PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Women's experiences with using patient-reported outcome and experience measures in routine perinatal care in the Netherlands: a mixed methods study
AUTHORS	Laureij, Lyzette; Depla, Anne; Kariman, Shariva; Lamain-de Ruiter, Marije; Ernst -Smelt, Hiske; Hazelzet, Jan; Franx, Arie; Bekker, Mireille; Team, Buzz

VERSION 1 – REVIEW

REVIEWER	Claudia Bull Monash University, School of Public Health and Preventive Medicine
REVIEW RETURNED	08-Jun-2022

GENERAL COMMENTS	Reviewer comments on Patients' experiences with using PROM and PREM in routine perinatal care in the Netherlands: a mixed methods study Major comments: • The authors refer to 'patients' throughout this manuscript, when in fact they should be referring to 'women'. Please change this throughout the manuscript. • The manuscript would benefit from a much more detailed methods section. Please describe the broad implementation study and how this evaluative component fits into it. It reads as though you administered the ICHOM PBC set in this study, but because those results are not presented, that must not be the case. It took me several reads to figure out that this was a small part of a larger body of research. Please walk the reader through this. • Patient and public involvement statement (pg. 8): you have not described PPI; you have simply restated that women were involved in the research as participants, and the study was designed in close collaboration with care professionals. This is not PPI. Please revise this statement appropriately. PPI occurs when research is undertaken with or by consumers (women in your case), rather than 'to', 'about' or 'for' them (https://qualitysafety.bmj.com/content/25/8/626). • As a reader, it is really hard to engage with the results presented because there is no information provided about the ICHOM PBC set. How many surveys comprise the set? What concepts do they capture? How valid and reliable are the included surveys? How long are the surveys? This information is pertinent to understanding the results; particularly when you are discussing when women felt a topic was raised too early or too late. o Please also define what is a PROM and what is a PREM. • You state in your discussion that "its [the study's] results supported further implementation of the outcome set…" (p. 23, line 15), but then go on to discuss that there were clear discrepancies

	between women's care timelines and the relevance of PROM and PREM questions. Ultimately, this meant that some women did not find questions relevant because they were asked too early, or they missed the opportunity to talk about some questions because they were asked too late. This suggests to me that the ICHOM PBC set may not be relevant to women across the perinatal continuum. I suggest you propose recommendations for when the ICHOM PBC set should be administered along the perinatal continuum, or for making the ICHOM PBC set more relevant to women irrespective of what stage of the perinatal continuum they are in. Minor comments: • There is some poor English used throughout this manuscript e.g. "participants' average age was 34 years [29-39 years] and the majority was higher educated…" (pg. 14); "Four participants received perinatal care for the first time; they were pregnant of or had given birth to their first child." (pg. 14). Please check this as there are mistakes like this throughout. • Pg. 4: Can 'patient-reported experience measures' be included as one of the key words? • Pg. 6, sentence stating "In routine care, patients complete PROM and PREM…": PROMs and PREMs are not exclusively disease-specific questionnaires; there are generic PROMs and PREMs, as well as PREMs designed for specific patient populations (e.g., patients experiencing homelessness). Please revise this sentence and cite appropriate references. • Pg. 8 – setting: How were women sent the evaluation surveu to complete? Or did they complete it at while at an obstetric appointment? This information should be included. • Pg. 8 – setting: How were the care professionals trained to interpret and discuss the results of PROMs and PREMs? Was a standardized education approach used? This information should be included. • Pg. 8 – setting: How did implementation plans differ among OCNs? Was the study designed to allow flexibility in PROM and PREM implementation? This information should be included. • Pg. 22: Another strength of your research is that providing PROMs and PREMs – which essentially outlines what high-quality care looks like – can inform women about what high-quality care looks like. Providing this information can be empowering to women and help them craft perinatal journeys that align with their preferences and values. • Supplementary Figure 1a: Can you quantify what 'short', 'good', 'a lot', and 'too much' time is in minutes?

