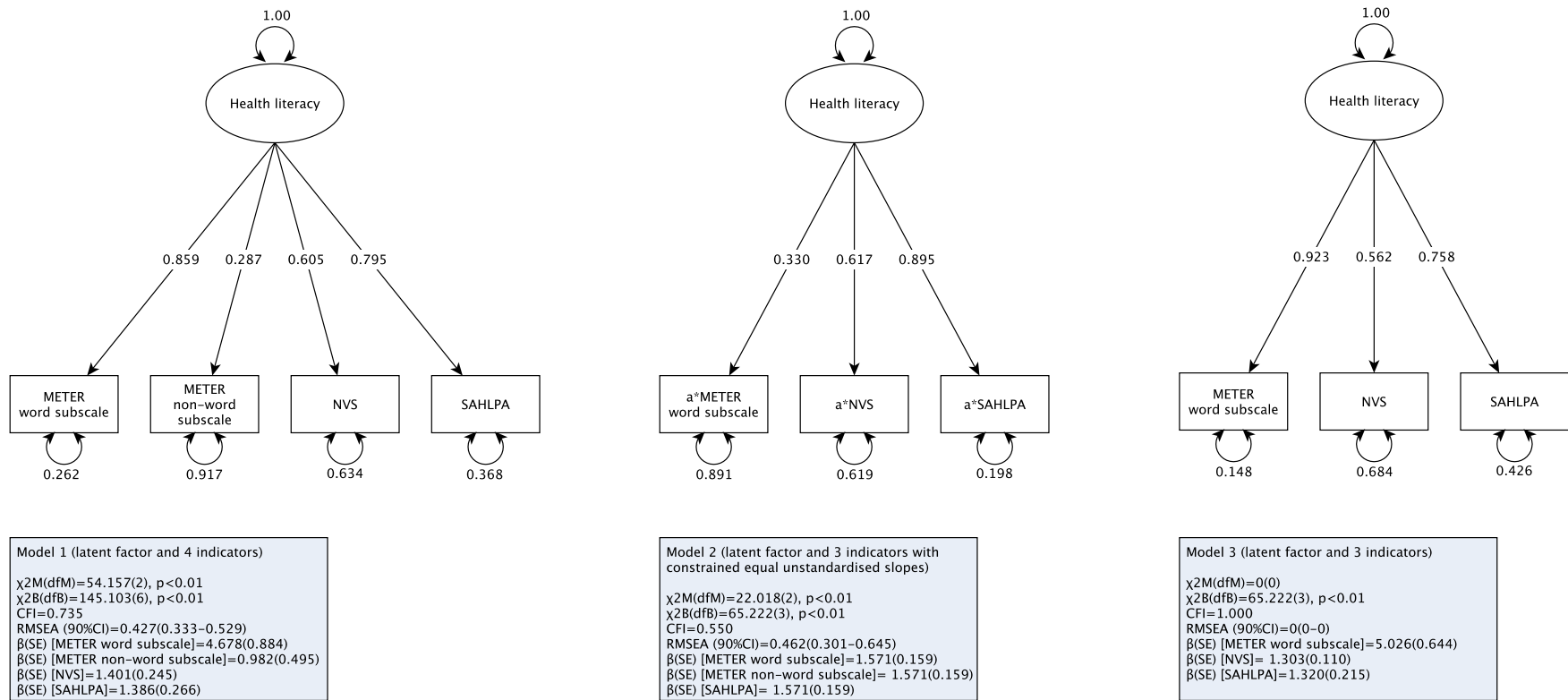
Table 2: Correlation matrix of the instruments

	METER word subscale	METER non-word subscale	NVS	SAHLPA
METER word subscale	1			
METER non-word subscale	0.137	1		
NVS	0.519	0.555	1	
SAHLPA	0.669	0.227	0.426	1

Table 3: Sensitivity analysis

	r_{METER_w}	$r_{METER_{nw}}$	r_{NVS}	r_{SAHLPA}	$\chi^2(df)$	p	CFI	RMSEA(90%CI)
1st sensitivity analysis: n=151 (engineering researchers and laypersons)								
Model 1	0.862	0.180	0.550	0.791	50.698(2)	<0.001	0.725	0.411(0.318-0.513)
Model 2	0.306	-	0.632	0.829	20.098(2)	<0.001	0.518	0.458(0.290-0.649)
Model 3	0.913	-	0.523	0.755	-	-	-	-
2nd sensitivity analysis: n=146 (health researchers and laypersons)								
Model 1	0.838	0.221	0.534	0.822	56.343(2)	<0.001	0.707	0.432(0.339-0.533)
Model 2	0.304	-	0.642	0.819	19.271(2)	<0.001	0.517	0.458(0.286-0.654)
Model 3	0.890	-	0.506	0.785	-	-	-	-
3rd sensitivity analysis: n=101 (laypersons)								
Model 1	0.775	-0.010	0.334	0.863	25.832(2)	<0.001	0.741	0.332(0.226-0.452)
Model 2	0.201	-	0.660	0.559	48.313(2)	<0.001	0.327	0.464(0.292-0.659)
Model 3	0.768	-	0.334	0.871	-	-	-	-

r , standardized correlation coefficient with the latent factor, χ^2 , scaled chi-squared test statistic; df , degrees of freedom of the model; CFI, comparative fit index; RMSEA, root mean square error of approximation; 90%CI, 90% confidence interval; Model 1: latent factor and 4 indicators; Model 2: latent factor and 3 indicators with equal unstandardized slopes; Model 3: latent factor and 3 indicators - saturated model.



χ^2 , scaled chi-squared test statistic; df, degrees of freedom of the model; M, depicted model; B, baseline model; CFI, comparative fit index; RMSEA, root mean square error of approximation; 90%CI, 90% confidence interval; $\beta(SE)$, unstandardised slope estimate and respective standard error.

Figure 1: Models and correlation coefficients between the instruments and the latent factor

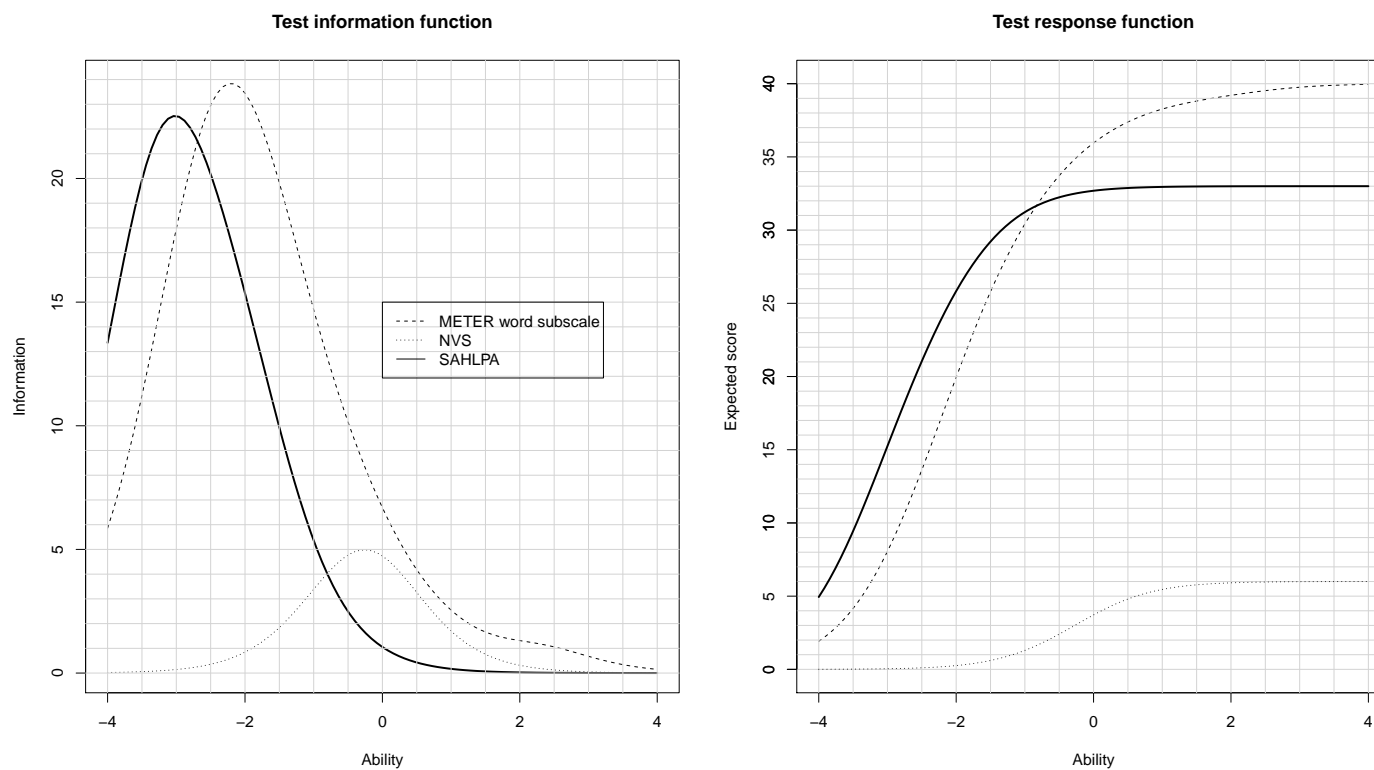


Figure 2: Test information and response functions for the METER word subscale, NVS and SAHLPA instruments

4.5 PATIENT-CENTRED COMMUNICATION IN TYPE 2 DIABETES: THE FACILITATING AND CONSTRAINING FACTORS IN CLINICAL ENCOUNTERS

Patient-centred communication in type 2 diabetes: the facilitating and constraining factors in clinical encounters

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Abstract

Objective

To explore the perceptions of the constraining and facilitating factors to patient-centred communication in clinical encounters of patients with type 2 diabetes and the providers involved in their care.

Data sources/Study setting

Patients (n=12) and providers (n=33) involved in diabetes care in northern Portugal.

Study design

Seven focus groups.

Data collection/extraction methods

Grounded theory using open, axial and selective coding.

Principal findings

Patients focused on the patient-provider relationship, while providers emphasized the constraining factors when exchanging information and the facilitating factors regarding disease and treatment-related behavior. Patients and providers both agreed on some constraints (power imbalance, avoidance of criticism, disease minimization, use of jargon, and insufficient competencies and consistency among providers) and facilitators (seeing patients as persons, providing tailored information in plain language, and recognizing the 'wake-up call'). Patients perceived an aggressive attitude as a barrier to communication, but providers perceived it as a facilitator. Patients included issues related to trust, respect, and psychosocial support as important factors to them. Only providers mentioned the influence of macro-level interventions and patients' socioeconomic position as essential factors.

Conclusions

Improvements in patient-centred communication depend on fostering the patient-provider relationship, patients' participation and involvement, and training providers' communication skills.

Keywords: Diabetes mellitus, type 2; patient-centered; communication; patients; health personnel, physician-patient relations

Introduction

Approximately 422 million adults worldwide were estimated to have diabetes in 2014, and this number is expected to rise to 700 million people by 2025.¹ This projection is due primarily to the growing prevalence of type 2 diabetes, which closely follows populations that are aging, overweight, obese and that engage in unhealthy lifestyles.¹ Over 1.5 million people die of diabetes each year, and diabetes globally ranks 6th as a cause of death.² Diabetes also represents one of the leading causes of disability, which results from associated complications, including acute myocardial infarction, stroke, blindness, renal failure, and lower limb amputations.³ In 2015, Portugal was estimated to have the highest age-adjusted prevalence of diabetes in adults aged 20-79 years in the European Union; its crude prevalence was estimated at 13.6%.⁴ To reduce the morbidity and mortality burden, both the Chronic Care Model and the World Health Organization's Innovative Care for Chronic Conditions emphasize the need for patient-centered care and self-management support for people with chronic illnesses.^{5,6}

Patient-centred communication is acknowledged as a core dimension of patient-centred care.^{7,8} Moreover, communication is considered to be a basic clinical competency, and communication skills have been regarded as a crucial component of the health literacy of providers.^{9,10} In the context of type 2 diabetes, it has been associated with improved disease knowledge,¹¹ self-care,¹² quality of life,¹³ and better measures of metabolic control.¹⁴⁻¹⁶ Consistent with this evidence, leading organizations, including the American Diabetic Association and the International Diabetes Federation, currently advocate for patient-centred communication in the management of diabetes.^{17,18} Furthermore, patients and patient advocacy organisations have expressed a desire for more personalised and humane medical care.^{8,19} Despite these recommendations, the results from the Diabetes Attitudes, Wishes and Needs (DAWN2) study suggest that patient-centred care is often unavailable and that the psychosocial needs of patients with diabetes worldwide are not being met,²⁰ at least partly due to communication failures between providers and patients with diabetes.²¹⁻²³ Communication failures are one of the most common patient complaints and contribute to patient harm.^{24,25} This is especially problematic for people with a lower health literacy with whom health professionals report feeling unprepared to communicate.²⁶ Consequently, several experts have proposed clear communication and health literacy curricula for health professionals in the United States,^{27,28} and Europe.²⁹ Training in these competencies has shown the potential to improve communication skills in the short term,^{28,30-32} but it has been suggested that training would have to be ongoing, as improvements were not sustained.³³

Patient-centred communication between patients with diabetes and the providers who care for them is paramount to fill the gap between recommendations and clinical practice.^{19,34} The reconciliation of the perspectives of various stakeholders has been pinpointed as essential to improve clinical communication. Therefore, it is important to involve both patients and providers in the dialogue about effective patient-centred communication to develop new, or to improve on existing, people-centred health services.³⁵ The literature from communication theories provides recommendations for effective patient-centered communication in the following dimensions: fostering healing relationships, making decisions, exchanging/gathering and providing information, responding to emotions, and enabling patients' self-management of disease and treatment-related behavior.³⁶⁻³⁸ However, the few studies that have addressed the constraining and facilitating factors to patient-centred communication with patients with type 2 diabetes have mostly disregarded communication theories in framing these issues.³⁹⁻⁴¹

We aimed to explore the perceptions on the constraining and facilitating factors to patient-centred communication in the clinical encounters of patients with type 2 diabetes and the providers who are involved in their care, by emphasizing the matches and mismatches to the potential areas of improvement for both sides.

Materials and Methods

A qualitative study involving focus groups was conducted that included patients with diabetes and providers who care for type 2 diabetes in northern Portugal. The participants were purposively sampled to include the standard range of areas of expertise involved in the care of type 2 diabetes patients in Portugal (family medicine, endocrinology, nursing, pharmacy, nutrition, ophthalmology, nephrology, vascular surgery, and psychology),

and the typical range of diabetes' micro- and macrovascular complications (without any complications, diabetic retinopathy, diabetic nephropathy, diabetic foot, ischaemic heart disease and cerebrovascular disease). The number of focus groups was predetermined based on these characteristics to aim for the maximum variation of provider roles and patients' disease burden (assuming that the patients with more serious complications tend to have a higher disease burden). This number was not surpassed because data saturation was reached. Within the groups, heterogeneity was pursued regarding age and professional experience/disease duration. An individual direct approach was used to recruit providers who work in primary care and hospital care from several health institutions other than the institutions from where the patients were recruited. Individual physicians who work in one primary care health center and five different hospital departments (Ophthalmology, Nephrology, Diabetic Foot, Cardiology and Neurology) from one university hospital were contacted and asked to directly invite patients without complications and with specific complications, respectively. We conducted two focus groups of providers in 2012 at a research institute and five focus groups of patients between 2015 and 2016 at a health centre for the group without diabetes complications or a hospital for the remaining groups. The participant characteristics can be observed in table 1.

All focus groups followed the same semi-structured set of questions that were aimed at capturing the experiences in the communication between patients living with type 2 diabetes and their providers. These questions were developed by the authors based on the literature that links patient-centered communication with health literacy communication strategies. They covered the factors that constrain and facilitate communication, patients' information needs, and the methods used for gathering and providing information. All the focus groups included a trained moderator and a co-moderator. The focus group discussions lasted from 56 to 93 minutes, with a median duration of 90 minutes. The audio of the focus groups was recorded, professionally transcribed verbatim and checked for accuracy.

The data were analysed independently by the first two authors according to grounded theory,⁴² by using NVivo 10 (QSR International, USA, 2013), and were merged by consensus following continuous and iterative discussions to strengthen coding consistency. This triangulation was further supported by the researchers' different backgrounds (medicine and sociology). In addition, the classifications were always discussed and validated by the last author. Open coding, axial coding and selective coding were used. The quotations with similar meanings were synthesized into categories (open coding), which were then grouped into themes (axial coding), and then into core themes (selective coding). During selective coding, inductive themes were laden with interpersonal patient-centred communication theory in consultation with the existing literature.^{36–38} The most illustrative verbatim quotes were selected by the first and the second authors, and the translation was checked by a native English speaker.

The Ethics Committees of the Instituto de Saúde Pública da Universidade do Porto, the Centro Hospitalar de São João, and the Centro Hospitalar do Porto granted ethics approval for the study, and the National Centre for Data Protection approved the data collection. All participants formalized their collaboration through written informed consent.

Results

Table 2 summarizes the constraining and facilitating factors that were experienced by the participants during their communication in clinical encounters, which were grouped by patients and providers in relation to the following three core themes that emerged from the data analysis: 1) the 'patient-provider relationship', which included the leading values, roles and responsibilities of patients and providers when addressing psychosocial distress and emotions, and partnership in decision making; 2) 'disease and treatment-related behavior', when the quotations identified the issues that emerged from communication to enable self-management, behavior change or maintenance; and 3) 'gathering and providing information' where the factors included references to information exchange and the methods used to respond to information needs. The constraining and facilitating factors are illustrated by the anonymized quotes that were drawn from the focus group interviews presented in

the text and are supplemented by Tables 3 and 4.

Constraining factors (Table 3)

The patients and providers who were interviewed for this study agreed that power imbalance (C1a; C1b), the avoidance of criticism (C1c; C1d), disease minimization (C2a; C2b), the use of jargon (C3a; C3b), the inconsistency between providers (C3c; C3d) and the insufficient competencies of providers (C3e; C3f) were constraining factors to effective patient-centered communication in clinical encounters. The misrecognition of power imbalance as natural, necessary, and legitimate refrained the patients from asking questions and supported their nondisclosure of medical information, particularly about high self-monitored glycemic values, because they did not want to be reprimanded. The providers acknowledged that patients lied to them, but they did not attempt to change it:

We think we are being lied to, but we also don't tell them [the patients], 'I don't understand what you are telling me', right? (FG7)

The inconsistency among different providers was especially challenging for the patients, who stated that they were sometimes harmed by conflicting or inaccurate recommendations:

I lost nine and a half kilos in a month and a half because here [at the hospital] someone incorrectly informed me of the type of diet I should be doing, right? And I almost died of starvation. (FG5)

Only the patients mentioned as constraining factors nonsupportive (C1e) and/or distrustful (C1f) patient-provider relationships, an inadequate response to emotions (C1g), a disrespect for basic courtesy behaviors (C1h), an aggressive attitude from providers to motivate adherence to their recommendations (C2c), and the use of inappropriate analogies, such as describing a banana as an expensive potato instead of providing nutritional recommendations for diabetes (C3g). The patients described episodes when doctors gathered around them and discussed them as cases while ignoring their presence. When doctors did not address the patients' concerns,

Sometimes they leave the offices ranting because the doctor didn't address their concerns. (FG2)

The patients also argued that they did not have help from providers to build meaning around why they had diabetes (C1i). They named situations of ineffective communication when providers were blunt, hurt their feelings and walked away, which left the patients without psychosocial support, and situations when they felt disrespected as patients and human beings.

