

# Validation of a Health Literacy test in a Danish population – Results from a pilot study

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## Abstract

*The authors of this paper translated and adapted the original American full-length Test of Functional Health Literacy in Adults (TOFHLA) into a Danish version. As a part of a pilot study the Danish TOFHLA was validated for use in a Danish population. The purpose of the pilot study was to test and validate the Danish version of TOFHLA on 42 consecutively selected patients diagnosed with chronic obstructive pulmonary disease (COPD), and to explore tendencies and associations between health literacy and demographic characteristics, educational attainment, and mean response time. The 42 COPD patients were recruited from two different settings (the municipality of Aalborg and the municipality of Hjørring). Based on a Cronbach's alpha coefficient of 0.943, a reliable Danish TOFHLA has been successfully developed. The results of the pilot study showed no statistical significant differences between COPD patients recruited from the municipality of Aalborg and those recruited from the municipality of Hjørring. More research is needed to explore the level of health literacy among Danish COPD patients.*

**Keywords:** Denmark, chronic obstructive pulmonary disease, TOFHLA, validity, Health literacy

## Introduction

During the past decade, health literacy has become a rather vibrant area of research [1]. In spite of the rapid development in the research area, there is still no consensus regarding the definition and conceptualisation of health literacy [2]. The definitions from the Institute of Medicine [3], the WHO [4] and the American Medical Association (AMA) [5] are the ones most frequently cited in the relevant qualified literature and also the most acknowledged ones [2]. These definitions are slightly different in content, but they are very similar in terms of their emphasis on the individual ability to evaluate, access and use health-related information to make appropriate health decisions and maintain good health [2].

In recent years, health literacy has received increased attention in European legislation and politics, and also as an important area of research [6]. Research on health literacy has been carried out in the UK [7], Japan [8], Australia [9,10], Switzerland [11], Korea [12], and the Netherlands [13]. The lack of consensus regarding the conceptualisation and

definition causes disagreement about the measurement of health literacy [1]. In the literature, the *Rapid Estimate of Adult Literacy in Medicine (REALM)* [14] and the *Test of Functional Health Literacy in Adults (TOFHLA)* [15] are the screening instruments most widely used to assess health literacy, but they are only available in an English/American and Spanish version [16]. To date, there is no standardised approach to assess health literacy in most European countries [17]. Therefore, as in many European countries the research into health literacy in the Danish context is at an infant stage.

There is a higher prevalence of low health literacy among elderly people with a chronic disease like for example chronic obstructive pulmonary disease (COPD) [16]. The association between COPD and health literacy is rather unexplored, but three recent studies investigated the association between various health outcomes and health literacy among COPD patients; one study found that COPD patients with a low level of health literacy often have a poorer overall health status compared to more health-literate COPD patients [18]. The second study found that poorer health outcomes seem to be associated with a low level of health literacy among COPD patients [19]. The third study emphasizes the role of health literacy in chronic disease self-management; it states that good doctor-patient communication is important to support self-management among COPD patients [20]. The third study also points out that recognition of low health literacy as a problem, and suitable screening instruments for identifying patients with a low level of health literacy in a proper and respectful way, are required to achieve better health outcomes [20]. Baker et al. [21] have also stated the importance of identifying patients vulnerable to low health literacy, so that education efforts regarding chronic disease management and medication can be tailored according to their needs [21]. On this basis, a logical first step is the development of proper health literacy screening instruments. The full-length original American TOFHLA has been used to assess functional health literacy in various populations and health conditions. Functional health literacy, as assessed in the original American TOFHLA, comprises basic numeracy, reading and writing skills applied in a healthcare setting [15]. Functional health literacy is the foundation in the concept of health literacy [22].

As the original American TOFHLA is well described and widely used in existing literature, the authors of this paper translated and adapted the original American TOFHLA into a Danish version. As a part of a pilot study the Danish TOFHLA

was validated for use in a Danish population based on a sample of patients with COPD. The purpose of the pilot study was to test and validate the Danish version of TOFHLA on consecutively selected COPD patients from two different settings, and to explore tendencies and associations between health literacy and demographic characteristics, level of education, and mean response time.

