Reviewer’s report

Title: Using a Business Model Approach and Marketing Techniques for Recruitment to Clinical Trials

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Reviewer: Sue Ross

Reviewer’s report:

Thank you for the opportunity to review this very interesting and useful paper. It will be of relevance to all researchers and clinicians who conduct trials – because the issue of poor recruitment is the single most challenging and universal problem associated with trials.

The authors set out with three stated goals:
1. to describe what is known about interventions to improve recruitment to trials
2. to describe a business approach to trials
3. to discuss the implementation of the business approach using 4 case studies as illustrations.

Review of known interventions
The first goal is achieved in a brief section reviewing the literature. This section naturally moves into a description of the model.

Description of the model
The next section is equally brief, providing a concise description of the model. The figure provides a graphical depiction of the model and sets the scene extremely well, particularly when supported by Table 1, which provides a “translation” of the model components for trialists. This section underpins the whole paper. In addition, this section stresses the need to consider the 12 components of the model as links in a chain: to identify specific weak links that might weaken the whole chain.

Case studies
The paper goes on to use 4 case studies to describe specific uses of the model in each of 3 particular ways: to design a recruitment plan (case study 1), as a diagnostic tool when recruitment is a problem (case study 2), as an audit tool to monitor progress of recruitment (case study 3).

Case study 1 – using the model to develop trial processes
This section of the paper describes in detail the use of the model from the set-up of the CRASH-2 trial. This case study is developed systematically using the model components as a basis for evaluating the , and provides a convincing description of the utility of the model.
Case study 2 - using the model as a diagnostic tool
This case study, using TXTSTOP as an example, is described very briefly, and it is not clear how the model worked in this trial. Neither the review of recruitment, nor the changes in the recruitment practices seem any different from what would happen with a more “traditional” approach.

Case study 3 – using the model as an audit tool
The case study in which the model was used to audit the LIFELAX trial to find out why recruitment was failing. As with case study 2, it is hard to see how review of this case was enhanced using the model.

Case study 4 – interview with an experienced trialist
Adding this final “case” was an interesting idea. It did not help that the interviewee seemed to be agreeing with the interviewer’s points rather than endorsing the model wholeheartedly, or commenting specifically on how the model changed his/her ideas or practice.

Discussion
The discussion is interesting, noting the resistance to marketing concepts by medical researchers.

One point that is clear from case study 2 is the vulnerability of trials to external unpredictable influences (eg large-scale stop smoking campaigns). The model may not be able to cope with these externalities.

Suggestions for the authors

Major compulsory revisions
1. The sections summarising the reviews of interventions to improve trial recruitment, and the one describing the business model, could be incorporated into the background. The paper would then have a single goal: To discuss the implementation of the business approach using case studies as illustrations.
2. The case studies are the most important part of the paper, illustrating exactly how the model works in practice. The text of the case study section could be supplemented using a table. This would increase the amount of information given for cases 2 and 3 (without more text), and help the reader understand exactly how the model works in practice. (see attached table)
3. Case study 4 could be dropped without any loss of useful information.
4. The Discussion would need a bit of tweaking to match with the Introduction and Case study sections.

Minor essential revisions
1. The headings for the case study sections should highlight the particular aspects of the model, rather than the actual trials. This would ensure that the model is the focus of the paper.
2. Use same numbering of domains and components throughout the figure,
tables and text (eg Ia, Ib, 2c), particularly providing headings within each of the case study descriptions. This would improve the flow of the paper and be easy for the reader to follow. It would also help the reader to understand exactly how useful the model was in practice.

**Level of interest:** An article of outstanding merit and interest in its field

**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 a potential competing interest with two of the authors, McDonald and Campbell. I hope to undertake a sabbatical next year at HSRU in Aberdeen where they are based. I have in the past (around 10 years ago) published papers with them.