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Health Literacy in Italy – A study protocol of the validation process of health literacy measures in Italian language

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Health Literacy in Italy – A study protocol of the validation process of health literacy measures in Italian language

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ABSTRACT

Introduction

Health literacy (HL) concerns the knowledge and competences of persons to meet the complex demands of health. The aims of this study are: to assess the level of HL in a sample using the Italian version of the Newest Vital Sign; to assess the association of HL and selected antecedents and health outcomes; to develop and validate the Italian version of the three Brief Health Literacy Screeners, two subjective numeracy items, the short and the short-short forms of the European Health Literacy Survey Questionnaire.

Methods and analysis

The study adopts a cross-sectional design and will be conducted in Florence. Information will be collected through telephone interviews. The population-based sample will be randomly selected using the registries of eight General Practitioners (GPs). Based on a power calculation, 480 subjects will be included.

Participants will be randomized to two different questionnaires, each containing different HL measures. Data on socio-demographics and important antecedents and consequences of HL will be collected.

The distribution of HL levels will be calculated. The mediating role of HL will be assessed using Preacher and Hayes' model. To assess the concurrent validity of the HL scales, correlation and Receiver Operating Characteristic analyses will be performed.

Ethics and dissemination

The study protocol was approved by the Ethics Committee of the Area Vasta Centro. Results will be disseminated via scientific journals and conference presentations. Individual data will be made available to the GPs.

Strengths and limitation of this study

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This is the first study in Italy that attempts to assess HL and its related antecedents and outcomes, and to validate a variety of different measures.

One limitation of this study is that the sample was randomly selected among people living in Florence but among individuals registered as patients at different GPs. Moreover, the GPs were recruited using convenience criteria.

BACKGROUND

Health literacy (HL) concerns the knowledge and competences of individuals to meet the complex demands of health in modern society. According to Sørensen and colleagues` conceptual framework, "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".[1] In their framework the authors identified 12 dimensions of HL, as well as proximal and distal factors (antecedents) that influence HL and related outcomes (consequences). Distal factors include societal and environmental factors, whereas proximal factors are situational and personal determinants, such as general literacy, individual characteristics and prior experience with illness and the healthcare system. On the other hand, the consequences at the individual and population level refer to health service use and health costs; health behaviour and health outcomes; participation and empowerment in health issues; equity and sustainability of public health issues. Despite this and other conceptual models (see also for example the models of Nutbeam[2], Paasche-Orlow and Wolf[3], Schulz and Nakamoto[4]), to this date the causal relationships between antecedents, HL and health outcomes is still unclear. Only few studies have systematically investigated the role of HL as a mediator between antecedents and different health outcomes, while many authors have described HL as co-factor or confounder in predicting health outcomes.[5-13]

Many tools exist to measure HL but until this date none of them is considered to be the gold standard. Measures largely vary in their approach and design, as well as in terms of their purpose. Some of them are screening tools that were originally developed for the clinical setting to quickly identify patients with lower HL levels. Other tools were developed with the aim to measure the broader concept of HL to provide an in-depth assessment of the different dimensions of HL and to explore its relationship with determinants, or outcomes. Moreover, HL measures are either performance-based (objective) or self-reported (subjective).[14-17] This means that they either evaluate an individual's HL level by asking individuals to directly apply their skills to a healthcare-related task or that individuals are asked to report on their skills, such as being confident enough to fill out medical forms on their own (see for example, the studies of Chew[18,19]). Overall, there has been relatively little systematic research that has compared the performance

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of performance-based to self-reported measures, specifically with regard to possible relationships between HL and health outcomes. As suggested in a recent review, further studies that assess HL by using, at the same time, performance-based and self-reported tools are needed to clarify these aspects.[20]

In Italy, research on HL is still relatively new and only a few studies have assessed and published results on HL in Italian samples.[21,22] Therefore, the aims of this study are:

1. to assess the level of HL in a population-based sample in Florence, Italy, using the Italian version of the Newest Vital Sign (NVS-IT);
2. to assess the association of HL, selected antecedents and health outcomes, so as to evaluate whether HL is a mediator, a confounding or a cofactor in predicting the outcome variables;
3. to develop and validate the Italian version of three subjective Brief Health Literacy Screeners (BHLS) and two subjective numeracy items, and to assess their diagnostic accuracy in detecting subjects with limited HL when compared to the NVS-IT (concurrent validation); and
4. to develop and validate the Italian version of the short form (HLS-EU-Q16) and the short-short form (HLS-EU-Q6) of the European Health Literacy Survey Questionnaire (EU-HLS), and to assess their diagnostic accuracy in detecting subjects with limited HL when compared to the NVS-IT (concurrent validation).

METHODS

The study adopts a cross-sectional design and is conducted in Florence, Italy and its surroundings. It started in February 2017 and will presumably end in September 2017. Information is collected through telephone interviews.

Study population and sampling criteria

The population-based sample was randomly selected by the registries of eight General Practitioners (GPs) working in primary health care ambulatories of the municipality of Florence, a sampling method that has also been suggested by other authors (see for example the study of Toçi[23]) (Figure 1). According to the regulation of the National Healthcare System and the Constitution of the Italian Republic, in Italy every citizen and foreign resident above the age of 18 has the right to be registered as a patient with a GP. Health care provided by GPs is free of charge for all patients. In the municipality of Florence about 200 GPs provide continuing and comprehensive health care to individuals that are registered as patients. For each GP, the number of registered and assisted patients is on average 1100, with a maximum limit of 1500 patients per doctor.

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The GPs were recruited using convenience criteria. Both the President of the Provincial Medical Council and the representative of the GPs at the University Hospital of Florence informed their colleagues to join the study by using either e-mail or verbal contacts. The first eight who voluntarily joined the study were included. Each GP randomly selected 80 subjects among those who were registered as one of his/her patients.

Inclusion criteria were the following: 18-69 years old, Italian-speaking (given that the survey is conducted in Italian). Exclusion criteria included cognitive impairment, severe psychiatric diseases, end-stage diseases. Each GP, when selecting the sample, verified the inclusion and exclusion criteria.

Sample size was calculated based on the first aim of this study. Since no data on HL in Italy is publically available yet, data from the EU-HLS was used as a reference. Based on the original study that assessed HL across eight different European countries (Italy not included)[6], the country, namely Spain, with the highest rate of limited HL when assessed with the NVS was chosen (34.3%). Considering a confidence level of 95% and a margin of error equal to 0.05, the sample size was determined to be 480 people. An oversampling of 160 individuals is planned to account for problems in recruitment (i.e. subjects not available for telephone interviews or refusal rates). If oversampling will not be sufficient, a second random sample will be drawn.

Each subject is randomly allocated to one of the two arms of the study (A and B), according to the questionnaire that is used during the interview (type-I and type-II questionnaire, respectively).

Procedures - data collection

Each selected subject is contacted via postal mail. Subjects receive an informative letter signed by both the GP and the responsible of the study. Further, the letter contains a consent form, a short description of the study, and an invitation to participate. Participants are asked to sign a consent form and to return it by mail to the researchers in charge. Further, the letter contains the nutritional label of the NVS-IT. For further information, email addresses and telephone numbers of the responsible researchers are provided in the letter. After receipt of the signed consent forms, the subjects are contacted via phone to be interviewed.

Nine interviewers who are part of the research group carry out the phone calls. Written instructions on how to conduct the interview have been developed and shared within the research team, so as to standardize the procedure and limit interviewer bias. Each subject is contacted for a maximum of six times before considering him/her unreachable. Each subject is randomly assigned to one of the nine interviewers.

Data is collected using an electronic database and is anonymized by assigning a numeric code to each recruited person.

To meet the aims of the study, two questionnaires (type I and type II) were developed, each of which containing different sections on possible antecedents and consequences of HL, as well as different items to assess HL (Table 1). Both questionnaires contain a general section that includes questions on socio-

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demographics and familial data (antecedents), and health-related outcomes. Further, both questionnaires include the NVS-IT items. Yet, whereas Type-I-questionnaire contains the three BHLS and two subjective numeracy items, the Type-II-questionnaire contains a section with the HLS-EU-Q16.

The questionnaires have been both pre-tested in a small sample of voluntaries, and take about 20 and 25 minutes depending on the questionnaire.

Measurements

Newest Vital Sign (NVS)

The Newest Vital Sign (NVS) is a commonly used measure of HL. It is an objective measure of HL and was originally developed in the United States (US) for English- and Spanish-speakers[24]. However, in recent years, the NVS has seen increased application in other countries than the US[6,25-30], including Italy (NVS-IT)[31].

The NVS-IT consists of an ice-cream nutrition label, with seven associated questions that measure literacy and numeracy. It produces a final score ranging from 0 to 6, allowing 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 be administered (three to five minutes), and has been found to be easily acceptable to patients in different settings.[32,33] Since the information to answer the questions have to be derived by the nutritional label, which is part of the test, the label will be included in the postal mail which will be sent to the GPs' assisted people.

Health Literacy and Numeracy Screeners

In addition to the NVS-IT, the type-I-questionnaire contains items of two other measurement tools: three Brief Health Literacy Screeners (BHLS), and two subjective numeracy items. Both measures are self-reported measurement tools with Likert-type responses, validated for predicting NVS scores by a previous study.[34]

The three BHLS were initially developed and validated in English[18]. They assess literacy, interaction, comprehension and confidence (self-efficacy) skills. Even though originally developed for the clinical setting they have seen increased application in population-based studies.[35-40]

The two subjective numeracy items, adapted from the STAT-confidence that assess people`s confidence in understanding medical statistics[41], were initially also validated in English. The two questions assess individual`s confidence in medical statistics by evaluating numeracy, comprehension, application/function, decision making and confidence. Both tools produce a score, which is used to measure the HL levels.

HLS-EU-Q16 and HLS-EU-Q6

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In addition to the NVS-IT, the type-II-questionnaire contains the HLS-EU-Q16 and the HLS-EU-Q6, which are, respectively, the short and the short-short form of the European Health Literacy Survey Questionnaire (HLS-EU-Q47). Briefly, the HLS-EU was developed with the aim to measure and compare HL levels of populations in different European countries. Based on the conceptual model proposed by Sørensen et al.[1] , a European Union funded working group developed the HLS-EU-Q47.[42] It includes 47 items covering 12 subdomains (including domains such as accessing and obtaining, understanding, or appraising information relevant to health care, disease prevention or health promotion). It is a self-reported tool with Likert-type responses ("very easy", "fairly easy", "fairly difficult", "very difficult") and an associated final score, which measures interaction, comprehension, information seeking, application/function, decision making/critical thinking, evaluation, responsibility, confidence and navigation skills. Based on the extended version, two short versions were developed by selecting 16 items for the HLS-EU-Q16 and respectively 6 items for the HLS-EU-Q6. Even though the reduction of items has decreased the informative value and theoretical scope of the measure, it has increased its utility due to its shortened administration time, while maintaining strong correlations with the full instrument.[43]

To generate the score for the HLS-EU-Q16 answers are dichotomized ("don´t know" answers are coded as missing values). "Fairly difficult" and "Very difficult" are both coded with 0 (zero), whereas "Fairly easy" and "Very easy" are both coded with 1. The HLS-EU-Q16 score is a sum score (range: 0-16) and according to the final score, three levels of HL have been defined: inadequate HL (0-8); problematic HL (9-12); sufficient HL (13-16).

Scores for the HLS-EU-Q6 are calculated similarly to those of the HLS-EU-Q47 (from 1 for "very difficult", to 4 for "very easy"). The final score is the mean score that is calculated if at least 5 of the 6 items are completed and range from 1 to 4. According to the final score, three possible levels of HL have been defined: inadequate HL (1-2); problematic HL (2-3); sufficient HL (3-4).

Translation of health literacy measurements

The English versions of the BHLS, two subjective numeracy items, the HLS-EU-Q16, and the HLS-EU-Q6, were translated and adapted using standard procedures, including forward- and back-translation (performed by Italian and English native speakers). A final Italian version was drafted, which was then shared and discussed with members of the research group.[44] Table 2 reports on the Italian versions of the tools.

Antecedents

Data on antecedents of HL were collected according to what has been proposed by the HLS-EU (HLS-EU Consortium, 2012) and the Italian lifestyle surveillance system PASSI (Progress by local health units towards a healthier Italy -PASSI).[45] Besides including questions on gender, birth year, nationality, number of years

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living in Italy (for those who were born abroad), educational level, marital status, the questionnaire also contains questions on the number of family members living in the same household, whether one has ever received training or is/has been employed in the field of health care, employment status (currently having a paid job), financial situation, and whether a family member or a friend normally accompanies him/her to medical appointments.

Health outcome variables

According to the Sørensen model (Sørensen, 2012), many outcomes are associated with HL. According to what has been already made public by the HLS-EU[6], the following information is collected: self- assessed health status (excellent, very good, good, so and so/fair, bad), weight and height to calculate body mass index, health service use in the last 12 months (number of doctor visits; hospital admissions; emergency department visits; use of healthcare services, such as dentists, physiotherapists, psychologists, dieticians or opticians. Responses are coded as follows: 0, 1-2 times, 3-5 times, 6 times or more, don't know/refusal). To measure health status, subjects will be asked on long term-illnesses (illnesses that have lasted or are expected to last for at least six months), coded in four categories: yes, more than one; yes, one; no; don't know/refusal).

Statistical analysis

Statistical analysis will be performed using IBM SPSS Statistics for Windows, Version 24.0 (Armonk, NY: IBM Corp), and StataIC 11 (Lakeway Dr, College Station, TX: StataCorp). For each analysis, an alfa level of 0.05 will be considered as significant.

Prior to the main analysis, data will be assessed for non-normality.

Descriptive statistics will be calculated and data will be presented as percentage or as mean ± standard deviation. Associations between variables will be tested using Fisher exact test for categorical data or Student's t test or ANOVA for continuous data. Linear regression analysis will be performed to assess the linear relationships between HL and covariates. ROC analysis will be performed for validation. According to the aims of the study, different analyses will be run.

Aim 1. To assess the level of HL in a population-based sample in Florence, Italy, using the Italian version of the Newest Vital Sign (NVS-IT).

The distribution of health literacy levels will be calculated, with results projected back to the target population through inference analysis aimed at calculating estimates for the target population.

Aim 2. To assess the association of HL, selected antecedents and health outcomes, so as to evaluate whether HL is a mediator, a confounding or a cofactor in predicting the outcome variables.

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Linear regression analyses will be performed, in order to assess the linear relationship between NVS-IT scores, antecedents and health outcomes. In a first step, the association between antecedents (independent variables) and NVS-IT scores (dependent variable) will be assessed, followed by the assessment of the association between NVS-IT (Independent variable) and health outcomes (dependent variable).

The potential mediating role of HL will be assessed using Preacher and Hayes' model.[46] The model is based on a normal theoretical approach and bootstrapping approach for obtaining reliable intervals between variables.[47,48] This approach supports the traditional methods of Baron and Kenny[47] in studying the effects of mediating variables.[49]

Aim 3. To develop and validate the Italian version of three BHLS and two subjective numeracy items, and to assess their diagnostic accuracy in detecting subjects with limited HL compared to the NVS-IT (concurrent validation)

Aim 4. To develop and validate the Italian version of the short form (HLS-EU-Q16) and the short-short form (HLS-EU-Q6) of the European Health Literacy Survey Questionnaire, and to assess their diagnostic accuracy in detecting subjects with limited HL compared to the NVS-IT (concurrent validation).

To assess the concurrent validity (the degree of agreement between two different tools in measuring the same concept) and the diagnostic accuracy of the HL scales, correlation (Pearson or Spearman) and Receiver Operating Characteristic (ROC) analyses will be performed. To verify that the thresholds suggested in the original validation studies can distinguish individuals with lower HL levels from individuals with higher HL levels, sensitivity, specificity, positive and negative predictive value, and total accuracy will be calculated for each potential threshold value. Based on the already validated NVS-IT, two different analyses will be performed. The first analysis will consider those participants with "adequate HL" on the NVS-IT as being high literate and those with "possibility of limited HL" and "high likelihood of limited HL" as being low literate. The second analysis will use a different grouping and assign those with "Possibility of limited HL" on the NVS-IT to the high literate group. The area under the ROC curve (AUROC) will be used as a and measure of accuracy.[50] To assess the level of agreement, Cohen's kappa will also be calculated.

Ethics and dissemination

The study was designed according to the principles of the Helsinki Declaration. The protocol was approved by the Ethics Committee of the "Area Vasta Centro" (Local Health Unit of Tuscany-Center, Careggi University Hospital, and Meyer University Hospital; Rif. CEAVC: 10113, 01/12/2016). As briefly described above, after data collection information will be anonymized by assigning a numeric code to each participant. Any original identifiable information will be destroyed once the study is completed.

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Results will be disseminated via peer-reviewed scientific journals and conference presentations. Moreover, grouped data will be made available to the GPs. Finally, the results will be discussed with policy-makers of the Tuscan Region.

DISCUSSION

Strengths and limitation

To the best of our knowledge this is the first study in Italy that comprehensively attempts to assess HL and its related antecedents and outcomes, as well as attempts to validate a variety of different measures.

Using a validated measure (NVS-IT) HL levels will be assessed in a population-based sample. The NVS has seen application across different countries and contexts[25-30] and has also been used in the EU-HLS[6]. This will allow the systematic comparison of data with those obtained in the eight countries involved in the European survey. Comparability will be made easier also by the fact that this study will involve a population-based sample of adults, similarly to those included in the EU-HLS. Further, given that the NVS-IT has already been validated in Italian, the analysis will allow to systematically test concurrent validity of the newly validated measures.

Another strength regards the HL measures themselves, as that they have been already validated in different languages and/or settings. Therefore, the diagnostic accuracy of the newly validated measures could and will be compared with that identified in other studies.

Another strength of this study is the direct involvement of GPs, who signed the informative letter and agreed with the aims of the study. Due to the GP`s strong involvement, participants might be more motivated to participate in the study, which is expected to result in higher compliance (see for example the study of Toçi[23]).

One limitation of this study is that the sample was randomly selected among people living in Florence but among individuals registered as patients at different GPs. Moreover, the GPs were recruited using convenience criteria, which might introduce a selection bias. To contain some of the bias, GPs were chosen according to their geographic location with the aim to cover different districts in Florence that may present different characteristics of the residents. Moreover, the variable that identify the subject's GP, as well as the number of registered patients, will be considered and included as a confounder in the analyses.

Implications

This study will have a number of important implications. First of all, the results of the study will be useful in assessing the abilities of community members in seeking, finding and using health services. Moreover,

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obtaining validated HL measures in Italian will support current research efforts on HL and related outcomes in Italy, whether it is on a population-based level or in the clinical setting. As suggested by other authors[43], it is proposed to use the HLS-EU-Q16 for other research than HL-specific research in Italy. More precisely, it is currently planned to integrate the HLS-EU-Q16 as a covariate in the Italian lifestyle surveillance system PASSI.

