Reviewer's report

Title: Understanding Barriers to Optimal Disease and Medication Management for Those Requiring Long-term Dialysis: Rationale and Design for an Observational Study of a Multi-ethnic New Zealand Cohort

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Reviewer: Karthik Tennankore

Reviewer's report:

Aspden, Marshall and colleagues present a protocol to evaluate factors associated with medication non-adherence in a cohort of New Zealand dialysis patients. The study will examine a random sample of 100 patients in a cross-sectional design and evaluate medication non-adherence using a validated instrument. Additional objectives are to determine ethnic differences in illness in medication perception, evaluate reasons behind adherence and examine health literacy of patients involved in the study.

Overall I feel this is an important study, acknowledging that non-adherence is very common in dialysis and associated with poor outcomes (as the authors identify). I feel the protocol is well-presented, clear and that the study will adequately test the posed hypotheses. Their use of valid instruments to assess their objectives only strengthens the protocol.

However, I feel there are a few necessary major/minor revisions before this can be accepted for publication.

Major Revision:
Although including all the approximately 650 patients dialyzed would be ideal, I acknowledge that from a cost/resource standpoint, this may not be feasible. However, there should be more detail around how the random sample will be selected. How will random selection occur (computer based, random number etc...)? How will you ensure a reasonable sample of home modality (PD and HHD) and in-center patients will be included? Will there be consideration for equal selection of ethnic groups? (Maori/Pasifika). Will there be any weighting that will occur? To limit bias and ensure the representation is a true cut of your current population, I would include this in the protocol.

Minor Revisions:
- How were the qualitative questions derived? was there choice from a number of questions after which consensus was achieved? Details around this should ideally be included in the protocol.

- Appreciating that a more detailed statistical analysis is usually present in the manuscript, it would still be ideal to add a few details to the analysis plan.
- For the comparisons—what groups will be compared (low adherence vs normal/high, three levels etc...). This will be relevant when considering statistical analysis—ANOVA/Kruskal Wallis might be more appropriate for multiple group comparisons.

- How will the Likert scale items be treated? Continuous normal, continuous non-normal etc...

- For the regression analysis: what will the dependent variable be? Normal/High vs. poor compliance? What variables will be included in the multivariable regression model? If it is unknown at this point—what will be the threshold for statistical significance to include variables in the model?

Discretionary Revisions:
- Consider including details around cause of ESRD, and whether or not patients had a failed kidney transplant. There may be some information to gather from potentially non-compliant transplant patients that did not adhere to their anti-rejection medications.

- In addition to the NZDep score, I would also present the sub-components (income, employment etc...) separately as there may be interesting information to derive from this.

- Consider adding the Morisky Scale as a figure to the manuscript. As it is the primary outcome, it would be a valuable piece of information for readers.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests