Reviewer's report

Title: Breast cancer screening: evidence of benefit depends on the method used

Version: 1 Date: 20 March 2012

Reviewer: Elsebeth Lynge

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Major Compulsory Revisions

Autier and Boniol have reviewed various methods for evaluating the impact of mammography screening on breast cancer mortality. This is an important topic both methodologically and from the public health point of view. A decision on acceptance or rejection can, however, not be taken before the authors have responded to major compulsory revisions.

1) Page 4. Selection of controls. Not “women who did not die from breast cancer” but “women still under risk of dying from breast cancer at the time of the date of death of the case”.

2) Page 6. The discussion of the correction for selection bias is inaccurate. It is clear that the Duffy-correction does not capture the full picture in the situation listed in Table 1. This description is, however, not in line with the original proposal by Duffy et al. Appl Stat 2002. There the comparison group was not “before screening” but “uninvited controls (Duffy, Table 3)”. This is a completely different situation. Therefore the entire section on correction for self-selection bias and the concluding remark “Hence, …” need to be completely re-written.

3) Pages 7-9. The discussion of IBM studies is selective in including only 4 studies that can be critisised in one way of another. The 2 first Swedish studies are basically the same, so way not restrict it to the newest one (SOSSEG, 2006). It is correct that it is a limitation here that only historical controls were used. I agree also that the correction for lead time bias in the Helquist study is a bit difficult to follow. Somewhat more indepth discussion of the Kalager study would have been warranted. And why has the authors omitted the best available IMB studies from Finland and Denmark. These studies actually overcome the critical points raised here. So, concluding remark on page 14 “IBM studies are likely to obtain biased results when secular trends in mortality and increasing treatment effectiveness are not considered.” Yes, indeed, in order to illustrate the potential of the IBM method, the authors should concentrate on the studies where these factors have been controlled for.

4) Pages 9-11. A discussion should be added on a possible short term effect on breast cancer mortality from detection of advanced stage breast cancers and a possible longer term effect from detection of early stage breast cancers.

5) Pages 11-13. Looking at time trends in routine statistics is of cause the most
simple approach in evaluating the impact of mammography screening on breast cancer mortality, but it is an extremely insensitive method, see e.g. Olsen et al., Epidemiology, 2006. The authors should give much more thoughts to when and where trend analyses are appropriate. Now, they mostly quote outcomes from trend papers, where the uninformed reader may not know the underlying local situations. It was for instance not correct that no screening took place in Norway prior to the organized programme as claimed in the Autier et al, BMJ 2011 paper.

6) Page 14. The conclusions should summarize pros and cons of the different methods. The statement “Furthermore, the gathering of data for IBM analysis may be subject to bias.” is out of the blue, and definitely not substantiated by shown data.

7) Abstract. More than half of the text is about the case-control studies, and part of the arguments are based on the misinterpretation of the Duffy correction. The sentence saying the IBM studies are “often flawed” is really far too general based on the very selected reviewed material. The last sentence “Evaluation should rest on…” indicate that there is one method only. This is not correct. There are several methods, and they all have their strengths and weaknesses. This should be reflected in the text as well as in the Abstract.

**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