Author's response to reviews

Title: Novel study design to assess the utility of the COPD Assessment Test in a primary care setting

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Author's response to reviews: see over
Arlene Pura, Journal Editorial Office
BioMed Central, BMC Medical Research Methodology

Re: MS 5373690927172598 entitled “Novel study design to assess the utility of the COPD Assessment Test in a primary care setting” – Response to reviewers’ comments

Dear Arlene,

On behalf of my colleagues, I would like to thank you for your review and feedback on our manuscript. We have addressed the comments made by the reviewers below, and made amendments to the manuscript as required. We have submitted the amended manuscript and figures.

Reviewer 1 comments

I would find more detail on the methods used helpful to support the claim that they were ‘robust’. In particular, how the physicians were recruited including rates of consent, how many took part, number of assessors, country of origin, training. For example, the manuscript states that 2 or 4 locations were used, depending on the number of physicians required, but it isn’t clear how this number was reached. Also, I would like to find out more about how physicians in the CAT+ arm were trained. Davidson et al (2003) in Implementation Science, gave guidelines for reporting the content of behaviour change interventions which could help to frame this description.

Response: Additional information requested has been added to the manuscript, including a new Table 1 which sets out the number of participants, group size, locations and number of assessors per country. Please note, for consent rate, it is only possible to comment on the number of physicians who agreed to participate in the study but did not attend the filming, as we do not have access to information on the number of physicians contacted by the market research agencies but did not consent to participate in the study (much like in a clinical study, it is not possible to collect information on eligible patients who do not consent to enrol in the study).

The guidance/training given to assessors on how to rate consultations should be summarized within the manuscript. For example, what consisted ‘acceptable’ understanding. For patients with only 4 issues, the maximum A score might be lower- how this was dealt with should be discussed. The authors might wish to give examples of physician consultations where issues were addressed or not to assist with understanding.

Response: Additional information requested has been added to the manuscript. While it is acknowledged that the inclusion of descriptions of example consultations could help readers to understand the assessment criteria, it was felt that this would be an overly wordy way address the reviewer’s concerns. Therefore, we have just included a description of the difference between ‘acceptable’ and ‘accurate’ understanding scores, and between ‘some’ and ‘high’ scores for sub-scores A and B.

The authors might wish to consider the impact of different countries on physician communication skills. Under physician recruitment they state that ‘location is unlikely to affect physician communication skills’- I would think that the different healthcare systems and social
norms regarding healthcare systems in different countries might have an impact on consultation content. Further discussion of relevant literature around this would help to put these results in context.

Response: The manuscript text quoted here should refer to rural versus urban-based physicians within an individual country, rather than across the countries (this has been clarified in the text).

We agree there are differences in healthcare practices across the countries involved. Country of physician was therefore included as a likely confounder in the statistical analysis we conducted – as laid out in the statistical sections of the manuscript – to ensure that the results generated from the study could be considered generalisable across multiple countries.

'physicians were consented' should be 'physicians consented'.

Response: amendment made

The authors might wish to include more discussion of the hierarchical nature of their data. My understanding of the method is that the assessments of physician performance could be clustered within actors, participant physicians, physician group, country and assessor. Any implications that this might have for analysis strategies (e.g. using ICCs) or power should be discussed.

Response: We agree that the structure of the design shows a complexity that affects the power of the analyses. We decided to analyse the data in the primary analysis with a mixed model with repeated measures, the physician being at the basis of the model, considering he is the unit on which the randomisation (CAT - / CAT +) is applied, the other variables being taken as adjustment variables in the model. The structure of the model indeed has implications on the power of the study but we took a conservative approach during the sample size determination, taking the worst case standard deviation observed in the pilot study, to give us the best chance of a clear outcome. In the final result, the standard error of the mean difference between the groups was 0.71, with a 95% CI of [-1.04;1.77], showing a precision which would have allowed a sufficient power to detect a difference of 4 points (10% of the scale), should such a difference have existed.

The researchers use the term 'patient issues' in several places. A definition of this term, and description of how these issues differ from the medical histories section of Table 1 is needed.

Response: A definition of 'patient issues' has been included in the manuscript text, and additional clarification is provided in the legend for table 2 (formerly table 1).

The authors state that physicians were unaware of the goals of the study but from the recruitment strategy it seems possible to me that some of the participants might have been able to guess what the study goals were. If there is any information available to support the assumption e.g. physician checks, this would help support this claim.

