PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Determinants of Completion of Advance Directives: A Cross-Sectional Comparison of 649 Outpatients from Private Practices versus 2158 Outpatients from a University Clinic
AUTHORS	Pfirstinger, Jochen; Bleyer, Bernhard; Blum, Christian; Rechenmacher, Michael; Wiese, Christoph; Gruber, Hans

VERSION 1 – REVIEW

REVIEWER	Michelle Howard McMaster University, Canada
REVIEW RETURNED	10-Jul-2017

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. The strengths are the multi-site design of the survey. The results are informative. There are some areas for revision that would strengthen the paper to make it suitable for publication. The main points are: clarifying the hypotheses similarities or differences in university and community settings, providing more details about the survey to demonstrate validity, providing more details of the study recruitment methods and response rate to demonstrate representativeness, and presenting the results according to primary and secondary objectives. See specific suggestions below: Pg 5 para 3: Please provide more information about why the question of similarity of the two types of clinics is important. What are private practices (in some countries this could mean health care that is not part of a publicly funded system)? If the main difference in the types of clinics is that University provides specialty disease care for sicker patients and private practice provides general primary care, it is not clear why one would attempt to generalize results of studies from one setting to the other. Pg 5 para 4: Could you state the objective to reflect the main comparison e.g. to compare patients from the two types of clinics regarding their….. Pg 5 para 5: Please state the overall study design in the methods e.g. multi-site survey… Pg 6: How was the sample size decided? Why was there a larger sample size in the university clinic sample? Pg 6: Please move the results of the demographics in the 2 settings to the results section.

	Pg 6: Questionnaire. Please describe more about the development of the questionnaire. Were the items generated from previous patients? A conclusion of the study is that patients completed AD as a way to prevent forms of therapy. The question wording seems biased towards this finding. What was the response scale- did patients check all that apply, or was there a rating scale e.g. agreement with statement? Please describe how the questionnaire was designed to ensure that it measured patient motives in a valid way. Pg 7 para 2: What was the study period? Pg 7 para 3: Please describe the primary and secondary outcome variables and the analyses/comparisons done and align the results in the same way. Pg 7 para 3: It was hypothesized that there would be no difference between the types of settings in the motivations to complete AD. How was the sample size computed to test this? Pg 7 para 4: Please state the overall response rate and how it varies across clinics. Some of the above issues are described in the STROBE checklist, it may be helpful to review. If it was included as supplementary materials I do not see it in the online system. Pg 7- 12 results: The results could be shortened to 2-3 pages. The statistical significance of comparisons should be presented in brackets next to the results statement instead of as separate paragraphs. The statistical significance testing should also be presented in the tables. There are many analyses and tables presented and it is difficult to follow the results. The results become confusing to read. Perhaps sub-headings would be helpful to orient the reader which outcomes are being described. The two main comparisons a) and b) in the abstract may be helpful. Pg 14 para 4: These are new results (comments from additional responses). They should be presented in the results section and described in the methods. Related to the above comment about the questionnaire development, was the questionnaire valid for measuring the concepts of barriers to completing AD if 325 patients provided additional reasons that were not on the survey? How do you interpret why a large number of patients provided other reasons? Discussion: The concept of negative autonomy is an interesting finding. However it is concerning that the survey may not have been validated to elicit all of the relevant reasons for completing or not completing AD, or the relative importance of each issue. Perhaps the authors could comment on this issue in the Discussion.

