PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A mixed-methods investigation of health consumers' perception and experience of participation in patient safety activities
AUTHORS	Lee, Nam-Ju; Ahn, Shinae; Lee, Miseon

VERSION 1 – REVIEW

REVIEWER	Justin Waring University of Birmingham, UK
REVIEW RETURNED	03-Dec-2019

GENERAL COMMENTS	The paper addresses an important issue but it is currenlty too vague and imprecise in its focus, design and reporting. The following comments and suggestions may help: The aim is a little unclear. What is meant by involvement in healthcare, please define and give an example, so the reader understands your meaning. Again, a few examples of empowerment might be useful. What do you mean by 'factors that influence patient participation' - do these operate on different dimensions, e.g. knowledge and skill,, belief and value, willingness and motivation; through to opportunity and support; time and resources etc. This is important showing how the study is different from existing research that focus in willingness. I cannot comment on the rigour of the survey design and statistical procedure. More information is required about the focus groups, including structure and facilitation, recruitment and data collection and analysis The findings from the focus group seem very general, i.e. about involvement in general and not really about involvement in safety related issues. Again this highlights a sense of vagueness in the study design. There is a lack of primary qualitatative data to demonstrate the views of participants The discussion is not focused sufficiently on the primary issue or question - which seems a problem for the paper in general - it needs to be kept more focused on the specific challenges for involvement in safety related activities.

	Some of the limitations around recruitment and design might be made more explicit.

REVIEWER	Prof, Mojtaba Vaismoradi Nord University, Norway.
REVIEW RETURNED	04-Dec-2019

GENERAL COMMENTS	Thank you for the submission of Your article to this journal. Here they are my comments: Abstract Under the main outcome measures, nothing about the qualitative study has been said. Also, the overal outcome of the mixed-methods study should be described. The approach of data analysis for qualitative data should be recognised before the results. The results must include the overal findings of the mixed-methods study rather than each substudy. Introduction Please add a breif review of similar studies conducted in your own context. That would be needed to show the gap in the literature that motivated you to conduct this study. Methods What was the reason that you chose a mixed-methods approach. It should be supported using literature. The type of mixed-methods used in your study should be described. What was the reason that a qualitaive study was performed after the survey? How did you plan to connect the study phases as 'survey' and 'focus group' as is the main aim of conducting a mixed-methods design? Since both qualitative and quantitative data analysis have been used, the heading should be changed to 'data analysis' in stead of 'Statistical analysis'. The process of recruitment of samples for the Focus group, holding sessions, and group dynamics should be described. More datails on the qualitative data analysis should be added to the text. There must be a section at the end of the results as an interpretation indicating the connection of the results of qualitative and quantitative studies as is the aim of the mixed-methods design. A figure would be fine to summarise the steps taken in the methods. Discussion You should present the results of each study phase here and compare them with those of international studies. When you compare your findings, the degree and quality of similarity With those of other studies should be described in detail. You should discuss the qualitative and quantitative findings Conclusion The practical implications for education, future Research and policy making should be added.

REVIEWER	Jason Scott Northumbria University, UK
REVIEW RETURNED	10-Dec-2019

GENERAL COMMENTS	I found this to be an excellently written article that was very interesting to read. The methods are described in detail, allowing for replication, and the findings are reported concisely and cohesively, which can be challenging when reporting mixed