Response: The physicians were asked again at the filming session some of the screening questions (whether they had used the CAT and what their experience of managing COPD patients was). Those physicians who reported a working knowledge of CAT at this stage were excluded from the primary analysis.

Additional wording has been added to the manuscript to reflect this.

My understanding is that some actors and assessors were used to evaluate consultations in countries which they were not native to. This approach might have some strengths (e.g. allowing for the same actors/assessors in different countries) and some limitations (e.g. if assessors were more or less well-disposed to physicians from different countries). A description of where the overlap took place, and discussion of these strengths and limitations, and any steps
to overcome these effects could assist the reader in understanding the validity of these techniques.

**Response:** Additional information is provided in the manuscript relating to the number of actors and assessors who worked across two or more countries. Many of the actors were either native to, or had previously lived in, the countries in question, plus they spent time with local patients to be able to portray and discuss their disease accurately. It is worth noting that the feedback on the actors from the physicians involved was always how believable they were. Any impact of assessors from the UK and Germany scorning physicians from Ireland and Austria differently would have been accounted for in the statistical modelling described.

**Reviewer 2’s comments**

Understanding how the CAT may impact the conduct of a visit is a very interesting and potentially important outcome. However, it is not the main outcome of interest which is whether or not the use of the CAT modifies therapy and most importantly patient outcomes such as quality of life or functionality. This must be stated clearly and described as a limitation of this clever study design.

**Response:** At the time it was conducted there were no treatment / management guidelines based on CAT results available. Although this has now changed, with the inclusion of CAT in the GOLD diagnosis, management and prevention of COPD assessment framework, the study design presented would still be unable to address whether any changes in physician / patient communication driven by the CAT would impact outcomes. This has been included as a limitation in the manuscript.

**Associate Editor’s Comments:**

I agree with the reviewer for the need for a definition of "patient issues".

**Response:** As above, a definition of 'patient issues’ has been included in the text, and clarified in the legend for table 2.

Additionally, I would recommend that the authors address applicability in different healthcare systems.

**Response:** We decided to conduct a multi-national study as we wanted to see how the CAT performed across different cultural and health system differences in Europe, and to produce data that was reasonably generalisable across the region. Physician’s characteristics, including country, were included as a potential confounder in the planned secondary analysis in case any differences across the countries impacted the comparison between the arms. Although not appropriate to present the results of the study analyses in this manuscript, we can confirm that this secondary analysis showed no difference in the outcome of the study when these potential confounders were taken into account.

Additional detail is needed regarding methods employed in this assessment study, including, but not limited to; physician recruitment, participation rates, and training (see reviewer's report). Included in this is the need for additional information on assessment (e.g., training given to assessors, number of assessors employed, guidance for grading, etc.).

**Response:** As above, additional information has been provided, including a new Table 1, and clarifications have been provided to address reviewers’ concerns.

Additionally, it is recommended that the author(s) consider the impact of the intervention on the total context of care and outcomes ("CAT impact on the conduct of the visit" - see reviewer's report). If not assessed, this should be identified as a potential limitation.

**Response:** As above, this limitation is noted in the concluding remarks of the manuscript.
Tables: Please ensure that the order in which your tables are cited is the same as the order in which they are provided. Every table must be cited in the text, using Arabic numerals. Please do not use ranges when listing tables. Tables must not be subdivided, or contain tables within tables. Please note that we are unable to display vertical lines or text within tables, no display merged cells: please re-layout your table without these elements. Tables should be formatted using the Table tool in your word processor. Please ensure the table title is above the table and the legend is below the table. For more information, see the instructions for authors on the journal website.

Response: Of these requirements, we can only find the inclusion of vertical lines as out of compliance (however, this was in accordance with the instructions on the authors’ checklist). These have therefore been removed. We have also replaced the special ± symbol with +/- in case this is an issue, although it isn’t stated as such here or in the authors’ checklist.

Figure cropping: It is important for the final layout of the manuscript that the figures are cropped as closely as possible to minimise white space around the image. For more information, see the instructions for authors: http://www.biomedcentral.com/info/ifora/figures.

Response: Figures 1, 2, and 4 have been cropped and included in the resubmission. Unfortunately figure 3 cannot be cropped further without loss of information.

We thank you for your time in reviewing this resubmission, and we look forward to a successful conclusion to the review process. If any questions should arise, please feel free to contact me at: Helen.c.marsden@gsk.com.

Yours faithfully

Dr Helen Marsden