Author's response to reviews

Title: The health services burden of heart failure: an analysis using linked population health data-sets

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Response to Reviewers

Thank you for the opportunity to reply to the reviewers of our paper. We found the reviewers’ comments insightful and extremely helpful. We address each of their concerns and suggestions in turn below.

Reviewer 1

Major Compulsory Revisions

1. A 2-year look-back period is reasonable given available data. Please clarify whether a 2006 admission would be considered “index” if the patient was admitted in 2003 (and included in that year’s index population)? More generally, how were patients handled who met the definition of “index” in multiple years? How commonly did this occur? If patients were included in the first—but not subsequent—“index” admission cohorts, the observed decline in index rates may be an artefact of the study design.

While a look back period greater than 2 years is highly desirable, as noted by the reviewer, it was not possible in this data set.

To ensure a consistent definition throughout the study period we used only 2 years of prior information for each index admission. Therefore those patients who had two heart failure or hypertensive heart disease admissions which were two or more years apart were treated as two separate individuals. This was to ensure that no bias to the rate of new heart failure admissions was introduced. There were 587 patients of our cohort of 29,161 patients (2.0%) who fell into this category.

2. Although a primary aim of the study was to assess the typical profile and trajectory of a cohort of Australian patients with heart failure, the methods do not describe how “typical” was defined. Moreover, the value of a separate discussion of the “typical patient and typical trajectory” is unclear because, in many cases, it restates information provided in the results. Is “typical” defined by mean (or median) values of study variables? From Table 1, the distribution of patients by sex appears to be quite even. Please clarify how, from these data, one would identify the “typical” patient as female.

We accept that there is a degree of licence in ascribing characteristics to a ‘typical’ or ‘average’ patient. The inclusion of the description of a typical patient and trajectory was an attempt to bring together the various elements of the analysis and to put the numbers into a clinical context to present the more human face of heart failure and its impact.

We agree that Table 1 shows even distribution of index admissions for heart failure across males and females; however this is overall for each year. In the older age groups, females predominate. The comments in the description of the typical patient have been modified to reflect this (page 15, paragraph 3).
3. It is unclear whether mortality was considered a competing risk for readmission. With mortality rates of 10% at 1 month and almost 30% at 1 year, readmission rates will be underestimated if death is not considered a censoring event.

Death was treated as a censoring event in our analyses. This has been noted in the revised manuscript (page 7, paragraph 3).

4. Distributions of selected comorbidities over the entire study period are provided in the text, but not shown by year in Table 1. Please comment on whether the comorbid burden remained constant over the study period.

We have added the mean (standard deviation) and median (interquartile range) of comorbidities for the Charlson Index derived for the admission index and the modified Charlson index (based on admissions in the 2 years prior to the index admission) as a new Table 2. We have added new text to the manuscript and commented on a small increase in comorbidity burden over the time period of our analyses (page 9, paragraph 3).

5. In the footnote of Table 7, please list all variables included in the Cox regression model. Please also clarify why individual comorbidities and the Charlson score was included in the multivariable model. The score and individual components are correlated and may explain why the hazards ratio for diabetes flips in the multivariable model.

We thank the reviewer for the comments on the Cox regression model. We agree there will be correlation between the Charlson score and the components of the index. We have re-run the analysis and revised the table (now Table 8) and removed the estimates relating to peripheral vascular disease, coronary artery disease, diabetes and stroke that are included in the Charlson Index. The estimates for hypertension and depression (not included in the index) remain. The text of the manuscript has been revised accordingly (page 11, paragraph 3). The variables included in the adjusted Cox regression models have been listed in the footnote to Table 8.

**Minor Essential Revisions**

1. The presence of diabetes is protective in the adjusted model (HR 0.92, 95% CI 0.87-0.97). The statement of risk factors for hospital readmission needs to clearly state the direction of the association (abstract and results).

With the re-analysis of Table 8 (see point 5 above), comments related to diabetes being a risk factor for hospital readmission have been removed from the manuscript.

2. The authors appropriately refer to “index” admissions in the abstract Results, but reach a conclusion regarding the incidence of heart failure. Given a limited (2-year) look-back period, it is likely that index admissions overestimate incidence (Health Serv Res. 2011 Sep 23). The abstract Conclusion should refer to “index admissions.”

We thank the reviewer for alerting us to this reference; it was published after our manuscript was submitted. The abstract conclusion has been modified as suggested (page 3).

