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Definition of therapeutic limits and do-not-resuscitate decision in Oncology: the perception of different healthcare professionals in a portuguese hospital

Definição de limites terapêuticos e decisão de não reanimação em Oncologia: a perceção de diferentes profissionais de saúde de um hospital português

Cristiana Honrado-Martins, Marta Viana-Pereira, Ma. Manuel Pereira, Diogo Lopes, Catarina Ferreira, Jorge Rodrigues, and Catarina Portela*

Serviço de Oncologia Médica, ULS de Braga, Braga, Portugal

Abstract

Introduction: *The definition of therapeutic limits and the establishment of do-not-resuscitate decisions are complex decisions that involve multidimensional assessments and the consideration of individual, prognostic, and ethical factors. In cancer patients, this is often necessary in advanced stages of the disease, in the absence of therapeutic options, and with a prognosis of short-term irreversibility.* **Analysis and Methods:** *The terminology used and the clarity of the information are essential in the management of cancer patients by multidisciplinary teams, with different healthcare professionals from various fields. This project aims to assess the perception of different healthcare professionals regarding the definition of therapeutic limits and do-not-resuscitate decisions in cancer patients, through the application of an anonymous questionnaire with responses based on a Likert scale and one open-ended question.* **Discussion:** *These data will be analyzed with the goal of developing more robust future tools for therapeutic decision-making. It is expected that this could positively contribute to the prevention of dysthanasia and the minimization of suffering for patients and their families.*

Keywords: *Therapeutic limits. Do-not-resuscitate decision. Terminology. Healthcare professionals. Oncology.*

Resumo

Introdução: A definição de limites terapêuticos e o estabelecimento de decisões de não reanimação são processos complexos que envolvem avaliações multidimensionais e a consideração de fatores individuais, prognósticos e éticos. Em pacientes oncológicos, essas decisões tornam-se frequentemente necessárias em estágios avançados da doença, na ausência de opções terapêuticas e diante de um prognóstico de irreversibilidade a curto prazo. **Métodos e Análise:** A terminologia utilizada e a clareza das informações são essenciais na gestão dos pacientes com câncer por equipes multidisciplinares, compostas por diferentes profissionais de saúde de diversas áreas. Este projeto tem como objetivo avaliar a percepção de diferentes profissionais de saúde em relação à definição de limites terapêuticos e às decisões de não reanimação em pacientes oncológicos, por meio da aplicação de um questionário anônimo com respostas baseadas em escala

***Correspondence:**
Cristiana Honrado-Martins
E-mail: cristiana.honrado.martins@ulsb-min-saude.pt

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Likert e uma questão aberta. **Discussão:** Esses dados serão analisados com o intuito de desenvolver ferramentas futuras mais robustas para a tomada de decisões terapêuticas. Espera-se que isso possa contribuir positivamente para a prevenção da distanásia e a minimização do sofrimento dos pacientes e de suas famílias.

Palavras-chave: *Limites terapêuticos. Decisão de não reanimação. Terminologia. Profissionais de saúde. Oncologia.*

Introduction

The definition of therapeutic limits and the establishment of do-not-resuscitate decisions are complex decisions that involve multidimensional assessments and the consideration of individual, prognostic, and ethical factors[1,2]. In cancer patients, they are often necessary in advanced stages of the disease, in the absence of therapeutic options, and in situations with a prognosis of short-term irreversibility[3]. This type of decision is frequently made by the attending medical team, rather than by an individual decision-maker. Empiricism and prior experiences should not be exclusive factors in the decision-making process; instead, decisions should be clearly and comprehensibly documented in the clinical record[3,4]. Effective communication is key, and the terminology used, as well as the clarity of the information, are essential in the management of cancer patients by multidisciplinary teams, with different healthcare professionals from various fields. The perception of the communicated information quality should be assessed, to ensure the provision of optimal healthcare[5]. Despite the available literature about the definition of therapeutic limits and do-not-resuscitate decisions in the general population of patients[6-8], for the cancer patient was not possible to find information regarding previously established studies or instruments aimed at standardizing terminology when defining therapeutic limits in this setting.

This project aims to assess the perception of different healthcare professionals regarding the definition of therapeutic limits and do-not-resuscitate decisions in cancer patients, as well as the quality of communicated information. We hope this work will help in the development of robust future tools for therapeutic decision-making. It is expected that these tools could positively contribute to the prevention of dysthanasia and the minimization of suffering for patients and their families.

Materials and methods

Study design

This was longitudinal, prospective, and single-center study.

Study timeline

The study schedule is planned to take place between January 2024 and January 2026.

Participant identification, inclusion and exclusion criteria

The study's first target is the identification of healthcare professionals with potential direct contact with cancer patients, among different departments of *Hospital de Braga*, *ULS de Braga*.

The inclusion criteria are:

- 18 years of age or older
- Hospital de Braga healthcare professionals, among the following groups:
  - Medical Oncology Doctor (the one who provides care to the cancer patient in the context of urgent consultation in the oncology day care unit and/or the medical oncology ward, including residents and specialists)
  - Internal Medicine Doctor (the one who provides care to the cancer patient in the context of the emergency department and/or the internal urgency service and/or the internal medicine ward, including residents and specialists)
  - Emergency Department Doctor (the one who provides care to the cancer patient in the context of the emergency department (medical and/or surgical areas), including residents and specialists from different fields/medical specialties, as well as doctors with no differentiation/medical specialty)
  - Intensive Care Medicine Doctor (the one who provides care to the cancer patient in the context of the intensive care medicine department (level 2 and 3 of care), including residents and specialists)
  - Oncology Day Care Unit Nurse
  - Ward Nurse (oncology and/or internal medicine ward).
- Contact with cancer patients (defined as a contact that occurs at least once a month).

