STREAMLINED **GER**IATRIC AND **ON**COLOGICAL EVALUATION BASED ON IC **TE**CHNOLOGY
FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT
FOR OLDER MULTIMORBID PATIENTS

HORIZON 2020 PROGRAMME – TOPIC H2020-SC1-BHC-24-2020
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D3.7: PROTOCOL FOR IMPLEMENT STUDY

Lead Beneficiary: 8-BOC

Involved Beneficiaries: 10-DCU, 1-UBx, 2-KUL, 3-DIAK, 4-OUS, 5-UCD, 6-ESE, 11 - MPS

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V3.0	2024-12-24	Lucia Ferrara, Vittoria Ardito, Alessandro Furnari, Alberto Ricci, Carla Rognoni	Implementation of suggested changes and final reading

Table of Content

Executive Summary

This document is aimed at developing the protocol for the IMPLEMENT Study. This report corresponds to the deliverable D3.7, that is part of work-package 3 “Developing the methods for Geronte” which supports GERONTE Objective 5.5 “Describe the care pathways for older multimorbid patients across several European countries”.

This protocol illustrates the methods that will be used to conduct an observational cross sectional study design that involves the systematic observation of several clinical sites across different European Countries.

Scientific Background and Rationale:

Older adults represent an increasing proportion of the population, with a high prevalence of multimorbidity, defined as having two or more health conditions. Among those aged 65 to 84, 65% experience multimorbidity, increasing to 81% in those aged 85 or older. This condition often leads to reduced quality of life, significant disease burden, impaired health outcomes, and increased risk of premature mortality. Current healthcare systems, structured around a single disease model, are not equipped to address the complex needs of multimorbid patients, resulting in suboptimal care and increased healthcare costs.

Integrated, patient-centered care has shown protective and beneficial effects. However, the implementation and evaluation of such care models are challenging due to the complexity of conditions and care processes involved. Economic and implementation evaluations are scarce and often tailored to specific contexts, which complicates their broader application.

Objectives:

The IMPLEMENT study aims to provide a comprehensive description of the oncology care pathway for older multimorbid patients across several countries from patient, clinical, organizational, implementation, and economic perspectives. This study will address the following research questions:

1. What are the current care pathways for multimorbid patients with cancer in Europe?
2. What are the costs associated with managing multimorbid patients, and what factors influence these costs?
3. What are the challenges, barriers and facilitators described by the different stakeholders involved in the care pathway?
4. What approach to data collection, analysis, and synthesis best enables comprehensive economic, management, and implementation evaluations?

Methods:

The IMPLEMENT study will adopt an observational cross sectional study design that involves the systematic observation of several clinical sites (i.e., hospitals in at least 5 different European countries). Researchers will use a mixed-method approach to collect data on variables of interest in order to have a clear understanding of complex phenomena and complex dynamic organizational systems. This strategy combines both qualitative and quantitative data collection techniques, enabling the capture of a wide range of perspectives and insights. By integrating surveys, interviews, focus groups, and observational methods (where appropriate such as clinician’s non-patient work routines), we aim to achieve a more holistic understanding of the stakeholders' practices, views, experiences, and needs.

This approach ensures that our findings are well-rounded and reflective of the varied dimensions of the issues at hand.

Significance:

The IMPLEMENT study is part of the GERONTE Project, which aims to improve the quality of life for older multimorbid patients while reducing care costs. To this end, GERONTE has co-designed an innovative, patient-centered holistic health management system, referred to as the GERONTE intervention. GERONTE will use an ICT-based application, with functionality tailored to meet stakeholders' informational, practical, and support needs, for real-time collection and integration of standardized clinical and home patient-reported data. GERONTE will be tested and evaluated in a prospective randomized stepped wedge design clinical trial in France, called FRONE.

By adopting effectiveness-implementation hybrid designs (type 1 for FRONE and type 3 for IMPLEMENT), the results of the two studies conducted as part of the GERONTE Project will be analysed in a combined way to capture the full impact of comprehensive care models and inform the transition to integrated care models.

Ethics and dissemination. This protocol will be presented to Bocconi University Ethics Committee for approval. IMPLEMENT study results will be disseminated via scientific, peer-reviewed publications and conference presentations.

Conclusions. Evidence from the IMPLEMENT Study will contribute to describe the oncology care pathway for older multimorbid patients across several countries from different perspectives (clinical, organizational, and economic perspectives).

