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PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Using patient reported outcome measures (PROMs) to promote quality of care in the management of patients with established kidney disease requiring treatment with haemodialysis in the United Kingdom (PROM-HD) – A qualitative study protocol.
AUTHORS	Anderson, Nicola; Calvert, Melanie; Cockwell, Paul; Dutton, Mary; Aiyegbusi, Olalekan; Kyte, Derek

VERSION 1 – REVIEW

REVIEWER	Kara Schick-Makaroff Faculty of Nursing, University of Alberta, Canada
REVIEW RETURNED	25-Feb-2018

GENERAL COMMENTS	**Using patient reported outcome measures (PROMs) to promote quality of care and safety in the measurement of patients with established kidney disease requiring treatment with haemodialysis (PROM HD) – A qualitative study protocol** Thank you for the opportunity to review your manuscript. The use of PROMs in routine clinical dialysis care is, for the most part, an unexplored field. I believe that this paper will be a valuable contribution to the literature and of great interest to the readers of BMJ Open. Below you will find my specific comments on the paper. Overall The paper is very well written and a pleasure to read. The most important recommendation explained below, which I consider a requirement for publication, is identification of the specific qualitative methodology that will guide your study. Title How does “safety” tie into the concepts addressed in this study? Introduction In the first paragraph, do the statistics include home hemodialysis (or just in-centre /hospital /satellite dialysis)? Study Objectives Twelve different questions/objectives are identified here under bullets. I recommend going “up” levels of abstraction to identify between 1-3 main study objectives, and 1-3 key guiding research questions. Many of the bullets could be grouped together under an overarching objective. In qualitative research, the research question guides the methodology, so this should be clearly stated as an actual question that you will answer in your research findings.

	Methods and Analysis Project participants: Why are you considering interviewing housekeepers, and what role would they play in use of PROMs in dialysis? Recruitment methods: Will you mail the information sheet to potential participants? Do you have ethical approval for them to be contacted in this manner if they have not yet consented to be contacted? Who will discuss this study with them when they come to their dialysis? IE will a research assistant be in the waiting room at all times? Data Collection: What is your guiding qualitative methodology? This is a very important step in any qualitative study because it outlines your research approach. For example, it sounds like you are drawing upon a descriptive exploratory design? Or perhaps interpretive description (by Sally Thorne) might fit? (Whereas your design does not seem to align with, for example, narrative inquiry, phenomenology, or grounded theory?) Please clearly state your chosen methodology and provide references. Data Analysis: I recommend you consider analyzing your patient data separate from your MDT data first, and then comparing. - You explain that you will send a summary of the main points to participants for comments. This is called “member checking”. Please add a reference for this. Will you do this for both patients and MDT? How will you respond to participants who disagree with your analysis? Discussion - Page 11, line 23-24, you discuss “consulting records to complete responses” – but this seems to go against the premise of instruments being completed by a patient him/herself, from their point of view. Further, in principle, they have the “right” to skip questions they do not wish to answer. - Why is privacy required to complete a PROM? If they are not verbally discussing it, but completing it on a tablet or paper, that seems to be as private as completing any other health requested information on paper/tablet? - Page 12, line 6-7, you write that “this hypothesis will be explored” but hypotheses are not used in qualitative research. So this needs to be revised so it is consistent with your approach. - Page 12, lines 11-13, you reference symptoms alerts being managed. I am assuming that you are referring to electronic capture of PROMs and automatic scoring with alerts to clinicians or maybe patients also, but perhaps you could clarify. Conclusion The last sentence could be honed to add greater specificity to your anticipated outcomes. Figure 2 Is one row of circles intended to represent patients, and one row to represent MDTs? If so, this could be clarified. - Interviews are mentioned, but focus groups could be incorporated into this figure as well. Thank you for the opportunity to provide feedback on your manuscript.

