PEER REVIEW HISTORY

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ARTICLE DETAILS

| TITLE (PROVISIONAL) | Protocol for the development and multi-site validation of the Quality of Dying and Death-Revised Global Version scale |
|---------------------|-------------------------------------------------------------------------------------------------------------|
| AUTHORS             | An, Ekaterina; Tilly, Alyssa; Mah, Kenneth; Lewin, Warren; Chandrakumar, Mano; Baguio, Arnell; Jaffer, Nazira; Chikasema, Maria; Thambo, Lameck; Ntizimira, Christian; Namisango, Eve; Hales, Sarah; Zimmermann, Camilla; Wolofsky, Kayla; Goombs, Mary; Rodin, Gary |

VERSION 1 – REVIEW

| REVIEWER             | White, Nicola University College London, Marie Curie Palliative Care Research Department |
| REVIEW RETURNED      | 23-May-2022 |

| GENERAL COMMENTS     | Reviewing the manuscript “Protocol for the development and multi-site validation of the Quality of Dying and Death-Revised Global Version scale”. Overall, I enjoyed reading this protocol and I look forward to the results. I have a couple of comments for the authors to consider: • I note that they used the STROBE cross-sectional check list. There is a checklist specific for protocol reporting (SPIRIT). I would recommend the authors use this instead for clarity of reporting. • I would strongly encourage the authors to include PPI in this. Given that it is for caregivers to complete, it is essential to get their input - particularly in terms of dissemination and application. Eigenvalues and cognitive interviews only tell you so much. The revision of the scale would have also benefited from the input of a PPI group - although I appreciate that this work has already been done now. • With the current format, I find it difficult getting an overall picture of what is being done. I understand why the authors have separated in to “arms”, however this does make the protocol slightly difficult to follow. I find myself scrolling between the two arms to see if they went through the same procedure. Instead, I recommend that the authors use the headings from SPIRIT and use subheadings for location (if it is different). A section of the study overall would be helpful - why was Malawi selected as a site (other than it is already a collaborator)? • Related to the above comment, the analyses are nested within each arm, but I think it would be clearer to have this section on its own. • Perhaps the addition of a study flowchart would help to give an overall picture of the study. |
Table 1 shows the additional measures. Is there a particular reason why Malawi caregivers are not being asked the same questions as others? E.g., demographic data is not being collected? I think if the authors do change the layout to remove the “arms” then it will be clearer what measures are being collected from who and why (or why not).

REVIEWER Ceylan, Serdar
Hacettepe Universitesi

REVIEW RETURNED 15-Jun-2022

GENERAL COMMENTS In conditions where older adults and cancer patients are increasing, studies on end-of-life care and quality of death are of great importance. Another important point is that one of the countries with a low socioeconomic level, which is generally in the background, is also included in this study. The protocol is very well designed. Only the dates of the study is not included in the protocol. It would be appropriate to correct this minor deficiency.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

3. I note that they used the STROBE cross-sectional checklist. There is a checklist specific for protocol reporting (SPIRIT). I would recommend the authors use this instead for clarity of reporting.

--Please see response to Editor comment 1.

4. I would strongly encourage the authors to include PPI in this. Given that it is for caregivers to complete, it is essential to get their input - particularly in terms of dissemination and application. Eigenvalues and cognitive interviews only tell you so much. The revision of the scale would have also benefited from the input of a PPI group - although I appreciate that this work has already been done now.

--Because the QODD-RGV was developed by revising the items of the original QODD to enhance the scale’s cultural generalizability while maintaining conceptual similarity with the comprehensive domains the QODD assesses, patient and public involvement in the scale development phase was not included, as indicated at the top of p. 9.

5. With the current format, I find it difficult getting an overall picture of what is being done. I understand why the authors have separated in to “arms”, however this does make the protocol slightly difficult to follow. I find myself scrolling between the two arms to see if they went through the same procedure. Instead, I recommend that the authors use the headings from SPIRIT and use subheadings for location (if it is different). A section of the study overall would be helpful.

--We appreciate that separating the descriptions of the North American and Malawian study arms increased the complexity of the protocol. Although the central goal of both arms is the same, the validation of the QODD-RGV with their respective populations, the two arms have somewhat different recruitment and data collection procedures to accomplish this goal. Thus, we elected to keep the descriptions of their procedures separate. However, we have now added a new figure (Figure 1), a flowchart to illustrate the steps of the recruitment and data collection procedures for the two arms, and refer to it at the beginning of Methods: Phase 2: Psychometric evaluation of the QODD-RGV, at the
top of p. 10. We hope that the flowchart will facilitate readers’ comprehension of the procedural steps for the two arms.

6. Why was Malawi selected as a site (other than it is already a collaborator)?

--Our research team has been collaborating with palliative care teams in sub-Saharan African countries to conduct much-needed clinical research on patient- and caregiver-reported end-of-life care outcomes, specifically the quality of dying and death, in low-resource end-of-life care settings. We recently conducted studies of patients’ quality of dying and death, using the original QODD, with bereaved caregivers in Kenya and Uganda. Malawi was selected as the site for the present scale development and validation study because: 1) one of the co-authors (AT) holds a central position in the UNC Project-Malawi Cancer Program, which conducts oncologic research in the region and collaborates with Kamuzu Central Hospital in Lilongwe, Malawi, towards improving the country’s oncology palliative care services; and 2) it presented unique opportunities a) to validate the scale in another African country that, like Kenya and Uganda, has a relatively advanced global ranking of palliative care services (Global Atlas of Palliative Care, 2020), b) to evaluate the scale’s cultural generalizability to this care setting, and c) to enable cross-cultural comparison of quality of dying and death between low- and high-resource care settings.

7. Related to the above comment, the analyses are nestled within each arm, but I think it would be clearer to have this section on its own.

--Please see response to Reviewer 1 comment 5. As with the procedures, the validity analyses are somewhat different for the North American and Malawi arms, and so we also elected to maintain separation of their respective analyses.

8. Perhaps the addition of a study flowchart would help to give an overall picture of the study.

--See response to Reviewer 1 comment 5. We agree that a flowchart of the procedures for the North American and Malawi arms of the study would be a useful aid in this respect and have now created one for the protocol (Figure 1).

9. Table 1 shows the additional measures. Is there a particular reason why Malawi caregivers are not being asked the same questions as others? E.g., demographic data is not being collected? I think if the authors do change the layout to remove the “arms” then it will be clearer what measures are being collected from who and why (or why not).

--Our apologies: there was missing information in Table 1, in that, as indicated in the description of the Malawi arm procedures, p. 19, Malawi caregiver participants will be asked to provide caregiver and patient demographic and medical information, and the medical staff will also be asked for relevant patient medical information. We have now corrected Table 1 to include this information.

Reviewer 2

10. Only the dates of the study is not included in the protocol. It would be appropriate to correct this minor deficiency.

--We have now indicated our estimated timeframes for data collection for the North American arm (June 2022–2023) at the top of p. 10 and for the Malawi arm (November 2022–2024) at the bottom of p. 17. These timeframes are also included in new Figure 1.
| REVIEWER               | White, Nicola  
|                       | University College London, Marie Curie Palliative Care Research Department |
| REVIEW RETURNED       | 05-Jul-2022    |
| GENERAL COMMENTS      | The edits made (table & figure) have improved the clarity of the protocol. Nothing further to add. |