The exclusion criteria are:
- Healthcare professionals having contact with cancer patients less than once a month
- Healthcare professionals of pediatric cancer patients.

Data collection

Data collection will be performed through the application of an anonymous questionnaire to assess the perceptions of healthcare professionals regarding the definition of therapeutic limits and the establishment of do-not-resuscitate decisions. The definition of the terms "therapeutic limits" and "do-not-resuscitate decisions" was established based on previous internal institutional consensus[6]. The questionnaire was developed after extensive bibliographic research, based on previous studies that included both cancer and non-cancer patients. It comprises the following domains: (1) sociodemographic characteristics; (2) professional category (physician/nurse) and respective specialty; (3) nature and frequency of contact with cancer patients; (4) perceptions regarding the terminology and communication practices used by healthcare professionals when defining therapeutic limits and do-not-resuscitate decisions; (5) perceptions regarding the quality of communicated information towards other healthcare professionals, the patient and the family; and (6) perceived adequacy of diagnostic, treatment, and follow-up plans in light of those decisions. Majority of the questions require an answer based on a Likert scale. The last question is an open-ended question and demands the enumeration of variables that the respondents consider most relevant for the definition of therapeutic limits in cancer patients.

The questionnaire will be developed and distributed through digital form, through the *Microsoft Forms* online tool, available on the institutional *Office 365* (service provided by the Portuguese regulator, *Serviços Partilhados do Ministério da Saúde*).

The initial approach, contact, and recruitment of potential participants will be made after previous contact with the different team leaders (for doctors, the department director, and for nurses, the nurse manager). Through the mailing list of the department, which encompasses each healthcare professional's institutional email address, team leaders will divulge the study, as well as the access link to the questionnaire.

The questionnaire will demand a completely anonymous answer. No information that would allow a subsequent identification of the respondent will be collected. No further information about the participant will be collected other than the answers obtained through the questionnaire. A random numerical code will be assigned to each questionnaire, and the analyzed data will be protected to minimize the possibility of the identification of an individual. The approach to potential participants (through the divulgation of the study by team leaders) is another measure to minimize the personal data processing, aiming for quasi-anonymization.

Data analysis

The data will be collected by the investigation team and compiled in a *Microsoft Excel* file (directly exported from *Microsoft Forms*). This file will be protected by a robust password (according to *ULS de Braga* policies and internal procedures). The collected data will be analyzed using the software *IBM Statistical Package for the Social Sciences Statistics* version 29. A descriptive analysis will be performed for each question on the questionnaire. Inferential analysis will be conducted in an exploratory manner, focusing on the most relevant sociodemographic and clinical variables in accordance with the objectives of the study. The selection of an appropriate statistical model will be guided by the nature and distribution of the collected data. All subsequent inferential analyses will consider a p-value inferior to 0.05 as statistically significant.

Ethical considerations

The application of the questionnaire will begin following formal approval by the Institutional Data Protection Officer and Ethics Committee. Data collection will be carried out exclusively by the investigators through a secure electronic platform. No additional data will be collected beyond the responses to the questionnaire, and no information enabling direct identification of participants will be gathered. Data will be stored securely within Microsoft Office 365 cloud environments contracted by the institution, with access restricted to the investigators' team. All files will be password-protected and anonymized, in accordance with institutional data protection policies.

Team leaders will be contacted in advance to support and share the access link to the electronic questionnaire among their teams. This step serves as an additional measure to minimize the handling of personal data and promote quasi-anonymization.

The prospective application of a questionnaire demands the previous signature of informed consent.

Participants will provide digitally documented informed consent through *Microsoft Forms*, accessible exclusively through authenticated institutional login credentials, with a time-stamp record. Given that the questionnaire will be answered through *Forms*, the first page of the questionnaire will have the digital informed consent. Access to the questionnaire will be conditioned by the acceptance of the informed consent on the first page. The participant will not have access to the study questions until this step is fulfilled. This procedure ensures authentication and confidentiality while ensuring the reliability of the participant's signature of informed consent in accordance with ethical standards and data protection regulations.

Throughout the study, ethical conduct and good clinical practices will be upheld to ensure compliance with the principles outlined at the Declaration of Helsinki (including the amendments of Tokyo 1975, Venice 1983, Hong Kong 1989, Oviedo 1997, Washington 2002, Tokyo 2004, Seoul 2008); the EMEA Guidelines on Good Clinical Practice (London 2000); the World Health Organization International Ethical Guidelines for Health-Related Research Involving Humans (Geneva 2002); the International Ethical Guidelines for Epidemiological Studies of the Council for International Organizations of Medical Sciences (Geneva 2009); and Resolution No. 1/2001 of the Portuguese Assembly of the Republic.

This study will respect the current legal provisions relating to clinical research (Law No. 21/2014, 73/2015 and 49/2018; Directive of the European Parliament 2001/20/CE), as well as the rules of Ethical Conduct and Good Practice, to fulfill the precepts of the Declaration of Helsinki, the Good Clinical Practice of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use 2021 and the "*Parecer sobre Bioética e Saúde Mental*," of the *Conselho Nacional de Ética para as Ciências da Vida* (CNEV, National Council of Ethics in Life Sciences). The study will also respect the data protection legislation (Law No. 58/2019 and European Union Regulation (EU) 2016/679).

This investigation study was approved by *Comissão de Ética para a Saúde* (Health Ethics Committee) of *Hospital de Braga*, *ULS de Braga*, approval reference No. 222_2024, on 27/November/2024.

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Conflicts of interest

None.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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