Deliverable work status

Deliverable	Completion status in %	Deviation	Data complete or to be updated
D3.7 Protocol for IMPLEMENT Study	100%	None, delivered at M45	Deliverable is complete
Associated Deliverables	D5.7 Evaluation report of IMPLEMENT Study		
Associated Objectives	Objective 5.5 "Describe the care pathways for older multimorbid patients across several European countries".		

Description of deliverable

This deliverable describes the protocol of the IMPLEMENT study that will be submitted to the relevant authorities for approval. Specifically, this document explains the background, rationale, objectives and methods that will be adopted to conduct the IMPLEMENT Study.

This deliverable is connected to D3.6 "Care pathways in the 3 trial countries" as the analysis will complements the interviews already conducted as part of that deliverable; D4.3. First study subject approvals package for FRONE which include the final version of the FRONE trial protocol, as part of the clinical sites that will be involved in the IMPLEMENT study are also part of the FRONE study. This deliverable will inform D5.7 Evaluation report of IMPLEMENT Study which will report the full evaluation

of the IMPLEMENT Study and D5.6 “Policy paper on how to improve the management of older multimorbid patients, due M60.

The deliverable is associated to WP3 objective of analysing the distinctive elements of the care pathways for older multimorbid patients at the local level and to align GerOnTe model with these existing care pathways and to the specific requirements of different healthcare systems.

Attainment of the objectives and explanation of deviations

The objectives related to this deliverable have been achieved in full and as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Justification for delay in deliverable submission

The objectives related to this deliverable have been achieved on time and as scheduled in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Data associated

D3.7 has been submitted as a Deliverable. The Deliverable can be found at https://10.5281/zenodo.14589096

1. Introduction

1.1 GERONTE and its objectives

GERONTE is a 5-year research and innovation project (April 2021 to March 2026) funded by the European Union within the framework of the H2020 Research and Innovation programme, in response to the health societal challenge topic SC1-BHC-24-2020 "Healthcare interventions for the management of the elderly multimorbid patient". The overall aim of GERONTE is to improve quality of life - defined as well-being on three levels: global health status, physical functioning, and social functioning- for older multimorbid patients, while reducing overall costs of care. To this end, GERONTE will co-design, test, and prepare for deployment an innovative cost-effective patient-centred holistic health management system, hereafter referred to as the GERONTE intervention. GERONTE intervention will rely on an ICT based application for real-time collection and integration of standardised clinical and home patient-reported data. GERONTE intervention will be demonstrated in the context of care of multimorbid patients having cancer as a dominant morbidity, and be adaptable to any other combination of morbidities.

The objectives of the GerOnTe project are the following:

O1: INFORMATION gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management

O2: **TOOLS** develop ICT tools for the GERONTE intervention to be implemented

O3: METHODS develop socio-economic methods for evaluating the impacts of the implementation of the GERONTE intervention

O4: **DEMONSTRATION** demonstrate in 16 study sites from three EU countries the feasibility and effectiveness of the GERONTE intervention

O5: **REPLICATION** develop recommendations for the replication of GERONTE best practices in all European health systems

O6: ENGAGEMENT engage all stakeholders by co-designing the GERONTE intervention

1.2 Rationale

The current work corresponds to deliverable D3.7. D3.7 is the output of Task 3.6 "Develop the protocol for IMPLEMENT study", which is part of work-package 3 which supports GERONTE Objective 5.5 "Describe the care pathways for older multimorbid patients across several European countries".

The development of the current protocol follows the STROBE (Strengthening the reporting of observational studies in epidemiology) guidelines.

1.3 Relationship with other deliverables

This document complements the following deliverables and internal documents

- D3. Care pathways in the 3 trial countries which includes the analysis of the care pathway in France, Belgium and The Netherlands before the start of GerOnTe study
- D4.3. First study subject approvals package for FRONE which include the final version of the FRONE trial protocol

This deliverable will inform

- Task 5.3 “Economic evaluation” and D5.3 Economic evaluation of GerOnTe, due M60
- Task 5.5 “Support the definition of new care pathways and healthcare models for the management of older multimorbid patients” and its related D5.6 “Policy paper on how to improve the management of older multimorbid patients, due M60.
- Task 5.6 “Conduct the IMPLEMENT (IMplementation of comPrehensive oncoLogy carE in MultImorbid patiENTs) Study and D5.7 “Evaluation report of IMPLEMENT Study”, due at M60.

1.4 Ethical Approval

This protocol will be submitted to Bocconi University Ethics Committee for approval.

