Framework of
Core Research Competencies for Palliative Care Clinicians

Palliative Care Research
RESPACC
attitude - communication - competence

Erasmus+

September 2021

DISCLAIMER

This project has been funded with support from the European Commission by ERASMUS+ agreement #: 2020-1-RO01-KA202-080128

July 2021

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FRAMEWORK OF **CORE RESEARCH COMPETENCIES FOR PALLIATIVE CARE CLINICIANS**

BACKGROUND The RESPACC ERASMUS+ funded project will identify core research competencies for palliative care clinicians. The notion of **competence** corresponds to the ability to apply knowledge and skills to successfully perform an activity at work.

We focus on enhancing core research competences for those clinicians in multidisciplinary palliative care **teams,** considering a team level but also an individual level. Some competencies could be considered essential to do research in a team, but they would not be essential for every team member, because it would be enough that someone on the team has the competence for the investigation to be carried out.

AIM: To identify a set of core research competencies that should be demonstrated by the multidisciplinary palliative team, to carry out a successful clinical study.

METHODS: A multi-method approach was adopted which included three phases

- Phase One – a literature review of research competency frameworks
- Phase Two - a Nominal Group Technique (NGT) study in three European countries eliciting the views of palliative care clinicians regarding clinical research
- Phase Three - an international palliative care professional's consultation.

RESULTS:

- Phase One - Eight competency research frameworks were identified and analysed as part of the literature review. Based on the TDR Global Competency Framework for Clinical Research (TDR) (1), from the WHO, a structure of seven domains for a new framework for palliative care clinicians was adopted to work in the next phases of the study.
- Phase Two - Nominal Group Technique (NGT) was utilised in three countries (Greece, Spain and Romania). 31 palliative care clinicians generated 19 core competencies in seven domains. The 19 competencies identified during NGT meetings were compared to relevant frameworks in the literature and were adapted to the specific panorama of palliative care research.
- Phase Three - An international palliative care professional's consultation was undertaken to review and improve the framework of the core competencies developed by the RESPACC team. The survey was sent to 120 persons and 59 questionnaires were returned, among which 53 were complete. The response rate was 44%. Respondents were from a total of 17 European countries. After this consultation, two competencies were eliminated and two were rephrased including additional examples. An additional competency, linguistic skills was added at the end of the framework.

The findings are offered in English, Spanish, Greek and Romanian. A self-administered quiz is being developed, as a tool to appraise the individual level of research literacy and competencies for clinicians working in palliative care. The process and the outcomes will be submitted for a peer-reviewed publication.

1. The clinical context	–1.1. Awareness of specific aspects of doing research in palliative care contexts
2. Scientific thinking and research design	–2.1. Knowledge of basic research principles/terms –2.2. Ability to accurately formulate and understand a research question –2.3. Knowledge about research methodologies –2.4. Ability to read and undertake a basic literature review –2.5. Uses critical and analytical thinking
3. Ethics and regulatory framework for research	–3.1. Incorporates and considers the care, safety and protection of all persons in the conduct of research –3.2. Understands the role and remits of research ethics committees in clinical research
4. Study and site management	–4.1. Considers the feasibility of a potential project in own working setting –4.2. Coordinates/Conducts the study based on the research protocol –4.3. Documents all the activities in a research study
5. Data management and informatics	–5.1. Basic knowledge and skills in statistics, qualitative data analysis and informatics –5.2. Basic knowledge and skills of data management (collection, management, analysis)
6. Communications and relationships	–6.1. Ability to effectively communicate the content and relevance of clinical research findings for various audiences –6.2. Posseses interviewing and good communication skills
7. Research leadership	–7.1. Incorporates and promotes team working skills in the conduct of clinical research –7.2. Develops and applies the principles and practices of leadership and mentorship in clinical research

