Author’s response to reviews

Title: The value of the PRECIS wheel in an ongoing study: the BLISTER trial

Authors:

Daniel J Bratton (DBratton@ctu.mrc.ac.uk)
Andrew J Nunn (ajn@ctu.mrc.ac.uk)
Fenella Wojnarowska (fenella.wojnarowska@ndm.ox.ac.uk)
Gudula Kirtschig (g.kirtschig@vumc.nl)
Anna Sandell (anna.sandell@nottingham.ac.uk)
Hywel C Williams (hywel.williams@nottingham.ac.uk)

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Author’s response to reviews: see over
Reviewer's report

**Title:** The value of the PRECIS wheel in an ongoing study: the BLISTER trial

**Version:** 1 **Date:** 7 January 2012

**Reviewer:** Shaun Treweek

**Reviewer's report:**

General
It was very interesting reading this paper on the application of PRECIS in an ongoing trial, which helps to build up information on the applicability of the tool in trial design. The recommendation to include PRECIS wheels in trial protocols or trials is an excellent idea but not just for the benefit of researchers; clinicians and patients may also be interested. Some specific comments are given below, most important first and then by section heading.

*Response: Thank you – good point. We have now mentioned in the recommendation section that highlighting which trials are pragmatic may be useful to clinicians and patients.*

Major compulsory revisions
There is no quantitative information presented, a particular problem in Results because it makes it hard for readers to know whether some of the authors' statements are correct. It would also be useful to know how big, physically, the PRECIS tool sent to the six members of the BLISTER team was e.g. 4cm, 6cm spokes on the PRECIS wheel and there is no mention of a scale 0-4 or 0-10. The original PRECIS article by Thorpe et al does not provide a scoring system but it sounds as though the authors of the current paper have used one; it would be good to know what it was.

*Response: We agree that the addition of quantitative data would help to qualify our interpretations. We have now added a table displaying the scores from each member of the trial team and the mean and SD of these scores in each domain. The size of the wheel should not influence scoring but nonetheless all trial members were sent the same sized wheel. We have now given the size in the manuscript (approximately 15cm in diameter). We have now explained in the revised paper that a scale was not added to the spokes of the wheel but trial members were given the option of scoring the pragmatism of the trial in each domain out of 10 if this was easier. All scores were then transformed onto the same 0-100 scale before being averaged.*

So, for example, the authors say ‘there was a relatively narrow range of scores’ but it’s hard to know how true this is without a table providing numerical information on individual scores. Looking at Figure 1 does suggest that agreement was not as good as the statement suggests, something also true of the statement ‘the results were quite consistent’. The PRECIS spoke for eligibility criteria looks like there was a lot of disagreement within the
group, similarly for participant compliance. I think highlighting and making explicit these differences in trial teams is one of the strengths of the PRECIS tool so I don’t see it as a particular problem but some of the authors’ statements do suggest a greater level of consensus than the figure seems to show and, additionally, some numerical data are essential for readers to come to their own conclusions.

Response: Looking back, it is certainly possible that we may have overstated the level of consensus in this study and have now amended our conclusions. As you say, highlighting areas where consensus was less is of interest and value which is now available in the additional table. We have also now stated that highlighting differing opinions within the trial team is a strength of the PRECIS wheel.

Minor essential revisions

Abstract
Page 2. As mentioned above, some of the statements should be revisited, eg. ‘A relatively narrow range of scores were obtained on most of the ten domains of the PRECIS wheel showing evidence of a consensus among the team.’ I think the words ‘readily be’ should be dropped as using PRECIS can be tricky (and I say this as someone who was part of its development) and the authors highlight their own difficulties. Also “in such a way” is redundant.

Response: Some aspects of PRECIS use can indeed be tricky. We have now made your suggested changes in the text

Introduction

1. Page 3, 2nd paragraph. It would be helpful to the reader to list the ten characteristics of a trial that PRECIS considers.

Response: Done

2. There are two additional recent references using PRECIS that the authors may wish to look at and, if they feel it appropriate, reference:


Response: Thank you for these very useful additional references. We have now included them in the background section as examples of the PRECIS tool being applied to trials.

The BLISTER Trial
A bit of text along the lines of ‘...despite reporting standards such as CONSORT, there may be inadequate reporting...’ The authors are quite correct that inadequate reporting is a problem for retrospective completion of PRECIS. Tosh and colleagues (see reference above) mention inadequate reporting and used “0” to score a domain with no information. That’s one way of dealing with the problem and it would be worth mentioning.

Response: Thank you for this suggestion. We have now referenced the CONSORT guidelines and discussed how one might handle poorly reported domains. We feel the suggestion by Tosh et al. is inappropriate since scoring a domain as 0 out of 5 (at the centre of the wheel) is equivalent to saying it is completely explanatory. There is no more reason to score it as 0 as there is to score it with any other number.

Method
It would be useful to provide a blank PRECIS wheel to give readers an idea of what it looks like and what the authors used to score the trial. I don’t think it would be difficult to get permission to do this.

Response: We have now added this in figure 1

Benefits and Drawbacks of PRECIS
Page 6. Please specify the ‘more methodological domains’ that some of the clinicians found tricky.

Response: By this we meant just the “primary analysis” domains, so we have now specified this in the text.

Recommendations
Page 7, second paragraph, 3rd line. Spelling error – help researchERS not researches.


References
The following reference has now been published (it’s given as in press, which no doubt it was at submission).

Response: Thanks – now updated.

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

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
Reviewer's report

Title: The value of the PRECIS wheel in an ongoing study: the BLISTER trial

Version: 1 Date: 8 January 2012

Reviewer: Vilemne Carayanni

Reviewer's report:
I have read with a great interest the article of Bratton et al, which appeared to be a meticulously designed conducted and described study of applying the PRECIS tool to an ongoing trial (BLISTER) to determine whether the initial feeling among some team members that the trial was rather pragmatic was the consensus. It constitutes certainty a thorough work and an article of importance in its field. The writing is meticulous. The question posed is well defined and concerns an ongoing trial. The title and the abstract accurately convey what has been found and the discussion is well formulated and adequately supported by the data.

Response: thank you for these encouraging comments

I have some minor remarks:
Discretionary Revisions
1. The background needs enrichment. The PRECIS instrument is new and, therefore, the research community needs further publications that help to demonstrate whether it is, or is not, useful. The background must comprise a brief review (in few sentences) of the recent debate concerning the exact points of distinction between the two attitudes and the reason of adopting finally the PRECIS tool approach to classify their trial. These sentences could replace some of the ones in the first paragraph of Background which are too general.

Response: We take your point that a little more introduction to the main points of distinction between explanatory and pragmatic studies is needed. We have now said a little more on the differences between the design of pragmatic and explanatory trials to make the first paragraph a little less general. We feel the second paragraph of the background section adequately describes the reasons for adopting the PRECIS wheel.

2. The study was descriptive (this should be stated in the text by one sentence) and certainty could not be otherwise because of the number of observations. Nevertheless, it would be helpful for the interested reader to present, –beyond the range given on the Figure,- the mean scores and variation in scores for each domain on a Table.

Response: We agree. The mean and variation in scores have now been added to the paper and we have also reinforced the fact that our study is a descriptive one in the final paragraph of the background section.

Level of interest: An article of importance 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 declare that I have no competing interests'

**Reviewer’s report**

**Title:** The value of the PRECIS wheel in an ongoing study: the BLISTER trial

**Version:** 1 **Date:** 11 January 2012

**Reviewer:** Charlie Goldsmith

**Reviewer's report:**
In general, this article is a little too short and lacks details to be useful to typical readers. There should be more data presented, and the wheel should have some software identified to produce it, and there should be a discussion about trying to have a scale on each axis that is displayed. This tends to look like a Spydergram or windrose plot that has others names as well.

*Response:* We take your point, which echoes the two other referees and have responded by now adding a table and expanding on some of the text in the manuscript. We have been unable to identify any specific software used to plot results on a PRECIS wheel. We manually plotted the means on the PRECIS wheel using Microsoft Paint! We are open to suggestions for using other, more accurate software. No scales were added to the spokes of the wheel since they are individual continuums; however, some trial members were given the option of scoring each domain out of 10 if this was easier.

The following comments are more specific suggestions for improvement.

1. *P(age) 3, p(aragraph) 2, l(ine) 4.* Suggest that [in order] in front of [to] be deleted as the words are redundant in English.

   *Response:* Although “in order” is technically redundant we feel it reads better as “in order to”

   Also *P 4, p 3, l 5.* Also *P 7, p 4, l2.*

2. *P 6, p 3, l 4.* [BP] does not seem to be defined. It would be helpful to have a list of short forms used in the paper. A good location for this is just before the *R(eference)s on P 8.*

   *Response:* Thank you for this suggestion. We have now added a list of abbreviations and changed BP for bullous pemphigoid

3. *P 7, p 2, l 9.* Consider rewriting the sentence to avoid a dangling participle [in]. **OK**

   The Rs were checked for citation accuracy. Trials also like to list ALL authors to manuscripts. This reviewer also likes to use issue numbers as they make it easier to find the paper when it is needed.

4. *P 8, R 1, l 3.* Insert [(4)] after [15].
5. P 8, R 2, l 2. Add another author [Chalkidou K]. On l 4, insert [(5)] after [62].
6. P 8, R 3, l 4. Insert [(1)] after [63].
7. P 8, R 4, l 4. Replace [In Press, Corrected Proof] by [2011;64(10);1095-101].
9. P 8, R 5,l 2. Add the additional authors.
10. P 9, R 5, l 4. Insert [(7)] after [129].
11. P 9, R 6, l 2. Add the additional authors. On l insert [(5)] after [346].

Response: we appreciate these suggestions for improving the text and have made all of the above changes

12. P 9 as part of the Legend. It might be prudent to include the summary statistics that are used to create the wheel. A table would be fine including all the 10 dimensions. Is there software to create the wheel? If so, it should be cited

Response: We only used Microsoft Paint – could another type of software be used? A table of summary statistics has now been added.

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests: I declare that I have no competing interests.