This year in May, I had another appointment with her. (...) I got there and I waited for two and a half hours. I left, as I had to get to work. (...) Then, my doctor wrote another letter, and I went there again. And then, she said, 'Did you bring any tests?' 'No, I didn't. I haven't been here in two years, what tests would you like me to bring?' 'If you came for prescriptions, it's no use, you're not getting any.' And I said 'Look, I actually have someone I can ask for prescriptions,' and I walked out the door... and she didn't assist me, and I walked out the door and left. (FG3)

The providers seemed to partially dismiss their own responsibility in communication improvement regarding behavior change by suggesting that it was the role of other professionals (C2d). They added constraints that related to the patients' family obstruction (C2e) and their low health literacy (C2f), socioeconomic position – education (C2g) and income (C2h) that caused a lack of access to and understanding of health information to better manage the disease.

I have patients that see me and at first sight [say], 'Please read this to me because I don't know how to read. I don't know how to take these medicines.' (FG6)

The lack of time to communicate effectively (C3h) and patients' low literacy and education (C3i) were sometimes used as justifications for not routinely checking for patients' understanding (C3j) and for being unaware of patients' information needs (C3k).

Facilitating factors (Table 4)

Seeing patients as persons (F1a; F1b), providing tailored health information in plain language (F3a; F3b), and recognizing the 'wake-up call' (a critical moment that is typically caused by a scare such as a complication of the

disease or the near death of someone close) as an opportunity to improve the communication between providers and patients (F2a; F2b) were regarded by both groups as facilitators to effective communication. The patients focused on the need for practical management information, i.e., knowing exactly how certain behaviors should be performed (F2c) and what to do in specific situations such as changing doctors (F2d), and expressed the desire to participate in peer group meetings for this purpose (F2e). The providers emphasized the importance of adjusting the information to the patients' day-to-day context (F2f) and comorbidities (F2g). Some patients stated that playing a more active role in consultations by looking providers in the eye and asking direct questions helped them to facilitate communication (F1c), while the providers wanted more shared decision making (F1d) through increased collaborative goal setting.

I always hope to be able to somehow negotiate with the individual what his plan is. Negotiate, that is to say, make this something two-sided that is not prescriptive. (FG6)

Only the patients mentioned the use of analogies as an important tool to facilitate communication (F3c) and suggested additional factors that mainly related to the patient-provider relationship, such as being actively listened to and building a trustworthy relationship (F1e) and receiving psychosocial support from providers who recognized their distress and helped them to recover (F1f), sometimes by using humor:

We [patient and nurses] all played, talked, in a friendly, spontaneous way (...) laughed, told jokes... [as a way to relieve distress]. (FG5)

The providers, in contrast, focused on overcoming the barriers concerning the communication of recommendations to promote behavior change, namely, increasing patients' responsibility by holding them accountable and providing knowledge (F2h), using an aggressive communication style (F2i) or a positive communication style by reinforcing the benefits of adherence to recommendations (F2j), investing in diabetes educators (F2k), receiving support from family to facilitate the engagement of healthier choices, in particular the choices that relate to eating habits (F2l), and macro-level interventions, such as overtaxing unhealthy foods (F2m), investing in children's health literacy in schools (F2n), or even building more trails for people to exercise more (F2o). The providers also defended the increasing consistency of information provided to patients (F3d) and improving their communication skills through training (F3e) as the facilitating factors that relate to gathering and providing information. Having more time to communicate with the patient also emerged as a facilitator to communication in clinical encounters (F3f), which created the opportunity to repeat information to improve understanding (F3g).

Discussion

This study identifies several aspects that can be useful in improving patient-centered communication in type 2 diabetes from the sides of both patients and providers. These aspects may help in fostering the patient-provider relationship, patients' participation and involvement, and providers' communication and relational skills in a context where the perceptions of the patients and the providers may apply to other chronic diseases. In this way, this study reinforces the communication theories in patient-centered communication regarding the essential elements of the communication skills that are relevant to clinical encounters, specifically the patient-provider relationship, followed by communication strategies that lead to improved disease and treatment-related behavior and information gathering and provision. Furthermore, this study adds to the literature by comparing the views of patients and providers who manage a complex chronic illness on the differential value and effect of each of these elements for effective patient-centered communication. This study also complements the idea that patients can push for patient-centered communication in clinical encounters and feel empowered to do this by peer group support.

Our data suggest a mismatch between what is more valued by patients and providers in clinical communication. The patients tended to be more focused on interactional factors (e.g., trust, respect, use of analogies, and supportive patient-provider relationships), and providers tended to be more focused on system-level factors (e.g., the availability of diabetes educators, patient and family socioeconomic position, macro-level interventi-

ons, and lack of time), whereas each of these factors almost did not come up for the providers and patients, respectively. These findings draw attention to the need to promote participatory care planning and delivery through active dialogue among the representatives of decision-makers, providers, patients and caregivers where knowledge and experiences can be elicited and exchanged and transformative change, i.e., change that leads to more equitable and dialogic relationships, can emerge. As part of what has been called relationship-centered care, treating patients with consideration and respect and providing psychosocial support is essential in establishing and maintaining trust.⁴³ Although promoting trust is at the core of medical communication curricula^{44,45} and patient centered-communication,^{8,46} this study calls attention to the need for constant sensitivity in enacting such guidelines throughout daily clinical encounters. Narrative medicine, or 'the clinical practice fortified by narrative competence—the capacity to recognize, absorb, metabolize, interpret, and be moved by stories of illness', might help to improve attentive, empathic, and person-centered care and communication.^{47,48} A lack of time is a common justification not to provide person-centered care,^{40,49} but in contrast with earlier findings, the patients did not mention short consultations as a barrier.⁵⁰ This omission may reflect their resigned acceptance of a social norm that is perceived as immutable or the fact that they place a higher value on overcoming health literacy-related barriers and on fostering the relationship dimension in communication.

Our data suggest that the patients regarded an aggressive attitude as a barrier, while some providers viewed it as a facilitator to persuade patients to change their behavior. The facilitator perception also conflicts with chronic disease management guidelines and communication curricula that encourage supportive communication styles to promote behavior change.^{17,18,44} These recommendations support the need for motivational interviewing by providers that uses an empathic nonconfrontational style to increase the motivation for behavior change, engage patients with treatment and build therapeutic relationships.^{51–55} Nonetheless, there is still no consensus on the outcomes of threatening interpersonal communication, with recent literature showing contradictory results.^{56–58} Future studies should explore the effect of communicator styles on patient-oriented outcomes.

