PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving regional care in the last year of life by setting up a pragmatic evidence-based Plan-Do-Study-Act cycle: Results from a cross-sectional survey
AUTHORS	Voltz, Raymond; Dust, Gloria; Schippel, Nicolas; Hamacher, Stefanie; Payne, Sheila; Scholten, Nadine; Pfaff, Holger; Rietz, Christian; Strupp, Julia

VERSION 1 – REVIEW

REVIEWER	Jinfeng Ding University of Western Australia
REVIEW RETURNED	28-Jan-2020

GENERAL COMMENTS	Thank you for this important study. It was a pleasure to review this paper. This study reported the context, nature, and quality of care provided for patients in the last year of life from the perspective of relatives of the patients. Some problems related to level of satisfaction with care provided by acute hospital staff were highlighted, based on which target interventions were proposed. I only have a couple of suggestions or questions for the authors: 1. Could the authors provide Odds Ratios value and Confidence Intervals instead of P-value in line 31-31 page 2, Abstract section 2. The authors used a large amount of space to describe and highlight the design of the PDSA cycle, such as title, background and the first paragraph of Discussion section. I understand that this design is one of the major strengths for whole LYOL-C project. However, for this paper itself, the focus is to present the primary findings of a cross-sectional survey. Overemphasis on PDSA cycle could lead readers to expect to see how the findings in relation to PDSA design had improved end of life care in this paper. 3. I was confused with the description in lines 8 – 18, page 10, the Results section, and Figure 2 without seeing the original questions in the questionnaire. How was it possible to calculate the percentages of time spent in each care setting against time approaching death? Could the authors provide key questions included in this report? 4. Table 3 also easily causes confusions: - Could the authors please clearly indicate what the ‘N’ represents in each column? I assume the authors include all patients for whom the corresponding question was responded in the first ‘N’ (larger), but only counted the number of patients that had answers to both hospital general ward/ICU and corresponding the other setting in the second ‘N’ (smaller). This should be clearly described in Table annotation. - In addition, a much larger number of responses/patients were excluded from the first ‘N’ when conducting the comparisons. The overall satisfaction for patients between the first ‘N’ and second ‘N’

	could be largely different. Is it still appropriate to present the results of overall satisfaction and comparisons in the same table? - Could the authors please give reasons why the comparison of Palliative Care unit versus General ward/ICU was not conducted using paired test (Wilcoxon singed-rank test) as other comparisons?

REVIEWER	Martina Orlovic Imperial College London, UK
REVIEW RETURNED	18-Feb-2020

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. It addresses an interesting topic and provides learnings that can be applied in other developing countries when it comes to organisation of the end-of-life care. Overall, the paper is well written, but some sections need to be strengthen to make it suitable for publication. Please find the comments below: Introduction is missing a paragraph on what is important to dying patients - what are dimensions of good quality EoL care. The paper frequently refers to "quality of care provided", but it is not clear what quality represents. Also, it is important to address the difference between patients' and caregivers' perspective as this may differ, especially at the end of life and lead to many decision-making conflicts. The paper assumes that these perspectives are fully aligned. Pg. 2 Abstract- Conclusion should be more concrete, especially referring to last sentence Pg. 3 line 27 - why patients are regraded venerable? They may lack decision capacity. Please add context Pg. 3 line 59/60 - Please disclose preferences regarding place of death and where people die in Germany Pg. 4 line 24 - suggest using "caregivers" instead of relatives Pg. 4 line 43 expression "relying on pragmatic yet evidence-based" is confusing. Pg. 4 line 46 suggest "implement" instead of "install" Pg. 4 line 54 please correct "satisficing" Pg. 4 line 59 suggest adding "to improve regional end-of-life care" Pg. 5 line 36 - who are relevant health and social care providers Pg.6 first paragraph in Results section should be shortened Pg. 10 line 36 add % next to 161 Pg. 12 line 8-14 - it is stated that "Differences in informants' reports of satisfaction with care in hospital general wards and ICUs were statistically significant in comparison to care…" Please state what this means e.g. better, wore, etc? Pg.12 Table 3 in table notes add interpretation key (e.g. what is null hypothesis)? Pg. 13 Table 4 should be removed, please present results of logistic regression. OR are interpreted on the next page, but not presented. The reader is more interested in logistic regression results than univariate analyses. Pg. 14 principal findings should be discussed further. I would be interested to read why home terminal care was also rated as "not satisfactory" for symptom control and what does that mean.

	Pg. 14 Limitations should reflect that proxy's view does not have to align with patient's. You should not overstate conclusions - these are still views from bereaved relatives. Also, these findings come from urban setting, we don't know would it be applicable to rural settings. Pg.15 What do you mean that palliative care is not included in hospitals - please explain further. Also, WHO views are encouraged, but what is the situation in Germany? Pg. 16 line 17 - How do you know beginning of the last year of life. Implication section should be rephrased and strengthened.

REVIEWER	Lisa W Le University Health Network Canada
REVIEW RETURNED	23-Mar-2020

GENERAL COMMENTS	1) Missing data should be excluded from the calculation of percentages throughout the entire paper. 2) Page 7. The cut-off of entering the variable selection is too restrictive at p<=0.05 on univariable analysis. It is possible that one variable may become significant in the multivariable analysis while it’s not significant (p>0.05) on the univariable analysis. 3) Page 12. P-values presented in Table 3 should be adjusted for multiple testing. 4) Page 13, line 60. Avoid the word “predict” where “associate” is more appropriate. 5) Page 14. The 95%CIs of odd ratios were wide. Did authors check the model convergence for either complete or quasi-complete separation, given the small cell counts of 8 and 4 shown in Table 4? 6) Page 14. c-statistic or AUC are more useful model performance measures for logistic models than R^2 or its variants.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Jinfeng Ding

Institution and Country: University of Western Australia

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

Thank you for this important study. It was a pleasure to review this paper. This study reported the context, nature, and quality of care provided for patients in the last year of life from the perspective of relatives of the patients. Some problems related to level of satisfaction with care provided by acute hospital staff were highlighted, based on which target interventions were proposed.
I only have a couple of suggestions or questions for the authors:

Dear Reviewer,

Thank you very much for taking the time to make constructive criticism on how this manuscript can be improved. We agree with all comments and think that the manuscript has benefitted greatly from changes. More detailed responses to each comment are given below.

1. Could the authors provide Odds Ratios value and Confidence Intervals instead of P-value in line 31-31 page 2, Abstract section
>> We have changed this accordingly.

2. The authors used a large amount of space to describe and highlight the design of the PDSA cycle, such as title, background and the first paragraph of Discussion section. I understand that this design is one of the major strengths for whole LYOL-C project. However, for this paper itself, the focus is to present the primary findings of a cross-sectional survey. Overemphasis on PDSA cycle could lead readers to expect to see how the findings in relation to PDSA design had improved end of life care in this paper.
>> We have reduced the amount of space that relates to the design of PDSA cycle.

3. I was confused with the description in lines 8 – 18, page 10, the Results section, and Figure 2 without seeing the original questions in the questionnaire. How was it possible to calculate the percentages of time spent in each care setting against time approaching death? Could the authors provide key questions included in this report?
>> In order to calculate the percentages of time spent in each care setting against time approaching death, participants were asked to provide the settings in which the patients had received care during the last year of life (e.g. home, hospital, nursing home, hospice, rehabilitation clinic), and the period of time spent per stay in a table with chronological order. We have added a more detailed description in methods section.

4. Table 3 also easily causes confusions:
- Could the authors please clearly indicate what the ‘N’ represents in each column? I assume the authors include all patients for whom the corresponding question was responded in the first ‘N’ (larger), but only counted the number of patients that had answers to both hospital general ward/ICU and corresponding the other setting in the second ‘N’ (smaller). This should be clearly described in Table annotation.
- In addition, a much larger number of responses/patients were excluded from the first ‘N’ when conducting the comparisons. The overall satisfaction for patients between the first ‘N’ and second ‘N’ could be largely different. Is it still appropriate to present the results of overall satisfaction and comparisons in the same table?
- Could the authors please give reasons why the comparison of Palliative Care unit versus General ward/ICU was not conducted using paired test (Wilcoxon singed-rank test) as other comparisons?
>> We have split the original table 3 into 3a (presentation of overall satisfaction) and 3b (comparisons) and added more detailed description in table annotations to eliminate confusion. Where possible, we used the Wilcoxon signed-rank test for paired samples to assess the statistical significance of differences in informants’ reports between two care settings (general hospital care vs. other care setting). Due to the design of the VOICES-questionnaire, it was not possible to apply the Wilcoxon signed-rank test to compare care in a Palliative Care unit versus General ward/ICU. We have data for either Palliative Care unit or General ward/ICU and therefore applied the Mann-Whitney-U-Test for two random, independent samples.

Reviewer: 2

Reviewer Name: Martina Orlovic

Institution and Country: Imperial College London, UK

Please state any competing interests or state ‘None declared’:None declared.

Please leave your comments for the authors below: Thank you for the opportunity to review this manuscript. It addresses an interesting topic and provides learnings that can be applied in other developing countries when it comes to organisation of the end-of-life care.

Overall, the paper is well written, but some sections need to be strengthen to make it suitable for publication.

Please find the comments below:

Dear Reviewer,
Thank you very much for taking the time to make constructive criticism on how this manuscript can be improved. We agree with all comments and think that the manuscript has benefitted greatly from changes. More detailed responses to each comment are given below.

Introduction is missing a paragraph on what is important to dying patients - what are dimensions of good quality EoL care. The paper frequently refers to "quality of care provided", but it is not clear what quality represents. Also, it is important to address the difference between patients' and caregivers' perspective as this may differ, especially at the end of life and lead to many decision-making conflicts. The paper assumes that these perspectives are fully aligned.
>> In Germany, the evidence-based guideline “Palliative care” was published in 2015 to promote quality end-of-life care by all healthcare professionals. This palliative care guideline guided the LYOL-C survey. Introduction section now comprises the recommendations of the guideline to improve quality of end-of-life care: “(…) providing palliative care services in both a timely manner and in accordance with the affected persons’ needs, treating the common symptoms according to current scientific evidence and clinical expertise, enabling conversations with patients and their families to be held and treatment goals to be set together, ensuring that support in the dying phase can be appropriately and optimally given.”
Relatives’ reports of care experiences after the death of a loved one are important to determine the quality of end-of-life care. This method is, of course, not without its limitations, especially in relation to memory, the impact of bereaved relatives’ feelings, and the concordance between patient and proxy reports. Discussion section addresses these aspects in more detail.

Pg. 2 Abstract- Conclusion should be more concrete, especially referring to last sentence
>> We have rephrased and strengthened conclusion.

Pg. 3 line 27 - why patients are regraded venerable? They may lack decision capacity. Please add context
>> We have added the following sentence for more context: “Due to the fact that they are often dependent on others to meet their physical care needs, they can deteriorate unpredictably and rapidly and their ability to make informed choices may be reduced due to cognitive impairment. (Addington-Hall et al. 2007)”

Pg. 3 line 59/60 - Please disclose preferences regarding place of death and where people die in Germany
>> We have added data on preferences and place of death of patients in Germany.

Pg. 4 line 24 - suggest using "caregivers" instead of relatives
>> We have changed this accordingly.

Pg. 4 line 43 expression "relying on pragmatic yet evidence-based" is confusing.
>> We have deleted the sentence due to another reviewer's comment.

Pg. 4 line 46 suggest "implement" instead of "install"
>> We have deleted the sentence due to another reviewer's comment.

Pg. 4 line 54 please correct "satisficing"
>> With "satisficing" we would like to relate to the concept developed by Parker et al. We have put the word in quotation marks to eliminate confusion.

Pg. 4 line 59 suggest adding "to improve regional end-of-life care"
>> We have added this accordingly.

Pg. 5 line 36 - who are relevant health and social care providers
>> We have invited all health and social care practitioners who are involved in the care of patients in the last year of life and their families in Cologne (i.e., care homes, nursing services, hospices, bereavement cafés, doctors, hospitals, undertakers and the local public health department) as well as providers of grief work. We have changed this sentence in the manuscript accordingly.

Pg.6 first paragraph in Results section should be shortened
>> We have shortened this paragraph.

Pg. 10 line 36 add % next to 161
>> We have added this accordingly.

Pg. 12 line 8-14 - it is stated that "Differences in informants' reports of satisfaction with care in hospital general wards and ICUs were statistically significant in comparison to care…" Please state what this means e.g. better, wore, etc?
>> They were least satisfied with the care provided in acute hospitals (general wards and ICUs). We tested the differences in informants' reports of satisfaction with acute hospital care versus all other health and social care practitioners (e.g. hospital general ward/ICU vs. hospice). Table shows the results of comparisons.

Pg.12 Table 3 in table notes add interpretation key (e.g. what is null hypothesis)?
>> We have split the original table 3 into 3a (presentation of overall satisfaction) and 3b (comparisons) and added more detailed description in table annotations.