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REVIEWER	John D Peipert Northwestern University Feinberg School of Medicine, Medical Social Sciences
REVIEW RETURNED	06-Jun-2018

GENERAL COMMENTS	Review: *Overall Comments* This is a well-written protocol describing a qualitative study that will assess feasibility and ideal approaches to including patient-reported outcome measures in routine hemodialysis care in the UK. There is significant enthusiasm for the project, and the authors have demonstrated both the need for the study, and an overall approach that is likely to succeed. I have given some suggestions for small ways the manuscript could be improved in specific comments attached, but these are mostly minor. *Abstract* - It is unusual to see references placed in the abstract. Please confirm this is allowable under the journal's rules. - Although this manuscript has been submitted to BMJ Open, it is likely worth noting in the abstract (as well as in the introduction of the paper) that this study will be implemented in the UK, and that the general context for describing the study's need is oriented toward the UK. For instance, the authors state that "PROMs have not been introduced into the routine clinical care for patients undergoing HD" in the abstract. This is likely the case for the UK, but in the US this statement is not totally true, since the KDQOL-36 is often administered annually and the ICH-CAHPS is administered bi-annually with every HD patient. - If there is space, it would be good to have a few words about how the sample size for patient interviews and provider focus groups (30 and 18, respectively) were determined. - Can you add a short note about the difference between professional and non-professional staff? - In the second to last bullet under the Strengths and Limitations table in the abstract, it would be good to be a bit more specific about what will be investigated in the routine use of ePROMs with HD patients. Patients' interest in, or ability to, complete ePROMs? How often ePROMs should be administered? - The final section of the abstract is titled, "Strengths and Limitations of this study protocol," but I do not see any limitations mentioned. *Introduction* - On p. 4, line 37, you write-out "quality of life," but the QOL

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	acronym has already been introduced. - In the bulleted list of research questions on p. 6, the acronyms for KDQOL-SF, KDQOL-36, and IPOS-Renal have not been given. - In the same bulleted list mentioned above, be sure that each bullet can stand on its own. Some of them are fragments. For example, “The optimal timing of collection i.e. before or during dialysis sessions, from the patient and clinical perspective,” should start with “To examine,” “To determine,” “To explore” or something like that. There are a few that need to be corrected. - I have a few concerns about the bullet regarding “The most effective mode of administration […].” First, it is not clear what you mean by “most effective.” Easiest for patients to use? Leads to less bias in response? This should be clarified. Second, it should be made explicit either here or in the methods what a qualitative study is able to determine around mode of administration. Certainly, a qualitative study can determine patients’ preferences for mode and the types of issues that might be encountered by patients using different modes. However, there are many things a quantitative mode comparison (e.g., a mode trial) would investigate that could not be explored here, like whether there are differences in scores by mode, differences in reliability by mode, etc. It should be made explicit somewhere in the manuscript what the scope of the current study is for understanding mode. *Methods and Analysis* - Overall, the rationale for the sample being selected is very clear and appropriate. However, the authors should consider whether they intend to stratify recruitment of subgroups (e.g., racial groups) to ensure they get sufficient representation, and how many of each subgroup they hope to represent. For example, of the 30 patients, what proportion do you hope to fall into different racial/ethnic, gender, dialysis vintage, or other categories? It is best to have this pre-specified, and to also indicate that the clinics you’ll be recruiting from have sufficient patient populations to support your recruitment plan. - Since the KDQOL-36 is a subset of the KDQOL-SF, it should be made more clear what about each instrument patients and providers will review. Will you ask participants to compare them directly? Will you ask if the KDQOL-36 is adequate to cover patients’ interests in comparison to the broader KDQOL-SF? - Since reference 38 regards only the KDQOL-SF, the authors should consider citing recent psychometric work on the KDQOL-36: Peipert JD, Bentler PM, Klicko K, Hays RD. Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-

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	36) in the United States. *Am J Kidney Dis*. 2018;71(4):461-468. Peipert JD, Bentler P, Klicko K, Hays RD. Negligible impact of differential item functioning between Black and White dialysis patients on the Kidney Disease Quality of Life 36-item short form survey (KDQOL$^{(TM)}$-36). *Qual Life Res*. 2018. - Regarding data analysis, how will you know when saturation is reached? Is there a formal approach to this that you will use? *Discussion* - In the short paragraph on p. 11, lines 21-25 about questionnaire burden, the authors should include reference to some literature about how patients tend to evaluate survey burden in clinic settings, and report whether it is likely that patients will feel burden to respond to PROMS in this setting. - In general, you should mention more potential limitations to the study in comparison to other approaches and study designs.

