Author's response to reviews

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

Authors:

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Author's response to reviews: see over
Dear Dr Bucceri

Re: MS: 6284730791563378 - The impact of consent on observational research: a comparison of outcomes from consenters and non consenters to an observational study

Thank you very much for the opportunity to update our manuscript again. We have uploaded a revised manuscript and detail below changes made to it on the basis of the reviewers’ reports you sent us. Our changes are detailed below and numbered as per the review.

1. We have added the suggested text to the discussion (first line under ‘Limitations of the study’). [This now reads: This study presents a hypothetical worst-case scenario based on a number of assumptions.]

2. We have removed the sentence the reviewer suggests. [Deleted sentence: In a recent study, for example, 1285 out of 1464 (87.6%) respondents to a questionnaire gave consent for their case records to be examined. [14] This is a similar response to that found by other researchers.[15]]

3. We have revised the paragraph which discusses the gate-keeping role of GPs. [The paragraph now reads: A further limitation is that before we were able to ask patients to take part in the study by completing the questionnaire, there was a degree of ‘gate-keeping’ by general practitioners who could either not engage with the study or decided that their patient wasn’t suitable to be included. We were unable to determine which of these explanations was most pertinent in this study. Gate keeping by clinicians is a feature of studies from health service lists, and may have both positive and negative aspects from a research point of view. On the one hand, clinicians often screen potential lists of participants to exclude approaches in cases of severe illness or other circumstances where an approach would be inappropriate; on the other hand, clinicians may have no interest in facilitating research and relegate this task below competing demands on their time. In either situation, the net effect in a study such as ours is to increase loss to follow-up. The role that clinicians may have in gate-keeping in this way is an important and under-researched area.]

4. We acknowledge the reviewer’s arguments about the records of deceased patients. We have changed the last sentence of the second last paragraph in the ‘main findings of this study’ section of the Discussion. [New material:

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Although many of the women with advanced or metastatic cancer would have been deceased by the time of our data collection and so we would likely have been able to obtain their data without consent, we would argue that having the benefit of the whole sample enabled us to produce these comparisons with some confidence.

We hope that we have dealt with your points satisfactorily and look forward to hearing from you.

Kind regards

Yours sincerely

Una Macleod

Graham Watt