Reviewer’s report

Title: Eligibility determination for clinical trials: development of a case review process

Version: 1

Date: 17 July 2014

Reviewer: Gordon Doig

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Review of Trial MS entitled “Eligibility determination for clinical trials: development of a case review process”

This is a very interesting and well written descriptive paper. Although this paper provides a detailed description of a process used at one research site, it would benefit immensely from presentation of performance measures that demonstrate whether the extra work from this panel process is time well spent. Please address the following issues with changes / additions to your manuscript.

1. Page 9, lines 186. 225 patients were ‘excluded’ through this process. Please provide more detail for each reason, with numbers. For example, how many were excluded because explicit Inclusion Diagnostic Criteria clearly were not met? How many were excluded because explicit Exclusion Criteria were clearly met? How many were excluded because team consensus was not met? How many were excluded for non-specific reasons/judgements made by panel?

2. Page 9, line 186-188. Of the 72 patients not allocated, how many refused consent and how many were excluded based on explicit criteria ascertained on response at interview?

3. Page 10, Line 204. In this detailed list of exclusions, please explicitly indicate whether each of these reasons was an exact eligibility criteria listed by the study under consideration. It is very important to understand how many patients were excluded by your panel because of explicit study eligibility criteria and how many were excluded due to other reasons, not explicitly defined by the study. Please also explicitly report whether any of the patients who were enrolled were later reported to be inappropriate by the trials central office? How does your case review process conduct eligibility screening ‘better’ than a normal process?

4. Page 10, Line 214. Please provide more detail overall with regards to the exclusion for ‘safety concerns’. It is very important to understand whether these exclusions were consistent with explicit study eligibility criteria or whether these were additional ‘safety’ judgements made by the panel.

5. Tables for Trial 1 and Trial 2 can be moved to the main manuscript. Please also provide a similar table for all trials.

6. Page 10. Please report an average time. If only 15 minutes are required for
each patient, and 697 patients were screened by a committee of 6 to 12 (average 10) people who earn $50/h, this process cost $87,125. If 30 minutes are required, these costs are doubled. Based on the data presented in Line 221-220, your panel review process costs $1,500 per week. This issue needs to be addressed in your Discussion. This paper should provide some measure of quantifiable ‘information gain’ that justifies these costs.

7. The opinions expressed in the first paragraphs of your Discussion are very interesting, but are not supported by any data or hypothesis tested in your Results. For example (Line 243), your data does not demonstrate how this panel mitigates clinician conflict between what they understand as their responsibility to their patient vs. the trial nor (Line 262) does it demonstrate how electronic access to protocols improves the consistency of interpretation of eligibility criteria. You have a wonderful opportunity in this paper to actually show that your review panel improves trial conduct. Given the resources consumed by your panel, please take a step back and re-think your primary reason for publishing this paper.

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests.