PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Exploring the phase for highest impact on radicality—a cross-sectional study of patient involvement in quality improvement in Swedish health care
AUTHORS	Gremyr, I; Elg, Mattias; Smith, Frida; Gustavsson, Susanne

VERSION 1 – REVIEW

REVIEWER	Dr Elizabeth Fradgley University of Newcastle, Australia
REVIEW RETURNED	12-Mar-2018

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript focused on the involvement of consumers within the quality improvement cycle. The study relied upon survey data from 155 health professionals, and sought to identify at which time-point of consumer involvement was perceived to be most impactful on quality improvement change. I believe this is an interesting and novel question, but this paper would be strengthened greatly by providing more details about the participants, as they essentially are presented as an expert panel capable of identifying this time-point. Specific comments include: Keywords: 1. If editorial policy allows an additional keyword, please also include a term for consumer involvement in online submission form. Abstract: 2. Please note the response rate in abstract. 3. Please consider a more descriptive term under study design (‘exploratory cross-sectional survey). 4. It is unclear in the Abstract Results description that this was perceived impact – this is an important distinction. Introduction: 5. Given the importance of the 4 phases outlined in survey measure, please explain why Bates and Robert approach was the most appropriate choice? Methods:

6. As participants could be seen as experts in quality improvement and the data relies upon their experience, please describe the form of training was completed and how this was assessed in the survey.

7. How was the sampling frame developed?

8. Given the heterogeneous background of respondents, was there a difference in perceived optimal phase of involvement by speciality (e.g. dentistry v primary)?

9. Given the importance of the single-item dependant variable, was there any other existing measures of radicality of improvement that had been validated or was a study-specific tool required?

10. Were participants asked to reflect on a specific quality improvement initiative, and if so, what were the instructions for this? Do you believe that the participants reported on a broad range of initiatives and therefore the data is relevant to quality improvement regardless of specific objectives or target service?

Results:

11. Please review Line 21 on Page 7 for clarity.

12. The ‘Other’ category within Table 2 represents a third of respondents. If it is not possible to recode into more descriptive categories, please provide some examples of professions within the grouping.

Discussion:

13. There is no mention of how the proposed consumer involvement aligns with current codesign frameworks, and if a paradigm shift is required to incorporate patients specifically within the identified timepoints. This could strengthen the utility of this article, and is a suggestion for the authors to consider.

14. There is an argument that in order to align with rigorous co-design principles, consumers should be involved throughout the quality improvement cycle. Could authors please comment on if there were any participants who responded 4 or more for each item on the scale, or why consumers should be involved in only one aspect or time point in the quality improvement cycle? Would it be more likely that a QI project would have the greatest impact if consumers were involved in all aspects?

15. Limitations: Please note the selection bias inherent in online surveys, in combination with your response rate, and the likelihood that those individuals who responded may be more favourable to reporting an impact.

With regards to BMJ Open criteria - Are the references up-to-date and appropriate? – I marked Yes,.

However, please confirm there is not a more appropriate reference for # 6.

I wish the authors best wishes for this important work.

Thank you for the opportunity to review this manscript focused on

Introduction:

16. Given the importance of the 4 phases, please explain why Bates and Robert was the appropriate division of this?

Methods:

17. As participants could be seen as experts in quality improvement and the data relies upon their experience, please describe the form of training completing and how this was assessed in the survey.

18. How was the sampling frame developed?

19. Given the heterogeneous background of respondents, was there a difference in optimal phase of involvement by speciality (e.g. dentistry v primary)

20. Given the importance of the single-item dependant variable, was there any other existing measures of radicality of improvement that had been validated or was a study-specific tool required?

21. Were participants asked to reflect on a specific quality improvement initiative, and if so, what were the instructions for this? Do you believe that the participants reported on a broad range of initiatives and therefore the data is relevant to quality improvement regardless of specific objectives or target service?

Results:

22. Please review Line 21 on Page 7 for clarity.

23. The ‘Other’ category within Table 2 represents a third of respondents. If it is not possible to recode into more descriptive categories, please provide some examples of professions within the grouping.

Discussion:

24. There is no mention of how this aligns with current codesign frameworks, and if a paradigm shift is required. This could strengthen the utility of this article.

