Author’s response to reviews

Title: IDentification of patients in need of general and specialised PALLiative care (ID-PALL©): item generation, content and face validity of a new interprofessional screening instrument.

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Author’s response to reviews:

Dear Ms Zalm,

Please find attached our revised manuscript entitled "Identification of patients in need of general and specialised palliative care (ID PALL©): item generation, content and face validity of a new interprofessional screening instrument”.

Below is a list of the changes made in response to the reviewers' feedback. We thank the reviewers for their constructive comments, which we believe have strengthened the quality of the manuscript.

We hope that you will find the revised version of sufficient quality to merit publication in BMC Palliative Care.

Sincerely yours

Fabienne Teike Lüthi

PhD candidate in Nursing Sciences
Reviewer #1 comments

Q: Can you please add to your flow chart which stage included specialist palliative care healthcare professionals and disease specific healthcare professionals?

Our answer: The Delphi process was conducted with specialist PC healthcare professionals, only. We modified the title of this figure to make it more explicit.

Changes: Annexes, p. 22, line 576: Figure 1: Delphi process flowchart with specialist palliative care healthcare professionals

Q: Line 117: A committee of interdisciplinary clinical experts: Please clarify that they are experts in palliative care.

Our answer: We have changed the text

Changes: Methods, p. 6, line 133: This process was completed by a committee of interdisciplinary clinical experts in PC (CICE), including one clinical nurse specialist (FTL), one psychologist (MB) and two physicians (MB, GDB).

Q: Line 125: Qualitative part and quantitative part: Please specify each part, it is difficult to see the qualitative section, were there interviews or focus groups or was this just examining the written comments? The manuscript does not identify the number of written comments or the themes that were identified in the qualitative section, despite stating that they were to conduct thematic analysis using Braun and Clarke.

Our answer: We agree with your comment. We did not do a true thematic analysis. There were in fact some open questions and the responses were examined. The changes we made are the following

Changes: Methods, p. 6, line 163: In each round, a questionnaire including a list of items to be ranked according to the level of importance and one or two open questions for comments was sent to participants.

Methods, p. 7, line 173: Each comment was reviewed for its pertinence by the CICE and through consensus was reworded when judged appropriate. Thus, the choice of items was influenced by the overall consistency of the items selection and by the pertinence of the comments.

Results, p. 7, line 267: Following the review of the written comments, some items were reworded. The goal of developing a short, consistent and user-friendly clinical instrument justified this process.
Q: Line 140-141: Keeping items with a mean of ≥3.5 or those selected by more than half of the participants. Please explain the purpose of using a mean score if items potentially had a mean score of 1.8 yet were selected by more than half, what was the purpose of using a mean score?

Our answer: The wording was indeed misleading. During the first round, only items that had an average of ≥3.5 AND were chosen by more than half of the participants were selected. The wording was corrected.

For the second round, the decision was to keep items that met a mean of ≥ 3.5 OR were selected by more than half of the participants. The explanations were given at line 149 of the original manuscript.

Changes: Methods, p. 7, line 171: The CICE recommended keeping items with a mean of ≥ 3.5 and selected by more than half of the participants.

Methods, p. 8, line 179: As none of the items were chosen by more than half of the participants and reached a mean of ≥ 3.5, the CICE decided that only one of these two conditions had to be met.

Q: Line 142: Reference to qualitative analysis: There is no qualitative analysis presented in this paper.

Our answer: This is correct, see comment line 125.

Changes:

Q: Line 145: A questionnaire sent to all participants: This should be included in the manuscript. Were the questionnaires sent after the selection of items and more importantly, what was the purpose of the questionnaires? This is not explained in the manuscript.

Our answer: The questionnaires sent to all participants at Round 1, 2 and 3 included the list of items to be selected at each round of the delphi process.

To be clearer we have changed the text as follows

Changes: Methods, p. 6, line 147: A modified Delphi technique involving a questionnaire with open and closed-ended questions was used to assess the relevance and the comprehensiveness of items related to general versus specialised PC from the final list generated in Step 2. This occurred in the three rounds which allowed the content validity of the instrument to be established.
Q: Line 149-152: Round 2. Why were additional items added for round 2?

Our answer: You are right, we were not clear enough.

In the second round, the participants had to choose from the list of the items remaining from the first round. We clarified the sentence.

As mentioned in the manuscript, it is also true that following the comment review of the first round, 3 items were added to those chosen by the participants.

Changes: Methods, p. 8, line 178: In round 2, the same participants were asked to choose the items they believed should be retained for the instrument from the list of the items remaining from the first round.

