Author's response to reviews

Title: Evaluation of an open access echocardiography service in the Netherlands: a cohort study of indications, outcomes, patient management and trends

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Author's response to reviews: see over
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BMC Health Services Research
Evaluation of an open access echocardiography service in the Netherlands: a mixed methods study of indications, outcomes, patient management and trends
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Maastricht, 24th of November, 2009

Dear Editor,

We were very grateful for getting the opportunity to revise our manuscript. We are happy to say, that we succeeded in addressing all comments of your referees. Many of their suggestions were incorporated in the text. Please find the details here below.

We hope you will reconsider publication in your Journal.

On behalf of all authors,

Yours sincerely.

Dr. Henri E.J.H. Stoffers
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Replies

A. Associate Editor:
Please revise the paper and specifically clarify the study design and provide more information on the development of the questionnaire.

→ We included a paragraph on the study design and adapted the title accordingly; see our reply to colleague Scherer.

→ We have translated the Questionnaire; I will try and upload it as ‘supplementary material’

B. Editorial requests:
- We recommend that you copyedit the paper to improve the style of written English. If this is not possible, you may need to use a professional copyediting service. Examples are those provided by the Manuscript Presentation Service (www.biomedes.co.uk), International Science Editing (http://www.internationalscienceediting.com/) and English Manager Science Editing (http://www.scientemanager.com/). BioMed Central has no first-hand experience of these companies and can take no responsibility for the quality of their service.

→ We checked the text carefully, adapted it whenever necessary, and finally used a web-based copyediting service

- Please clarify ethical approval. Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

→ We included the required information in the text
- Informed consent must also be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.

We included the required information in the text.

C. Referee 1

General comment: We would like to thank colleague Damiani for his thoughtful suggestions, most of which we could incorporate in the text.

Major compulsory revisions:
1. In “Background” section, authors presented quite clearly the findings of some relevant studies about the impact of open access echocardiography services. But there is no reference of the paper “Impact of specialist care in patients with newly diagnosed heart failure: a randomized controlled study” Rao A, Walsh J. Int J Cardiol. 2007 Feb 7;115(2):196-202. The authors may discuss shortly the evidence reported in this article.

Reply: We thank the referee for his interesting suggestion. We reviewed the reference, however did not consider it appropriate to discuss it in the Background section. It describes an RCT of specialist vs. primary care for patients with LVSD, who were diagnosed via two different ‘open access’ echocardiography services (‘community’ and ‘hospital’). Therefore, the case mix in that study might be different from our group of patients seen in primary care. Unfortunately, the ‘patient characteristics’, as described in Table 1 page 199, do neither make it easy to deduce figures for the entire ‘open access population’, nor for the ‘community open access’ group separately. Furthermore, we could not well compare referral procedures and source population with our situation.

We decided not to discuss this paper in our article.

2. In “Methods” section it is reported that a questionnaire on management by the GP was used: please give more details about the questionnaire (structure and items).

Reply: It was a short questionnaire, almost fitting on one A4-page, containing 5 multiple choice questions with multiple answer options, on: (1) their considerations for the echocardiography request, (2) examinations/procedures already performed before the echocardiography request, (3) known morbidity at that time, (4) medication at that time, and (5) actions of the GP after the echocardiography result had been received ([a] changes in cardiovascular or pulmonary medication, [b] other actions including referral to cardiologist of other medical specialist), respectively.

We adapted the text to make this clearer.

Some methodological elements should be clarified:
a) the questionnaire was sent in 2007 but information can also refer to previous five years. a1) Did authors control for a “memory effect” on any question?

Reply: The invitational letter was accompanied by a list of patient IDs (ID numbers with birth dates), and including for each patient the date on which the echocardiogram was made. The instruction to the GPs was to check the record of each patient, i.e. to locate the echocardiogram result and check the requested referral (before cardiac ultrasound) and management (after cardiac ultrasound) information in the patient record.

We adapted this in the text.

a2) Was the requested information all available in the GP’s electronic patient record?