	methods research. I only have a few minor comments to improve the article before I can recommend it for publication: 1. In the second paragraph of the introduction, please make it clear which country the policies relate to so that the article is more accessible to an international audience. 2. In the methods (participants and data collection), the websites through which participants are recruited are provided. Some additional brief explanation here would be beneficial for an international audience, for instance are these official government / health service websites or websites of private providers? Is there any data you can cite on who uses these sites? I am pleased however to see that the limitation of recruiting from these websites is appropriately acknowledged in the discussion. 3. Please include in the methods sections which language the focus groups were completed in. If they were conducted in a non-English language, please state at what point translation (for the quotes) was completed. Also please specify which authors conducted the focus groups and analysed the qualitative data. 4. In the results (participant characteristics), you provide the mean age of 31.7 years. Please also include the standard deviation here as well. 5. Overall I thought that the introduction and discussion provided a decent overview of the literature, however there is much more literature on the topic that I believe should be included in both sections.This literature covers the wider concepts surrounding patient involvement in safety, such as who is perceived to have responsibility for safety by patients. At present, these debates are not really covered. Heavey, E., Waring, J., et al. (2019). Patients' Conceptualizations of Responsibility for Healthcare: A Typology for Understanding Differing Attributions in the Context of Patient Safety. Journal of Health and Social Behavior, 60(2), 188-203. doi: 10.1177/0022146519849027 Fisher, K. A., Smith, K. M., et al. (2019). We want to know: patient comfort speaking up about breakdowns in care and patient experience. BMJ Quality & Safety, 28(3), 190-197. doi: 10.1136/bmjqs-2018-008159 Weingart, S. N., Weissman, J. S., et al. (2017). Implementation and evaluation of a prototype consumer reporting system for patient safety events. International Journal for Quality in Health Care, 1-6. doi: doi: 10.1093/intqhc/mzx060 De Brún, A., Heavey, E., et al. (2017). PReSaFe: A model of barriers and facilitators to patients providing feedback on experiences of safety. Health Expectations, 20(4), 771-778. doi: 10.1111/hex.12516 Sahlström, M., Partanen, P., et al. (2016). Patient participation in patient safety still missing: Patient safety experts' views. International Journal of Nursing Practice, 22(5), 461-469. doi: 10.1111/ijn.12476 Etchegaray, J. M., Ottosen, M. J., Aigbe, A., Sedlock, E., Sage, W. M., Bell, S. K., . . . Thomas, E. J. (2016). Patients as Partners in Learning from Unexpected Events. Health Services Research, n/a-n/a. doi: 10.1111/1475-6773.12593

	Hrisos, S., & Thomson, R. (2013). Seeing It from Both Sides: Do Approaches to Involving Patients in Improving Their Safety Risk Damaging the Trust between Patients and Healthcare Professionals? An Interview Study. PLoS ONE, 8(11), e80759. doi: 10.1371/journal.pone.0080759

VERSION 1 – AUTHOR RESPONSE

Reviewer #1

Comment 1: The aim is a little unclear.

Response 1: We revised the objectives in the abstract and introduction to clarify the purpose of this study, as follows (Abstract; page 6, line 11-15).

Objectives
This study aimed to examine the factors influencing patient safety behaviors and to explore health customers' experiences of patient participation in the healthcare system.

Thus, in this study, we investigated health consumers' extent of willingness to participate in safety activities, their recognition of the importance of their participation, and their experience of participating in patient safety activities through the survey. Also, we explored the healthcare consumers' experience of patient participation and factors influencing the experience of engaging in healthcare behaviors in depth.

Comment 2: What is meant by involvement in healthcare, please define and give an example, so the reader understands your meaning. Again, a few examples of empowerment might be useful.

Response 2: In the introduction section, we added one paragraph describing the concept of patient participation and the extent of patient safety activities in which patients could participate. And we described examples of safety activities that patients could participate in while receiving care (page 4, line 7-19).

Comment 3: What do you mean by 'factors that influence patient participation' - do these operate on different dimensions, e.g. knowledge and skill, belief and value, willingness and motivation; through to opportunity and support; time and resources etc. This is important showing how the study is different from existing research that focus in willingness.

Response 3-1: In the quantitative analysis, we chose the variables based on the literature review, and we described the results of multiple linear regression to examine the relationship of the experience of patient participation with the variables, as follows (page 8, line 22 to page 9, line 3; page 12, line 4-6).

To explore the factors influencing patient participation, we grouped variables into the following three categories based on a literature review15 18 23-25: patient-related (willingness to participate, recognition of the importance of patient participation, and socio-demographic variables), illness-related (number of visits to medical institutions and prior experience of patient safety incidents), and healthcare environment-related (types of medical institutions).

