PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving the Quality of Person-Centred Healthcare from the Patient Perspective: Development of Person-Centred Quality Indicators
AUTHORS	Santana, Maria-Jose; Manalili, Kimberly; Zelinsky, Sandra; Brien, Susan; Gibbons, Elizabeth; King, Jenny; Frank, Lori; Wallström, Sara; Fairie, Paul; Leeb, Kira; Quan, Hude; Sawatzky, Richard

VERSION 1 – REVIEW

REVIEWER	Dr. Kirsten Smits Radboud university medical center, Nijmegen, The Netherlands
REVIEW RETURNED	24-Feb-2020

GENERAL COMMENTS	This study is nicely performed and presents a list of person-centered quality indicators to assess the quality of person-centered care. They have used a robust method making use of an extensive expert panel including both scientific and medical experts as well as patients and caregivers. However, I do have some concerns regarding the manuscript. 1. The actual indicators with definitions, numerators and denominators are not added to the manuscript, not even as an appendix. This is an essential part of the results and I would highly recommend the authors to present these results. 2. I have some difficulties with the manuscript order. The introduction ends with a paragraph that concludes the study and which should be part of the discussion, while the discussion begins with a paragraph that clearly describes the aim of the project (which is lacking in the introduction). Furthermore, the methods section is somewhat chaotic and some flaws have been identified (see attached file). It is unclear to me what constitutes a "good" indicator. 3. The RAND/UCLA appropriateness method (RAM) is being used, which is indeed one of the best methods to develop quality indicators. However, the RAM also describes the use of the interpercentile range adjusted for symmetry as a measurement for agreement. Is there a specific reason why this has not been used in this study? 4. Certain information in the results section is missing. First of all the description of the panel members belongs here. Furthermore, did all panel members participate in all 4 rounds? Was everyone physically present at the face-to-face meeting? I miss the discussion of the panel members along this study. This may help the reader understand why certain changes were proposed or certain quality indicators discarded or not. Why would the authors choose to publish this separately while it is an explicit part of the current study?

	5. In the discussion I am missing a large part focusing on the studies' limitations, and comparisons with other similar work that has been done in the field of quality improvement. What makes this set of indicators unique amongst all the others that already exist? Which areas have been covered and which areas may be missing in this set? What is the overall conclusion of this project? Overall, I think this project is very useful and that these indicators may give an unique insight in quality of healthcare. However, the manuscript needs rewriting. I wish the authors all the best.

REVIEWER	Dr Noleen McCorry Centre for Public Health, Queen's University Belfast, UK
REVIEW RETURNED	05-Mar-2020

GENERAL COMMENTS	The paper's objective is "To develop and validate person-centred care quality indicators (PC-QIs) measuring PCC at a healthcare system level through a synthesis of the evidence and a person-centred consensus approach to ensure the PC-QIs reflect what matters most to people in their care". This is an worthy and valuable objective. However, upon reading the paper, I believe that either the objective need should be modified somwhat, or the research methods (used to fulfill the sated objective) need to be further defined. In particular, and relevant to the study's objective: 1. the PC-QIs were identified from existing PC-QIs in the literature, rather than being 'developed' based on the evidence supporting each individual indicator. From the process described, it appears that the existing indicators were prioritised or consolidated into a refined list. 2. related to the above point, it is not clear whether, and how, any 'new' indicators were developed, for example as a result of the consultations / focus groups with stakeholders prior to round 1. Given that the authors argue the shortcomings of existing indicators because they have not been developed using from the patient perspective, this opportunity to identify areas of PCC (previously unidentified) is key. It would be useful if the authors could elaborate on the methods and results of this phase of the research - and specfically what (if any) potential indicators resulted from these consultations. The paper states - "Through a synthesis of the evidence from phase 1, unique PC-QIs were developed or modified iteratively by the research team." Please describe what 'evidence' was synthesised and how? 3. Please describe what 'evidence' was presented to panels about the indicators. The paper mentions that a description of the indicator, type of indicator, numerator denominator etc was described, but this doesn't constitute evidence of their appropriateness as an assessment person-centred care. 4. Please describe what is meant by 'diverse patients'. Does this refer to patients from a diversity of background, characteristics, healthcare experience etc etc? 5. The protocol for the scoping review is published separately, but it would be useful for the reader to know the criteria utilised for identifying / selecting indicators from the existing literature 6. Please elaborate on the features of your 'participatory approach' and of the 'transformative framework'. 7. It appears that the researchers have departed from the specific methods used by the RAND/UCLA approach. For example, using the RAND/UCLA approach the panel does not reach need to reach 'consensus' per se, but rather the panel discusses the evidence / ratings etc and each member subsequently indepedently rates the indicators again on 'appropriateness'. The researcher may then