There is an argument that in order to align with rigourous codesign principles, consumers should be involved throughout the quality improvement cycle. Could authors please comment on why consumers should be involved in only one aspect or time point in the quality improvement cycle? Would it be more likely that a QI project would have the greatest impact if consumers were involved in all aspects?

With regards to BMJ Open criteria:

	I marked “Yes” to 8. Are the references up-to-date and appropriate? However, please confirm there is not a more appropriate reference for # 6.

REVIEWER	Kenneth L Miller Touro College, United States
REVIEW RETURNED	14-Mar-2018

GENERAL COMMENTS	Including patient involvement in quality improvement is a novel one by adding a receiver perspective to the issues being addressed. Here are recommendations to make the paper a stronger one. 1. Move the strengths and weaknesses from the beginning of the paper to the discussion section of the manuscript. 2. What practice settings do the researchers have experience. (Bullet 1 from strengths and weaknesses). 3. Page 4 paragraph beginning Patient involvement - would you consider adding patient involvement is patchy because the healthcare QI personnel do not value patient involvement? For patient involvement to truly be valuable, the patients comments must have currency with the QI personnel. 4. In discussion section, would you want to add some of the QI processes such as SWOT, fishbone analyses and how to incorporate the patient in these processes? 5. Conclusion section, consider adding tracer methodology using the patient being self aware as a tracer of their own experience. What tools would the patient use to capture the QI data?

REVIEWER	Michelle Farr University of Bristol, UK
REVIEW RETURNED	15-Mar-2018

GENERAL COMMENTS	The article is clear, well-written, informative and interesting. My thoughts and suggestions for improvement are: Background. Line 26-7 “As a response to this challenge…”. This phrase which begins this sentence doesn’t really give acknowledgement to the many diverse influences that have contributed to the development of patient involvement. These include democratisation, challenges to professional power, and welfare rights social movements. For example, see Peter Beresford’s work on the politics of participation and the differentiation between managerialist/ consumerist models of involvement and democratic models of involvement. In the discussion section I feel that some of the assertions possibly overstretch the results and data. The assertion that “patient involvement in these phases can help to reduce the risk of tokenism” does not give acknowledgement to the full range of ways in which tokenism can happen. Tokenism may also occur though particular methods and processes of public involvement, which the article doesn’t seem to discuss. The phrase re: identify and prioritise “these are better performed by the QI team”. Again I’m not sure that the data supports the assertion that these tasks are better performed by the QI team. There may be other reasons for this finding. As far as I understand the data, there was no real exploration of why particular phases contributed to more radicality (this could be added to limitations of the study?). Also the methods used did not really explore contextual constraints on PI in QI.

	Comment on phrase: "this knowledge can help to save resources spent on patient involvement by identifying which phases are best handled by healthcare professionals alone." (p.11). Whilst I can see that there is an economic rationale for focussing scarce resources on just one or two phases of patient involvement, should there be some more acknowledgement in the paper that if a more democratic perspective to patient involvement is taken, then it may still be important to involve patients in all four phases outlined, as a matter of good practice and democratisation of health services. As acknowledged in future research needs, a further limitation of the study is that it does not explore the influence of context on PI and QI, which may influence the extent to which radical changes can be instigated within services.

