Reviewer's report

Title: Development and assessment of a questionnaire for health care utilization and costs for cardiac patients

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Reviewer: Heather Hadjistavropoulos

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1. Is the question posed by the authors well defined?

Overall, the purpose of this research is well defined. This paper is focused on the development and validation of a health care utilization and costs questionnaire for use with patients following an acute cardiac event. The authors are addressing an interesting topic that is important to studies of health economics. As the authors point out in their paper, administrative data is not always easy to access and does not capture some important costs for patients.

2. Are the methods appropriate and well described?

The methods that were used are appropriate. My main concern, however, is that some further information needs to be collected to assess this questionnaire. That is, the information the authors collect is valuable, but nonetheless incomplete. In particular, I am concerned that individuals over the age of 65 were not studied. Also as noted by the authors later in the manuscript, the main costs for patients include days off work, hospital admissions, and medications. It seems that to appropriately assess this questionnaire further comparison of the questionnaire to administrative data is needed with respect to hospital admissions and medications. In their study, the authors only compared retrospective report of days off work to administrative data.

Some further information is needed in the method section. In terms of the questionnaire, why did the authors ask about paid and unpaid help, travel expenses and physical activities over four weeks? All other items were collected for the last 12 weeks. Also, the authors need to explain why the questionnaire begins with areas that are “regular” but “relatively unimportant”. It seems that it would have been better to begin the questionnaire with the main cost drivers (e.g., items that are regular and frequent).

The description of items that were compared between the diary and the questionnaire could be improved. The authors state that since some cost items were retrospectively assessed for the last four weeks (Table 1), comparisons with the diary were possible for these cost items. In reviewing Table 1, this then lead me to believe that the diary method would be compared to the questionnaire for use of paid and unpaid help, travel expenses and physical activities. When I looked at Table 3, however, it appears that it was possible to compare the diary with the questionnaire for number of physician visits, inpatient days, days off work, hospital admissions, and medications.
work, number of drugs, etc.

In terms of criterion validity, I am not familiar with the term “sickness funds”. The authors should describe this in further detail to ensure understanding of this fund for readers from other countries.

3. Are the data sound?

There are several factors that limit the data. Convergent validity was assessed by comparing information from the questionnaire with a prospective cost diary. I wonder, however, if completing the diary then resulted in greater accuracy in completing the questionnaire than would normally be the case.

A major limitation is that data is only available for 48 out of the 106 patients studied, with 29 patients not consenting, 5 sickness funds not providing data, and 11 patients being privately insured. This is less than 45%, which seems problematic given the importance of this type of information for validating the questionnaire.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

The authors assessed the completion rate by examining response to the filter questions. It would be helpful to learn about response rates to the non-filter questions specifically. What percentage of individuals provided information for non-filter questions when they responded positively to the filter question? Is the response rate as high for the detailed information that is required if the filter question is responded to positively?

On page 12, the authors state, that “except for medications, the retrospectively measured mean values of health care utilization tended to be lower than the prospective measurement”. When I review Table 3, however, it appears that retrospective reports result in higher estimates compared to the cost diary for number of physician visits, days off work, and cost of medical aids.

Figure 1 is not a helpful way to show the relationship between underreporting of costs and sick leave days. Could this not be described in terms of a correlation?

On page 13, the authors report that “mean sick leave days agreed highly between diary and sickness fund (17.1 vs. 17.6) while there was a slight underreporting of sick leave in the questionnaire (16.3)” It would be helpful to provide the statistics supporting this statement.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

The authors have collected some evidence to support their questionnaire, but they need to be more cautious about its validity given the limitations of this study.

The ICC between the cost diary and the questionnaire varied from .57 to .90. There was also some discrepancies in medication using both methods. The
sickness fund and the questionnaire resulted in significant differences in number of total sick days. Further attention needs to be given to whether this data supports the questionnaire.

6. Do the authors clearly acknowledge any work upon which they are building?

This appears to be a new project. On page 10, however, in brackets they report “as in the subsequent clinical trial”. They should clarify how this study is linked to this subsequent study.