VERSION 1 – AUTHOR RESPONSE

Comments: Reviewer 1 (J D Peipert)

Abstract:

- "It is unusual to see references placed in the abstract. Please confirm this is allowable under the journal's rules."
  - Author response: Thank you. References have now been removed from the abstract.

- "Although this manuscript has been submitted to BMJ Open, it is likely worth noting in the abstract (as well as in the introduction of the paper) that this study will be implemented in the UK, and that the general context for describing the study's need is oriented toward the UK. For instance, the authors state that "PROMs have not been introduced into the routine clinical care for patients undergoing HD" in the abstract. This is likely the case for the UK, but in the US this statement is not totally true, since the KDQOL-36 is often administered annually and the ICHCAHPS is administered bi-annually with every HD patient".
  - Author response: The location of the study (UK) has been added to the title, and clarification that this study refers to the UK has been made within the abstract and introduction (page 1, line 7, page 2, line 67, page 3, line 97).

- "If there is space, it would be good to have a few words about how the sample size for patient interviews and provider focus groups (30 and 18, respectively) were determined."

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- Author response: Reasoning for sample size is included in methods section page 6, lines 250-259, page 6 lines 274-276.

- "Can you add a short note about the difference between professional and non-professional staff?"
- Author response: Difference between professional and non-professional staff: the reasoning for including non-professional staff members in the focus groups has been added to the methods section (page 6, line 266-273).

- "In the second to last bullet under the Strengths and Limitations table in the abstract, it would be good to be a bit more specific about what will be investigated in the routine use of ePROMs with HD patients. Patients' interest in, or ability to, complete ePROMs? How often ePROMs should be administered?"
- "The final section of the abstract is titled, "Strengths and Limitations of this study protocol," but I do not see any limitations mentioned."
- Author response: Both of the above comments have now been addressed, strengths and limitations table has been rewritten (page 2, line 89).

Introduction:

- "On p. 4, line 37, you write-out "quality of life," but the QOL acronym has already been introduced."
- Author response: 'Quality of life' removed and acronym used.

- "In the bulleted list of research questions on p. 6, the acronyms for KDQOL-SF, KDQOL-36, and IPOS-Renal have not been given."
- Author response: Acronyms for KDQOL-SF, KDQOL-36 and IPOS-Renal written out in full (page 5, lines 217-219)

- "In the same bulleted list mentioned above, be sure that each bullet can stand on its own. Some of them are fragments. For example, "The optimal timing of collection i.e. before or during dialysis sessions, from the patient and clinical perspective," should start with "To examine," "To determine," "To explore" or something like that. There are a few that need to be corrected. - I have a few concerns about the bullet regarding "The most effective mode of administration […]." First, it is not clear what you mean by "most effective." Easiest for patients to use? Leads to less bias in response? This should be clarified. Second, it should be made explicit either here or in the methods what a qualitative study is able to determine around mode of administration. Certainly, a qualitative study can determine patients' preferences for mode and the types of issues that might be encountered by patients using different modes. However, there are many things a quantitative mode comparison (e.g., a mode trial) would investigate that could not be explored here, like whether there are differences in scores by mode, differences in reliability by mode, etc. It should be made explicit somewhere in the manuscript what the scope of the current study is for understanding mode."
- Author response: Bullet points in objectives section have been reworded, as suggested (page 4 line 178 to page 5 line 23).
- Bullet point regarding 'Most effective mode of administration' has been clarified to demonstrate we are referring to usability and preferences (page 5, lines 201-203). As

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suggested, the limitations of the chosen methodology on assessing effectiveness of administration is included in the methods and analysis section (page 11, lines 472-475)

Methods and Analysis:

