Reviewer’s report

Title: Outcome measures in rheumatoid arthritis randomised trials over the last 50 years

Version: 1 Date: 16 June 2013

Reviewer: Kent Johnson

Reviewer’s report:

Yes to all the seven below
1. Is the question posed by the authors new and well defined?
2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
3. Are the data sound and well controlled?
4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
5. Are the discussion and conclusions well balanced and adequately supported by the data?
6. Do the title and abstract accurately convey what has been found?
7. Is the writing acceptable?

The aim of the paper is to describe the (conceptually simple notion of the) extent of uptake over time of the ACR/WHO/ILAR core set in RA trials. The article is well written and convincing, and, as noted in the first sentence of the discussion it “demonstrates that a community of trialists can come together to improve the consistency of outcomes that are measured”.

Major compulsory revisions: none

Minor Essential revisions

1-Figure 3: Better to use the early date, 1996, for FDA, as you did for EMA using 1998? I find Figure 3 confusing. The vertical axis is the percentage reporting the full RA COS for pharmacologic (red) and non-pharmacologic (blue) trials, and the vertical axis is also the average clinical outcomes (core and non-core), the black line, for all trials – this cannot be a percentage? This is confusing and should be clarified, using separate graphs if necessary. And how is it that the “average clinical outcomes” graph starts close to zero at the beginning time point of 1982. By the way, the color coding gets lost in black and white printings while dots, dashes, etc. do not. And could you comment why there are no non-pharmacological trials before 1992 or after 2004 – just a feature of Cochrane?

2-Table 1: For the novice, could you identify what the abbreviations for DMARD, SSAARD, and SMARD are at the bottom of the table?
Discretionary revisions

I have only a few suggestions. Some readers long involved with RA might like more commentary regarding a number of related topics such as the following (I realize this would expand the scope of the paper).

1-Brief mention of the methodology and rationale used to construct the ACR20, in particular, the use of the DMARD trial data sets from the Cooperative Clinics trials to adjudicate, along with expert opinion, the exact construction of the ACR20 – the choice and number of components and the algorithm for declaring success – 20% improvement in TJ and SJ plus 20% improvement in 3 of the other 5 components.

2-Comparisons with the DAS including uptake over time. Has anyone studied the DAS in a similar fashion? Are there examples in other disease settings of similar outcome creation using a combination of trial data and expert opinion, then subsequently studied regarding its uptake by the trialist community?

3-Possible intrinsic limitations of the ACR20 including the argument, albeit it made with observational, not randomized data, that ACR measures underrepresent morbidity in the long term because damage and disability are not sufficiently represented (e.g., Pincus. Clin Exp Rheumatol. 2004 Sep-Oct;22(5 Suppl 35):S50-6)

4-Consider calling all “trials” rather than “studies” in Figure 2

5-Web Table 4: add the word “only” before “Erythrocyte” and before “C-reactive”

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: no competing interests