RESEARCH PROJECT

NÚCLEO DE GASTRENTEROLOGIA DOS HOSPITAIS DISTRITAIS 2022

TITLE: *Translation to Portuguese and validation for the Portuguese population of the "Quality of Dying and Death" tool: a first step for improvement of the end-of-life of patients who die under gastroenterologist care*

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B. RESEARCH PROPOSAL

1. SCIENTIFIC AIM

The quality of dying is a critical outcome to ensure high quality of care near the end of life for people with serious, life-limiting diseases. It is influenced by medical, individual, social and cultural factors.[1] Positive experiences in these dimensions contribute to what has been termed a 'good death', defined as a death 'free from avoidable distress and suffering for patients, families and caregivers, in general accord with patients' and families' wishes, and reasonably consistent with clinical, cultural and ethical standards."[2,3] Although evaluating the quality of the dying and death is essential to ensure the quality of end-of-life care, measures and metrics are needed to assess it.

A first step to improve the quality of death is to have validated instruments to assess outcome measures. Few tools have been developed specifically to assess the quality of the dying and death.[2,4] The Quality of Dying and Death (QODD) score is the best-validated and most widely used.[2,4] However, translation to Portuguese and validation for the Portuguese population is lacking, although this instrument is already validated in several countries [5,6].

Our **global aim** is to improve end-of-life quality of care but, in order to achieve that, the specific goal of translating to Portuguese and validating a Portuguese version of Quality of Dying and Death (QODD) scale is the first step. Later, we will use this tool to assess, the caregiver's perspective about the quality of death of patients who die with cancer and advanced chronic liver disease at our hospital.

2. BACKGROUND

Traditionally Medicine and HealthCare focus on treating curable diseases, managing chronic diseases to avoid or delay events that shorten life or impair quality of life, while trying to reduce the risk for preventable disease or disability. Nevertheless, providing a dignified death for those whose disease inexorably leads to rapid decline and avoiding futile treatments and procedures is equally important. How people die and the quality of care provided to individuals at the end of life and to their family members has become an important health and social issue across the world.[7,8] However, although improving care at the end of life has become an international priority, knowledge about the care provided at the end of life in Portugal across care settings is still limited.[9]

We decided to investigate this topic in our hospital, particularly in our department. We conducted a retrospective study on patients who died at *Hospital Beatriz Ângelo* with

malignancy vs advanced chronic liver disease, assessed clinical atitudes and therapeutical gestures and concluded that there was, in general, a late referral to palliative care and that there was difference in end-of-life care between patients with malignancy and patients without malignancy. Our work was selected for two oral presentations at *Semana Digestiva 2022 as well as* for oral presentation at United European Gastroenterology Week (UEGW) 2022 and for poster presentation at ESMO (European Society for Medical Oncology) Conference 2022, which encouraged us and confirmed the clinical relevance of this problem.

In fact, it is imperative to select and apply quality of death metrics in patients, aiming to improve care, manage expectations and resources. However, to evaluate the quality of care at the end of life, it is necessary to use standardized and validated tools, including those that measure caregivers/families' satisfaction as an important proxy indicator of the quality of care.[10–13]

In 2001, North American researchers from the University of Washington, Seattle, USA, proposed measuring the quality of death and dying, as well as evaluating patients' and their family members' perceptions of death, through the development of an instrument called the Quality of Dying and Death (QODD).[14] The QODD includes 31 content items assessing different aspects of the dying and death experience. Items are rated on the patient's experience, from 0 (terrible experience) to 10 (almost perfect experience), in six conceptual domains: symptoms and personal care, time with family, whole patient concerns, treatment preferences, preparation for death and the moment of death. Because it is not feasible for most patients to complete the scale near the end of life,[2] the QODD is completed retrospectively by proxy raters, such as bereaved caregivers or healthcare workers who provided care to the patient prior to death.

To our knowledge, this is the best-validated and most widely used scale[4], however it is not translated and validated for the Portuguese population yet. In this way, we decided to translate this scale to Portuguese and validate it for the Portuguese population as a step for assessing the quality of death of patients who die in our hospital and in our country under gastroenterologist care and improve it.

Significance and innovation
To our knowledge, this study is the first that propose a translation and cultural adaptation of the Quality of Dying and Death in Portugal. It may provide a reliable and reproducible scale for collecting and analyzing data on the quality of dying and death, given the lack of Portuguese studies that have produced or used scales in this topic, and be a first step to develop metrics in quality of end-of-life care in our country.

Primary objective:
- Perform the translation and cultural adaptation into Portuguese of the Quality of Dying and Death Scale.

Secondary objective:
- Assess the caregiver's perspective about the quality of death of patients who die with cancer and advanced chronic liver disease in a tertiary hospital.