REVIEWER	Sabina De Rosis Scuola Superiore Sant'Anna, Institute of Management - Laboratorio Management e Sanità
REVIEW RETURNED	13-Jun-2022

GENERAL COMMENTS	I described above my concerns about generalizability. Please discuss the equity issues related to the selection bias and describe the selection bias in the results by adding the characteristics of the reference population and of the involved women. Otherwise, very special caution is needed about the extent to which generalizations can be made on the basis of these research findings. Page 25. There are other key PREMs and PROMs implemented in the perinatal care pathways, to be referenced here (i.e. see the works of Manila Bonciani in Italy). SUPPLEMENTARY. page 33 Table2: please add the characteristics

	of participants for time points and add further analysis and drop out/attrition rate)

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
4. Comment:
Thank you for the opportunity to review this manuscript entitled 'Patients' experiences with using PROM and PREM in routine perinatal care in the Netherlands: a mixed methods study', where the authors describe a mixed-methods study that evaluated the use of the ICHOM PBC Set across 7 obstetric care networks in The Netherlands.
I have suggested major revisions for this manuscript. I have attached my feedback to this submission for the authors to review.
Importantly, the authors need to more clearly articulate how this mixed-methods study fits within the broader implementation study. I had to read the manuscript several times to gauge that this was the case. The authors should spend more time in their methods section discussing the broader implementation study and its purposes, and how this evaluative study fits within it. I believe this will make it clearer to the reader the purpose of your study and better explain the results.

Response:
We thank the reviewer for her positive feedback and valuable comments on our manuscript. We agree with the reviewer that it may be hard to understand how this study was part of the larger project. Based on the individual reviewer's comments, we have revised the Method section to provide more clarity about this implementation project. Please see our responses to comment #6 and 8 for detailed changes made to the manuscript.

5. Comment:
The authors refer to 'patients' throughout this manuscript, when in fact they should be referring to 'women'. Please change this throughout the manuscript.

Response:
We agree with the reviewer that the term 'patients' is not correct in this manuscript and changed this into 'women' throughout the manuscript, including its title.

6. Comment:
The manuscript would benefit from a much more detailed methods section. Please describe the broad implementation study and how this evaluative component fits into it. It reads as though you administered the ICHOM PBC set in this study, but because those results are not presented, that must not be the case. It took me several reads to figure out that this was a small part of a larger body of research. Please walk the reader through this.

Response:
We thank the reviewer for addressing this issue and have rewritten the Method section, added a Table, and provided a Figure to improve the readability and clarity of the manuscript. Please refer also to our responses to comment #8.
"Alongside the implementation project in clinic, this study was performed to evaluate women's experiences with this innovation in routine care. The implementation project aimed integration of the PCB Set into routine perinatal care, i.e. that women were invited to complete PROMs and PREMs and discuss them with their care professional as part of routine perinatal care at five time points during their pregnancy or postpartum period. At these time points, different care professionals may have been responsible for the participants' health (see Figure 1). Women received an information leaflet regarding the purpose of the PROM and PREM before filling out their first PROM and PREM questionnaire and could complete the questionnaires digitally at home. Care professionals were

informed about the content of the PCB Set (Figure 2) and how to interpret the results. Training on how to discuss the outcomes was available if needed. Care professionals discussed the results of the PROM and PREM during the next regular visit directly after each time point, also at six months postpartum. Implementation plans differed among the OCNs to enhance local implementation; OCNs collected PROM and PREM during at least one time point, this was not necessarily time point 1 (see Table 1).” (page 7, lines 142-157)

7. Comment:
Patient and public involvement statement (pg. 8): you have not described PPI; you have simply restated that women were involved in the research as participants, and the study was designed in close collaboration with care professionals. This is not PPI. Please revise this statement appropriately. PPI occurs when research is undertaken with or by consumers (women in your case), rather than ‘to’, ‘about’ or ‘for’ them (https://qualitysafety.bmj.com/content/25/8/626).