Results, p. 11, line 247 (line 218 of the original manuscript): In addition and following the comments’ review by the CICE, three items were added to the Round 2 list, providing a list of 25 items.

Q: Is this the specialist palliative care expert panel? Is this the same panel described in step 2, with 4 people?

Our answer: The expert panel are the PC specialists who participate to the Delphi process.

The CICE is the research group which analysed the questionnaires and developed the instrument based on the participant’s answers. Expert panel and CICE are not the same group.

Changes: As it appears not to be clear, we replaced the wording of "expert panel" with “participants”.

Q: Please clarify which of the CICE conditions had to be met and why.

Our answer: We corrected the sentence as follows

Changes: Methods, p. 8, line 179: As none of the items were chosen by more than half of the participants and reached a mean of ≥ 3.5, the CICE decided that only one of these two conditions had to be met.

Q: Line 202: Table 1: Why are steps 1 and 2 excluded from this table? This provides more information than the flow chart (figure 1)

Our answer: In this table, we wanted to highlight only the two steps focusing on item selection, not the whole of the methodological process. Because step 1 of the process of instrument
development is the determination of the concept to measure, we decided not to include it in the table. We have now modified the first column and added the name of the step rather than only the development step number in order to avoid confusion.

Changes: Results, p. 10, line 233: see the corrected table

Q: Line 207: See table 2 for professional and demographic characteristics: This is not presented in table 2. Table 2 states Item selection.

Our answer: Given the relatively few demographic characteristics, we decided against a table, the data are directly in the text. The sentence in brackets which referred to a table has been removed.

Changes: Results, p.11, line 238: In the first round 19 nurses and 17 physicians participated; in the second 18 and 13; and in the third 15 and 14, respectively. Most of the participants had a specific training in PC (78%), with an average of 13 years of PC clinical practice experience.

Q: I feel a table outlining what items were eliminated following each step and round would be beneficial. It would provide the reader with a lot of clarity.

Our answer: We agree that a separate table summarizing the process could be useful. However, in our opinion it makes more sense for the reader to keep in mind the retained items rather than the eliminated ones.

Changes: Results, p. 12, line 275 Table 3

Annexes, p. 24, line 606

Q: Line 218-219: The original criteria of a mean ≥3.5 seems to be completely ignored in the document, can you please address this in the manuscript?

Our answer: As explained at question for line 140-141 for the second round, the selection criteria were different for round 1 and round 2. In the first round, only items that had an average of more than 3.5 AND were chosen by more than half of the participants were selected. In the second round, items that had an average of more than 3.5 OR were chosen by more than half of the participants were selected. We corrected the wording accordingly.

Changes: Methods, p. 7, line 170: The CICE recommended keeping items with a mean of ≥ 3.5 and selected by more than half of the participants.
Methods, p. 8, line 179: As none of the items were chosen by more than half of the participants and reached a mean of ≥ 3.5, the CICE decided that only one of these two conditions had to be met.

Q: Line 237: Table 2: See comments re line 207. I find this table 2 confusing. Line 140 states you keep items with a mean of ≥3.5, and selected by more than half of the participants, yet the table suggests that nearly all items were retained despite reporting a mean ≤3.5. What is the purpose of defining a selection criteria and not adhering to it? If you are not adhering to the selection criteria then please explain this in the manuscript.

Our answer: See answer to question on Line 202 above.

Changes:

Q: Line 239: Why is step 4 not included in table 1?

Our answer: See answer to question on Line 202 above.

Changes:

Q: Line 262: Qualitative comments: There were no qualitative comments analysed in this manuscript, how does the reader know whether they were relevant or not? Who analysed them and why is the analysis hidden?

Our answer: See answer to Line 125 above

Changes:

Q: Line 263: You mention data saturation in the discussion, yet there is no mention of thematic analysis in the results section. You cannot discuss data saturation without presenting results.

Our answer: Yes, you are right. With reference to the answer above (Line 125), the qualitative part was in fact some open questions, which were examined by the CICE. Therefore, we did not realise a thematic analysis and cannot use the terminology “data saturation”.

Changes: We removed “data saturation” from the discussion

Q: Line 264: "Each expert thought about their choices and comments in terms of what they saw as logical": How do you know this is fact? Where did the experts record their thought processes? Were they requested to keep notes on this? How did you interpret the experts thoughts?
Our answer: The Delphi process is a well acknowledged method for selecting items in instrument development. It makes the assumption that each participant follow a personal logical process through rounds. But you are right, we cannot confirm this assumption. A think-aloud method would have been necessary to do so. However, we do believe that such method was not justified in the context of our study. We have changed the text as follows

Changes: Discussion, p.14, line 306. Concerning the content validity, the qualitative feedback from the experts was pertinent and these comments allowed consensus to be achieved about the reformulation of certain items. However, in some instances, it was unclear as to how some comments could be used to modify the items because each participant contributed individually without a global vision of the instrument development that only the CICE had

Q: Line 267-271: There was no mention of 'intensive discussions' by the CICE in the methods or results sections of the manuscript. What was the outcome of the intensive discussions and why is this not discussed in results and corresponding tables?