2. IMplementation of comPrehensive oncoLogy carE in MultImorbid patiENTs (IMPLEMENT Study).

2.1 Scientific background and rationale

Older adults represent an increasing proportion of population, and while they are a heterogeneous group, most experience increased, and relatively high rates of, multimorbidity. Among those aged 65 to 84, 65% experience multimorbidity, and this proportion increases to 81% in those aged 85 or older. Multimorbidity, typically defined as having two or more health conditions, refers to patients with a broad and diverse range and mix of health diagnosis (such as cardiac, neurological, neurosurgical, renal, or immunological conditions).

People with multimorbidity can often experience reduced quality of life, significant disease and cost burdens, impaired health outcomes, and an increased risk of premature mortality. Health and social research identify the protective and beneficial effect of holistic patient-centred care. Developing, implementing, and adapting interventions, and in turn the broader system, to address this group's complex and intricate health, social, and support needs present practical, professional (skill), and financial challenges for healthcare systems currently structured around a single disease model. As a result, coexisting conditions, which are common in older patients, are often under-evaluated and under-managed, leading to inappropriate drug prescriptions, avoidable hospital admissions, delays in treatment, and ultimately suboptimal care. This translates into a considerable increase in healthcare costs and resource utilization as well as in a worse patient experience and a likely increase in related social costs. Given the growing population of older adults with complex health and support needs, it is crucial to co-develop innovative, patient-cantered, proactive, and well-coordinated integrated care approaches. These approaches should maintain the benefits (specialisation) of current disease-centred models while enabling co-ordination and integration of the different healthcare professionals (skills) needed to provide health care and support to patients experiencing multimorbidity. Developing and effectively supporting (economic and process evaluations) and implementing (baseline evaluation to identing and develop contextualised/ locally applied guides) will provide a practical and impactful way to improve the care for a priority and vulnerable population, while optimizing healthcare resource utilisation, and developing an approach (to care coordination) that can be scaled-up and also adapted and applied to other groups (needing a defined structured approach to coordinate care). This offers broader benefits to patients, providers, and society.

Despite significant research and investment in integrated care programs and their growing implementation in recent decades, many studies show that evaluations of these programs, particularly economic evaluations, remain scarce and complex and difficult to apply outside their original context. It has been evidenced that there are inherent complexities in evaluating integrated care which arise from both the broad and mix of conditions, care, professionals, and organisations involved; and the varying definitions and scope related to the condition and care and who provides it. Despite, and in a sense, partially because of the complexity, a robust, comprehensive, and practical approach to undertake economic, process, and implementation evaluation is needed to explain and justify the needed changes and how to support effective and timely implementation so as to capitalise on the benefit and value of such changes. This is even more relevant and urgent given the established demographic and epidemiological trends showing an aging population and an increase in chronic conditions and multimorbidity.

In such a scenario, evaluating programs targeting multimorbid patients necessitates a combination of innovative evaluation methods that can capture the full impact of these comprehensive models. Therefore, one of the aims of IMPLEMENT is to adopt hybrid approaches to study and describe existing care pathways for multimorbid patients in multiple centers.

The IMPLEMENT study is part of the GERONTE Project which aims to improve the quality of life—defined as well-being on three levels: global health status, physical functioning, and social functioning—for older multimorbid patients, while reducing overall costs of care. To this end, GERONTE will co-design, test, and prepare for deployment an innovative, patient-centered holistic health management system, referred to as the GERONTE intervention that will be demonstrated in the context of caring for multimorbid patients with cancer as a dominant morbidity and will be adaptable to any other combination of morbidities.

The GERONTE project will adopt hybrid evaluation methods, focusing on testing the efficacy and cost-effectiveness of the GERONTE intervention through a stepped wedge randomized controlled trial (called FRONE) and an observational study aimed at observing and gathering information on current care pathway for multimorbid patients (called IMPLEMENT).

2.2 General objectives

The general objective of the IMPLEMENT study is to gain a comprehensive description of the oncology care pathway for older multimorbid patients in several countries from patient, clinical, organizational, implementation, and economic perspectives.

This objective relates to four research questions:

RQ.1. What are the current care pathways for multimorbid patients with cancer in Europe?

RQ.2. What are the costs associated with the management of multimorbid patients, and what factors influence these costs?

RQ.3. What are challenges, barriers and facilitators described by the different stakeholders involved in the care pathway?

RQ.4. What approach to data collection, analysis, and synthesis best enables a comprehensive approach to the economic, process, and implementation evaluations required to support and guide a change (from the current disease-specific models) to integrated care model of care?

