Author's response to reviews

Title: Standardisation of information submitted to an endpoint committee for cause of death assignment in a cancer screening trial - lessons learnt from CAP (Cluster randomised triAl of PSA testing for Prostate cancer)

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Author's response to reviews: see over
Re: Manuscript 7187595281431144

Title: Standardisation of information submitted to an endpoint committee for cause of death assignment in a cancer screening trial – lessons learnt from CAP (Cluster randomised triAl of PSA testing for Prostate cancer)

Dear Editors,

Thank you for your email of 12 December 2014. My colleagues and I appreciate your willingness to consider a revision of this manuscript.

We are grateful to the referees for their helpful comments. Below we have outlined the changes we have made in response to their comments:

**Referee 1:** I only have some minor essential points for revision: 1) The loss of clinical information in an attempt to blind the reviewer is certain to have an effect on the accuracy of the determination of UCD. This is mentioned briefly in the discussion but some further comment is needed. Did reviewers feel that loss of this information influenced the confidence with which they could assign UCD. This would be important to establish.

In the Discussion (4th paragraph) we have added the confidence ratings given by the reviewers for their UCD decision to address this point.

2) Figure 2 and 3 are redundant as the information presented is sufficiently evident within the tables and text.

We have removed Figure 2 and 3 from the manuscript.

**Referee 2:** The manuscript has improved considerably. I have two minor additional items: 1) The abstract and the text do not specify an aim of the paper/investigation (It only states that it “describes procedures…” Is there a point in avoiding to make an aim explicit?

We have replaced the phrase “describe procedures” with an explicit aim in both the Abstract and main text (Background - last paragraph).
2) From a practical perspective, it would be useful to know the necessary man hours for implementing the vignette based blinding procedure. This information would make the planning of similar procedures in future trials easier.

Thank you for the suggestion. Implementing the vignette based blinding procedure did not require additional time; in fact, it shortened vignette writing time as the amount of clinical data presented became more streamlined. This point of discussion has been added to the 4th paragraph of Discussion.

Referee 3: The manuscript is well written and improved. The interpretation of the results from phase 1 and phase 2 are still difficult. The main results is that the percentage of reviewers that were unable to answer was higher. This is the results that should be highlighted the most.

The main result has been highlighted in Abstract (Results section) and also in the 1st paragraph of Discussion. We have now emphasised that following the standardisation of information submitted for UCD ascertainment, the percentage of cases whereby reviewers were unable to determine trial arm has increased.

Thank you for your consideration of this manuscript. We look forward to hearing from you in due course.

Yours sincerely,

Elizabeth Hill on behalf of all co-authors

Research Associate, CAP Study