Reply: Yes, we assumed it would be possible to find this information, since it was standard information GPs normally would enter in their patient record (i.e. signs and symptoms, problem definition, medication at various moments in time, requests and results of diagnostic procedures, actions after a diagnostic result has been received, a list of diagnoses, referral letters). We tried to
make a realistic survey questionnaire. Of course, we cannot entirely rule out that in some cases the GP will have relied on his memory when he did not find the exact answer to the question in the patient record. Only when information was found, it was counted as a positive result.

→ We added a sentence on this issue in the Discussion section.

b) no explicit reference on any formal validation procedure (Cronbach’s alpha, Spearman-Brown Split Half Coefficient or others) was reported. On the contrary in the “Strength and limitations of the study” authors write “The questionnaire response rate was high (82.7%) indicating good validity”. A high response rate doesn’t ensure validity of questionnaire but only absence of selection bias. Authors should better explain this topic.

Reply: Indeed, we did not ‘validate’ this survey questionnaire. However, as stated previously, this short survey questionnaire - which two experienced GPs and two experienced cardiologists had made - was constructed to get factual, real life data from the medical records of the GPs. Our survey questionnaire did not measure a ‘concept’ like severity of depression or anxiety. Therefore, we do not agree with the suggestion that calculation of a ‘Cronbach’s alpha’ or a ‘Spearman-Brown Split Half Coefficient’ would have been appropriate. Both are measures for internal consistency of a questionnaire that tries to measure a certain reality (e.g. depression or anxiety) by asking various questions, that all have to be related to this concept. With the term ‘validity’ on page 13, we meant ‘validity of the study results’, not the ‘validity of the questionnaire’. Absence of selection bias contributes to the validity of the study.

→ We adapted the text.

3. Authors selected first and last 250 patients: could you please explain why you have chosen this sample size?.

Reply: The choice to compare the 250 first vs. 250 most recent patients out of 1001 available records was made arbitrarily, without formal sample size calculation. The main reason was to create contrast in time. Including half of the total population seemed a large enough sample.

→ We adapted the text.

4. Authors didn’t make adjustments for some confounders like age, gender and others. To assure the comparability between the two groups authors should apply a stratified analysis and/or at least show clearly the two samples composition by an added descriptive statistics table.

Reply: One could argue whether in a descriptive analysis like ours, a stratified or multivariate analysis would be a good option. However, in an earlier draft of the paper, we had included a comparison of patient characteristics: “Of the first group of 250 patients, 147 (58.8%) were female and 103 (41.2%) were male. Mean age of the patients in this group was 62.6 years (SD 18.0). Of the last group of 250 patients, 151 (60.4) were female and 99 (39.6) were male. Mean age of the patients in this group was 59.5 years (SD 19.1). There were no significant differences in sex (p = 0.715) and age (p = 0.057) between the two groups.”

→ Given these results, we did not perform a multivariate analysis. However, we have included the age and gender results in Table 5.

5. Table 3 is not quite clear. Specifically the sum of percentages concerning “Advice” is not 100. Is there any other kind of specified advice that is not reported in the table? Is each kind of advice (“refer to cardiologist”, “repeat echocardiogram in x years” and others) not mutually exclusive?

Reply: The bold entries ‘Advice’ and ‘No advice’ in Table 3 do sum up to 100%. Indeed, the cardiologist could give more than one advice. Therefore, the sub-percentages of ‘Advice’ cannot be summed.
We adapted the text in the last paragraph of ‘Methods/The open access echocardiography service’ on page 6: We also stated this in the legend of Table 3 and adjusted the alignment of the columns in the table.

Minor Essential Revisions
In the paragraph “Strength and limitations” of the study on page 13 at lines 3-4, the authors write: “However, in some echocardiography reports no information was given about certain structures or functions”. Could you please clarify the essential message of this sentence?
Reply: The essential message is that we interpreted ‘missing echocardiography information’ as ‘no relevant cardiologic abnormalities’. All echocardiography examinations were performed by experienced physicians. The chance that they would have missed relevant information can be neglected. Therefore, we assumed that if certain (positive or negative) information was missing in the echocardiography reports, there were no relevant cardiologic abnormalities.

