

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Measuring health literacy combining by performance-based and self-assessed measures. The roles of age, educational level, and financial resources in predicting health literacy skills: a cross-sectional study conducted in Florence (Italy)
AUTHORS	Lorini, Chiara; Lastrucci, Vieri; Paolini, Diana; Research Group, Florence Health Literacy; Bonaccorsi, Guglielmo

VERSION 1 – REVIEW

REVIEWER	Gillian Rowlands Institute of Population Sciences Newcastle University Newcastle upon Tyne Uk
REVIEW RETURNED	06-Dec-2019

GENERAL COMMENTS	<p>The basic premise (that a measure of health literacy capturing both objective and subjective measures of health literacy would provide a more holistic assessment of health literacy) is, I'm sure, correct. However, I'm not clear about how showing that combining the measures provides a better association with antecedents helps much. What is important, it seems to me, is whether a combined measure gives a better prediction of outcomes - health, levels of illness etc. Why not add in that analysis? Why would a combination measure be better than using two separate measures?</p> <p>There are some other important points</p> <ol style="list-style-type: none">1. Subjective health literacy measures also measure the balance between skills and environment. They are therefore situation-specific, whereas absolute skills measured objectively will be the same whatever peoples' environment. See the HEALIT4EU study which shows this well. This needs bringing in the the background, and the implications should be addressed in the discussion.2. Methods. Enough details need to be given in this paper to assess representativeness of sample. For example how were the GPs selected? Were they urban / rural? In deprived or wealthy neighbourhoods?3. Methods. There needs to be clarity about the number of patients. Sometimes the paper talks about the whole study, sometimes just about the single arm.4. Methods. What might be the impact of the postal invite in a study on health literacy?5. Throughout English needs checking6. Author page needs proof reading.
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REVIEWER	Peter J Schulz
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	Institute of Communication & Health, University of Lugano, Switzerland
REVIEW RETURNED	08-Dec-2019

GENERAL COMMENTS	<p>This paper addresses the increasingly complex situation with regard to health literacy, the concept and its measurement. The idea is to compare two different measures, HLQ-15 and the NVS in this case. They differ in a number of respects. The former captures general (the authors' term), the latter functional health literacy. The former is a (self-)perception-based, the latter a performance-based measure. The former is pluralistic in subjects, the latter limited to nutrition. The latter point does not play a part in the analysis, but the former two are invoked several times, with some suggestion that the base of the measure or the dimension are somehow to be blamed for the differences between the two measures. How they should or could be remains open, though. I have not quite understood why the comparison is done for the grouping of respondents on the scales rather than the scale values themselves.</p> <p>Desiderata</p> <ul style="list-style-type: none"> • A visual or table-style depiction of how the scale values are made into groups with complete N's and cut-off values • A short but critical narration on how the cut-offs evolved • A discussion of the question of whether cut-off points established in one country can be taken in another one? • Erasure of misleading and confusing false terms: =self-performed based and perception-based measures (very beginning of the abstract, again p. 5, line39, 5), "using a performance-based measure of functional HL (the NVS) and a self-performed measure ..." • Careful copyediting
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REVIEWER	Jordan, Susanne Robert Koch-Institute, Berlin, Germany
REVIEW RETURNED	05-Jan-2020

GENERAL COMMENTS	<p>The article "Measuring health literacy combining performance-based and perception-based measures. The role of age, educational level and financial resources in predicting health literacy skills" addresses a research topic that is of great relevance and actuality in health literacy research. It is about understanding the relationship between the two health literacy constructs of functional (performance-based) health literacy and general (self-assessed) health literacy and some of its sociodemographic determinants (antecedents). For the first time, an attempt is being made to develop a joint new variable (called "health literacy skills") from two measuring instruments, each representing one of the constructs. Two widely used measurement tools were used for this: the NVS for functional health literacy and the HLS-EU-Q16 for self-assessment of general health literacy. The paper is well structured, gives new insights and makes a relevant contribution to the further development and deeper understanding of the health literacy construct and some of its sociodemographic determinants. However, the article should go into some aspects in more detail and extend the discussion section.</p> <p>The section "strengths and limitations of this study" (page 3) only reports a kind of summary, please add limitations as well.</p>
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	<p>Check the consistent use of the terms “dimension” and “domain” throughout the text as well as the description of Nutbeam’s definition in the introduction, which is not completely correct on page 4.</p> <p>In the introduction, the fragmentation of research due to the use of different health literacy measurement tools is presented as an argument for their research question. However, there are also good arguments for developing measurement tools for specific topics, e.g. diseases. For example, a person suffering from diabetes needs specific health literacy as opposed to a young healthy person, for example. This argument should therefore also be mentioned in the introduction.</p> <p>Although the methods section refers to other articles describing the study design, this section needs more clarification on study design directly in this article. The different sample sizes mentioned in the text are confusing (also in the results section, p. 9). I recommend to only discuss the description of study arm B here. Please adjust this accordingly in the results section. In addition, information on the calculation of the sample size for the research question of the article is required. Please give a response rate instead of a compliance equal.</p> <p>Please give reasons in the methods section for the selection of the unusual and very different big age groups. This should also be addressed as a limitation in the discussion section, as the sample is above average "old" and could be used as an explanation for the partly unusual distribution of health literacy levels. From which study did the question on financial status originate or did you develop the question yourself? Please provide information in the methods section.</p> <p>Reason the construction of the new variable in the methods section. Some alternatives would be conceivable. Also discuss in the discussion section what consequences an alternative formation of the new variable might have had on the results.</p> <p>Explain and reason the definition of “low health literacy” (page 10) already in the methods section. I had expected for this only the lowest category of each instrument, but here the middle and lowest category were merged.</p> <p>In order to assess the results on p. 10/11 (Figure 2), information on the confidence intervals (preferably supplemented by p-values) is required. Since Figure 2 is very descriptive, an additional table with the data for Figure 2 would be recommended.</p> <p>In the discussion section the observed vulnerability of older, less educated and poorer groups is presented. But no possible explanations are considered, which would be of great interest. Please complete. Would different results have been expected if the new variable had been formed differently? It is also of interest whether the determinants still enhance each other? Has this been tested?</p> <p>Since health literacy and gender were associated in various studies, please explain in the limitations why this was not considered in the study. On page 14, last sentence of the limitations, could you</p>
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	<p>please go more into detail, in what form the results could be affected due to the aforementioned distribution of education, age and income in the sample?</p> <p>In the conclusion it might be of interest referring to the current discussion on the definition of health literacy. It focuses on the role of society and health services to promote health literacy and not the individual (see “Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions” (https://www.federalregister.gov/documents/2019/06/04/2019-11571/solicitation-for-written-comments-on-an-updated-health-literacy-definition-for-healthy-people-2030). Could you draw a conclusion of this based on your results? So your results could become more practical relevance.</p> <p>Some general aspects: I recommend to use the expression “self-assessed measure” (or “self-reported”) instead of “perception-based measure”, as this expression is more widespread and common. Also use the term “performance-based” consistently, but without mixing it with the term “self-performance based”. At some places in the text (e.g. “author” on page 5, “countries” on page 12), in the headings (e.g. Figure 1) and in titles of journal articles in the bibliography (e.g. No. 11, 15, 16, 24, 25) lower case letters must be used. In sentence 1 “deals” should be used. It might be worth considering having the text reviewed by a native speaker. Indicate directly where you have taken sentences literally from other publications mentioned here. This refers in particular to the methods section.</p>
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REVIEWER	Daniel T Dibaba University of Tennessee Health Science Center
REVIEW RETURNED	11-Jan-2020

GENERAL COMMENTS	<p>The authors examined the association between age, education and financial resources and health literacy using a perception based method and performance based method.</p> <p>The authors should summarize what the B arm of the main study stand for. In addition, the authors should describe in a more detail the types of random selection of the participants by the care providers.</p> <p>For the statistical analysis, a detail description of the models would help to understand the study better and all statistical analysis should be described under the Statistical Analysis section not under Results section. Besides age, education, and financial resources, have the authors adjust for other potential confounding variables?</p> <p>Results: The results should include the summary of the main findings. In the tables reporting OR and 95%CIs, you need not report the SE as the 95%CIs also provide the same information. The OR and 95%CIs are usually presented as OR (95%CIs) rather than appearing as different columns with other columns between them.</p>
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REVIEWER	Maria Kompoti
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	Intensive Care Unit, Thriassio General Hospital of Eleusis, Athens, Greece
REVIEW RETURNED	16-Jan-2020