Further, since the results will be presented and discussed with the Regional policy-makers, including the General Directors of Local and Hospital Health Units, data on HL will also be taken into account while planning community-based health activities and marketing and educational strategies to be used in educational campaigns or campaigns to support the introduction of new services, screening initiatives (e.g., bowel or skin cancer) or vaccination programs.[51]

On the patient level, an important implication of the study relates to the direct involvement of the GPs. Besides becoming more familiar with the concept of HL and its assessment tools, GPs will receive individual data for their patients, which will allow them to address findings in their day-to-day practice and to potentially improve their care relationships.

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Figure 1. Sampling procedure

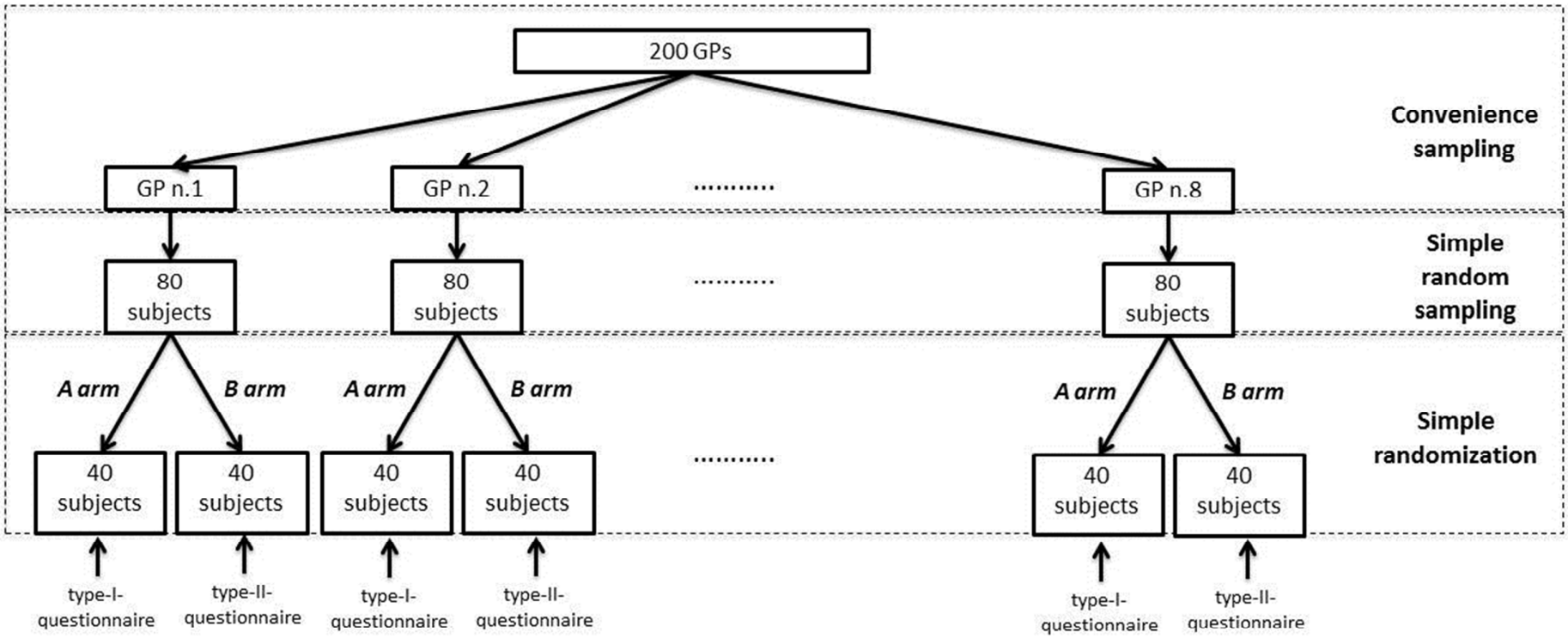

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Table 1. Summary of the content of the two types of questionnaires that will be used in the study.

Questionnaire sections	Questionnaire type 1	Questionnaire type 2
General section	X	X
Health literacy measurements		
NVS-IT	X	X
The 3-items BHLS	X	
Two subjective numeracy items	X	
HLS-EU-Q16 and HLS-EU-Q6		X
Health outcome variables	X	X

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Table 2. The 3-items HL screening, the two subjective numeracy items, the HLS-EU-Q16, and the HLS-EU-Q6 with answers and scoring (English and Italian versions).

Measurement tool	English version	Italian version
3-items HL screening	1. How often do you have problems learning about your medical condition because of difficulty understanding written information? *Always (1); often (2); sometimes (3); occasionally (4); never (5)*	1. Quanto spesso ha difficoltà a comprendere informazioni scritte che riguardano il suo stato di salute? *Sempre (1); spesso (2); a volte (3); raramente (4); mai (5)*
	2. How often do you have someone help you read hospital materials? *Always (1); often (2); sometimes (3); occasionally (4); never (5)*	2. Quanto spesso ha qualcuno (un familiare, un amico o un'altra persona) che la aiuta a leggere il materiale sanitario? *Sempre (1); spesso (2); a volte (3); raramente (4); mai (5)*
	3. How confident are you filling out medical forms by yourself? *Extremely (1); quite a bit (2); somewhat (3); a little bit (4); not at all (5)*	3. Quanto si sente sicuro nel compilare da solo moduli medici? *Moltissimo (1); Molto (2); abbastanza (3); poco (4); per niente (5)*
Two subjective numeracy items	1. In general, how easy or hard do you find it to understand medical statistics? *Very easy (1); easy (2); hard (3); very hard (4)*	1. In generale, quanto è facile o difficile per lei comprendere risultati di indagini statistiche condotte in ambito medico? *Molto facile (1); facile (2); difficile (3); molto difficile (4)*
	2. How much do you agree or disagree with the following statement? In general, I depend on numbers and statistics to help me make decisions about my health. *Strongly agree (1); somewhat agree (2); somewhat disagree (3); strongly disagree (4)*	2. Quanto è d'accordo o in disaccordo con la seguente affermazione? In generale, mi baso su numeri e statistiche per prendere decisioni sulla mia salute. *Totalmente d'accordo (1); abbastanza d'accordo (2); abbastanza in disaccordo (3); molto in disaccordo (4)*
HLS-EU-Q16 and HLS-EU-Q6 (*)	On a scale from very easy to very difficult, how easy would you say it is to …. *Very easy; fairly easy; fairly difficult; very difficult; (don´t know)°*	Su una scala da estremamente difficile a estremamente facile, secondo Lei, quanto è difficile… *Molto difficile; abbastanza difficile; abbastanza facile; molto facile; (non so)°*
	1)…find information on treatments of illnesses that concern you?	1) …trovare informazioni sui trattamenti delle malattie che La riguardano?
	2)…find out where to get professional help when you are ill?	2)…identificare dove trovare personale sanitario quando è malato/a?
	3)…understand what your doctor says to you?	3) …capire cosa Le dice il Suo medico?
	4)…understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?	4) …capire le istruzioni del Suo medico o del Suo farmacista su come assumere un farmaco che Le è stato prescritto?
	5)…judge when you may need to get a second opinion from another doctor?*	5) …giudicare quando è necessaria una seconda opinione da parte di un altro medico?*
	6)…use information the doctor gives you to make decisions about your illness?*	6) …usare le informazioni che il medico Le fornisce per prendere delle decisioni a proposito della Sua malattia?*
	7)…follow instructions from your doctor or pharmacist?	7) …seguire le istruzioni del Suo medico o del Suo farmacista?
	8)…find information on how to manage mental health problems like stress or depression?*	8) …trovare informazioni su come gestire problemi di salute mentale, come lo stress o la depressione?*

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	9)…understand health warnings about behaviour such as smoking, low physical activity and drinking too much?	9) …capire avvertenze per la salute riguardanti comportamenti come fumare, fare poca attività fisica e bere troppo alcool?
	10)…understand why you need health screenings?	10)…capire perché è necessario sottoporsi agli screening (come mammografia, PAP test, ricerca di sangue occulto nelle feci, determinazione glicemia, misurazione della pressione sanguigna)?
	11)…judge if the information on health risks in the media is reliable?*	11) …giudicare se le informazioni sui rischi per la salute riferite dai mezzi di comunicazione siano attendibili?*
	12)…decide how you can protect yourself from illness based on information in the media?	12) …decidere come può proteggersi da una malattia basandosi sulle informazioni riferite dai media?
	13)…find out about activities that are good for your mental well-being?*	13) …identificare attività che fanno bene al benessere mentale?*
	14)…understand advice on health from family members or friends?	14) …capire consigli da parte di familiari o amici riguardo alla salute?
	15)…understand information in the media on how to get healthier?*	15) …capire le informazioni riferite dai mezzi di comunicazione su come migliorare il suo stato di salute?*
	16)…judge which everyday behaviour is related to your health?	16) …giudicare quali comportamenti quotidiani hanno un impatto sulla Sua salute?

° for HLS-EU-Q16, “fairly difficult” and “very difficult” are coded with 0 while “fairly easy” and “very easy” are coded with 1; for HLS-EU-Q6 the coding is as follow: Very easy=4; fairly easy=3; fairly difficult=2; very difficult=1; for HLS-EU-Q16 and HLS-EU-Q6, don’t know is coded as “missing”

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Authors' contributions

CL, SM and GB: conception and design; drafting the article; give final approval of the version to be submitted. FS, MG, VV, VL and AB (Alessadro Bussotti): conception and design; give final approval of the version to be submitted. AB (Angela Bechini) and SB: drafting the article; give final approval of the version to be submitted.

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Health Literacy in Italy—A cross-sectional study protocol to assess the health literacy level and its association in a population-based sample, and to validate health literacy measures in the Italian language

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Health Literacy in Italy—A cross-sectional study protocol to assess the health literacy level and its association in a population-based sample, and to validate health literacy measures in the Italian language

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ABSTRACT

Introduction

Health literacy (HL) concerns the knowledge and competences of people to meet the complex demands of health. The aims of this study are to assess the level of HL in a sample using the Italian version of the Newest Vital Sign; to assess the association of HL and selected antecedents with health outcomes; to develop and validate the Italian version of the three Brief Health Literacy Screeners, two subjective numeracy items, and the short and the short-short forms of the European Health Literacy Survey Questionnaire.