Multiple linear regression was used to examine the relationship of the experience of patient participation with three sets of factors: patient-related, illness-related, and healthcare environment-related (Table 4).

Response 3-2: We conducted a novel analysis of our qualitative data. The results of the content analysis produced three themes affecting patient participation: patient-related factors, factors involving the relationship between patients and healthcare providers, and healthcare environment factors (Table 5, page 12 line 13 to page 14, line 18).

Response 3-3: We added integrated results of both quantitative and qualitative data on factors influencing patient participation, in the results section, as follows (page 14, line 20-24).

By integrating the results of the quantitative and qualitative data analysis, this study showed that the factors influencing patient participation in medical institutions could be categorized into four factors: patient-related factors, illness-related factors, factors involving the relationship between patients and healthcare providers, and healthcare environment factors.

Response 3-4: In discussion section, we discussed the overall qualitative and quantitative findings about factors that influence patient participation (page 15 to page 18).

Comment 4: More information is required about the focus groups, including structure and facilitation, recruitment and data collection and analysis

Response 4: In the participants and data collection section and data analysis section, we added more details about the focus group interviews including structure, facilitation, recruitment, interview process, main interview questions for data collection, and data analysis. And we specified the authors' roles in the focus group interviews and analysis (page 7, line 19 to page 8, line 13; page 10, line 1-4).

Comment 5: The findings from the focus group seem very general, i.e. about involvement in general and not really about involvement in safety related issues. Again this highlights a sense of vagueness in the study design.
There is a lack of primary qualitative data to demonstrate the views of participants

Response 5: We conducted a new analysis of our qualitative data in light of the reviewer's comment. We applied more focus on safety-related issues of patient participation and added primary qualitative quotes (Table 5; page 12, line 13 to page 14, line 18).

Comment 6: The discussion is not focused sufficiently on the primary issue or question - which seems a problem for the paper in general - it needs to be kept more focused on the specific challenges for involvement in safety related activities.

Response 6: We revised the discussion section based on our research objectives and findings, which focused on factors influencing patient participation. And we revised the discussion focus more on patient participation in safety activities (page 15 to page 18).

Comment 7: Some of the limitations around recruitment and design might be made more explicit.

Response 7: We revised the limitations more explicitly (page 18, line 16-23).

Reviewer #2

Comment 1: Abstract:
Under the main outcome measures, nothing about the qualitative study has been said. Also, the overall outcome of the mixed-methods study should be described.

The approach of data analysis for qualitative data should be recognized before the results.
The results must include the overall findings of the mixed-methods study rather than each substudy.

Response 1: We revised the abstract according to the reviewers' comments (Abstract).

Comment 2: Introduction:
Please add a brief review of similar studies conducted in your own context. That would be needed to show the gap in the literature that motivated you to conduct this study.

Response 2: We revised introduction section. We added more sentences through the review of similar previous studies to clarify the exact reasons why we conducted this study. Also, we added one paragraph describing the concept of patient participation and the range of patient safety activities in which patients could participate. And we described examples of safety activities that patients could participate in while receiving care (page 4 to page 6, line 15).

Comment 3: Methods:
What was the reason that you chose a mixed-methods approach. It should be supported using literature. The type of mixed-methods used in your study should be described.
What was the reason that a qualitative study was performed after the survey? How did you plan to connect the study phases as 'survey' and 'focus group' as is the main aim of conducting a mixed-methods design?

Response 3-1: We added some sentences and citations of previous literature to provide support for the reason that we used a mixed-methods approach, as follows (page 6, line 4-10).

A mixed-methods design has the advantage of not only producing a measure of experience of participation but also deeply exploring patients' perspectives about patient participation. However, there is a lack of studies focusing on patient participation using mixed methods. To examine the factors influencing actual participation in various safety practices or to investigate the relationship between intention and actual behavior, the need for a qualitative focus group interview or a mixed method using quantitative and qualitative approaches has been suggested.15 16

Response 3-2: We described the type of mixed-methods design in the study design section and added a sentence providing the reason we performed the focus group interviews after the survey, as follows (page 6, line 19-22).