2.3 Specific objectives

The specific objectives of the IMPLEMENT Study are:

1. To document and describe the management of care pathways for older multimorbid patients with cancer in each center (this is linked to RQ1, RQ3).
2. To characterize the patients referred to each pathway and their caregivers (this is linked to RQ1).
3. To describe the costs of the current care pathways from a health service perspective (this is linked to RQ2).

4. To classify the factors that determine differences in the observed care pathways (in terms of activities and costs), distinguishing between standardizable and non-standardizable elements, and consequently, between factors those generate “natural” variability and factors those generate “artificial” and controllable variability (this is linked to RQ2, RQ3 and RQ4)

5. To use realist evaluation to understand how and for whom the current care pathways work (this is linked to RQ3).

To assess the capacity of each center to implement and use the GERONTE patient-centered system in the future (this is linked to RQ1).

2.4 Study design

The IMPLEMENT study will adopt an observational cross sectional study design that involves the systematic observation of several clinical sites (i.e., hospitals in different countries). This approach allows for the examination of cancer care pathway as they naturally occur in their settings, providing valuable insights into real-world clinical and organisational practices and processes, and how they create or influence patient care and experiences. To gather comprehensive and robust data from these diverse stakeholders, we will adopt a mixed-method approach. This strategy combines both qualitative and quantitative data collection techniques, enabling us to capture a wide range of perspectives and insights. By integrating surveys, interviews, focus groups, and observational methods (aligned with the research questions and context), we aim to achieve a holistic analysis, description and understanding of the different stakeholders' (patient, clinicians, organizations) practices, processes, views, experiences, and needs, and how in the local context influences them. This approach ensures that our findings are well-rounded and reflective of the varied dimensions of the issues at hand.

This study will use realist research, a theory-driven approach, and implementation science approaches. Collecting, analysing, and making sense of such a broad scope of data requires a comprehensive, structured, and evidence- and theory-driven approach. The core principle of realist research is identifying the ‘context, mechanism of action (how it works), and outcomes’ for the phenomenon of interest. A realist research approach is chosen to provide a theoretical lens to focus and structure the research question and data collection. Realist research asks the question ‘in what ways and context and for who (patient, care givers, clinicians, and organisation’), does the phenomenon of interest (care pathway and service, support) works.

The Consolidated Framework for Implementation Research (CFIR) will be used to scope and identify what data to collect and analyse.

The CFIR, developed by the Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI), is one of the most commonly used determinant frameworks to assess the contextual factors that impact implementation. It identifies and outlines 5 domains to consider: inner and outset setting, the innovation, the individual, and the implementation process. Moreover, the NASSS framework will be use as a comprehensive and validated framework for identifying factors in the healthcare context that impact the implementation of technology.

2.5 Setting

The study will involve up to 20 hospitals, with a maximum four hospitals per country. Therefore, the maximum number of countries involved in the IMPLEMENT study will be five. Since healthcare system configurations vary from one country to another and have a strong impact on the delivery of care and patient health status, the inclusion and analysis of diverse delivery, funding, and organisational models and systems (i.e., Ireland, France, Italy, Belgium and the Netherlands) will help identify many of the

main factors that impact the care and management of multimorbid patients. The proposed duration for the study is 15 months and this timeframe will be structured in three phases (Figure 1):

1. **Data collection (M1-M9)** (Jan- Sept 2025): we will adopt a mixed-method approach, combining both qualitative and quantitative data collection techniques such as interviews, surveys and focus group with healthcare professionals, administrative staff, documentary analysis, and possibly on-site visits and observations.

2. **Data analysis (M3-M12)** (March - December2025): Quantitative data will be analysed using statistical methods to identify patterns, and trends. Concurrently, qualitative data will be examined through thematic analysis, coding responses to uncover underlying themes and insights. By integrating these two approaches, and analysing, synthesising, and reporting the findings in line with the questions and data (using the appropriate methods such as convergent parallel synthesis) and the future use of the data such for economic and policy papers or implementation guides, we will triangulate the findings, allowing for robust and contextualised understanding of the data.