REVIEWER	HYL Chan CUHK, Hong Kong
REVIEW RETURNED	12-Jul-2017

GENERAL COMMENTS	It is a large scale cross-sectional correlational study to examine the determinants of completing advance directives in Germany. The study is timely to address a heated topic worldwide, but the manuscript need extensive revision in order to convey clear message. Introduction - The terms advance directives and living will are used interchangeable but it is unclear if there are any different interpretations between the authors and the readers. Also, it is unclear how the authors define advance care planning, as it is stated as an instrument. Please define and elaborate these concepts in the background. - The background need substantial revision. The authors start the manuscript with the concept of autonomy and informed consent as the fundamental principles, but regarding end of life treatment decision, the principles of beneficence, best interests and futility are also highly important. In fact, the results showed that the respondents valued the concept of no suffering more than making decision on their own. Hence, I would suggest the authors to use different perspectives to explain the nature and purpose of advance directives so that to give the readers, especially for those who are not familiar with this concept, a broader overview. - The claim 'many investigaton...." in the fifth paragraph is not supported with any references. Methods - It is noted that the patients for university hospital were recruited from "outpatient clinics / departments" but this has not been clarified or inconsistent to the abstract. - It is necessary to give more details about the questionnaire, for example, the term "knowledge of AD" is very vague. The results show that it is just about "familiarity of AD". Results - The results are not clear. In P.8 line 3, it is stated that 31% of persons completed both LW and HCP, but this percentage is out of 64% of the total number of people. This can be misleading. - P.8 line 41, it is unclear for what mean by "informed themselves" and to whom they had discussed their decision. - Since the authors had not provided sufficient information about the roles of doctors and lawyers in the AD completion process in the local context, it is also difficult for the readers to understand why the patients who to consult the lawyers. - The statement which discusses the finding (p.8 line 8 - 14) should be moved to discussion part. Discussion - It is stated that there were three research questions, but i could only find two in the abstract and study objectives. - Who are "actors" in p.12 line 19? - The linkage between findings and discussion is lacking. It is unclear how the discussion from p.14 line 18 - p.16 line 8) were drawn from the findings. Is this part about implications for practice? - Study limitations had not been discussed. Overall, the presentation of this manuscript is poor. The writing and grammatical errors affect the clarity of the paper. Professional editing is required in order to improve the paper quality.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Michelle Howard
Institution and Country: McMaster University, Canada Competing Interests: None declared

Thank you for the opportunity to review this manuscript. The strengths are the multi-site design of the survey. The results are informative. There are some areas for revision that would strengthen the paper to make it suitable for publication. The main points are: clarifying the hypotheses similarities or differences in university and community settings, providing more details about the survey to demonstrate validity, providing more details of the study recruitment methods and response rate to demonstrate representativeness, and presenting the results according to primary and secondary objectives.

See specific suggestions below:

Pg 5 para 3: Please provide more information about why the question of similarity of the two types of clinics is important. What are private practices (in some countries this could mean health care that is not part of a publicly funded system)? If the main difference in the types of clinics is that University provides specialty disease care for sicker patients and private practice provides general primary care, it is not clear why one would attempt to generalize results of studies from one setting to the other.

Response: The paragraph has been revised. Private practices in Germany are part of the publicly funded primary care (introduction page 5/6).

Pg 5 para 4: Could you state the objective to reflect the main comparison e.g. to compare patients from the two types of clinics regarding their…..

Response: ... AD completion rate, familiarity with AD, source of information about AD, prior experience with own life-threatening disease or family members in need for care, and motives in favour of and against completion of AD

Pg 5 para 5: Please state the overall study design in the methods e.g. multi-site survey…

Response: revised (method paragraph 1)

Pg 6: How was the sample size decided? Why was there a larger sample size in the university clinic sample?

Response: We decided about a sampling period of 12 weeks in the university clinics and wanted to reach a minimum of 2000 questionnaires. For practical feasibility we sent 50 questionnaires to each practice of the GP academic teaching practice network and asked each physician to hand the questionnaires to 50 consecutive patients, which explains the different sample size.

Pg 6: Please move the results of the demographics in the 2 settings to the results section.