	calculate median for 'appropriateness'. Please describe where the methods have been modified from the original RAND/UCLA process. Sometimes in further rounds there is a rating of 'necessity' etc. 8. It isn't clear what the purpose of the subsequent rounds were, if final agreement about the indicators was reached during the face-to-face panel meeting. Please elaborate further. 9. During the panel meeting, please describe how the deliberations were moderated, and how agreement was achieved / identified. 10. It would be useful to have further description of each indicator. For example, it isn't clear what 'compassionate care' refers to (a process indicator), and how it is assessed. Simliarly, 'trusting relationship with healthcare provider' - how would this be assessed (as a process indicator). The authors should provide more clarity about the methods (as above), and address whether, and how they have advanced the identification of person-centred indicators from the perspective of the patient etc. It appears that indicators have been drawn from an existing pool of previously developed indicators - which the authors have criticised as not benefitting from the involvement of patients. How have new indicators / areas of care relevant to the patient been identified from existing literautre or any primary evidence generated by the research team?

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1 *Please find additional comments from this reviewer attached to this email*

Reviewer Name: Dr. Kirsten Smits
Institution and Country: Radboud university medical center, Nijmegen, The Netherlands
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
This study is nicely performed and presents a list of person-centered quality indicators to assess the quality of person-centered care. They have used a robust method making use of an extensive expert panel including both scientific and medical experts as well as patients and caregivers. However, I do have some concerns regarding the manuscript.

1. The actual indicators with definitions, numerators and denominators are not added to the manuscript, not even as an appendix. This is an essential part of the results and I would highly recommend the authors to present these results.
- We greatly appreciate the reviewer’s recommendation and agree that the complete details for the PC-QIs should be included as part of the results. As the final monograph is quite long and detailed, we have uploaded it onto our website and included a link in the manuscript: https://www.personcentredcareteam.com/s/PC-QIs_Monograph_Santana-et-al-2019.pdf . Here, you will find the indicator definitions, numerators and denominators, along with the relevant evidence for these indicators and proposed tools that can be used for measurement. Please see Pg. 19, line 5.

2. I have some difficulties with the manuscript order. The introduction ends with a paragraph that concludes the study and which should be part of the discussion, while the discussion begins with a

paragraph that clearly describes the aim of the project (which is lacking in the introduction). Furthermore, the methods section is somewhat chaotic and some flaws have been identified (see attached file). It is unclear to me what constitutes a "good" indicator.

- Thank you for the suggestion to revise the manuscript order. Based on the reviewer's suggestion we have switched the text from the discussion to the introduction, and vice-versa (pg. 6-7, lines 22-7; pg. 19-20, lines 11-2). We hope that this provides some clarity around the aim of the project at the outset of the paper. We have also included some details in the methods around the validation of the indicators (face validity and construct validity), to provide additional clarity around our stated objective (see pg. 12, lines 13-15)
- With regards to the comments on the attached file provided by the reviewer, we have included some details around:

o Figure 1 has been updated to show the programme of research, to provide the greater context for the study. We note that this was a previous error in our submission as it was not originally included despite the intention to do so.

o Our updated Figure 2, which shows the flowchart for the rating process is now part of the Results section

o We have accepted the authors suggestions to remove repetitions in the text with regards to our patient engagement for the study.

o Based on the reviewer's question about the difference between the focus groups and consultations, we have removed the wording around "consultations." For consistency, we have maintained the use of the words "focus groups" and "interviews" to ensure clarity.

o We have added some additional details which confirm that the panelists did have access to the scores from the first round (pg. 13, lines 15-16).

- We agree that some additional description is needed for what constitutes a "good indicator." We have followed the criteria set up by the National Quality Forum, which states the criteria for evaluating a new measure: importance, scientific acceptability, feasibility, and usability (pg. 12, lines 4-6).

3. The RAND/UCLA appropriateness method (RAM) is being used, which is indeed one of the best methods to develop quality indicators. However, the RAM also describes the use of the interpercentile range adjusted for symmetry as a measurement for agreement. Is there a specific reason why this has not been used in this study?

- Thank you for your question. As a modified RAM approach, we did not adjust for symmetry. The modified approach is consistent with the use of a face-to-face meeting and at least one additional round of voting. With these opportunities to continue engaging our panelists, any disagreements were resolved through the face-to-face consensus discussion and multiple rounds of voting, making adjustments unnecessary. This approach is consistent with other studies that have developed quality indicators, including previous work for developing trauma quality indicators (now implemented widely):

Stelfox HT, Khandwala F, Kirkpatrick AW, Santana MJ. Trauma center volume and quality improvement programs. J Trauma Acute Care Surg 2012;72:962-8.

Santana MJ, Stelfox HT. Development and evaluation of evidence-informed quality indicators for adult injury care. Ann Surg 2014;259:186-92.

4. Certain information in the results section is missing. First of all the description of the panel members belongs here. Furthermore, did all panel members participate in all 4 rounds? Was everyone physically present at the face-to-face meeting? I miss the discussion of the panel members along this study. This may help the reader understand why certain changes were proposed or certain quality indicators discarded or not. Why would the authors choose to publish this separately while it is an explicit part of the current study?

- As noted by the reviewer, we have moved the final composition of the panel (numbers, description of panelist, and proportions) to the results section. We have also included some additional details around which panelists were present for the face-to-face meeting and rounds 3 and 4 (pg. 15-16).
- We have also included some additional details about the discussion during the face-to-face meeting (pg. 13-14), including some of the consideration for merging and discarding. Some of the specific details around merging and modifications are also found in Appendix 1 and Table 2. We agree that these details are helpful for the reader and have removed the sentence about publishing this separately. We would like to clarify that the intent of publishing a separate study is to present results regarding some of the observed dynamics between patients/caregivers/community members and the researchers/clinicians/quality improvement experts. This separate paper will highlight the unique contributions of patients in a context where we have attempted to address power dynamics. We did not feel that these details would fit within the scope of this particular paper, but we have included some key information about how the discussions were guided (e.g. feasibility, importance, etc).

5. In the discussion I am missing a large part focusing on the studies' limitations, and comparisons with other similar work that has been done in the field of quality improvement. What makes this set of indicators unique amongst all the others that already exist? Which areas have been covered and which areas may be missing in this set? What is the overall conclusion of this project?
- We appreciate the reviewer's comments regarding comparisons to other similar work. While this is the first study to develop a generic set of Person-Centred Quality Indicators to our knowledge, we also acknowledge other work in this field, namely in cancer care. We feel the that unique contribution of this work is related to the significant patient and public involvement throughout the study, which is absent from previous research related to measuring and evaluating patient/person-centred care (pg. 20-21)
- With regards to our study limitations, we agree that more discussion is needed. Namely, these indicators have not been implemented and evaluated, although this is part of our future research (pg. 22, lines 2-9)

Overall, I think this project is very useful and that these indicators may give an unique insight in quality of healthcare. However, the manuscript needs rewriting. I wish the authors all the best.
- Thank you very much for your comments and well wishes.

Reviewer: 2

Reviewer Name: Dr Noleen McCorry
Institution and Country: Centre for Public Health, Queen's University Belfast, UK
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below
The paper's objective is "To develop and validate person-centred care quality indicators (PC-QIs) measuring PCC at a healthcare system level through a synthesis of the evidence and a person-centred consensus approach to ensure the PC-QIs reflect what matters most to people in their care". This is an worthy and valuable objective. However, upon reading the paper, I believe that either the objective need should be modified somwhat, or the research methods (used to fulfill the sated objective) need to be further defined. In particular, and relevant to the study's objective:

1. the PC-QIs were identified from existing PC-QIs in the literature, rather than being 'developed' based on the evidence supporting each individual indicator. From the process described, it appears that the existing indicators were prioritised or consolidated into a refined list.
2. related to the above point, it is not clear whether, and how, any 'new' indicators were developed, for example as a result of the consultations / focus groups with stakeholders prior to round 1. Given that

the authors argue the shortcomings of existing indicators because they have not been developed using from the patient perspective, this opportunity to identify areas of PCC (previously unidentified) is key. It would be useful if the authors could elaborate on the methods and results of this phase of the research - and specfically what (if any) potential indicators resulted from these consultations. The paper states - "Through a synthesis of the evidence from phase 1, unique PC-QIs were developed or modified iteratively by the research team." Please describe what 'evidence' was synthesised and how?
• Thank you for your questions. This has highlighted the need for greater clarification in our methods with regards to how the indicators were not only identified, but also developed. While we indeed identified PC-QIs in the literature as well as those used in current practice, the focus groups and interviews with stakeholders allowed us to identify what is really important to patients and the users of the indicators. This allowed us to look at the indicators that were identified and determine the gaps – how could these indicators best reflect what matters most to people? While indeed, some existing indicators did not change (i.e. Timely access to care; communication with physician/nurse; overall experience with care), most indicators were either newly developed, modified, or refined as a result of the focus groups and interviews, and through the consensus process. We have included some additional details in the manuscript about how the evidence was synthesized (pg. 9-10) as well as in Table 1, which shows which data sources informed the development of each PC-QI.

