Author's response to reviews

Title: Prognostic value of physicians assessment of compliance and other factors regarding all-cause mortality in patients with type 2 diabetes: primary care follow-up study

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Author's response to reviews: see over
BMC Family Medicine
Prognostic Value of Physicians’ Assessment of Compliance in Patients with Type 2 Diabetes: Primary Care Follow-up Study

Response to reviewer Martha M Funnnel (“A generally very interesting study…”)

General remark: Please note that the contact details and the affiliation of Hermann Brenner and Dietrich Rothenbacher have changed meanwhile to: Division of Clinical Epidemiology and Aging Research, The German Cancer Research Center, Bergheimer Str. 20, D-69115 Heidelberg/ Germany (see page 1).

Point 1 (“The authors have greatly limited the impact of their findings…”)
Response: In response to the comments of both reviewers we changed the title to: “Prognostic Value of Physicians’ Assessment of Compliance and Other Factors Regarding All-Cause Mortality in Patients with Type 2 Diabetes: Primary Care Follow-up Study” (page 1, title).

Point 2 (“Two more minor issues that need to be addressed: Reference 10-14 support the importance of glucose control, not compliance.”)
Response: We changed the citation accordingly (page 4, para 2, line 2).

Point 3 (“It also was not clear how providers separated what they knew about the patients’ health status of concrete measures and their impression of compliance. It would be helpful to understand what they were instructed prior to rating the patient”)
Response: The physicians were asked to fill out the questionnaire at the time the patients came to the office. At this time they just could rely on the information they already had recorded in their charts or that they remembered. Almost all of these patients with diabetes were well known by the physicians as the study area is located in an area in the South of Germany characterized by small towns and villages. The physicians did actually not know the HbA1c-value measured at the current visit when filling out the questionnaire.

The qualitative survey among physicians by means of a standardized questionnaire was done after all patients had been recruited. This survey was intended to find out which aspects for the assessment of patient compliance in general were of strong or very strong importance when the physicians made the assessment on an individual basis. We now provide more information about these details (page 5, para 2 and page 6, para 1).

In addition, we added recent results of the DAWN study (page 11, para 1, lines 4-10 and reference mo. 22)
Response to reviewer Marcel Adriaanse (“This paper reports the results of a prospective cohort study…”).

**General remark:** Please note that the contact details and the affiliation of Hermann Brenner and Dietrich Rothenbacher have changed meanwhile to: Division of Clinical Epidemiology and Aging Research, The German Cancer Research Center, Bergheimer Str. 20, D-69115 Heidelberg/ Germany (see page 1).

**Point 1:** (“Title, P1;…”)  
Response: We changed the title accordingly and incorporated also the suggestion of reviewer No. 1 to highlight the different areas mirrored in this article to: **Prognostic Value of Physicians’ Assessment of Compliance and Other Factors Regarding All-Cause Mortality in Patients with Type 2 Diabetes: Primary Care Follow-up Study**. (page 1, title).

**Point 2:** (“p 2, Please impute a clear and separate Objective…”)  
Response: We tried to write the objective of the study more clearly (page 2, para 1, lines 4-6).

**Point 3:** (“p2. In the Methods section the authors should include…”)  
Response: We included the exact wording and the way the question was operationalized in more detail (page 2, para 2, lines 4-6).

**Point 4:** (“p 2.; the authors used also more qualitative (standardized questionnaire) methods in a sample of 15 physicians […] this should be included in part of the methods section.”)  
Response: We included the more qualitative methods also in the methods section (page 2, para 2, lines 7-10).

**Point 5:** (“p 2. In the methods the authors write “Active…. to determine vital status”. What do the authors mean?”)  
Response: We now use the precise definition “living status (alive/dead)” (page 2, para 2, line 10).

**Point 6:** (“p 2.: please provide in the abstract…”)  
Response: We now provide in the abstract that data were gathered by a standardized questionnaire and provide age (SD) and sex distribution (page 2, para 2, line 2 and lines 4-5).

**Point 7:** (“p2, the first sentence of the results section is not (really) a result…”)  
Response: According to the suggestion we moved this sentence to the methods section (page 2, para 2, lines 1-4).

**Point 8:** (“p 2, l 14; the authors used the word “very poor”)  
Response: We now use throughout the whole paper the same terminology.

**Point 9:** (“p 2.; The second sentence of the results section (The physician’s…”)
Response: We removed this sentence as suggested.

Point 10: (“One of the outcomes is ”Patient compliance was judged by he physicians as rather to very good for 63% of the total population.”…Is this not an outcome that should be presented in this abstract?)
Response: We incorporated the % results in the abstract (page 2, para 3, lines 4-7).