REVIEWER	Jill Stocks University of Manchester, UK
REVIEW RETURNED	09-Apr-2018

GENERAL COMMENTS	Identifying the right phase—increasing the impact of patient involvement in quality improvement. Thank you for giving me the opportunity to review this interesting work addressing the question of when is the most effective time for patient involvement in QI. It is clearly important that patient and staff resources are used as efficiently as possible. I have one major concern about the interpretation of this study. Since the QI professionals made the decision about what stage(s) to involve patients in the improvement cycle the opportunity for patients to contribute at each stage was already decided by the QI professional. It could be a self-fulfilling prophecy – the greatest impact was at the stages already selected by the QI professional as the most useful/important. Ideally the results should be adjusted on the basis of a question asking whether or not the patients had been given the opportunity to contribute at each stage or the results stratified according to which stage(s) the patients had been invited to contribute. In light of above I think that the use of the word identify is too strong in both the title and abstract. It would be better to replace with a word such as "explore" or "investigate" or "inform" or similar unless the authors can consider the above in their analysis. Generally this needs to be discussed as a weakness. Please emphasise throughout the manuscript that this is all from the QI professional perspective and is not objective and does not consider the patient perspective. Also in light of the above re-consider this statement in the discussion. "This might also explain why patient involvement in the identify and prioritise phase was not so strongly linked to radicality, as these tasks are better performed by the QI team." If the QI team are already of the view that they can perform this task better, they are less likely to ask for contributions from patients and/or less likely to value contributions from patients. Also likewise in the conclusion unless the authors can give some evidence that the patients were given the opportunity to contribute equally to all stages by the QI professional (or this is accounted for) they don't really identify the stages contributing to the most radical changes in an objective way, the opinion of the PI professional in designing the patient involvement in the QI cycle biases the results. In the methods it is not really clear how the single-item for measuring radicality was it chosen or designed. Has it been used previously (this is not clear in reference 30 and ref29 is a book that needs to be purchased). Was the face validity investigated at all?

	Where other composite measures considered? Are there any validated measures for this concept? There is no statement about PPI at the end of the methods as required by this journal. This type of work would really benefit from PPI so it is important to explain why this was not undertaken, for example as part of the focus group that evaluated the pilot questionnaire. The work is very much from the professional perspective and this is acknowledged in the strengths and weaknesses but there is no reason given why this is the case. (Patients would like to be involved at the identifying and planning stage but are rarely asked.) Some information about the type of QI projects that the respondents had undertaken would have been interesting. A translated version of the 44 questions would be very helpful as supplementary information. Is there any way that the non-responders could be compared with the responders in terms of gender or role? Is the high proportion of female responders simply reflecting the QI workforce or is it a response bias? Minor issues P3 explicates – is this the right word? Are the authors saying that it increases or intensifies the tension for change? P4 “Thirdly, there may be validity issues with patient involvement studies where academic dissemination is preceded …” Can this be explained differently as the meaning is unclear.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:
Reviewer: 1
Reviewer Name: Dr Elizabeth Fradgley
Institution and Country: University of Newcastle

Thank you for the opportunity to review this manuscript focused on the involvement of consumers within the quality improvement cycle. The study relied upon survey data from 155 health professionals, and sought to identify at which time-point of consumer involvement was perceived to be most impactful on quality improvement change. I believe this is an interesting and novel question, but this paper would be strengthened greatly by providing more details about the participants, as they essentially are presented as an expert panel capable of identifying this time-point.

Thank you for the encouraging comments on our topic, as regards to details about the participants we have made some amendments in response to your questions/suggestions below.

Specific comments include:
Keywords:
1. If editorial policy allows an additional keyword, please also include a term for consumer involvement in online submission form.

The editorial system did not allow for additional (more paper specific) keywords.

Abstract:
2. Please note the response rate in abstract.

Thank you, we have added this information to the abstract.

3. Please consider a more descriptive term under study design (‘exploratory cross-sectional survey).

We agree that the suggested term in a good way describes our research design.

4. It is unclear in the Abstract Results description that this was **perceived** impact – this is an important distinction.

We agree that it is important to clearly spell out that the respondents have judged the radicality themselves, i.e. their perception of the radicality of the improvements. We have added "perceived radicality" in the suggested paragraph, as the impact per se was calculated by the PLS-method.

Introduction:

5. Given the importance of the 4 phases outlined in survey measure, please explain why Bates and Robert approach was the most appropriate choice?

The four phases that has been selected for further investigation are routinely used in patient involvement initiatives, out of which one commonly used is the phases within Experience-Based Co-Design. This has been motivated in the manuscript (end of Background): "These four phases are also generally found in other forms of patient involvement in quality improvement cycles [8]."

Methods:

6. As participants could be seen as experts in quality improvement and the data relies upon their experience, please describe the form of training was completed and how this was assessed in the survey.

