Reviewer’s report

Title: Do we want more cancer patients on clinical trials? If so, what are the barriers to greater accrual?

Version: 1 Date: 24 April 2008

Reviewer: Mike Clarke

Reviewer’s report:

I enjoyed reading your views and agree with much of what you have written. However, I feel that you need to support some of your statements with a relevant reference to external data or more clearly identify them as your opinion. I have highlighted the statements below, but have arranged my comments in the order of the manuscript, subdivided into the types of Revisions suggested by Trials.

Major compulsory revisions

1. Abstract: the two parts of the sentence “The financial and regulatory problems ...up; it has been estimated ... conducted abroad” do not necessarily support each other. Since the second part is the current situation and you provide no information on what proportion of US-sponsored trials were conducted abroad before the financial and regulatory problems. Do you have data on that? Does the article you cite in the main text (reference 9) make the comparison over time?

2. Discussion, How do get more patients on clinical trials, paragraph 1: you should reference the “one estimate” that 95c of every dollar of cancer research funding goes to basic research. You should also reference the statement that the funding of the co-operative groups has been flat for years.

3. Discussion, How do get more patients on clinical trials, paragraph 3: your statement “I do not believe ...requirements” is very sweeping. Do you really not believe that anyone has noticed this? What if someone is working in a centre that streamlined their committees? If you keep the sentence, I suggest that you indicate whether you are talking about the USA or the world. It might also be worth you adding something about how much of the documentation is due to regulation and how much is due to the researchers desire to collect lots of information (probably more than they need) - similar to the issues I touch on in point 6.

Minor Essential Revisions

4. Introduction: can you add a reference to the statement that about 5% of cancer patients participate in clinical trials.

5. Discussion, paragraph 2: you appear to be critical of phase 2 trialists for not being prepared to go on to do phase 3 trials. In some cases, the skills needs for phase 2 and phase 3 trials are quite different and perhaps the challenge to phase 2 trialists (and the funders of phase 2 trials) should be that they should more
actively promote the uptake of their results in phase 3 trials. What do you think?

6. Discussion, How do get more patients on clinical trials, paragraph 2: you mention the need to spend a week on the “paperwork” for a single patient. How much of this is generated by regulation and how much is generated by poor design (e.g. excessive data collection) by the researchers?

7. Conclusions: are you able to give any reference to support the lack of sufficient randomised evidence for radiotherapy versus surgery for men with prostate cancer? For example, is there a systematic review that identifies this gap?

8. Are you able to include any examples of the “right clinical trials”.

Discussionary revisions

9. Discussion, How do get more patients on clinical trials, paragraph 2: I was surprised to read that even a single centre trial would have to go through so many committees. If there is space in your editorial, would you be able to expand this to provide the reader with an illustration of the things that each of these committees would oversee for the trial.

10. You might wish to mention initiatives in other places to facilitate randomised trials. For example, the European Union funded TENALEA project (www.tenalea.com) is providing an online, 24 hour registration and randomisation service for clinical trials.


12. Do you want to add anything to the article to comment on the definition of clinical trials used by the National Cancer Research Institute in the UK which was used in achieving the government target that 10% of cancer patients would be in “clinical trials”.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Declaration of competing interests: I am employed to work on systematic reviews and randomised trials. This article is relevant to both of these and, therefore, to my employment.