The patients and providers interviewed for this study agreed on some constraining factors that relate to gathering and providing information (the use of jargon and insufficient competencies and consistency among providers), the patient-provider relationship (the power imbalance and avoidance of criticism) and disease and treatment-related behavior (disease minimization). The patients and providers also identified common strategies to facilitate effective patient-centered communication in clinical encounters such as using plain language, seeing patients as active persons, providing tailored practical information, and recognizing the 'wake-up call' as a useful and 'teachable moment',⁵⁹ i.e., a crucial moment to prompt an investment in communication towards lifestyle and treatment-related change. The use of technical language or medical jargon is a commonly acknowledged barrier to effective communication, particularly in chronic disease management,⁶⁰ that reinforces the power imbalance in the communication in clinical encounters.⁶¹ Disease minimization may partially be explained by a lack of clear-cut explanations concerning diagnosis and disease causation in a language or with analogies that patients can understand.⁵⁵ An inconsistency among different sources of health information, e.g., providers, undoubtedly decreases the likelihood of patients taking action or changing their behavior based on this information.⁶² The avoidance of criticism has also been reported in other studies⁴¹ and relates to the concept of being a 'good patient' in which patients seek to present themselves to their doctors as compliant and grateful individuals.^{63,64} The avoidance of criticism is deeply rooted in the power imbalance that is typical of a paternalistic model of care and aims to avoid judgment and confrontation.⁶³

A lower health literacy and education, as well as an adverse socioeconomic context, can make communication more challenging. Clear communication strategies are essential to address these difficulties and may help lessen the health literacy demands for patients.^{65–67} However, receiving clearer information does not necessarily equate with behavior change, such as leading healthier lifestyles, but patients become better equipped to make decisions regarding their health.⁶⁸

Strengths and limitations

The findings of this study can be used as a baseline to subsequent quantitative or qualitative studies within different populations and other chronic illnesses to contribute to the relevant literature in the field of effective patient-centered communication. The inclusion of participants across the entire spectrum of type 2 diabetes complications and all the health professions involved in their care is also a strength of this study. Previous studies that included patients and providers have focused on only one type of provider.^{22;41;69}

The possibility of selection bias from physicians recruiting patients and from the research team in recruiting providers cannot be excluded. The clinical setting where the patients' group discussions occurred may have hampered the full disclosure of the barriers to effective communication. In addition, the group interviews may have limited the discussion of the factors concerning the Social Determinants of Health, in particular among patients who may have felt uncomfortable acknowledging these issues in a group. The education of the patients who participated in our study is left-skewed, which reflects the low education levels of the Portuguese population in the same age range.⁷⁰

We did not aim to assess the differences in the perceptions among the providers or among the patients, and future studies should explore them by assessing the constraining and facilitating factors in patient-centered communication according to clinical and social characteristics. In other countries and health settings where more diverse staffing roles are available, mapping out health literacy mediators and including them in the dialogue about effective patient-centered communication could help bridge the gaps between patients and providers.⁷¹ Although there is a time gap between the two sets of focus groups (2012 for providers vs. 2015-2016 for patients), the recommendations for type 2 diabetes care did not meaningfully change in this period.

Implications for practice

Providers in general and physicians in particular, as well as patients, need to be aware of the core dimensions of patient-centered communication. Providers need more training in motivating patients to change unhealthy or unfavorable behaviors to promote and improve their health. Overcoming patients' health literacy barriers to communication is insufficient for effective communication to occur. Providers should make a greater effort to foster a therapeutic relationship with their patients by actively listening, building rapport and connection, showing empathy, and respecting patients' values and decisions. Furthermore, patients can claim a more active role in communication, and health institutions should help patients to better navigate their services and promote and steer them toward patient discussion groups to support peer distributed health literacy to enable disease and treatment-related behavior.

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Declarations of interest

None.

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Table 1: Sample characteristics

	Total (n=45)	Focus group 1 (n=7)	Focus group 2 (n=7)	Focus group 3 (n=5)	Focus group 4 (n=7)	Focus group 5 (n=7)	Focus group 6 (n=6)	Focus group 7 (n=6)
Type of participants								
Patients	33	Without complications	Diabetic retinopathy	Diabetic nephropathy	Diabetic foot	Ischemic heart disease or cerebrovascular disease		
Providers	12						Primary care physician, nurse, nutritionist, pharmacist, ophthalmologist, vascular surgeon	Endocrinologist, nurse, nutritionist, pharmacist, psychologist, nephrologist
Gender, n								
Female	17	4	4	0	1	2	4	2
Age in years, n								
<50	12	1	2	0	1	1	3	4
50-65	23	2	4	2	5	5	3	2
>65	10	4	1	3	1	1	0	0
Education (years)								
0-4	17	3	4	4	3	3	0	0
5-11	11	2	3	1	3	2	0	0
≥12	17	2	0	0	1	2	6	6
Length of professional experience/disease duration, n								
<1 year	4	0	1	0	0	3	0	0
1-9 years	15	3	2	1	2	2	2	3
≥10 years	26	4	4	4	5	2	4	3

Table 2: Outline of the factors that influence patient-centered communication as viewed by patients and providers

	Constraining factors [C]		Facilitating factors [F]	
	PATIENTS	PROVIDERS	PATIENTS	PROVIDERS
Patient-provider relationship				
Power imbalance [C] / patients playing more active role [F]/ increasing partnership in decision making [F]	✓	✓	✓	✓
Avoiding criticism	✓	✓		
Non supportive [C] / patient as person [F]	✓		✓	✓
Mistrusting [C] / trusting the provider [F]	✓		✓	
Lack of [C] / psychosocial support [F]	✓		✓	
Disrespecting the patient	✓			
Patients not being helped to give meaning to diabetes	✓			
Disease and treatment-related behaviour				
Disease minimization [C] / increasing patients' responsibility [F]	✓	✓		✓
Aggressive attitude [C/F] / positive communication approach [F]	✓			✓
Dismissing providers' responsibilities [C] / investing in diabetes educators [F]		✓		✓
Family obstruction [C] / family support [F]		✓		✓
Patients' low health literacy/education/income		✓		
Providing tailored practical information			✓	✓
Wake-up call			✓	✓
Macro-level interventions				✓
Gathering and providing information				
Use of jargon [C] / plain language [F]	✓	✓	✓	✓
Consistency between providers: lack of [C] / increased [F]	✓	✓		✓
Providers' skills: low competence [C] / improving communication [F]	✓	✓		✓
Analogies: inappropriate [C] / appropriate [F]	✓		✓	
Time: lack of [C] / more time [F]		✓		✓
Unawareness of patients' needs		✓		
Low patients' literacy/education		✓		
Not checking understanding [C] / repeating information [F]		✓		✓

Table 3: Participant quotes that illustrate the constraining factors to patient-centered communication in type 2 diabetes