## Materials and Methods

### Procedures

A Danish version of the original American TOFHLA was developed and evaluated for cultural equivalence for the Danish population. This cross-cultural adaptation process was conducted according to the guidelines for cross-cultural adaptation as defined by Beaton et al. [23]. In accordance with Beaton et al. [23], the Danish TOFHLA was pre-tested as a part of a pilot study, to ensure consistency and reliability of the instrument. The Danish TOFHLA was used to explore the level of functional health literacy among a sample of COPD patients in the region of Northern Jutland, Denmark.

### Participants in the pilot study

The participants in this pilot study were selected using consecutive sampling. Consecutive sampling seeks to include all accessible subjects at multiple data collection sites. In this case the consecutive sampling was carried out at the pulmonary outpatient clinic at Aalborg Hospital (the municipality of Aalborg) and the Health Centre in Hjørring (the municipality of Hjørring); it provided a sample of 42 Danish participants with COPD. The Health Centre in Hjørring and Aalborg Hospital are both located in the area of Northern Jutland, Denmark. This area represents a broad socio-demographic range, as it serves almost 45,000 people with COPD [24].

At each site, the contact with all accessible subjects was initiated by a healthcare professional. The healthcare professionals provided the subjects with a short written description (developed by the researcher), which explained the requirements of participants as well as the process should they agree to take part in the pilot study of the Danish TOFHLA. The healthcare professionals were asked to consider the following inclusion and exclusion criteria when potential subjects were invited to participate in the pilot study:

**Inclusion criteria:** Patients diagnosed with COPD (as assessed by the two healthcare professionals and afterwards the diagnosis of COPD was confirmed by self-report to the researcher), men and women, adult > 18 years, pregnant or non-pregnant, and able to read and understand Danish as judged by the researcher.

**Exclusion criteria:** Patients diagnosed with dementia (as assessed by the two healthcare professionals and afterwards this was confirmed by researcher's observation of the patient), being too ill to participate or blindness, unable to read or understand Danish as judged by the researcher, unable to understand the informed consent procedure also as judged by the researcher.

If a subject agreed to participate, the first step was to ensure that the participant was suitable for participation and inclusion in the pilot study; this was done by the researcher. The researcher also informed the participants orally about the purpose of the pilot study and about their rights to stop the interview/test and withdraw at any time. Relevant data (completion of the Danish TOFHLA and the face-to-face interview) were collected at the most convenient times for the participants either in their own homes or at the setting where they received health services. The participants were assured privacy and confidentiality conditions at all times during the pilot study.

### Data collection in the pilot study

Relevant data were collected for statistical analysis using two types of methods:

1. Each COPD patient entered a face-to-face interview to collect the following demographic data: *municipality, civil status, educational level, sex, and age*. The interviews were carried out by the researcher.
2. After the face-to-face interview, each COPD patient was asked to complete the Danish TOFHLA. The original American TOFHLA consists of a numeracy part containing 17-items and a reading comprehension part containing 50-items [15]. This structure is maintained in the Danish TOFHLA. In the Danish TOFHLA, the numeracy part concerns the participant's ability to keep a clinical appointment, understand instructions for taking medication, understand financial assistance, etc. For example, a participant could be asked to read prescription medication instructions or an appointment reminder card, and afterwards, s/he would be asked about what had been read. The reading comprehension part of the Danish TOFHLA is constructed as a modified Cloze procedure. In a Cloze procedure words are randomly deleted from a reading passage [25]. In this case of health-related reading passages, every fifth to seventh word is removed from the text, and then the participant is asked to select the most suitable word from a list of four possible words. The total health literacy scores for the Danish TOFHLA are divided into three levels: **inadequate (score: 0-59)**, **marginal (score: 60-74)** and **adequate (score 75-100)** – just like the original American TOFHLA [15].