This study used a mixed-methods sequential explanatory design including a survey and focus group interviews. According to this design proposed by Creswell and Zhang,22 we gathered and analyzed quantitative data first, and then used qualitative data collection and analyzed that qualitative data later to help explain the quantitative results.

Response 3-3: We added integrated results of both quantitative and qualitative data on factors influencing patient participation, to the results section, as follows (page 14, line 20-24).

By integrating the results of the quantitative and qualitative data analysis, this study showed that the factors influencing patient participation in medical institutions could be categorized into four factors: patient-related factors, illness-related factors, factors involving the relationship between patients and healthcare providers, and healthcare environment factors.

Response 3-4: In order to overcome the weakness of a single quantitative design, and to explore participants' experiences of patient participation, we used a mixed-methods approach in our study. We discussed the interpretation of the overall qualitative and quantitative findings about factors that

influence patient participation (page 15 to page 18).

Comment 4: Since both qualitative and quantitative data analysis have been used, the heading should be changed to 'data analysis' instead of 'Statistical analysis'.

Response 4: We changed the sub-heading ‘Statistical analysis’ to ‘Data analysis’ (page 9, line 13).

Comment 5: The process of recruitment of samples for the Focus group, holding sessions, and group dynamics should be described. More details on the qualitative data analysis should be added to the text.
There must be a section at the end of the results as an interpretation indicating the connection of the results of qualitative and quantitative studies as is the aim of the mixed-methods design.

Response 5-1: In the participants and data collection section and data analysis section, we added more details about focus group interviews including recruitment, holding the sessions, group dynamics, the interview process, the main interview questions for data collection, and the data analysis. And we specified the authors who conducted the focus group interview and analysis (page 7, line 19 to page 8, line 13; page 10, line 1-4).

Response 5-2: We added integrated results of both quantitative and qualitative data on factors influencing patient participation, in the results section, as follows (page 14, line 20-24).

By integrating the results of the quantitative and qualitative data analysis, this study showed that the factors influencing patient participation in medical institutions could be categorized into four factors: patient-related factors, illness-related factors, factors involving the relationship between patients and healthcare providers, and healthcare environment factors.

Comment 6: A figure would be fine to summarize the steps taken in the methods.

Response 6: We added a flow diagram to summarize the steps (Supplementary figure 1).

Comment 7: Discussion:
You should present the results of each study phase here and compare them with those of international studies.
When you compare your findings, the degree and quality of similarity. With those of other studies should be described in detail.
You should discuss the qualitative and quantitative findings

Response 7: We revised the discussion section based on our quantitative and qualitative findings which focused on factors influencing patient participation. We added new sentences that compare our findings with previous studies in the discussion section, and also added references that can support the sentences (page 15 to page 18; reference list).

Comment 8: Conclusion:
The practical implications for education, future Research and policy making should be added.

Response 8: We revised the conclusion to address the results and added implications for education, future research and policy suggestions (page 19, line 1-15).

Reviewer #3

Comment 1: In the second paragraph of the introduction, please make it clear which country the policies relate to so that the article is more accessible to an international audience.

Response 1: We added country and sentences to explain international efforts for patient safety and quality of care (page 4, line 20 to page 5, line 6)

Comment 2: In the methods (participants and data collection), the websites through which participants are recruited are provided. Some additional brief explanation here would be beneficial for an international audience, for instance are these official government / health service websites or websites of private providers? Is there any data you can cite on who uses these sites? I am pleased however to see that the limitation of recruiting from these websites is appropriately acknowledged in the discussion.

Response 2: We added a brief description of the websites (page 7, line 5-12).