3. **Dissemination and identification of policy implications (M11-M15)** (Nov 2025 - March 2026): the results of the study will be discussed with a panel of experts to provide key lessons and policy recommendations for the management of multimorbid older patients at the European level. The findings on the A) description, B) costs, and, C) stakeholders' (patients, carers, clinicians, service/ business/ IT managers) experiences and needs related to the care pathways (and what factors influence these) will be reported and presented for peer review at relevant clinical, management/ organisational, and clinical conferences to ensure robust review, feedback and cost-effective use of research methods and findings. The implementation guides and business plan will be reviewed and refined by the broader GERONTE Project team and the stakeholders at the IMPLEMENT study's sites, to ensure the development of contextualised and user-friendly guides.

Each center participation will be dependent on their ability to commit to the entire duration of the study. A center's commitment to participate will be requested before each center's involvement to avoid center withdrawal after the project starts.

Figure 1 GANTT reporting the timing for the different activities

Tasks	2025												2026		
Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Data collection															
• Documentary analysis															
• Interviews															
• Survey															
• Focus group															
2. Data analysis															
3. Dissemination and identification of policy implications															

2.6 Participants

Each clinical site involved in the project will be selected based on four criteria:

1. Experience and expertise that these centers and clinicians have within the field of geriatric oncology (e.g., volume of activities, involvement in research and publication on geriatric oncology)
2. Knowledge of older care recipients with multimorbidity and an oncological condition.
3. Different healthcare organizational and institutional configurations (e.g., teaching hospital, general hospital, cancer center, etc.).
4. Willingness to participate until the end of the study.

The project will involve different stakeholders:

- **Healthcare professionals:** involving around 2-3 healthcare professionals (i.e., clinicians, nurses) at each site to provide insights into the context, interests, interrelations, and management of cancer patients and the consumption patterns of multimorbid older patients.
- **Administrative staff**: involving around 2-3 staff members (e.g., administrative staff, financial office, IT department) at each site to collect information about the organization, information systems, and costs of the clinical site.

At each clinical site we will identify a reference contact to facilitate the link with the other professionals involved.

Considering the study's timeframe, the possibility and feasibility to perform additional analyses on a subset of clinical sites (for example involving patients and caregivers) will be evaluated during the conduct of the study.

2.7 Variables

Based on the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009), the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) (Greenhalgh et al., 2017), and other relevant theoretical frameworks that we will adopt during the study, at each clinical site we will collect various data and information. Here is an example:

1. Data on the organizational model of the site
    - Volumes of activities and patient characteristics (e.g., the number of patients treated by the center per year, age groups, needs) for patient volume planning and control.
    - Long-term policy of the institution (strategic planning).
    - Institutional engagement, experience, or policy and financial documents or reports identifying the supporting structures for change management or quality improvement.
    - Operational strategy, in terms of available professionals, equipment, and space (resource planning and control).
    - Institutional funding model (public/private/mixed) and service type and use by the proportion of public/private patients (if mixed).
    - Relevant recent or current service or innovation changes or improvements taking place.
    - Patient engagement and feedback procedures.
    - Staff recruiting, training, development, retention, and service development practices.

2. Data on the delivery and service model for multimorbid patients:
    - Multidisciplinary models (e.g., MDT).
    - Description of core and peripheral contents of the service offered by the center.
    - Patient access points, process standardization, and interaction methods with patients and families.
    - Services dedicated to taking charge of the patient (e.g., physical location, organizational dependence, dedicated clinics, specialization).
    - Description of the care pathway in different phases: referral, diagnosis, treatment, and follow-up.
    - Professionals involved, activities, timing, spaces.

3. Costs incurred by each clinical site
    - Healthcare resource use
    - Cost data for each factor of production considered in care delivery (time, space, medical equipment, personnel)

2.8 Data sources

To gather comprehensive and robust data from diverse stakeholders, we will adopt a mixed method approach. This strategy combines both qualitative and quantitative data collection techniques, enabling us to capture a wide range of perspectives and insights. The main sources of data include:

1. Data on the organizational model of the site participating in the project: collected through review of relevant documents, questionnaires to the clinical site, interviews, and focus groups with the clinicians and different stakeholders involved
2. Data on the delivery and service model for multimorbid patients: collected through interviews, focus groups and survey. To guide the interview 8 case vignettes were developed. The use of case vignettes is particularly beneficial as they provide a structured and standardized way to explore clinicians' decision-making processes. By presenting realistic, well-defined scenarios, vignettes enable researchers to elicit specific insights into clinical reasoning, variations in practice, and the application of guidelines in real-world settings. They also help reduce ambiguity and ensure that all interview participants address comparable situations, facilitating meaningful comparisons and analysis across responses.
3. Costs incurred by each clinical site from the provider perspective collected with survey, focus groups, and interviews

The draft outlines of the semi-structured interviews, questionnaires, and case vignettes are provided in the Appendix.