Pg. 13 Table 4 should be removed, please present results of logistic regression. OR are interpreted on the next page, but not presented. The reader is more interested in logistic regression results than univariate analyses.
>> Thank you for this valuable indication. We have replaced the results of the univariate analyses by logistic regression results. Consequently, we listed the variables entered into the model in methods section.

Pg. 14 principal findings should be discussed further. I would be interested to read why home terminal care was also rated as "not satisfactory" for symptom control and what does that mean.
>> We have further addressed findings in discussion section.

Pg. 14 Limitations should reflect that proxy's view does not have to align with patient's. You should not overstate conclusions - these are still views from bereaved relatives.
Also, these findings come from urban setting, we don't know would it be applicable to rural settings.

>> The reports of relatives cannot be seen as a direct substitute for a self-assessment of patients, although a good agreement has been shown on service evaluations and observable symptoms (McPherson CJ, Addington-Hall JM, 2003). Nevertheless, the retrospective approach bypasses the difficult task of identifying the terminally ill, avoids putting an additional burden on very sick participants, and minimises missing data due to poor functional status. Discussion section addresses these aspects in more detail.
We have also added the following sentence: "The present study was conducted in Cologne, a city with one million inhabitants in Germany. It is not clear whether these results are transferable to other regions, rural as well as urban areas. Nevertheless, this study describes a pragmatic template based on patient experiences (PDSA cycle) which can be used to determine improvement priorities by other regions."

Pg.15 What do you mean that palliative care is not included in hospitals - please explain further. Also, WHO views are encouraged, but what is the situation in Germany?
>> In Germany, palliative care accounts for only a small part of hospital care. The majority of patients who are cared for in hospital receive acute therapy. However, since almost 30% of all hospital patients are expected to be in their last year of life (Clark et al. 2014), a further integration of palliative care could improve patient care.
We have also added the following sentences: "In Germany, the evidence-based guideline "Palliative care" was published in 2015 to promote quality end-of-life care by all healthcare professionals. This palliative care guideline presents the fundamental principles of palliative care which, in organ specific guidelines, would be repetitive and/or not able to be dealt with in a comprehensive manner."

Pg. 16 line 17 - How do you know beginning of the last year of life.
>> We will use a German version of the Gold Standards Framework developed in UK. Its three-step process comprises the surprise question ("Would you be surprises if the patient were to die in next year, months, weeks, days?"), general indicators of decline, and specific clinical indicators.

Implication section should be rephrased and strengthened.
>> Thank you for this valuable indication. We have rephrased and strengthened implication section accordingly.

Reviewer: 3

Reviewer Name: Lisa W Le

Institution and Country: University Health Network Canada

Please state any competing interests or state 'None declared':
None to be declared

Please leave your comments for the authors below

Dear Reviewer 3,
Thank you very much for taking the time to make constructive criticism on how this manuscript could be improved. We agree with all comments and think that the manuscript has benefitted greatly from changes. More detailed responses to each comment are given below.

1) Missing data should be excluded from the calculation of percentages throughout the entire paper.
>> We have excluded missing data accordingly.

2) Page 7. The cut-off of entering the variable selection is too restrictive at p<=0.05 on univariable analysis. It is possible that one variable may become significant in the multivariable analysis while it’s not significant (p>0.05) on the univariable analysis.
>> We have changed the cut-off of entering the variable selection to p<=0.1 on univariable analysis. There were no changes in the selection of variables. Therefore, presentation of results remained unchanged.

3) Page 12. P-values presented in Table 3 should be adjusted for multiple testing.
>> We have adjusted p-values using Bonferroni correction for multiple comparisons (see table 3b).

4) Page 13, line 60. Avoid the word “predict” where “associate” is more appropriate.
>> We have changed this accordingly.

5) Page 14. The 95%CIs of odd ratios were wide. Did authors check the model convergence for either complete or quasi-complete separation, given the small cell counts of 8 and 4 shown in Table 4?
>> Thank you for this valuable indication. We agree on wide CIs which is attributed to the small cell sample sizes. Model run converged successful and finished without warnings and errors. Therefore, presentation of results remained unchanged.

6) Page 14. c-statistic or AUC are more useful model performance measures for logistic models than R^2 or its variants.
>> We have calculated the c-statistic/area under the ROC curve and added to result section (see table 4).