Reviewer’s report

Title: How health system factors affect primary care practitioners' decisions to refer patients for further investigation: protocol for a pan-European ecological study

Version: 1 Date: 23 Jan 2018

Reviewer: Jean Karl Soler

Reviewer’s report:

Dear Sir,

Thank you for asking me to review the paper by Harris and Taylor titled "How health factors affect primary care practitioners' decisions to refer patients for further investigation: protocol for a pan-European ecological study."

In the first instance I must declare a conflict of interest, since I am a member of the European General Practice Research Network, and I know the lead author, and some of the Orenas group, very well. I hope you trust that this review is, nevertheless, balanced.

This article is written in perfect English, is very well structured and well justified, deals with a relevant and important topic, and uses sound methodology to address a specific research question. It is also an international study prepared by a research network. As such, it is an important paper and should be published.

I suggest that this article should be published, but I would recommend numerous compulsory minor revisions as necessary before the article is published in BMC Health Services Research

Recommended changes:

1. The introduction is long, and may be shortened

2. Variation in one-year survival is hypothesised as a predictor of early diagnosis. There are many factors which may also affect this, such as treatment, access to investigations and others. The limitations need to be further explored. This assumes homogeneity in other variables between countries or groups of countries, and I have my doubts on this.

3. The postulated negative link between gatekeeper function and one-year cancer survival is based on one reference. First contact is one of the Primary Care characteristics shown by Starfield to predict better health outcomes in general. This needs to be further discussed.

4. In line 80 on page 5, I believe that the word "variation" may be put after the word "Survival."

5. The issues of an appropriate probability threshold for cancer referrals, and the weak power of predictive symptoms need to be better explored in the introduction or
discussion. The decision to refer for cancer symptoms is prone to over- and under-diagnosis, and it seems that this paper simply considers under-diagnosis.

6. This paper seems to assume that specialists do not mis-diagnose and mis-treat cancer, or over-diagnose patients. It also assumes that tests do not have significant false positive rates. This should be discussed in the introduction or discussion.

7. In the section on differing beliefs, health systems and behaviour on pages 6 and 7, I should like to believe that there is more literature on this topic than the few references cited.

8. I would define "diagnostic intensity" on line 130 on page 7.

9. Reference 23 is used to justify using vignettes to study doctor behaviour. I understand that this is a recognised methodology, but still there are serious doubts about differences between reported behaviour and actual behaviour, and between real patients and vignettes. In Europe, excepting the UK, most family doctors know their patients personally. Their behaviour with patients who they know well, and with whom a minor behaviour change or expressed concern may trigger the doctors' "gut feeling", may be very different from textbook cases in vignettes.

10. In line 152 on page 8, the future tense is used to refer to past events in November 2015 and at the end of 2016. Is this a study in progress or a completed study?

11. The "Design" section on lines 149-152 on page 8 is very short, and does not describe other data collection, such as from registries and of survival rates.

12. Doctors are eligible if they work in primary care. Does one distinguish whether they are clinicians, academics or administrative workers?

13. Is a sample size of 50 sufficient? The plan to group countries in the analysis indicates that this is not. The sample size was based on a calculation on the width of the 95% confidence interval. This is not a prevalence or incidence study, but rather a factor analysis and a comparison between countries shall be performed. As such, an appropriate sample size and power calculation should be performed. This is currently inadequate.

14. How valid is it to group countries? What shall be the criterion to group countries?

15. I am not convinced of the Orenas group developing a list of factors influencing doctors' decisions to refer or not. This should have been done on the basis of a proper literature search.

16. On line 182 on page 10, one factor was found to be invalid and excluded. But, how could one check for missing factors?

17. On Lines 189/190 the translation process is described as ongoing. Is this complete or not?

19. On line 200-203 it seems to be stated that specialists who are not family doctors can be included in this study. Is this valid?

20. In the questionnaire design, I am surprised that the following factors were not included: rural/urban location of practice, workload (actual workload, not perceived effect of workload), option of watchful waiting. The questionnaire seems to conceptualise the decision to refer/not to refer as a cut-off. In real life, the option of watchful waiting is an essential tool in primary care to resolve uncertainty.

21. A 5 point likert is more "user-friendly" but is often converted into a three-point score in the analysis. As such, what is the point?

22. The exploratory factor analysis will group all countries together. I would like the validity of this to be discussed. After all, one is exploring differences between countries, and as such a grouped factor analysis should be justified.

23. Will the interaction between country (as a variable) and other variables be studied in the analysis?

24. What is the power of this study to avoid type II error. What is the cut-off p-value to avoid type I error?

25. I missed the "Strengths" section in the discussion.

26. The limitations section needs to address the issue of differences between reported behaviour and actual behaviour, and the limitations of vignettes.

27. I would include a section on the expected impact of this study and the continuation of the group's further research based on this study.

I hope that these suggestions help you to improve the article.

Sincerely

Jean K Soler

Malta

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.
I know the first author personally, and some of the Orenas group members too. We do not share financial or academic interests, beyond work within the European General Practice Research network, which is entirely voluntary.

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