The training was not specifically accessed in the survey, as this was part of the inclusion criteria. The inclusion criteria have been elaborated on in the manuscript and now reads as follows:

> "The original sample consisted of 472 participants who had training and practical experience in patient involvement in QI. The training ranged from a two-week course to a two-year part-time university education. All training consisted of a combination of theoretical elements (focusing QI and patient involvement in healthcare) as well as practical improvement projects. Regarding the practical experience of QI and patient involvement (besides the projects being part of the training), the experience ranged from one to more than 10 completed projects. The participants came from 3 (out of 20) Swedish healthcare regions, responsible for the provision of primary care, healthcare, dental care, etc. in a specific geographical area."

7. How was the sampling frame developed?

The sampling frame was given by access to e-mail lists from three of the largest providers of courses on QI in healthcare, the e-mail lists included all their previous participants. The providers were: Centre for Healthcare Improvements at Chalmers University of Technology, the healthcare region of Skåne, and Swedish Association of Local Authorities and Regions (SALAR). In addition to this, see answer above on inclusion criteria. A sentence on the sampling frame has been provided in the sample description in the method section.

8. Given the heterogeneous background of respondents, was there a difference in perceived optimal phase of involvement by speciality (e.g. dentistry v primary)?

To be able to distinguish based on speciality would be interesting. However, we did not ask about speciality. Hence, we don't have the data needed to perform this analysis.

9. Given the importance of the single-item dependant variable, was there any other existing measures of radicality of improvement that had been validated or was a study-specific tool required?

Reading your comment, we realized that the reference for this item was not included in the manuscript, which we apologize for. The single-item dependent variable is based on the foundational work by Cooper (1979), in his work on developing "The dimensions of industrial new product success and failure". He suggested 6 factors underlying new products, one of which is Newness to the Firm. The item we have used is a variable ("Product use (needs served) new to firm") loading on this factor. The choice is aligned to the background to (and motivation for) our study:

> "patient involvement in quality improvement (QI) has increasingly been viewed as a means to generate more radical ideas for new healthcare services [2-5]. Radicality can be defined as the potential or novelty of a QI idea for meeting new needs of patients, thus generating solutions or innovations that range from incremental ('the same but better') to radical ('really different') [6,7]."

In light of this, we chose an item focusing on potential in meeting new needs of the patients. The item was translated into Swedish and adapted to a healthcare context. The reference to Cooper (1979) is now in the manuscript.

10. Were participants asked to reflect on a specific quality improvement initiative, and if so, what were the instructions for this? Do you believe that the participants reported on a broad range of initiatives and therefore the data is relevant to quality improvement regardless of specific objectives or target service?

In answering the questions about PI in various phases and in evaluating the perceived radicality of the improvement the participants were asked to focus on one specific project. This was an instruction after the introductory questions on demographic variables and background; "In the following, please think about one specific improvement project."

The participants reported on a very wide range of projects, e.g. improving the eating environment at hospitals, less compulsory care in psychiatry, palliative care, and improvements in cancer care. Although it's always hard to claim that something is universally applicable we believe that our sample has captured a broad range of projects. The number is likely equivalent to one project per respondent, i.e. 155 projects, however there might be some respondents referring to the same project. Examples of projects are now given in the manuscript.

Results:
11. Please review Line 21 on Page 7 for clarity.

The sentence has been revised for increased clarity.

12. The 'Other' category within Table 2 represents a third of respondents. If it is not possible to recode into more descriptive categories, please provide some examples of professions within the grouping.

Three examples have been added in Table 2: public health scientists, psychotherapist, and quality manager.

Discussion:
13. There is no mention of how the proposed consumer involvement aligns with current codesign frameworks, and if a paradigm shift is required to incorporate patients specifically within the identified timepoints. This could strengthen the utility of this article, and is a suggestion for the authors to consider.

We greatly thank the reviewers for pointing this important aspect out. We have added a discussion of how the results of our study may contribute to a more general understanding of the importance of engaging patients in various phases. Although it is not possible to cover all different co-design frameworks we thematise our discussion on three levels: general change models, specific co-creation frameworks and specific techniques/methods in quality improvement.

14. There is an argument that in order to align with rigourous codesign principles, consumers should be involved throughout the quality improvement cycle. Could authors please comment on why consumers should be involved in only one aspect or time point in the quality improvement cycle? Would

it be more likely that a QI project would have the greatest impact if consumers were involved in all aspects?