To prevent potential misunderstanding, we deleted the last sentence of this paragraph: It is possible that some patients were considered healthy while they were not.’

D. Referee 2
General comment: we would like to thank colleague Scherer for his constructive comments. They were very useful to improve the paper.

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

We found a confusing error in Table 2: a column was under wrong column title. We have corrected this.

1. Title: “Evaluation of an open access echocardiography service in the Netherlands: a cohort study of indications, outcomes, patient management and trends”. I am not convinced that this is a cohort study. That should be corrected (see also 2.)
2. As far as I understood your analysis correctly, you present data from consecutively referred patients. There is a longitudinal aspect in your study, since you present data on trends/changes of indications (but different samples) and information of how and to what extent GPs dealt with the cardiologists’ advice. But you do not present clinical follow up data. Therefore, you have one cross-sectional study part on the patient level (table 1 and 2), a cross-sectional analysis on the GP level (table 3 and 4) and a quasi-longitudinal comparison of two independent samples of consecutively referred patients (table 5). In table 5 you also compare cardiologists’ advice (another level of comparison) in the first and the second 250 patients (see also 3.). The paper would benefit from a “Study design” paragraph at the beginning of the methods section.
3. You may also include a figure in order to illustrate study design and the multiple comparisons.

Reply to comments 1, 2 and 3: the reviewer is completely right and thanks to his comments, we could easily adapt the text.

We replaced the term ‘cohort’ in the Title by ‘mixed methods’. Furthermore, we inserted a ‘Study design’ paragraph in the Method section. Consequently, we also changed the ‘Statistical analysis’ paragraph, partly by removing the ‘analysis of changes over the years’ sub-paragraph, to the ‘Statistical analysis’ paragraph. In summary, we made a clear distinction between ‘data collection’ and ‘analysis’. Therefore, we think we can do without (an extr)a Figure. We slightly adapted the ‘Method’ section in the Abstract.

4. How was the cut-off made of the first and the second sample of 250 patients?
Reply: see answer to Comment 2. Its is described in the ‘Statistical analysis’ part.
Was this planned and defined a priori?

Reply: After the cross-sectional analyses had been done, we thought it would be worthwhile to study trends in indications and outcome. Since we were one year further, the database had grown to approximately 1000 patients, providing an opportunity to create enough contrast between the first and last quarter of the patients, respectively. This is described in the text under ‘Statistical analysis’.

5. The paper is rather lengthy and might benefit from some shortening (especially in the description of the data collection part).

Reply: This was a difficult comment, since the comments of the reviewers forced us to include more text. After all comments of all reviewers had been elaborated, we tried to formulate the text as concise as possible. However, we are prepared to shorten the text further, if the Editor advises us where they think this would be most appropriate.

6. Could the authors describe exclusion/inclusion criteria of patients, patient recruitment and flow through the study in detail?
7. How was informed consent obtained?
8. Was the study approved by the local ethics committee?

Reply to comments 6, 7, and 8.
→ We have provided the requested information in the new paragraph ‘Study design’, previously described in our reply to Comment 2. We added information on ethical issues.

9. There is lots of data being presented. Especially table 4 is somewhat difficult to read. You should simplify that table. This might be done by leaving out echocardiographic diagnosis.

Reply: Okay.
→ We adapted Table 4 according to this suggestion. As a consequence, we added some figures in the text of the Results sub-paragraph on ‘GP management’.

E. Referee 3.

General comment: we thank colleague Verheij for his reflective comments. Some of his suggestions led to adaptations of the text of the Discussion section. Other comments are discussed in the following text.

1. English language leaves room for improvement.

Reply: Both other reviewers found the level of English ‘acceptable’.
→ Nonetheless, we checked the text carefully and finally used a web-based copy-editing service to improve the text further.

