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: 1 Date: 2 November 2007

Reviewer: Don Willison

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General
The authors estimate the impact that individual patient consent for record review research would have on sampling bias and on study conclusions regarding quality of care in a breast cancer study. They do this by comparing a previous medical record study conducted by them using virtually 100% of records with the subset of records that would have been available had 100% of participants in a subsequent survey consented to the chart review.

The paper contributes to a growing body of literature addressing biases in sampling and conclusions associated with requirement to obtain consent for observational research. It is very clearly written.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

caution in this whole analysis is that this is a hypothetical case that constitutes a “worst case” scenario that is unlikely to come to pass in policy. In the current environment, it is still commonplace to conduct a medical record review without requiring individual patient consent. In most cases where researchers have been required to first contact the patient for permission, the decision-making bodies have adjusted their policies to require, instead, notification with opt-out. That is, non-response to a request for permission would be regarded as “no objection”. Working under a scenario of notification and opt-out, it has been estimated that approximately 1 in 1000 patients chooses to opt out of the UK GPRD. Therefore, the scenario put forward by the authors consists of a “worst case” scenario that is unlikely to come to pass in policy.

My chief concern is with how the initial hypothetical sampling frame is assembled. The authors assume that the 81% of those who consented to the survey after 3 attempts to contact would be the same sample as those willing to have their medical record reviewed. It is conceivable that, among those contacted, many of the 19% of respondents who refused the survey may have been willing to have their medical record reviewed, because it involved no additional effort on their part beyond, whereas the survey required some additional personal input. So, even in an unlikely opt-in system, it is conceivable that the estimate of participation rate and who participates is actually low. By
contrast, the authors indicate in the Discussion section that their estimate of participation is likely high.

In addition, in the first paragraph under “Methods”, the authors indicate they went from the full sample (n=366) to the general practice records (n=278) to those agreeing to the survey (n=177). It is not clear what was the reason for the loss of numbers at the level of general practice records. This is a very important loss of sample that should be explained. Is this 25% of general practices refusing to participate in the approaching of patients or accessing of records?

Mention has been made of differential findings regarding clinical staging when data are gathered from different data sources (full medical record vs. the pathologist report). The authors also acknowledge that gatekeeping by clinicians is a common features of studies from health service lists. The bias introduced by the consent scenario put forward by the authors should be put into the context of the biases introduced by these other sources. In particular, the gatekeeper issue is simply taken as a given.

In the third paragraph of the “Results” section, the authors point out that the reduced dataset contains no information about the 12% of women presenting with locally advanced or metastatic cancer. It is important to note how much of this loss of information was due to different sources of loss of participation – refusal to participate or inability to contact – or to missing data in those records.

Finally, the numbers in Table 1 need clarification. For example: for the whole sample, the sums of the totals for the affluent and deprived add up to 366 for size, grade, and nodal status, but totals 416 for clinical stage at presentation. This latter number is greater than the entire sample size. Why? By contrast, for the consented sample, the numbers are lower than the total 177 expected for size, grade, and nodal status, with substantial discrepancies for grade. Again, it is not clear why, particularly for grade. Finally, it is not clear what the entry of “100%” for clinical stage at presentation for the consented sample actually means.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

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.