We agree with the reviewers that there are frameworks that emphasize that customers should be involved throughout the improvement cycle. However, to the best of our knowledge there hasn't been any empirical studies focusing on the relative importance of their engagement in various phases. Our findings can open up for a more selective use of patients thus further developing concepts and principles that have practical relevance and impact.

With regards to BMJ Open criteria: I marked "Yes" to 8. Are the references up-to-date and appropriate? However, please confirm there is not a more appropriate reference for # 6.

We have changed to a more context relevant reference: Bessant, J., & Maher, L. (2009). Developing radical service innovations in healthcare—the role of design methods. International Journal of Innovation Management.

Reviewer: 2
Reviewer Name: Kenneth L Miller
Institution and Country: Touro College, United States

Including patient involvement in quality improvement is a novel one by adding a receiver perspective to the issues being addressed. Here are recommendations to make the paper a stronger one.

1. Move the strengths and weaknesses from the beginning of the paper to the discussion section of the manuscript

*This was instructed to be displayed as bullet points in instructions to authors: "***An Article Summary, placed after the abstract, consisting of the heading 'Strengths and limitations of this study'**, and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods. They should not include the results of the study."

2. What practice settings do the researchers have experience. (Bullet 1 from strengths and weaknesses).

Due to instructions above, this is not included in the bullet point, but this is the experience of the researchers: Two are professors in Quality Management with experience from several development initiatives in both health care and private corporations, one is a PhD in Quality Improvement in healthcare working with continuous improvement daily and one is a specialist nurse/PhD in oncology working as an improvement developer for national, regional and local cancer care in Sweden as well as a researcher.

3. Page 4 paragraph beginning Patient involvement - would you consider adding patient involvement is patchy because the healthcare QI personnel do not value patient involvement? For patient involvement to truly be valuable, the patients comments must have currency with the QI personnel.

Agree. We have reformulated the beginning of this paragraph.

4. In discussion section, would you want to add some of the QI processes such as SWOT, fishbone analyses and how to incorporate the patient in these processes?

We have, in line with previous reviewer comment 14 added this to our discussion.

> ”The findings from this study have practical implications for improvement projects that involve patients. Generally, as healthcare is co-created and produced within the interactions between patients and health professionals [12], the staff's perspective should be balanced with that of patients. Power and ethics could be a barrier to forging a true partnership between patients and staff, but our results can nevertheless help by defining when patient involvement is most beneficial for radicality. Besides proving the criticality and usefulness of patient involvement, this knowledge can help prioritise resources spent on patient involvement. Hence, current change models (e.g. Nolan's

> model for quality improvement, PDSA) and more specific patient involvement frameworks (e.g. Experienced Based Co-Design, tracer methodology) may benefit from infusing the findings from the present study in their work. Further, the findings can be used in order to identify specific methods, e.g. process mapping and fishbone analyses, where incorporation of the patient might be efficient.
> In further research, a general question to be asked in relation to these frameworks and methods is if patients are invited to participate in various phases and activities and if they are effectively engaged. The findings can also be used as basis for understanding the relative importance of various patient activities in co-creation models where patients are involved as representatives in trial management groups, steering committees, and data monitoring teams"

5. Conclusion section, consider adding tracer methodology using the patient being self aware as a tracer of their own experience. What tools would the patient use to capture the QI data?

Same as above. We have added this to our discussion.

Reviewer: 3
Reviewer Name: Michelle Farr
Institution and Country: University of Bristol, UK

The article is clear, well-written, informative and interesting. My thoughts and suggestions for improvement are:

Background. Line 26-7 "As a response to this challenge…". This phrase which begins this sentence doesn't really give acknowledgement to the many diverse influences that have contributed to the development of patient involvement. These include democratisation, challenges to professional power, and welfare rights social movements. For example, see Peter Beresford's work on the politics of participation and the differentiation between managerialist/ consumerist models of involvement and democratic models of involvement.

We agree with the reviewer. Patient involvement has far-reaching possibilities and consequences. Although our focus is on radically new and more resource-efficient ways of delivering healthcare we have added a sentence of the broader notion of patient involvement. This introduction then narrows down to the focus of our work.

