Author’s response to reviews

Title: Limiting Treatment and Shortening of Life: Data from a Cross-sectional Survey in Germany on Frequencies, Determinants and Patients' Involvement.

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Author’s response to reviews:

Cover letter

Dear editors,

we would like to thank the Associate Editor and the two reviewers very much for their detailed and constructive comments and for the opportunity to revise the manuscript.

Please find attached the revised version of our manuscript and a detailed point to point response to the reviews. Given that the manuscript has been worked on substantially by all authors and the proof readers we decided against a tracked version but highlighted those parts of the manuscript in which we made substantiate changes as consequence of the Reviews.

We hope that in its current form the manuscript is of interest for BMC Palliative Care.

Best regards on behalf of all authors
Birte Dahmen
Response to review

We would like to thank the Associate Editor and both peer reviewers for their detailed and helpful feedback. Please find below a point-by-point response to the comments. All references to line numbers are made with respect to the tracked change version.

Associate editor:

I think the paper needs a clear aim or research question(s) at the end of the introduction which can be answered in the discussion. This will probably also bring more focus to the paper, as reviewer 1 suggests.

The aim of this paper is to provide an in depth empirical analysis of practices of treatment limitation (i.e. withholding and withdrawal of treatment with possible or intended shortening of life) of a sample of German physicians. The data has been gathered with an internationally acknowledged instrument and in this respect has advantages over earlier German studies focusing on particular specialties or using less robust methodology. In addition, and in line with the interdisciplinary working group encompassing physicians, a nurse and philosophers we provide an analysis of the empirical findings in light of more recent ethical and legal debates about the end of life in Germany.

- We have set out this aim now more clearly in the introduction (see lines 25-26, 101-107)

Both reviewers ask for more details in the methods section (methods, analyses, characteristics, etc).

- We now incorporate subheadings in order to structure the methods section and provide more details in this respect (see lines 111, 125, 143, Box 1, Box 2)

The paper lacks information about the population studied. The authors refer to another paper, but this paper is in German and probably does not show this sub population of 104 physicians. Please add patient and physician characteristics as also reviewer 2 suggests. This could be done by adding another table or by including this information to table 1 for instance. This will also
give more information about table 4. It is not clear, for instance, how many physicians had a specialization and or age distribution of patients.

- We have added tables with physician- and patient characteristics (see tables 1-3)

It is also confusing to me why authors chose to focus on DNR decision in table 3, also using another denominator.

- Given that DNR decisions are a particular discussed practice of limiting treatment we intended originally to include these data as well as. However, in light of the reviewers’ comments we realise that this part of the survey findings is rather confusing within the current manuscript and therefore deleted this part of the paper.

More results from other studies using similar methods could be added to the discussion, to get better idea of the German situation compared to the situation in other countries. There is for instance several papers in which the decision making process is described in other countries.

- We have incorporated in the introduction and discussion sections now references from several studies from other countries using similar methods/research design

(see lines 62-66 + 262-264 + 269-284)

The authors conclude that that limitation of treatment is frequently practiced in Germany. But what is frequently? % of all deaths? More frequent that other medical decisions at the end of life?

- We have specified this in the sense that the frequencies are high, for example in comparison also to recently published data from Switzerland, Netherlands and Belgium as well as the older data from the EURELD study (see line 62-66, 269-284).
Reviewer #1

General

In this questionnaire study about end-of-life decision-making practices 734 doctors across different disciplines were approached (403 responded). This specific study focuses on the forgoing of potentially life-prolonging treatment including doctors' estimated life-shortening effect, the type of treatment withheld or withdrawn, and communication with doctors and patients. Although the response rate is not that high, the study provides data from Germany and also includes some new variables such as involvement of a palliative care specialist and religious affiliation. I however have some comments/suggestions to further strengthen the paper.

Major

1) Throughout the article the authors state that analyzing the data from an ethical perspective is important. However, the authors predominantly mention that they analyze the data ethically. I suggest to do this more thoroughly in the Discussion part of the paper.

- By “ethical analysis” we refer to an analysis which takes into account ethical issues of limiting treatment recently discussed in the German debate. We clarify this in the introduction of the paper (see line 104-107).

2) For instance: line 245/246. The authors question whether a different disease trajectory will eventually result in different life-limiting practices. I agree with this assumption, but would strongly suggest to refer to relevant literature and for instance refer to limiting treatment in an older population and a cancer population; perhaps the default approach is different due to different patient characteristics and ‘doctor cultures’?

- We would like to thank the reviewer for this point with which we very much agree. However to our knowledge there is little robust empirical research substantiating the potential relevance of different disease trajectories or age for decisions near the end of life. In case the reviewer has such research has at hand we will consider to include this prior to publication.
3) For instance: The early integration of palliative care is a heavily debated topic right now; do the authors have any idea why there is no significant association? Perhaps, some types of treatment are more frequently withheld by palliative care specialists, and other types of treatment not? What is in fact the number of doctors with a specialization in palliative care?

- We do have no conclusive evidence for the lack of a significant association between palliative care specialists and limiting treatment. However, we discuss this point in the revised version suggesting the following possibilities (see line 343-346)

1. Selection bias with regards to those physicians who participated in the study with regards to a more active stance towards limiting treatment decisions (regardless their specialization)

2. Selection bias with regards to high number of reported cancer patients which may influence the findings on associations between the groups of (non-) specialist palliative care

3. Small number of physicians with additional qualification in palliative care. We have added the number at the end of the discussion section

(see line 343-346)

In the introduction section of the paper, and in the final conclusion of the abstract; the role of value laden aspects is mentioned. It is however not made very clear what the authors mean with value laden aspects. By doing an ethical analysis, this warrants more attention.

- In line with the aim presented in the introduction of the revised manuscript we restrict the analysis of normative aspects with reference to recent end-of-life debates – namely in the context of legislating advance directives (2009) and assisted suicide (2015). As added in the revised manuscript both debates preceding the legislation the topic of limiting treatment was an important feature in scientific and popular articles/media contribution (see line 80-85, 289-295,310-315)

I am not sure about the most important findings of this paper; is/would you expect the German situation to be very different from other European countries? Are new questions adding new information to the literature (such as information about expertise in palliative care / religion)? Or are the data analysed in a different way (e.g. ethically)? Please be more specific.
- In the revised version we now state in the introduction the following aims of this paper

1. To contribute to the empirical literature by means of data from Germany elicited with a robust instrument in a, for Germany, rather large sample. Given that international research has shown considerable differences between countries we hold it to be justified to replicate existing international research in Germany.

2. To analyse the data “ethically” in the sense of making reference to normative aspects which have been debated in particular within the debates on end of life legislation (see above)

(see lines 62-63, 65-66, 73-80, 94-107)

It would be good to check the paper for English grammar.

- The revised version has been checked by a native speaker

Minor

- Abstract.

If the ethical and legal aspects are mentioned in the introduction section, you would expect this aspect in the paper more extensively. If not, I suggest to focus on doing a descriptive analysis to picture German practice with respect to life-extending treatment, anno 2013. I also think that there are in fact quite some interdisciplinary in-depth analyses about this topic (which contrasts with what the authors suggest).

- In the revised version we focus on descriptive aspect and restrict the normative analysis to the more recent ethical and legal debates about end-of-life legislation (see above).

- Introduction.

Line 64;  Is 'limiting' treatment a correct English term. I am not sure about this.
“Limiting treatment”, to our knowledge, encompasses the more often used terms of “withholding” and “withdrawal of treatment”. We avoided otherwise frequently used but unhelpful terms such as for example “passive euthanasia” to be as descriptive as possible.

Line 67; I think that there are other diseases than cancer in which dilemmas due to uncertainties may arise.

- We agree that there are other diseases than cancer, in which such dilemmas could arise and reframed this part of the paper.(see lines 61-62)

Line 69; 'Hence…..' Please, explain this a little better

- We have added that these difference cannot be explained by medical factors. (see line 69-70)

Line 76-78; Could you please explain this a little more. For me, it is not altogether clear why the data are not valid for current end-of-life practices.

- We have changed this part by mentioning that a change of the ethico-legal framework may influence practice and in this sense has consequences for the elicited data. (see lines 79-85)

Line 83-84; I'm not sure whether this is true.

“Moreover, the published data often focuses on its relevance from health research and clinical perspective”?

- We deleted this sentence

The sentence, 'such data is important…. ' could be left out
- We deleted this sentence

Line 96; I suggested mentioning the year here too.

- We included the year (line 103)

- Methods.

