Author’s response to reviews

Title: Patient-reported outcome measurement in community-acquired pneumonia: Feasibility of routine application in an elderly hospitalized population

Authors:

Melanie Lloyd (melanie.lloyd@wh.org.au)
Clarice Tang (clarice.tang@wh.org.au)
Emily Callander (e.callander@griffith.edu.au)
Edward Janus (edward.janus@wh.org.au)
Amalia Karahalios (emily.karahalios@unimelb.edu.au)
Elizabeth Skinner (drlizzieskinner@gmail.com)
Stephanie Lowe (stephanie.lowe@wh.org.au)
Harin Karunajeewa (harin.karunajeewa@wh.org.au)

Version: 1 Date: 26 Jun 2019

Author’s response to reviews:

Dear Dr Parpia,

RE. Manuscript ID PAFS-D-19-00065

Thank you for the opportunity to amend our manuscript in response to the constructive feedback provided by the reviewers. We appreciate the time and effort both you and the reviewers have given in assisting us to improve our work. We have addressed each of the issues raised below and appended the updated manuscript (both clean and marked up versions)

Thank you for considering our manuscript.

Yours sincerely,

Melanie Lloyd (on behalf of the authors).

RESPONSE TO REVIEWER COMMENTS
Editor comment: Remove all results of statistical tests and associated p-values as the trial was not designed to make such hypothesis tests

We have removed all statistical test as requested. See changes to the abstract (Page 1, lines 21-22), statistical analysis methods (page 9, lines 193-202), Results (Page 11, line 233-245), and Table 3 (page 20) where the final two columns have been removed.

Reviewer #1

This is a well written paper which is of interest to PROM researchers and those managing patients with Community Acquired Pneumonia (CAP). There are limitations to the findings, but the authors appropriately acknowledge these in the manuscript.

I have some minor suggestions for improvement.

1. The authors should apply consistent use of the plural for data throughout (i.e. data are). There are instances of both singular and plural use within the manuscript.

This oversight has been addressed in the manuscript. See the following corrections to the marked-up manuscript:

- Page 4, line 79.
- Page 8, line 170.
- Page 11, line 228.

2. The abstract needs a little reworking. The results should mirror the methods and at present neither present a full picture of the manuscript as a whole. The methods for example do not present details of how the questionnaires were administered and what other information (for example demographic data) were collected from the patients. The methods describe feasibility outcomes (e.g. attrition rate, missing data etc), but only some of these data are presented in the abstract results. It would be useful to add that the limited sample size limits these results in the abstract conclusion.

We have updated both the Abstract and Methods as requested. Changes are listed below.

Abstract (Page 1, lines 7-24):

Methods: A sample of hospitalized subjects meeting a standardized CAP definition was recruited. Demographic and clinical data of those able and unable to participate in PROMs assessment were compared. The EQ-5D-5L, CAP-Sym 18 Questionnaire and Late-Life Function and Disability Instrument (LLFDI) were administered (via face-to-face interview) at admission
and discharge, and (via phone interview or mail) at 30 and 90 days post-discharge. Feasibility measures included proportion of individuals able to participate in assessment, attrition rates, data completeness and instrument completion times. Scores at admission and 30 days post-discharge were examined for association with age.

Results: Of 82 subjects screened, 44 (54%) participated. Cognitive impairment (n=12, 15%) commonly precluded participation. Seventeen (39%) participants were lost to follow-up by 90-days. Missing data at item level was negligible for all instruments, regardless of mode of completion. Completion of the three instruments collectively in a face-to-face interview took a median 17 [Inter-quartile range: 13-21] minutes per participant. Burden of reported symptoms at admission was higher for younger participants aged 18-74 years (mean (standard deviation) CAP-Sym 18 score at admission 34.2 (18.6) vs. 19.0 (11.3) for those aged ≥75 years).

Methods/Data collection and management (Page 8, lines 173-177):

“Demographic and clinical data (age, sex, language status, residential status, comorbidities and disease severity) were available for all CAP patients admitted during the SWAT analysis recruitment period via the main trial database. These data were used to identify differences in the characteristics of those individuals participating in the PROMs feasibility study compared to those who did not.”

The methods used to administer the questionnaires are detailed on Page 9 (lines 181-184).

Reviewer #2:

I wish to thank the editor and the authors for the opportunity to review the presented manuscript titled 'patient-reported outcome measurement in community-acquired pneumonia: feasibility of routine application in an elderly hospitalised population'. The presented manuscript describes a novel and interesting pilot study examining the feasibility of routinely collecting patient reported outcomes measures (PROMs) for elderly people admitted to hospital with community acquired pneumonia (CAP). The study appears well conducted, using appropriate analysis, and the paper is presented clearly. Although there are methodological issues related to potentially biased sampling and loss to follow up, these issues are precisely what the study is exploring. Therefore, the study has addressed its aims by identifying the issues related to collecting PROMs in this cohort. I have a number of minor comments, which I believe the authors will be able to address with minor changes or responses. My primary concern relates to the conclusions and framing of the results. I believe the authors should not shy away from the challenges involved with this work, and could more clearly emphasise that it did not appear feasible to collect PROMs in this cohort.

1. Abstract, conclusion: I'm not sure the conclusions adequately reflect the study findings. I have expanded more on this in my last comment regarding the conclusion section at the end of the paper.
Please see our response to Reviewer 2 comment 9 below.

2. Methods, feasibility outcomes, page 6: Can the authors please justify why the benchmark of 32% was chosen and why the particular reference was chosen? A small justification is needed to ensure there is no perception that the benchmark and reference were 'cherry picked'.