Methods and analysis

The study adopts a cross-sectional design and is conducted in Florence. Information is collected through telephone interviews. The population-based sample is randomly selected using the registries of eight General Practitioners (GPs). Based on a power calculation, 480 subjects are included.

Participants are randomized to two different questionnaires, each containing different HL measures. Data on socio-demographics and important antecedents and consequences of HL are collected.

The distribution of HL levels will be calculated. The mediating role of HL will be assessed using Preacher and Hayes' model. To assess the concurrent validity of the HL scales, correlation and Receiver Operating Characteristic analyses will be performed.

Ethics and dissemination

The study protocol has been approved by the Ethics Committee of the Area Vasta Centro. Results will be disseminated via scientific journals and conference presentations, and individual data will be made available to the GPs.

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Strengths and limitation of this study

- This is the first study in Italy that attempts to assess HL and its related antecedents and outcomes, and to validate a variety of different measures.
- The use of many measure tools will enable the systematic comparison of data with those obtained in other Countries.
- The direct involvement of General Practitioners (GPs) who signed the informative letter and agreed with the aims of the study could lead to a high compliance.
- One limitation of this study is that the sample has not been randomly selected among people living in Florence, but from individuals registered as patients with different GPs.
- Another limitation is that the GPs have been recruited using convenience criteria, potentially introducing a selection bias.

BACKGROUND

Health literacy (HL) concerns the knowledge and competences of individuals to meet the complex demands of health in modern society. According to the conceptual framework of Sørensen et al., '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'.[1] In their framework, the authors identified 12 dimensions of HL, as well as proximal and distal factors (antecedents) that influence HL and related outcomes (consequences). Distal factors include societal and environmental factors, whereas proximal factors are situational and personal determinants such as general literacy, individual characteristics, and prior experience with illness and the healthcare system. On the other hand, the consequences at the individual and population levels refer to health service use and health costs, health behaviour and health outcomes, participation and empowerment in health issues, and equity and sustainability of public health issues. Despite this and other conceptual models (see for example the models of Nutbeam[2], Paasche-Orlow and Wolf[3], Schulz and Nakamoto[4]), to date the causal relationships between antecedents, HL, and health outcomes are still unclear. Only few studies have systematically investigated the role of HL as a mediator between antecedents and different health outcomes, while many authors have described HL as a co-factor or confounder in predicting health outcomes.[5-13]

Many tools exist to measure HL but to date none of them are considered to be the gold standard. [14,15] Measures largely vary in their approach and design, as well as in terms of their purpose. Some of them are screening tools that were originally developed for the clinical setting—to quickly identify patients with lower HL levels. Other tools were developed with the aim of measuring the broader concept of HL to

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provide an in-depth assessment of the different dimensions of HL and of exploring its relationship with determinants or outcomes. Moreover, HL measures are either performance-based (objective) or self-reported (subjective).[14–17] This means that they evaluate an individual's HL level by asking individuals either directly to apply their skills to a healthcare-related task or to report on their skills, such as being confident enough to fill out medical forms on their own (see, for example, the studies of Chew[18,19]). Overall, there has been relatively little systematic research comparing the effectiveness of performance-based and self-reported measures, specifically in regard to possible relationships between HL and health outcomes. As suggested in a recent review, further studies that assess HL by using performance-based and self-reported tools at the same time are needed to clarify these aspects.[20]

In Italy, research on HL is still relatively new; only a few studies have assessed and published results on HL in Italian samples.[21,22] Therefore, the aims of this study are:

1. to assess the level of HL in a population-based sample in Florence, Italy, using the Italian version of the Newest Vital Sign (NVS-IT);
2. to assess the association of HL, selected antecedents, and health outcomes, so as to evaluate whether HL is a mediator, a confounding factor, or a cofactor in predicting the outcome variables;
3. to develop and validate the Italian version of three subjective Brief Health Literacy Screeners (BHLS) and two subjective numeracy items, and to assess their diagnostic accuracy in detecting subjects with limited HL in comparison to the NVS-IT (concurrent validation); and
4. to develop and validate the Italian version of the short form (HLS-EU-Q16) and the short-short form (HLS-EU-Q6) of the European Health Literacy Survey Questionnaire (EU-HLS), and to assess their diagnostic accuracy in detecting subjects with limited HL in comparison to the NVS-IT (concurrent validation).

METHODS

The study adopts a cross-sectional design and is conducted in Florence, Italy and its surroundings. It started in February 2017 and will presumably end in September 2017. Information is collected through telephonic interviews.

Study population and sampling criteria

The population-based sample was randomly selected from the registries of eight General Practitioners (GPs) working in primary healthcare ambulatories of the municipality of Florence—a sampling method that is also suggested by other authors (see, for example, the study of Toçi[23]) (Figure 1). According to the regulation of the National Healthcare System and the Constitution of the Italian Republic, in Italy every

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citizen and foreign resident above the age of 18 has the right to be registered as a patient with a GP. Healthcare is provided by GPs free of charge to all patients. In the municipality of Florence, about 200 GPs provide continuing and comprehensive healthcare to individuals who are registered as patients. For each GP, the number of registered and assisted patients is on average 1,100, with a maximum limit of 1,500 patients per doctor.

The GPs were recruited using convenience criteria. Both the President of the Provincial Medical Council and the representative of the GPs at the University Hospital of Florence informed their colleagues to join the study by using either email or verbal contacts. The first eight to voluntarily join the study were included. Each GP randomly selected 80 subjects among those registered as one of his/her patients.

Inclusion criteria were the following: 18–69 years of age and Italian-speaking (since the survey is conducted in Italian). Exclusion criteria included cognitive impairment, severe psychiatric diseases, and end-stage diseases. Each GP, when selecting the sample, verified the inclusion and exclusion criteria.

Sample size was calculated based on the first aim of this study. Since no data on HL in Italy using NVS as measurement tool is publicly available at present, data from the EU-HLS were used as a reference. Based on the original study that assessed HL across eight different European countries (Italy not included)[6], Spain—with the highest rate of limited HL when assessed with the NVS—was chosen (34.3%) as expected value. Considering a confidence level of 95% and a margin of error equal to 0.05, the sample size was determined to be 480 people. An oversampling of 160 individuals is planned to account for problems in recruitment (i.e. subjects not available for telephonic interviews or refusal rates). If oversampling will not be sufficient, a second random sample will be drawn.

Each subject is randomly allocated to one of the two arms of the study (A and B), according to the questionnaires used during the interview (Type-I and Type-II questionnaires respectively).

Procedures - data collection

Each selected subject is contacted via postal mail. Subjects receive an informative letter signed by both the GP and the person responsible for the study. Further, the letter includes a consent form, a short description of the study, and an invitation to participate. Participants are asked to sign the consent form and return it by mail to the researchers in charge. Further, the letter contains the nutritional label of the NVS-IT. For further information, email addresses and telephone numbers of the responsible researchers are provided in the letter. After receipt of the signed consent forms, the subjects are contacted via phone for the interview.

Nine interviewers, who are part of the research group, make the phone calls. Written instructions on how to conduct the interview are developed and shared within the research team so as to standardize the

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procedure and limit interviewer bias. Each subject is contacted a maximum of six times before being considered unreachable. Each subject is randomly assigned to one of the nine interviewers.

Data are collected using an electronic database and anonymized by assigning a numeric code to each recruited person.

To meet the aims of the study, two questionnaires (Type I and type II) were developed, each containing the sections on the possible antecedents and consequences of HL, as well as different items to assess HL (Table 1). Both questionnaires have a general section that includes questions on socio-demographics, familial data (antecedents), and health-related outcomes. Further, both questionnaires include the NVS-IT items. However, while the Type-I-questionnaire has three BHLS and two subjective numeracy items, the Type-II-questionnaire contains a section with the HLS-EU-Q16.

The questionnaires have both been pre-tested with a small sample of volunteers, and take about 20 and 25 minutes, depending on the questionnaire.

Measurements

Newest Vital Sign (NVS)

The Newest Vital Sign (NVS) is a commonly used objective measure of HL. It was originally developed in the United States (US) for English- and Spanish-speakers[24]. However, in recent years, the NVS has seen increased application in countries other than the US[6,25-30], including Italy (NVS-IT)[31].

The NVS-IT consists of an ice-cream nutrition label, with seven associated questions that measure literacy and numeracy. It produces a final score ranging from 0 to 6, allowing 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 very little time to be administered (three to five minutes), and has been found to be easily applicable to patients in different settings.[32,33] Since the information needed to answer the questions has to be derived from the nutritional label, the label is included in the postal mail to be sent to the GP-assisted people.

Health Literacy and Numeracy Screeners

In addition to the NVS-IT, the Type-I-questionnaire contains items of two other measurement tools—three Brief Health Literacy Screeners (BHLS), and two subjective numeracy items. Both measures are self-reported measurement tools with Likert-type responses, validated for predicting NVS scores by a previous study.[34]

The three BHLS were initially developed and validated in English[18]. They assess literacy, interaction, comprehension and confidence (self-efficacy) skills. Even though they were originally developed for the clinical setting, they have seen increased application in population-based studies.[35-40]

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The two subjective numeracy items—adapted from the STAT-confidence that assesses people's confidence in understanding medical statistics[41]—were initially also validated in English. The two questions assess an individual's confidence in medical statistics by evaluating numeracy, comprehension, application/function, decision-making, and confidence. Both tools produce a score to measure the HL levels.

