Reviewer's report

Title: Method of recruiting Victorian women with a primary invasive breast cancer to a cohort study of wellbeing

Version: 1 Date: 10 December 2007

Reviewer: Elizabeth Maunsell

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Please note: I have numbered paragraphs in the manuscript, starting at 1 in each new section (introduction, methods, etc) and use these to situate certain remarks.

SUMMARY:

The authors address a very important question which, to date, has been overlooked in psycho-oncology research, namely the importance of getting population-based data on quality of life of cancer survivors. To this end, in this manuscript the authors state their objective as reporting on the challenges associated with two strategies used concurrently to recruit to a large, population-based invasive breast cancer survivor cohort in the state of Victoria, Australia. These two strategies were: 1) a community-based approach involving doctors, breast cancer nurses and a public awareness campaign, and for women who had not volunteered to be part of the study as a result of this community approach, and 2) direct recruitment (with passive physician consent) via the Victorian Cancer Registry (VCR).

REVISIONS:

DISCRETIONARY

1. With respect to the population-based study in which these different strategies were tested, why did the authors decide to exclude women with DCIS from it? In Canada and the US, these women are now said to constitute about 13-18% of new breast cancer diagnoses, and they undergo many of the same treatments as women with invasive cancer (surgery, radiotherapy, hormone therapy, although not chemotherapy). Their exclusion might or might not be the right decision but I suggest that the authors explicitly address the rationale for it directly in future manuscripts reporting on findings from this study.

MINOR ESSENTIAL

2. The title of the paper states the subject, but not the conclusion. If as stated, this is BMC policy, the title will need adjustment to give the conclusion.

MAJOR COMPULSORY (not always in order of importance, but starting with the key points)
3. My most important comment on the whole manuscript is that I found the reporting of the key results on the proportion of eligible women recruited, by either method and overall, to be poorly presented. I refer here to the 1st three paragraphs of the results section. While there is a kind of theoretical flow chart for the VCR approach, it seems to me that it would be important to have some tables or a flow chart more clearly documenting actual performance of each method of recruitment. I confess my bias here, that one should move from the larger (ie those eligible) to the smaller numbers here (eventually, those recruited). But in this presentation, different numbers are presented going from small to large and back again.

- In the methods, the authors were aiming for 10,000 of 15,000 in a 5-year period, but only recruited 1684.

- Then in the results, we are told there were 7871 invasive breast cancer cases in a 31-month period, but this number somehow drops to 2898 on the basis of the criteria presented in table 1 (this drop not explained with figures, is this a guess? It would have been nice to see the distribution of reasons, in proportion).

- I feel that the authors could have presented this with a better synthesis, for example by removing the 63 women reported to be ineligible (but again, I am not clear because I thought we got from 7871 to 2898 on the basis of ineligibility, or were these guesses?) from both the numerator and the denominator of the proportion participating among eligibles, that is 1747-63, and 2898-63, or 1684 and 2835, respectively.

- If this is done, 1684 / 2835 = 60% participation and not over 80% (results, paragraph 3) as calculated with a denominator of 2135, who were all contacted women who agreed to participate but not all of whom in fact did. 763 eligible women (2892 - 2135 = 763) have in my view been incorrectly ignored in this calculation.

- With 60% participation, possible selection bias is of more concern and that is why I think it may be necessary to compare these participants to women with breast cancer generally on other characteristics besides age (a comparison which revealed that older women were underrepresented) (see following paragraph).

This whole section, which is the heart of the paper, could be quite confusing to the quick reader of this paper as it was to me. I also suggest that the authors report the exact dates (month, year) between which recruitment was conducted in results, paragraph 1.

4. The comparison of women recruited on the basis of age (table 2) is good, but limited. Given the 60% participation, and if this cohort is going to be followed up to look at a wide variety of quality of life outcomes (social, marital, and employment outcomes for example), I believe that it would be important to also compare those recruited to those targeted on the basis of percentages married, employed and so forth. If this cannot be done, it should be stated, and perhaps there should be some tempering of conclusions as to the representivity of the cohort recruited.
5. Little information is provided on the rationale for choosing this two-pronged approach to recruitment, and in particular the addition of the "community" approach. It is notoriously difficult to recruit women through clinical settings just on the basis of passively presented information (mentioned in paragraph 12, methods) and the brochure given to women, and selection bias using such an approach would be a real possibility. I doubt it was easy or even possible to document the proportion of eligible women to whom this brochure was given, although this is not reported. However, these are the kinds of things I would have expected to see on a paper reporting on and comparing two different approaches. I was unable to find a clear comparison of the proportion of eligible women recruited through this method and the VCR one, and this would seem to be essential.

6. There is considerable confusion in the presentation of study objectives vs manuscript objectives (which are the two strategies used and barriers to recruitment). The population-based prospective cohort study (with data collection by self-administered questionnaire in the first year and then 1, 2, 4, and 5 years thereafter) is the background to this manuscript's objectives. Currently, there is a great deal of information about the survivorship study itself (the first nine paragraphs of the method), and some of it, while interesting, may be non-essential (for example, paragraph 4 on the study advisory group). Only by paragraph 10 of the methods section do the authors begin to discuss the two recruitment strategies that would seem to be the focus of this manuscript. The authors might consider considerably summarizing information about cohort study.

7. The assertions in paragraph 5 that effects of breast cancer on family, employment and socio-economic consequences have not been quantified are in fact not true (although I agree that there is a great need for more studies in these areas), and there have been some population-based studies in these areas as well. I direct the authors to some of the key publications by the following authors: family issues after breast cancer, Dorval et al in Canada; work and economic consequences: Bradley and colleagues in the US; Drolet et al and Maunsell et al and colleagues in Canada, and Gordon and colleagues in Australia.

8. Methods, paragraph 6: although entitled "sample size calculation", this seems to be a bit of a misnomer.

- There is no "calculation" here (as one might expect in deciding how many of the incident cases in Victoria were needed for this cohort in order to be able to compare all relevant quality of life outcomes in subgroups, there is only reporting here that the aim was to recruit 2/3 of the 15,000 Victorian women diagnosed in a 5-year period. This section shows that it would in principle be feasible to recruit a large number of women, but provides little information about what for, which would depend on the outcome in question, and what types of differences could be detected.

- Some results (recruitment was more difficult and expensive than anticipated) are also reported in this same paragraph, which is unusual in the methods section.
- Then, in methods paragraph 8, the authors state that the sample size is "more than adequate" for modeling various determinants. This may well be so, but it is not shown in the manuscript, and one wonders which number this judgement is based on, the 10,000 women targeted or the 1684 who in fact completed EQs. I believe this needs clarification.

9. One of the barriers to recruitment using the VCR method was the problem of late reporting of incident cases to the registry. Again, although not reported, it would have been of interest to know what proportion of eligibles were recruited, for example, in the first 6 months after diagnosis and then in the next 7-9 months using this method, or something along these lines. Not knowing the proportion of women captured in these two time frames, I wondered whether the decision to cut off recruitment at 9 months was a good one (ie missing a substantial proportion of potentially eligible women?) from a population-based viewpoint, especially as it might be argued that quality of life of women at 12 months and at 15 months post-diagnosis might not be that different (and one could assess the affect of time since diagnosis if there was variation, and adjust for it if necessary).

10. Although the authors mention costs of each method which I agree is very interesting information to present - at present this is done unsystematically and only in the discussion. Could some of this information also have been summarized in the form of a table in the results? This is another very important barrier to conducting cohort studies of any kind, and one of interest to those thinking about this kind of study.

11. Some conclusions are speculative, since no data are presented to support them. Two examples:

- "It is not surprising that elderly women were less interested in volunteering for the study" (discussion, paragraph 4). What is this conclusion based on? Other studies? Other data from this study not reported?

- "where eligible women were invited to participate by the VCR, the relatively low active refusal rate may reflect the success of the public awareness campaign." Is this any quantitative or qualitative data to support this conjecture?

12. The introduction is very long (the first five paragraphs) and clinically oriented. Could this could be summarized somewhat because the reader is left wondering what the point of this will be? Getting to the objectives of the paper more quickly would help the reader.

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.