Some of these data will be collected throughout the clinical sites, while others may only be collected on a sub-sample of clinical sites. Details in the table below:

Table 1 Data sources

	All clinical sites	Subset of clinical sites
1. **Data on the organizational model**		
- Documentary analysis	X	
- Interviews	X	
- Focus groups		X
2. Data on the delivery and service model		
- Survey	X	
- Interviews	X	
- Focus groups		X
3. Costs incurred by each site		
- Survey	X	
- Interviews/focus groups		X

4. Additional potential analysis		
- Survey (with patients and / or caregiver)		X
- Interviews/focus groups (with patients and / or caregiver)		X

2.9 Bias

Including a representative sample of professionals (e.g. clinicians, administrative staff) is crucial to avoid bias. This will ensure that the study findings are reflective of the diverse perspective of the professionals involved. By employing this comprehensive mixed-method approach, we aim to provide a holistic and nuanced understanding of the organizational and service delivery models for multimorbid patients, thereby informing policy and practice improvements at both national and European levels.

2.10 Methodology employed

This study is designed as an observational cross-sectional study, which inherently does not require a predetermined sample size calculation. The research will be conducted across up to 20 hospitals, strategically distributed within different hospitals per country. By involving multiple countries and centers, we aim to capture a broad spectrum of clinical practices, which will contribute to the robustness and validity of our observational data.

Quantitative variables will be analysed through descriptive statistics (i.e., in terms of absolute frequency, mean, standard deviation, confidence interval of the mean, median, Q1, Q3, minimum, and maximum depending on the type of data). Qualitative variables will be described through text analysis.

As data will only be used for descriptive purposes, no handling of missing data (such as multiple imputation) is planned.

A formal realist research approach will be adopted. This will include:

a) The development of “initial program theories” about the context, mechanism of action, and outcomes.

b) The development of hypotheses, based on current research and stakeholder input, regarding who benefits, in what ways, and how the ‘current care pathway’ works.

c) The identification of for whom (patients, carers, clinicians, service/business/IT managers), in what ways, and in which contexts the described care pathway works.

d) The testing and refinement of the theories across multiple iterations and over time by verifying the accuracy of the statements against the research findings.

An early and broad theory for the IMPLEMENT study is that “the care pathway/service will work well (provide output and user-experience measures in line with best practices) for the stakeholders when all stakeholders' needs are well-defined and addressed, when the organizational structures and resources are accessible and engaged (helpful), user-focused, and adequately resourced and supported, tailored to the end-user needs (capacity, functions, time/accessibility). There should also be a culture of, resources and support for, and experience with change management/implementation,

and clear and strong clinical, policy (economic, business, environmental, and sustainability) evidence to support the practice. The work of the IMPLEMENT study will be to 'detail' and explain (evidence) each part of this statement (or to change, refine, and evidence these)."

Economic evaluation of costs and resource use will be analyzed from provider perspectives. This approach ensures a thorough understanding of the financial implications and resource allocation involved, considering only the direct costs incurred by providers. Healthcare providers incur costs related to the delivery of medical services. These costs can be mainly categorized into different key areas: personnel, medical equipment and supplies, treatment and administrative functions. These diverse costs reflect the complex nature of healthcare delivery and underscore the financial responsibilities healthcare providers must manage to ensure effective and efficient patient care. Indeed, the study aims at calculating costs over the entire care delivery value chain, ignoring boundaries between departments and organizations, capturing all processes in the care continuum for a multimorbidity patients. In this perspective, time driven activity-based costing (TDABC) represents the best technique to capture the complexity of healthcare processes and translate them into costs, calculating the total cost of staff and clinical resources involved at each process along the care continuum delivery path and, consequently, the cost of the patient's entire care cycle. Briefly, the TDABC steps involve (1) developing process maps for care delivery pathways; (2) measuring the time required for each process step and determining capacity cost rates for staff and clinical resources activated; and (3) calculating the total cost of care delivery.