HLS-EU-Q16 and HLS-EU-Q6

In addition to the NVS-IT, the Type-II questionnaire contains the HLS-EU-Q16 and the HLS-EU-Q6, which are, respectively, the short and the short-short form of the European Health Literacy Survey Questionnaire (HLS-EU-Q47). The HLS-EU was developed with the aim to measure and compare HL levels of populations in different European countries. Based on the conceptual model proposed by Sørensen et al.[1], a European Union-funded working group developed the HLS-EU-Q47.[42] It includes 47 items covering 12 subdomains (including domains such as accessing and obtaining, understanding, or appraising information relevant to healthcare, disease prevention, or health promotion). It is a self-reported tool with Likert-type responses ('very easy', 'fairly easy', 'fairly difficult', 'very difficult') and an associated final score that measures interaction, comprehension, information-seeking, application/function, decision-making/critical thinking, evaluation, responsibility, confidence, and navigation skills. Based on the extended version, two short versions were developed by selecting 16 items for the HLS-EU-Q16 and six items for the HLS-EU-Q6. Even though the reduction in the number of items has decreased the informative value and theoretical scope of the measure, it has increased its utility by reducing its administration time, while maintaining strong correlations to the full instrument.[43]

To generate the score for the HLS-EU-Q16 answers are dichotomized ('don´t know' answers are coded as missing values). 'Fairly difficult' and 'very difficult' are both coded with 0 (zero), whereas 'fairly easy' and 'very easy' are both coded with 1. The HLS-EU-Q16 score is a sum score (range: 0-16) and according to the final score, three levels of HL have been defined: inadequate HL (0-8); problematic HL (9-12); sufficient HL (13-16).

Scores for the HLS-EU-Q6 are calculated similarly to those of the HLS-EU-Q47 (from 1 for 'very difficult', to 4 for 'very easy'). The final score is the mean score that is calculated if at least 5 of the 6 items are completed and range from 1 to 4. According to the final score, three possible levels of HL have been defined: inadequate HL (1-2); problematic HL (2-3); sufficient HL (3-4).

Translation of HL measurements

The English versions of the BHLS, two subjective numeracy items, the HLS-EU-Q16, and the HLS-EU-Q6, were translated and adapted using standard procedures, including forward- and back-translation (performed by Italian and English native speakers). A final Italian version was drafted, which was then

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shared and discussed with members of the research group.[44] Table 2 reports on the Italian versions of the tools.

Antecedents

Data on antecedents of HL were collected according to the proposal of the HLS-EU (HLS-EU Consortium, 2012) and the Italian lifestyle surveillance system PASSI (Progress by local health units towards a healthier Italy -PASSI).[45] Apart from including questions on gender, birth year, nationality, number of years living in Italy (for those who were born abroad), educational level, and marital status, the questionnaire also has questions on the number of family members living in the same household, whether one has ever received training or is/has been employed in the field of healthcare, employment status (currently having a paid job), financial situation, and whether a family member or a friend normally accompanies him/her to medical appointments.

Health outcome variables

According to the Sørensen model (Sørensen, 2012), many outcomes are associated with HL. According to what has been already made public by the HLS-EU[6], the following information is collected: self-assessed health status (excellent, very good, good, so-so/fair, bad), weight and height to calculate body mass index, health services used in the last 12 months (number of doctor visits, hospital admissions, emergency department visits, and use of healthcare services such as dentists, physiotherapists, psychologists, dieticians, or opticians. Responses are coded as follows: 0, 1–2 times, 3–5 times, 6 times or more, don't know/refusal). To measure health status, subjects are asked about long-term illnesses (illnesses that have lasted or are expected to last for at least six months), coded in four categories: yes, more than one; yes, one; no; don't know/refusal.

Statistical analysis

Statistical analysis will be performed using IBM SPSS Statistics for Windows, Version 24.0 (Armonk, NY: IBM Corp), and StataIC 11 (Lakeway Dr, College Station, TX: StataCorp). For each analysis, an alfa level of 0.05 will be considered as significant.

Prior to the main analysis, data will be assessed for non-normality.

Descriptive statistics are calculated and data are presented as percentage or as mean ± standard deviation. Associations between variables are tested using Fisher's exact test for categorical data and Student's t test or ANOVA for continuous data. Linear regression analysis is performed to assess the linear relationships between HL and covariates. ROC analysis is performed for validation. According to the aims of the study, different analyses are run.

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Aim 1. To assess the level of HL in a population-based sample in Florence, Italy, using the Italian version of the Newest Vital Sign (NVS-IT).

The distribution of HL levels will be calculated with results projected back to the target population through inference analysis aimed at calculating estimates for the target population.

Aim 2. To assess the association of HL, selected antecedents, and health outcomes, so as to evaluate whether HL is a mediator, a confounding factor, or a cofactor in predicting the outcome variables.

Linear regression analyses will be performed to assess the linear relationship between NVS-IT scores, antecedents, and health outcomes. In the first step, the association between antecedents (independent variables) and NVS-IT scores (dependent variable) will be assessed, followed by the assessment of the association between NVS-IT (independent variable) and health outcomes (dependent variable).

The potential mediating role of HL will be assessed using Preacher and Hayes' model.[46] The model is based on a normal theoretical approach and bootstrapping approach for obtaining reliable intervals between variables.[47,48] This approach supports the traditional methods of Baron and Kenny[47] in studying the effects of mediating variables.[49]

Aim 3. To develop and validate the Italian version of three BHLS and two subjective numeracy items, and to assess their diagnostic accuracy in detecting subjects with limited HL compared to the NVS-IT (concurrent validation)

Aim 4. To develop and validate the Italian version of the short form (HLS-EU-Q16) and the short-short form (HLS-EU-Q6) of the European Health Literacy Survey Questionnaire, and to assess their diagnostic accuracy in detecting subjects with limited HL, compared to the NVS-IT (concurrent validation).

To assess the concurrent validity (the degree of agreement between two different tools in measuring the same concept) and the diagnostic accuracy of the HL scales, correlation (Pearson or Spearman) and Receiver Operating Characteristic (ROC) analyses will be performed. To verify that the thresholds suggested in the original validation studies can distinguish individuals with lower HL levels from individuals with higher HL levels, sensitivity, specificity, positive and negative predictive values, and total accuracy will be calculated for each potential threshold value. Based on the already validated NVS-IT, two different analyses will be performed. The first analysis will consider participants with 'adequate HL' on the NVS-IT as being highly literate and those with 'possibility of limited HL' and 'high likelihood of limited HL' as being less literate. The second analysis will uses a different grouping and assigns those with 'Possibility of limited HL' on the NVS-IT to the highly literate group. The area under the ROC curve (AUROC) will be used as a measure of accuracy.[50] To assess the level of agreement, Cohen's kappa will also be calculated.

Since the HLS-EU-Q16 was developed from the HLS-EU-Q47 using Rash analysis[43], this analysis will be performed on the Italian version of the *HLS-EU-Q16* to describe the 'test-item difficulty', its strengths, and its weaknesses.[51]

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Ethics and dissemination

The study was designed following the principles of the Helsinki Declaration. The protocol was approved by the Ethics Committee of the 'Area Vasta Centro' (Local Health Unit of Tuscany Centre, Careggi University Hospital and Meyer University Hospital; Rif. CEAVC: 10113, 01/12/2016). As briefly described above, after data collection, information will be anonymized by assigning a numeric code to each participant. Any original identifiable information will be destroyed once the study is completed.

Results will be disseminated via peer-reviewed scientific journals and conference presentations. Moreover, grouped data will be made available to the GPs. Finally, the results will be discussed with policymakers of the Tuscan Region.

DISCUSSION

Strengths and limitation

To the best of our knowledge, this is the first study in Italy that comprehensively attempts to assess HL and its related antecedents and outcomes and to validate a variety of different measures.

Using a validated measure (NVS-IT), HL levels will be assessed in a population-based sample. The NVS has seen application across different countries and contexts[25–30] and has also been used in the EU-HLS[6]. This will allow the systematic comparison of data with those obtained in the eight countries involved in the European survey. Comparability will be made easier by the use of a population-based sample of adults, similar to those included in the EU-HLS. Further, given that the NVS-IT is already validated in Italian, the analysis will enable to systematic testing of concurrent validity of the newly validated measures.

Another strength concerns the HL measures themselves, as they have been already validated in different languages and/or settings. Therefore, the diagnostic accuracy of the newly validated measures will be compared with that identified in other studies. Anyway, as noted by Reeve and Basalik[52], HL tests were primarily designed to detect illiteracy, so they often show ceiling effect when used in the general population. Ceiling effect can significantly skew distribution, and leads to concern about attenuated correlation. In our study, this phenomenon could be observed for NVS-IT, BHLS, and two subjective numeracy items, while the HLS-EU-Q47 and its short forms have initially been validated in the general population. Possible ceiling effect and skewed distribution will be considered in the statistical analysis.

Another strength of this study is the direct involvement of GPs, who have signed the informative letter and agreed with the aims of the study. Due to the GP`s strong involvement, participants might be more motivated to participate in the study, which is expected to result in higher compliance (see, for example, the study of Toçi[23]).

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One limitation of this study is that the sample was randomly selected among people living in Florence, but from individuals registered as patients at different GPs. Moreover, the GPs were recruited using convenience criteria, which might introduce a selection bias. To contain some of the bias, GPs were chosen according to their geographic location, with the aim of covering different districts in Florence that may present different characteristics of the residents. Moreover, the variable that identifies the subject's GP, as well as the number of registered patients, will be considered and included as a confounder in the analyses.

Implications

This study has a number of important implications. First of all, the results of the study will be useful in assessing the abilities of community members in seeking, finding, and using health services. Moreover, obtaining validated HL measures in Italian will support current research efforts on HL and related outcomes in Italy—whether at a population-based level or in the clinical setting. As suggested by other authors[43], it is proposed to use the HLS-EU-Q16 for research other than HL-specific research in Italy. More precisely, it is currently planned to integrate the HLS-EU-Q16 as a covariate in the Italian lifestyle surveillance system PASSI.

Further, since the results will be presented and discussed with the Regional policy-makers, including the General Directors of Local and Hospital Health Units, data on HL will also be taken into account while planning community-based health activities or marketing and educational strategies to be used in educational campaigns or campaigns to support the introduction of new services, screening initiatives (e.g. bowel or skin cancer), or vaccination programmes.[53]

On the patient level, an important implication of the study relates to the direct involvement of the GPs. Apart from becoming more familiar with the concept of HL and its assessment tools, GPs will receive individual data for their patients, which will allow them to address findings in their day-to-day practice and to potentially improve their care relationships.

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Figure 1. Sampling procedure

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Table 1. Summary of the content of the two types of questionnaires that will be used in the study.

Questionnaire sections	Questionnaire Type 1	Questionnaire Type 2
General section	**X**	**X**
Health literacy measurements		
NVS-IT	**X**	**X**
The three-item BHLS	**X**	
Two subjective numeracy items	**X**	
HLS-EU-Q16 and HLS-EU-Q6		**X**
Health outcome variables	**X**	**X**

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Table 2. The three-item HL screening, the two subjective numeracy items, the HLS-EU-Q16, and the HLS-EU-Q6 with answers and scoring (English and Italian versions).

Measurement tool	English version	Italian version
3-items HL screening	1. How often do you have problems learning about your medical condition because of difficulty in understanding written information? *Always (1); often (2); sometimes (3); occasionally (4); never (5)*	1. Quanto spesso ha difficoltà a comprendere informazioni scritte che riguardano il suo stato di salute? *Sempre (1); spesso (2); a volte (3); raramente (4); mai (5)*
	2. How often do you have someone help you read hospital materials? *Always (1); often (2); sometimes (3); occasionally (4); never (5)*	2. Quanto spesso ha qualcuno (un familiare, un amico o un'altra persona) che la aiuta a leggere il materiale sanitario? *Sempre (1); spesso (2); a volte (3); raramente (4); mai (5)*
	3. How confident are you in filling out medical forms by yourself? *Extremely (1); quite a bit (2); somewhat (3); a little bit (4); not at all (5)*	3. Quanto si sente sicuro nel compilare da solo moduli medici? *Moltissimo (1); Molto (2); abbastanza (3); poco (4); per niente (5)*
Two subjective numeracy items	1. In general, how easy or hard do you find it to understand medical statistics? *Very easy (1); easy (2); hard (3); very hard (4)*	1. In generale, quanto è facile o difficile per lei comprendere risultati di indagini statistiche condotte in ambito medico? *Molto facile (1); facile (2); difficile (3); molto difficile (4)*
	2. How much do you agree or disagree with the following statement? In general, I depend on numbers and statistics to help me make decisions about my health. *Strongly agree (1); somewhat agree (2); somewhat disagree (3); strongly disagree (4)*	2. Quanto è d'accordo o in disaccordo con la seguente affermazione? In generale, mi baso su numeri e statistiche per prendere decisioni sulla mia salute. *Totalmente d'accordo (1); abbastanza d'accordo (2); abbastanza in disaccordo (3); molto in disaccordo (4)*
HLS-EU-Q16 and HLS-EU-Q6 (*)	On a scale from very easy to very difficult, how easy would you say it is to …. *Very easy; fairly easy; fairly difficult; very difficult; (don´t know)°*	Su una scala da estremamente difficile a estremamente facile, secondo Lei, quanto è difficile… *Molto difficile; abbastanza difficile; abbastanza facile; molto facile; (non so)°*
	1)…find information on treatments of illnesses that concern you?	1) …trovare informazioni sui trattamenti delle malattie che La riguardano?
	2)…find out where to get professional help when you are ill?	2)…identificare dove trovare personale sanitario quando è malato/a?
	3)…understand what your doctor says to you?	3) …capire cosa Le dice il Suo medico?
	4)…understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?	4) …capire le istruzioni del Suo medico o del Suo farmacista su come assumere un farmaco che Le è stato prescritto?
	5)…judge when you may need to get a second opinion from another	5) …giudicare quando è necessaria una seconda opinione da parte di un

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	doctor?*	altro medico?*
	6)…use information the doctor gives you to make decisions about your illness?*	6) …usare le informazioni che il medico Le fornisce per prendere delle decisioni a proposito della Sua malattia?*
	7)…follow instructions from your doctor or pharmacist?	7) …seguire le istruzioni del Suo medico o del Suo farmacista?
	8)…find information on how to manage mental health problems like stress or depression?*	8) …trovare informazioni su come gestire problemi di salute mentale, come lo stress o la depressione?*
	9)…understand health warnings about behaviour such as smoking, low physical activity and drinking too much?	9) …capire avvertenze per la salute riguardanti comportamenti come fumare, fare poca attività fisica e bere troppo alcool?
	10)…understand why you need health screenings?	10)…capire perché è necessario sottoporsi agli screening (come mammografia, PAP test, ricerca di sangue occulto nelle feci, determinazione glicemia, misurazione della pressione sanguigna)?
	11)…judge if the information on health risks in the media is reliable?*	11) …giudicare se le informazioni sui rischi per la salute riferite dai mezzi di comunicazione siano attendibili?*
	12)…decide how you can protect yourself from illness based on information in the media?	12) …decidere come può proteggersi da una malattia basandosi sulle informazioni riferite dai media?
	13)…find out about activities that are good for your mental well-being?*	13) …identificare attività che fanno bene al benessere mentale?*
	14)…understand advice on health from family members or friends?	14) …capire consigli da parte di familiari o amici riguardo alla salute?
	15)…understand information in the media on how to get healthier?*	15) …capire le informazioni riferite dai mezzi di comunicazione su come migliorare il suo stato di salute?*
	16)…judge which everyday behaviour is related to your health?	16) …giudicare quali comportamenti quotidiani hanno un impatto sulla Sua salute?

° for HLS-EU-Q16, 'fairly difficult' and 'very difficult' are coded with 0 while 'fairly easy' and 'very easy' are coded with 1; for HLS-EU-Q6, the coding is as follow: Very easy=4; fairly easy=3; fairly difficult=2; very difficult=1; for HLS-EU-Q16 and HLS-EU-Q6, don't know is coded as 'missing'

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Authors' contributions

CL, SM and GB: conception and design; drafting the article; give final approval of the version to be submitted. FS, MG, VV, VL and AB (Alessadro Bussotti): conception and design; give final approval of the version to be submitted. AB (Angela Bechini) and SB: drafting the article; give final approval of the version to be submitted.

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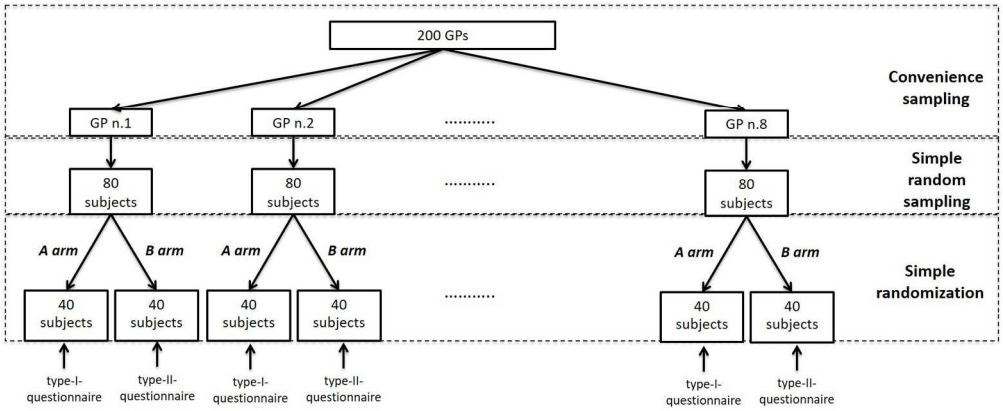

Figure 1. Sampling procedure

314x129mm (300 x 300 DPI)

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Health Literacy in Italy—A cross-sectional study protocol to assess the health literacy level in a population-based sample, and to validate health literacy measures in the Italian language

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Health Literacy in Italy—A cross-sectional study protocol to assess the health literacy level in a population-based sample, and to validate health literacy measures in the Italian language

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ABSTRACT

Introduction

Health literacy (HL) concerns the knowledge and competences necessary for people to meet complex health demands. The aims of this study are to assess the level of HL in a sample using the Italian version of the Newest Vital Sign and the association of HL and selected antecedents with health outcomes, and to develop and validate the Italian version of the three Brief Health Literacy Screeners, two subjective numeracy items, and the short and the short-short forms of the European Health Literacy Survey Questionnaire.

Methods and analysis

The study adopts a cross-sectional design and is being conducted in Florence, with information collected through telephone interviews. The population-based sample has been randomly selected using the registries of eight General Practitioners (GPs). Based on a power calculation, 480 subjects have been included.

Participants have been randomly offered two different questionnaires, each containing different HL measures. Data on socio-demographics and important antecedents and consequences of HL will be collected and the distribution of HL levels calculated. The mediating role of HL will be assessed using Preacher and Hayes' model. To assess the concurrent validity of the HL scales, correlation and Receiver Operating Characteristic analyses will be performed.

Ethics and dissemination

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The study protocol has been approved by the Ethics Committee of the Area Vasta Centro. Results will be disseminated via scientific journals and conference presentations, and individual data made available to the GPs.