	PATIENTS	PROVIDERS
C1 Patient-provider relationship		
Power imbalance	[C1a] Any patient talking with the doctor knows which side of the barricade he is on. (...) There are patients that do not heal faster because they sometimes have doubts and are almost humiliated asking questions. (FG4)	[C1b] There is an unbalanced relationship between the patient and the health professional (...) If I believe I'm right, you [patient] will do as I tell you because I was buried in textbooks studying that for many years to help you. That is a huge barrier, right? The power imbalance in that relationship. (FG7)
Avoiding criticism	[C1c] [Asked if she had told the doctor that she had had very high blood glucose readings because she did not take her diabetes medication] Oh no! He would reprimand me [laughter]! (FG2)	[C1d] Then they even give themselves the luxury of... nowadays the devices [glucose meters], most of them have memory... but they don't take them to the doctor and [instead they] make all the values up to show the doctor because doctors nag them, because doctors chew their ears off. (FG6)
Nonsupportive	[C1e] In a group consultation, when they [providers] come to the hospital ward one day of the week, sometimes Tuesday, sometimes Thursday, when it suits them, three or four doctors come with the doctor in charge [...] and tell her [the doctor in charge] 'This is Mrs. Mary, she was admitted for this and that.' I mean... we don't hear an explanation. (FG4)	
Mistrusting the provider	[C1f] In health centers, it's complicated [to ask for shifting the doctors based on mistrust]. If the person doesn't trust the doctor... 'Look I don't want this doctor because I don't trust him.' And where is trust? I mean it is not something that comes in a box and you can show it doesn't fit. It's hard. (FG5)	
Lack of psychosocial support	[C1g] A nurse came to do my dressing, removed that skin that was the callus and the doctor says out of nowhere: 'Mrs. Mary, that finger is not going to make it!' Like that and I immediately started to cry. [...] And she [doctor] walks away, for God's sake! (FG4)	
Disrespecting the patient	[C1h] We had a few doctors that didn't even greet people. (FG5)	
Patients not being helped to give meaning to diabetes	[C1i] [Questioned about having asked the doctor after saying that he did not know why he had diabetes] I have already asked but that she doesn't... uh... doesn't know how I picked this up too... (FG2)	

C2 Disease and treatment-related behavior		
Disease minimization	[C2a] Diabetes is the silent disease and that is very dangerous. (...) It doesn't hurt [laughter] and we mess up [laughter]. (FG1)	[C2b] People often don't accept they have diabetes and don't care much. [...] I mean, in type 2 diabetes people say: 'Everybody has it.' (FG6)
Aggressive attitude	[C2c] 'You have to do this!' With me it doesn't work, I was not used to it. (...) I get along better with the soldiers than I do with the officers. (FG5)	
Dismissing providers' responsibilities		[C2d] There has to be well-trained educators ... because otherwise we are wasting trained professionals [physicians' time and knowledge] that have to do other things, right? (FG7)
Family obstruction		[C2e] I ask who cooks (...) [and] it's his wife. Then, the next day, he [the patient] comes in with his wife and she is obese, weighs 200 kg. [Laughter] I mean, it's true that that woman will never (...) be the driver of change. (FG6)
Patients' low health literacy/education/income		[C2f] If we don't have economic development, we obviously don't have social development, we don't have more health literacy... we will always have poorer choices... (FG7) [C2g] Oh... and I have the tendency to think that this has also to do with the educational level. [...] And sometimes the person can be highly literate and have no education in terms of that specific area. (FG6) [C2h] People don't always have money to eat the healthier things or to buy all the drugs. (FG6)
C3 Gathering and providing information		
Use of jargon	[C3a] Because sometimes they [providers] use words that we don't understand. (FG2)	[C3b] Then another obstacle has to do with language; sometimes there is an encrypted language, a medical language (...) that may not be easily understood by people [the patients]. (FG7)
Inconsistency among providers	[C3c] I tell them [providers], but it's no good. Some [doctors] say: 'eat less', [others say] 'eat more during the day', [or] 'add a little more insulin', take less [insulin]'. (FG4)	[C3d] We had a really nice leaflet to not offend anybody just saying what was going on, just facts! The doctor didn't care, he said It's my job to treat this!' (FG6)

Insufficient communication competences of providers	[C3e] I divide doctors into three classes: assembly-line doctors, doctors-just-because, and doctors-doctors. And unfortunately, I get them all. (...) There's the doctor-just-because... he went through medical school and that was it. Then he forgot to study more, anyway. (FG4)	[C3f] Our own training (...) on insulins, how they work, is very limited (...) It is not something that allows me to tell patients that they need to do this and that. (FG7)
Inappropriate analogies	[C3g] So, she [doctor] prescribed me the pills, all right, [but] didn't give me additional explanations... [She] told me a story that a banana is like a potato but more expensive or something [and I didn't understand what she was talking about]. (FG5)	
Lack of time		[C3h] To communicate well, we need first to get to know the person and even ask what he/she knows about diabetes... not assume that he/she knows just because he/she has had diabetes for a while... it's just that we don't always have the time to do it. (FG6)
Low patients' literacy/ education		[C3i] Some people [the less educated] will never understand everything or... a great deal of things about the disease. (...) Some people objectively can't do it... [understand and manage medications]. (FG6)
Not checking understanding		[C3j] We want them [patients] to repeat it [what we said] but then we realize that the person didn't really listen. And what now, will we say just one [piece of information] to check if he/she listens or are we going to repeat everything one more time? No, repeating everything won't work because I don't have the time. (FG7)
Unawareness of patients' needs		[C3k] What do they [patients] need to know? I have some difficulty trying to understand exactly what they need to know to change the way they act. (FG7)

Table 4: Participant quotes that illustrate the facilitating factors to patient-centered communication in type 2 diabetes

	PATIENTS	PROVIDERS
	F1 Patient-provider relationship	
Seeing patients as persons	[F1a] I agree with that doctor of a certain age that could be my grand-father, he listened to me like a priest in confessional and told me: ‘You have to look after yourself and do more or less what you feel is right’ [feeling heard]. (FG4)	[F1b] The approach to diabetes is not the approach to diabetes or the diabetic. It is the approach of a human being in front of us that will probably have information. (FG7)
Patients playing a more active role/increasing partnership in decision making	[F1c] I had squabbles with doctors before, it is not that they showed me disrespect but: ‘You don’t know. Are you the doctor?’ and I reply: ‘In fact I am not a doctor, not even close, but I am my own man, and being my own man, I know my resolution to get better’... My suggestion is... to look the doctor in the eye and say: ‘Doctor, what is wrong with me?’ (FG4)	[F1d] Doctor and patient, side by side, both deciding, agreeing... (FG7)
Trustworthy relationships	[F1e] The trust between the patient-doctor’ is fundamental because [...] a person that doesn’t have trust... it’s complicated. (FG5)	
Psychosocial support	[F1f] I immediately started to cry. [...] And the nurse says: ‘Don’t worry because your finger is not lost, when you came in it was much redder, it had an infection but now is looking better.’ (FG4)	
	F2 Disease and treatment-related behavior	
Wake-up call	[F2a] I was supposed to take drugs for hypertension, diabetes, triglycerides, and cholesterol. (...) And I did not take them, so I ended up here [at the hospital] with a heart attack. Now, of course... after the warning, I started to take the medications, the insulin... (FG5)	[F2b] [When dealing with patients harder to motivate towards behavior change] I really think that only the wake-up call or the fact of having, for example, a brother with type 2 diabetes that had a heart attack and was at death’s door. Only a family wake-up call, an emotional wake-up call makes them change. (FG6)
Providing tailored practical information	[F2c] We needed to know exactly how we should and shouldn’t do it [follow recommendations]. (FG3) [F2d] People [patients] should also be able to change doctors anytime they don’t get along with them. Patient 2: But I don’t know what the argument is and how to do it. (FG5) [F2e] Many meetings like this one [focus group]. (...) It may not look like it, but we learn a great deal with one another. (FG2)	[F2f] We have to be very practical, very practical in what we say, very practical in the education we provide and think: How is your day?’ ‘It is this, this and this.’ Then, we will work through their day with that person. (FG7) [F2g] We sometimes tell people to walk, exercise, but you got to know the person well. If it’s someone with foot pain, he or she will never walk. It’s no good. (FG6)

Increasing patients' responsibility		[F2h] Actually he [the patient] doesn't need very precise knowledge early on and you have to hold people accountable and provide knowledge for that and all that. (FG6)
Aggressive attitude/positive communication approach		[F2i] I am usually not gentle. Because I get them [patients] at a stage when either we can save their leg or we have to amputate. So I just say it all and they are very shocked. (FG6) [F2j] Maybe we should talk more about the benefits, talk more about the positive side of the therapeutic management. (FG6)
Investing in diabetes educators		[F2k] There has to be well-trained educators ... because otherwise, we are wasting trained professionals [physicians' time and knowledge] that have to do other things, right? (FG7)
Family support		[F2l] 15 days ago, he [the patient] came by my office and weighed 80Kg. (...) 'I need to congratulate you!' (...) And I asked what happened? His daughter had entered the picture and removed the mother [his wife] from the kitchen, had started cooking and clearly squeezed the old man. (...) So, the family entered the picture. (FG6)
Macro-level interventions		[F2m] Maybe they [the fast-food and the candy] should be more expensive (...) and overtaxed. (FG6) [F2n] I think children have a... very important role. Maybe in schools if they talked about the disease and explained [healthy behaviors]... (FG6) [F2o] Some things [boardwalks] have contributed to that [patients having access to structures to support behavior change advice from providers]. (FG6)
F3 Gathering and providing information		
Plain language	[F3a] I wish they [the physicians] would speak small-town Portuguese: You are being treated for this, you need to do this and that! And you learn. Now, speaking in medical terms you wonder. I do! (FG4)	[F3b] Both the family doctor and the nurse (...) know exactly what educational limitations they [their patients] have, the difficulties understanding... They [providers] adjust the language. (FG7)
Appropriate analogies	[F3c] [Describing how another doctor explained that previous doctors had prescribed medication that caused him to feel very sick from very low blood sugar] 'My colleagues did the job at 80%. Because they started giving you airplane fuel when your car should have regular fuel.' (FG4)	

Increased consistency among providers and improving their communication skills	[F3d] There is another important aspect, which is for the entire team to use the same language because if everybody uses the same language they reinforce each other and that gives the patient a lot of confidence. (FG7)
Having more time	[F3e] I think there needs to be training of the professionals in ways to communicate [with patients]. (FG7)
Repeating information	[F3f] Because we categorize people by their attire, their gaze, the way they talk... and we believe the person is understanding everything but only if you take a little longer will you go the extra mile. (FG6)
	[F3g] No, at that moment [the diagnosis] very little will be taken in. Moments need to be repeated. (FG7)

What patients want is not rocket science, which is really unfortunate because if it were rocket science, we would be doing it. We are great at rocket science. We love rocket science. What we're not good at are the things that are so simple and basic that we overlook them.

L. Gilpin "Putting patients first: best practices in patient-centered care" (2009)

5

Discussion

This thesis is based on a multi-method approach combining quantitative and qualitative studies to assess health literacy and tackle the barriers caused by limited health literacy in type 2 *diabetes mellitus*.

We validated three different health literacy instruments in the Portuguese population and compared them, concluding they can all be useful in assessing health literacy in different settings. Using one of them, the Newest Vital Sign, we have estimated a national prevalence of limited health literacy of about three in four people. As neither of them assesses the communication sub-dimension of health literacy, we explored perceptions on the constraining and facilitating factors to patient-centred communication of both patients and providers in the care of type 2 diabetes. Findings from this last study suggested that communication skills of providers could improve considerably, especially in what concerns interpersonal and relational skills, such as active listening, expressing empathy, courtesy and respect. They also suggested that patients' participation and involvement in care could be claimed by patients and supported by providers and health systems.

WHAT DOES THIS WORK ADD?

When we began, there was no health literacy instrument available for use in research or clinical settings in Portugal. We validated the Medical Term Recognition Test, the Short Assessment of Health Literacy for Portuguese-Speaking Adults, and the Newest Vital Sign in the Portuguese population. Since then, another validation of the Newest Vital Sign was published²⁹⁴ and one more health literacy instrument was validated in Portugal by another research team - the HLS-EU-Q.²⁹⁵

Brief general health literacy instruments directly testing patient abilities such as the ones we validated, although narrow in scope, seem better suited to advance health literacy research in countries where health literacy is just starting to gain momentum in the context of public health and clinical settings.²⁹⁷ We validated three instruments that included the most commonly used ones (NVS) or cross-cultural adapted derivatives (METER and SAHLPA). While the REALM is one of the most commonly used health literacy instruments, it only tests pronunciation and, despite including medical terms, it is commonly classified as a general reading test.⁴⁶ Contrastingly, derived instruments such as the METER and the SAHLPA, because they test reading comprehension of medical terms as well, are presumed to assess health literacy,

albeit only partially. The NVS additionally assesses the ability to interpret and act on health information, as well as basic and complex numeracy skills. Judging from within Nutbeam's health literacy framework it is a more comprehensive instrument.¹³ Any of them could be used in specific research settings to assess health literacy as a determinant, confounding factor or outcome. In clinical settings they could be used to help tailor care and communication with patients and communities, potentially reducing social inequalities. Results from the calibration analysis now allow direct comparisons of scores in these three instruments across studies and respondents. The most vulnerable and disadvantaged groups of the population (older people, people with long-term health conditions or disabilities, disadvantaged socioeconomic groups, migrants and people from ethnic minorities) are more likely to have limited health literacy, engage less effectively with health systems, and present poorer health outcomes.²⁹⁸ Although we advocate for a universal precautions approach to health literacy (acting as if everyone could have limited health literacy), assessing it directly can enable providers and health organisations to target interventions that improve the health literacy of these groups and ultimately their health outcomes, within a broader strategy of improving the health literacy of providers, health, and social care systems, as well as addressing the conditions in which people are born, grow, live, work, and age.²⁹⁸

However, they all leave out the communication component of health literacy. While there is still some debate on whether health communication is a sub-dimension of health literacy or not, the fields of health literacy and health communication have been converging.^{299,300} At the very least, communication is a key skill to add to access, understanding and interpretation skills of health information, in order to make more informed decisions about health in the individual, community and political spheres. Thus, whether or not communication skills are included in the definition, they are an important strategy to mitigate the obstacles raised by limited health literacy.³⁰⁰

The lack of a consensual definition is a major issue in the health literacy field and interferes with the development and choice of assessment instruments. We chose a definition that excludes organisational health literacy and distributed health literacy, fairly recent topics of interest in the field.^{251,301} However, both conceptualisations rely on the health literacy of other stakeholders: the first on a health literate leadership and workforce, and the second on health literate providers, family, social networks and media. The concept of health literacy keeps evolving, however. Experts have recently proposed that it should be redefined to include system demands and complexities and not only the individual skills of the lay public and health professionals.⁶²

Findings from our qualitative study are key in identifying patient-centred communication gaps in type 2 diabetes clinical encounters and strategies to fill them, contributing to pinpoint the areas that should be covered in communication training for providers under the National Programme of Prevention and Control of Diabetes:³⁰² fostering the patient provider-relationship, enabling disease and treatment-related behaviour and gathering and providing information. They could also inform curricula for continuing education on general patient-centred communication skills of providers and contribute to the development of a more comprehensive health literacy instrument; one that also answers the call to rigorously assess the oral, numeracy, or writing skills of public health, health care, or private sector professionals.⁶²

WHAT IS BEING DONE IN PORTUGAL?

The Portuguese Health Plan 2012-2016 referred to health literacy as a strategy for citizenship empowerment and inequity reduction, as well as a factor to consider in the design of strategies to increase health quality and health policies to improve health outcomes.³⁰³ In 2015, the Plan was revised and extended to 2020.³⁰⁴ It included a new recommendation to foster health literacy promotion actions, namely in the areas of vaccination, screening, the use of health services and risk factors. In 2016, health literacy was targeted in a specific Health Programme, the 'Health Education, Literacy and Self-Management Programme'.³⁰⁵ The aims of this government initiative, subsequently merged with the 'Prevention and Management of Chronic Disease Programme' and renamed 'Health Literacy and Integrated Care', are to prepare and support informal caregivers in home-based care, preventing diabetes, obesity and promoting mental health and healthy ageing, as well as the rational and safe use of medicines.³⁰⁶ This triggered a process of change in the National Health System that was entitled 'SNS+ Proximidade' [NHS More Proximity] that aimed to centre Health Care on people, accompanying and supporting them throughout the life course.³⁰⁷ It focuses on two main goals: integrated citizen-centred care and promoting citizens health literacy. Integrated care aims to improve people's navigation experience in the National Health System, fostering timely and sustained access, coordinated care and information transmission between different providers (mirroring the international 'Patient-Centred Medical Home'³⁰⁸) as well as on defining tailored care plans for people with chronic illnesses.³⁰⁷ Improving citizens' health literacy focuses on improving health knowledge using strategies such as a National Health Literacy Library designed for citizens' health education,³⁰⁹ and improving quality of care.³⁰⁷

Several parallel studies and interventions are also being implemented to lower the health literacy demands for people and increasing their health literacy skills. For instance, in Porto University, the recently created Media Innovation Lab - Laboratório de Criação para a Literacia em Saúde (LACLIS) aims to use media to improve people's health literacy.³¹⁰ From the same university, a query suggestion system aims at improving web search for medical information tailored to people's health literacy,³¹¹ and a mobile phone app, HealthTalks, aims to improve patients' understanding of their clinical interactions with providers, proving transcripts and additional explanations of parts of the medical consultation.³¹²

WHAT IS LOST IN TRANSLATION?

We have documented that a high proportion of the Portuguese population has difficulties obtaining and translating health information into actions to improve health. Additionally, we have reported that there are probably some issues with the patient-centred communication skills of providers in type 2 diabetes as well.

Recent government investments in improving health literacy are not being matched by updates in diabetes care guidelines in Portugal. Although the 2013 national guidelines on the Integrated Care of Type 2 Diabetes Mellitus documented a wide range of patient-centred communication needs in both patients and providers, the current communication recommendation focuses on clear and precise information provision, disregarding the relational issues, such as empathy, courtesy and response to emotions.³¹³ This is what we seem to have lost and are missing. In a disease so complex and that demands so much of patients and providers as is type 2 *diabetes mellitus*, it is clearly not enough to increase the health literacy

of both sides of the equation. Providing continuous medical education of evidence-based practice, scientific literacy, plain language, and teach-back to providers and improvement in knowledge or navigation experience of patients is insufficient. We need to simultaneously promote a different type of training on patient-centred communication in type 2 diabetes, one that focuses on investing in the patient-provider relationship from both sides. Narrative medicine, i.e. the ability to recognise, absorb, interpret, and act on the stories and circumstances of others,³¹⁴ could aid to improve the relationship-related communication skills of both. Our conclusions can be translated to other chronic illnesses.

Training providers in patient-centred communication should not be restricted to pre-graduate studies or limited to the first years of pre-graduate studies³¹⁵ but integrated into continued education efforts,³¹⁶ that we suggest should no longer be optional in Portugal. Clinical management guidelines should explicitly include recommendations on patient-centred care and communication in all chronic conditions.³¹⁷

Unquestionably all of this can only happen if health systems and organisations become more responsive to the health literacy needs of the people and communities they serve, as well as on the needs of their workforce, integrating health literacy in its mission, structure, operations and planning.²⁵¹

Furthermore, strategies to improve health literacy of the general population, patients, providers, public health professionals, journalists, and politicians would benefit from being implemented in co-design between all the stakeholders.

6

Conclusion

We have validated three brief health literacy instruments that directly test patients' abilities in the Portuguese population: the METER, the SAHLPA, and the NVS. We compared them in terms of validity, precision and difficulty and calibrated them so it was possible to directly compare scores between studies or individuals using only one of them. Based on our findings we recommend using the METER when a continuous measure is needed or when health literacy is expected to be normally distributed within a sample, the SAHLPA in settings with expected very low health literacy, and the NVS when it is necessary to assess the numeracy sub-dimension of health literacy.

Using the NVS in a representative sample of the Portuguese population we estimated a prevalence of limited health literacy in Portugal of about three in four people, which is higher than estimates from other European countries.

Using focus groups, we explored the barriers and facilitators to patient-centred communication in type 2 diabetes clinical encounters. We identified core themes in the discourses of both patients and providers, highlighted the similarities and differences, and reported that improvements on patient-centred communication depend on fostering the patient-provider relationship, patients' participation and involvement, and training providers' communication skills.

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