Author's response to reviews

Title: The financial impact of increasing home-based high dose haemodialysis and peritoneal dialysis

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Version: 2 Date: 8 August 2014

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The Biomed Central Editorial Team

Subject: MS: 1254044738120795 - The financial impact of increasing home-based high dose haemodialysis and peritoneal dialysis

Thank you for consideration of our manuscript for publication in your journal.

We have reviewed the above manuscript according to your reviewer’s comments.

In addition, please note that when addressing the reviewer’s comments, it was necessary to make minor amends to the text in the manuscript to maintain the overall flow of the document. Due to the addition of a substantial amount of text in the discussion, which was required to respond to a reviewer’s comment, the summary of the results at the beginning of the discussion section has been reduced and reordered. Also, the Declaration of Conflict of Interest has been corrected and is presented at the bottom of page 17 of the manuscript.

Please find below specific responses to editorial and reviewers’ comments.

Editorial Request:

1. Keywords

Please remove the Keywords from the Title page. These should follow the Abstract instead.

Response: Updated.

2. Conclusions

Please provide a Conclusions section in your manuscript after your Discussion section.

Response: Conclusions added as a separate section.

3. Abbreviations

Please provide a list of the abbreviations used in the manuscript. This should be placed after the Conclusions section.

Response: Abbreviations list provided.

4. References
Please format your references as shown here:
http://www.biomedcentral.com/bmcnephrol/authors/instructions/researcharticle#formatting-references

Response: References reformatted according to BMC Nephrology output style.

5. Figures

For figure 1 to be displayed correctly in the published manuscript it should be removed from the main manuscript file and instead uploaded as a Figure File.

Response: Figure 1 uploaded as a separate file.

Reviewer #1: Jayne Smith-Palmer

Discretionary Revisions

1. The authors use the reference Chertow et al. N Engl J Med. 2010 Dec 9;363(24):2287-300, as the reference to define ESRD as #90% loss of renal function. It would be better to define ESRD in terms of GFR as in commonly used guidelines, for example, KDIGO/ K/DOQI or the renal association (http://www.renal.org/whatwedo/InformationResources/CKDeGUIDE/CKDstages.aspx)

Response: The definition of ESRD has been updated in line with renal association guidelines provided and is now described on page 4 of the manuscript: “End-stage renal disease (ESRD) is defined as the most severe stage of chronic kidney disease (i.e. stage 5, glomerular filtration rate <15mL/min/1.73 m^2 or on dialysis) [1].”

Minor Essential Revisions

2. There are some very small issues with grammar, particularly the use of "that" and "which".

Response: The grammar has been checked and amended accordingly.

Major Compulsory Revisions

3. The authors have utilized a discount rate of 3.5% per annum for their budget impact analysis, whilst this may be in line with the UK discount rate, ISPOR guidance does not recommend discounting in budget impact analysis as this is not relevant for most budget holders. In view of this the authors should also present undiscounted results in the results tables.

Response: We thank the reviewer for their comment. In line with ISPOR guidelines (http://www.ispor.org/budget-impact-health-study-guideline.pdf), discounting has been removed from the analysis and the results amended accordingly. This is explained on pages 9-10 of the
manuscript: “In line with International Society for Pharmacoeconomics and Outcomes Research (ISPOR) current guidelines for budget impact, costs were not discounted in the analysis [47].”

4. The lower ESA cost is stated as being a key driver of savings in some scenarios, but there is minimal mention of this in the discussion section. It warrants more attention in the discussion section, with inclusion of clinical data, as without this the reader cannot establish if this is driven by lower rates of anemia, or if anemia is going undetected/untreated in patients undergoing home based dialysis.

Response: We would like to thank the reviewer for this thoughtful comment. A discussion around ESA costs is now provided on pages 13-14 of the manuscript: “With respect to ESA costs, the latest data from the UK Renal Registry reports that 87% of HD patients and 69% of PD patients were receiving ESAs in 2012 (median ESA dose 7,248 IU/week and 4,250 IU/week, respectively) [55]. The lower ESA costs associated with PD versus HD in the current analysis is assumed to be due to a combination of both a lower prevalence of anaemia and also a lower recommended weekly dose of ESA treatment in PD patients compared with HD patients [41]. There is currently no conclusive evidence in the literature on significant differences in erythropoietin doses between dialysis patients receiving high dose HD and conventional HD [11-13]. Therefore, we assume the doses reported in the UK Renal Registry 16th Annual Report can be applied to all patients receiving HD.” Table 2 has also been updated to reflect the assumptions around ESA dosing.