Response:
We understand that the PPI as described originally raised questions on the involvement of women. For this study, women are the main participants and for the implementation project, we have built on important results that women have highlighted in our previous research. We have rewritten the PPI statement in the Method section:
“Both the clinical implementation project and this study were a continuation of previous projects that actively involved women as important stakeholders, which resulted in changes into the Dutch PCB Set as well as facilitators and barriers to be addressed during the implementation of the PCB Set in routine care. In this study, we sent out a survey and conducted interviews with women. The study was designed in close collaboration with care professionals, while taking into account previous findings from surveys, interviews and focus group interviews with women.[10, 11, 14]” (pages 8-9, lines 187-194).

8. Comment:
As a reader, it is really hard to engage with the results presented because there is no information provided about the ICHOM PBC set. How many surveys comprise the set? What concepts do they capture? How valid and reliable are the included surveys? How long are the surveys? This information is pertinent to understanding the results; particularly when you are discussing when women felt a topic was raised too early or too late.

Response:
We understand the concerns raised by the reviewer. We have added a figure (“Figure 2”) and a table (“Table 1”) to address the reviewer’s questions. Please see Figure 2 for the domains of the PCB set, with the timing and length of the questionnaires to capture them (title and legend on page 8, figure uploaded separate from the manuscript). Table 1 provides information on which time points were implemented in clinical care of the OCNs (page 8).

9. Comment:
Please also define what is a PROM and what is a PREM.

Response:
We thank the reviewer for addressing this unclarity. We have added the definition of PROM and PREM in the Introduction:
“PROM and PREM are defined as information that is provided by patients concerning the impact of their condition, disease or treatment on their health and functioning.[1, 2]” (page 5, lines 98-100)
Additionally, in our new Figure 2 (please refer also to our response on comment #8) we have explained which domains of the PCB set are defined as PROM and which as PREM.

10. Comment:
You state in your discussion that “its [the study’s] results supported further implementation of the outcome set…” (p. 23, line 15), but then go on to discuss that there were clear discrepancies between women’s care timelines and the relevance of PROM and PREM questions. Ultimately, this meant that some women did not find questions relevant because they were asked too early, or they missed the opportunity to talk about some questions because they were asked too late. This suggests to me that the ICHOM PBC set may not be relevant to women across the perinatal continuum. I suggest you propose recommendations for when the ICHOM PBC set should be administered along the perinatal continuum, or for making the ICHOM PBC set more relevant to women irrespective of what stage of the perinatal continuum they are in.

Response:
We appreciate the reviewer’s sharp and valuable comment, we share these concerns. In response, we have added our recommendations for this issue in the Discussion section and have added a reference to our recent publication about the PROM and PREM outcomes captured in this implementation study in clinic (not published yet when we submitted this manuscript).
“Synchronising the time points of the PCB set with routine perinatal care pathways may solve this barrier. Based on compliance to the PROM and PREM and results of the PROM and PREM, concrete recommendations to adapt the PCB set’s content and timeline have been suggested in a recent publication, and are in accordance with women’s experiences found in this evaluation study. [3]” (page 24, lines 442-446)
In addition, we described recommendations to implement PROM and PREM in general across the perinatal care continuum in the original discussion section below ‘Future research and implications’. (page 25-26, lines 484-491)

11. Comment:
There is some poor English used throughout this manuscript e.g. “participants’ average age was 34 years [29-39 years] and the majority was higher educated…” (pg. 14); “Four participants received perinatal care for the first time; they were pregnant of or had given birth to their first child.” (pg. 14). Please check this as there are mistakes like this throughout.

Response:
We appreciate the reviewer has acknowledged these mistakes. We have checked this throughout the manuscript and made changes accordingly to improve the English.

12. Comment:
Pg. 4: Can ‘patient-reported experience measures’ be included as one of the key words?

Response:
We have included this term into the ‘Key words’ section (page 4).

13. Comment:
Pg. 6, sentence stating “In routine care, patients complete PROM and PREM…”: PROMs and PREMs are not exclusively disease-specific questionnaires; there are generic PROMs and PREMs, as well as PREMs designed for specific patient populations (e.g., patients experiencing homelessness). Please revise this sentence and cite appropriate references.

Response:

We agree with the reviewer that PROM and PREM are not exclusively disease-specific questionnaires and changed this in the Introduction section. In line with the response on comment #9, we have added a clearer definition of PROM and PREM.
“PROM and PREM are defined as information that is provided by patients concerning the impact of their condition, disease or treatment on their health and functioning.[1,2] In routine care, patients complete PROM and PREM via standardised questionnaires – both generic and disease specific- between visits to care professionals.” (page 5, lines 98-102)

14. Comment:
Pg. 8 – setting: How were women sent the evaluation survey to complete? Or did they complete it at while at an obstetric appointment? This information should be included.

Response:
We thank the reviewer for addressing this. In addition to our original description in the Methods section below ‘Data Collection’, we have changed the Method section below ‘Participants’ to provide more clarity on the survey invitation:
“Women were invited to participate in this study via a digital link immediately after filling out a PROM/PREM questionnaire at home.” (page 9, lines 204-205)
Furthermore, we hope that the adaptations made to the subsection ‘Setting’, described at comment 6, can provide sufficient clarity on the timeline of PROM and PREM completion.

15. Comment:
Pg. 8 – setting: How were the care professionals trained to interpret and discuss the results of PROMs and PREMs? Was a standardized education approach used? This information should be included.

Response:
We agree with the reviewer that we have not elaborated on the training of the care professionals in this project. We made some changes in the Method section Setting:
“Care professionals were informed about the content of the PCB Set (Figure 2) and how to interpret the results. Training on how to discuss the outcomes was available if needed.” (page 7, lines 150-152)
The information and available training were part of the implementation project and were adapted to fit the local implementation strategy. The training on how to discuss PROM and PREM was offered optionally, as the questionnaires address topics that are already part of routine perinatal care and many care professionals therefore felt skilled to discuss them without additional training.

16. Comment:
Pg. 8 – setting: How did implementation plans differ among OCNs? Was the study designed to allow flexibility in PROM and PREM implementation? This information should be included.

Response:
We recognize this information should be included. The PCB set and its timeline were maintained as proposed, but the OCNs were in charge of their implementation process to fit clinical practice and thereby enhance implementation since it was primarily an implementation project to change clinical practice. Please refer to our responses on comments #6 and 8 for our adaptations to the manuscript to clarify this.

17. Comment:
Pg. 22: Another strength of your research is that providing PROMs and PREMs – which essentially outlines what high-quality care looks like – can inform women about what highquality care looks like. Providing this information can be empowering to women and help

them craft perinatal journeys that align with their preferences and values.

Response:
We thank the reviewer for bringing up this strength of our research. We added this in the Discussion session:
“Accordingly, by providing PROMs and PREMs throughout pregnancy and the postpartum period, women can become aware of what high-quality care encompasses, and complications or symptoms that can occur. This awareness can empower women and support them to adjust their care pathway to their individual preferences and values.” (page 22, lines 400-403)

18. Comment:
Supplementary Figure 1a: Can you quantify what ‘short’, ‘good’, ‘a lot’, and ‘too much’ time is in minutes?

Response:
We understand the question raised. Yet these were the original answer options: women were asked to indicate how they experienced the time to completing the PROMs and PREMs, because we meant to assess the experienced burden of completing them. Therefore, we did not ask to indicate the amount of time that was spent on completing them.

Reviewer 2:
19. Comment:
I described above my concerns about generalizability. Please discuss the equity issues related to the selection bias and describe the selection bias in the results by adding the characteristics of the reference population and of the involved women. Otherwise, very special caution is needed about the extent to which generalizations can be made on the basis of these research findings.

