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Assessment of Health Literacy and validation of single-item literacy screener (SILS) in a sample of Italian people

Guglielmo Bonaccorsi[1], Maddalena Grazzini[2], Luca Pieri[2], Francesca Santomauro[1], Maria Ciancio[1] and Chiara Lorini[1]

[1]*Dipartimento di Scienze della Salute, Università degli Studi di Firenze, Florence, Italy*
[2]*Scuola di Specializzazione in Igiene e Medicina Preventiva, Università degli Studi di Firenze, Florence, Italy*

Abstract

Background. Health literacy (HL) is a complex concept with multiple components; it involves the ability to effectively use and interpret texts, documents, and numbers. The aims of our study were: to measure HL levels among a sample of adult Italian patients; to develop and validate the Italian version of the single-item literacy screener (SILS); to assess the diagnostic accuracy of the SILS as an indicator of limited reading ability regarding health documents, compared to the newest vital sign (NVS).

Methods. The subjects were enrolled in emergency departments, primary care settings, and specialist departments. The Italian versions of the NVS and of the SILS were administered to the patients, as well as a questionnaire aimed in collected socio-demographic information.

Results. Overall, 174 patients completed the interview (compliance: 87%). Considering the NVS, 24.1% of the subjects presented high likelihood of limited HL, 13.2% a possibility of limited HL, and 62.6% adequate HL. SILS has shown a good concurrent validity compared to NVS (Spearman's rho r = -0.679; $p < 0.001$). The diagnostic accuracy of the SILS was high. The best performance parameters in assessing the diagnostic accuracy of SILS are found to be for threshold value of 2 in in identifying subjects with high likelihood of limited HL at the NVS (sensitivity: 83.3%; specificity: 82.6%; accuracy: 82.8%; positive predicted value: 60.3%; negative predicted value: 94%; Cohen's kappa: 0.6).

Conclusion. The Italian version of SILS – as an indicator of limited reading and understanding ability regarding health information – is a good tool to measure HL in comparison to more complex measurement instruments of functional HL, like NVS.

Key words
- health literacy
- validation
- Italian language
- screening
- diagnostic accuracy

INTRODUCTION

Health literacy (HL) is a complex concept with multiple components; it involves the ability to effectively use and interpret texts, documents, and numbers. These skills are highly correlated with one another [1-4].

The most recent and accepted definition of HL was proposed by Sørensen in 2012: "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" [5, 6].

After it was first introduced in the 1970s [7], the concept received increased attention in the early 1990s, particularly in the USA and Canada, with a progressive growth of scientific production. It has recently also gained importance in the European Union (EU), where it was integrated into the European Commission (EC) health strategy *Together for Health 2008-2013* [8].

Data from the European Health Literacy Survey (HLS-EU) show that about 50% of the EU population does not have adequate HL [9].

National population studies reveal several important factors associated with limited HL, such as lower levels of education, advanced age, and low socio-economic status [9,10] a condition worsened by the economic crisis in recent years [11].

Moreover, HL is independently associated with several undesirable health-related outcomes such as poorer overall health status [12], hospitalization [13], mortal-

Address for correspondence: Chiara Lorini, Dipartimento di Scienze della Salute, Università degli Studi di Firenze, Viale G.B. Morgagni 48, 50134 Florence, Italy. E-mail: chiara.lorini@unifi.it.

ity [14], and healthcare costs [15]. Individuals with low HL also have limited participation in screening for diseases, limited understanding of their illness or treatment plan, and difficulties in managing chronic conditions [1, 16-19].

For all these reasons, HL is a social determinant of health and should be recognized as an indicator in monitoring health population status.

In this age of new scientific knowledge, changes in the delivery of care, increased consumerism, and continuous technological advancements, patients need a high HL level in order to orient themselves orient themselves and make informed choices [20]. They are also encouraged to take more responsibility for their health in a system that is increasingly becoming more and more patient-centred and individualized. Nevertheless, a growing gap is still observed between the demand for skills and the actual skills of many patients [21].