GENERAL COMMENTS	The authors conducted a cross-sectional study, comparing a self-performed based with a perception-based measure of health literacy (HL). They investigated potential associations of HL skills with age, educational level and financial resources in a sample drawn from a large registry of Italian speaking participants, which were tested with the European Health Literacy Survey Questionnaire (HLS-EU-Q16) and the Newest Vital Sign (NVS). It is a well designed and properly conducted study. However, the interpretation of the estimates is not very clear. Regression of an ordinal dependent variable vs. an ordinal independent variable would be more informative if the parameter estimates with their standard errors in all dependent and independent variable levels would be presented, so that logits could be easily calculated using the regression equations. Tables 3 and 4 must be explained (was a cut-point of the dependent variable used in the analysis?)
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Gillian Rowlands

Institution and Country: Institute of Population Sciences

Newcastle University

Newcastle upon Tyne

Uk

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The basic premise (that a measure of health literacy capturing both objective and subjective measures of health literacy would provide a more holistic assessment of health literacy) is, I'm sure, correct. However, I'm not clear about how showing that combining the measures provides a better association with antecedents helps much. What is important, it seems to me, is whether a combined measure gives a better prediction of outcomes - health, levels of illness etc. Why not add in that analysis? Why would a combination measure be better than using two separate measures?

Reply. Thank you for this comment, that introduces a very interesting matter of discussion. In fact, we are now working on this topic – combined measures for better prediction of outcomes – for our next paper. In this manuscript, our intention was to give evidence to the first results obtained combining measures with respect to the main antecedents of HL, and then move towards the contribution in predicting the outcomes. Moreover, in our opinion, a better readiness on antecedents of health literacy could help identifying the predictors of low health literacy.

There are some other important points

1. Subjective health literacy measures also measure the balance between skills and environment.

They are therefore situation-specific, whereas absolute skills measured objectively will be the same whatever peoples' environment. See the HEALIT4EU study which shows this well. This needs bringing in the background, and the implications should be addressed in the discussion.

Reply. This is a very interesting point. We have added this theme both in the introduction and in the discussion

2. Methods. Enough details need to be given in this paper to assess representativeness of sample. For example how were the GPs selected? Were they urban / rural? In deprived or wealthy neighbourhoods?

Reply. More data on the sampling procedure was added in the introduction, as well as data regarding the municipality of Florence. It is important to note that the sample should be considered population-based as it was recruited from a list of residents available from the registers of general practices of the municipality of Florence but the sample was not designed to be representative of the overall Florentine population. Indeed, the population-based sample was obtained with a combination of convenience and probability sampling procedures: GPs were recruited with convenience criteria, and each recruited GP subsequently selected 80 subjects from its register through a random number generator. Thus, the sample cannot be considered representative. We have acknowledged this issue in the revised manuscript, and we have revised the discussion section in order to avoid any possible misunderstandings about the extrapolation of the findings to the whole Italian population.

3. Methods. There needs to be clarity about the number of patients. Sometimes the paper talks about the whole study, sometimes just about the single arm.

Reply. The methods section has been improved in order to clarify the number of people included.

4. Methods. What might be the impact of the postal invite in a study on health literacy?

Reply. In designing the study, we had taken into account the impact of postal invite. For this reason, when the consent form was not received within 2 weeks, a follow-up phone call was made by the research group to clarify any questions and to identify and support people with difficulties in completing the consent form (eg, reading difficulties). This information have been added in the methods.

5. Throughout English needs checking

Reply. The manuscript has been proofread

6. Author page needs proof reading.

Reply. The Author page has been proof read

Reviewer: 2

Reviewer Name: Peter J Schulz

Institution and Country: Institute of Communication & Health, University of Lugano, Switzerland

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This paper addresses the increasingly complex situation with regard to health literacy, the concept and its measurement. The idea is to compare two different measures, HLQ-15 and the NVS in this case. They differ in a number of respects. The former captures general (the authors' term), the latter functional health literacy. The former is a (self-)perception-based, the latter a performance-based measure. The former is pluralistic in subjects, the latter limited to nutrition. The latter point does not play a part in the analysis, but the former two are invoked several times, with some suggestion that the base of the measure or the dimension are somehow to be blamed for the differences between the two measures. How they should or could be remains open, though.