Response: Revised. All results can now be found in the results section

Pg 6: Questionnaire. Please describe more about the development of the questionnaire. Were the items generated from previous patients? A conclusion of the study is that patients completed AD as a way to prevent forms of therapy. The question wording seems biased towards this finding. What was the response scale- did patients check all that apply, or was there a rating scale e.g. agreement with statement? Please describe how the questionnaire was designed to ensure that it measured patient motives in a valid way.

Response: The development of the questionnaire is now described in more detail (Method, subsection: procedure and instruments, page 7).

Pg 7 para 2: What was the study period?

Response: The study period was 12 weeks from March until June 2012.

Pg 7 para 3: Please describe the primary and secondary outcome variables and the analyses/comparisons done and align the results in the same way.

Response: The results section has been completely revised.

Pg 7 para 3: It was hypothesized that there would be no difference between the types of settings in the motivations to complete AD. How was the sample size computed to test this?

Response: The study was not statistically prepared like a clinical pharmaceutical trial. We wanted to reach more than 2000 completed questionnaires with at least 500 from private practices, but did not in advance compute a minimum number of questionnaires in order to stop after this number was reached.

Pg 7 para 4: Please state the overall response rate and how it varies across clinics.
The overall response rate in the different university clinics was more than 80% of the distributed questionnaires, which could be achieved with the help of seven students, who distributed and collected the questionnaires in the university clinics. From the responding private practices we received 72% of the distributed 50 questionnaires per practice. But we cannot provide the number of patients who refused to take the questionnaire. Therefore we might have received a biased selection of answers despite the high number of returned questionnaires.

Response: Some of the above issues are described in the STROBE checklist, it may be helpful to review. If it was included as supplementary materials I do not see it in the online system.

Pg 7- 12 results: The results could be shortened to 2-3 pages. The statistical significance of comparisons should be presented in brackets next to the results statement instead of as separate paragraphs. The statistical significance testing should also be presented in the tables.

Response: The results section has been completely revised.

There are many analyses and tables presented and it is difficult to follow the results. The results become confusing to read. Perhaps sub-headings would be helpful to orient the reader which outcomes are being described. The two main comparisons a) and b) in the abstract may be helpful.

Response: The results section has been completely revised.

Pg 14 para 4: These are new results (comments from additional responses). They should be presented in the results section and described in the methods. Related to the above comment about the questionnaire development, was the questionnaire valid for measuring the concepts of barriers to completing AD if 325 patients provided additional reasons that were not on the survey? How do you interpret why a large number of patients provided other reasons?

Response: Revised. All results can now be found in the results section
Before the questionnaire was designed we conducted an interview study with seven interviewers and 70 patients. This has now been clarified in the text to confirm the validity of our questionnaire.
The questions concerning the reasons in favour of or against AD completion included a free line for additional reasons. These individual reasons were very variable and did not accumulate to a relevant motivation, which was not included in our questionnaire.

Discussion:
The concept of negative autonomy is an interesting finding. However it is concerning that the survey may not have been validated to elicit all of the relevant reasons for completing or not completing AD, or the relative importance of each issue. Perhaps the authors could comment on this issue in the Discussion.

Response: Before the questionnaire was designed we conducted an interview study with seven interviewers and 70 patients. This has now been clarified in the text to confirm the validity of our questionnaire.

Reviewer: 2
Reviewer Name: HYL Chan
Institution and Country: CUHK, Hong Kong Competing Interests: None declared

It is a large scale cross-sectional correlational study to examine the determinants of completing advance directives in Germany. The study is timely to address a heated topic worldwide, but the manuscript needs extensive revision in order to convey clear message.

Introduction
- The terms advance directives and living will are used interchangeable but it is unclear if there are any different interpretations between the authors and the readers. Also, it is unclear how the authors define advance care planning, as it is stated as an instrument. Please define and elaborate these concepts in the background.

Response: We hopefully became clearer in our terminology. The term "advance care planning" was omitted, because we think that the most important approach to reach a maximum number of patients is a repeated consultation offer about advance directives and living wills while strictly respecting the voluntary nature of these legal instruments. In our opinion most efforts to reach a higher AD completion rate pay only little attention to the voluntariness

- The background needs substantial revision. The authors start the manuscript with the concept of autonomy and informed consent as the fundamental principles, but regarding end of life treatment decision, the principles of beneficence, best interests and futility are also highly important. In fact, the results showed that the respondents valued the concept of no suffering more than making decision on their own. Hence, I would suggest the authors to use different perspectives to explain the nature and purpose of advance directives so that to give the readers, especially for those who are not familiar with this concept, a broader overview.

Response: We now look at the different aspects of end-of-life decisions in more detail focusing not only on legal aspects (introduction first paragraphs)

- The claim 'many investigaton...." in the fifth paragraph is not supported with any references.
This paragraph has been revised (introduction page 5/6).

Methods
- It is noted that the patients for university hospital were recruited from "outpatient clinics / departments" but this has not been clarified or inconsistent to the abstract.
has been clarified

- It is necessary to give more details about the questionnaire, for example, the term "knowledge of AD" is very vague. The results show that it is just about "familiarity of AD".

Response: "Knowledge" has been replaced by "familiarity"

Results
- The results are not clear. In P.8 line 3, it is stated that 31% of persons completed both LW and HCP, but this percentage is out of 64% of the total number of people. This can be misleading.

Response: This statement is now presented in relation to all participants, so that 20% of persons completed both LW and HCP.

- P.8 line 41, it is unclear for what mean by "informed themselves" and to whom they had discussed their decision.

Response: The questionnaire included several possible answers how participants informed themselves via media (e.g. books, TV, internet etc.) or different persons. Sources of information are discussed in a variety of other publications. Our investigation does not add relevant new aspects to this issue, that is why we do not present these results in detail.

- Since the authors had not provided sufficient information about the roles of doctors and lawyers in the AD completion process in the local context, it is also difficult for the readers to understand why the patients who to consult the lawyers.

Response: In Germany as in other countries there is no obligatory medical or legal consultation for AD completion. Every patient can write a living will himself or fill out and sign one of multiple different forms provided by policy or different religious groups etc. Lawyers offer a fee-based AD consultation. A medical AD consultation can be offered by a physician but is not covered by the health care insurance.

- The statement which discusses the finding (p.8 line 8 - 14) should be moved to discussion part.

Response: ... moved to discussion section ...

Discussion
- It is stated that there were three research questions, but I could only find two in the abstract and study objectives.

Response: The argumentation has been edited thoroughly.

- Who are "actors" in p.12 line 19?

Response: In Germany, ADs were reregulated by the third act amending German guardianship legislation, effective September 1st, 2009. In the preceding discussion it was assumed, that strengthening patient autonomy and the legal instruments of living will and health care proxy would lead to a greater acceptance and a higher number of completed ADs. The remaining low rate of completed ADs therefore resulted in disappointment in policy and medicine.

- The linkage between findings and discussion is lacking. It is unclear how the discussion from p.14 line 18 - p.16 line 8) were drawn from the findings. Is this part about implications for practice?

Response: Findings and discussion have been thoroughly revised. All results can now be found in the results section and the interpretation can be found in the discussion section.

- Study limitations had not been discussed.

Response: Study limitations have been included in the main file, but were already recorded in the ScholarOne system, that could be seen be the editorial office but obviously not be the reviewers.