In the discussion section I feel that some of the assertions possibly overstretch the results and data. The assertion that "patient involvement in these phases can help to reduce the risk of tokenism" does not give acknowledgement to the full range of ways in which tokenism can happen. Tokenism may also occur though particular methods and processes of public involvement, which the article doesn't seem to discuss. The phrase re: identify and prioritise "these are better performed by the QI team". Again I'm not sure that the data supports the assertion that these tasks are better performed by the QI team. There may be other reasons for this finding. As far as I understand the data, there was no real exploration of why particular phases contributed to more radicality (this could be added to limitations of the study?). Also the methods used did not really explore contextual constraints on PI in QI.

Thank you for your comments, it is indeed critical not to overstretch the results and we have rephrased the sentence to be clearer on the "type" of tokenism that we refer to in this paper. The sentence now reads as follows: "Thus, patient involvement in these phases can help to reduce the risk of tokenism, i.e. ensuring that the patients voice is listened to and acted upon."

Regarding the sentences on Identify & prioritise (including the sentence "these are better performed by the QI team"), we agree that this is stretching the data too far. These sentences are now excluded since our main message in relation to validity is that our model provides evidence that PI has an impact on radicality particularly in certain phases.

Comment on phrase: "this knowledge can help to save resources spent on patient involvement by identifying which phases are best handled by healthcare professionals alone." (p.11). Whilst I can see that there is an economic rationale for focussing scarce resources on just one or two phases of patient involvement, should there be some more acknowledgement in the paper that if a more democratic perspective to patient involvement is taken, then it may still be important to involve patients in all four phases outlined, as a matter of good practice and democratisation of health services.

We agree that this is of high importance, and the article aims to bring more knowledge on how to best perform PPI, both for patients and for the health care organizations. We do not claim that they should not be involved in all of the stages, we merely try to identify when it would be most effective in terms of radicality. The phrasing of "save resources" has therefor been modified and reads as: "Besides proving the criticality and usefulness of patient involvement, this knowledge can help prioritise resources spent on patient involvement." This as a means of not, unintentionally, convey a message that patient involvement should be decreased. In line with this, we have also deleted the following part of the sentence: "by identifying which phases are best handled by healthcare professionals alone."

As acknowledged in future research needs, a further limitation of the study is that it does not explore the influence of context on PI and QI, which may influence the extent to which radical changes can be instigated within services.

We fully agree that this is an area that would be of interest for future research, in the last paragraph in the Discussion we have also added that speciality is an additional "contextual" factor that would be of interest to investigate. This is also in line with the interests into this factor expressed by Reviewer 1 (comment 8) above.

Reviewer: 4
Reviewer Name: Jill Stocks
Institution and Country: University of Manchester, UK

Thank you for giving me the opportunity to review this interesting work addressing the question of when is the most effective time for patient involvement in QI. It is clearly important that patient and staff resources are used as efficiently as possible.

Q: I have one major concern about the interpretation of this study. Since the QI professionals made the decision about what stage(s) to involve patients in the improvement cycle the opportunity for patients to contribute at each stage was already decided by the QI professional. It could be a self-fulfilling prophecy – the greatest impact was at the stages already selected by the QI professional as the most useful/important. Ideally the results should be adjusted on the basis of a question asking whether or not the patients had been given the opportunity to contribute at each stage or the results stratified according to which stage(s) the patients had been invited to contribute.

Thank you for an important comment. Our reasoning is that the respondents only asked about the degree of involvement in each phase, and later the perceived radicality of the improved way of working on an overall level (i.e. the specific project the respondent was asked to think about when answering the questionnaire). The actual impact of PI in a certain phase on the overall radicality of the results are not "directly" evaluated by the respondents, but given by the PLS model per se.

In terms of your comment on whether or not patients have been invited to participate, we have added in the future research paragraph that such information would be of interest of further explore. Moreover, we have rephrased the sentences in the discussion regarding certain activities being better performed by staff (as this is not investigated). Patient involvement is of high value throughout improvement work and but our study show that it has more impact on radicality in certain stages. The fact that this study can model and impact on radicality stemming from patient involvement is an important contribution to the evidence building around patient involvement.