Line 336; Why do the authors choose for 4 variables beforehand (on the basis of literature); I would suggest doing the analysis by checking other variables also. Or is there a statistical power problem?

- It was our aim to conduct a statistical analysis which is informed by the state of the literature. For this purpose, we had formulated hypotheses based on the available literature. We have made this explicit now in the method section (see line 160-167).

- Results.

In general, I suggest to present the percentage instead of the absolute numbers.

We now present total numbers as well as %

- In general, the result section can be shortened; please provide the most important results

We have shortened the result section especially by taking out the part on DNR orders.

Line 149-152; I suggest leaving the sentence … In the following analyses we report…..out. This is Methods, but is not really necessary to mention I would think.

- We deleted this sentence
Line 182; Please leave out (wording according to questionnaire); this raises questions, instead of being explanatory.

- We have taken out the bracket. Since the wording is relevant for answering questions in particular on controversial aspects we think that reporting the wording is a matter of transparency and therefore have formulated key questions in box 1 (see also reviewer 2).

Line 200-203; Please bring this sentence to the methods section

- We included this phrase into the methods section

- Discussion.

In general, I suggest to focus on a few topics. It seems that there is no clear message while reading the discussion section. The number of topics can better be shortened.

- We have focused and structured the discussion in the revised version on the following aspects

1. The relative high frequency of limiting treatment
2. The frequencies of patient (non-)involvement
3. Clinical and non-medical factors possibly influencing treatment decision making about limiting treatment

Line 225; Please bring the strengths and limitations of the study in one paragraph (at the beginning or at the end)

- We now provide a paragraph with strengths and weaknesses at the end of the paper. (see lines 348ff.).
Reviewer #2:

ABSTRACT

low response rate: non-response analysis?

- Due to the anonymization-process we were not able to perform a non-response analysis and we make this explicit in the method section of the revised version (see lines 122-123).

more relevant/compelling results in abstract? (only one sentence about involvement of patient in decision...and not even a general result but specifically about DNR orders. Given that patient involvement is in the title.)

- In line with the re-set focus of the paper we have revised title, introduction and abstract (see also response to reviewer 1). The focus of the paper is now

1. Reporting and comparing frequencies of limiting treatment
2. Reporting percentages of patient involvement in decision making

- We also have structured the result and discussion sections accordingly no physician characteristics associated with outcomes? make explicit!

- We now make explicit that there was no significant association regarding physician characteristics (palliative care specialisation, religion).

(see lines 47-49)

Reading the abstract, this is not really an ethical analysis, so the title is misleading

- By “ethical analysis” we refer to an analysis of the empirical data in light of recent ethical and legal debates in Germany. We clarify this in the introduction of the paper (see lines 104-107) and have changed the title of the article.
INTRODUCTION is OK

METHODS

please use subheadings: participants, mailing procedure, questionnaire and analysis

- We subdivided the methods into subsections (see lines 111,125,143).

for the reader it would be best to provide the exact quesion(s) you posed for limiting treatment.

- We included these questions into the methods section (see line 139 / 547: Box 1).

you also treat patient involvement as a dependent variable in your results section, so need to discuss this in the methods section as well.

- This is correct. In our revised manuscript we have deleted DNR findings due to different samples and other content (advance decision making instead of reported practice) please also mention the patient and physician characteristics recorded

- We now include three tables concerning the physician- and patient characteristics (see tables 1-3).

best to clarify that you could only analyse decision making for treatment limitation decisions that were designated as the last-mentioned (and according to the logic of the questionnaire hence the most important) decision.

- We clarify this point in the method section (see also next point) (see Box 1, line 547)
RESULTS

overall, some more thought needs to go into the results.

the presentation of results is also a bit confusing: the denominators are different and the explanation of how you arrive at these numbers is confusing. And I'm well-acquainted with the survey and questionnaire, so for someone not acquainted it will be very difficult to follow.

In some tables you've lumped together withholding and withdrawing treatment. Like in Table 1 and 4. I wonder whether you are not missing certain evidence, because I can imagine the ethical weight of withholding potentially beneficial treatment will differ from withdrawing ongoing treatment, leading to differences in how the decision is reached and to differing views across sociodemographic traits. Did you analyse them separately and find no differences in associated characteristics?