3. Please describe what 'evidence' was presented to panels about the indicators. The paper mentions that a description of the indicator, type of indicator, numerator denominator etc was described, but this doesn't constitute evidence of their appropriateness as an assessment person-centred care.
• Thank you for this comment. Through our consensus, we sought to assess appropriateness by asking the panelists whether the PC-QIs are measurable (see rating tool: http://bit.do/PC-QI_RatingTool) . We have also included some definitions for the panelists as they assess the appropriateness. The panelists also discussed appropriateness and related evidence during the face-to-face round, particularly as the QI experts were able to provide their experience with using existing or similar measures.

4. Please describe what is meant by 'diverse patients'. Does this refer to patients from a diversity of background, characteristics, healthcare experience etc etc?
• We have included some additional description for ‘diverse patients’ in the manuscript (pg. 9-10, lines 22-2). In particular, we considered age, race, ethnicity, indigeneity, gender and sexual identities, rural/urban, disease conditions, and health care sectors accessed.

5. The protocol for the scoping review is published separately, but it would be useful for the reader to know the criteria utilised for identifying / selecting indicators from the existing literature
• We agree with adding this additional information, these details have been included (pg. 9; lines 8-10), where we state: To be eligible for inclusion, studies/articles had to (1) identify quality indicators for PCC and/or (2) identify PC-QIs in performance measurement (e.g., validation).[18] Indicators were assessed as being person-centred, based on the use of a PCC conceptual framework.

6. Please elaborate on the features of your 'participatory approach' and of the 'transformative framework'.
• Thank you for this suggestion. We previously did not elaborate due to space limitations, but we hope that it will provide greater context for our work and our unique approach to the development of the PC-QIs (pg. 7-8., lines 23-5)

7. It appears that the researchers have departed from the specific methods used by the RAND/UCLA approach. For example, using the RAND/UCLA approach the panel does not reach need to reach 'consensus' per se, but rather the panel discusses the evidence / ratings etc and each member subsequently indepedently rates the indicators again on 'appropriateness'. The researcher may then

calculate median for 'appropriateness'. Please describe where the methods have been modified from the original RAND/UCLA process. Sometimes in further rounds there is a rating of 'necessity' etc.
- The main departure from the RAND/UCLA approach is the addition of more people to the consensus panel (from 19 to 29 people). This was done to ensure we were able to get a diversity of perspectives from clinicians, researchers, quality improvements experts, patients, caregivers, and community members. To ensure address power dynamics, we wanted to ensure equal representation between patients/caregivers/community members and technical perspectives. We have included this clarification to our methods section (pg. 11, lines 4-6).
- We did include a fourth round of rating specifically assessing necessity (pg. 14, lines 17-19) – a yes/no question regarding keeping/discarding each PC-QI.

8. It isn't clear what the purpose of the subsequent rounds were, if final agreement about the indicators was reached during the face-to-face panel meeting. Please elaborate further.
- Thank you for your comment. We have included additional details in the text to clarify the purpose around rounds 3 and 4. With many modifications and refinements, it was necessary to go back to the panel to vote on the “new” PC-QIs and also to determine necessity (pg. 13-14).

9. During the panel meeting, please describe how the deliberations were moderated, and how agreement was achieved / identified.
- We have addressed a similar concern by Reviewer 1 about additional details around the face-to-face meeting. Additional details have been added to the manuscript (pg. 13-14, lines 17-5), including how the discussions were moderated and how agreement was achieved.

10. It would be useful to have further description of each indicator. For example, it isn't clear what 'compassionate care' refers to (a process indicator), and how it is assessed. Simliarly, 'trusting relationship with healthcare provider' - how would this be assessed (as a process indicator).
- Thank you. This was noted by Reviewer 1 as well. We have included the final monograph with the final PC-QIs as a link in the manuscript: https://www.personcentredcareteam.com/s/PC-QIs_Monograph_Santana-et-al-2019.pdf . Here, you will find the indicator definitions, numerators and denominators, along with the relevant evidence for these indicators and proposed tools that can be used for measurement. Please see Pg. 19, line 5.

