Reviewer’s report

Title: Feasibility study of a clinically-integrated randomized trial of modifications to radical prostatectomy

Version: 2 Date: 14 November 2011

Reviewer: Richard Platt

Reviewer’s report:

This report provides useful information about incorporating clinical trials into routine practice. This can be an important way to develop essential knowledge about what kinds of care work best for which patients.

-- Major Compulsory Revisions

• I recommend omitting the information about clinical outcomes by treatment group (last paragraph of the results). The authors correctly state that this was an underpowered feasibility study. It wasn’t intended to provide outcome data.

• Discussion, paragraph 7. “There is no clear mechanism by which missing data could cause bias.” It is not difficult to imagine that missing results could be strongly correlated with worse (or better) outcomes. At a minimum such missing poor results could bias the results toward the null. The discussion should give greater emphasis to the need to improve ascertainment of outcomes.

-- Minor Essential Revisions

• In several places, discussion points are included with the results. An example is the statement, in the 5th paragraph of Results, “We have no reason to believe that missing data reflected treatment choices…” These should be moved to the results section.

- Discretionary Revisions

• It will be helpful to consider the pros and cons of potential alternatives to this study design.

  o Is this kind of intervention a candidate for waiver of individual informed consent? Truog NEJM 1999;304:804 argued that IRBs should consider waiver under conditions that this trial appears to meet.

  o Is this approach amenable to (cluster) randomization by surgeon or by clinic?

• It appears the team developed implementation materials for medical personnel and, perhaps, for patients. It would be very helpful to others who would like to adopt their approach if they provide these in an on-line appendix.

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