Comment 3: Please include in the methods sections which language the focus groups were completed in. If they were conducted in a non-English language, please state at what point translation (for the quotes) was completed. Also please specify which authors conducted the focus groups and analyzed the qualitative data.

Response 3-1: We used the Korean language in our study and the target population was Korean people who speak Korean. We added about a specific description of the target population, as follows (page 7, line 4-5).

The target population comprised Korean-speaking Korean adults aged 19 years or older who had visited a medical institution within the most recent one year.

Response 3-2: We specified the authors who conducted the focus group interviews and analysis, as follows (page 7, line 24 to page 8, line 2; page 10, line 1-4).

Each interview involved all of the researchers. Two researchers (NL or SA) of the research team each facilitated one of the focus group interviews, and one researcher (ML) played a role as a note taker to produce accurate notes while assisting with the interviews.

One researcher (SA) led the first analysis by reading the transcript repeatedly, and two researchers (NL, ML) performed a second review. Emergent themes were discussed in depth, then the researchers extracted codes, categories, and themes together during content analysis until agreement was reached.

Comment 4: In the results (participant characteristics), you provide the mean age of 31.7 years. Please also include the standard deviation here as well.

Response 4: We added standard deviation to the results and Table 1, as follows (page 10, line 14; Table 1).
The mean age of the respondents was 31.7 years (SD: 10.52), 74.8% of respondents were female, most had graduated from college or above (n=373, 75.8%), and most were unmarried (n=310, 63.0%).

Comment 5: Overall I thought that the introduction and discussion provided a decent overview of the literature, however there is much more literature on the topic that I believe should be included in both sections. This literature covers the wider concepts surrounding patient involvement in safety, such as who is perceived to have responsibility for safety by patients. At present, these debates are not really covered.

Heavey, E., Waring, J., et al. (2019). Patients' Conceptualizations of Responsibility for Healthcare: A Typology for Understanding Differing Attributions in the Context of Patient Safety. Journal of Health and Social Behavior, 60(2), 188-203. doi: 10.1177/0022146519849027

Fisher, K. A., Smith, K. M., et al. (2019). We want to know: patient comfort speaking up about breakdowns in care and patient experience. BMJ Quality & Safety, 28(3), 190-197. doi: 10.1136/bmjqs-2018-008159

Weingart, S. N., Weissman, J. S., et al. (2017). Implementation and evaluation of a prototype consumer reporting system for patient safety events. International Journal for Quality in Health Care, 1-6. doi: doi: 10.1093/intqhc/mzx060

De Brún, A., Heavey, E., et al. (2017). PReSaFe: A model of barriers and facilitators to patients providing feedback on experiences of safety. Health Expectations, 20(4), 771-778. doi: 10.1111/hex.12516

Sahlström, M., Partanen, P., et al. (2016). Patient participation in patient safety still missing: Patient safety experts' views. International Journal of Nursing Practice, 22(5), 461-469. doi: 10.1111/ijn.12476

Etchegaray, J. M., Ottosen, M. J., Aigbe, A., Sedlock, E., Sage, W. M., Bell, S. K., . . . Thomas, E. J. (2016). Patients as Partners in Learning from Unexpected Events. Health Services Research, n/a-n/a. doi: 10.1111/1475-6773.12593

Hrisos, S., & Thomson, R. (2013). Seeing It from Both Sides: Do Approaches to Involving Patients in Improving Their Safety Risk Damaging the Trust between Patients and Healthcare Professionals? An Interview Study. PLoS ONE, 8(11), e80759. doi: 10.1371/journal.pone.0080759

Response 5: We thoroughly reviewed the articles that the reviewers suggested we cite, and updated literature review in the introduction. We revised the discussion sections by adding the articles to compare with our results or support our results and updated the list of references (Introduction, Discussion, reference list).

Additional change:

We added one sentence to the report of the quantitative results, as follows (page 11, line 2-4)

Among this study's findings on patient safety activities, average scores were as follows: recognition of the importance (3.27±0.51), the extent of willingness (2.62±0.52), and the experience of participation (2.13±0.63).

VERSION 2 – REVIEW

REVIEWER	Justin Waring University of Birmingham, UK
REVIEW RETURNED	28-Jan-2020

GENERAL COMMENTS	The authors have responded clearly and in full to my comments. I have one last concern related to the limitations of the study which stem from not involving patients or public in the design of the study. I think this merits more discussion in the limitations and in the discussion?

REVIEWER	Prof, Mojtaba Vaismoradi Nord University, Bodø, Norway.
REVIEW RETURNED	09-Jan-2020

GENERAL COMMENTS	The reviewer completed the checklist but made no further comments.

REVIEWER	Jason Scott Northumbria University, UK
REVIEW RETURNED	15-Jan-2020

GENERAL COMMENTS	The authors have made substantial changes to the paper following feedback. The paper is much improved as a result. There are a few further issues that require attention: 1. In the abstract (results), average scores are referred to. Please include these average scores (importance, willingness, experience). 2. Table 2 has been edited to include mean and standard deviation for age. Where this is placed makes it look like it only applies to the category 19-29. Perhaps move this into column 1 rather than having its own column? 3. Table 3 is very well presented. If there is no specific reason for the current order of the columns, I suggest that you swap them around so that they are presented in the order of 'Recognition of importance', 'Extent of willingness', then 'Experience of Participation'. This would be more logical, but I understand if you decide to leave it alone if the current order reflects how it is described in the methods and presumably the survey structure itself. The same point applies to other tables too. 4. Throughout the paper please change 'interviews' to 'focus groups' Note for editors: I'm unable to review and comment on the documents written in Korean.

VERSION 2 – AUTHOR RESPONSE

Reviewer #1

Comment 1: The authors have responded clearly and in full to my comments. I have one last concern related to the limitations of the study which stem from not involving patients or public in the design of the study. I think this merits more discussion in the limitations and in the discussion?

Response 1: We described the characteristics of our participants by comparing with the national public data in terms of the number of visits to medical institutions and discussed the possibility that the characteristics of these participants may influence the results of the study and the limitations of generalization. Additionally, we added suggestions for future research based on the limitations of this study (page 18, line 11-21; page 19, line 11-14).

Reviewer #3

Comment 1: In the abstract (results), average scores are referred to. Please include these average scores (importance, willingness, experience).

Response 1: We added average scores in the results of the abstract, as follows (Abstract; page 2, line 22-24).
The average score for experience of participation in patient safety behaviors (2.13±0.63) was found to be lower than those of recognition of the importance of participation (3.27±0.51) and willingness to participate (2.62±0.52).

Comment 2: Table 2 has been edited to include mean and standard deviation for age. Where this is placed makes it look like it only applies to the category 19-29. Perhaps move this into column 1 rather than having its own column?

Response 2: This comment seems to be referring to Table 1. We moved the mean and standard deviation for age into column 1 (page 25, Table 1).

Comment 3: Table 3 is very well presented. If there is no specific reason for the current order of the columns, I suggest that you swap them around so that they are presented in the order of 'Recognition of importance', 'Extent of willingness', then 'Experience of Participation'. This would be more logical, but I understand if you decide to leave it alone if the current order reflects how it is described in the methods and presumably the survey structure itself. The same point applies to other tables too.

Response 3: We changed the order to 'Recognition of importance', 'Extent of willingness', then 'Experience of Participation' throughout the abstract, manuscript, and tables (page 2, line 16-17; page 2, line 22-24; page 6, line 11-13; page 8, line 24 to page 9, line 1; page 9, line 4-7; page 9, line 15-21; page 12, line 3-4; page 15, line 10-11; page 26-30, Table 2-4).

Comment 4: Throughout the paper please change ‘interviews’ to ‘focus groups’

Response 4: We changed ‘interviews’ to ‘focus groups’ or ‘focus group interviews’ to clarify the meaning (page 2, line 14; page 7, line 21-22; page 8, line 3; page 10, line 1-2).