PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Design and Validity of a Questionnaire to Assess National eHealth Architecture (NEHA): A Study Protocol
AUTHORS	Mousavi, Seyyed Meysam; Takian, Amirhossein; Tara, Mahmood

VERSION 1 – REVIEW

REVIEWER	Dalibor Stanimirovic, PhD Head of the Centre for Healthcare Informatics, National Institute of Public Health, Slovenia
REVIEW RETURNED	20-Apr-2018

GENERAL COMMENTS	This manuscript has considerable potentials, however, it is rather superficial and imprecise in some areas. Some suggestions for improvement are listed below: The numbering of the figures is incorrect (Figure 1 is actually Figure 2, unlike what is stated in the text); flow of the study is described in Figure 2, not in Figure 1. In order to use the questionnaire in the methodologically appropriate and credible manner, the term eHealth Architecture should be precisely defined, as you understand it in your research. The ISO TR 14639 eHealth Architecture model you presented is very general and abstract in some areas, and in this respect, it can be inapplicable to your research in individual segments. Section Experts' opinions contains a rather modest description of experts (the same applies for the planning committee); - how many experts are we talking about? (6 in the planning committee) - their functions and expertise? - their affiliations, etc. Considering that all initiatives of such an extent as eHealth can be considered as huge and far-reaching socio-technical projects, special attention should be paid to social architecture and its transformation. Namely all socio-technical projects of this magnitude require significant changes in: - human behaviour - education and training - communication - security - technology acceptance, etc. These factors should be taken into account both in the survey and in the composition of the questionnaire, as well as in the actual building of an effective eHealth architecture.

| | When writing a planned manuscript, please bear in mind, that the adequate questionnaire is essential but not sufficient condition for publishing a good article.

The article contains some spelling and syntactic errors that need to be corrected. |

| REVIEWER | Teresa Iacono
La Trobe University, Australia |
| REVIEW RETURNED | 21-Apr-2018 |

| GENERAL COMMENTS | This protocol has the aim of designing and evaluating a questionnaire that will enable a standardised approach to gathering data on the status of national ehealth architecture (NEHA). It is evident from the introduction that the intention is that the questionnaire will be relevant for and used internationally, across low, middle and high income countries.
The approach appears reasonable, in general – use the literature to generate items, rely on a panel of experts to comment on the items and perhaps suggest further items, evaluate face validity and then content validity, then determine a range of possible scenarios for each item. However, each of these strategies required more details. Specific questions and concerns are listed below:
1. The planning committee does not have any consumer representatives. In an age of self-managed care, and research demonstrating consumer willingness to engage in various forms of ehealth, such representation would enhance the applicability and social validity of the questionnaire. I would like to have known if there were representatives from each of low, middle and high income countries, given the items will need to be relevant across them.
2. For review of the evidence, will the three international documents be the only ones used? I would have expected to see a systematic search of the literature, including grey literature – with some limiters given that that the net would be quite wide.
3. Specific questionnaire item development methods are needed – I suggest the authors look to relevant literature.
4. It is not clear what is meant by "the evaluation criteria" (p. 6, line 50), nor what is meant by "effectively written" (p. 6, line 54). Operational definitions would be helpful.
5. How many experts will be included in the panel (p. 7)?
6. I was very confused about the work of the expert panel and suggest that this section be reworked to make clear the information each panel receives and exactly what the panel member is asked to do. Are they generating new items or commenting on those provided through the evidence review?
7. Who will evaluate the "items gathered through experts' opinion"? How will this evaluation occur, and how will reliability of that evaluation be determined?
8. On p. 7, the paragraph beginning on line 22 was very difficult to follow – I really did not understand this paragraph. Perhaps it can be reworded more simply.
9. Phase 2, face validity – I really don't think that two members of the research team are well placed to conduct face validity, and whether this process will really serve the intended purpose. I would suggest asking representatives of groups who will be using the questionnaire to provide these data. |

	10. Will construct and internal consistency of the questionnaire be determined? This step will come at a later stage, requiring completion by a large number of participants, but without it, the questionnaire will not be ready for use.
	11. Relate to item 10, what is the target sampling size (p. 8)?
	12. More information is needed regarding analysis. It is not clear what data will be transcribed, and then how these transcribed data will be analysed.
	13. A clearer explanation of "scenarios" is needed. It seems that perhaps these will be simply descriptive examples – but of what exactly – each potential rating for each item on the questionnaire? Greater clarity through addressing these issues will help determine if the protocol meets publishable standards. I also note that some of the difficulties with following sections related to problems with expression and grammar, and punctuation errors. I appreciate the difficulty of writing a manuscript in a language other than the authors' first language. Obtaining the assistance of someone who can edit the manuscript carefully is recommended.

VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments to Author:
Reviewer 1:

1. The numbering of the figures is incorrect (Figure 1 is actually Figure 2, unlike what is stated in the text); flow of the study is described in Figure 2, not in Figure 1.

R: Thank you very much for discovering this error. This has been corrected now.

2. In order to use the questionnaire in the methodologically appropriate and credible manner, the term eHealth Architecture should be precisely defined, as you understand it in your research. The ISO TR 14639 eHealth Architecture model you presented is very general and abstract in some areas, and in this respect, it can be inapplicable to your research in individual segments.

R: We have now added the definition within the introduction section. The ISO TR 14639 eHealth Architecture model will be also comprehensively presented to the experts in our online platform. Due to word count limits, we moved the full description of four categories of eHealth architecture model and added it as a Supplementary File.

3. Section Experts' opinions contains a rather modest description of experts (the same applies for the planning committee);
- how many experts are we talking about? (6 in the planning committee)
- their functions and expertise?
- their affiliations, etc.

R: Thank you very much for this clarifying comment, which has been addressed in revised manuscript.

4. Considering that all initiatives of such an extent as eHealth can be considered as huge and far-reaching socio-technical projects, special attention should be paid to social architecture and its transformation. Namely all socio-technical projects of this magnitude require significant changes in:
- human behaviour
- education and training
- communication
- security
- technology acceptance, etc.
These factors should be taken into account both in the survey and in the composition of the questionnaire, as well as in the actual building of an effective eHealth architecture.

R: We appreciate the important considerations by the reviewer. It is important to bear in mind that we will be utilizing the ISO's eHealth Architecture Model. This model has four categories and each category consists of several components. We are not intending to change/revise the model, but we will try to consider different aspects of socio-technical changing within the components. Let alone that core members of the planning committee have extensive experience in sociotechnical changing model, which has been used, while customizing the questionnaire.

5. When writing a planned manuscript, please bear in mind, that the adequate questionnaire is essential but not sufficient condition for publishing a good article.

R: The authors understand and appreciate this comment. I would like to mention that this study is part of a bigger multi-research method research. When the designed questionnaire was validated, we will run the tool in several countries, both high and low-middle income countries, to learn from the international experiences and compare the findings to draw transferrable lessons learned.

6. The article contains some spelling and syntactic errors that need to be corrected.

R: The manuscript has been reworked and proofread by a native English to address these valid concerns.

Reviewer 2:

1. The planning committee does not have any consumer representatives. In an age of self-managed care, and research demonstrating consumer willingness to engage in various forms of ehealth, such representation would enhance the applicability and social validity of the questionnaire. I would like to have known if there were representatives from each of low, middle and high income countries, given the items will need to be relevant across them.

R: Thank you very much for this important comment. This questionnaire will be completed by representatives from both high and low-middle income settings, using an international survey to capture the current status of country-level eHealth architecture. By doing so, we will be able to learn more about experience of different countries for adopting and implementing the effective reforms. Second, the main important role of planning committee is managing and directing the whole process of the study. Three members of the committee have in-depth experience in low and middle-income country settings, in addition to at least five years of experience in high income countries e.g. United Kingdom, Australia, and Canada. One member of the committee is representative of a high-income country, with professional experience of at least 15 years.

As also mentioned in the manuscript, we will validate the questionnaire by international experts, in which we will use purposefully different consumer representatives to enhance the applicability and social validity of the questionnaire.

2. For review of the evidence, will the three international documents be the only ones used? I would have expected to see a systematic search of the literature, including grey literature – with some limiters given that that the net would be quite wide.

R: The authors appreciate the point that systematic search would have enhanced the depth and breadth of questionnaire. However, from the outset, and due to vast bulk of literature, we were certain to search and identify three validated documents that we will reach consensus about their comprehensiveness and applicability. The planning committee comprises of scholars who have established insight about the subject and all have approved that despite the limits, the three included documents would capture most relevant constructs that are applicable in all settings.

3. Specific questionnaire item development methods are needed – I suggest the authors look to relevant literature.

R: As explained in the manuscript, we have followed the standard method to develop and validate the questionnaire.