Therefore, HL has become a political matter and a public health challenge, which must not be underestimated by the decision-makers.

Nowadays, many tools are available to measure HL from basic screening items to more comprehensive assessments. One of the most commonly used such tools is the Newest Vital Sign (NVS), which measures both literacy and numeracy skills [22]. It consists of a food nutrition label and associated questions to measure literacy, comprehension, numeracy, application/function, and evaluation skills.

The NVS was developed in the USA in English and Spanish [23] and then validated and adapted in many other countries [12, 24, 25], including Italy [26].

To quickly identify subjects with low HL, a brief instrument was also developed by Morris *et al.* [27]: "the single-item literacy screener" (SILS), a tool designed to identify adults in need of help with written or printed health material regardless of the aetiology (limited education, language barrier, physical impairment, etc.).

The aims of our study were to measure HL levels among a sample of adult Italian patients, to develop and validate the Italian version of the SILS, and to assess the diagnostic accuracy of the SILS as an indicator of limited reading ability regarding health documents compared to the NVS instrument.

METHODS

Participants and recruitment

The study complies with the principles laid down in the Helsinki Declaration.

The study was conducted in Lagonegro (Potenza), a small town of about 5500 inhabitants in the southern part of Italy. A trained research assistant recruited subjects associated with public health services, specifically in emergency departments, primary care settings (e.g. family medicine ambulatories), and specialist departments. The study was performed from 1 February 2016 to 31 March 2016. We included patients who were 18 years or older, able to speak Italian, who we found sitting in waiting rooms at the time of recruitment. Patients with cognitive impairment were excluded. After all potential participants provided informed consent, the research assistant conducted one-on-one interviews.

The Italian version of the NVS (NVS-IT) and the SILS (SILS-IT) (hereinafter NVS and SILS respectively) were administered to the patients. Demographic information, including age, sex, nationality, education, years of schooling, and occupation, was also collected. Educational levels, following national [28] and international [29] classification systems, were divided into five stages: pre-primary education, primary education (or elementary school), lower secondary education (or middle school), upper secondary education (or high school), and tertiary education (or university).

Occupation was classified into nine groups: 1) Managers (e.g. chief executives, senior officials and legislators, administrative and commercial managers, etc.); 2) Professionals (e.g. science and engineering professionals, health professionals, etc.); 3) Technicians and associate professionals; 4) Clerical support workers; 5) Services and sales workers; 6) Craft and related trade workers, skilled agricultural workers, and forestry and fishery workers; 7) Plant and machine operators and assemblers; 8) Elementary occupations; and 9) Armed forces [30].

The burden of chronic diseases was assessed using Disease Count (DC) [31]. Patients were also asked about perceived global health status (using a scale from 0 for "poor health" to 10 for "excellent health") and number of family members living with them.

Procedures and measures

As already mentioned, the NVS-IT consists of a food nutrition label, with seven associated questions that measure literacy and numeracy. It produces a final score ranging from 0 to 6, allowing the subjects to be classified into three categories: high likelihood of limited HL (score: 0-1), possibility of limited HL (score: 2-3), and adequate HL (score: 4-6). This instrument takes little time to administer (three to five minutes), is acceptable to patients, and predicts HL levels more accurately compared to the Test of Functional Health Literacy in Adults (TOFHLA), which is generally considered the "gold standard" for measuring HL but which requires about 22 minutes for administration [32].

The SILS – a simple and brief instrument – asks: "How often do you need to have someone help when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible responses are: Never (1), Rarely (2), Sometimes (3), Often (4), and Always (5). Scores higher than 2 indicate some difficulty with reading printed health-related material. The English version of this tool was adapted for Italy using a standard procedure, namely translation and back-translation (performed by native Italian and English speakers), and the final Italian version was drafted and shared by the research group.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp.).