Reply. Thanks for the remarks. In fact, the two measurement tools are quite different, for many aspects, as they measure, in different ways, different facets of such a large and articulated construct. Since to date none of the measurement tools that have been performed are all-inclusive of all facets, our intention was, starting from comparing them, to integrate the two measures to better investigate

HL. Many Authors and papers have, by now, compared the results resulting from different measures of HL while, to the best of our knowledge, none have tried to integrate them. For this reason, although many limits of our study can be listed, we think that this paper can be considered as a starting point for a novel approach to investigate HL. This aspect has been stressed in the conclusion.

Regarding the NVS, it is one of the most widely used health literacy screening instruments. As reported by the lead author of the validation study (Weiss, 2005) and confirmed later by the same author (Weiss, 2018), correct responses to the queries that compose the tool require the ability to identify and interpret basic text and perform simple mathematical computations and the probability of a person having limited health literacy is estimated by counting how many of the six questions are answered correctly. So, although the tool is based on an ice cream nutrition label, it is considered as a measure of HL, not of nutritional literacy – the latter covering many other domains and aspects, see, as example, Vettori et al 2019. For this reason, as well as for the quickness and its ease-of-use, the NVS is widely used both in clinical and in population settings as a measure of (functional) health literacy (see, as example: Orkan, 2018; Victoria, 2017).

- Weiss BD. Et al. Quick assessment of literacy in primary care: The Newest Vital Sign. *Annals of Family Medicine*, 2005; 3(6), 514-522. doi:10.1370/afm.405.
- Weiss BD. The Newest Vital Sign: Frequently Asked Questions. *HLRP: Health Literacy Research and Practice*, 2018. 2(3), e125-e127.
- Orkan O, et al. Generic health literacy measurement instruments for children and adolescents: a systematic review of the literature. *BMC Public Health*. 2018; 18: 166.
- Victoria M. et al. Is the Newest Vital Sign (NVS) a Useful Measure of Health Literacy in HIV Disease? *J Int Assoc Provid AIDS Care*. 2017 Nov-Dec; 16(6): 595–602.
- Vettori V et al. Towards the Implementation of a Conceptual Framework of Food and Nutrition Literacy: Providing Healthy Eating for the Population. *Int J Environ Res Public Health*, 2019; 16 (24): 5041.

I have not quite understood why the comparison is done for the grouping of respondents on the scales rather than the scale values themselves.

Reply. The comparison of the two measures has been done using the categories instead of using the scores for consistency during the main text, since the tentative of combining the results has been done using the categories. Whether it could be considered useful, additional analyses and data considering the two scores could be added as supplementary material. Moreover, some of this information have been already published in the validation study of the HL-EU-Q16 in the Italian language (Lorini et al., 2019)

- Lorini C, Lastrucci V, Mantwill S, et al. Measuring health literacy in Italy: a validation study of the HLS-EU-Q16 and of the HLS-EU-Q6 in Italian language, conducted in Florence and its surroundings. *Ann Ist Super Sanita* 2019;55: 10-8. doi: 10.4415/ANN_19_01_04.

Desiderata

- A visual or table-style depiction of how the scale values are made into groups with complete N's and cut-off values

Reply. These data have been already published in a previous paper (Lorini et al., 2019)

- Lorini C, Lastrucci V, Mantwill S, et al. Measuring health literacy in Italy: a validation study of the HLS-EU-Q16 and of the HLS-EU-Q6 in Italian language, conducted in Florence and its surroundings. *Ann Ist Super Sanita* 2019;55: 10-8. doi: 10.4415/ANN_19_01_04.

- A short but critical narration on how the cut-offs evolved

Reply. In the methods section, information on how the cut-off values of both the NVS and the HLS-EU-Q16 has been added

- A discussion of the question of whether cut-off points established in one country can be taken in another one?

Reply. Thanks for this remark. This theme has been added in the discussion.

• Erasure of misleading and confusing false terms: =self-performed based and perception-based measures (very beginning of the abstract, again p. 5, line 39, 5), “using a performance-based measure of functional HL (the NVS) and a self-performed measure ...”