DOMAIN 1. THE CLINICAL CONTEXT	
Competence 1.1	**Awareness of specific aspects of doing research in palliative care contexts**
Concept	Understands the principles of palliative care and has the ability to apply them during the research process, according to the specific needs of the population. For example, assessing clinical history in a multidimensional way, using only relevant measures and samples, and providing appropriate safe care and treatment. (1) (2) (3) Demonstrates an understanding of the principles of palliative care and takes them into account to describe the objective and scientific techniques used to design studies. Is aware that palliative care populations might be vulnerable in different ways, especially those who have advanced disease or are experiencing distress.
Examples of how this competence is demonstrated	– Ensures that research aims are relevant to palliative care – Takes account of the potential vulnerability of patients and families (1) – Understands the specific barriers affecting recruitment and retention of patients in palliative care studies. – Understands psychological and physical impact of research in palliative care – Manages, always according to one's expertise, medical or psychosocial issues that arise during a study (1) – Ensures that data collection is suitable for palliative care (short and clinically applicable) (1)

DOMAIN 2. SCIENTIFIC THINKING AND RESEARCH DESIGN	
Competence 2.1	**Knowledge of basic research principles/terms**
Concept s	Understands that all research is guided by key principles. All research is based explicitly or implicitly on how researchers understand these basic concepts, which are briefly defined here: • **Ontology** –the nature of reality - what is known. • **Epistemology** – The relationship of the researcher to that which is being researched • **Methodology** – The overall approach to gaining knowledge which takes account of the nature of reality and how the world is known • **Paradigm** – A basic belief system that guides the research • **Methods –** the systematic procedures used to undertake research (4) Understands the differences between research, evaluation, and audit: **Research** – the generation of new knowledge, theory or methods using systematic, robust and replicable techniques; **Audit** - checking performance against benchmarks or established standards; **Evaluation** - the purpose of an evaluation is to determine if a new service or intervention works in that specific context - it does not seek to make generalisations to other settings. The difference between research and evaluation is the intention (purpose) not the methods used.
Examples of how this competence is demonstrated	- Has sufficient scientific knowledge of clinical research language, e.g., understanding of research terminology. - Can explain what paradigm means and give an example of a paradigm within palliative care research - Knows the difference between research methodology and methods - Understands the principles of an audit including its outcomes and limitations - Describes an evaluation study in a clinical palliative care context and recognise its outcomes and limitations - Ability to identify a published clinical research study in palliative care and be able to recognise its outcomes and limitations.
Competence 2.2.	**Ability to accurately formulate and understand a research question**
Concept	Understands the difference between a research question and a hypothesis and is able to identify differences between aims, objectives and outcomes in research projects. • A research question frames the problem or idea to be addressed in the research study. There are specific frameworks that can help frame the research question considering if it is a problem description, an intervention, a comparison, and an outcome (5). • A **hypothesis** is a **preliminary** statement regarding a mechanistic **explanation** for an observation. Hypotheses enable you to make predictions about future events and relationships that can be tested in research. • **Aims** are statements providing an exact focus for what you want to do in the research • **Objectives** define specific elements (or outcomes), that will address your study aim(s). • **Outcomes.** In clinical trial designs, there are **primary and secondary outcomes.** A **Primary Outcome** is the variable (factors, properties, or characteristics) of most interest in the study. **Secondary outcomes** – are variables that provide additional important information to be considered alongside the primary outcome.

