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)	Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in
	a Swedish context: A study protocol
AUTHORS	Wangdahl, Josefin M.; Dahlberg, Karuna; Jaensson, Maria; Nilsson, Ulrica

VERSION 1 – REVIEW

REVIEWER	Giulia Bravo
	Department of Medicine, University of Udine (Italy),
	Udine (Italy)
REVIEW RETURNED	10-Mar-2019

GENERAL COMMENTS	This is a very interesting paper concerning a major aim to reduce health inequity.
	The described methods to evaluate a Swedish and Arabic version of the HLS-EU-Q16 questionnaire and the eHEALS are appropriate Also the focus on evaluation of association between the HLS-EU-Q16 questionnaire and the eHEALS and the demographic variables is interesting and helps to achive the study goals.
	But in the protocol there is no information about the sample size calculation.
	Please, add some information about it. Why 300 Swedish and 300 Arabic participants? Justify it.
	Another statistical remark: in the Phase 4, you want to perform a binary logistic regression analysis to evaluate the association
	between questionnaires results and sociodemographic variables. You consider sociodemographic variables as dependent variables. But what do you think these variables depend on? How can the
	But what do you think these variables depend on? How can the "age" variable change, for example? And the country of birth? This is a methodological error! But I hope you have reversed the
	dependent and independent variables assignment. Finally, update the references, please.
	It's a good work.

REVIEWER	Julie Ayre Sydney Health Literacy Lab, Sydney School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
REVIEW RETURNED	18-Mar-2019
GENERAL COMMENTS	This paper outlines the protocol to evaluate the psychometric properties of Swedish and Arabic versions of the HLS-EU-Q16 and

eHEALS. The authors have thought carefully about translation processes and how to do this for both Swedish and Arabic speakers.

Conceptually this paper is well written although I think it could benefit from a careful read through as there were some grammatical errors (eg tense) and some sentences were quite convoluted. Abstract

- Line 23: should this read instead as 'conduct a psychometric evaluation of'
 Introduction
- This sentence was confusing to me: "Informed decision making requires people to have a certain level of health literacy when self-reporting measurements and health information." You could either rephrase to clarify what you mean or remove it
- Line 22 what is 'comprehensive' health literacy? Do you mean communicative? You might need to explain what is meant by this

Methods:

- How will you interpret your analysis of the interview responses in terms of content validity? What happens if difficulty understanding the translation occurs because of difficulty/ambiguity of the underlying English version rather than the translation? If possible, it would be helpful if you can include approaches to reducing interviewer biases that might arise from responses to participant questions about the meaning of, for example, health decisions, low quality health resources or 'evaluating' resources. It would be great if in the results paper you were able to describe the kinds of issues people brought up!
- Figure 2 hypotheses: can you list supporting references for these hypotheses? The references look as though they are listed on page 11.
- I was unsure whether you might need to mention specific hypotheses regarding the factor structure of these measures. You have mentioned using exploratory factor analysis for reliability, but the factor structure also points to the validity of the construct. I would suggest adding a sentence or two under validity with regards to single factor structure.
- Use of internet may be too crude a measure if you haven't already started recruitment for this study, you could use measures of internet use (or web2.0 use) that has been used in other validation studies. See for example: https://www.jmir.org/2015/3/e70/ or the reference in your list #11 (Van der Vaart et al 2011).

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Giulia Bravo

Institution and Country: Department of Medicine, University of Udine (Italy), Udine (Italy) Please state

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

Please leave your comments for the authors below Dear Authors, this is a very interesting paper concerning a major aim to reduce health inequity.

The described methods to evaluate a Swedish and Arabic version of the HLS-EU-Q16 questionnaire and the eHEALS are appropriate Also the focus on evaluation of association between the HLS-EU-Q16 questionnaire and the eHEALS and the demographic variables is interesting and helps to achive the study goals.

But in the protocol there is no information about the sample size calculation. Please, add some information about it. Why 300 Swedish and 300 Arabic participants? Justify it. Information about the sample size could be found in the first paragraph (now highlighted) in Phase 3: Psychometric testing of the Arabic and Swedish version of eHEALS and HLS-EU-Q16, page 9: "The chosen sample size was first guided by the 10:1 ratio 42: 16 items on the HLS-EU-Q16 × 10 = 160 participants. However, a general rule of thumb for factor analysis is 300 cases or the more enient 50 participants per factor 46. HLS-EU-Q16 consists of only one factor 19, therefore a sample size of 300 participants is considered most appropriate".				
evalua consid depend	or statistical remark: in the Phase 4, you want to perform a binary logistic regression analysis to the association between questionnaires results and sociodemographic variables. You ser sociodemographic variables as dependent variables. But what do you think these variables don? How can the "age" variable change, for example? And the country of birth? This is a dological error! But I hope you have reversed the dependent and independent variables			
	Thank you for noticing this mix-up. This has been changed in the manuscript.			
Finally,	update the references, please. The references has been checked up			
It's a g	ood work. Thanks a lot!			
Institut Medicii	ver: 2 ver Name: Julie Ayre ion and Country: Sydney Health Literacy Lab, Sydney School of Public Health, Faculty of ne and Health, The University of Sydney, Sydney, Australia Please state any competing ts or state 'None declared': None			
psycho authors Arabic	et			
• Introdu	Line 23 : should this read instead as 'conduct a psychometric evaluation of'			
	Changed as requested			
	This sentence was confusing to me: "Informed decision making requires people to have a level of health literacy when self-reporting measurements and health information." You could rephrase to clarify what you mean or remove it The sentence has been shortened which hopefully will clarify the information.			
•	Line 22 – what is 'comprehensive' health literacy? Do you mean communicative? You might			

It should be 'comprehensive' health literacy and the definition of it can be found on page 4. Now highlighted. We have choose to use the concept "comprehensive health literacy" because we want to be clear and transparent with which definition of health literacy we will measure. Therefore, we refers

need to explain what is meant by this

to studies using this definition though it exists several definitions of health literacy and sometimes only one dimension of health literacy are assessed in other studies.

Methods:

• How will you interpret your analysis of the interview responses in terms of content validity? What happens if difficulty understanding the translation occurs because of difficulty/ambiguity of the underlying English version rather than the translation? If possible, it would be helpful if you can include approaches to reducing interviewer biases that might arise from responses to participant questions about the meaning of, for example, health decisions, low quality health resources or 'evaluating' resources. It would be great if in the results paper you were able to describe the kinds of issues people brought up!

Thank you for highlight this important issue and YES we have had some problem with the translation from English to Swedish that we will bring up in the results paper. Especially when it comes to concepts/words such as health resource a concept/word that did not really fit the Swedish language/context. This was also something that we discussed with the translator that translated the English version to Arabic. The translator speaks English, Swedish and Arabic, which is some sort of guarantee that the word/concepts have the same meaning in all three languages. This translation "problem" also lead to several contacts with the developer of eHEALS, Dr. Cameron Norman, to check up that we did not change the meaning of the items/words/concepts.

- Figure 2 hypotheses: can you list supporting references for these hypotheses? The references look as though they are listed on page 11.
- As the reference to the hypotheses are listed in the manuscript we think it do not add anything more if referring to the reference in the figure and maybe it will be messy if the Figure also includes reference number.
- I was unsure whether you might need to mention specific hypotheses regarding the factor structure of these measures. You have mentioned using exploratory factor analysis for reliability, but the factor structure also points to the validity of the construct. I would suggest adding a sentence or two under validity with regards to single factor structure.
- As this is a protocol study we have not yet performed any exploratory factor analysis (EFA) and therefore we do not know anything about factor structure for the Swedish and Arabic versions of eHEALS and HLS-EU-Q16. This is an important message from the Reviewer and this is something that we will discuss in our future manuscripts when we have the results from the EFA.
- Use of internet may be too crude a measure if you haven't already started recruitment for this study, you could use measures of internet use (or web2.0 use) that has been used in other validation studies. See for example: https://www.jmir.org/2015/3/e70/ or the reference in your list #11 (Van der Vaart et al 2011).
- Unfortunately, the data collection of the Swedish sample is finished and the data collection of the Arabic sample has just started.