Overall, the presentation of this manuscript is poor. The writing and grammatical errors affect the clarity of the paper. Professional editing is required in order to improve the paper quality.
We thoroughly proofread the manuscript and hopefully found and eliminated all errors

VERSION 2 – REVIEW

REVIEWER	Michelle Howard McMaster University Canada
REVIEW RETURNED	12-Sep-2017

GENERAL COMMENTS	Thank you for the opportunity to review this revised paper. The clarity is improved in many areas. There are some areas that would require further edits. The question about response rate has not been addressed. Response rate means the proportion of people who completed the survey among the number who were invited. If this information was not collected it should be stated. The results section is still quite long (5.5 pages) and could be more concise. For example the text could note the most and least common reasons for completing AD or not, referring the reader to the tables for the list of all reasons which are ordered by frequency of endorsement. I am still confused about whether you are trying to identify predictors of completing an AD, or trying to determine if the predictors are different between groups. For example why were these 2 associations between selected predictors and the outcome of AD presented, but not all the other potential predictors of AD? (for example- page 13) More participants who had cared for a relative until her/his death had completed an AD compared to participants lacking such an experience (X^2 (1) = 30.70; p = .001; Φ = .10, OR = 1.61). Similarly, participants who had suffered from an own life-threatening disease had a higher rate of completion of AD than participants without this experience (X^2 (1) = 40.89; p = .001; Φ = .13, OR = 1.77).

	I appreciate that the authors developed a survey from concepts in the literature and used it previously in 70 patients but this does not guarantee that the survey is valid and reliable. The unknown properties of the survey should be mentioned as a potential limitation. The other potential limitation to be mentioned in the Discussion is that there are no data on the response rate to the survey. The methods describe that all patients were given a survey and returned it at the end of the visit but typically in surveys some eligible patients are not invited and not all those invited agree to complete the survey. The uncertain representativeness should also be mentioned as a limitation.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Michelle Howard
Institution and Country: McMaster University, Canada
Competing Interests: None declared
Thank you for the opportunity to review this revised paper. The clarity is improved in many areas. There are some areas that would require further edits.
The question about response rate has not been addressed. Response rate means the proportion of people who completed the survey among the number who were invited. If this information was not collected it should be stated.

Response: The fact that the response rate has not been collected can now be found in the introduction, the discussion, and the strengths and limitations section.

Comment: The results section is still quite long (5.5 pages) and could be more concise. For example the text could note the most and least common reasons for completing AD or not, referring the reader to the tables for the list of all reasons which are ordered by frequency of endorsement.

Response: The results section has been shortened.

Comment: I am still confused about whether you are trying to identify predictors of completing an AD, or trying to determine if the predictors are different between groups. For example why were these 2 associations between selected predictors and the outcome of AD presented, but not all the other potential predictors of AD? (for example- page 13)
More participants who had cared for a relative until her/his death had completed an AD compared to participants lacking such an experience (X^2 (1) = 30.70; p = .001; Φ = .10, OR = 1.61). Similarly, participants who had suffered from an own life-threatening disease had a higher rate of completion of AD than participants without this experience (^{2} (1) = 40.89; p = .001; Φ = .13, OR = 1.77).

Response: We try to do both:
to identify predictors of completing an AD and
to determine if the predictors are different between groups.
Two of the fundamental assumptions and research questions of our survey were that there would be no relevant differences between patients from university clinics compared to private practices and that personal experience with life threatening and end-of-life situations would lead to a higher AD completion rate, which can be used as an indicator for the maximum proportion of completed ADs that can be achieved by educational approaches.

Comment: I appreciate that the authors developed a survey from concepts in the literature and used it previously in 70 patients but this does not guarantee that the survey is valid and reliable. The unknown properties of the survey should be mentioned as a potential limitation. The other potential limitation to be mentioned in the Discussion is that there are no data on the response rate to the survey. The methods describe that all patients were given a survey and returned it at the end of the visit but typically in surveys some eligible patients are not invited and not all those invited agree to complete the survey. The uncertain representativeness should also be mentioned as a limitation.

Response: These limitations are now mentioned.

VERSION 3 – REVIEW

REVIEWER	Michelle Howard McMaster University
REVIEW RETURNED	30-Oct-2017

GENERAL COMMENTS	Thank you for addressing the suggested revisions. One final minor suggestion, perhaps move the limitations to the paragraph before conclusions so the paper does not end with limitations.