	In a research study, the **aim** should be specific and phrased in such a way that it is possible to identify when it has been achieved. **Research objectives** outline the specific steps that you will take to achieve your **research aim**. **Objectives** define the what, why, who, when and how questions.
Examples of how this competence is demonstrated	- Formulates a research question, for instance, using the PICO process describing: **P**opulation, **I**ntervention, **C**omparison and **O**utcome - Identifies the research hypothesis in a clinical study (3) - Explains the difference between research aims and objectives - Can explain what a variable is in the context of clinical palliative care research.
Competence 2.3.	**Knowledge about research methodologies**
Concept	Is aware that there are many different approaches to research methodology that are underpinned by how the researcher understands reality and how that reality can be known. From this, each paradigm gives rise to different research methods, and the research question must be compatible with the paradigm selected. A **research protocol** is a formal statement describing the process of conducting a research project. A basic account of possible research **methodologies** is: • Quantitative research - works with numbers and statistics to explain observations, where reality is fixed, observable and measurable. Quantitative research designs include surveys, non-experimental observational or cohort studies, pre-post experimental studies, randomised trials • Qualitative research - works with words and people's own stories to explain observations, where reality is dynamic and requires interpretation. Qualitative research designs include participatory and non-participatory observational studies, ethnographic studies, exploratory interview studies, focus group studies • Mixed methods design: Quantitative and qualitative data in a single study. Mixed methods designs may include organisational case studies, consensus methods. **Research designs** are descriptions of how specific research methods will be used to answer a research question.
Examples of how this competence is demonstrated	- Understands the different types of research methods and study designs, the different sources of data, and recognises when each method might be used in palliative care, and the basic strengths and weaknesses of the approaches. - Identifies the key elements of a clinical research protocol (3) - Maintains up-to-date understanding of palliative care research methods, - Illustrates how research may improve practice and care - Contributes clinical palliative care input into study designs and protocols (1)
Competence 2.4.	**Ability to read and undertake a basic literature review**
Concept	Understands that a literature review is an analysis and synthesis of work (normally research evidence) that has been undertaken in a particular area. A literature review involves identifying a question (or questions) which is then answered by the comprehensive and systematic identification, analysis and synthesis of a relevant body of published, and sometimes unpublished research, and other evidence. The aim of a literature review is to identify what we know and do not know about the question identified. There are many different types of literature review methods, including narrative, scoping and systematic review (7)
Examples of how this competence is demonstrated	- Understands the importance of how to systematically critique and synthesise literature appropriately (1) - Describes how to select an appropriate method for reviewing the literature (7) - Identifies appropriate databases to undertake a literature search (7) - Be able to list key words and concepts for a literature search (7) - Describes the literature review process and be able to interpret the implications for palliative care. (7)

	- Be aware of the hierarchy of evidence and its limitations - Demonstrates ability to read and critique a literature review and identify implications for practice.
Competence 2.5.	**Uses critical and analytical thinking**
Concept	Is aware that in some approaches, the process of **analysis** (systematic use of research procedures such as statistics or qualitative analysis) of results and the **synthesis** (combining and interpreting results) are considered separate activities, while in other approaches, these two elements are synonymous (analysis and interpretation are reciprocal and iterative). Critical and analytical thinking skills help to identify hidden bias or hidden assumptions that would preclude a valid answer to the research question posed.
Examples of how this competence is demonstrated	- Identifies and understand the meaning of study results for palliative care contexts (3). - Describes the study result in the context of the research question and apply to palliative care (3). - Identifies bias in a research text. - Explains the meaning of the study results in the context of what is already known (from the literature review) and in the context of clinical palliative care experience.

DOMAIN 3. ETHICS AND REGULATORY FRAMEWORK FOR RESEARCH	
Competence 3.1.	**Incorporates and considers the care, safety and protection of persons in the conduct of clinical research**
Concept	Understands how to apply ethical theory in the context of clinical research design and operations. Understands the rationale and value of research but can also balance its harms and benefits by considering participants' clinical situation and interests. Be able to provide sound and balanced review of the likely risks and benefits of a study to the participant, and to adapt this review based on the specific situation and the given setting. Aware that palliative care populations might be vulnerable to coercion and undue influence, especially patients who have advanced disease, children, patients living in low-resource settings or experiencing distress. On a daily basis, apply ethical principles and ensure that the inclusion and exclusion criteria, confidentiality and privacy of the participant is respected at all times.
Examples of how this competence is demonstrated	– Ensures that the research study is necessary; takes a balanced view of the likely harms and benefits of a research project on the participant (1) – Understands that palliative care patients are a vulnerable group and accurately describes additional safeguards that are put in place for them (3) – Identifies the inclusion and exclusion and eligibility criteria from a set of sample cases for an upcoming clinical study (3) – Knows how to correctly obtain informed consent from patients and families who are invited to be part of the research project – Reports any concerns that arise during research activities with patients or other participants (2)
Competence 3.2.	**Understands the role and remits of research ethics committees in clinical research**
Concept	Recognises the need to ensure that appropriate ethical opinion and governance approvals are obtained before any research activities are undertaken. Must be aware of the regulations that apply to the studies (research registry, regulatory, ethics, and any others such as national or local requirements) and know how to submit applications to regulatory bodies. May contribute or write the ethical submissions for the committee. The protocols should clearly show the rationale of the study in a vulnerable population and how it will contribute to improving standard clinical practice. Maintains the required documents and provides appropriate updates, for example in the case of protocol amendments or for annual reporting purposes. Must keep written records of the relevant approvals, the ethical review and the decisions of the submission and communicate clearly to those involved regarding those decisions.
Examples of how this competence is demonstrated	– Identifies the regulatory permissions that have been obtained for the studies currently in progress – Has knowledge of Research Ethical Committees, Research and Development Departments and their functions (2) – Understands the application process for ethical/regulatory approvals. – Submits protocol and amendments to relevant authorities.