3. Appendices

3.1 Draft of organizational questionnaire

The organizational questionnaire aims to describe the main characteristics of the hospitals included in the project and will cover these domains:

- Volumes of activities and patient characteristics (e.g., how many patients are treated by the centre, age group, needs) (*Patient volume planning and control)*
- Long-term policy of the institution *(strategic planning)*
- Institutional engagement, experience, or policy document supporting change management
- Operational strategy, in terms of available professionals, equipment and space (*resource planning and control*)
- Multidisciplinary models (e.g. MDT)
- Institutional funding model (public/ private/ mixed), and service type and use by proportion of public/ private patients (if mixed).
- Relevant recent or current service or innovation changes or improvement taking place
- Patient engagement and feedback procedures
- Staff recruiting, training, development, and retention and service development practices
- Professional representation and decision-making around service delivery
- Patient representation and decision-making around service delivery

3.2 Layout of semi-structured interview

The aim of the interviews is to describe the organizational model of the site participating in the project and in particular the delivery and service model. We're especially interested in people who have cancer, but also have some other health issues. These might be single conditions like diabetes or COPD, or more complex conditions like frailty, or both.

1. Interview layout for Clinicians

- Can you explain the long-term policy of the institution *(strategic planning)*?
- Can you explain the organizational model of the site?
    - Describe core and peripheral contents of the service offered by the centre.
    - Patient access points, process standardization, interaction methods with patients and families
    - Services dedicated to taking charge of the patient (e.g., physical location, organizational dependence, dedicated clinics, specialization)
- Can you describe how older people with cancer and other complex health needs are cared for right now – is there a formal care pathway, or how is it done? (*Patient planning and protocol*)

- Description of the care pathway in the different phases: sending, diagnosis, treatment and follow up
- Who is involved? What do they do? When? Where? Why?

- How do you interact with other professionals / specialities and nodes of the network (e.g., GP, other professionals, facilities, other units)?
- Do you have regular team meetings – multi-disciplinary team meetings? For which patients? How do these meetings work?
- How do you typically access and share information about your patients?
- What would improve this communication process?
- What difficulties do you currently face in the management of older multimorbid patients?
- What work, or informal practices do you do, or try to do, to fix problems or delays in the system? How do you typically access and share information about your patients?
- What makes care work well? What makes care doesn't work well?
- What gets in the way of delivering the care you would like to give?
- What would you like to see that you haven't yet have?

3.3 Case vignettes

To guide the interview with clinicians, we have developed eight case vignettes, with two vignettes per tumor type.

The use of case vignettes is particularly beneficial as they provide a structured and standardized way to explore clinicians' decision-making processes. By presenting realistic, well-defined scenarios, vignettes enable researchers to elicit specific insights into clinical reasoning, variations in practice, and the application of guidelines in real-world settings. They also help reduce ambiguity and ensure that all interview participants address comparable situations, facilitating meaningful comparisons and analysis across responses.

Breast cancer

Case 1: Surgical pathway (+ radiotherapy / +/- systemic therapy)

1/ breast cancer: ductal carcinoma grade II, ER PR pos, HER2 neg, stage cT3N1. 79y

Comorbidity: diabetes type II but has become insulin dependent, atherosclerotic hearth disease, moderate renal insufficiency.

Treatment options: in principle first surgery, then consider radiotherapy and adjuvant endocrine therapy (and chemotherapy). Alternative: aromatase inhibitor till progression.

Involved settings / units (hypothesis): surgery, radiotherapy, oncology

Case 2: Systemic therapy

2/ breast cancer: ductal carcinoma grade III, ER neg, HER2+, upfront metastatic. Stage cT4dN2M1. 6 lung metastases, asymptomatic. 90y

Comorbidity: Relatively fit – no cognitive impairment)

Treatment options: in principle taxane trastuzumab pertuzumab but not easy at that age. Alternative: antiHER2 without taxane; palliative care; …

Involved settings / units (hypothesis): oncology, palliative care/BSC – best supportive care

Lung cancer

Case 3: Surgical pathway

3/ Lung cancer: NSCL stage 2, non-squamous, no driver mutations. 78y

Comorbidity: prior myocardial infarction, weight loss >6 kg / 5 months, poor appetite

Treatment options: in principle induction chemoimmunotherapy followed by surgery. Alternative: surgery, radiotherapy/SBRT, systemic therapy alone, wait and see, …

Involved settings / units (hypothesis): surgery, radiotherapy, oncology

Case 4: Systemic pathway

4/ Lung cancer: NSCL stage IV with liver metastases, non-squamous, no driver mutations, PDL1 10% (low). 80y

Comorbidity: kidney disfunction eGFR 28 ml/min, requires a walking aid

Treatment options: in principle doublet chemo + immunotherapy. Alternative: palliative care – best supportive care, immunotherapy alone, chemo alone, brain RT.

Involved settings / units (hypothesis): radiotherapy, oncology

Colorectal cancer

Case 5: Surgical pathway

5/ Colorectal cancer: stage III. 78y.

Comorbidity: congestive heart failure

Treatment options: in principle surgery followed by adjuvant chemotherapy. Alternative: surgery alone, palliative care.

Involved settings / units (hypothesis): surgery, oncology, palliative care

Case 6: Systemic pathway

6/ Colorectal cancer: upfront stage IV with 5 liver metastases. No dMMR/MSI-H, no RAS/BRAFm. Right sided. 80y.

Comorbidity: mild dementia

Treatment options: in principle chemo + bevacizumab. Alternative: chemo alone, palliative care – best supportive care.

Involved settings / units (hypothesis): oncology, palliative care – best supportive care.

Prostate cancer

Case 7: Surgery / radiotherapy pathway

7/ Prostate cancer: clinically localized, high-risk, PSA 6 ng/ml, Gleason score 9, 82y.

Comorbidity: 2 x hospitalization in the last year because of falls, previous delirium

Treatment options: in principle radiotherapy + ADT or radical prostatectomy. Alternative: ADT, palliative care.

Involved settings / units (hypothesis): surgery, radiotherapy, oncology, palliative care – best supportive care.

Case 8: Systemic pathway

8/ Prostate cancer: upfront stage IV, asymptomatic bone metastases, progression after ADT + abiraterone (multiple bone metastases, high-volume).

Comorbidity: COPD, physical inactive

Treatment options: in principle docetaxel. Alternative options: other systemic therapy, radiotherapy, wait and see.

Involved settings / units (hypothesis): oncology, radiotherapy, palliative care – best supportive care.

4. Conclusion

This document reports the protocol that will be used to conduct the IMPLEMENT Study.

Deliverable 3.7 is the output of Task 3. “Develop the protocol for economic evaluation of GerOnTe in the three countries”, and supports Objective 3.3 “Develop a model to perform economic evaluation of complex healthcare services”, Objective 4 “Demonstrate in 16 study sites from three EU Countries the feasibility and effectiveness of the GerOnTe model” and Objective 5.3 “Perform economic evaluation of complex healthcare services, using the model developed under O3 and the data gathered under O4”. This document complements the following deliverables and internal documents

deliverable D3.7, that is part of work-package 3 “Developing the methods for Geronte” which supports GERONTE Objective 5.5 “Describe the care pathways for older multimorbid patients across several European countries”.

This deliverable is connected to D3.6 “Care pathways in the 3 trial countries” as the analysis will complements the interviews already conducted as part of that deliverable; D4.3. First study subject approvals package for FRONE which include the final version of the FRONE trial protocol, as part of the clinical sites that will be involved in the IMPLEMENT study are also part of the FRONE study. This deliverable will inform D5.7 Evaluation report of IMPLEMENT Study which will report the full evaluation of the IMPLEMENT Study and D5.6 “Policy paper on how to improve the management of older multimorbid patients, due M60.

The deliverable is associated to WP3 objective of analysing the distinctive elements of the care pathways for older multimorbid patients at the local level and to align GerOnTe model with these existing care pathways and to the specific requirements of different healthcare systems

- D3.1. Literature review on the cost-effectiveness of healthcare services for older multimorbid patients, which describes what are the existing methods and models suitable to capture the main potential of GerOnTe and identifies the distinctive feature of service and delivery interventions that pose challenges to the economic analysis of GerOnTe model.
- D3.3 Definition of a dashboard of indicators for the clinical trials, that is intended to finalize and consolidate the first list of QKPIs identified in the annexe on essential information for clinical studies for the evaluation of RCT FRONE and TWOBE.
- D4.3. First study subject approvals package for FRONE which include the final version of the FRONE trial protocol
- D4.4. First study subject approvals package for TWOBE which include the final version of the TWOBE trial protocol

This deliverable will inform

- Task 5.3 “Economic evaluation” and D5.3 Economic evaluation of GerOnTe, due M60
- Task 5.5 “Support the definition of new care pathways and healthcare models for the management of older multimorbid patients” and its related D5.6 “Policy paper on how to improve the management of older multimorbid patients, due M60.

D3.2 was delivered as planned at M12, and is 100% complete. Despite the protocol is 100% complete we expect to update the document at M50 to take into account any change in the development of the trial, in the identification of the clinical sites and any unplanned and unforeseen change that could occur before the economic evaluation will be performed.

5. Bibliography

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