Q: In light of above I think that the use of the word identify is too strong in both the title and abstract. It would be better to replace with a word such as "explore" or "investigate" or "inform" or similar unless the authors can consider the above in their analysis. Generally this needs to be discussed as a weakness. Please emphasise throughout the manuscript that this is all from the QI professional perspective and is not objective and does not consider the patient perspective.

We agree and this has also been pointed out by other reviewers and the editor. The title has been changed to: Exploring the phase for highest impact on radicality—a cross-sectional study of patient involvement in quality improvement in Swedish health care. *Some amendments in the abstract under*

Results and Conclusion have also been made. As also pointed out by reviewer 1, it is the <u>*perceived*</u> *radicality of the QI-staff that is reported in the survey, not the patients or any objective measurement. We agree that it is important to clearly spell out that the respondents have judged the radicality themselves, i.e. their perception of the radicality of the improvements. We have added "perceived radicality" in the suggested paragraph, as the impact per se was calculated by the PLS-method.*

Q: Also in light of the above re-consider this statement in the discussion. "This might also explain why patient involvement in the identify and prioritise phase was not so strongly linked to radicality, as these tasks are better performed by the QI team." If the QI team are already of the view that they can perform this task better, they are less likely to ask for contributions from patients and/or less likely to value contributions from patients. Also likewise in the conclusion unless the authors can give some evidence that the patients were given the opportunity to contribute equally to all stages by the QI professional (or this is accounted for) they don't really identify the stages contributing to the most radical changes in an objective way, the opinion of the PI professional in designing the patient involvement in the QI cycle biases the results.

The sentence mentioned above is also addressed by Reviewer 3, and has been addressed as: Regarding the sentences on Identify & prioritise (including the sentence "these are better performed by the QI team"), we agree that this is stretching the data too far. These sentences are now excluded since our main message in relation to validity is that our model provides evidence that PI has an impact on radicality particularly in certain phases.

As to the lack of objective ways of identifying stages contributing to radicality we have (as discussed in response to other comments) in this study chosen the healthcare professionals as respondents. We have, as outlined in the answer to your first comment, not asked the respondents to evaluate the connection between involvement in various phases and the radicality of results. This is modeled by the PLS method, and the model was evaluated according to standard procedures showing that reliability was confirmed and that the discriminant validity was sufficient. This is described in the paragraphs following Table 2.

Q: In the methods it is not really clear how the single-item for measuring radicality was it chosen or designed. Has it been used previously (this is not clear in reference 30 and ref29 is a book that needs to be purchased). Was the face validity investigated at all? Where other composite measures considered? Are there any validated measures for this concept?

Thank you for pointing to the need of clarification in relation to the single-item used, this was also pointed out by Reviewer 1. As answered above: Reading your comment, we realized that the reference for this item was not included in the manuscript, which we apologize for. The single-item dependent variable is based on the foundational work by Cooper (1979), in his work on developing "The dimensions of industrial new product success and failure". He suggested 6 factors underlying new products, one of which is Newness to the Firm. The item we have used is a variable ("Product use (needs served) new to firm") loading on this factor. The choice is aligned to the background to (and motivation for) our study:

> *"*patient involvement in quality improvement (QI) has increasingly been viewed as a means to generate more radical ideas for new healthcare services [2-5]. Radicality can be defined as the potential or novelty of a QI idea for meeting new needs of patients, thus generating solutions or innovations that range from incremental ('the same but better') to radical ('really different') [6,7]."

In light of this, we chose an item focusing on potential in meeting new needs of the patients. The item was translated into Swedish and adapted to a healthcare context. The reference to Cooper (1979) is now in the manuscript. We searched for other measures of radicality for the purpose of our study but could not identify any such measures that fitted our needs.

Related to the face validity, the focus group and the discussions herein created confidence in the items and their measure of the phenomena we wanted to investigate. A sentence on this has been added in *the manuscript: "This contributed to clarifications of questions and instructions in the survey, and ensured an understanding of the survey and its item among the focus group participants."*

Q: There is no statement about PPI at the end of the methods as required by this journal. This type of work would really benefit from PPI so it is important to explain why this was not undertaken, for example as part of the focus group that evaluated the pilot questionnaire. The work is very much from the professional perspective and this is acknowledged in the strengths and weaknesses but there is no reason given why this is the case. (Patients would like to be involved at the identifying and planning stage but are rarely asked.)