3. METHODS

3.1 STUDY DESIGN

We propose to conduct a methodological study of translation and cross-cultural adaptation of QODD (Appendix 1) into Portuguese spoken in Portugal, according to international recommendations.[14–17]

3.2 TRANSLATION, CROSS-CULTURAL ADAPTATION AND VALIDATION PROCESSES

The following stages compose the translation and semantic and cultural adaptation of the instrument[14–17]:
- Translation – We aim to have two bilingual translators (Portuguese-English) who are native to Portugal and have no prior knowledge of the questionnaire. A synthesis and review of the first translation will be obtained.
- Back-translation – This step is necessary to verify that the translated version reflect the same content as the original version, in addition to any inconsistencies. The result of the first translation will be back-translated into English by two other bilingual natives who have no prior knowledge of the questionnaire, resulting in two back-translated, which will be later summarized into a single version.
- Committee of Experts – The final translated version will be evaluated by a Committee of Experts to obtain cross-cultural equivalence.
- Pre-test phase – This step is necessary to assess the validity of the questionnaire. We propose to use a sample of 20 bereaved family members, which aim to verify the understanding of the items, evaluate the ease of using the response set, and estimate the response time. After the face validity of the instrument is analyzed, its psychometric properties will be examined. The literature proposes the inclusion of 5–10 participants per item for the sample.[18] In this way, we would need to have a minimum of 155 bereaved family members. The sample size will be confirmed with the support of our statistical analyst. If it is necessary

maximize our sample, we consider conducting the study prospectively or/and converting it in a multicentric study.

3.3 PARTICIPANTS, SETTING AND PROCEDURE

The participants will be bereaved caregivers knowledgeable about the healthcare provided during the last year of life to an adult decedent (aged 18 years and older) who died at *Hospital Beatriz Ângelo* due to advanced chronic liver disease or gastroenterological malignancy. They must be able to complete study questionnaires and interviews in Portuguese. We will verify the caregiver of reference through consulting the patient's process. A first phone call will be made to inform the participants about the study's aims and the voluntary nature of their participation. They will also be given guarantees of data confidentiality and anonymity. Informed consent will be obtained from each bereaved caregiver. After that, a phone interview will be scheduled at a date of the bereaved caregiver's preference and the instrument will be applied by a health professional who has not directly provided care to the deceased patient, to minimize bias.

All interviews will be conducted three to 12 months after death. As the period of bereavement is recognized as a sensitive time, this interval was decided to respect the family bereavement period but also to avoid bias of oblivion and guarantee that the memory of the experience was recent enough to be considered reliable.

3.4 DATA ANALYSIS

Descriptive analysis will be performed: continuous variables will be described as mean, median and range, while categorical variables will be expressed as frequency and percentage.
The $\chi 2$ test, Fischer's exact test, t test, Pearson's correlation coefficient, ANOVA and uni and multivariate logistic regressions will be used when appropriate.
The internal consistency will be measured with Cronbach's alpha coefficient and the reproducibility will be assessed using the intraclass correlation coefficient (ICC).
The relevance of other statistical tests will be evaluated with the support of our statistical analyst.
The data will be analyzed using SPSS, version 23. A level of significance of 0.05 will be used for all analyses.

3.5 STUDY TIMELINE

The study protocol has already been submitted for consideration and approval to the research ethics committee. The study follows the Declaration of Helsinki. A given informed consent from all participants will be obtained.

The study will start in November 2022.
- Scale validation (Translation, Back-translation, Committee of Experts): 4 months
- Data collection (Pre-test phase): 4 months
- Data and statistical analysis: 2 months
- Data presentation: 2 months
- Manuscript preparation and revise: 2 months

4. BUDGET

Study co-ordinator (12-month period)	500€
Bilingual translators	2000€
Statistical analysis	3600€
Indirect costs (20%)	1220€
TOTAL	**7320€**

5. REFERENCES

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APPENDIX 1

Quality of Dying and Death Scale

Each item was asked with the following leader: "How would you rate this aspect of (patient's name) dying experience?" The response scale was from 0 to 10 where 0 was a "terrible experience" and 10 an "almost perfect experience".

1. Having pain under control.
2. Having control of event.
3. Being able to feed oneself.
4. Having control of bladder, bowels.
5. Being able to breathe comfortably.
6. Having energy to do things one wants to do.
7. Spend time with your children as much as you want. (or I have no children)
8. Spend time with your friends and other family as much as you want.
9. Spend time alone.
10. Be touched and hugged by loved ones.
11. Say goodbye to your loved ones.
12. Have the means to end your life if you need to.
13. Discuss your wishes for end-of-life care with your doctor and others.
14. Feel at peace with dying.
15. Avoid worry about strain on your loved ones.
16. Be unafraid of dying.
17. Find meaning and purpose in your life.
18. Die with dignity and respect.
19. Laugh and smile.
20. Avoid being on dialysis or mechanical ventilation.
21. Location of death (home, hospice, hospital).
22. Die with/without loved ones present.
23. State at moment of death (awake, asleep).
24. Have a visit from a religious or spiritual advisor.
25. Have a spiritual service or ceremony.
26. Have health care costs provided.
27. Have funeral arrangements in order.
28. Spend time with spouse, partner. (or I have no spouse, partner)
29. Spend time with pets. (or I have no pets)
30. Clear up bad feelings. (or there were no bad feelings to clear up)
31. Attend important events. (or there were no important events to attend)