Author's response to reviews

Title: Differences in patient outcomes and chronic care management for oral anticoagulant therapy: an explorative study

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Author's response to reviews: see over
Dear editor,

On behalf of my co-authors, I am submitting the *revised* manuscript ‘Differences in patient outcomes and chronic care management for oral anticoagulant therapy: an explorative study’ for possible publication in the *BMC Health Services Research*. We like to thank the reviewers for their comments. We have adapted the manuscript according to the comments from the review process.

Thank you for considering our manuscript for publication in your journal. We look forward to your final decision.

Yours sincerely,

Hanneke Drewes
Referee: 1

Version: 1
Date: 29 September 2010
Reviewer: Hanna Kaduszkiewicz

Reviewer's report:
This is an interesting study analysing the associations between patient outcomes in oral anticoagulant therapy and elements of the chronic care model. It is of general interest and should be published after small revisions.

Major Compulsory Revisions
Methods:
I disagree with the sentence: “The CCM is used to make the concept of chronic care management measurable.” The CCM describes areas of action, but this is far away from making chronic care measurable. It should be stated that up to now there exists no well validated instrument that measures the degree of having implemented the chronic care model. Therefore a questionnaire had to be developed for your study (How did you develop it and was it validated?). This (the assumed lack of validation) also is a limitation of the study and should be added to the discussion.

We understand the concerns of reviewer 1. The CCM is indeed a broad concept which described areas of action but this is not yet made measurable by the orginal authors. Therefore, we selected the CCM items based on this model and made them measurable based on the literature and about twenty expert’s working in the thrombosis field regarding the chronic care management and/or thrombosis. Since the above mentioned sentence ‘The CCM is used…..measurable’ was incorrect, we deleted this sentence and added the following sentences on page 6:
‘The Chronic Care Model (CCM) of Wagner is used to identify the elements of chronic care management. The CCM captures six components which all conceive elements on practice level to structure chronic care such as software applications for decision support or education for self management support. [7] The CCM elements that were included in our questionnaire were selected and made measurable based on the literature and the expert’s opinion of about twenty professionals working in the thrombosis field.’

We agree that a validated questionnaire is preferred, though, this is not yet available for OAT. In addition, the following text is added to our limitations:
“Furthermore, chronic care management could not be measured by a validated instrument since these are not yet available for OAT. However, we selected and made the elements measurable based on the literature and the expert’s opinions of about twenty professionals working in the thrombosis field.’

Discussion:
- Do you have any hypotheses why the number of specialized nurses versus doctors is significantly associated with patient outcomes? Do patients tell nurses more than doctors? Do nurses better adhere to protocols? Or is the
ratio staff/patients better in these anticoagulant clinics because nurses are cheaper? I think that some thoughts related to this finding should be added to the discussion.

Indeed it can be hypothesized based on our data that the time spent with the patient is higher with a better patient orientation and higher number of specialized nurses versus doctors. The following text is added to our manuscript:

'It could be hypothesized that patient orientation and ratio of specialized nurses versus doctors results in more patient centered care since there is more time spent per patient which is likely to result in a higher quality of care. However, the data for this study were not specific enough to test the hypothesis and should be further studied.'

- I’m not sure if “Insight in waiting times” is a good proxy for self-reflection. A more close interpretation would be that it is a proxy for patient orientation.

We appreciate the suggestion considering insight in waiting times as proxy for patient orientation which is more closely interpretation of the situation. Consequently, we adopted patient orientation as proxy for insight in waiting times and replaced self-reflection by patient orientation in our paper.

- I don’t understand the limitation which is described in the two sentences of which the first starts with “next”. The quality of care during and after hospitalization was not an objective of this study. The two sentences should be rephrased.

We rephrased the two sentences (see red sentences page 14). The following sentences are added to the manuscript:

‘Next, the highly developed documentation of the ACs on national level is in contrast with the scarcely developed documentation in the clinical setting. As a consequence, gaps exist in the follow-up of patients (e.g. INR values around hospitalization) which could reveal more insight in the influence of chronic care management on the quality of care.’

Minor Essential Revisions
- page 4: fourth line from the bottom: … is provided by “61” ACs, not 59, as I have understood

The referee is fully correct. The numbers are mistakenly confused. We have inserted the right numbers. There are 61 ACs at the time of our study. However, two relatively new ACs were excluded for this study, because their patients only include self-management patients, making comparison incorrect. The remaining 59 ACs in the Netherlands take care of more than 375,000 OAT patients users in 2008, including about 99% extramural thrombosis care in the Netherlands.

- Results, first sentence: “patients” (instead of “patient”)

We have made the adjustment the reviewer asked.

- Page 10: what are FTE? Please exemplify.
We can understand the confusing since the abbreviation is not explained. The abbreviation is fully explained in the text (see red sentence page 10). Full-time equivalent (FTE) is a way to measure the relative employment of the worker for a specific job/project.

- Page 10: about “an” INR...
- Page 11, second line: patients (instead of patient)
- Page 12, middle: percentage of patients (“of” is missing)
- Page 13: the validation of these “instruments” is limited... and the next sentence: “A validated instrument ... “is” useful ... or “would be” useful?” I prefer “would be”.
- Page 13: working “mechanisms”
- Page 14: .... Which could “have caused” bias...”resulted” (instead of result)
- Page 14: other “variations”...
- Page 15: third line: patient (this time an “s” too much)

We have made all adjustments as by the reviewer suggested.

- Tables 1 and 2: Abbreviations: What do “TD”, “IKA” and “VIM” mean? (and “NA” in Table 2 only)

We have added the following footnote to table 1 explaining all used abbreviations:
*GP* (general practitioner), IKA (system to report ideas, complaints and deviations), INR (International normalized ratio), VIM (safe reporting incidents).

We have added the following footnote to table 2 explaining all used abbreviations:
*GP* (general practitioner), IKA (system to report ideas, complaints and deviations), INR (International normalized ratio), NA (not assessed), VIM (safe reporting of incidents).

We have deleted the abbreviation TD since this is the Dutch abbreviation for specialized anticoagulant clinic (AC).

**Discretionary Revisions**

**Discussion:**
- The second sentence states that patient outcomes are good compared to other countries. As a reader I would like to get some examples, e.g. from Italy, where there also are specialized anticoagulant clinics.

We understand that the reviewer would like to get some examples. However, it is hard to cite comparable results since the diversity between study populations and INR ranges is great. For that reason we have decided to delete this sentence. Nevertheless, the Dutch ACs provide OAT as is recommended by the ACCP guidelines and is good regarding the criteria stated by the Dutch National Network of ACs. Therefore we have rephrased the second sentence: ‘Although the Netherlands manage OAT with specialized clinics as is recommended by the ACCP guidelines and achieve a good quality of care according to the criteria of the Dutch National Network of ACs, remarkable differences exist. The percentage of patients in the correct INR ranges differed with more than 20%-point. Furthermore, differences existed ....’
The same applies to page12 (comparison with routine medical care). Also some examples would be good.

We have added the following example in the second paragraph of the discussion:

'It was already shown in previous research that the quality of OAT provided by ACs is higher than OAT provided by routine medical care. For example, Ansell and colleagues showed that the percentage of patients within the correct INR ranges and time-in-range is 3 to 10% higher in anticoagulant clinics in Spain and Italy than in routine medical care in France, U.S. and Canada (Ansell et al., 2007).

Quality of written English:
Acceptable
limitations in the “Discussion”. Title and abstract seem accurate and the writing of
the manuscript is acceptable.

Discretionary Revisions
None
We thank the reviewer for thoroughly reading the paper and his complements.

Minor Essential Revisions:
1. As the title proposes, this is an explorative study. Considering the results,
the authors should propose in the “Discussion” further evaluations of the
relationship between CCM elements and clinical outcomes (complications)
obtained prospectively. Especially relevant would be the analysis of the role of
specialized nurses relative to these clinical outcomes. This should be easier to
do in such a setting, the Dutch Network of AC, than in any other country.
In line with the suggestions of reviewer 1 we added the following text:
‘It could be hypothesized that patient orientation and ratio of specialized nurses
versus doctors results in more patient centered care since there is more time spent
per patient which is likely to result in a higher quality of care. However, the data for
this study were not specific enough to test the hypothesis and should be studied
further.’

2. In Table 1, there should be a footnote defining IKA, VIM, TD, GP and INR.
We added the following footnote to table 1 explaining all used abbreviations:
GP (general practitioner), IKA (system to report ideas, complaints and deviations),
INR (International normalized ratio), VIM (safe reporting incidents).

We added the following footnote to table 2 explaining all used abbreviations:
GP (general practitioner), IKA (system to report ideas, complaints and deviations),
INR (International normalized ratio), NA (not assessed), VIM (safe reporting of
incidents).

We have deleted the abbreviation TD since this is the Dutch abbreviation for
specialized anticoagulant clinic (AC).

Major Compulsory Revisions:
None

Level of interest: An article whose findings are important to those with closely
related research interests
We thank the reviewer for his complements.
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