Strengths and limitations of this study

- This is the first study in Italy to attempt to assess HL and its related antecedents and outcomes, and to validate a variety of different measures.
- The use of numerous measures will enable the systematic comparison of data with those obtained in other countries.
- The direct involvement of GPs who signed the information sheet and agreed with the aims of the study could lead to high compliance.
- One limitation of this study is that the sample has not been randomly selected among people living in Florence, but from individuals registered as patients with different GPs.
- Another limitation is that the GPs have been recruited using convenience criteria, potentially introducing a selection bias.

BACKGROUND

Health literacy (HL) concerns the knowledge and competences of individuals necessary for meeting the complex health demands of modern society. According to the conceptual framework of Sørensen et al., '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'.[1] In their framework, the authors identified 12 dimensions of HL, as well as proximal and distal factors (antecedents) that influence HL and related outcomes (consequences). Distal factors include societal and environmental factors, whereas proximal factors are situational and personal determinants such as general literacy, individual characteristics, and prior experience with illness and the healthcare system. On the other hand, the consequences at the individual and population levels refer to health service use and health costs, health behaviour and health outcomes, participation and empowerment in health issues, and equity and sustainability of public health issues. Despite this and other conceptual models (see for example the models of Nutbeam[2], Paasche-Orlow and Wolf[3], Schulz and Nakamoto[4]), to date the causal relationships between antecedents, HL, and health outcomes are still unclear. Only a few studies have systematically investigated the role of HL as a mediator between antecedents and different health outcomes, while many authors have described HL as a co-factor or confounder in predicting health outcomes.[5-13]

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Many tools exist to measure HL but to date none of them are considered the gold standard. [14,15] Measures largely vary in their approach and design, as well as in terms of their purpose. Some of them are screening tools that were originally developed for the clinical setting—to quickly identify patients with lower HL levels. Other tools were developed for the purpose of measuring the broader concept of HL to provide an in-depth assessment of the different dimensions of HL and exploring its relationship with determinants or outcomes. Moreover, HL measures are either performance-based (objective) or self-reported (subjective).[14–17] This means that they evaluate an individual's HL level by asking individuals to either directly apply their skills to a healthcare-related task or report on their skills, such as being confident enough to fill out medical forms on their own (see, for example, the studies of Chew[18,19]). Overall, there has been relatively little systematic research comparing the effectiveness of performance-based and self-reported measures, specifically in regard to possible relationships between HL and health outcomes. As suggested in a recent review, further studies that assess HL by using performance-based and self-reported tools at the same time are needed to clarify these aspects.[20]

In Italy, research on HL is still relatively new; only a few studies have assessed and published results on HL in Italian samples.[21,22] Therefore, the aims of this study are:

1. to assess the level of HL in a population-based sample in Florence, Italy, using the Italian version of the Newest Vital Sign (NVS-IT);
2. to assess the association of HL, selected antecedents, and health outcomes, so as to evaluate whether HL is a mediator, a confounding factor, or a cofactor in predicting the outcome variables;
3. to develop and validate the Italian version of three subjective Brief Health Literacy Screeners (BHLS) and two subjective numeracy items, and to assess their diagnostic accuracy in detecting subjects with limited HL in comparison to the NVS-IT (concurrent validation); and
4. to develop and validate the Italian version of the short form (HLS-EU-Q16) and short-short form (HLS-EU-Q6) of the European Health Literacy Survey Questionnaire (EU-HLS), and to assess their diagnostic accuracy in detecting subjects with limited HL in comparison to the NVS-IT (concurrent validation).

METHODS

The study adopts a cross-sectional design and is being conducted in Florence, Italy and its surroundings. It started in February 2017 and will presumably end in November 2017, with information collected through telephonic interviews.

Study population and sampling criteria

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The population-based sample was randomly selected from the registries of eight General Practitioners (GPs) working in primary healthcare centres of the municipality of Florence—a sampling method that is also suggested by other authors (see, for example, the study of Toçi[23]) (Figure 1). According to the regulations of the National Healthcare System and the Constitution of the Italian Republic, in Italy every citizen and foreign resident over the age of 18 has the right to be registered as a patient with a GP. Healthcare is provided by GPs free of charge to all patients. In the municipality of Florence, about 200 GPs provide continuing and comprehensive healthcare to individuals who are registered as patients. For each GP, the number of registered and assisted patients is on average 1,100, with a maximum limit of 1,500 patients per doctor.

The GPs were recruited using convenience criteria. Both the President of the Provincial Medical Council and the representative of the GPs at the University Hospital of Florence informed their colleagues to join the study via either email or verbal contact. The first eight to voluntarily join the study were included. Each GP randomly selected 80 subjects among those registered as one of his/her patients.

Inclusion criteria were the following: 18–69 years of age and Italian-speaking (since the survey is conducted in Italian). Exclusion criteria included cognitive impairment, severe psychiatric diseases, and end-stage diseases. Each GP verified the inclusion and exclusion criteria when selecting the sample.

Sample size was calculated based on the first aim of this study. Since no data on HL in Italy using NVS as a measure is publicly currently available, data from the EU-HLS were used as a reference. Based on the original study that assessed HL across eight different European countries (Italy not included)[6], Spain—with the highest rate of limited HL when assessed with the NVS—was chosen (34.3%) as the expected value. Considering a confidence level of 95% and a margin of error equal to 0.05, the sample size was established as 480 subjects. An oversampling of 160 individuals is planned to account for problems in recruitment (i.e. subjects not available for telephonic interviews or refusal rates). If oversampling is not sufficient, a second random sample will be drawn.

Each subject is randomly allocated to one of the two arms of the study (A and B), according to the questionnaires used during the interview (Type-I and Type-II questionnaires respectively).

Procedures - data collection

Each selected subject is contacted via postal mail. Subjects receive an information sheet signed by both the GP and the person in charge of the study, which includes a short description of the study, an invitation to participate, and a consent form. Participants are asked to sign the consent form and return it by mail to the researchers in charge. The mail also contains the nutritional label of the NVS-IT. For further information, email addresses and telephone numbers of the researchers are provided in the letter. After receipt of the signed consent forms, the subjects are contacted by phone for the interview.

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the Student's t test or ANOVA for continuous data. Linear regression analysis will be performed to assess the linear relationships between HL and covariates. ROC analysis will be performed for validation. According to the aims of the study, different analyses will be carried out.

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The distribution of HL levels will be calculated with the results projected back to the target population through inference analysis aimed at calculating estimates for the target population.

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Linear regression analyses will be performed to assess the linear relationship between NVS-IT scores, antecedents, and health outcomes. In the first step, the association between antecedents (independent variables) and NVS-IT scores (dependent variable) will be assessed, followed by an assessment of the association between NVS-IT (independent variable) and health outcomes (dependent variable).

The potential mediating role of HL will be assessed using the Preacher and Hayes model,[47] which is based on a normal theoretical approach and bootstrapping approach for obtaining reliable intervals between variables.[48,49] This approach supports the traditional methods of Baron and Kenny[48] in studying the effects of mediating variables.[50]

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To assess the concurrent validity (the degree of agreement between two different tools in measuring the same concept) and the diagnostic accuracy of the HL scales, correlation (Pearson or Spearman) and Receiver Operating Characteristic (ROC) analyses will be performed. In order to verify that the thresholds suggested in the original validation studies are capable of distinguishing individuals with lower HL levels from individuals with higher HL levels, the sensitivity, specificity, positive and negative predictive values and total accuracy will be calculated for each potential threshold value. Based on the already validated NVS-IT, two different analyses will be performed. The first analysis will consider participants with 'adequate HL' on the NVS-IT as being highly literate and those with 'possibility of limited HL' and 'high likelihood of limited HL' as being less literate. The second analysis will use a different grouping and assign those with 'Possibility of limited HL' on the NVS-IT to the highly literate group. The area under the ROC curve (AUROC) will be used as a measure of accuracy.[51] To assess the level of agreement, Cohen's kappa will also be calculated.

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Since the HLS-EU-Q16 has been developed from the HLS-EU-Q47 using Rash analysis[44], this analysis will be performed on the Italian version of the to describe the 'test-item difficulty', its strengths and weaknesses.[52]

Ethics and dissemination

The study has been designed following the principles of the Helsinki Declaration. The protocol has been approved by the Ethics Committee of the 'Area Vasta Centro' (Local Health Unit of Central Tuscany, Careggi University Hospital and Meyer University Children's Hospital; Ref. CEAVC: 10113, 01/12/2016). As briefly described above, after data collection, information will be anonymized by assigning a numeric code to each participant. Any original identifiable information will be destroyed once the study has been completed.

Results will be disseminated through peer-reviewed scientific journals and conference presentations. Moreover, grouped data will be made available to GPs. Finally, the results will be discussed with policymakers of the Tuscan Region.

DISCUSSION

Strengths and limitation

To the best of our knowledge, this is the first study in Italy that comprehensively attempts to assess HL and its related antecedents and outcomes and to validate a variety of different measures.

HL levels will be assessed in a population-based sample via use of a validated measure (NVS-IT), which has been applied in different countries and contexts[25–30,32] and has also been used in the EU-HLS[6]. This will allow for systematic comparison of data with those obtained in the eight countries involved in the European survey. Comparability will be made easier via use of a population-based sample of adults, similar to those included in the EU-HLS. In addition, given that the NVS-IT is already validated in Italian, the analysis will enable the systematic testing of the concurrent validity of the newly validated measures.

In this study, telephone interviews are used to collect NVS-IT data, while in almost all the studies face-to-face interviews are used. To date, no data have been published concerning the comparison of NVS data collected using different methods of administration. Compared to face-to-face interviews, telephone interviews offer several advantages[45], namely, the elimination of any bias caused by the appearance of the interviewer, lower costs related to the transfers of the interviewer or the person interviewed, and lower administrative costs. Moreover, there is some evidence that people are more likely to report health-related events on the phone rather than in face-to-face interviews.[45] The potential problems with telephone interviewing are instead as follows: the respondent may seek help from another person at home, and there

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is no assurance who the person is at the other end on the line. This second risk is difficult to completely eliminate, while the first one is minor[45] since the interviewer would be able to notice the involvement of other people (i.e. the person on the phone would have to repeat each question or use the hands-free mode).

Another strength concerns the HL measures themselves, as they have already been validated in different languages and/or settings. Therefore, the diagnostic accuracy of the newly validated measures will be compared with that identified in other studies. In any case, as noted by Reeve and Basalik[53], HL tests were primarily designed to detect illiteracy, so they often show a ceiling effect when used in the general population. The ceiling effect can significantly skew distribution, giving rise to concern about attenuated correlation. In our study, this phenomenon might be observed for NVS-IT, BHLS, and two subjective numeracy items, while the HLS-EU-Q47 and its short forms have initially been validated in the general population. Any possible ceiling effect or skewed distribution will be considered in the statistical analysis.

Another strength of this study is the direct involvement of the GPs who have signed the information sheet and agreed with the aims of the study. Due to their strong involvement, participants might be more motivated to participate in the study, which is expected to result in higher compliance (see, for example, the study of Toçi[23]).

One limitation of this study is that while the sample was randomly selected among people living in Florence, it includes individuals registered as patients with different GPs. Moreover, the GPs were recruited using convenience criteria, which might introduce a selection bias. To curb some of the bias, GPs were chosen according to their geographic location, in the aim of covering different districts in Florence that may present different characteristics of the residents. Furthermore, the variable that identifies the subject's GP, as well as the number of registered patients, will be considered and included as a confounder in the analyses.

Implications

This study has a number of important implications. First of all, the results of the study will be useful in assessing the ability of community members to seek, locate, and use health services. Moreover, obtaining validated HL measures in Italian will support current research efforts on HL and related outcomes in Italy—both at a population-based level and in the clinical setting. As suggested by other authors[44], it is proposed to use the HLS-EU-Q6 for research other than HL-specific research in Italy. More specifically, the current plan is to integrate the HLS-EU-Q6 as a covariate in the Italian lifestyle surveillance system PASSI.

In addition, since the results will be presented and discussed with the Regional policy-makers, including the General Directors of Local and Hospital Health Units, data on HL will also be taken into account when planning community-based health and marketing activities, educational strategies to be used in educational

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campaigns or campaigns to support the introduction of new services, screening initiatives (e.g. bowel or skin cancer), and vaccination programmes.[54]

At a patient level, an important implication of the study relates to the direct involvement of the GPs. Apart from becoming more familiar with the concept of HL and its assessment tools, GPs will receive individual data for their patients, which will allow them to address findings in their day-to-day practice and potentially improve their care relationships.

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Figure 1. Sampling procedure

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Table 1. Summary of the content of the two types of questionnaires that will be used in the study.

Questionnaire sections	Questionnaire Type 1	Questionnaire Type 2
General section	X	X
NVS-IT	X	X
The three-item BHLS	X	
Two subjective numeracy items	X	
HLS-EU-Q16 and HLS-EU-Q6		X
Health outcome variables	X	X

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Table 2. The three-item HL screening, the two subjective numeracy items, the HLS-EU-Q16, and the HLS-EU-Q6 with answers and scoring (English and Italian versions).

Measurement tool	English version	Italian version
3-items HL screening	1. How often do you have problems learning about your medical condition because of difficulty in understanding written information? " / ! * / + / . / # 0	1. Quanto spesso ha difficoltà a comprendere informazioni scritte che riguardano il suo stato di salute? & / & * / # + / . / 0
	2. How often do you have someone help you read hospital materials? " / ! * / + / . / # 0	2. Quanto spesso ha qualcuno (un familiare, un amico o un'altra persona) che la aiuta a leggere il materiale sanitario? & / & * / # + / . / 0
	3. How confident are you in filling out medical forms by yourself? 1 / 2 $ * / + / $. / 0	3. Quanto si sente sicuro nel compilare da solo moduli medici? 3 / 3 * / $$ 4 + / & . / & 0
Two subjective numeracy items	1. In general, how easy or hard do you find it to understand medical statistics? / * / + / # .	1. In generale, quanto è facile o difficile per lei comprendere risultati di indagini statistiche condotte in ambito medico? 3 ! / ! * / !! + / !! .
	2. How much do you agree or disagree with the following statement? In general, I depend on numbers and statistics to help me make decisions about my health. / * / + / .	2. Quanto è d'accordo o in disaccordo con la seguente affermazione? In generale, mi baso su numeri e statistiche per prendere decisioni sulla mia salute. 5 / $$ 4 5 * / $$ 4 + / .
HLS-EU-Q16 and HLS-EU-Q6 (*)	On a scale from very easy to very difficult, how easy would you say it is to …. / ! / ! !! / # !! / 6 7 8	Su una scala da estremamente difficile a estremamente facile, secondo Lei, quanto è difficile… 3 !! / $$ 4 !! / $$ 4 ! / ! / 8
	1)…find information on treatments of illnesses that concern you?	1) …trovare informazioni sui trattamenti delle malattie che La riguardano?
	2)…find out where to get professional help when you are ill?	2)…identificare dove trovare personale sanitario quando è malato/a?
	3)…understand what your doctor says to you?	3) …capire cosa Le dice il Suo medico?
	4)…understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?	4) …capire le istruzioni del Suo medico o del Suo farmacista su come assumere un farmaco che Le è stato prescritto?
	5)…judge when you may need to get a second opinion from another doctor?*	5) …giudicare quando è necessaria una seconda opinione da parte di un

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		altro medico?*
	6)…use information the doctor gives you to make decisions about your illness?*	6) …usare le informazioni che il medico Le fornisce per prendere delle decisioni a proposito della Sua malattia?*
	7)…follow instructions from your doctor or pharmacist?	7) …seguire le istruzioni del Suo medico o del Suo farmacista?
	8)…find information on how to manage mental health problems like stress or depression?*	8) …trovare informazioni su come gestire problemi di salute mentale, come lo stress o la depressione?*
	9)…understand health warnings about behaviour such as smoking, low physical activity and drinking too much?	9) …capire avvertenze per la salute riguardanti comportamenti come fumare, fare poca attività fisica e bere troppo alcool?
	10)…understand why you need health screenings?	10)…capire perché è necessario sottoporsi agli screening (come mammografia, PAP test, ricerca di sangue occulto nelle feci, determinazione glicemia, misurazione della pressione sanguigna)?
	11)…judge if the information on health risks in the media is reliable?*	11) …giudicare se le informazioni sui rischi per la salute riferite dai mezzi di comunicazione siano attendibili?*
	12)…decide how you can protect yourself from illness based on information in the media?	12) …decidere come può proteggersi da una malattia basandosi sulle informazioni riferite dai media?
	13)…find out about activities that are good for your mental well-being?*	13) …identificare attività che fanno bene al benessere mentale?*
	14)…understand advice on health from family members or friends?	14) …capire consigli da parte di familiari o amici riguardo alla salute?
	15)…understand information in the media on how to get healthier?*	15) …capire le informazioni riferite dai mezzi di comunicazione su come migliorare il suo stato di salute?*
	16)…judge which everyday behaviour is related to your health?	16) …giudicare quali comportamenti quotidiani hanno un impatto sulla Sua salute?

° for HLS-EU-Q16, 'fairly difficult' and 'very difficult' are coded with 0 while 'fairly easy' and 'very easy' are coded with 1; for HLS-EU-Q6, the coding is as follow: Very easy=4; fairly easy=3; fairly difficult=2; very difficult=1; for HLS-EU-Q16 and HLS-EU-Q6, don't know is coded as 'missing'

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CL, SM and GB: conception and design; drafting the article; give final approval of the version to be submitted. FS, MG, VV, VL and AB (Alessadro Bussotti): conception and design; give final approval of the version to be submitted. AB (Angela Bechini) and SB: drafting the article; give final approval of the version to be submitted.

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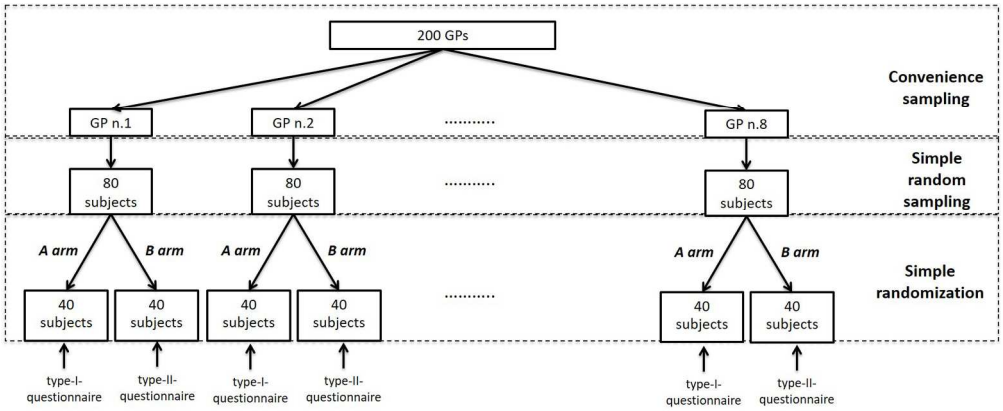

Figure 1. Sampling procedure

314x129mm (300 x 300 DPI)

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