Reply. The terms have been checked in all the manuscript

• Careful copyediting

Reply. Done

Reviewer: 3

Reviewer Name: Jordan, Susanne

Institution and Country: Robert Koch-Institute, Berlin, Germany

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The article “Measuring health literacy combining performance-based and perception-based measures. The role of age, educational level and financial resources in predicting health literacy skills” addresses a research topic that is of great relevance and actuality in health literacy research. It is about understanding the relationship between the two health literacy constructs of functional (performance-based) health literacy and general (self-assessed) health literacy and some of its sociodemographic determinants (antecedents). For the first time, an attempt is being made to develop a joint new variable (called “health literacy skills”) from two measuring instruments, each representing one of the constructs. Two widely used measurement tools were used for this: the NVS for functional health literacy and the HLS-EU-Q16 for self-assessment of general health literacy. The paper is well structured, gives new insights and makes a relevant contribution to the further development and deeper understanding of the health literacy construct and some of its sociodemographic determinants. However, the article should go into some aspects in more detail and extend the discussion section.

The section “strengths and limitations of this study” (page 3) only reports a kind of summary, please add limitations as well.

Reply. The section “strengths and limitation” has been totally revised

Check the consistent use of the terms “dimension” and “domain” throughout the text as well as the description of Nutbeam’s definition in the introduction, which is not completely correct on page 4.

Reply. The use of the terms “dimension” and “domain” has been checked. Moreover, the reference for the definition of functional, critical and interactive health literacy has been changed.

In the introduction, the fragmentation of research due to the use of different health literacy measurement tools is presented as an argument for their research question. However, there are also good arguments for developing measurement tools for specific topics, e.g. diseases. For example, a person suffering from diabetes needs specific health literacy as opposed to a young healthy person, for example. This argument should therefore also be mentioned in the introduction.

Reply. This aspect has been added in the introduction.

Although the methods section refers to other articles describing the study design, this section needs more clarification on study design directly in this article. The different sample sizes mentioned in the text are confusing (also in the results section, p. 9). I recommend to only discuss the description of study arm B here. Please adjust this accordingly in the results section. In addition, information on the calculation of the sample size for the research question of the article is required. Please give a response rate instead of a compliance equal.

Reply. The methods and the results have been changed according to the requests

Please give reasons in the methods section for the selection of the unusual and very different big age groups. This should also be addressed as a limitation in the discussion section, as the sample is above average "old" and could be used as an explanation for the partly unusual distribution of health literacy levels. From which study did the question on financial status originate or did you develop the question yourself? Please provide information in the methods section.

Reply. One of the possible implications of our larger study was to integrate the short-short form of the HLS-EU-Q as a covariate in the Italian behavioural risk factor surveillance system PASSI. For this reason, in order to obtain results that should be useful to address this issue, the target population (18-69 years old) and the administration mode of the questionnaire (telephone interview) were the same of PASSI. Moreover, also some questions of the questionnaire were taken from PASSI, including that on financial status. These information have been added in the methods.

Please, note that PASSI, a national surveillance coordinated by the Italian Ministry of Health, is conducted each year since 2008 on representative samples of the Italian population aged 18–69 years using a standardized questionnaire, and that many papers have been published by now using PASSI data.

For what concern the age group selected in this study, in our opinion it is not a limitation but a strength, as it made possible to evaluate the effect of age on a larger scale.

Reason the construction of the new variable in the methods section. Some alternatives would be conceivable. Also discuss in the discussion section what consequences an alternative formation of the new variable might have had on the results.

Reply. This is a very interesting point. Our primary aim was to test the possibility to integrate different measures of health literacy. In doing that, we would like to use a simple approach, so the combination of health literacy categories seemed the best starting point (for the choice of the categories, please see the following comment). Another option was to test the possibility of combining the items of the two measures in a single scale, using the classic approach (Principal Component Analysis, reliability assessment) but, in our opinion, it will be the next step. In fact, we think that this paper can be considered as a starting point for a novel approach to investigate health literacy, not the end point. This aspect has been added both in the methods and in the discussion.

Explain and reason the definition of "low health literacy" (page 10) already in the methods section. I had expected for this only the lowest category of each instrument, but here the middle and lowest category were merged.

Reply. Previous studies (for example, Levin-Zamir, 2016) conducted using the NVS or the HLS-EU-Q-16 have grouped together the lowest and the middle categories in order to better identify the subjects with a good level of HL ("sufficient" for the NVS and "adequate" for the HLS-EU-Q-16) and those with some limitations. For this reason, we have merged the middle and lowest category and have defined the subjects with "low health literacy" as those with limitation -major or minor -in both assessments. This aspect has been added in the methods

In order to assess the results on p. 10/11 (Figure 2), information on the confidence intervals (preferably supplemented by p-values) is required. Since Figure 2 is very descriptive, an additional table with the data for Figure 2 would be recommended.