4. It is not clear what is meant by "the evaluation criteria" (p. 6, line 50), nor what is meant by "effectively written" (p. 6, line 54). Operational definitions would be helpful.

R: Thank you very much for the comment. In the Methods section, we have now provided more information about the evaluation criteria. "Effectively written" means that statements will be written effectively to ensure and enhance the clarity and conciseness of each statement.

5. How many experts will be included in the panel (p. 7)?

R: As explained in the manuscript, we will ask at least four experts to participate in the item generation and selection process.

6. I was very confused about the work of the expert panel and suggest that this section be reworked to make clear the information each panel receives and exactly what the panel member is asked to do. Are they generating new items or commenting on those provided through the evidence review?

R: The expert panel will be recruited for developing and selecting items' phase that aim to clarify the meaning and wording of items and remove or merge the overlapping ones. This phase is a crucial step before beginning the validation phase. Also, if there is an item(s) that is/are overlooked by reviewing the evidence, we will ask the experts to add the item(s) during this phase. This approach, namely combining review of evidence and expert opinions to generate, develop, and select an item pool has been also used in previous studies, i.e. (1-6).

7. Who will evaluate the "items gathered through experts' opinion"? How will this evaluation occur, and how will reliability of that evaluation be determined?

R: The planning committee is responsible to evaluate the "items gathered through experts' opinion". The same evaluation criteria of "applicability" and "relevancy" will be used, as also alluded in the manuscript.

8. On p. 7, the paragraph beginning on line 22 was very difficult to follow – I really did not understand this paragraph. Perhaps it can be reworded more simply.

R: Thank you for raising this concern, which has been now addressed in the revised manuscript.

9. Phase 2, face validity – I really don't think that two members of the research team are well placed to conduct face validity, and whether this process will really serve the intended purpose. I would suggest asking representatives of groups who will be using the questionnaire to provide these data.

R: The authors appreciate this concern that has been carefully discussed among the research team. However, our approach to face validity has its roots in the literature, for instance, few experts who are knowledgeable scholars with global exposure in the field, will conduct the job. We have done our utmost attempt to reach out our global network, from across various countries, to encourage them to fill in the questionnaire. We anticipate that given multiple dimensions to be covered, the questionnaire will be rather long, hence the degree of compliance from international experts to read and comment will not be high. Therefore, we have decided to conduct face validity, which refers to what the items that appear to be measured are supposed to measure, by two experts who are internationally experienced during the development phase. We acknowledge that this might be impose some limitations, but given the circumstances, this will be our most viable and reliable option to follow, which has been endorsed as a valid method in previous studies.

10. Will construct and internal consistency of the questionnaire be determined? This step will come at a later stage, requiring completion by a large number of participants, but without it, the questionnaire will not be ready for use.

R: Relating to construct validity, I would like inform you that in situations in which a gold standard is lacking, construct validation should be used to provide evidence of validity (7). Therefore, as described in the manuscript, we have adopted ISO's conceptual model for constructing the questionnaire. It should be highlighted that the ISO proposes a maturity model and relating development levels that have been defined for each of the eHealth architecture components, and we will consider this maturity model and their development levels as a gold standard.
Relating to internal consistency of the questionnaire, I would like to highlight here that the reliability step using statistical method, Cronbachs' alpha specifically, has been in our initial plan. We need to do this at a later stage, after the validation phase will be over. We did not mention this in the manuscript, but will be happy to add a sentence if the editor decides so.

11. Relate to item 10, what is the target sampling size (p. 8)?

R: As you may agree, sample size depends on several factors. We will be able to estimate the appropriate sample size after finalizing and validating the items in the previous phases.

12. More information is needed regarding analysis. It is not clear what data will be transcribed, and then how these transcribed data will be analysed.

R: Thank you for this suggestion, which has now been addressed in the revised manuscript.

13. A clearer explanation of "scenarios" is needed. It seems that perhaps these will be simply descriptive examples – but of what exactly – each potential rating for each item on the questionnaire?

R: The scenarios will be descriptive example for each item in the questionnaire. Similar to the WHO's toolkit of 2007 (8), we will use different scenarios for each item. This will help determine the different scenarios for each item, which will allow us to gather more complete and reliable information on the current status of NEHA in selected countries.

Again, thank you very much for giving us the opportunity for improving our work. I hope that you and your colleagues find our revision to your satisfaction and we can now proceed to publication. I look forward to your decision in due course.