Data were presented as percentage or as mean ± standard deviation, as appropriate. The associations between variables were tested using Fisher exact test

for categorical data and Student's t-test or ANOVA for continuous data. Linear regression analysis was done to assess the linear relationships between HL and the covariates. Specifically, two models were used, on the basis of which the measure of HL was considered as the dependent variable (the NVS score in the first one and the SILS score in the second one). First, univariate analysis was performed by including each collected variable. Then the variables statistically associated with the outcome were entered into a multivariate model. The last step was conducted using a stepwise backward procedure.

To assess the concurrent validity (i.e. the degree of agreement between two different tools while measuring the same concept) and the diagnostic accuracy of SILS with respect to NVS, Spearman's rho and Receiver Operating Characteristic (ROC) analysis were performed. To identify the threshold values of the SILS score that can distinguish less health-literate from more heath-literate subjects, the sensitivity, specificity, positive predicted value, negative predicted value, and total accuracy were calculated for each potential threshold SILS value (i.e. each score that can be obtained when administering the test). Specifically, more health-literate subjects were identified as those with SILS score lower than or equal to the threshold value while less health-literate subjects as those with SILS score higher than the threshold value.

Two different analyses were performed. The first one considered those with "adequate HL" at the NVS as more health-literate subjects and those with "high likelihood of limited HL" or "possibility of limited HL" at the NVS as less health-literate subjects (Model A). The second one considered those with "adequate HL" or "possibility of limited HL" at the NVS as more health-literate subjects and those with "high likelihood of limited HL" at the NVS as less health-literate subjects (Model B).

Area under the ROC curve (AUC) was used as a test performance criterion and a measure of accuracy [33].

To assess the level of agreement, Cohen's kappa was also used.

For each analysis, an alpha level of 0.05 was considered as significant.

RESULTS

We identified 200 subjects who met our inclusion criteria. Of these, 174 (87%) completed the interview and were included in analyses while 26 (13%) declined to participate.

Of all the interviews, 40.2% took place in the emergency department, 27.6% in family medicine settings, and 32.2% in specialist departments.

Table 1 provides the descriptive statistics. The participants' mean age was 51.0 years (± 19.4 years), ranging from 19 to 90 years. Basing on age-classes, we classified patients into three categories: 24.9% were young (18-34 years), 46.8% were adults (35-64 years), and 28.3% were old (≥ 65 years). Among the participants, there were 90 females (51.7%), and 170 (97.7%) subjects were born in Italy.

With regard to educational level, five subjects (2.9%) reported to have never attended school, 19 (10.9%) have had primary education, 41 (23.6%) lower secondary education, 80 (46%) upper secondary education, and 29 (16.7%) tertiary education.

There were 83 (47.7%) workers, while 23 (13.2%) were unemployed (housewives included), 14 (8%) were students, and 54 (31%) were retirees. Occupations were represented as follows: 1 (1.2%) manager, 17 (20.5%) professionals, 6 (7.2%) technicians and associated professionals, 10 (12%) clerical support workers, 13 (15.7%) services and sales workers, 19 (22.9%) craft and related trade workers, skilled agricultural workers, and forestry and fishery workers, 9 (10.8%) plant and machine operators and assemblers, 3 (3.6%) in elementary occupations, and 5 (6%) in the armed forces.

On average, the participants reported belonging to a family of three including themselves (range from one to six). Accordingly to DC, the mean of reported diseases was 1.4 ± 1.3 per person, ranging from a minimum of 0 to a maximum of five. Specifically, 59 (33.9%) patients did not suffer from any diseases, 43 (24.7%) had one disease, and 72 (41.4%) had more than one.

We also evaluated self-perceived health using a scale of 0 (poor health) to 10 (excellent health). On average, subjects declared a good self-perceived health status (mean 7.8 ± 1.8; 90% with a score higher than five).