The study referred to here (Mangen et al 2017 BMC Infectious Diseases) was the largest observational study of CAP where recovery was measured using PROMs that had been published at the time we were designing our study. It had been recently published in a high impact journal and we therefore felt it set a useful benchmark for our work.

The manuscript has been updated to reflect our reasoning for this choice of benchmark (See page 7, lines 149-151).

“Ability to participate in questionnaire-based assessment, as measured by:

a) proportion willing and able to participate in the study in comparison to a recent large observational cohort benchmark (where recovery from CAP was assessed using PROMs as the primary outcome) of 32%,4”

3. Methods, data collection and management, page 7: At what point of admission to the ward was the survey conducted (e.g. within 24hours)? The same question applies to point of discharge.

This has been clarified in the manuscript text – see page 9, lines 181-184, of the marked up version.

“Admission assessments were completed on the first day of hospital admission, and discharge assessments on the last day of stay on the acute ward (ie. immediately prior to discharge either home or to an interim sub-acute rehabilitation facility).”

4. Figure 1: Please spell out the acronym 'NESB', or provide a footnote.

The abbreviations are included in the legend of Figure 1 which is on page 21 of the marked-up manuscript.

6. Table 2: Why does Table 2 omit 90day data? I know you didn't wish to analyse 90day data due to attrition. But this table only presents summative data, so it may be appropriate to include?

All time points were included in the missing data analysis (where relevant as not all three questionnaires were completed at all time points).
For the instrument completion time data, we chose to present the admission and 30-day time points as these were the only times when all three questionnaires were completed concurrently. We felt that these time points gave the clearest "snapshot" of the time burden associated with instrument completion in order to allow the reader to compare between instruments and modes of completion (face-to-face vs. phone). We are not convinced that adding the discharge and/or 90-day data will provide further useful information, and are worried that this will overly complicate the message that Table 2 is communicating, given the differences in questionnaires completed at different time points which would then need to be explained to the reader in order for them to understand the table.

6. Table 2: It might be interesting to see face to face, phone and mail data broken down to admission, discharge, 30day and 90day (e.g. is it more likely that postal methods were used for 90day follow up - can this partly explain failure?).

This suggestion would be most relevant for the missing data at instrument level (given negligible missing data at item level). We have reviewed the missing data by time point as suggested and found that the amount of mail-out questionnaires that were not completed was fairly similar at 30-days (7/10 missing) vs. 90-days (5/10 missing). The key point that Table 2 is communicating here is that mailed questionnaires have a poor completion rate, and it would appear that this is a problem regardless of how recently the patient was enrolled in the study. We have therefore elected to leave the table unchanged to avoid overcomplicating the results given that the time period does not appear to explain failure as queried by the reviewer.

7. Discussion, page 12, line 1: I think the use of the word 'extremely' is subjective and emotive. Perhaps something like 'more symptomatic relative to elderly' would be more appropriate.

Thank you for your suggestion. We have revised the sentence (Page 13, line 294-295) of the marked-up manuscript accordingly.

“Younger individuals generally need to be more symptomatic relative to elderly to be hospitalized.”

8. Discussion, page 12, line 7: point three is a little assumptive. Perhaps 'may be accustom to poor health' would be more appropriate.

Again, thank you for the suggestion, we have revised the sentence (Page 13, line 298) accordingly.

“Older individuals with chronic illness may be accustom to poor health meaning the marginal impact of an acute episode is reduced.”
9. Conclusions: I think the conclusions need to better emphasise what the study found. Stronger emphasis is needed regarding the difficulties sampling people from non-English speaking backgrounds and those with impaired cognitive function. Additionally the loss to follow up should also be a main focus. I would be tempted to state that collection of PROMs using the described method was not feasible.

Also in relation to the sentence on future research, I don't think this adequately captures the lessons learned. I am less concerned about maximising efficiency as I am concerned with finding a feasible method for routinely collecting PROMs. For example, do we need to link in with primary care? Should patients complete these measures during follow up with their GP? Could technology help through the use of 'push notifications'? Are we better contacting a family member to facilitate? Perhaps more focus on recommendations for future research should be placed in the discussion section more generally.

We have rewritten the Discussion and Conclusion in response to the reviewer’s suggestions. The revised sections are provided below.

Discussion (Page 13, lines 285-288):

“Future research could consider alternative methods to reduce attrition, such as facilitation via a family member, carer or primary care clinician, or the use of technology to provide reminders and internet-based options for instrument completion.”

Conclusion (Page 15, lines 331-340)

“A modular approach to PROMs, comprising routine application of three short instruments (EQ5D, LLFDI and CAP-Sym), can provide valuable information relating to multiple aspects of clinical recovery for individuals hospitalized with CAP. However, the heterogeneous characteristics, acuity of illness and complex underlying health status of this population preclude participation of a significant proportion of individuals in PROMs assessment, introducing challenges to feasibility and interpretability of these instruments. The exclusion of individuals from diverse language backgrounds and with cognitive impairment from PROMs assessment is a particular concern, and high rates of attrition also affected the feasibility of repeated assessments with these instruments.”

Reviewer #3:

This paper examines the clinical utility of measuring patient related outcome measures (PROMS) in patients admitted to hospital acutely with community acquired pneumonia. While the sample size is small, the novelty of this paper lies in its generalisability with respect to the disease and age group. Further work needs to be undertaken in examining the clinical utility of PROMS in culturally and language diverse populations.

No further changes required from Reviewer #3.