What was it about the interprofessionality of the group that was a central element?

Our answer: Yes, you are right. We have changed the text as follows in the methods to explain that there were discussions within the CICE. However, we can only describe how these discussions were (intensive) in the Results section. As we did not record these discussions, it is now impossible to detail their content. These discussions resulted in the final choice of the items. Thus, during these discussions decisions were made about which items were kept or discarded, the reformulation of items and the consolidation of similar items into one more comprehensive item’

The aspect of interprofessionality was better explained in the Results and the Limits.

Changes: Methods, p.6, line 133: This process was completed by a committee of interdisciplinary clinical experts in PC (CICE) including one clinical nurse specialist (FTL), one psychologist (MB) and two physicians (MB, GDB). This CICE was in charge of ensuring the relevance, comprehensiveness and comprehensibility for clinical practice, by analysing the data and the answers to the open questions, as well as by reformulating, adding or clustering items through discussions and deliberations.

Methods, p. 6, line 138: An interprofessional working group was central in order to ensure that the different dimensions of PC were taken into account. The composition of the group was representative of the three professions most commonly involved in PC in Switzerland.

Limits, p.15, line 347: In addition, while the CICE was an interprofessional working group, the absence of chaplains and social workers may limit its representativeness of the different dimensions of PC, particularly concerning spiritual and social aspects.
Q: Line 279: The results of the face validity phase: This phase you mention is not defined in the methods or results.

Our answer: We believe that the current text already contains the requested information: in methods, p.9, line 193 (line 159 of the original manuscript). In order to be more precise, we modified the title of this step in the methods and the results

Changes: Methods, p. 9, line 188 and Results, p. 13, line 277: Step 4: administer items to a sample of the target population for face validity

Q: Line 305: face validity only performed with hospital healthcare professionals? This was not stated in the methods or results. It should not be presented for the first time in the limitations section of the manuscript.

Our answer: We believe that the current text already contains the requested information in the methods, line 161 of the first manuscript, currently Methods, p.9, line 195. We added the place of work in the Results.

Changes: Results, p. 13, line 278: Twenty nurses and eight physicians out of a total of 24 invited nurses and 24 invited physicians working in acute care setting at a Swiss university hospital participated in the face validation (57%)

Reviewer # 2 comments

Q: This tool proposes to identify generalist and specialist palliative care need, and is targeted at generalist health professionals, but as I understand it, all involved in the item generation were professionals with specialist palliative care experience. Generalists, patients or service users were not involved. Could the authors justify this decision in the manuscript. How do the authors think their decision to focus on specialist professionals may have affected the findings?

Our answer: A. We did not focus only on specialised PC professionals. We followed the recommendations of Polit and Yang (ref 49) for content validity (with PC specialists) and face validity (with non specialised PC professionals). We provided justification for the choice of the population. Experts are recommended, because at the stage of development of an instrument that aims to be a gold standard for the identification of patients in need of PC, we want to be certain that the process is informed by experts. The findings are therefore reflected by expert opinions, but that’s what we want. Experts are, by definition, specialists in their fields.

B. Patients were not involved in this instrument development because the target population for this instrument are clinicians. Experts in PC were involved in Step 2 & 3 and professionals non-specialised in PC in Step 4. We specified this:

Changes: Methods, p. 7, Line 147: A modified Delphi technique involving a questionnaire with open and closed-ended questions was used to assess the relevance and the comprehensiveness of
items related to general versus specialised PC from the final list generated in Step 2. This occurred in the three rounds which allowed the content validity of the instrument to be established. The content validity can be enhanced during the development of an instrument through inclusion of experts of the discipline (49).

Methods, p. 6, line 125: This instrument is designed to be a clinician-reported outcome measure. As a result, the target population are non-specialised healthcare professionals and not patients.

Q: I think given the focus on generalist vs specialist palliative care need in the results/discussion, this needs to be discussed in more detail in the background. Could the authors explain more clearly why it is important to distinguish between specialist and generalist need.

Our answer: We agree with this comment. The background was modified and some explanations were given in order to be more explicit.

