Author's response to reviews

Title: Vascular staging for diabetes: a useful instrument for severity adjustment in economic modeling

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Author's response to reviews: see over
Dear Editor

RE: Addressing Reviewers comments; manuscript: 1697168230607543

Thank you for editorial requests and sending our manuscript out for review. We have addressed the Editorial requests by including a title page and the abstract in the manuscript file and structuring both according to BMC HSR guidelines. The manuscript including the references, tables and graphs have been prepared to conform to the journal style.

We would also like to acknowledge that the Reviewers comments have strengthened the manuscript. We would like thank the Reviewers and we greatly appreciate their time and effort taken to provide constructive feedback on our manuscript. We have actioned the comments and suggestions of both Reviewers by making changes to the manuscript. Below is how we addressed the Reviewers comments.

Addressing review comments by Carlo Bruno

1. Incorrect use of ACR.

Yes we agree with the reviewer and have adjusted the sentence as follows, ‘Albumin/creatinine ratio (ACR) was chosen as a measure of the early sign of diabetic nephropathy’ (page 5, last paragraph). This sentence ‘Serum creatinine was replaced with albumin/creatinine ratio (ACR) a more sensitive measure of early renal disease’ has been deleted. Serum creatinine has been added to the items excluded (page 6, first paragraph).
2. There is clear correlation between the degree of vascular stage, death and cost – this is well known and should be presented as confirmatory results.

Yes we agree with the reviewer and have added this referenced sentence in the results section, ‘As found in other studies, in-patient hospital cost [15] and mortality [16] increased with each increase in vascular disease severity, meeting out test for construct validity’ {pages 9-10}. In the discussion we have included, ‘A clear association between the degree of vascular severity, hospital cost [25] and mortality [16] is established in the literature’ {page 12, last paragraph}.

3. Suggested that we comment that the main value of the paper is the instrument we propose.

Yes we agree with the reviewer and now have one clear objective that was, ‘to revise the NSW diabetes classification system to derive a singular diabetes severity score that predicted hospitalisation and mortality and that used only data collected routinely in health practice settings’ {page 4, second paragraph}. Following on we explain, ‘This paper describes the revisions made to the NSW instrument, the method used to match health screening data with hospital separation and death data, and the performance of the new instrument mapped against hospital cost and mortality when applied to our study population’.

4. Main limitation of the paper is the study population which may preclude the generalisation of the results – needs to be better commented on in the discussion.

The limitation of the paper with regards to the study population has been added to the discussion, as follows, ‘It is unknown if this instrument would have good construct validity when applied to data of other population groups. The sample size is small, the cohort is young and Indigenous Australians have a lipid profile which differs from that of non-Indigenous Australians [9]. However given the structure of the instrument, there is no reason to presume it will not prove useful in other populations’ {page 10, last paragraph}. 
Addressing review comments by Björn Stollenwerk

Economic Modeling

1. Choose a title closer to the study objective. Some results in this article might be used for economic modeling in the future (yes) – but this is true for a wide range of articles that have nothing to do with economic modeling. Also the word useful is not appropriate as it’s not certain the instrument is useful. Possibly discuss use for economic modeling in discussion.

   The title has been changed to better reflect the article. It is now, ‘A simple diabetes vascular severity staging instrument and its application to a Torres Strait Islander and Aboriginal adult cohort of north Australia’. The word useful to describe the instrument is no longer used and economic modeling is no longer referred to in the manuscript.

2. Suggested not to mention economic modeling in the conclusion. A detailed discussion is missing. Draw conclusion from the results.

   Economic modeling has been withdrawn from the conclusion. The discussion has been strengthened. In the discussion there is a focus on the instrument and the use of the instrument to inform population level health care planning for diabetes management and monitoring vascular disease progression over time{page 12, last paragraph to page 13, first paragraph}.

   The conclusion has been revised and drawn from the results. The conclusion now reads, ‘Many population groups are experiencing an increase in type 2 diabetes incidence and prevalence. This instrument discriminates between levels of diabetes-related vascular disease severity, displays good construct validity by predicting increased hospital cost and mortality with worsening severity and can be populated with routinely collected data. It may assist with future health service research, particularly in its current form, when working with small Australian Aboriginal and Torres Strait Islander cohorts. Its use could be extended to practice settings for health care planning for diabetes management programs and monitoring vascular disease progression’, {page13, last paragraph}. 

Focus on Australia

3. Australian population and hospital costs complicate transferability. Put Australian in title and abstract. Mention issue with transferability to other populations and how these data are valid for other countries – are they?

Australia is now in the title and the abstract. The issue with transferability has been addressed in the last paragraph on page 10, ‘It is unknown if this instrument would have good construct validity when applied to data of other population groups. The sample size is small, the cohort is young and Indigenous Australians have a lipid profile which differs from that of non-Indigenous Australians [9]. However given the structure of the instrument, there is no reason to presume it will not prove useful in other populations’.