### Data Analysis

The statistical software SPSS version 21 [26] were used to analyse the results obtained from the Danish TOFHLA and the basic demographic interview. A variety of statistics were performed on the obtained data to describe the study participants in terms of *frequency, percent, mean, standard deviations*, etc. Cronbach's alpha coefficient was used to analyse the internal consistency of the Danish TOFHLA; this was conducted as an overall analysis of the Danish TOFHLA followed by an analysis on the two subcategories (numeracy

and reading comprehension). The criteria for reliability set by Houser [27], requires a Cronbach's alpha coefficient that exceeds a value of 0.7 before an instrument is considered reliable.

Descriptive statistics were applied to explore the health literacy score by demographic characteristics, level of education, and mean response time to the Danish TOFHLA. ANOVA test and independent t-test were used to assess statistical significant differences between groups [28]. Finally, a multiple linear regression analysis was conducted to explore the association between health literacy and educational level – adjusted for age and sex.

## Results

Our sample constituted 42 Danish COPD patients); mean age was 68.7 years (range 34-86 years) with a standard deviation of 11.49. 42.9% of the participants were recruited from the municipality of Hjørring (Health Centre) and 57.1% were recruited from the municipality of Aalborg (Hospital). The basic demographics of the 42 participants are shown in *Table 1*.

*Table 1 - Basic demographics of the 42 participants*

<b>Number of participants</b>	42
<b>Age</b>	Mean = 68.7 (range 34 – 86 years)
	<b>Frequency (percent)</b>
<b>Sex</b>	
Men	20 (47.6)
Women	22 (52.4)
<b>Recruitment</b>	
Municipality of Aalborg (Hospital)	24 (57.1)
Municipality of Hjørring (Health Centre)	18 (42.9)
<b>Civil status</b>	
Married or living with a partner	23 (54.8)
Living alone	19 (45.2)
<b>Level of education</b>	
9 <sup>th</sup> or 10 <sup>th</sup> grade or less (some only completed 7 <sup>th</sup> grade)	18 (42.8)
High school	6 (14.3)
Higher education	2 (4.8)
Skilled worker (trade, industry, office etc.)	16 (38.1)

<b>Correct answer to question about COPD stage.</b>	4 (9.5)
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The basic demographics of the 42 COPD patients are fairly balanced with 20 men and 22 women, 23 reported having a partner and 19 participants reported not having a partner. The distribution of educational attainment is skewed as only approximately 19% of the participants had a higher education or completed high school. It should be noted that only four of the 42 participants could provide a correct answer when they were asked about their COPD stage.

In the Danish TOFHLA, the internal consistency was determined to 0.943 by the Cronbach's alpha coefficient. A Cronbach's alpha coefficient of 0.943 indicates that the Danish TOFHLA fulfils the criterion for reliability (> 0.7 as set by Houser [27]). When the Cronbach's alpha coefficient was calculated for the two sub-categories, the following reliabilities were observed: reading comprehension  $\alpha_{\text{com}} = 0.940$  and numeracy  $\alpha_{\text{num}} = 0.750$ .

The health literacy score was explored among the 42 COPD patients. The distribution of the health literacy score by health literacy category, various demographics and educational level are shown in *Table 2*.

*Table 2 - Distribution of health literacy (HL) score*

	Obs (n)	Mean	Std. Dev.	Min	Max
<b>Overall HL score</b>	42	72.43	18.14	29	95
<b>HL score by health literacy category</b>					
Inadequate	11	47.09	8.84	29	59
Marginal	8	67.38	3.54	62	73
Adequate	23	86.30	6.47	76	95
<b>HL score by civil status *</b>					
Married or living with a partner	23	75.39	17.77	40	95
Living alone	19	68.84	18.39	29	94
<b>HL score by gender *</b>					
Men	20	76.05	17.48	40	95
Women	22	69.14	18.49	29	95
<b>HL score by educational level *</b>					
9 <sup>th</sup> or 10 <sup>th</sup> grade or less (some only completed 7 <sup>th</sup> grade)	18	71.61	19.37	29	95
High school	6	71.67	21.45	40	95
Higher education	2	75	11.31	67	83
Skilled worker (trade, industry, office etc.)	16	73.31	17.58	41	94

office etc.)					
<b>HL score by recruitment site *</b>					
Municipality of Aalborg (Hospital)	24	70.75	19.15	40	95
Municipality of Hjørring (Health Centre)	18	74.67	16.96	29	95

\*No statistical significant differences were observed in health literacy score.

