Reviewer's report

Title: The impact of consent on observational research: a comparison of outcomes from consenters and non consenters to an observational study

Version: 2 Date: 23 January 2008

Reviewer: Don Willison

Reviewer's report:

Thank you for the opportunity to re-review this manuscript. I have read the revised manuscript and the authors’ replies to my comments. Below are my responses, using the authors’ numbering scheme. I would classify these as major compulsory revisions.

1. The authors have acknowledged this is a “worst case” scenario in their reply and have made revisions to the Background and Discussion section. However, they have avoided acknowledging in the manuscript that this is a “worst case” scenario. I suggest that the authors revise their sentence in the Discussion section to read “This study presents a hypothetical WORST-CASE SCENARIO based on a number of assumptions.” (The CAPITALIZED text indicates suggested added words.)

2. The authors now acknowledge in the manuscript that their scenario is likely to have under-estimated the level of consent that would have been obtained. However, the sentence that follows has been unchanged. This sentence presents the argument for their assertion that they over-estimated the level of consent. So, this next sentence no longer makes sense. It is probably best if they simply provide the remaining logic behind the counter-argument I had provided originally: that a proportion of the women who did not wish to complete their survey may well have consented to a review of their medical record, as it involved no additional time or effort on their part that would have been required by participating in the survey.

3. Role of gatekeepers: It is interesting that the authors describe the gatekeeper issue as a limitation to this particular study to assess the effect of consent on bias to study findings, and acknowledge that this is commonplace. Looking at the data, the proportion of patients “lost” to the study as a result of the gatekeepers non-engagement is greater (88/366 = 24%) than the loss due to individual refused to participate in the survey (41/218 = 19%). From a policy perspective the non-engagement of general practitioners should be highlighted in this paper to be as great a problem over data loss as non-consent on the part of patients and not simply dismissed as “a common feature of studies from health services lists” It seems very odd that there is such a concern over patient consent yet a lack of concern over general-practitioner non-participation.

4. The authors argue that the information from women presenting with locally
advanced or metastatic disease would not have been available from the chart, as they would likely have been dead at the time of chart review. The laws may well be different in the U.K. but death of the data subject is often considered by ethics boards in Canada to be sufficient grounds for exemption from the need for consent, not exclusion of data from the analysis. If not exempted, the worst case scenario would be permission required from the next closest relative. So, again, the assumptions of this scenario under-estimate the likely level of consent for medical record review. If the UK laws are similar on this matter, then the authors should acknowledge that, in making this assumption, they may be providing an over-estimate of consent bias. If the laws in the UK or MRC guidance do not permit such an exemption, then no changes are needed.

With the revisions suggested above, this reviewer feels the manuscript would be ready for publication.

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

**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.