Reply. The table with the confidence interval has been added as supplementary file.

In the discussion section the observed vulnerability of older, less educated and poorer groups is presented. But no possible explanations are considered, which would be of great interest. Please complete.

Reply. A brief discussion on why older, less educated and poorer groups presented lower HL skills has been added.

Would different results have been expected if the new variable had been formed differently?

Reply. In our opinion, a consistency of the results would be expected also whether changing the combination of the two measures but maintaining the same approach (i.e. combining the categories). The results that will be obtained combining the items of the two measures into a new scale would be tested.

It is also of interest whether the determinants still enhance each other? Has this been tested?

Reply. It is an interesting point. The interaction of the three determinants has not been tested but we can assume that there is an enhancement. If it could be of interest, we can add other analyses in order to assess this aspect, but the paper is already quite long regarding the Editorial guidelines.

Since health literacy and gender were associated in various studies, please explain in the limitations why this was not considered in the study.

Reply. In the limitation, this aspect was added

On page 14, last sentence of the limitations, could you please go more into detail, in what form the results could be affected due to the aforementioned distribution of education, age and income in the sample?

Reply. In the limitation, this aspect was added

In the conclusion it might be of interest referring to the current discussion on the definition of health literacy. It focuses on the role of society and health services to promote health literacy and not the individual (see "Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions" (<https://www.federalregister.gov/documents/2019/06/04/2019-11571/solicitation-for-written-comments-on-an-updated-health-literacy-definition-for-healthy-people-2030>)). Could you draw a conclusion of this based on your results? So your results could become more practical relevance.

Reply. The conclusion has been improved as required

Some general aspects: I recommend to use the expression "self-assessed measure" (or "self-reported") instead of "perception-based measure", as this expression is more widespread and common. Also use the term "performance-based" consistently, but without mixing it with the term "self-performance based".

Reply. Done

At some places in the text (e.g. "author" on page 5, "countries" on page 12), in the headings (e.g. Figure 1) and in titles of journal articles in the bibliography (e.g. No. 11, 15, 16, 24, 25) lower case letters must be used.

Reply. Done. Moreover, the text has been edited by professionals

In sentence 1 "deals" should be used.

Reply. Done

It might be worth considering having the text reviewed by a native speaker.

Reply. The text has been edited by professionals

Indicate directly where you have taken sentences literally from other publications mentioned here.

This refers in particular to the methods section.

Reply. The sentences taken from other publications have been reworded

Reviewer: 4

Reviewer Name: Daniel T Dibaba

Institution and Country: University of Tennessee Health Science Center

Please state any competing interests or state 'None declared': None declared.

Please leave your comments for the authors below

The authors examined the association between age, education and financial resources and health literacy using a perception based method and performance based method.

The authors should summarize what the B arm of the main study stand for. In addition, the authors should describe in a more detail the types of random selection of the participants by the care providers.

Reply. The methods section has been changed according to the requests

For the statistical analysis, a detail description of the models would help to understand the study better and all statistical analysis should be described under the Statistical Analysis section not under Results section. Besides age, education, and financial resources, have the authors adjust for other potential confounding variables?

Reply. All the statistical analyses have been described into the methods section. In the results, the references to the methods have been removed. No others confounding variables have been considered.

Results: The results should include the summary of the main findings.

Reply. A description of the results described in Tables 3 and 4 has been added

In the tables reporting OR and 95%CIs, you need not report the SE as the 95%CIs also provide the same information. The OR and 95%CIs are usually presented as OR (95%CIs) rather than appearing as different columns with other columns between them.

Reply. The tables have been changed according to the suggestions

Reviewer: 5

Reviewer Name: Maria Kompoti

Institution and Country: Intensive Care Unit, Thriassio General Hospital of Eleusis, Athens, Greece

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The authors conducted a cross-sectional study, comparing a self-performed based with a perception-based measure of health literacy (HL). They investigated potential associations of HL skills with age, educational level and financial resources in a sample drawn from a large registry of Italian speaking participants, which were tested with the European Health Literacy Survey Questionnaire (HLS-EU-Q16) and the Newest Vital Sign (NVS).

It is a well designed and properly conducted study. However, the interpretation of the estimates is not very clear.

