



STREAMLINED **GERIATRIC** AND **ONCOLOGICAL** EVALUATION BASED ON
IC TECHNOLOGY
 FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT
 FOR OLDER MULTIMORBID PATIENTS

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D1.3: PROTOCOL FOR INTRINSIC CAPACITY EVALUTION

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Version	Date	Author	Description of change
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V1.1	2022-02-14	Marije Hamaker	Numbering changed
V1.2	2022-02-18	Marije Hamaker	Paragraph added on the impact of identified issues for the composition of the health care professional consortium
V1.3	2022-03-07	Marije Hamaker	Final version with dataset references added
V1.4	2023-01-12	Marije Hamaker	Revision after input from European Commission
V1.5	2023-02-21	Marije Hamaker	Final version after revision

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Executive Summary

Deliverable work status

Deliverable	Completion status in %	Deviation	Data complete or to be updated
D1.3 <i>Protocol for intrinsic capacity evaluation</i>	100 %	Minor deviations in content explained below; no deviation in time-line	Data complete
Associated Deliverables	D4.1 (D1.3. is used as input for the new care pathway which is evaluated in the clinical trials)		
Associated Objectives	GERONTE objective O1: INFORMATION (Gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management).		

Description of deliverable

This deliverable reports on the development of a protocol that can be used to evaluate intrinsic capacity and provide subsequent interventions for impairments or issues that were identified. For the development of the protocol, a scoping review of literature on intrinsic capacity and frailty assessment was performed, both within the field of geriatric oncology and in community and geriatric medicine. In addition, to assess how best to incorporate the geriatric evaluation of intrinsic capacity/frailty in the Geronte care pathway, we performed a systematic literature review to update a prior systematic review on this subject published in 2018. This highlighted the importance of having a pre-defined intervention plan to support health care providers in optimizing the patient's health status after evaluating intrinsic capacity/frailty. Therefore, Intrinsic Capacity Evaluation and Intervention Protocol (GERDAT005 published online at <https://doi.org/10.5281/zenodo.6334779>) also contains recommendations for potential interventions for each of the items that are evaluated.

Attainment of the objectives

D1.3 *Protocol for intrinsic capacity evaluation* is part of work-package 1 which supports GERONTE objective O1: INFORMATION (Gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management). There are no specific subobjectives linked to this deliverable.

The objectives related to this deliverable have been achieved in full (100% COMPLETED) and as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218 without deviations. This deliverable is now finalized, no further changes are expected in future.

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.

1. Introduction

.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.

Objectives

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

.2. Rationale

Deliverable D1.3 is part of work-package 1 which supports GERONTE objective O1: INFORMATION. An important component of Geronte is to take account of intrinsic capacity. Most older patients who are diagnosed with cancer also suffer from other illnesses and impairments that could affect their prognosis, priorities and ability to tolerate and benefit from treatment. For tailored oncologic decision making, it is essential to obtain a complete overview of the patient’s health status. This deliverable describes the process of developing a protocol for evaluation intrinsic capacity and potential interventions for impairments or vulnerabilities that were identified in this evaluation.

2. Developing the evaluation and intervention protocol

For this deliverable, DIAK (Marije Hamaker, Nelleke Seghers), OUS (Siri Rostoft) and UCD (Shane O’Hanlon) worked closely together. No Geronte partners outside the work package group were involved. In total there were eight online meetings. An overview of these meetings can be found in Annex 1. Full minutes are available upon request; as this is a public deliverable and some of the information in the minutes is privacy sensitive, we choose not to deposit them publicly.

Overview of contributions

Partner	Person(s)	Contribution
DIAK	Marije Hamaker, Nelleke Seghers	Involved throughout
OUS	Siri Rostoft	Involved throughout
UCD	Shane O’Hanlon	Involved throughout, leader

2.1 Developing a core dataset of intrinsic capacity items to be include in Geronte

Deliverable 1.1 – CORE DATASETS OF HEALTH CARE PROFESSIONALS, MULTIMORBIDITY AND INTRINSIC CAPACITY FOR GERONTE MODEL described the process of establishing a list of intrinsic capacity items that should be routinely assessed prior to oncologic decision making and for optimizing the subsequent care trajectory. The overview of this dataset, GERDAT003, can be found online at <https://doi.org/10.5281/zenodo.6334723>.

2.2 Intrinsic capacity, frailty and the comprehensive geriatric assessment

Intrinsic capacity can be defined as the composite of all the physical and mental capacities that individuals can draw on at any point in their life.¹ It is a dynamic construct: lifestyle, injuries, events at different points across the life course will have a significant impact on the intrinsic capacity trajectory, as will health-related or social interventions. While there is a general tendency for intrinsic capacity to decline from mid-adulthood onward, there will be significant variation between individuals. Furthermore, intrinsic capacity may wax and wane as an individual experiences various setbacks and potential recoveries in their life course.

While intrinsic capacity focuses on the evolution of reserves over time, a frailty assessment can be seen as a snapshot taken at a specific moment. Through an evaluation of geriatric domains, a patient’s vulnerabilities and strengths are uncovered and used as input for modifying treatment as well as implementing interventions to optimally support the patient.

For clinical utility, intrinsic capacity has been divided into subdomains that can inform clinical responses, including mobility/locomotor, cognitive, sensory, psychosocial and vitality/energy domains. In geriatric oncology, the most commonly assessed geriatric domains include the ability to perform basic and instrumental activities of daily living (ADLs and IADLs), mobility, nutritional status, cognition, mood and social support, and geriatric syndromes, in addition to comorbidity and related medication use.

¹ Islene Araujo de Carvalho, et al. Operationalising the concept of intrinsic capacity in clinical settings .WHO Clinical Consortium on Healthy Ageing 21–22 November 2017

Combining the perspectives of frailty and intrinsic capacity, assessment of the following domains is included in the Geronte care pathway:

- Function/locomotor
- Nutrition/vitality
- Cognition and psychological status
- Geriatric syndromes and sensory impairments
- Social support/environment
- Comorbidity and medication

The items from the intrinsic capacity dataset described in Deliverable 1.1 were each assigned to one of these categories. Some were rephrased for practical reasons to facilitate end-users.

No differentiation was made in the evaluation according to gender, age or cancer type, as frailty and intrinsic capacity occur irrespective of these factors.

2.3 Assessing and grading of impairments included in the intrinsic capacity dataset

Frailty is commonly assessed by geriatricians using a comprehensive geriatric assessment (CGA). In the Geronte project, the CGA will be used to assess the items in the intrinsic capacity dataset. To maximize compatibility and feasibility of the Geronte care pathway with routine geriatric care, we chose not to provide mandatory protocols on how items of the intrinsic capacity dataset should be assessed. Multiple instruments are available and research thus far has not been able to demonstrate superiority of one over another. In addition, interpretation of results derived by using the instruments will always be necessary, based on the patient's history and background.

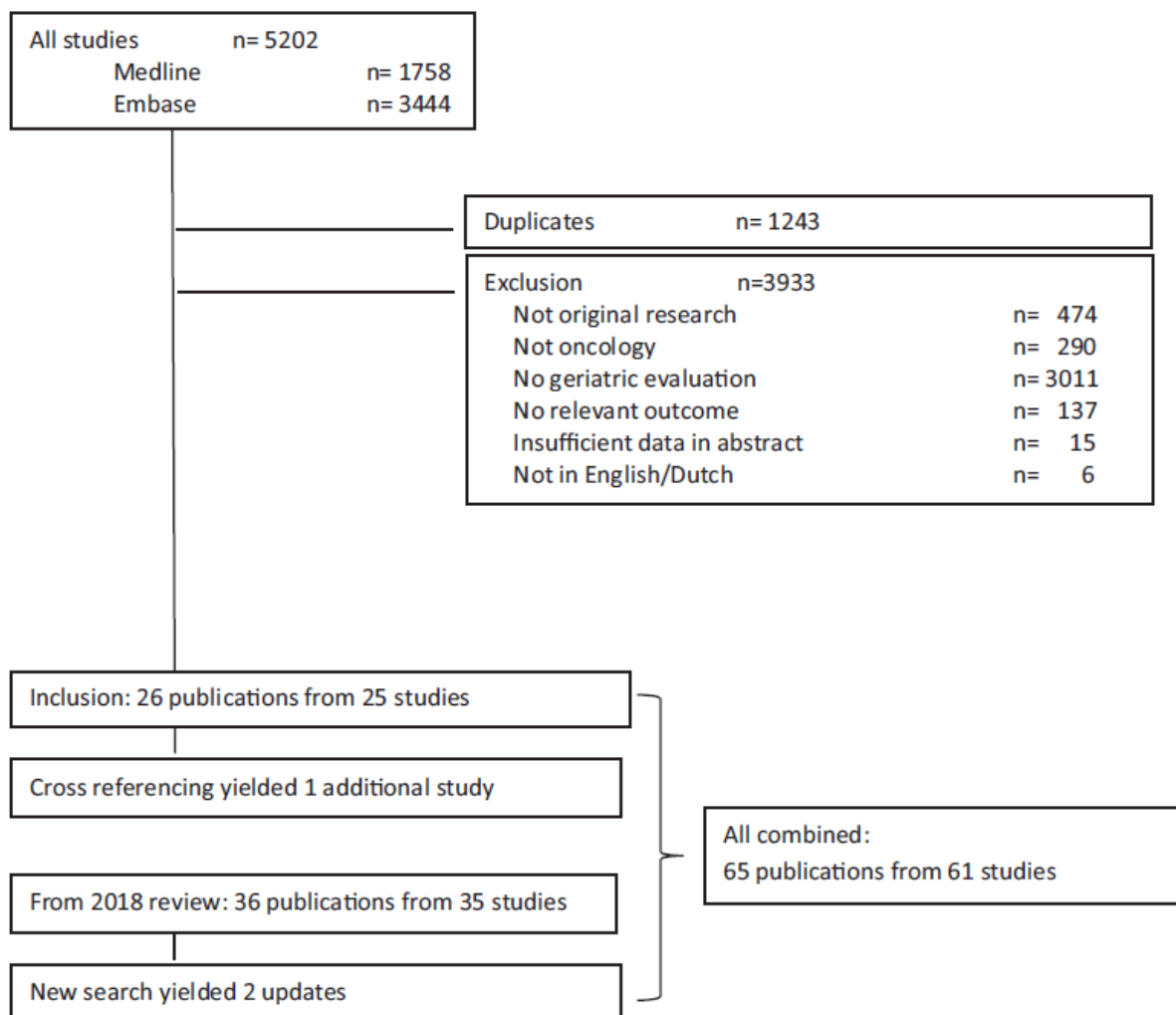
Therefore, it was determined that a geriatrician would use the data yielded by the geriatric assessment to rate each item in the intrinsic capacity dataset in terms of its severity (no impairment, mild impairment, moderate impairment, severe impairment). This is in line with scoring the severity of comorbidities as described in Deliverable 1.2 to ensure consistency in the trial.

However, to accommodate geriatricians and other health care providers in the Geronte care pathway, we performed a scoping literature search on instruments that can be used to assess various domains. As this was a scoping literature search, details of the search were not recorded. The literature search included both frailty and intrinsic capacity publications, from geriatric oncology but also from community or geriatric medicine as well as publications from WHO. An overview of the literature that was included can be found in Annexe 2. The instruments themselves are listed in the dataset GERDAT003 published online at <https://doi.org/10.5281/zenodo.6334723>.

In addition, we provided further guidance for geriatricians on how to fill out the comprehensive geriatric assessment results in the Geronte dashboard; this can be found in Annexe 3.

2.4 Systematic review on the impact of a geriatric evaluation on the management of older patients with cancer

To assess how best to incorporate the geriatric evaluation of intrinsic capacity/frailty in the Geronte care pathway, we performed a systematic literature review to update a prior systematic review on this subject published in 2018 (also listed in Annexe 1). The 2021 literature search identified 4613 new citations (1655 from Medline and 2958 from Embase), of which 1207 were duplicates. After exclusion of 3381 publications, 25 publications from 24 studies were included. From the 2018 systematic review, 36 publications from 35 studies were included. Cross-referencing yielded two additional results. Thus, the combined results of the 2018 review and the 2021 update was 63 publications from 60 studies. Full details of the search have been deposited at <https://doi.org/10.5281/zenodo.7143942>. The systematic review itself is available at <https://doi.org/10.1016/j.igo.2022.04.008>. The flow diagram of the search is shown below.



We found that after a geriatric evaluation, the oncologic treatment plan was altered in a median of 28% of patients (range 7-56%), with highest change rates in studies using a multidisciplinary evaluation. Non-oncologic interventions were recommended in a median of 72% of patients (range 6-100%), irrespective of the type of geriatric evaluation, provided that an intervention plan or specific expertise was in place. The geriatric evaluation led to lower toxicity/complication rates (60% of studies), especially if the evaluation was considered in decision making, improved likelihood of treatment completion (67%), and leads to better physical functioning (100%) and quality of life (67%).

From this systematic review, we could draw several important conclusions for the Geronte care pathway:

- For maximum benefit, the outcome of the geriatric evaluation must be taken into account during oncologic decision making; treatment must be adapted to the patient's health status, vulnerabilities and resources.
- Multidisciplinary input – as is created within the Geronte health care professional consortium – is important.
- A predefined intervention plan increases the likelihood of having non-oncologic interventions implemented that can assist in optimizing the patient's health status.

2.5 Non-oncologic interventions for impairments and issues identified in the geriatric evaluation

The first two conclusions described above were already incorporated in the Geronte care pathway. As the systematic review described above demonstrates, a predefined intervention plan may be helpful to assist in optimizing the patient's health status. For this reason, in addition to providing guidance on how geriatric domains can be assessed, we extend the literature search described in section 2.3/Annexe 2 to include recommendations for potential interventions for impairments and issues that are identified in the geriatric evaluation. These can be found in the Intrinsic Capacity Evaluation and Intervention Protocol (GERDAT005, published online at <https://doi.org/10.5281/zenodo.6334779>).

2.6 Composition of the health care professional consortium based on impairments and issues identified in the geriatric evaluation

In the Geronte care pathway, comorbidities are classified according to five multimorbidity profiles. Initially, it was the intention to formulate for each patient profile which core members should be involved in the health care professional consortium and which additional members could be added. However, based on the input from the expert panel, as described in D1.1, we determined that the heterogeneity of patients, even within a profile of similar care needs – did not allow for further specification of who should be involved for all patients within a profile (in addition to the core members – cancer specialist, advance practice nurse, geriatrician, primary care physician).

To resolve this limitation, we added suggestions in the Intrinsic Capacity Intervention and Evaluation Protocol about which health care professional could potentially be added to the health care professional consortium based on the patient's specific impairments, issues or comorbidities as identified in the geriatric evaluation.

Conclusion

This document reports on the development of the intrinsic capacity evaluation and intervention protocol. Intrinsic capacity will be assessed through a comprehensive geriatric assessment performed by the geriatrician and each item will be graded for severity. In the Geronte care pathway, this will subsequently be included in the oncologic decision making. To support non-oncologic optimization of

the patient, the protocol contains recommendations for potential interventions for each of the issues or impairments that may be identified.

D1.3 *Protocol for intrinsic capacity evaluation* is part of work-package 1 which supports GERONTE objective O1: INFORMATION (Gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management). There are no specific subobjectives linked to this deliverable.

The objectives related to this deliverable have been achieved in full (100% COMPLETED) and as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218. This deliverable is now finalized, no further changes are expected in future.

These deliverables were also used to inform and obtain other objectives and subobjectives in the project.

- Objective 2 is to develop the Holis™ GV tool for the GerOnTe model to be implemented. The first subobjective of this objective is to develop an ICT tool useful for health professionals (presenting patients' quality data on digital dashboards, helping shared decision-making, and enhancing communication inside the HPC and with patients). Deliverable 1.3 provided the information that should be included in the ICT tools for both the HPC as well as the patients.
- Finally, Deliverable 1.3 aided in the development of the Geronte care pathway, which is the foundation of Objective 4 of the GERONTE project (Demonstrate in 16 study sites from three EU countries the feasibility and effectiveness of the GerOnTe model). In particular, the deliverable 1.3 was used to develop the care pathway and trial protocol for subobjective 4.1 (Establish the protocol for two RCT (FRONE in France, TWOBE in both Belgium and the Netherlands) to demonstrate the clinical relevance of GerOnTe).

Annexe 1: Work package meetings

Meetings were already started prior to the official start of the project.

Members of the work package team were Siri Rostoft (SR) from OUS, Shane O’Hanlon (SO) from UCD, and Marije Hamaker (MH) and Nelleke Seghers (NS) from DIAK. Any additional persons who joined will be listed below

Date	Present	Topics discussed
23-3-2021	All	Content expert panel surveys, geriatric interventions/ management
13-4-2021	All	Survey round 1, intrinsic capacity/frailty
30-8-2021	All	Intrinsic capacity evaluation and management protocol
13-10-2021	All	Symptom monitoring, measurement objective physical functioning, health literacy, HPC decision making process
1-11-2021	All	Intrinsic capacity, outcome patient focus groups, OPT tool for soliciting patient preferences
8-12-2021	NS SR	Objective physical functioning, institutionalization
10-1-2022	All	Preparation for Dublin meeting
26-1-2022	All	Writing of deliverables and possibilities for publication

Annexe 2: Papers assessed in intrinsic capacity and frailty literature review

Araujo de Carvalho I, Martin FC, Cesari M, Sumi Y, Thiyagarajan JA, Beard J. Operationalising the concept of intrinsic capacity in clinical settings. WHO clinical consortium on health ageing meeting report. November 21-22 2017. Geneva, Switzerland

Beard JR, Jotheeswarean AT, Cesari M, Araujo de Carvalho I. The structure and predictive value of intrinsic capacity in a longitudinal study of ageing. *BMJ Open* 2019;9:e026119

Cesari M, Belloni G. Frailty and intrinsic capacity: Two distinct but related concepts. *Frontiers in Medicine* 2019;6 :a133.

Derman BA, Kordas K, Ridgeway J, et al. Results from a multidisciplinary clinic guided by geriatric assessment before stem cell transplantation in older adults. *Blood Adv.* 2019 Nov 26; 3(22): 3488–3498.

Hamaker ME, te Molder M, Thielen N, van Munster BC, Schiphorst AH, van Huis LH. The effect of a geriatric evaluation on treatment decisions and outcome for older cancer patients - A systematic review. *J Geriatr Oncol.* 2018 Sep;9(5):430-440.

Integrated care for older people (ICOPE): Guidance for person-centred assessment and pathways in primary care. Geneva: World Health Organisation; 2010 (WHO/FWC/ALC/19.1). Licence : CC BY-NC-SA 3.0 IGO

Integrated care for older people: guidelines on community-level interventions to manage declines in intrinsic capacity. Geneva: World Health Organisation; 2017. Licence: CC BY-NC-SA 3.0 IGO

Kalsi T, Babic-Illmann G, Ross PJ, Maisey NR, Hugnes S, Fields P, Martin FC, Want Y, Harari D. The impact of comprehensive geriatric assessment interventions on tolerance to chemotherapy in older people. *Br J Cancer.* 2015 Apr 28; 112(9): 1435–1444.

Magnuson A, Lemelman T, Pandya C, Goodman M, Noel M, Tejani M, Dougherty D, Dale W, Huuria A, Janelins M, Vankee F, Heckler C, Mohile S. Geriatric Assessment with Management Intervention in Older Adults with Cancer: A Randomized Pilot Study. *Support Care Cancer.* 2018 Feb; 26(2): 605–613.

Mohile SG, Dale W, Somerfield MR, et al. Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Chemotherapy: ASCO Guideline for Geriatric Oncology. *J Clin Oncol.* 2018 Aug 1;36(22):2326-2347.

Ommundsen N, Wyller B, Nesbakken A, Bakka O, Jordhoy MS, Skovlund E, Rostoft S. Preoperative geriatric assessment and tailored interventions in frail older patients with colorectal cancer: a randomized controlled trial. *Colorectal Disease* 2018;20 :16-25

Sattar S, Alibhai SM, Brennenstuhl AS, Kulik M, MacDonald ME, et al. Health status, emergency department visits, and oncologists' feedback: An analysis of secondary endpoints from a randomized phase II geriatric assessment trial. *Clinical Trial J Geriatr Oncol.* 2019 Jan;10(1):169-174. doi: 10.1016/j.jgo.2018.06.014. Epub 2018 Jul 21.

Van der Heide I, Snoeijs S, Melchiorre MG, Quattrini S, Boerma W, Schellevis F, Rijken M, on behalf of the ICARE4EU project team. Innovating care for people with multiple chronic conditions in Europe : an overview. Nivel report 2015

Wildiers H, Heeren P, Puts M, et al. International Society of Geriatric Oncology consensus on geriatric assessment in older patients with cancer. *J Clin Oncol.* 2014 Aug 20;32(24):2595-603.

Annexe 3: Guidance for geriatricians participating in the Geronte care pathway

In GERONTE we will make a dashboard to give a summary of the patient's cancer specific information, resources, and vulnerabilities during multidisciplinary meetings. As a geriatrician, you are asked to fill out the dashboard's comorbidity and the frailty/intrinsic capacity sections based on the geriatric assessment. In Geronte, the terms intrinsic capacity and frailty will be used synonymously. While intrinsic capacity assesses reserves and resources longitudinally, frailty is a cross sectional measurement of these reserves and resources at a specific time-point.

The advanced practice nurse (APN) will add other aspects like living situation, partner status, chair stand test, clinical frailty scale, and patient goals.

The aim of this guidance is to indicate what minimally needs to be assessed during the comprehensive geriatric assessment in the GERONTE project, to be able to complete the Geronte dashboard. We ask you to use the tools that you are familiar with, but give some suggestions in the Intrinsic capacity evaluation and intervention protocol (included as Annexe to trial protocol).

Comorbidity assessment

In addition, you will be asked to look at the patient's comorbidities. For every comorbidity, we would like you to fill out four items: whether it should have a prominent place on the dashboard, its severity (mild, moderate, severe), its impact on daily functioning (none, mild, moderate, severe) and scoring according to a disease specific measurement (if available). The dashboard contains examples of the most common comorbidities that our expert panel considered relevant for older patients with cancer and their treatment (Table 1). However, if the patient has other relevant comorbidities, you can add these as well. While adding comorbidities you can indicate whether you consider the comorbidity relevant enough to give it a prominent spot on the dashboard in the avatar.

Finally, after rating the impact of comorbidities and impairments, you need to select a multimorbidity profile out of the five that are shown in Table 2. These profiles are based on the type of care that a patient needs. If a patient fits in more than one profile, we ask you to choose the most important one.

Intrinsic capacity/frailty assessment

Table 3 lists the intrinsic capacity/frailty items to be filled out in the dashboard. For each, you will be asked to rate every item as either not impaired- mildly-moderately or severely impaired based on your clinical judgement. This will then result in a colour-coding (green, yellow, orange, red) on the dashboard.

Annexe 3: Guidance for geriatricians participating in the Geronte care pathway (continued)
Table 1. Comorbidity assessment

Comorbidities	Disease specific measurement
Answer options	
Congestive heart disease	LVEF, NYHA
Non Alcoholic Fatty Liver Disease (NAFLD) Alcoholic liver disease Liver disease	Child Pugh score, lab results
Ischaemic heart disease	LVEF, type of treatment/ revascularisation
Cardiac arrhythmia	Type, pacemaker/ICD, medication
Heart valve disease	NYHA, LVEF
Pulmonary hypertension	LVEF
COPD Obstructive Sleep Apnoea Syndrome (OSAS)	GOLD classification, supplemental oxygen CPAP use
Diabetes mellitus with complication	Hba1c
Morbid obesity	BMI
Renal disease	eGFR, dialysis (yes/no)
Neuropathy	
Parkinson's disease Parkinsonism	
Cerebrovascular disease	Sequelae - describe
Current smoking Alcohol abuse Other substance abuse	years of usage, frequency
Depression Anxiety Other mood disorder	medication-institutionalisation
Schizophrenia Psychotic disorder	Medication - institutionalisation
Concurrent cancer Previous cancer	Type, (previous) treatment, stage of disease
Mild cognitive impairment Dementia	
Severe malnutrition	Weight loss, BMI
Impaired mobility	
Other..	

Table 2. Multimorbidity profiles

Profile 1	Cardiovascular, metabolic and pulmonary disease
Profile 2	Disability, dependency and caregiver burden
Profile 3	Psychosocial health and cognitive impairment
Profile 4	Nutritional status and digestive system disease
Profile 5	Concurrent or previous cancer

Annexe 3: Guidance for geriatricians participating in the Geronte care pathway (continued)

Table 3. Frailty/ Intrinsic capacity items that need to be completed in the dashboard

CGA/ Intrinsic capacity Domain	Components that you have to rate for GERONTE
Function/ Locomotor	1. ADLs
	2. iADLs
	3. Performance status and Clinical Frailty Scale
	4a. Mobility 4b. Balance 4c. Falls 4d. Walking aid use
	5. Continence
	6. Fatigue
	Medication
Nutrition/ vitality	1. Nutritional status
Cognition and psychological status	1. Cognitive status
	2. Delirium risk
	3. Mood
	4. Anxiety
	5. Loneliness
	6. Substance abuse
Geriatric syndromes/ sensory	1. Vision
	2. Hearing
Social support/environment	1. Caregiver burden
	2. Social network
	3. Transportation issues
	4. Health literacy



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