Thank you and with kind regards,
Amirhossein Takian
Corresponding author

References:
1. Ie K, Ichikawa S, Takemura YC. Development of a questionnaire to measure primary care physicians' scope of practice. BMC Family Practice. 2015;16(1):161.
2. Santosh P, Tarver J, Gibbons F, Vitoratou S, Simonoff E. Protocol for the development and validation of a questionnaire to assess concerning behaviours and mental health in individuals with autism spectrum disorders: the Assessment of Concerning Behaviour (ACB) scale. BMJ Open. 2016;6(3).
3. Rafferty AM, Philippou J, Fitzpatrick JM, Pike G, Ball J. Development and testing of the 'Culture of Care Barometer' (CoCB) in healthcare organisations: a mixed methods study. BMJ Open. 2017;7(8).
4. Bai Y, Li J, Bai Y, Ma W, Yang X, Ma F. Development and validation of a questionnaire to evaluate the factors influencing training transfer among nursing professionals. BMC health services research. 2018;18(1):107.
5. Paap MC, Lenferink LI, Herzog N, Kroeze KA, van der Palen J. The COPD-SIB: a newly developed disease-specific item bank to measure health-related quality of life in patients with chronic obstructive pulmonary disease. Health and quality of life outcomes. 2016;14:97.
6. Sheferaw ED, Mengesha TZ, Wase SB. Development of a tool to measure women's perception of respectful maternity care in public health facilities. BMC Pregnancy and Childbirth. 2016;16(1):67.
7. De Vet HC, Terwee CB, Mokkink LB, Knol DL. Measurement in medicine: a practical guide: Cambridge University Press; 2011.
8. Health Metrics Network, World Health Organization. Assessing the national health information system: an assessment tool: World Health Organization; 2008.

VERSION 2 – REVIEW

REVIEWER	Dalibor Stanimirovic, PhD

	Head of the Centre for Healthcare Informatics, National Institute of Public Health, Slovenia
REVIEW RETURNED	21-Sep-2018

GENERAL COMMENTS	Proposed suggestions and comments have been considered satisfactorily in this resubmission. At this point, I would like to outline once again: Considering that all initiatives of such an extent as eHealth can be considered as huge and far-reaching socio-technical projects, special attention should be paid to social architecture and its transformation. Namely all socio-technical projects of this magnitude require significant changes in: - human behaviour - education and training - communication - security - technology acceptance, etc. These factors should be taken into account both in the survey and in the composition of the questionnaire, as well as in the actual building of an effective eHealth architecture. When writing a final manuscript, please bear in mind, that the adequate questionnaire is essential but not sufficient condition for publishing a good article.

REVIEWER	Teresa Iacono La Trobe University, Australia
REVIEW RETURNED	14-Sep-2018

GENERAL COMMENTS	I appreciate that the authors have addressed concerns raised in the initial review. There remains only some written expression issues to address, which can be readily completed. I detail these below. Abstract - Insert "the" before "status of NEHA Strengths and weaknesses - Replace ; with . at the end of the second last dot point Introduction - Second sentence – "This" is not compatible with previous sentence, in that plural opportunities are envisioned – hence change to "These". End of page 3 – problem with the expression on the last line "have been well- known for long" (is it periods or a long time?) Top of page 4, change "investment on" to "investment in" Page 4 – difficult to follow expression – "less advance settings need to learn from transferrable lessons" – firstly, settings can't learn, but the meaning is really unclear. Page 4 – change "to develop a national eHealth architecture (NEHA)" to "the development of …" Page 4 – "at the national level in priori" – the meaning is unclear Page 4, change "with focus" to "with a focus" Bottom of page 4 Change "Through: 1- painting a clearer picture of the existing situation, and 2- as well as creating" to Through firstly painting a clearer picture of the existing situation, and secondly …" Page 5, remove "of" from before "the following four categories" Same sentence, correct the typo on "infrastructure" Change "committee have regular meetings" to "the committee holds .."

	Page 7 – abbreviation for low-middle income countries should be used to maintain consistency.
	Table on page 8 needs to be re-labelled, as these are not tasks, but rather criteria to apply to items in making judgements about face validity.
	Page 8 – why are italics used for a) relevancy and b) clarity. Also, a, and b, are not needed.
	Page 8 – I am unsure as to what is meant by "the important items" or how importance is judged.
	Page 9 – suggest changing "what they are is expected to do" to "the requirements for completing the task"
	Page 9 – suggest "fill in the questionnaire" be changed to "complete the questionnaire"
	Page 9, remove comma after "A member of planning committee (SMM)" and add "the" to before Limesurvey.
	Page 9, insert "a" before "descriptive example"
	Add "the" before "selection process."
	What the planning committee will do first (page 9) is described, but there is no second or third, etc?
	Page 10, second paragraph, change "aim" to "aims" and change "for" to "of" in "need for improvement"

VERSION 2 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer 1:

Proposed suggestions and comments have been considered satisfactorily in this resubmission.