DOMAIN 4. STUDY AND SITE MANAGEMENT	
Competence 4.1.	**Considers the feasibility of a potential project in own working setting**
Concept	Is aware that feasibility is a process of evaluating the possibility of conducting a particular clinical study in a palliative care setting with the overall objective of optimum project completion in terms of timelines, targets and cost. This process includes alignment of the research project in terms of study design, patient type, with the local environment. In palliative care, due to patient vulnerability, special consideration must be given to problems with recruiting and maintaining patients in the study as part of the feasibility risk assessment.
Examples of how this competence is demonstrated	- Demonstrates an understanding of baseline determinants of study at a research site in order to be able to do the study at the site, including availability of a specific study population - Understands how risk assessments are conducted for study operations and palliative care patient safety
Competence 4.2.	**Coordinates/Conducts the study based on the research protocol**
Concept	Should have a good knowledge of the planned study operations to be able to execute them appropriately from the start, and a thorough knowledge of the whole process according to the protocol. Understands the needs of the research sites that must be addressed before the study starts. Understands the project scope, milestones and timelines and can appropriately track the progress of these against the originally planned targets. They comply with quality assurance procedures during the research study (1)
Examples of how this competence is demonstrated (3)	- Explains the process for gaining approval to conduct clinical research in the palliative care setting - Develops and implements strategies to manage participants in the study and track study activities - Performs quality assurance activities to assure data integrity - Understands palliative care research study – scope, milestones, timelines - Uses progress tracking to anticipate risk issues, so that initiatives can be taken for resolution
Competence 4.3.	**Documents all the activities in a research study**
Concept	Ensures that accurate source documentation and maintaining essential documents occurs throughout the study and that these documents validate integrity in the conduct of the research study (1)
Examples of how this competence is demonstrated	- Records and stores data on approved study formats and platforms (6) - Demonstrates a knowledge and understanding of source data: Assesses documentation for discrepancies and ensures that inaccurate or discrepant documentation is addressed in the medical record or other source documents (1) - Maintains the privacy and confidentiality of patients' source documents (3)