The authors should provide more clarity about the methods (as above), and address whether, and how they have advanced the identification of person-centred indicators from the perspective of the patient etc. It appears that indicators have been drawn from an existing pool of previously developed indicators - which the authors have criticised as not benefitting from the involvement of patients. How have new indicators / areas of care relevant to the patient been identified from existing literautre or any primary evidence generated by the research team?
- Thank you. We believe we have addressed this comment previously. We have added additional details in the manuscript about the specific role of patients and other stakeholders in identifiying existing gaps in person-centred care measurement (pg. 9-10). Table 1, which shows which data sources informed the development of each PC-QI can also provide some clarity on the areas of care that were informed by the focus groups and interviews.

VERSION 2 – REVIEW

REVIEWER	Dr. Kirsten Smits Radboud university medical center, Nijmegen, The Netherlands
REVIEW RETURNED	14-Jul-2020

GENERAL COMMENTS	I complement the authors for the improvement of their manuscript. The study and results are more clear to me now. I have some final,

	small comments to make before the manuscript is ready for implementation. a) Please be consistent in your writing. The last two sentences of the introduction belong in the discussion, as this already shows the conclusion of your study. The introduction is meant as a justification for your study, and of course you can hypothesize about the outcome of the study, but actual results and conclusions should go into those sections. Similarly, please move the last paragraph of the methods, starting with “Appendix 1, displays …” to the results, as this paragraph discusses results of your study. b) Figure 1 shows a Phase 3 to your project, but this is not mentioned anywhere in your manuscript. Please be consistent. If you mention Phase 3 in the figure, please explain phase 3 in the text. c) Table 1 and Appendix 1 show a lot of similarities and Appendix 1 gives limited additional information. Please consider whether these tables can be merged into 1. I would like to thank the authors for their great work, this manuscript gives a great example of how QI can be developed in cooperation with patients, caregivers and the general public.

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Dr. Kirsten Smits
Institution and Country: Radboud university medical center, Nijmegen, The Netherlands
Competing interests: None declared

Please leave your comments for the authors below
I complement the authors for the improvement of their manuscript. The study and results are more clear to me now. I have some final, small comments to make before the manuscript is ready for implementation.
Thank you very much for your thorough review and valuable comments throughout the review process. We feel that we have been able to strengthen the manuscript and to ensure there is sufficient clarity and consistency in our reporting.

a) Please be consistent in your writing. The last two sentences of the introduction belong in the discussion, as this already shows the conclusion of your study. The introduction is meant as a justification for your study, and of course you can hypothesize about the outcome of the study, but actual results and conclusions should go into those sections.

Thank you for your comment. While our intent was to entice the reader by providing the outcome of the study, we agree with the reviewer that these statements are most appropriate for the discussion. We have combined this section with similar statements in our discussion section in this latest revision, while ensuring there is no redundancy (pg. 21, lines 6-8).

Similarly, please move the last paragraph of the methods, starting with “Appendix 1, displays …” to the results, as this paragraph discusses results of your study.

We appreciate this comment and agree that this is best included as part of the results section. The sentence regarding the Appendix has been moved to the results section (pg. 16, lines 19-22) and modified to clarify what is included in the appendix (compared to Table 1).

b) Figure 1 shows a Phase 3 to your project, but this is not mentioned anywhere in your manuscript. Please be consistent. If you mention Phase 3 in the figure, please explain phase 3 in the text.

Thank you. This is a detail that we have missed previously and concur that an explanation of Phase 3 should be provided. We have included the description of Phase 3 on pg. 7, lines 12-17. It is also referred to in the discussion section with regards to the next steps of our research (pg. 13, line 23).

c) Table 1 and Appendix 1 show a lot of similarities and Appendix 1 gives limited additional information. Please consider whether these tables can be merged into 1.
I would like to thank the authors for their great work, this manuscript gives a great example of how QI can be developed in cooperation with patients, caregivers and the general public.

We appreciate the reviewer's comment regarding the similarities between Table 1 and Appendix 1. We have clarified the information provided in Appendix 1 (see note above; pg. 16, lines 19-22). While we do agree that there are some redundancies between the two tables as, we wanted to ensure that we could provide a brief summary within the text of the paper of our findings, as presented on Table 1. But, at the same time, we wanted to ensure there were enough details about the modifications that were made to the PC-QIs to provide transparency in our process of modifying the PC-QIs. As such, we have decided to maintain the larger table as an Appendix, for those who may be interested in this additional information.

VERSION 3 – REVIEW

REVIEWER	Dr. Kirsten Smits Radboud university medical center, Nijmegen, the Netherlands
REVIEW RETURNED	08-Oct-2020

GENERAL COMMENTS	I would like to congratulate the authors on the revision of their manuscript. I have no further comments and would recommend the editorial office to accept the manuscript as it is.