Author's response to reviews

Title: Participation of older newly-diagnosed cancer patients in an observational prospective pilot study: an example of recruitment and retention

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Author's response to reviews: see over
Montreal, May 11th, 2009,

Dear professor Alam,

We were very pleased to receive the review of our paper “Participation of older newly-diagnosed cancer patients in an observational prospective pilot study: an example of recruitment and retention”.

Thank you very much for the attention that you have given to the manuscript. We experienced the comments from the reviewers as constructive and helpful. We have added the analyses requested by both reviewers. For many of these variables many cells were empty and therefore we have used them in a descriptive manner.

Considering of the large number of variables we examined, multiple testing would lead to spurious findings.

We have used track changes in the revised version to highlight our adjustments and we have added a clean copy of the manuscript.

Below, we describe how we have dealt with the comments. If you have any questions, please contact us.

Looking forward to your response,

Sincerely,

Professor Howard Bergman
on behalf of all authors,
Reviewer Dr. M. Pijls-Johannesma,

Major revisions

1. Why chose subgroups based on median age? It would be more clinically relevant to compare groups based on functional status, tumor type and with different comorbidities? We had chosen to examine by age because it is often hypothesized that conducting research with older (75 years and over) is difficult in terms of recruitment and retention. Thank you for pointing out that it does not provide the information about which subgroups is more suitable for research. Therefore, we have added the results of the analyses comparing the groups based on functional status, tumor type, stage of disease (early vs. advanced), sociodemographic information (living situation, born in Canada, gender) and number of comorbidities. As the number of patients with a certain comorbid condition is low, we have calculated a sum score of the total number of comorbid conditions at baseline (0, 1,2,3, or 4 + conditions) and used that score to compare the groups in terms of time needed for interviews, number of interviews and postponement of interviews. There was no clear subgroup identifiable but it seemed those with a poorer functional status needed more time to complete the interviews, the study and more meetings to complete an interview. This has been added in the results, see page 15, Table 5 and pages 18/19 of the discussion.

2. Table 3. Please include the number of patients alive at the study end point per tumor site in the table. The number of patients alive at the study end point per tumor site has been added to Table 3. The patients diagnosed with colorectal cancer had the lowest compliance rate (77.8%, followed by breast (93%) and both for lung cancer patients and hematological patients all patients alive completed the study. The fact that the patients with colorectal cancer were recruited differently might have had an impact on the retention (less involvement of the surgeon in the study, the surgeon did not introduce the member of the research team). We think this is more likely than the offered explanation that patients with a poorer prognosis are more compliant. Our breast cancer patients who generally have a good prognosis and in our study most were stage 1&2, still
had a very high compliance rate of 93%. For all other cancer patients the oncologists and surgeons were more involved in the study influencing the recruitment and retention. This has been added to the discussion on pages 19/20.

3. List of recommendations.
   More clinically relevant recommendations have been added to the list.

Minor essential revisions
1. The concept of frailty is introduced but no clarification is given. A clarification of the concept has been added to the introduction on page 5.
2. Other studies have reported that recruiting older patients. Please give a definition of older patients. The studies referred have used no age cutoff, greater/equal 65 and greater/equal 70 years. This has been added in the text on page 6.
3. Authors mentioned that patients might also be asked for participating in a trial as well as in an observational study. Unfortunately we do not have information on clinical trial participation of the non-respondents. We know that only one person mentioned the study burden to participating in our observational study as well as in a clinical trial specifically as a reason to refuse participation. For participants we compared if the number of participants who completed the study, refused follow-up or died were different in terms of how often they participated in a clinical trial. None of the patients who refused follow-up was participating in a clinical trial. This has been added to the discussion on page 20.
4. Last alinea page 6, the aim of the study is not clear. We have clarified the aim and included an explanation of the concept of frailty in the second paragraph of the introduction, see page 7.
5. Patients and methods, why age 65 and why only breast, colorectal, lung and hematological malignancies. As this was a pilot study and little information is available on the feasibility of observational prospective studies with older
cancer patients, we choose the most common cancers among older persons in Canada (breast, colorectal and lung) which we thought have most likely a different functional trajectory so that would provide use with more information in which population a larger study on health and functional status would be feasible. We did not include patients with prostate cancer. After meeting with the physicians who treat prostate cancer, it was not feasible to recruit for logistic reasons. We have added the hematological malignancies as the department of hematology is very much involved in the care for the elderly patients and wanted to participate in this study as well as it provided us an opportunity to obtain information of the feasibility of such a study in that population, as many older patients with hematological malignancies undergo extensive treatments. We have chosen the age cutoff of 65 which is in agreement with most longitudinal aging studies around the world. In addition, as the NCCN and the SIOG both recommend to do geriatric assessment with patients aged 70 years and over, this study provided us the opportunity to see if patients between the ages of 65-70 are that much different in terms of adverse outcomes of cancer and its treatment. We have added this explanation in an abbreviated form in the methods section on page 7/8.

6. Study description. Please add more information on what questionnaire was used to measure what. We have added appendix A with an overview of the data collection by interview and includes all the questionnaires which were used to measure health and functional status in this study.

Reviewer Dr. D. Poon.

1. For international readers who might not have a good understanding of the treatment facility and workflow in the centers recruiting these patients, a brief description may aid the judgment as to whether the methodology applies to their own centers outside Canada. A flow chart of how patients flow through the center (see figure 1) has been added as well as a description of the Segal Cancer Centre can be found in the methods section on page 7.
2. In addition, the number and constitution of the research team may be described along with costs of doing such a study. The constitution of the members of the research team that has done the recruitment has been added. MP worked fulltime on the recruitment of participants, and the conduct of all the interviews. VG has worked fulltime on this project until May 2007 and MM has assisted on an if needed basis to assist with interviews. Unfortunately we do not have the exact costs but we have calculated the numbers of hours needed so that other readers have an idea of the time investment required for such a study. This has been added on page 9 and 16 (methods and discussion).

3. There is no necessity to report information already presented in tables. The feedback given by participants may be tabulated. The results section has been revised and the feedback has been tabulated.

4. Perhaps an analysis of the baseline functional status of patients and its impact on participation refusal, duration, number of interviews and postponement may be useful. We have added these analyses, see also response under point 1 to reviewer Dr. Pijls-Johannesma.