As seen in *Table 2*, 23 COPD patients were categorised as having an adequate level of health literacy with an average health literacy score of 86.30, 8 were categorised as having a marginal level of health literacy with an average health literacy score of 67.38, and 11 were categorised as having an inadequate level of health literacy with an average health literacy score of 47.09. Those living alone had an average health literacy score of 68.84 ± 18.39, whereas those living with a partner had an average health literacy score of 75.39 ± 17.77. The average health literacy score among the 20 male COPD patients was 76.05 ± 17.48, and 69.14 ± 18.49 among the 22 female COPD patients. An average health literacy score of 75 ± 11.31 was observed among COPD patients, whose highest educational attainment was higher education, and an average health literacy score of 71.61 ± 19.37 was observed among those, whose highest educational attainment was 9<sup>th</sup> or 10<sup>th</sup> grade or less. COPD patients recruited from the municipality of Hjørring had an average health literacy score of 74.67 ± 16.96 and those recruited from the municipality of Aalborg had an average health literacy score of 70.75 ± 19.15.

The mean response time to the entire Danish TOFHLA was explored; it was explored if educational level or health literacy category affected the mean response time; results are summarised in *Table 3*.

*Table 3 – Mean response time*

	Obs (n)	Mean	Std. Dev.	Min	Max
<b>Mean response time</b>	42	18.38 (18 min 23 sec)	2.93	10	22
<b>Mean response time by health literacy category **</b>					
Inadequate	11	20.18 (20 min 11 sec)	1.99	17	22
Marginal	8	19.88 (19 min 53 sec)	1.89	17	22
Adequate	23	17 (17 min)	2.94	10	21
<b>Mean response time by recruitment site *</b>					
Municipality of Aalborg (Hospital)	24	18.21 (18 min 13 sec)	3.18	10	22
Municipality of Hjørring	18	18.61 (18 min 37)	2.64	13	22

(Health Centre)		sec)			
<b>Mean response time by educational level *</b>					
9 <sup>th</sup> or 10 <sup>th</sup> grade or less (some only completed 7 <sup>th</sup> grade)	18	18.17 (18 min 10 sec)	3.13	12	22
High school	6	19.33 (19 min 20 sec)	2.16	17	22
Higher education	2	18.5 (18 min 30 sec)	2.12	17	20
Skilled worker (trade, industry, office etc.)	16	18.25 (18 min 15 sec)	3.17	10	22

\*No statistical significant differences were observed in mean response time.

\*\* Statistical significant difference was observed in mean response time between groups (Sig. = 0.002).

The mean response time for the completion of the entire Danish TOFHLA was 18 minutes and 23 seconds (95% CI: 17 min 28 sec; 19 min 18 sec). COPD patients in the lowest health literacy category (inadequate) had a mean response time of 20.18 ± 1.99 and COPD patients in the highest category had a mean response time of 17 ± 2.94. The mean response time among COPD patients recruited from the municipality of Aalborg was 18.21 ± 3.18 and 18.61 ± 2.64 among those recruited from the municipality of Hjørring. A mean response time of 18.5 ± 2.12 was observed among COPD patients, who had a higher education, and a mean response time of 18.17 ± 3.13 was observed among those, whose highest educational attainment was 9<sup>th</sup> or 10<sup>th</sup> grade or less. It should be noted that no difference was observed between genders in response time to the entire Danish TOFHLA.

A multiple regression analysis was conducted to explore the association between health literacy score and level of education – adjusted for sex and age; results of this analysis is presented in *Table 4*.

*Table 4 – Multiple regression analysis*

Model	B	Std. Err.	Beta	t	Sig.
(Constant)	115.09	21.17		5.4	0.00
Level of education	-0.99	2.39	-0.08	-0.4	0.68
Age	-0.42	0.24	-0.27	-1.7	0.09
Sex	-7.59	6.53	-0.21	-1.2	0.25

The multiple regression analysis provided a Sig. value of 0.68 (> 0.05) between health literacy score and level of education - adjusted for sex and age.

## Discussion

As the American TOFHLA is one of the screening instruments primarily used to measure health literacy in existing literature, the authors chose to translate and adapt it for use in a Danish population instead of developing a new screening instrument. It is easier to validate a Danish version of the original American TOFHLA on the assumption that it has a sufficient level of validity and reliability. Additionally, it will be possible to make more accurate comparisons of the results in the literature with the results obtained with the Danish TOFHLA. However, the original American TOFHLA could not just be directly translated into a Danish version, as the American healthcare system is very different from the Danish healthcare system. Therefore, to make sense in the Danish context, some of the questions in the original American TOFHLA were modified in the translation and adaptation process, after being discussed carefully by the expert panel (stage IV as defined by Beaton et al. [23]). If modifications of the original instrument are made without changing the original intent of the questions and the criterion for internal consistency of the new instrument is fulfilled, then it is reasonable to assume that a relatively reliable instrument has been developed. In the Danish TOFHLA, the internal consistency was determined to 0.943 by the Cronbach's alpha coefficient. A Cronbach's alpha coefficient of 0.943 indicates that the Danish TOFHLA fulfils the criterion for reliability ( $> 0.7$  as set by Houser [27]). On this basis, a reliable Danish version of the original American TOFHLA has been developed.

In this pilot study more than 50% of the 42 COPD patients were categorised as having an adequate level of health literacy; a result that seems to contradict observations in existing literature where elderly people with a chronic disease like for instance COPD are considered at risk of low health literacy [29]. No statistical significant differences were observed between COPD patients recruited from the municipality of Aalborg and those recruited from the municipality of Hjørring; both the average health literacy score and the mean response time were very similar among COPD patients at the two recruitment sites.

Educational attainment did not influence the average health literacy score and the mean response time, as no statistical significant differences were observed between the four education groups; this was not expected as educational attainment has been known to play a predictably strong role in health literacy – people with lower education are more likely to have a low level of health literacy [16]. Additionally, the multiple regression analysis, conducted in this pilot study, provided a Sig. value of 0.68 ( $> 0.05$ ) between health literacy score and level of education -indicating no association.

The mean response time was significantly influenced by health literacy category (Sig. = 0.002). The greatest difference in mean response time between groups was observed between COPD patients with adequate health literacy and those with inadequate health literacy (difference: 3 min 11 sec). An ANOVA test was used to explore if the difference between the three (health literacy category) groups was significant; an ANOVA test only tells you there is a difference between

groups, but not exactly between which groups [28], so we cannot be sure between which of the three health literacy category groups there is a significant difference in mean response time.

A limitation to this pilot study is the sample size of only 42 COPD patients; it is a rather small sample size at least when compared to other international studies that also assesses health literacy [9,30].

## Conclusion

In this pilot study, the Danish TOFHLA demonstrates strong consistency with the original American TOFHLA. Based on a Cronbach's alpha coefficient of 0.943, a reliable Danish version of the original American TOFHLA has been successfully developed. As the cultures, languages, and the structure of healthcare systems are quite similar within Scandinavia, it should be easier to develop an instrument to assess health literacy in other Scandinavian populations.

The results of the pilot study showed no statistical significant differences between COPD patients recruited from the municipality of Aalborg and those recruited from the municipality of Hjørring. Educational attainment did not affect the average health literacy score and mean response time in this pilot study. A statistical significant difference was observed in mean response time between the three health literacy category groups. Hence, the health literacy score seem to influence the mean response time in this pilot study.

This is a small pilot study including 42 COPD patients, and more research is needed to explore the level of health literacy among Danish COPD patients.

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