7. Are the limitations of the work clearly stated?

In the discussion, the authors note limitations of the research, including the focus on individuals under age 65 and the need to compare medication and physician visits administrative data and their questionnaire.

The authors also acknowledge that generalizability across countries is not possible.

They also acknowledge that the study is focused on patients with class 1 (83%) heart problems according to the NYHA classification. The authors note that there was a weak correlation between measures of disease severity and questionnaire acceptance, but I don’t think they have enough patients with higher disease severity to assess this relationship.

8. Do the title and abstract accurately convey what has been found?

The title should make clear that this paper is focused on development and preliminary assessment of validity.

The abstract needs to be improved. In terms of the results, the authors report that the ICC range between .57 and .9, but do not specify which items have lower ICC. Given the limitations of the study (under 65, class 1 NYHA, inability to compare important questionnaire items to administrative data, only 45% of patients could be compared for administrative and questionnaire, significant differences between data collected with the diary and administrative data and the questionnaire), the authors should be more cautious about the questionnaire and the need for further research before the questionnaire is used.

Is the writing acceptable?

Overall the writing is acceptable, although there are several areas that require clarification.

Recommendations described above have been divided into discretionary, minor and major revisions.

Discretionary Revisions

I’d prefer if the questionnaire was attached in an appendix. Since there are no restrictions on the page limit for this journal, I wonder if the authors would consider this. This would then allow for others to research this questionnaire.
Minor Essential Revisions

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One area that could be strengthened in the introduction is the potential value of measuring some costs, such as over the counter drugs, travel expenses, costs of paid and unpaid informal care. These costs are relatively small in comparison to other costs and elaboration on how this information is helpful is needed.

The authors should clarify why they ask about paid and unpaid help, travel expenses and physical activities over four weeks; all other items are collected for the last 12 weeks.

The authors report that they began the questionnaire with areas that are “regular” but “relatively unimportant”. It seems that it would have been better to begin the questionnaire with items that are regular and frequent… the main cost drivers. This decision should be further explained.

The description of items that were compared between the questionnaire and diary needs to be improved. The authors state that since some cost items were retrospectively assessed for the last four weeks (Table 1), comparisons were possible for these cost items. This lead me to believe that the diary method would be compared to the questionnaire for use of pain and unpaid help, travel expenses and physical activities. When I looked at Table 3, however, it appears that it was possible to compare the diary with the questionnaire for number of physician visits, inpatient days, days off work, number of drugs, etc.

The authors should describe “sickness funds” in greater detail for individuals who are not familiar with this term.

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In the introduction, the authors stated that one goal of the study was to identify the cost structure and the overall level of disease related costs in patients after an acute cardiac event. How do the results reported in Table 6 compare to other findings in the literature? Is this new knowledge?

Major Revisions

Further data needs to be collected to examine this questionnaire in individuals over the age of 65 and those with greater disease severity. In this study, 83% of patients had a class 1 score on NYHA classification. Patients with greater disease severity may have significantly greater difficulties with this questionnaire. Also to appropriately assess this questionnaire further comparison of the questionnaire with administrative data on hospital admissions and medications is needed.

If the authors do not collect this information, a stronger case needs to be made for why to publish this questionnaire without this essential information. The risk of publishing the questionnaire without this information is that the measure will be used prematurely before adequate attention is given to validity of the measure.

The authors need to address the fact that they were only able to compare the sickness fund and the questionnaire for 45% of patients. This is a major problem and somehow needs to be addressed.

The authors also need to address the fact that completing the diary may have resulted in greater accuracy in completing the questionnaire than would normally be the case.

The authors need to be more cautious in their interpretation of the data. The ICC between the cost diary and the questionnaire varied from .57 to .90. The information gained about medications differed depending on whether the authors examined the diary method or the questionnaire. The sickness fund and the questionnaire resulted in different number of total sick days.
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.