- "Overall, the rationale for the sample being selected is very clear and appropriate. However, the authors should consider whether they intend to stratify recruitment of subgroups (e.g., racial groups) to ensure they get sufficient representation, and how many of each subgroup they hope to represent. For example, of the 30 patients, what proportion do you hope to fall into different racial/ethnic, gender, dialysis vintage, or other categories? It is best to have this pre-specified, and to also indicate that the clinics you'll be recruiting from have sufficient patient populations to support your recruitment plan."
  - Author response: Whilst we agree with your comments on the need for sufficient representation, for the 30 patients we have chosen not to pre-specify the subgroups. Purposive sampling methods will be used with data on participant characteristics to be collected as the study progresses to monitor and maintain sample diversity. Details of sample diversity will be published in final manuscript. We are confident given the wide geographical region served by the recruiting centre, that sufficient representation in terms of age, gender, ethnicity, dialysis vintage, urban v rural centre, can be maintained.

- "Since the KDQOL-36 is a subset of the KDQOL-SF, it should be made more clear about each instrument patients and providers will review. Will you ask participants to compare them directly? Will you ask if the KDQOL-36 is adequate to cover patients' interests in comparison to the broader KDQOL-SF?"
  - Author response: As suggested, clarification on completion of KDQOL-36 and KDQOL-SF included in methods section (page8 lines 337-340).

- "Since reference 38 regards only the KDQOL-SF, the authors should consider citing recent psychometric work on the KDQOL-36:
  Peipert JD, Bentler PM, Klicko K, Hays RD. Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States. Am J Kidney Dis. 2018; 71(4):461-468.
  Peipert JD, Bentler P, Klicko K, Hays RD. Negligible impact of differential item functioning between Black and White dialysis patients on the Kidney Disease Quality of Life 36-item short form survey (KDQOL(TM)-36). Qual Life Res. 2018."
  - Author response: Additional references on psychometric work of the KDQOL-36 have been added to table 1 (page 8).

- "Regarding data analysis, how will you know when saturation is reached? Is there a formal approach to this that you will use?"
  - Author response: 'Saturation can be described as existing when no new codes, themes or categories are emerging from the data and the relationships between them can be explained' – p6 lines 276-278.

Discussion:

- "In the short paragraph on p. 11, lines 21-25 about questionnaire burden, the authors should include reference to some literature about how patients tend to evaluate survey burden in clinic settings, and report whether it is likely that patients will feel burden to respond to PROMS in this setting."

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- Author response: References and comment on survey burden have been added to manuscript (Page 10, lines 446-449 refs 50-51).

- In general, you should mention more potential limitations to the study in comparison to other approaches and study designs.
- Author response: Potential limitations have been added to methodological strengths and limitations box (page 2-3).

Comments: Reviewer 2 (K Schick-Makaroff)

Title:

- "How does "safety" tie into the concepts addressed in this study?"
- Author response: It is agreed that the concept of safety has not been directly addressed in this study. Therefore, this aspect has been removed from the title. However, it is noted PRO symptom data can help inform safety monitoring.

Introduction:

- "In the first paragraph, do the statistics include home hemodialysis (or just in-centre /hospital /satellite dialysis)?"
- Author response: Yes, the statistics include both centre-based and home HD. This has been clarified (page 3, line 98-100).

Study Objectives:

- "Twelve different questions/objectives are identified here under bullets. I recommend going "up" levels of abstraction to identify between 1-3 main study objectives, and 1-3 key guiding research questions. Many of the bullets could be grouped together under an overarching objective. In qualitative research, the research question guides the methodology, so this should be clearly stated as an actual question that you will answer in your research findings."
- Author response: As suggested, the level of abstraction has been altered and under main study aim we outline four key objectives, with associated key questions listed beneath (page 4, line 173 – page 5 line 223).

Methods and Analysis:

- "Project participants: Why are you considering interviewing housekeepers, and what role would they play in use of PROMs in dialysis?"
- Author response: Interviewing housekeepers: it was considered that Satellite Unit Housekeepers often develop unique and close relationships with patients (in the UK they are responsible for bringing round drinks/food etc.) and that patients might discuss the burden of treatment and symptoms with non-professional staff as much as professional staff. Therefore, the views of non- professional team members in terms of how we might use and implement PROMs might be useful. The manuscript has been amended to provide rationale for including non-professional MDT staff (page 6, lines 266-273).