We have also included this sentence in the discussion, ‘Validating the instrument in future research and testing its generalisability with similar and diverse population groups would be desirable {page 13, last sentence, second paragraph}.

Study Objective

4. Need one clear objective. Details of what is done to address the objective can be moved from the background to the methods section (i.e. revising the classification system).

There is now one objective which was, ‘Our objective was to revise the NSW diabetes classification system to arrive at a simple diabetes vascular severity staging instrument that used only data collected routinely in health practice settings, plus hospitalisation data. Construct validity was assessed by testing for the expected relationship between the new diabetes severity score and hospitalisation and mortality’, {page 4, second paragraph}. (This also addresses Reviewer 1, comment 3).

Comparing the staging instruments

5. The reason for why the results of the new and old vascular staging instrument cannot be compared need to be discussed explicitly.

This sentence has been included in the discussion, top of page 12, ‘Comparing the performance of the NSW instrument and the simplified version was not feasible, given the more extensive data requirements of the more complex NSW instrument’.
6. Why is the simplified instrument more appropriate for the study population? Discuss this.

The statement that this instrument would be more appropriate for the study population has been replaced by this discussion, ‘It is unknown if this instrument would have good construct validity when applied to data of other population groups. The sample size is small, the cohort is young and Indigenous Australians have a lipid profile which differs from that of non-Indigenous Australians [9]’ {last paragraph page 10}. (This also addresses Reviewer 1, comment 4).

Minor Essential Revisions

7. Explicitly state the meaning of microvascular and macrovascular disease stages.

A paragraph addressing this has been added at the beginning of the methods, last paragraph page 4 to top of page 5.

*Defining microvascular and macrovascular disease stages*

A microvascular complication was defined as early signs of diabetic nephropathy or evidence of established diabetic nephropathy or retinopathy. Macrovascular complications captured clinical risks of acquiring, or evidence of, cardiovascular disease, peripheral vascular disease or cerebrovascular vascular disease. Generally an early sign of a vascular complication was determined by pathology results taken during a health screen (abnormal lipid profile, high blood pressure), and evidence of a vascular complication was determined by being hospitalised for the condition.

7.1 *Figure 3 is not cited in the text – please add this citation*

Figure 3 is now cited in the text in the first paragraph on page 10, ‘Figure 3 shows the percent of people who died during the 5 year follow-up period by vascular stage’.

7.2 *Table 2 has not been quoted in the text – please quote table 2*

Table 2 is now quoted in the text on page 9 paragraph 2, ‘Table 2 shows the study cohort characteristics’.

7.3 *Table 2 - include minimum and maximum range of age, and min, max & sd of BMI.*

Age range, and BMI range and SD is now included in table 2, page 23.
7.4 Report standard errors for cost estimates in the results part. Figure 2 include CI’s (these could be derived from bootstrapping)
Confidence intervals for cost estimates are reported by using bootstrapping and are shown in figure 2. In the analysis section, we have included the sentence, ‘Mean monthly in-patient hospital costs were presented by vascular stage and confidence intervals were derived by bootstrapping’ {page 8, last paragraph}. We would prefer not to report confidence intervals on figure 2 rather than standard errors in the text.

7.5 Figure 3 Stage 1 should be added and the word diseased replaced by deceased
Stage 1 is added to figure 3. Diseased is replaced by deceased in the title of figure three, page 20.

7.6 In the discussion do not use correlation, instead use association
Correlation has been replaced by association, on page 10 second paragraph and page 12, last paragraph. The word correlation is not used in the manuscript.

7.7 Change, ‘our primary study aims to evaluate’ to ‘our primary study aim is to evaluate’
This sentence has been deleted from the manuscript.

7.8 Use style formatting for citations
The manuscript is formatted as per author’s instructions for BMC HSR.

Discretionary Revisions
8. Insert citations after the sentence, ‘These complications are a great burden to patients and society, incur high health service use and contribute excessively to the cost of health care.
These are now cited, as follows, ‘These complications are a great burden to patients and society [5], incur high health service use and contribute excessively to the cost of health care [6]’ {page 3, first paragraph}.

8.1 Do not report results twice, once in the figures and tables and text. Describe figures and tables without repeating all the information.
The results have been rewritten to decrease repetition. The results are on pages 9 and 10.
8.2 After the sentence, Two existing severity indexes that use administrative data were found… insert corresponding citations.

The citations have been inserted close to being mentioned. Two existing severity indexes that use administrative data were found [21, 22], but both are more complex…[page 12, first paragraph].

We hope that these edits accurately address the Reviewers comments and that the document is formatted correctly to BMC Health Service Research requirements. We look forward to hearing from you at your nearest convenience.

With regards

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