Point 11: (“P 2. One of the outcomes of this study is that “high HbA1C-values…”
Response: We added this outcome to the results section as suggested (page 2, para 3, lines 7-8).

Point 12: (“P2.; the last sentence of the results section…”
Response: We clarified this sentence (page 2, para 2, lines 7-8).

Point 13: (“p2.; perhaps the authors could impute some Keywords…”
Response: We added some key words to the abstract (page 3, para 2).

Introduction
Point 14 (“P3, l 4-5; Patients..”)
Response: We added the respective information (page 4, para 1, lines 5-6).

Methods:
Point 15: (“Replace “und” by “and.””)
Response: We replaced “und” by “and” (page 5, line 2).

Point 16: (“p 4.1 4-5.. Perhaps… “)
Response: Some surgeries were shared by 2 GPs, in total 15 physicians were involved. We clarified this sentence as suggested (page 5, Para 1, lines 5-7).

Point 17: (p 4, “Did the patients in the study gave written informed consent ?”)
Response: The study was part of the quality assessment requirements physicians in Germany are required to do (page 5, para 2, line 1, page 11, para 3, lines 1-3) . The study was conducted in the context of a geographically organized quality circle of all primary care physicians in a coherent region in the South of Germany. For this purpose, only information available in the patient’s chart or explored during medical history to take adequate care for patients with diabetes according to the current state of the art was collected and analysed in an entirely anonymous manner.

Point 18: (“p 4, l 8; please impute if these are…”)
Response: We now state that these are ADA criteria (page 5, para 1, line 9).

Point 19: (“I appreciate the fact that the authors gather additional data. Please…”
Response: We now provide the reader with more information with respect to the additional questionnaire (page 5, para 2, lines 13 and page 6, para 1, lines 1-12).

Point 20: (“p 5, l 4; The authors write that “patients’ living status was recorded”. What do the authors exactly mean?…”
Response: We now use the precise definition “living status (alive/dead)”. (see also response to point 5) (page 6, para 3, line 2-3).
Point 21: (“Of crucial importance in this study how “physicians’ assessment of compliance” is measured…”)
Response: We now more clearly describe how physicians’ assessment of patients compliance was assessed. Rather as measuring specific aspects of treatment adherence such as treatment adherence (pills counts) or the compliance with a special diet (all aspects for which validated questionnaires exist), we intended to investigate physicians’ assessment of the patient compliance as an integrative measure. In addition we carried out a small qualitative survey among the physicians to get important clues which aspects of compliance were important for them in general when making this assessment for an individual patient. With this qualitative approach we tried to include many psychological, social and environmental aspects beside the specific aspects of treatment adherence (page 5, para 2, lines 13 and page 6, para 1, lines 1-12).

Point 22: (“In this study the authors merged the categories “very good or rather good” (table 4) and compared them with the category “rather bad” and “very bad”…”)
Response: We were interested in a more differentiated assessment of levels of compliance that might be relevant for prognosis and we feel confirmed in this intention by the strongly different results for both categories. Merging them would conceal very important information.

Statistical analysis

Point 23: (“p 5, l 17. In this section the authors showed that microvascular and macrovascular complications were measured/used as yes or no…”)
Response: The definition of macrovascular complications in the context of this study included the prevalence of the following diseases: myocardial infarction, apoplexy, and peripheral occlusive disease. The definition of microvascular complications in the context of this study included the following diseases or results: diabetic retinopathy, and diabetic nephropathy as indicated by microalbuminuria; neuropathological complications were not included as they were difficult to assess in the context of such a (quality assessment) study in primary care (page 7, para 2, lines 6-9).
The physicians were asked to report the respective diseases if they were already known and documented in the patient’s chart. A respective list of diseases was presented in the physician’s questionnaire and a response was possible in no/yes categories. If the respective disease was present, the time since first diagnosis (in five year categories) was asked for. Usually the diseases are based on respective reports of specialists (ophthalmologists, internists, etc.) and the diagnoses are made according to standards of care in Germany.

Results Point 24: (“p 6, l 2. The authors show that all eligible patients with DM were 88%. Could it be possible that those other 12% were had different characteristics…”).
Response: Unfortunately we had no further information of the patients who did not participate in this quality improvement approach. It is plausible that patients with a less good compliance are less likely to participate in such an approach. Therefore, it is likely that especially patients with a less favourable assessment of compliance are underrepresented. This, however, does very unlikely affect the internal validity of the described results, as they are based on a prospective study approach.