- We agree that it is not easy to get through the structure of the questionnaire and presenting clearly the findings. As steps to be more clear here we have taken the following measures

1. Box 1 on key questions

2. Box 2 regarding different steps of analysis and respective subsample

3. Deleting DNR findings due to different sample and other content (advance decision making instead of reported practice)

4. Structuring the result and discussion sections accordingly

- While some commentators emphasise the normative difference between withholding and withdrawal of treatment this is a matter of rather controversial ethical debate. Against this background we have decided to present the data separately for withholding and withdrawal (see table 4, line 561) but refrain from a further analysis.

Related to this, better to mention how many cases you end up with when combining the 174 withholding and 144 withdrawal instances. Because there is overlap correct?
Correct, there is an overlap because some physicians have performed a withholding as well as a withdrawing of treatment. All in all 219 physicians (54.34%) have performed a limitation of treatment, containing 174 cases of withholding and 144 cases of withdrawing treatment. We included this number in the manuscript now. (see lines 179-182)

Table 3: why only DNR orders shown? Are other decisions not giving statistically significant differences? If so, you should say this as reason why you only show DNR.

Also on light of the comments of the editor and reviewer 1 we have decided that these results referring to a different subsample might be confusing and probably too much information, so now we decided to delete this part.

line 171-188: so much information, why not provide a table? This is core information on decision making in general, for me more important than the data on DNRs. Especially since you devote quite some discussion to these findings. If you decide against a table, you need to specify in the text "data not shown".

We now have put these data in a table 6  
(see line 227, 575).

line 200: based on which earlier findings?

- We reformulated this to “based on our hypotheses (see method section)  
(see lines 235-238).

DISCUSSION

- subdividing into subheadings would give more structure to the discussion. Now the structure is not very clear
- We structured the discussion with regards to the three foci (frequencies of limiting treatment, patient involvement and determinants) (see lines 268,297,317,348)

line 282-284: I'm not sure this is the correct explanation. It's not about how old you are, it's about how close you are to death that determines your health condition. And are you going to overlook ageism as an explanation? Or is that what you mean with the ensuing discussion, undertreatment of elderly?

- Based on our own qualitative research our clinical experience and also given the health-economical debate about the role of age versus closeness to death as factor for expenditure we argue that both factors, age and closeness to death should be considered as possible explanations. However, closeness to death is difficult to determine prospectively in clinical practice so we focus in our discussion on age as determinant.

With regards to possible undertreatment of elderly patients we refer indeed to possible stereotypes regarding elderly which may lead to a more restrictive approach to treatment.

like I expected from the abstract, this paper's discussion is not really an ethical analysis. Best to take this out of the title.

- By “ethical analysis” we refer to an analyse which focuses on normative relevant empirical brought up in the more recent debates on end-of-life legislation (i.e. advance directives 2009 and assisted suicide 2015. We clarify this in the introduction of the paper (see lines 104-107), changed the title and refer to the debates in the discussion section (see line 289-295,310-315).

OVERALL: English language could be improved considerably..

- The revised version has been proof read by a professional native proof reading service
Minor comments:

- line 67: why do you say cancer specific when the issue is likely not limited to cancer patients and treatment?

  - Correct, we have deleted “cancer specific”

  (see lines 61-62).

line 76: please briefly touch on the specific changes to the ethico-legal framework.

- We made several brief references in the introduction (see lines 80-85) as well as in the discussion (see lines 289-295, 310-315) to the more recent ethico-legal debates and legislations about end of life care in Germany.

line 111: if there was no ID code on the questionnaire, how could you determine which doctors had answered and which had not when sending the reminders?

- All physicians received the questionnaire twice. We acknowledge that there is a possibility of bias due to double responses although given the workload of the target group we expect this to be a minor risk. We explain the procedure now in the method section. (see lines 118-119, 122-123).

line 128: "regarding the type", leave out "to"

- We deleted “to”

line 142: statistically significant, not significantly

- We changed this accordingly
line 160: is it not estimated instead of expected life shortening?

- We changed “estimated” to “expected”

Table 3: instead of multiple answers possible, better to make clear that doctors could have both withheld and withdrawn treatment in the same patient, and could have withheld or withdrawn more than one treatment

- Thank you for this suggestion. We changed this accordingly. Due to the differing sample and already extensive findings we deleted the findings on DNR (=table 3, see also reviewer 1).

Table 4: what is the "thereby" doing in the column heading?

- We deleted the confusing word “thereby”

Table 4: multivariable regression

- Correct, we changed this accordingly