Newest vital sign

The mean score of the NVS was 3.5 ± 2.3. Of the subjects, 24.1% presented high likelihood of limited HL, 13.2% a possibility of limited HL, and 62.6% adequate HL. The classification according to NVS categories was significantly associated with age class, educational level, years of schooling, number of family members, number of diseases, and perceived health. Specifically, greater prevalence of high likelihood of limited HL was observed among patients older than 64 years (63.3%), with pre-primary (100%) or primary education (73.7%). Moreover, patients with high likelihood of limited HL had fewer years of schooling (mean value: 7 ± 3.8 years), fewer family members/cohabitants (mean value: 1.93 ± 1.0), more diseases (mean value: 2.5 ± 1.2), and lower level of perceived health (mean value: 6.2 ± 1.9).

Validation of single item literacy screener

The Italian version of the SILS that we have developed and tested can be expressed as: "Quante volte ha bisogno di qualcuno che la aiuti quando legge istruzioni, opuscoli o altro materiale che le è stato consegnato dal proprio medico o farmacista? 1) mai; 2) raramente; 3) qualche volta; 4) spesso; 5) sempre" ("How often do you need to have someone help when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible responses are: 1) never; 2) rarely; 3) sometimes; 4) often and 5) always).

Considering Spearman's rho, SILS has shown a good concurrent validity compared to NVS ($r = -0.679$; $p < 0.001$).

Figure 1 shows the ROC curves. One of these (A) considers those with "adequate HL" at the NVS as more health-literate subjects and those with "high likelihood of limited HL" or "possibility of limited HL" at

Table 1
Demographic characteristics and NVS (newest vital sign) and SILS (single-item literacy screener) scores of study participants (N = 174)

Characteristics and scores	High likelihood of limited HL		Possibility of limited HL		Adequate HL		Total	
	n	%	n	%	n	%	n	%
All	42	24.1	23	13.2	109	62.6	174	100.0
Gender								
male	24	28.6	8	9.5	52	61.9	84	48.3
female	18	20.0	15	16.7	57	63.3	90	51.7
Age (mean ± SD)*	72.2 ± 12.1		61.1 ± 13.1		40.4 ± 14.1		51.0 ± 19.4	
Age classes*								
18-34 years	0	0.0	0	0.0	43	100.0	43	24.9
35-64 years	11	13.6	12	14.8	58	71.6	81	46.8
> 64 years	31	63.3	11	22.4	7	14.3	49	28.3
Years of schooling (mean ± SD)*	7 ± 3.8		8.3 ± 2.6		13.9 ± 2.7		11.5 ± 4.3	
Education*								
never attended school	5	100.0	0	0.0	0	0.0	5	2.9
primary	14	73.7	5	26.3	0	0.0	19	10.9
lower secondary	15	36.6	14	34.1	12	29.3	41	23.5
upper secondary	8	10.0	4	5.0	68	85.0	80	46.0
tertiary	0	0.0	0	0.0	29	100.0	29	16.7
Working status*								
Workers								
managers	0	0.0	0	0.0	1	100.0	1	1.2
professionals	0	0.0	0	0.0	17	100.0	17	20.5
technicians and associate professionals	1	16.7	0	0.0	5	83.3	6	7.2
clerical support workers	0	0.0	0	0.0	10	100.0	10	12.0
service and sales works	2	15.4	1	7.7	10	76.9	13	15.7
craft and related trade workers etc.	2	10.5	2	10.5	15	78.9	19	22.9
plant and machine operators and assemblers	1	11.1	0	0.0	8	88.9	9	10.8
people in elementary occupations	0	0.0	0	0.0	3	100.0	3	3.6
people in armed forces	0	0.0	0	0.0	5	100.0	5	6.0
All workers	6	7.2	3	3.6	74	89.2	83	100.0
Non-workers								
housewives	2	12.5	5	31.3	9	56.3	16	17.6
unemployed	0	0.0	1	14.3	6	85.7	7	7.7
students	0	0.0	0	0.0	14	100.0	14	15.4
retirees	34	63.0	14	25.9	6	11.1	54	59.3
All non-workers	36	39.6	20	22.2	35	38.4	91	100.0
Number of family members (mean ± SD)*	1.9 ± 1.0		2.7 ± 1.5		3.1 ± 1.2		2.8 ± 1.3	
Number of associated diseases*								
0	1	1.7	2	3.4	56	94.9	59	33.9
1	8	18.6	7	16.3	28	65.1	43	24.7
>1	33	45.8	14	19.4	25	34.7	72	41.4
Perceived global health status (mean ± SD)*	6.2 ± 1.9		7.2 ± 1.5		8.5 ± 1.4		7.8 ± 1.8	
SILS score*								
never	2	3.8	3	5.7	48	90.6	53	30.5
rarely	5	7.9	9	14.3	49	77.8	63	36.2
sometimes	16	43.2	9	24.3	12	32.4	37	21.3
often	12	92.3	1	7.7	0	0.0	13	7.5
always	7	87.5	1	12.5	0	0.0	8	4.6