5. The authors emphasize the benefits of home based dialysis but there is no mention of the limitations or the fact that some patients may prefer in center dialysis, this should be included in order to make the article more balanced.

Response: We appreciate this comment from the reviewer. This is now addressed on page 15 of the discussion: “Other barriers to successful implementation of home dialysis are reported as business practices of dialysis providers such as appropriate staffing, availability of pharmaceuticals and delivery of supplies [62]. It is acknowledged that choice of dialysis modality is also influenced by patient preferences which are in turn influenced by factors such as patient age, physical status, presence of comorbidities and lifestyle [63, 64]. PD patients report less illness intrusion, better renal care and greater independence and satisfaction [65, 66] while HD patients cite benefits of social and staff interaction and fear of social isolation as reasons for not choosing home HD [63, 67]. NICE clinical guideline 125 for PD states that healthcare professionals should acknowledge that dialysis patients priorities may differ to their own clinical priorities, thus treatment decisions should take into account
the patient’s needs and preferences [5]. Although it has been suggested that 50% of dialysis patients would choose PD if possible [68], the most recent data from the UK reports that in 2012, PD was used by only 22% and 14% of incident and prevalent patients, respectively [3, 4].”

Level of interest: An article whose findings are important to those with closely related research interests

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.

Reviewer #2: Sandip Mitra

Reviewer’s report:

Major Compulsory Revisions
1. The abstract needs editing for the readership – clarity in summarising the results, and consistency such as in the use of prefix (variably used in the abstract and discussion).

Response: The results of the abstract have been rewritten.

2. Scenarios need to be well defined and described in a separate Table/chart.

Response: This information is already presented for all scenarios among both incident and prevalent patients in Table 3. The individual scenarios are described on page 10 of the manuscript. No further amendments made to the manuscript.

3. Table of scenarios/output for the current and proposed tariff impact would be helpful.

Response: Definitions of the scenarios tested are provided in Table 3. Table 4 which presents the results has been restructured to make it clearer.

4. Transport and ESA cost not in the existing UK tariff, so its inclusion in the model is inaccurate and overestimates the model impact. This must be corrected.

Response: The analysis is from the payer perspective, and therefore needs to include all relevant costs to the payer, specifically the National Health Service (NHS). Clarification of this is provided on page 13 of the manuscript: “Although ESA and transport costs are not included in the current UK tariff, these
costs are paid to dialysis providers or reimbursed directly to patients by the NHS in addition to the dialysis tariff and are therefore included in the analysis.”

5. Dialysis time and frequency bear a differential cost burden - not differentiated in the model.
Response: We agree that because consumables/staffing costs differ with dialysis session duration and frequency; this would be a consideration for the provider. However, the current analysis is conducted from the payer perspective and the costs inputs therefore reflect the current UK tariff structure. The modelling approach is therefore considered appropriate. An explanation of the dialysis tariffs in England are now provided on page 9 of the methods under cost elements: “The budget impact analysis is conducted from the perspective of the payer in the England NHS. As such, PbR tariffs, which represent the fixed reimbursement payments made by payers to providers for procedures undertaken, and are based on national average costs from previous years, are used for estimating costs of providing RRT for ESRD patients. The tariff for ICHD is a cost per session whereas the home HD tariff is a fixed weekly tariff and does not vary with the number of dialysis sessions conducted per week (the original tariff was calculated on the basis of 3 sessions per week).” Sensitivity analysis was also conducted to consider the impact of a variation in the weekly tariff.

6. Budget impact closely linked to PD but the proportional prevalence of each home modality split between PD and HHD not described, could be important for overall service design.
Response: This information is already presented. “Home” patients are not grouped together; they are either described as PD or home HD and are presented in Table 3. For example, Scenario 2 considers patients receiving PD, conventional ICHD, conventional home HD and high dose HD at home. No further amendments made.

7. The article talks about a favorable tariff for cost of high dose dialysis, however the rate limiting factor is often patient choice or centre attitude (human factors). This is not discussed. The interaction of a therapy cost to other human factors need to be discussed.
Response: As this point is also raised by reviewer #1, please see the response to reviewer #1, comment 5.

8. Training cost has not been defined. This is an important aspect of HHD setup.
Response: We accept that from a provider perspective, significant upfront costs for home HD including training costs would be a concern. However, since the analysis adopts the payer perspective, the PbR tariff is the appropriate source of costs. The home HD tariff is designed to cover the upfront costs associated with home HD – the provider is able to recover the initial investment over time. This is now explained on page 13 of the manuscript: “Note also that the current fixed home HD tariff covers initial training and any necessary home modification costs. It is designed such that the dialysis provider is able to recover their initial investment over time.”

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

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