Changes: Background, p. 3 line 60: This distinction is, nevertheless, crucial to better understand the level of need in the population and thus improve access to appropriate PC and provide appropriate care (2-4). Indeed, despite the development of PC, access to such care remains inequitable due to access to both specialists and generalists. This is particularly true for non-oncological patients and vulnerable populations (5). Improved differentiation between patients requiring general and specialised PC will help the healthcare system to (i) better cope with the increase of PC needs related to demographic evolution, (ii) identify and meet the training needs of non-specialised PC professionals, (iii) allow more efficient health spending through more equitable resource allocation and distribution (4-7). Since significant increases in PC needs are predicted, PC patient identification is an increasingly important public health concern.

Q: I recognise that there is limited space to describe each stage of this study, but it is important to include details such as how participants were identified and the analysis used (see specific comments below). They could consider adding more detail as supplementary files in line with relevant reporting guidelines.

Our answer: A. Yes, you are right. Explanation about the participants’ identification has been provided

B. We clarified that we did not perform an in-depth qualitative analysis (see responses to reviewer 1 above); thus, it does not seem necessary to add supplementary files:

Changes: Methods, p. 7, line 153: A list of all nurses and physicians working in the different community-based specialist palliative care teams and all executive nurses and physicians of the PC units was compiled.

Methods, p.8, line 196: An invitation to participate was send to all clinical nurse specialists of the hospital, as well as to senior residents collaborating with the hospital’s mobile PC team.
Q: Whilst I accept that the authors conducted thematic qualitative analysis of free text responses, I think that it is inaccurate for the authors to say their methodology was qualitative and quantitative. It would be more accurate to say that this was a questionnaire study with fixed option and free text questions, then detail the different analysis methods used for different response types. They could consider including additional details of the qualitative analysis as a supplementary file.

Our answer: See response to reviewer 1 (line 125)

Changes:

Q: Though it is possible to extract the information from table 2, it is quite difficult for the reader to see at a glance what the final set of items was. Could these be listed in the text or included as a separate figure?

Our answer: We agree that a separate table summarizing the process could be useful and we inserted one

Changes: Results, p. 12, line 275 Table 3

Annexes, p. 24, line 606

Q: Could the authors include more detail about the tool and how completion of the tool would be used in clinical practice. What number of criteria would need to be met for a person to 'have' generalist/specialist needs? This may be something to be covered in future research, but should still be considered here

Our answer: We agree with this proposal and have added some information about the instrument. A criterion validity study has recently been completed.

Changes: Results, p.13, line 291: A yes/no response categories are provided for each item. If one item is positive for the first part, the patient can be considered as in need of general PC. Evidence based recommendations for practice are then proposed and professionals are invited to complete the second part of the instrument. If two items are positive, the patient can be considered as in need of specialised PC.

Q: The background sets up the study well, but I think it could be more clearly structured, with fewer points per paragraph (and so on)

Our answer: The background was reworded accordingly

Changes: Background, p. 3, line 58 and following
Q: P3 line 64 - can the authors specify why identification of palliative care patients is a public health concern, and why particularly in the last 10 years

Our answer: The background was modified accordingly

Changes: Background, p. 3, line 58: Palliative care has been clearly defined (1), but identifying individuals with palliative care needs is an ongoing challenge. In addition, the definition proposed by the World Health Organisation does not shed light on the distinction between needs for general and specialised PC. This distinction is, nevertheless, crucial to better understand the level of need in the population and thus improve access to appropriate PC and provide appropriate care (2-4)

Q: P4 line 91 Could the authors expand slightly on their argument that an instrument is needed that is targeted at nurses/non-physicians?

Our answer: Yes we can, we gave two arguments for this choice

Changes: Background, p. 4, line 89: Interprofessional perspectives in PC are essential in order to provide holistic care for both patients and relatives throughout the disease trajectory until death. It is therefore crucial that professionals other than physicians are also involved from the beginning of the trajectory, especially at the identification stage. In addition, nurses generally have the closest contact with patients and relatives, which facilitates the assessment of their needs. Indeed, in daily clinical practice, nurses often identify PC needs and try to relay them to physicians. A new instrument should help nurses to systematize their evaluation and provide them with the necessary tools for accurately reporting these needs to interprofessional teams.

Methods, p. 5, line 107: The target users of the instrument are mainly nurses and physicians, but potentially other healthcare professionals like social workers or physiotherapists.

Q: P4 line 87. Isn't this the aim of the study, rather than the aim of the paper

Our answer: Yes, you are right, the change was made

Changes: Background, p. 4, line 97: The aim of this study is to describe the development of a new PC screening instrument to identify patients in need of general and specialised palliative care independently of their disease.