3. An alternative assessment of comorbidities is described, but results are not presented.
We described the derivation of the Charlson Index based on data available for the index admission and then recalculated the index using data available on other admissions in the previous two years. As noted above (point 4), these data have been included in Table 2 and reported in the revised manuscript.

4. The evidence regarding the efficacy of HF disease management programs is weak at best (Am Heart J. 2005 Apr;149(4):722-9). The statement regarding the ability of heart-failure specific management programs to reduce mortality and improve quality of life (page 15) needs to be tempered.

We agree with the reviewer that the evidence on the benefits of this intervention is not conclusive; none-the-less these programs are recommended in heart failure management guidelines (Guidelines for the prevention, detection and management of chronic heart failure in Australia, Heart Foundation, Updated October 2011).

We have acknowledged in the manuscript that multifaceted community based programs may not always reduce readmission rates and cite a recent study of telemonitoring that failed to show a benefit of enhanced surveillance. We have suggested that intensive intervention early after the first hospital admission for heart failure may reduce readmission rates (page 15, 16).

5. Table 1: Please provide distributions of all comorbidities and the mean (SD) for the Charlson score.

Given that the Charlson Index is based on 17 clinical conditions and the prevalence of some of these in the study population was very low, we do not believe a table summarising all conditions for all years of analysis is informative. Details on the Charlson Index and the most common comorbidities in the cohort have been reported in the text of the revised manuscript (page 9, paragraphs 3-4).

Discretionary

1. Table 2: Please clarify the number provided for each 5-year age group. Is it the total number of patients in the age group over all years? Please provide the number and rate in each cell.

Yes the number shown in the column ‘5 Year Age group’ is the total number of patients in the age group over all years. The numbers of males and females contributing to the calculation of the rates of index admissions have not been added to each cell of Table 3 – we prepared a table in this suggested format; however it was very cluttered and difficult to read.

2. 30-day readmission and mortality is a common metric in the U.S. Calculation of 30-day rates would enable comparisons with U.S. data as well.

In the discussion section of the manuscript we have compared our 28-day and one year mortality rates (NSW) with the 30-day and one year estimates from another Australian state (Western Australia). The results are broadly comparable (10%, 28% in NSW and 9.5%, 26.7% in Western Australia). We respectfully suggest that recalculation of 30-day estimates is not required to enable comparisons with studies conducted in other settings; differences between 28- and 30-day mortality are likely to be small and one-year mortality estimates provide a directly comparable measure.
Reviewer 2

Major issues

1. No data are presented regarding background medication therapy or device therapy, both of which have proven evidence to improve outcomes. Whether this may or may not have changed the results is likely, but to what extent is difficult to answer. However, some mention of this limitation is required in the limitations section. Furthermore, this knowledge would greatly facilitate initial attempts to improve outcomes. For example, would a program such as get with the guidelines heart failure (in the United States) be of benefit or not?

We agree with the reviewer that information on the background medication therapy or device therapy would be valuable information. Unfortunately, at this point in time, the NSW administrative data sets that are available for analysis are not linked to patient medication data. This limitation has been noted in the manuscript (page 16, paragraph 4). We agree that this information is critical to interpreting the appropriateness of the clinical management of heart failure patients. In the absence of linkage to data medication and device information, such analyses require reference to individual patient medical records, which was beyond the scope of this study.

2. The author’s discussion of potential policy changes are timely and important.

   However, they do not address sufficient choices. Rather there is only one suggestion per highlighted point. Given, that the data does not specifically point towards an intervention (e.g. improve evidence based uptake of CRT), a broader perspective needs to be presented. (e.g. greater adherence to guidelines? Improved research in acute heart failure? Better risk stratification? Improved access to transplant/VAD? Better palliative care?)

We agree that the solutions to achieving better outcomes in heart failure patients are multifactorial. While there are limited comments relating to each highlighted point in the text, we address the issues of better control of hypertension, adherence to evidence-based guidelines for the management of chronic heart failure, community-based outreach programs and some inconsistencies in the results of such programs, and better palliative care programs and more hospice places across these points (pages 15, 16).

Minor issues

1. Page 4 background, 1st paragraph, 2nd sentence. Although ischemic heart disease is a substantial contributor to heart failure, other etiologies deserve mention. (e.g. Hypertension, valvular disease). In addition, evidence-based therapies for heart failure (e.g. beta blockers, ace inhibitors, aldosterone blockers, device therapies) have also contributed to the improved outcomes and longer survival seen in chronic heart failure.