DOMAIN 5. DATA MANAGEMENT AND INFORMATICS	
Competence 5.1	**Basic knowledge and skills in statistics, qualitative data analysis and informatics**
Concept	Understands the basic purpose of statistics (e.g., using descriptive and inductive statistics; testing a null hypothesis; bias; randomization; sample size, etc), qualitative data analysis (selecting appropriate methods of analysis) and informatics (generation, handling, communication, storage, retrieval, management, analysis) as they relate to clinical studies. (1) (3) Understands the processes to establish the validity and reliability of quantitative research methods, and credibility and transferability of qualitative research methods Understands that data analysis and informatics depend upon obtaining high quality of data and its management throughout the research process (6)
Examples of how this competence is demonstrated	- Understands the basic concepts of statistics and qualitative analysis (such as sampling method, sample size, bias, analysis, etc), as applied in the context of palliative care populations (3) - Understands how to interpret statistical analysis and qualitative data analysis into new knowledge (6) - Understands the role of informatics in clinical palliative care studies (3) - Demonstrates ability to extract and use data from the internet, use computer software (Word, Excel etc), and use a statistical software package (SPSS, STATA etc) for analysis (1) - Be aware of the principles of different types of qualitative analysis software and how they can facilitate the manipulation, indexing and retrieval of data from large volume data (audio, text, videos etc.) (8) - Creates and operates data management systems (1) - Designs databases appropriately for data specifications, user requirements, edit rules, query logic and data validations - Collaborates with Information Technologist (IT), in order to manage and troubleshoot the physical infrastructure of the database, as well as the software interface and the data itself (1)
Competence 5.2	**Basic knowledge and skills of data management (collection, management, analysis)**
Concept	Is aware that data may be collected from different sources and should be accurate, complete, and verifiable from source documents, upon entry to the database (1) Database creation and management for a clinical research project requires theoretical knowledge and practical skills in data collection, entry, and maintenance, including verification (1) Knowledge that data management is operated through a Data Management System (DMS) which encompasses regular backup and safe storage in line with ethical requirements, quality management strategies for the data, timely resolution of database queries, and review reports generated, as required.
Examples of how this competence is demonstrated	- Describes the basic concepts of data management (purpose, scope, process workflow etc.) (3) - Identifies and applies standard and best practices for data management in palliative care clinical research. (3) - Identifies the various sources (text, video, audio etc.) and manages data collection and insertion into Case Report Form (CRF) or other storage format, ensuring the data is accurate and complete - Maintains a log of incomplete or missing data: considering the frail and vulnerable nature of the palliative care patient population - Ensures safe and secure storage of data

	- Manages the flow of data in the study: how it is acquired, cleaned, and stored - Demonstrates appropriate knowledge of the data flow plan, processes and guidelines, and good project management skills - Oversees quality of data management and data systems available, with specific application to palliative care - Operates the data management system or assist in defining data specifications, summaries, and data listings - Reconciles data transfers

DOMAIN 6. COMMUNICATIONS AND RELATIONSHIPS	
Competence 6.1.	**Ability to effectively communicate the content and relevance of clinical research findings for various audiences**
Concept	Requires language and communication skills to disseminate findings, and the ability to synthesise complex information to explain to others. Is aware of the importance of presenting the results of research, and of the various dissemination formats available for different audiences: to colleagues, advocacy groups and the general community. Is able to develop or contribute to content for advertising and advocacy materials concerning research findings. Is able to prepare and submit an abstract for a conference, and subsequently prepare a suitable poster or oral presentation (or assist others to do so). (1) Is aware that reports can take the form of oral or written accounts of activities, which may take place at scheduled meetings or upon request from team members or stakeholders.
Examples of how this competence is demonstrated	- Communicates outcomes of a clinical research study to sponsors, colleagues and the general community. - Explains the scientific underpinnings of a research study in terms and formats that can be accessible and understood by the non-scientific community (leaflets, flyers, letters etc) - Writes summaries of research studies for a journal club or to potential patient populations - Is aware of the concept of plagiarism and of requirements for citations of others' work - Writes and submit abstracts, with/under supervision, to conferences or journals - Prepares or assists in the preparation of and/or delivers oral or poster presentations at conferences and meetings - Delivers effective presentation using oral and artistic skills to express ideas effectively in the time allotted to the presentation - Coordinates or contributes to writing the final research report
Competence 6.2.	**Possession of interviewing and good communication skills**
Concept	Is aware of the importance of clear and continuous communication with all people involved in research activities, including patients and families as potential participants in the study, colleagues as potential members in the study team, and various stakeholders from the scientific and lay community. Interacting with involved people requires good interpersonal skills and a good understanding of the patient, his/her family reality, social and cultural aspects that could influence the research. (1) (2) Needs specific knowledge and skills in two areas: a) Enrolment and retaining of participants in the study and b) Liaison and links to colleagues and other communities. For the first area, the individual who recruits participants will be involved in outreach activities (informing potential participants about the study), screening potential participants, and using strategies to help retain participants in longitudinal studies. Needs a good understanding of the way to enrol participants in the study, including the inclusion/exclusion criteria and participant recruitment strategies. Can explain the study adapting the language to a participant's level of understanding (for example, a child, younger, or older person). For the task of liaison and link to colleagues and communities and ensure good communication in order to create a suitable context for the research. Will need to maintain regular communications and interactions with the clinical team and relevant departments to ensure smooth and successful implementation of the research