Point 25: (“The number of patients and collection is not real clear to me…”)
Response: All patients with known type 2 diabetes, aged 40 and over, who were under medical treatment in one of 11 participating practices of general practitioners (general practitioners or internists working in primary care in a coherent region in South Germany) between April and June 2000 were asked to participate in this quality assessment approach. In
addition to the patients seen in the surgeries all patients who were seen in nursing homes or visited at home by the participating GPs were also included (page 5, para 1, lines 1-9).

Point 26: (“The authors should try to avoid double information…”)
Response: We deleted all p-values in the text as they can be seen in the tables (see results section) and we reduced the redundant information with respect to table 5 in the text (page 9, para 2).

Point 27: (“p 7, last paragraph. In general, qualitative research does not seek to quantify data…”)
Response: We deleted the percentages from the text and added the actual numbers instead as requested by this reviewer. However, we would like to keep table 5 for illustration purposes of the various aspects of compliance considered in this study (page 9, para 2, lines 1-7 and table 5).

Discussion

Point 28: (“There is no good research without limitations. The authors should discuss some other limitations…”)
Response: We now discuss the additional listed limitations of this study (page 11, para 2, lines 3-10).

Point 29: (“The authors should try put there results in the light of other national and international studies…”)
Response: On the national level there are no comparable published studies from the primary care sector. However, we now updated the reference list and added more recent references (see introduction, discussion section and reference no. 3 and reference no. 6). In addition, we discussed also recent results of the DAWN study (page 11, para 1, lines 4-10 and reference no. 22)

Tables

Point 30: (“Perhaps I’m mistaken, but…it seems to me that the numbers in tabe 1, 2 and 3 are incorrect…”)
Response: We apologize for the errors in the tables. We had included in table 1 four subjects of whom the living status was not clear. We now excluded them from the beginning and as a consequence from all the tables. The total number of patients is now 1014 instead of 1018. In addition, we corrected some transmission errors from the SAS output. Nevertheless, the sum of the columns does not always add up to total due to missing information in few items. We now included this information as footnote to the respective tables (see tables 1-3).

Point 31: (“Moreover; the numbers presented in table 1 do not correspond with the numbers presented in table 2 and 3…”).
Response: See also response to Point 30.
We apologize for the errors in the tables. We had included in table 1 four subjects of whom the living status was not clear. We now excluded them from the beginning and as a consequence from all the tables. The total number of patients is now 1014 instead of 1018. In addition, we corrected some transmission errors from the SAS output. Nevertheless, the sum of the columns does not always add up to total due to missing information in few items. We now included this information as footnote to the respective tables (see tables 1-3).
Point 32: (“The tables present numbers and percentages…”).
Response: We skipped percentages in table 4. However, we would like to keep the numbers and percentage in table 1 to 3 as it provides both, information about the actual numbers the relative distribution in the categories.

Point 33: (“p 16. Table 4 does not present microvascular complications…”).
Response: We used multivariate logistic regression with a backward variable selection procedure to identify the independent association of various factors with all-cause mortality. We then eliminated step by step all variables (description of variables see Methods section) which did not contribute to the model in a statistically significant way (p > 0.1). Microvascular complications did not qualify for the final model.

Miscellaneous:

Point 34: (“The authors gathered information from Gp’s and internists (p 4.): perhaps they could use the word physician throughout the paper.”)
Response: We now use the word physicians throughout the paper with the exception of the methods section, in which we describe the participating physicians with respect to their background.

Point 35: (“HbA1C and cholesterol are continuous variables, why not presenting them that way…”)
Response: We would like to keep the format of these variables in table 3 as this way the reporting is consistent with the reporting of other categorical variables (see table 2 and 3). In the multivariable part, however, both variables were included in the multivariable models as continuous variables (see page 7, para 1, lines 9-10).

Point 36: (“Perhaps it would be interesting to test the sociodemographic and medical characteristics between the Patients presenting at office and Care home patients,….”)
Response: We would like to refrain from statistical comparison between the two patient groups. These are clearly two different patient groups as can be seen in the description of table one. The purpose of table 1 is a merely descriptive one, i.e. to characterize the two patient groups and the whole study populations, and to show the distribution of socioeconomic variables and traditional risk factors. Point 37: (“The authors should try to up-date their references…”)
Response: We up-dated the reference list (see reference list).

Point 38: (“I read reference 16 (Brit J Gen Practice…”).
Response: We now used a consistent translation of the items from German language to English language. In the former analysis, in which the variable was used as a descriptive item (and not used as an independent covariate) the translation was suboptimal.

Point 39: (“Moreover, it is possible that by using different formats this will generate different outcomes?…”)
Response: The formats are due to different wording and translation from German language to English. However, we now use a more consistent wording. As the number in the cells are the same, the results are not affected.