- "Recruitment methods: Will you mail the information sheet to potential participants? Do you have
ethical approval for them to be contacted in this manner if they have not yet consented to be contacted? Who will discuss this study with them when they come to their dialysis? IE will a research assistant be in the waiting room at all times?"
- Author response: Yes, we have ethical approval to post REC approved information to patients prior to consent. A member of the research team will discuss the study with them when they

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come for dialysis and as part of the consent process, but information about the study has been given to clinical staff so they know the broad aspects of the study and objectives as well as contact details for the researchers in a member of the research team is unavailable. The manuscript has been clarified – page 7, lines 294-301.

- "Data Collection: What is your guiding qualitative methodology? This is a very important step in
  any qualitative study because it outlines your research approach. For example, it sounds like you
  are drawing upon a descriptive exploratory design? Or perhaps interpretive description (by Sally
  Thorne) might fit? (Whereas your design does not seem to align with, for example, narrative inquiry, phenomenology, or grounded theory?) Please clearly state your chosen methodology and
  provide references."
  - Author response: The methods section has been clarified to state we are using thematic analysis methods, as described by Braun & Clarke, references provided within manuscript (page 8, lines 345-349, page9 365-366, refs 40,41).

- "Data Analysis: I recommend you consider analysing your patient data separate from your MDT
  data first, and then comparing."
  - Author response: As suggested, data from patients and MDT will be analysed separately and then compared (page 9, lines 370-371).

- "You explain that you will send a summary of the main points to participants for comments. This is called "member checking". Please add a reference for this. Will you do this for both patients and MDT? How will you respond to participants who disagree with your analysis?"
  - Author response: Section on 'member checking' with associated references has been added to the manuscript (Page 9, lines 371-376 Ref 43).

Discussion:

- "Page 11, line 23-24, you discuss "consulting records to complete responses" – but this seems to go against the premise of instruments being completed by a patient him/herself, from their point of view. Further, in principle, they have the "right" to skip questions they do not wish to answer."
  - Author response: Thank you, agreed, the manuscript has been clarified following your comment and includes the point that there always remains a right to refuse to answer questions (page 10, lines 442-446).

- "Why is privacy required to complete a PROM? If they are not verbally discussing it, but completing it on a tablet or paper, that seems to be as private as completing any other health requested information on paper/tablet?"
  - Author response: Some patients might need practical (verbal) assistance from staff to complete a PROM (e.g. where clarification around item wording is needed), a safe and private space may be required in order to facilitate this. We have clarified this in the manuscript (page 11, lines 451-454).

- "Page 12, line 6-7, you write that "this hypothesis will be explored" but hypotheses are not used

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in qualitative research. So this needs to be revised so it is consistent with your approach."
  - Author response: Thank you, agreed, word 'hypothesis' removed and reworded in line with qualitative methodology.

- "Page 12, lines 11-13, you reference symptoms alerts being managed. I am assuming that you
  are referring to electronic capture of PROMs and automatic scoring with alerts to clinicians or maybe patients also, but perhaps you could clarify."
  - Author response: Clarification that this relates to adverse event reporting has been made (page 11, lines 492-493).

Conclusion:

- "The last sentence could be honed to add greater specificity to your anticipated outcomes."
  - Author response: Conclusion has been replaced with Ethics and Dissemination section, as requested by BMJ-Open Editorial Guidelines.

Figure 2:

- "Is one row of circles intended to represent patients, and one row to represent MDTs? If so, this
  could be clarified - Interviews are mentioned, but focus groups could be incorporated into this figure as well"
  - Author response: Figure 2 amended in line with reviewer comments.

VERSION 2 – REVIEW

REVIEWER	John Devin Peipert Department of Medical Social Sciences, Northwestern University, USA
REVIEW RETURNED	10-Aug-2018

GENERAL COMMENTS	The authors have done a good job responding to all my questions and comments. Kudos on a nice paper.

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