HL: health literacy; SILS: single-item literacy screener.; *p<0.05.

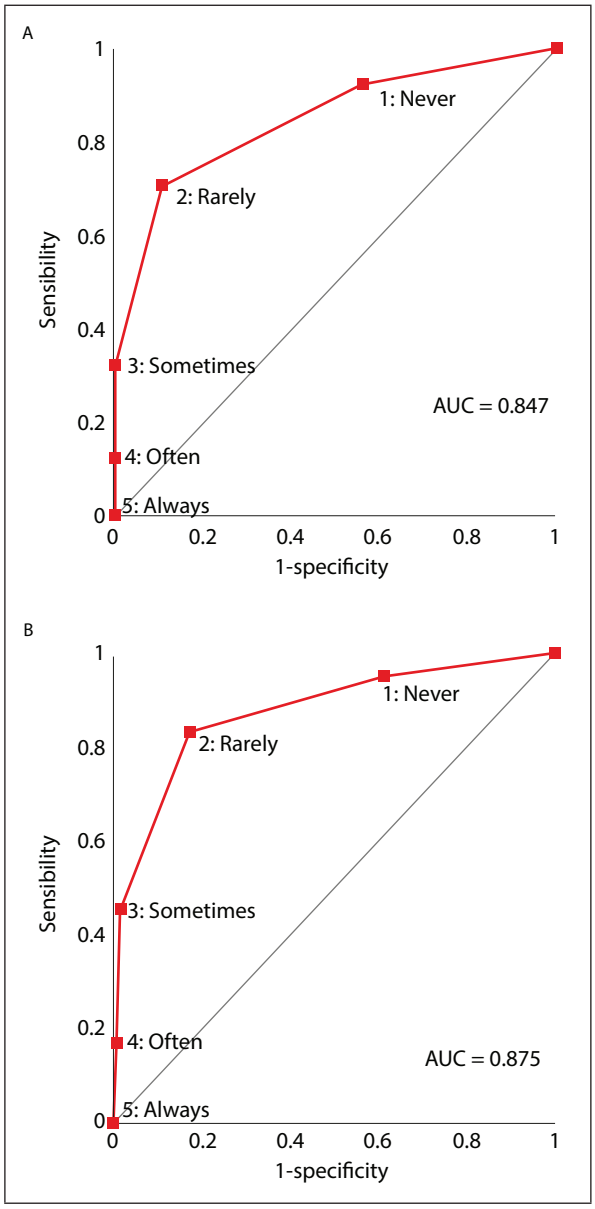

Figure 1
Receiver Operating Characteristic (ROC) curves of the SILS (single-item literacy screener) with respect to NVS (newest vital sign). A: high likelihood or possibility of limited HL (health literacy) *versus* adequate HL; B: high likelihood of limited HL *versus* possibility of limited HL or adequate HL; AUC = area under the ROC curve.

the NVS as less health-literate subjects. The other (B) considers those with "adequate HL" or "possibility of limited HL" at the NVS as more health-literate subjects and those with "high likelihood of limited HL" at the NVS as less health-literate subjects. In both curves, the AUC value was very high (0.847 for A; 0.875 for B), which indicates that the test was good. Sensitivity, specificity, positive predicted value, negative predicted value, and kappa value of SILS using different threshold values to indicate positive (i.e. less health-literate) subjects are reported in *Table 2*.