These additional causes of heart failure and further detail on the medical managements used have been included in the revised manuscript (page 4, paragraph 1).
2. Page 9, last paragraph. Although the authors do list percentages later in the sentence and manuscript, it would be helpful to have the percentages or proportions immediately after the numbers. For example, what is the percentage that 7415 represents?

The 28-day and 1 year probabilities presented as percentages take into account deaths in the cohorts (death was a censoring event) and are derived from the Kaplan-Meier survival curves. The raw proportions if presented as percentages would be misleading to the reader and would underestimate the readmission rates, particularly at one year.

3. Results: depending on the target audience, the authors may want to consider inserting the average length of stay in the United States as well as the average length of stay from the European heart failure surveys (as well as mortality) to put the authors’ results into additional context. Furthermore, this may help the reader who is not familiar with the Australian health care system. For example, the mean length of stay of 4 days in the US contrasts sharply with what is reported here.

Do these differences allow for different opportunities to improve outcomes?

We have added some additional text to the discussion to include estimates of mortality and average length of stay in US and UK (page 14, paragraphs 1, 2). There are wide variations in the reported LOS within studies (e.g. 6.4 days SD 5.1 in the Medicare study of Beuno et al, JAMA 2010;302:2141-2147) and variations by age; some differences may also reflect practice patterns and financial arrangements in different countries. Despite the shorter mean LOS in the study by Beuno et al, the 30-day mortality rate (10.7% in 2006) was similar to our estimate. Based on the available data, we don’t believe we can meaningfully speculate on different approaches that could be used in different settings to improve outcomes.

4. Discussion: Consider adding reference2 which also supports the authors’ findings.

We thank the reviewer for this reference; it has been added to the manuscript.

5. Page 13, last paragraph, last sentence, length of stay: this last sentence, “this highlights the need to stabilize patients with heart failure before discharge...” is not fully supported by the data presented. While it is possible that the reason for readmission is due to lack of or limited stability of patients prior to discharge, more data or references are needed to support the statement. It is also possible that the patients are just sick, and those are the ones who come back irrespective of what happens during hospitalization. Another possibility is that patients are not treated well or treated inconsistently when compared to guidelines, and it is this lack of adherence that is contributing to poor outcomes. Or perhaps they were unable to obtain timely follow up. There are other possibilities as well (3). Given the importance of this topic, and the impressive data presented, some other possibilities as to why there’s such a high readmission rate is important to discuss. However, this discussion needs to be broader than what is currently present.

A similar point can be made, for the 1st paragraph at the top of page 15. Why certain patients are readmitted, versus those that are not is unclear. It may be that hospitalization identifies a high-risk subgroup. If that is the case, then chronic disease management, while
important for both groups, may need to be tailored differently for those who never get admitted, versus those who are admitted frequently. Although this reviewer agrees that the authors’ data in general identifies a typical patient, the heterogeneity of the patient population is something that should not be ignored. While general principles may be used, also identifying which patients may benefit most from certain tailored interventions is also important. If the authors want to suggest health policy implications, a broader discussion is needed. One possibility would be to present the data and discussion, but avoid policy suggestions.

We thank the reviewer for the additional comments and clinical perspective brought to the interpretation of the study results. We agree that comments as to the causes of and solutions to the high readmission rates remain speculative. As noted in our response to major issues in point 2 above, it was not our intention to suggest there were single solutions to these complex issues, rather across the individual points raised we have mentioned issues of better control of hypertension, adherence to evidence-based guidelines for the management of chronic heart failure, community-based outreach programs, better palliative care programs and more hospice places.

Our major point based on the results of this study was that particularly for elderly patients with frequent readmissions, clinicians need to be particularly aware of the risks for readmission. Given the enormous pressure on public hospital beds in Australia and pressures for shorter hospital stays, it may be that for at least some of these patients a short hospital stay may add to the risks of readmission.

6. Conclusion: this should be strengthened. The authors highlight several key points both from their data and in the discussion. These should be briefly highlighted.

We have added some additional comments to the conclusion in the manuscript (page 17).

7. Table 7: Please list all the other confounding factors.

The confounding factors have been added in the footnote to Table 8 (previous Table 7).