Q: P4 lines 89-93 - I think this discussion of the target users of the instrument would probably fit better in the methods, e.g. in the study design section.

Our answer: Yes, you are right, we moved this paragraph in the method section
Changes: Methods, p.5, line 107: The target users of the instrument are mainly nurses and physicians, but potentially other healthcare professionals like social workers or physiotherapists.

Q: P5 line 102. I don't understand this sentence. The overall concept of 'identifying palliative care needs' has already been outlined in the background. As it is described, the authors have conducted a focused literature review to identify existing definitions of palliative care need. I think 'determine the concept to measure' is therefore a bit confusing in this section, though I recognise it comes from the streiner model. Could the authors rephrase to clarify that the literature review was conducted to identify existing definitions of palliative care to inform item generation, not determine a new concept.

Our answer: Yes, you are right. Although very much close to what David Streiner advocates in his most recent textbook, we used Terwee’s criteria, that are now integrated in the new COSMIN recommendations. We, therefore, put an emphasis on the determination of the concept, as recommended by COSMIN.

We modified the sentence as suggested.

Changes: Methods, p. 5, line 113: A literature review was conducted to identify existing definitions of general and specialised palliative care to inform item generation.

Q: How did the authors extract their findings from the literature? Did they conduct any form of synthesis of the literature? I think this should be mentioned in the manuscript.

Our answer: Yes we agree, we have changed the text as follows

Changes: Methods, p. 6, line 118: All articles identified were collated and uploaded into EndNote X8/2016 (Clarivate Analytics, PA, USA). Titles and abstracts were then screened in order to keep only full texts related to the topic of interest. Definitions were extracted from the selected full text articles and collated in an Excel file for comparison.

Q: P5 line 115. 'first author'. There were two first authors - please specify which author(s) did this bit.

Our answer: Yes, you are right, we have changed the text as follows

Changes: Methods, p. 6, line 131: Regardless of whether the items referred to generalised or specialised PC, the first author (FTL) selected the relevant items from the literature, including published identification instruments.

Q: Was there any patient or service user input into the CICE? If not, please comment in the discussion how this may have affected the results.
Our answer: No patient and no non-specialised professionals were included in the CICE. Since the aim of the study was to develop a screening tool for professionals, we did not believe that patient participation in the CICE was required. However, we agree that the absence of service user input into the CICE can be considered a limitation and have included the following sentence in the discussion.

Changes: Strengths and limitations, line 354: A further limitation of this study is the absence of service user input into the CICE. Service user input will feature prominently in the pilot implementation studies of the new validated instrument.

Q: Please state more overtly what the proposed output of step two was - was it a list of possible items to include in the measure?

Our answer: Yes, we have changed the text as follows.

Changes: Methods, p. 6, line 123: The aim of the second step was to obtain a list of possible items to include in the instrument. These items had to be relevant to the construct and the target population of interest, as well as for the context in which the instrument is intended to be used.

Q: How were potentially eligible participants for the delphi survey identified and approached?

Our answer: We clarified this point as follows.

Changes: Methods, p. 7, line 153: A list of all nurses and physicians working in the different community-based specialist palliative care teams and all executive nurses and physicians of the PC units was compiled. Each of these professionals was contacted by email.

Q: How did the authors decide on their approach for step 4 and did they consider alternative/additional approaches e.g. cognitive interviewing to evaluate face and content validity of the tool? If not, this should be considered in future research.

Our answer: Alternative approaches were considered, and the decision was made to conduct these interviews during the implementation study. We added this point in the limitation section.

Changes: Limits, p. 16, line 350: With respect to the face validity, cognitive debriefing during the completion of the instrument may have provided valuable insights into the ways in which the instrument is completed and the different factors taken into account when responding. Cognitive debriefing has thus been planned as part of the implementation study.

Q: P8 line 181 - 'general palliative care concerns nearly 80%....' I think there is ongoing uncertainty as to what proportion of palliative care needs are general vs specialist. Suggest this statement is qualified, e.g. 'may concern up to 80%.'
Our answer: The change was made

Changes: Results, p.9, line 212: General PC may concern up to 80% of the proportion of patients requiring PC

Q: Table 1 is quite technical, and would perhaps be better as a supplementary file. Instead, the authors could consider including details of participants in steps 3 and 4 in a table of participant characteristics. I recognise some details are included in the text, but it would be helpful to include more detail and a table would be clearer. If available, it would be helpful to report more details of participants (e.g. age, gender, profession, level of experience of palliative care)

Our answer: As mentioned in the responses to reviewer 1, given the relatively few demographic characteristics available, we decided to include the data directly in the text to save space.

Changes: no