Reviewer’s report

Title: A guide to doing a peer review of randomised controlled trials

Version: 1 Date: 18 June 2015

Reviewer: Caroline Sabin

Reviewer’s report:

This was an interesting paper – although the authors didn’t intend to, I think they actually raise some interesting discussion points about the role and expectations of journal reviewers, not all of which I necessarily agree with. It would be interesting to read their thoughts on some of these points (in the spirit in which they are intended).

Overall, I thought the manuscript was clearly written. My only major comment (but not an essential one) is that it would have been nice to see a few examples of particularly good (or poor) practice as I think that is what new reviewers really appreciate.

- Major Compulsory Revisions
  None.

- Minor Essential Revisions
  None.

- Discretionary Revisions
  1. Paragraph 2. The authors raise an interesting point here. Whilst I agree that it’s important for reviewers to be careful in their wording, I’m not sure that I agree that we should always be ‘positive’. In my experience as a reviewer, I’ve often seen authors mis-interpret ‘positively’ phrased criticisms as not being critical (I’ve also done it myself as an author); as an editor, I also receive letters from authors who are confused as to why their ‘positively reviewed’ paper was subsequently rejected. So, I think there is a balance to be reached between being polite but being clear about the critical nature of any comments (this is often further complicated when reviewers and authors are not writing in their first language when nuances in tone may be lost). So, I would prefer this to say ‘carefully and constructively’ rather than ‘carefully and positively’.

  2. In the same section, I think it’s a little unfair to blame reviewers for the fact that the author is so hurt and wounded that s/he never re-submits. Rejection is a necessary and hard part of academic life and we all have to get used to it – if this is all it takes for someone to stop submitting, then I would argue that that person wasn’t destined for a career in this field (or doesn’t have a particularly good mentor/supervisor). Dealing with rejection is a learning curve – you can sometimes get to the point where particularly rude and negative comments are actually more amusing than they are distressing.
3. Key steps. I think there is actually a midway step between step 2 (checking for fatal flaws) and step 3 (major flaws) and that is checking to see that all of the required documentation that is required by the journal for submission is present. I'm thinking particularly about the CONSORT checklist (if appropriate and if required by the journal) and conflict of interest statements. The CONSORT checklist is mentioned by the authors later in the manuscript, but as it is so helpful when undertaking a review, it's better to check that it has been submitted at an early stage when there is still time for the journal editors to chase the authors for this information.

4. Fatal flaws – personally I would add ‘lack of information on sample size calculations’ to the list of fatal flaws. It would be highly unlikely for an author just to ‘forget’ to include this information in a paper relating to a randomised trial. In my experience, there are usually two real reasons why this information isn’t included: 1) no sample size calculation was performed, or 2) a sample size calculation was performed but the number of participants was substantially lower than anticipated. Both raise questions about the ethics of the trial and therefore this should be treated in a similar way to lack of information on ethical approval or informed consent.

5. Major flaws – this section might be improved if the bullets were re-ordered to reflect the ordering of the sections within a typical manuscript (so comments about the Methods before the Results, before the Conclusions etc.). I would suggest that the comment about the Methods section should also explicitly mention the Statistical Methods (which should also be described in sufficient detail to allow authors to replicate the analysis) – authors are often very good about describing laboratory and clinical methods in excessive detail but then summarise their Statistical Methods in a single sentence (usually along the lines of ‘Data were analysed using SPSS using a p-value of 0.05 as statistically significant.’). In the bullet on post-hoc analysis, it might be helpful to emphasise at the start (rather than the end) that post-hoc analyses are not necessarily bad, they just need to be clearly labelled as such to avoid over-interpretation.

6. Statistical analysis of RCTs. In fact, the analysis of most RCTs is generally a lot less complicated than that of many observational studies where there are many other sources of bias that need to be taken into consideration. So maybe just reword this as ‘The statistical analyses of RCTs can sometimes be complex.’ (‘can sometimes be very complicated’ sounds a bit patronising).

7. Be nice – I’m not convinced by this (and I think I am generally nice!) – there are times when it is hard to find anything positive to say about a manuscript and then any positive comments are token gestures – I would personally prefer a reviewer to be honest and constructive (and not rude) than for them to feel that they have to be nice to me.

8. Confidentiality – I don’t think there are many journals that still use a system whereby the submitting authors are anonymised (certainly, none of the journals in my own field do this) – even if they do, then it is almost always easy for reviewers to work out who the authors are based on the information in the Methods section (and as these are all randomised trials, they’ll all be registered
anyway, so the investigators will be listed online). So, I’d edit the second sentence to say ‘…(who may also be anonymous).’ The statement about the comments to the editor section is also an interesting one. In fact, as an editor, this is the section that I usually find the most helpful as it is the one place where reviewers are often honest and clear about their views (as their comments to the authors are always so positive, constructive and helpful that you never really get an overall view about how they actually feel about the manuscript!). So, I would encourage people to write something useful in that section that summarises their own feelings about the manuscript. I also tend to write fairly extensive reviews (as demonstrated here) - some editors may see a long list of comments and automatically reject the article without reading through them in detail – this section therefore gives me the opportunity to tell the editor that I actually rather like the manuscript but that my comments might improving it further. Finally in this section, I’m not sure I agree that ‘the trend is for open and transparent comment’ – in fact, there are many negative outcomes of open reviewing and not that many journals now use this approach (BMC being one notable exception). Also, it spoils my fun as an author – one of the first thing I always try to do is to work out who the reviewer is – and I’m sure I’m not alone in that...

9. Don’t be late – again, being a bit controversial, I would disagree that the rate-limiting step is usually the referee’s reports (actually, I think that the slowest part of the process is trying to find reviewers who will take on the task in the first place – once they have agreed, then the rest of the process is usually relatively quick), and I would argue that in many instances, the reviewer’s time IS more precious than the authors. Quite often, the reviewer has been selected as they do have specialist knowledge that other people don’t possess. They may receive requests from journals for reviews on a weekly or even daily basis (statisticians and health economists are often in this situation, for example) and so there are multiple demands on their time. And reviewing does take time if you want to do it properly, particularly for papers of a more technical nature. We have grown so used to getting instant gratification that we now find it difficult to wait for more than two weeks to hear back from a journal... So, whilst I agree that it’s important to stick to deadlines (and I generally do myself), we also have to recognise that different people have different priorities...

10. Final comments – it might be worth making the point that reviewing papers of others is actually a very good way of improving your own writing and research skills (if you identify mistakes that others make, you may be less likely to make them yourself in the future). Or you may just get better at covering them up…!

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests, although I do run several training courses for junior clinicians and researchers on appraising research.