VERSION 2 - REVIEW

REVIEWER	Giulia Bravo
The state of the s	Department of Medicine, University of Udine (Italy)
REVIEW RETURNED	29-May-2019
GENERAL COMMENTS	Many thanks for the corrections to the manuscript.
	Please, make some corrections to the spelling text (i.e Introduction instead of Introduction, and others). In my opinion it's a well described protocol with good detailed

phases.

REVIEWER	Julie Ayre Sydney Health Literacy Lab, Sydney School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
REVIEW RETURNED	22-May-2019

GENERAL COMMENTS	Thank you for your feedback on the comments that myself and the other reviewer gave last time. I have a few small points: 1. Thank you for clarifying the sentence in the first paragraph of the introduction. I have a small suggestion to link it a little more closely to the previous sentence and help it flow a bit more: "In this way/As such, a patient's health literacy also influences their ability to take part in informed decision-making." Or "As such/in this way, higher health literacy also supports better informed decision-making." 2. The Sorensen paper that you reference for the definition of health literacy (reference 2) refers to a 'comprehensive definition of health literacy' rather than comprehensive health literacy i.e. the definition is comprehensive and refers to all aspects of health literacy. I would strongly recommend using the above phrasing rather than 'comprehensive health literacy' to avoid confusion. 3. That's fine not to list the references in the Figure 2 hypotheses if you think it will look messy. Can you also please indicate the directions of association in the text, and if possible, the figure? There is some ambiguity. For example, you could say "We hypothesise that there will be positive correlations between HLS-EU-Q16/eHEALS and level of education, self-perceived general health and quantity of Internet use; and negative correlations between HLS-EU-Q16/eHEALS and age. Moreover, we hypothesise positive correlations between eHEALS, HLS-EU-Q16 and certain HLs-EU-Q16 items." All other comments have been adequately addressed for me. Thank you and good luck with your research!

VERSION 2 – AUTHOR RESPONSE

Reviewer 1

Please, make some corrections to the spelling text (i.e Introduction instead of Introdiction, and others).

- Corrections has been made

Reviewer 2

- 1. Thank you for clarifying the sentence in the first paragraph of the introduction. I have a small suggestion to link it a little more closely to the previous sentence and help it flow a bit more: "In this way/As such, a patient's health literacy also influences their ability to take part in informed decision-making." Or "As such/in this way, higher health literacy also supports better informed decision-making."
- changed as suggested
- 2. The Sorensen paper that you reference for the definition of health literacy (reference 2) refers to a 'comprehensive definition of health literacy' rather than comprehensive health literacy i.e. the definition is comprehensive and refers to all aspects of health literacy. I would strongly recommend

using the above phrasing rather than 'comprehensive health literacy' to avoid confusion.

- changed as suggested
- 3. That's fine not to list the references in the Figure 2 hypotheses if you think it will look messy. Can you also please indicate the directions of association in the text, and if possible, the figure? There is some ambiguity. For example, you could say "We hypothesise that there will be positive correlations between HLS-EU-Q16/eHEALS and level of education, self-perceived general health and quantity of Internet use; and negative correlations between HLS-EU-Q16/eHEALS and age. Moreover, we hypothesise positive correlations between eHEALS, HLS-EU-Q16 and certain HLs-EU-Q16 items."
- Changed as suggested in the text and we are also referring to Figure 2 after this clarification of the associations.