	protocol and to ensure that they constantly update and circulate new information to all parties involved.
Examples of how this competence is demonstrated	- Encourages, appreciates, and values the contribution of study participants in all areas of research; promotes patient and family involvement - Understands and applies the criteria for the inclusion and exclusion of participants in clinical trials and other research designs, randomizes trial participants, follows recruitment figures and reports to relevant groups when necessary - Uses their interpersonal and communication skills to provide information about the study or formulate requirements in a clear, accessible, non-technical way, appropriate to the level of understanding, physical and mental health, and builds trusting relationship. - Understands problems that may occur during the processing of informed consent, anticipates, prevents, and manages the difficulties that may arise on the part of the patient to mitigate these risks.

DOMAIN 7. RESEARCH LEADERSHIP	
Competence 7.1.	**Incorporates and promotes team working skills in the conduct of clinical research**
Concept	Understands the importance of an interdisciplinary team and the values each member can bring to clinical research (awareness of responsibilities) (2). The palliative care team leader identifies the respective skills, roles, and responsibilities of each member of the team and understands that communications within a clinical study team is vital to promote team working in research. Demonstrates interpersonal skills (e.g., negotiating, influencing, resolving conflict) and mentors others on how best to work in a multi-functional clinical study team. On a daily basis, must demonstrate skills in teamwork, resolving team related issues and evaluating outcomes and solutions for the project (3)
Examples of how this competence is demonstrated	- Understands the professional roles and clinical practice domains of all members of the clinical research team. (3) - Has awareness of responsibilities of key personnel in clinical research and effectively collaborates in inter-professional teams (2) - Creates positive working relationships to conduct the study (2) - Contributes to team building and encourages development of colleagues' research abilities within the multidisciplinary team. (2) - Consistently works within own roles and responsibility whilst seeking advice and support as appropriate to conduct the project. (2) - Collaborates with different team members to make decisions - Describes the composition of the team needed to implement the palliative care research project
Competence 7.2.	**Develops and applies the principles and practices of leadership and mentorship in clinical research**
Concept	Demonstrates an understanding of how to recruit, train, mentor and supervise other colleagues who are necessary to be part in the process to ensure the success of the research project. Promotes an appropriate culture for continued improvement, knowledge exchange and expansion of activities at the organizational level and maximizes the effectiveness of the team. Promotes research capacity building for their institutions; by using and creating new opportunities for research activities, collaboration, and knowledge sharing. Requires good problem-solving skills and creative thinking to find new ways to enhance effectiveness, and excellent interpersonal skills to network, guide and motivate others. (1) Delivers effective training in a meaningful way to others by adapting the context and approach appropriately (1) Has the ability to lead, motivate, mentor, supervise, monitor, train and advise staff in their research work, acting as a resource (1).
Examples of how this competence is demonstrated	- Has initiative to propose conducting research and motivate others to collaborate. - Actively seeks to collaborate and enhance clinical research. - Be ready to support others conducting research within her/his own abilities. (1) - Contributes to the education and development of research abilities in the palliative care service. (1) (2) (10). - Supports other team members in doing research. (1) - Evaluates and assigns work and delegates to others, based on an individual's strengths and interests. (2)

	- Trains and mentors new staff members and team members (3) - Leads and takes responsibility for research in as principal investigator or co-investigator. (2) (9)

ADDITIONAL COMPETENCY

An understanding of international languages has been identified as important as this enables access to up-to-date articles regarding new developments in palliative care may that improve clinical practice. Therefore, mastery of an international language is a desirable skill which can facilitate research in palliative care.

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