Response:
We appreciate the reviewer’s comments on our manuscript. We agree that caution is necessary regarding generalizability of the results of our study because of selection bias, which was addressed as limitation in the original Discussion section (page 22-23, lines 407-411). In response to the reviewers comment we have added the consequences of this limitation for interpreting the results and future implementation of PROM and PREM:
“This limitation should be taken into account when interpreting our findings and stresses the importance of future efforts to engage all women when implementing PROM and PREM to prevent further health inequities.” (page 23, lines 411-414)
As this was, to our knowledge, the first attempt to integrate PROM and PREM in clinic to guide individual care, the scope of this paper was to provide insights into the experiences of women with this new type of routine perinatal care. We believe that for the aim of this study a reference population is not applicable. Therefore, we feel that the limitations of the generalizability of our results have been highlighted sufficiently now.

20. Comment:
Page 25. There are other key PREMs and PROMs implemented in the perinatal care pathways, to be referenced here (i.e. see the works of Manila Bonciani in Italy).

Response:
We appreciate that the reviewer has highlighted a recent and important paper about the PCB set’s PROM and PREM (Ferrari 2022 in Int J Gynaecol Obstet.). We are aware of this study, which contributes to the growing global knowledge about the PCB Set’s measures, their validation and reference values. In contrast to the setting and scope of our study, this paper did not describe integration of PROM and PREM in clinic to guide individual care. We have also reviewed Manila

Boncianci's other papers (e.g., in JMIR Med Inform 2022, Healthcare Papers 2017) with great interest, but remain unaware of publications regarding PROM/PREM integration to guide individual care, as those papers addressed aggregated PROM/PREM use for quality purposes. In response to the reviewer's comment, we have clarified this further in the Discussion section of our manuscript: "Although challenging in terms of inter-organisational collaboration and IT infrastructure, this project was one of the first to attempt system wide implementation of PROM and PREM as a standard part of individual perinatal care to guide individual care and personalised care pathways." (page 25, lines 474-477)

21. Comment:
SUPPLEMENTARY. page 33 Table2: please add the characteristics of participants for time points and add further analysis and drop out/attrition rate)

Response:
We would like to refer to our reply to comment #3 (from the editor) regarding response rates per time point. In addition, characteristics of participants have not been collected since the survey was anonymously sent out to decrease the response burden (and response bias) in women who already had completed the full PROM and PREM questionnaire. However, we understand the need to clarify this in the manuscript and have therefore changed the Method section below 'Data collection':
"This anonymous survey was offered to participants via a digital link directly after completing their PROM and PREM. One OCN collected this evaluation survey on paper. No case mix questions were asked to minimise response burden for women who had already completed the PROM and PREM questionnaire." (page 9-10, lines 215-218)

VERSION 2 – REVIEW

REVIEWER	Claudia Bull Monash University, School of Public Health and Preventive Medicine
REVIEW RETURNED	15-Sep-2022

GENERAL COMMENTS	I commend the authors on the research they have undertaken and appreciate the care they have given to addressing my comments. In particular, the addition of Table 1, Figures 1 and 2, and additional methods section content make the methods very clear. I am satisfied that this study is suitable for publication and makes an important contribution to the literature.

REVIEWER	Sabina De Rosis Scuola Superiore Sant'Anna, Institute of Management - Laboratorio Management e Sanità
REVIEW RETURNED	19-Oct-2022

GENERAL COMMENTS	Dear Authors, Congratulations for your manuscript. I think that the corrections that you been made to the article provide a better understanding of women's engagement. The description of the implementation phase and the elements that clarify your methodology have improved your work. I just ask you to briefly illustrate the practical implications of your research, at the academic, clinical, and managerial levels, particularly in terms of uptake of the people perspective. With kind regards,

VERSION 2 – AUTHOR RESPONSE

Response to reviewers:

We thank the reviewers for their congratulations and appreciate to hear that our changes have improved the clarity of our work.

Response to reviewer 2 (“I just ask you to briefly illustrate the practical implications of your research, at the academic, clinical, and managerial levels, particularly in terms of uptake of the people perspective”): We thank the reviewer for highlighting this relevant information. Several practical implications derived from our work are described already in the ‘future research and implications’ section in the discussion. In response to this comment, we have added the general implications in terms of uptake of the people perspective at different levels to the same section (page 26, lines 475-479).