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:

Una Macleod (u.macleod@clinmed.gla.ac.uk)
Graham CM Watt (G.C.M.Watt@clinmed.gla.ac.uk)

Version: 2 Date: 21 December 2007

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 and to reply to the reviewers’ comments which we found very helpful. We have uploaded a revised manuscript and detail below changes made to it on the basis of the reviewers’ reports you sent us.

Reviewer report by D Willison

1. The reviewer argues that we have presented a hypothetical case that constitutes a “worse case” scenario that is unlikely to come to pass in policy and that many decision-making bodies have adjusted policies to ‘opt-out’

Our response: we acknowledge this is a worst case scenario but are pointing out the implications of this scenario which we believe is relevant considering that a move to “opt-out” is not yet universal. We are concerned particularly with the implications for research which require records which cannot be anonymised (unlike GPRD which can).

Changes made: the following sentence has been added to the Background section:
In some instances, ethics committees have permitted an opt-out arrangement where researchers have been required to first contact the patient for permission to review records, and asking them to reply if they object to their records being reviewed; this is not yet in universal practice, particularly in cases where, due to the requirements of the particular study, records cannot be anonymised.

In addition we have changed the first sentence under ‘Limitations of this study’ in order to emphasise again that we are describing a hypothetical scenario.

Changes made: new sentence added to Discussion section:
This study presents a hypothetical case based on a number of assumptions.

2. Assembling of initial sampling frame.
i) The reviewer argues that we may have under-estimated (rather than over-estimated) those willing to have their records reviewed.

Dr Una Macleod
MBChB PhD FRCGP FHEA
Senior Lecturer in General Practice
General Practice and Primary Care, 1 Horselethill Road, Glasgow G12 9LX. Tel: 0141 330 8330 Fax: 0141 330 8332
u.macleod@clinmed.gla.ac.uk
Our response: we acknowledge this to be correct and have amended the paragraph in the Discussion where this is dealt with.

**Changes made:** new sentence added to Discussion section:

This assumption is likely to have under-estimated the level of consent as women who did not complete the questionnaire may still have been willing for their records to be reviewed.

**ii) The reviewer also asks for clarification of the loss of the sample at various stages throughout the study.**

Our response: the actual numbers are detailed in the results section. We have added a paragraph to the method to make this clearer.

**Changes made:** new sentences added to Methods section:

Cases were “lost” for the purpose of this retrospective study at two points: at the general practice data collection stage and at the questionnaire stage. The issue at the point of reviewing general practice records was that we required practices to facilitate us collecting data from their records; a number of practices did not engage with the study with respect to this after many contacts by letter, fax and phone and so we were only able to review 78% of potential records: we did not request practices to obtain consent from patients. As we were contacting women several years after their diagnosis of cancer, we decided to check with general practitioners before sending out questionnaires as to whether the women were alive and well.

The actual numbers are detailed in the last paragraph of the results section (no change to previous version):

Although the response rate to the questionnaire was 81%, the women returning a questionnaire comprised only 48% of the original population of women with early breast cancer. Missing categories comprised women who had died (n=20) or left the area (n=3), and practices which declined to take part in study (n= 19), did not respond to requests to see records after numerous contacts (n= 46), or did not confirm that the patient was alive and well at time of survey (n= 60).

**3. Role of GPs as gatekeepers to general practice records: the reviewer says we have simply taken this as a given.**

Our response: we agree with this and have expanded our discussion of the gatekeeping role under ‘Limitations to the study’ in the Discussion section.

**Changes made:** revised sentences in Discussion section:
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. Gatekeeping by clinicians is a common feature of studies from health service lists and includes necessary screening of inappropriate requests for access but may also result in loss of follow-up in studies of this kind.

4. Women presenting with locally advanced or metastatic disease: the reviewer asks how this information was lost.

Our response: our point is that this information would have been unavailable using our methodology as these women are likely to have been deceased by the time of this retrospective study. We have added a sentence to this effect to the discussion.

Changes made: new sentence in Discussion section:
If patient consent had been required for the study detailed here, it would not have been possible to obtain this information as these patients would have likely all been deceased.

5. More information is requested on the numbers in Table 1

Our response: these have been clarified by the use of footnotes to Table 1 indicating that size, grade and nodal status were potentially available for the 366 women (146 affluent and 220 deprived) who had operable breast cancer. In addition, there were typos in the draft submitted which implied that we had full data for the women with operable cancer; this was not the case and Table 1 has been updated to reflect this.

Reviewer report by Rustam Al-Shahi Salman

The reviewer raises the issue of the relevance of the distinction between audit and observational research.

Our response: we agree this is an important point which we haven’t covered and have added it to the background and discussion sections.

Changes made: new sentence in Background section
These arguments have not however been applied to audit which is considered an essential part of good clinical practice, and for which patient consent is not required.

Changes made: new sentences in Discussion section
If this work were considered to be audit rather than research the issues raised here would have been irrelevant. We viewed it to be research, as did several
journals [10-12] because we were asking a new question of data collected for clinical purposes. There may be other examples where the boundary between audit and research is blurred sufficiently for research to be carried out in the name of audit, so avoiding this difficulty. This is confusing at best and unethical at worst.

In addition we have noted the minor point and updated the manuscript accordingly.

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