At this point, I would like to outline once again:

Considering that all initiatives of such an extent as eHealth can be considered as huge and far-reaching socio-technical projects, special attention should be paid to social architecture and its transformation. Namely all socio-technical projects of this magnitude require significant changes in:

- human behaviour

- education and training

- communication

- security

- technology acceptance, etc.

These factors should be taken into account both in the survey and in the composition of the questionnaire, as well as in the actual building of an effective eHealth architecture.

When writing a final manuscript, please bear in mind, that the adequate questionnaire is essential but not sufficient condition for publishing a good article.

R: I would like to once again thank the reviewer for raising this important consideration. As also mentioned in our previous correspondence, we will be considering aspects of socio-technical changing within the components. It is important to bear in mind that core members of the planning

committee have extensive experiences in sociotechnical changing model, and have published several in-depth papers in this regard. We will certainly use the socio-technical changing model to design the final questionnaire.

Reviewer 2:
I appreciate that the authors have addressed concerns raised in the initial review. There remain only some written expression issues to address, which can be readily completed. I detail these below.

1. Abstract - Insert "the" before "status of NEHA.

R: We applied this comment.

2. Strengths and weaknesses - Replace ; with . at the end of the second last dot point

R: We applied this comment.

3. Introduction - Second sentence – "This" is not compatible with previous sentence, in that plural opportunities are envisioned – hence change to "These".

R: We applied this comment.

4. End of page 3 – problem with the expression on the last line "have been well- known for long" (is it periods or a long time?)

R: We applied this comment. It means "for a long time".

5. Top of page 4, change "investment on" to "investment in"

R: We applied this comment.

6. Page 4 – difficult to follow expression – "less advance settings need to learn from transferrable lessons" – firstly, settings can't learn, but the meaning is really unclear.

R: This sentence was revised to make the meaning clear.

7. Page 4 – change "to develop a national eHealth architecture (NEHA)" to "the development of …"

R: We applied this comment.

8. Page 4 – "at the national level in priori" – the meaning is unclear

R: We rewrote the whole sentence to make it clear. I hope this is clear now.

9. Page 4, change "with focus" to "with a focus"

R: We applied this comment.

10. Bottom of page 4, Change "Through: 1- painting a clearer picture of the existing situation, and 2- as well as creating" to Through firstly painting a clearer picture of the existing situation, and secondly …".

R: We applied this comment.

11. Page 5, remove "of" from before "the following four categories".

R: We applied this comment.

12. Same sentence, correct the typo on "infrastructure".

R: We checked the word again, and see nothing wrong to address here.

13. Change "committee have regular meetings" to "the committee holds ..".

R: We applied this comment.

14. Page 7 – abbreviation for low-middle income countries should be used to maintain consistency.

R: We applied this comment.

15. Table on page 8 needs to be re-labelled, as these are not tasks, but rather criteria to apply to items in making judgements about face validity.

R: We applied this comment.

16. Page 8 – why are italics used for a) relevancy and b) clarity. Also, a, and b, are not needed.

R: We applied this comment.

17. Page 8 – I am unsure as to what is meant by "the important items" or how importance is judged.

R: We will do our utmost effort, through asking selected number of experts to provide further items, which the planning committee might have overlooked. This step will be necessary to determine an inclusive approach to all possible items.

18. Page 9 – suggest changing "what they are is expected to do" to "the requirements for completing the task".

R: We applied this comment.

19. Page 9 – suggest "fill in the questionnaire" be changed to "complete the questionnaire".

R: We applied this comment.

20. Page 9, remove comma after "A member of planning committee (SMM)" and add "the" to before Limesurvey.

R: We applied this comment.

21. Page 9, insert "a" before "descriptive example".

R: We applied this comment.

22. Add "the" before "selection process."

R: We applied this comment.

23. What the planning committee will do first (page 9) is described, but there is no second or third, etc?

R: We have revised the sentence.

24. Page 10, second paragraph, change "aim" to "aims" and change "for" to "of" in "need for improvement"

R: We applied this comment.