We agree that this is of high importance, and the article aims to bring more knowledge on how to best perform PPI, both for patients and for the health care organizations. We do not claim that they should not be involved in all of the stages, we merely try to identify when it would be most effective in terms of radicality. This section has been added under the headline Patient Involvement:

> "Patients were not included in the sampling for this study. It is considered appropriate [25,26] for evaluation of improvement projects to choose people with a long track record of experience with a specific process, in our case the QI-staff. Patients have invaluable knowledge of the experience from other dimensions, but have less knowledge about the organization, and what can be considered as radical might thereby have a completely different meaning than for the QI-staff and should therefore not be compared."

Q: Some information about the type of QI projects that the respondents had undertaken would have been interesting.

This was also requested by reviewer 1 and has been clarified accordingly: The participants reported on a very wide range of projects, e.g. improving the eating environment at hospitals, less compulsory care in psychiatry, palliative care, and improvements in cancer care. Although it's always hard to claim that something is universally applicable we believe that our sample has captured a broad range of projects. The number is likely equivalent to one project per respondent, i.e. 155 projects, however there might be some respondents referring to the same project. Examples of projects are now given in the manuscript.

Q: A translated version of the 44 questions would be very helpful as supplementary information.

All the questions used in the analysis are translated and included in Table 1, and the question on radicality is found in the paragraph following Table 1. To provide more ionfo about thesurvey as a whole we have added a list of the "themes" addressed in the questionnaire:

> "Most of the questions were close-ended (examples can be seen in Table 1), with a few being open-ended, and covered: the participants' demographic and background information, motivation and organisation of improvement projects, experiences of patient involvement in QI, the organisational culture, and the perceived results of PI in QI."

Q: Is there any way that the non-responders could be compared with the responders in terms of gender or role? Is the high proportion of female responders simply reflecting the QI workforce or is it a response bias?

We have tested population to sample variation with respect to gender and role by formal statistics. The hypothesis that there is a different proportion between gender (stratified by roles) is rejected. Similarly, a chi-square test of difference between the expected proportion of roles (Swedish healthcare) and the sample could not be established. This indicates that the sample seem to be representative of the total population of Swedish healthcare. The following has been added to the manuscript "The distributions of gender and professions are in line with the total distributions in Swedish healthcare."

Minor issues
P3 explicates – is this the right word? Are the authors saying that it increases or intensifies the tension for change?

This has been changed to "intensifies".

P4 "Thirdly, there may be validity issues with patient involvement studies where academic dissemination is preceded …" Can this be explained differently as the meaning is unclear.

Thank you, this has been changed and hopefully clarified to: "Thirdly, there might be validity issues with patient involvement studies and therefore, more rigorous evidence of their outcome is desirable (15), for such studies to be confirmed and accepted as high-quality research."

VERSION 2 – REVIEW

REVIEWER	Elizabeth Fradgley Priority Research Centre for Cancer Research Innovation and Translation, University of Newcastle. Australia.
REVIEW RETURNED	31-May-2018

GENERAL COMMENTS	I appreciate the authors thoroughly considered all reviewers' comments, and strengthened the paper accordingly. I have no further suggestions.

REVIEWER	Kenneth L Miller, PT, DPT, GCS, CEEAA Adjunct Professor, Touro College, United States
REVIEW RETURNED	16-Jun-2018

GENERAL COMMENTS	The revised manuscript is much more clear and addresses concerns of this reviewer. I believe this is an important topic to be published. Just one recommendation prior to publication. Please review references for style. Reference #13 needs correction. Looks like a hybrid from AMA and APA. Please insure all references are properly formatted.

REVIEWER	Jill Stocks, Lecturer in Public Health University of Manchester, UK
REVIEW RETURNED	25-Jun-2018

GENERAL COMMENTS	I would like to thank the authors for responding to the comments appropriately and making the changes to the manuscript suggested by the reviewers. All my comments have been satisfactorily addressed. It is interesting work and I definitely recommend publication.