In both models (A and B), sensitivity and negative predicted values decrease with the increase in the threshold value, while specificity and positive predicted values increase. Considering "high likelihood or possibility of limited HL" *versus* "adequate HL (Model A), the highest accuracy (82.2%) and kappa value (0.61) were those related to a threshold of 2; considering "high likelihood of limited HL" *versus* "possibility of limited HL" or "high likelihood of adequate HL" the highest accuracy (85.6%) was the one related to a threshold of 3 while the highest kappa (0.6) value was related to a threshold of 2. Moreover, with regard to Model B, a high accuracy value was found for the threshold of 2 as well (82.8%).

Linear regression analysis

In the univariate linear regression analysis, by considering either NVS or SILS score as the dependent variable, the independent variables associated with statistical significance were age, years of schooling, working status, number of family members, number of diseases, and perceived global health status. Gender was associated only with SILS score. The final models of multivariate linear regression analysis are reported in *Table 3*. Gender was included also in the model with NVS score, as the adjustment variable. Age and years of schooling were significantly associated with HL: the higher the age, the less was the HL (for NVS: β = -0.05; for SILS: β = 0.01) while the more the years of schooling, the more was the HL (for NVS: β = 0.22; for SILS: β = -0.130). Gender was statistically associated with the SILS score, with females presenting lower HL than males (β = 0.38).

DISCUSSION

In our sample, according to NVS, 62.6% of the subjects had adequate HL, 13.2% had the possibility of limited HL, and 24.1% had high likelihood of limited HL. Comparing our results to those obtained in the European HL survey [34], it is seen that the percentage of subjects with adequate HL in Lagonegro is higher than that observed in the eight countries involved in the European survey (55.3%). The same is the case for high likelihood of limited HL (21.2% in the European survey). However, the percentage of subjects with possibility of limited HL is lower than that in the European survey (23.5%). In our study, sampling procedure is different from what has been used in the European survey; in our research, the subjects were recruited among people accessing public health services (emergency department, primary care settings, and specialist departments) while in the European survey the sample was randomly selected from the general population of each of the eight countries. Since low HL is a major barrier to accessing health services for many people [2], we can assume that the higher percentage of subjects with adequate HL, as found in our sample, is mostly a result of differences in sampling procedure due to the different aims of the studies.

With regard to the diagnostic accuracy of the SILS, the AUC values of both our used models (0.847 for A; 0.875 for B) are higher than that reported by Morris *et al.* in the SILS validation paper with respect to S-TOF-

Table 2
Performance of SILS in identifying subjects with limited HL at different thresholds. Reference test is NVS, considering, in Model A, "high likelihood or possibility of limited HL" as positive for limited HL and in Model B, "high likelihood of limited HL" as positive for limited HL. SILS score higher than the threshold value identifies less health-literate subjects

Model	SILS threshold	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV	NPV	K value	Yield (%)
A	1	92.3	44.0	62.1	49.6	90.6	0.3	69.5
	2	70.8	89.0	82.2	79.3	83.6	0.6	33.3
	3	32.3	100.0	74.7	100.0	71.2	0.4	12.1
	4	12.3	100.0	67.2	100.0	65.7	0.2	4.6
	5	0	100.0	62.6	100.0	62.6	0	0
B	1	95.2	38.6	52.3	33.1	96.2	0.2	69.5
	2	83.3	82.6	82.8	60.3	94.0	0.6	33.3
	3	45.2	98.5	85.6	90.5	85.0	0.5	12.1
	4	16.7	99.2	79.3	87.5	78.9	0.2	4.6
	5	0.0	100	75.9	0.0	75.9	0	0

SILS: single-item literacy screener; HL: health literacy; NVS: newest vital sign; PPV = positive predicted value; NPV = negative predicted value.