2. I would appreciate some more reflection on the impact of this service on the health care system as a whole.

Reply: We found this comment a bit vague. We did not estimate costs. We also did not ask the patients what their experiences and opinions were (although that might be an interesting idea). To measure the impact on health care, a RCT should be designed comparing two scenarios and including cost-effectiveness.
→ We added this in the Discussion, in the paragraph on ‘Strengths and limitations’

3. The question how can it be avoided that GPs become less strict in their indications is not addressed.

Reply: One of the results of our analysis is that the original strict indication criteria perhaps were too strict: it appeared that the indication ‘suspicion of LVH in patients with hypertension’ was associated with substantial echocardiographic abnormalities. To improve the service in the future, we suggest
evaluating the service regularly in joint meetings of GPs and cardiologists, to discuss potential adaptations of criteria for referral and wishes for the communication of results.

4. Economic aspects are completely neglected; what were the costs; was it cost efficient?

   Reply: Economic evaluation was beyond the scope of this study.

   → We added this limitation in the Discussion section.

who paid for the service?

   Reply: The open access echocardiography service was paid by the major regional insurance company.

The authors claim that the service is efficient. Efficiency is about benefits and costs, but this study only hardly addresses the costs.

   Reply: We did not use the word ‘efficient’ in its financial sense. On page 16 of the original manuscript, we explained what we meant by ‘efficient’: ‘... less efficient (less pathological results of the echocardiographic examinations).’

   → We added an explanation in the Conclusion of the Abstract, and adapted the text on page 16.

5. Is the Heerlen region the only region in which this service is offered? How many other hospitals offer a similar service?

   Reply: We are certain that the Heerlen region was the first region in the Netherlands, who offered the service. Later more hospitals and diagnostic centres in the Netherlands started a similar service.

6. I do not understand why cardiologists gave advice in only half of the cases.

   Reply: We discussed this with the cardiologists. In many cases in which the echocardiography findings were normal, or abnormal but of low clinical relevance, but also in cases of which the cardiologists thought that the diagnosis was clear enough for GPs to manage the patients themselves, an advice was not given. In retrospect, this appeared not to be justified and the cardiologists increased their proportion of advice.

7. I find the number of cases in which the GP does not adhere to the specialist’ advice rather high. This is hardly commented.

   Reply: We compared the results of the retrospective GP questionnaire with the echocardiography reports. Given the retrospective nature of the GP survey, we could not correct for possible missing data in the medical records. Therefore, there may have been a negative bias.

   → This was added to the paragraph on ‘Strengths and limitations’.

   It is not entirely clear why GPs did not follow the advices given by the cardiologist in about one third of the cases. Because of the retrospective nature of our questionnaire on management, we could not ask for the specific reason why they had chosen for a certain management. From our results, you can deduce that GPs varied in their adherence behaviour, depending on their original reason for referral and the outcome: e.g., in patients referred because of a ‘cardiac murmur’ or ‘peripheral oedema’, the GPs followed the advice of the cardiologist more closely. In addition, when the outcome was ‘valve disease’ or ‘LVD’, GPs more often adhered to the cardiologist’s advice. Possibly, GPs weigh the advice of the cardiologist in relation to what they already know of the patient. The same is true for referring patients in case the cardiologist gave no positive advice to do so.

   → This was discussed in the text on ‘Patient management’.

8. The authors may have a conflict of interest. As some of them work at the hospital where the echocardiography service is provided.

   Reply. No one of the authors (2 GPs that work in the region, 2 cardiologists of the hospital providing the service, and – at that time - three medical students) did at any time receive payment or other financial support for the work under consideration for publication. There were no relevant financial relationships outside the submitted work that have an interest related to the submitted work. Both
previous statements also hold for our spouses, partners and children. There were no relevant non-financial associations or interests.

In our analyses and discussion we tried to be as objective as possible. Our conclusion [“... Indications might be widened with ‘suspicion LVH’. Further specification of the indications for open access echocardiography - by defining a stepwise diagnostic approach including ECG and (NT-pro)BNP - might improve the service.”] is balanced and based on the analysis and discussion of our results. The GPs in our region, not the cardiologists, widened the indications for echocardiography with ‘suspicion of LVH’. The cardiologists did not at all stimulate this. In fact, the relatively high number of hypertensive patients in the database surprised the cardiologists in the author group when we were discussing the results.

We did not change our statement on competing interests