Regression of an ordinal dependent variable vs. an ordinal independent variable would be more informative if the parameter estimates with their standard errors in all dependent and independent variable levels would be presented, so that logits could be easily calculated using the regression equations.

Reply. In our opinion, adding all the OR values (i.e. OR for each level of the HL skills by each categories of the covariates) could limit the readiness of the results. In order to better interpret the results, a broader description has been added. If it could not be considered sufficient, we can change the regression model, replacing the multivariate ordinal logistic regression with a multivariate multinomial logistic regression.

Tables 3 and 4 must be explained (was a cut-point of the dependent variable used in the analysis?)
 Reply. A description of the results described in Tables 3 and 4 has been added. A cut-off point of the dependent variable was not used since it was ordinal (“HL skills”, as described in the methods) and not continuous

VERSION 2 – REVIEW

REVIEWER	Peter J. Schulz Institute of Communication & Health, University of Lugano
REVIEW RETURNED	10-Apr-2020

GENERAL COMMENTS	<p>The authors have reacted appropriately to the desiderata formulated in my first review of this study. The study is reported in very detailed fashion, clear, well-structured. Methodological information is also given in great detail, as are the results and their documentation in tables and figures.</p> <p>Still, I have reservations about publishing. The basic idea is to combine two different measures of health literacy into one, but it is not at all clear to me which problem would be solved by that. An example: the literature review notes that health literacy is being predicted by age, education and income. The new combined measure finds the same. Where is the gain in knowledge in all of this?</p> <p>A smaller matter: The newly added “Strength and limitations” says, as the third and last point: “A different approach in combining the two measures could have led to different results.” That is trivial, as it is true of every empirical study ever done. Shortly before that, in the first item listed under strengths, the combination is called a new variable. That designation could also be contested: if you combine two valid measures of the same variable, you do not get a second variable, but a third measure.</p>
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REVIEWER	Maria Kompoti Intensive Care Unit, Thriassio General Hospital, Eleusis, Greece
REVIEW RETURNED	29-Mar-2020

GENERAL COMMENTS	The authors have added a more informative description of the results, which is adequately clear.
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VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 5

Reviewer Name: Maria Kompoti

Institution and Country: Intensive Care Unit, Thriassio General Hospital, Eleusis, Greece

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The authors have added a more informative description of the results, which is adequately clear.

R: Thanks for the reply

Reviewer: 2

Reviewer Name: Peter J. Schulz

Institution and Country: Institute of Communication & Health, University of Lugano

Please state any competing interests or state 'None declared': n.a.

Please leave your comments for the authors below

The authors have reacted appropriately to the desiderata formulated in my first review of this study. The study is reported in very detailed fashion, clear, well-structured. Methodological information is also given in great detail, as are the results and their documentation in tables and figures.

Still, I have reservations about publishing. The basic idea is to combine two different measures of health literacy into one, but it is not at all clear to me which problem would be solved by that. An example: the literature review notes that health literacy is being predicted by age, education and income. The new combined measure finds the same. Where is the gain in knowledge in all of this?

R: As suggested by our results, the combination of two different measures of health literacy, in particular of two with different characteristics (objective-functional plus subjective-general) is strongly associated with age, educational level, and financial resources more than those observed using each single measures (please, compare tables 3 and 4). The results let us to this conclusion "Moreover, as widely described for diagnostic and screening tests, the use of parallel tests (i.e., two tests administered at the same time followed by subsequent combination of the results) results in an increase in sensitivity—in this case, the identification of people with low HL skills". Future results will be useful to assess whether this combination could be beneficial to better predict health outcomes.

A smaller matter: The newly added "Strength and limitations" says, as the third and last point: "A different approach in combining the two measures could have led to different results." That is trivial, as it is true of every empirical study ever done.

R: Thanks for the remark. In fact, this statement was added according to one of the reviewer's suggestion, in the previous wave. In fact, what the reviewer asked us to highlight was that a different combination the two measures, for example, by adding the scores, should generate different results. As a matter of fact, we have chosen one way of combining measures (maybe the simplest one). As we stated at the end of the discussion "the chosen methodology is related to the aim of giving an initial, simple approach for assessing the possibility of integrating different measures of HL, and this will be refined with future studies".

Shortly before that, in the first item listed under strengths, the combination is called a new variable. That designation could also be contested: if you combine two valid measures of the same variable, you do not get a second variable, but a third measure.

R: Yes, of course. This aspect has been changed