HLA (0.73) [27], and those reported in other studies where a similar version of the SILS was used with respect to NVS (0.47) [35] or to S-TOFHLA (0.32) [36]. These results indicate that the test performance in our study is very high. Specifically, in our data, the best performance parameters in assessing the diagnostic accuracy of SILS are found to be for threshold value of 2 in Model B, namely in identifying subjects with high likelihood of limited HL at the NVS. Comparing our results to that obtained by Morris [27] with the same threshold value (score higher than 2), the Italian version of SILS presents a better diagnostic accuracy using the NVS as comparison, with higher sensitivity (83.3% *vs* 54.0%) and a similar specificity (82.6% *vs* 83.0%). The better performance is also confirmed by considering studies where a rather similar version of the SILS was used with respect to NVS [35, 36]. Therefore, the Italian version of SILS presents both high sensitivity and specificity, reducing the likelihood of underestimating the burden of low HL.

Moreover, the Italian version of the SILS presents a strong correlation with the NVS (rho = -0.679), which is higher than that observed between NVS-UK and S-TOFHLA (0.49) [12] and between NVS and HLS-EU-Q47 in the European survey (0.25) [34]. Finally, our data show that the same variables – with the exception of gender – predict both the NVS and SILS scores with the same strength.

The limits of the study pertain to both the study design and the characteristics of the SILS. Considering the first one, the sample size, the geographical area (i.e. a small town in the south of Italy) in which the study was conducted, and the sampling procedures (i.e. the selection of a convenient sample) affect the generalizability of the results. With regard to the SILS, patient response could be influenced by social desirability bias and inaccurate perception of his/her reading ability, affecting both the accuracy and the precision of data.

In conclusion, the Italian version of SILS – as an indicator of limited reading and understanding ability regarding health information – is a good tool to measure HL in comparison to more complex measurement instruments of functional HL, like NVS. A recent literature review has stated that the NVS is the most practical HL instrument to use in busy clinical settings at present, since it is quick to administer, measures both prose and numeracy skills, and presents good psychometric parameters [37]. According to our results, the Italian version of the SILS is a good alternative to the NVS due to its high performance, although it assesses only the ability to understand written texts. Moreover, as a self-rated reading ability, SILS can be uses either by patients themselves or by healthcare workers. SILS is quickly and easily administered in busy clinical set-

Table 3
Multivariate linear regression analysis (for NVS, higher scores indicate higher levels of HL; for SILS, higher scores indicate lower levels of HL)

	NVS*			SILS**		
	b	SE	p	b	SE	p
Gender (females)	-0.26	0.208	0.21	0.38	0.111	0.001
Age (years)	-0.05	0.007	< 0.001	0.01	0.004	< 0.001
Schooling (years)	0.22	0.033	< 0.001	-0.130	0.018	< 0.001

NVS: newest vital sign; SILS: single-item literacy screener; HL: health literacy.
*N = 173; Prob. > F = 0.0000; Adj. R-squared: 0.6345.
**N = 173; Prob. > F = 0.0000; Adj. R-squared: 0.5571.

tings by healthcare professionals at various levels of training, to identify subjects with difficulties in understanding health information. Furthermore, it should be used in particular situations, such as for people living with chronic illnesses and requiring self-management care, or for patients who show low compliance to medical advice. In these circumstances, it can also be used as an indicator of patient experience, to check the usability and relevance of support and the empowering processes. Considering our results with regard to the predictive effect of age and years of schooling, future researches can assess the patients' subgroups for which HL routine measurements should be omitted, so as to optimize resources focusing on patients with more likelihood to have low HL.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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