Reviewer's report

Title: A Statistical Framework for Quantifying Clinical Equipoise for Decision Making Regarding Recruitment in Randomized Controlled Surgical Trials

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Reviewer: Jonathan Alistair Cook

Reviewer's report:

The authors present an interesting way to represent uncertainty related to the treatment choice for a patient in a mathematical framework. An example is given where surgeons undertook an elicitation process from a current RCT and the results are represented numerically and in a graphical form.

Major compulsory revisions

1. Some of the results/conclusions in the abstract and conclusions are not justified by what is presented in the paper. It is stated that the methods holds considerable promise for improving recruitment rates. However, the results presented show the use of the framework to graphically represent beliefs and give no evidence on its use nor how it might influence surgeons’ decision making. To represent something is one thing but to modify the behaviour is something completely different.

2. I have a strong concern related to the three aspects used to graphically represent opinion and specifically why there are three aspects. Intuitively “belief” and “disbelief” would seem they same aspect (but reversed). The use in the paper implies this is not how they are being used and this would seem to be the case as defined in section 2.2. However, it appears “belief” related to belief one procedure over another and “disbelief” relates to certainty about whether it would improve or not the condition of this particular patient. Taking this is the correct interpretation, the constraint (equation 1) and the ternary plot implies that certainty about which treatment is best cannot be held with strong uncertain about whether it will work for a particular treatment. In my opinion this is a highly dubious restriction. For example there are clinical areas where the most effective treatment (e.g. treatment of some cancers) is very clear but it does not work universally. Thus you can be very certain about which treatment is the best but also have a large degree of uncertainty about whether it will work for a particular person. I would personally say there is typically uncertain about particular case for many clinical scenarios despite the choice of preferred treatment often being clear. Another scenario which seems in conflict with the proposed framework is a good degree of confidence that a treatment works but a large degree of uncertainty that it is the best treatment. No discussion of whether this framework applies in the context (or any?) is made of this which is to me a critical point and only a reference given but no discussion. The authors need to clearly defend the application of a restrictive framework to represent equipoise. On page 9 analogous to probability is suggested for the restriction in equation 1 (the three
aspects summing to 1). This is only true if the elements summed to one are mutually exclusive and together exhaustive. As presented, I am not clear that either is the case here.

3. As defined in section 2.2. “belief” refers to the choice but “disbelief” only refers to a single intervention. Based upon the interpretation should not a full representation of equipoise (a state relating to a decision) not require at least two disbeliefs (or alternatively equilateral triangles) one for each of intervention?

Minor essential revisions
1. P4: The 5 widely used approaches need some fleshing out to clarify for the regard what they are and specifically how they differ.
2. Figure 3 would benefit for clarity about which side related to which aspect the scale relates to.
3. I would suggest “disbelief” is not used to describe one of the three aspect when another is called belief as it creates unnecessary confusion.
4. P13: The “80:20” rule should be more clearly explained both in its introduction and its application to this study.
5. More explanation of the steps in 2.3.2 and justification would be helpful for readers.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests