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D7.1 ADLIFE Patient Reported Outcome Measures

Deliverable No.	D7.1	**Due Date**	31/01/2021
Description	This Deliverable presents the activities that have been conducted aimed at the identification, selection and definition of the PROMs that will be deployed in Patient Empowerment Platform (PEP) to be used by the seven pilot sites during the ADLIFE intervention.		
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Authors

Name and surname	Partner name	e-mail
Dolores Verdoy	Kronikgune	dverdoy@kronikgune.org
Ana Ortega Gil	Kronikgune	aortega@kronikgune.org
Itziar Vergara	Osakidetza	MARIAICIAR.VERGARAMITXELTORENA@osakidetza.eus
Maider Mateo	Kronikgune	mmateo@kronikgune.org
Anne Dichmann Sorknæs	OUH	anne.dichmann.sorknaes@rsyd.dk
Søren Udby	OUH	Soren.Udby@rsyd.dk
Irati Erreguerena	Kronikgune	ierregurena@kronikgune.org
Laura de la Higuera	Osakidetza	LAURA.DELAHIGUERAVILA@osakidetza.eus
Esteban de Manuel	Kronikgune	edemanuel@kronikgune.org
Ane Fullaondo	Kronikgune	afullaondo@kronikgune.org

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29/01/2021	1.0	Final Deliverable

Key data

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Abstract

ADLIFE aspires to create an outcome-based personalized care model that achieve gains in patient health status and improves Patient Reported Outcomes, through a large-scale pilot study involving seven pilot sites: Osakidetza (Spain), NHS Lanarkshire (United Kingdom); Odense University Hospital (Denmark), FALKHOSP Lower Silesia (Poland), Werra-Meißner Kreis (Germany), Region Jämtland-Härjedalen (Sweden), and Assuta Ashdod Hospital and Maccabi Healthcare Services Southern Region (Israel).

In ADLIFE, health outcomes will be measured by the use of Patient-Reported Outcome Measures (PROMs), in addition to other clinical tools and variables. PROMs allow capturing the information on the effectiveness and the quality of the care delivered as perceived by the patients themselves. Thus, PROMs will contribute to assessing health outcomes but also will assist both physicians and patients through clinical management. In particular, data collected from patients through PROMs will guide treatment, shared decision-making, and self-management. PROMs will be delivered to patients through the Patient Empowerment Platform (PEP), which will also present the personalized care plan to the patient highlighting the activities to be performed by the patient.

This deliverable shows the conceptual data framework developed to organize the process of definition and traceability of the health outcomes in ADLIFE, and the methodology followed to identify, review, and agree on the proposed set of PROMs to be used in the ADLIFE technical components. The document presents the research that has been carried out, the results obtained, specific aspects related to each PROM, and the next steps to be taken. This document will be used as a reference to provide the final selection of PROMs to be used in ADLIFE Clinical Decision Support Services and to develop the PEP supporting PROMs.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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1 Definitions and acronyms

Patient-generated health data (PGHD)

PGHD is defined as health-related data (including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information) created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern[1]. PGHD helps to address a health concern[2,3] and can be collected frequently, over long periods of time and outside of clinical encounters[4].

In addition to data captured by sensors, PGHD can also be obtained through patient data entry, such as information related to mood, social history, or medication adherence.

Patient reported outcomes (PRO)

PROs are information providing the status of a patient's health outcomes that come directly from the patient, without interpretation of that patient's response by a clinician or anyone else[5].

PROs measure symptoms, or effects, of a disease or intervention from the patients' perspective alone. PROs identify disease and therapy effects that are important to patients and may not mirror those perceived to physicians as important or impactful[6–8]. PROs can evaluate short- and long-term symptom burden and treatment toxicity and can highlight patient concerns from diagnosis through survivorship, including psychological, emotional, and financial issues.

Patient reported outcome measures (PROMs)

PROMs are standardized, validated questionnaires that are completed by patients' to ascertain perceptions of their health status, perceived level of impairment, disability, and health-related quality of life[9]. PROMs are a means of collecting information on the effectiveness of care delivered to patients as perceived by the patients themselves. They capture quality of life issues that are the very reasons why most patients seek care: to address a bothersome symptom, limited function, or ailing mental health.

Patient reported experience measures (PREMs)

PREMs (also referred to as client reported experience measures [CREMs]) are standardized tools that enable patients to provide feedback on their experience of the service provided. They are indicators of the quality of the care provided, although they do not measure it directly. PREMs do not focus on the outcomes of care but the impact of the process of the care on the patient's experience[10].

Table 1: List of abbreviations and acronyms

Abbreviation/Acronym	Defintion
AMCA	Samson Assuta Ashdod University Hospital
BDI	Baseline dyspnea index
CAT	COPD Assessment Test
CDSS	Clinical Decision Support Services
COPD	Chronic obstructive pulmonary disease
COPDF	COPD Foundation
CREM	Client reported experience measures
D7.1	Deliverable 7.1
DOA	Description of the Action
EHR	Electronic health records
EQ-5D-5L	5-level EQ-5D version
EQ-VAS	EQ visual analogue scale
FALK	Falkiewicz Specialist Hospital
FEV_1	Forced expiratory volume in 1 second
FHIR	Fast Healthcare Interoperability Resources
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HADS	Hospital Anxiety and Depression Scale
HL7	Health Level Seven
IADL	(Lawton) Instrumental Activities of Daily Living Scale
ICHOM	International Consortium for Health Outcomes Measurement
ICT	Information and Communications Technology
JITAI	Just-in-time adaptive interventions
KCCQ	Kansas City Cardiomyopathy Questionnaire
mMRC	Modified Medical Research Council Dyspnea Scale
NICE	National Institute for Health and Care Excellence
NYHA	New York Heart Association
OCD	Oxygen cost diagram
OM	OptiMedis AG

OUH	Odense University Hospital
PACIC	Patient Assessment of Chronic Illness Care
PCMP	Personalized Care Plan Management Platform
PCQ-P	Person-centered Climate Questionnaire – patient version
PCQ-S	Person-centered Climate Questionnaire – staff version
PEP	Patient Empowerment Platform
PGHD	Patient generated health data
PREM	Patient reported experience measures
PRO	Patient reported outcome
PROM	Patient reported outcome measures
QALYs	Quality-adjusted life years
RJH	Region Jämtland Härjedalen
SWEMWBS	Short version of the WEMWBS
USTRAT	University of Strathclyde
WEMWBS	Warwick-Edinburgh Mental Wellbeing scale
WP	Word Package
ZBI-12	Zarit Burden Interview: 12-item version
ZBI-22	Zarit Burden Interview: 22-item version

2 Scope and purpose of the deliverable

The work which supports the production of this deliverable (D7.1) has been completed within Task 7.1 “Patient reported outcomes measurements”, led by Kronikgune as described in the Description of the Action (DOA), in the framework of Work Package (WP) 7 “Empowerment of patient, caregivers and communities” led by Odense University Hospital. Kronikgune has been responsible for the design of the conceptual data framework that organizes the definition and traceability of the health outcomes in ADLIFE, the identification and description of the PROMs to be used in the project, the planning of the review process conducted by the pilot sites and the preparation of the current proposal that outlines the selected set of PROMs to be used in ADLIFE. This work has been performed at the seven pilot sites via the participation of local multidisciplinary team members and in close collaboration with all ADLIFE consortium, especially with WP9 and WP11 members.

2.1 Purpose of the deliverable

ADLIFE aims to develop innovative digital health solutions to support the healthcare planning and care delivery for patients over 55 years old with advanced (severe) long-term conditions (chronic obstructive pulmonary disease [COPD] and/or heart failure).

The purpose of this deliverable is to present the activities that have been conducted as part of the ADLIFE Task 7.1, aimed at the identification, selection and definition of the PROMs that will be deployed in the Patient Empowerment Platform (PEP) to be used by the seven pilot sites during the ADLIFE intervention. These pilot sites are: Osakidetza from Basque Country, NHS Lanarkshire from the United Kingdom, Southern Denmark from Denmark, FALKHOSP Lower Silesia from Poland, Werra-Meißner Kreis from Germany, RJH (Region Jämtland Härjedalen) from Sweden, and Assuta Ashdod Hospital and Maccabi Healthcare Services Southern Region from Israel.

To get started, the document describes the conceptual data framework that has been developed in the project to identify which health areas are relevant for the target population of ADLIFE. Then, the document discusses the key role played by PROMs in this project, describing the general features of these instruments (definition, classification, intended use, clinical implications, etc.) and highlighting their specific contribution during the different phases of ADLIFE. The report also presents an overview of the methodology carried out by the pilot sites to identify, select, and agree upon the set list of PROMs to be included in order to fulfill the different ADLIFE project needs. In particular, it outlines the list of PROMs to be used in the ADLIFE project, and details the criteria and process followed to guide the selection as well as their main characteristics. Finally, the deliverable explores the current status of the task and the next steps to be taken.

This deliverable is one of the key documents in contributing to truly patient-centered care and enables the personalized care plan development, patient follow-up and clinical management.

2.2 Context

ADLIFE is divided into 11 different WPs, three transversal (WP1, WP2, WP10) and seven technical ones. WP7, along with WP6, is devoted to change the care model and empowering patients, while WP3, WP4, WP5 are devoted to the technical development of ADLIFE toolbox. These five WPs will allow completing the Phase 1 (“Organizational issues and Information and Communications Technology [ICT] platforms implementation”) and lead to obtaining the ADLIFE toolbox and model that will be implemented in Phase 2 (WP8) and evaluated in seven different health systems (WP9) in Phase 3.

All issues dealt with in this document are aligned with WP6 on the ADLIFE care model, WP4 on technical specifications of the PEP, WPs 3-5 on ICT specifications, WP8 on pilot implementation, and WP9 on evaluation framework.

WP7 is responsible for the identification, collection, and analysis of patient and care professional needs, wishes and requirements to ADLIFE in order to ease the empowerment of both parts. Therefore, the objective of WP7, in close collaboration with WP4, is to enhance patients' and caregivers' quality of life and empowerment. WP4 develops the PEP as the technical infrastructure that will assist patients and their caregivers through the care plan where all the materials, PROMs and self-management interventions designed in WP7 will be delivered. The joint aim of the WPs is both to support and empower patients and, furthermore, to enhance the patients and their caregivers' quality of life by means of the PEP.

As stated before, WP7 is intended to change the care model and empower patients and their caregivers. This is a complex enterprise involving clinical, technical, and organizational aspects. One of the key aspects of the project involves the use of PROMs to record the diseases' effects on the health status of patients and caregivers and the exploration of their needs. Nonetheless, the selected PROMs are just one of the elements that support the more holistic education in empowerment and training for both caregivers and patients that will be using ADLIFE during the trial (WP8). PROMs are a part of the global set of outcome indicators that will be used for the evaluation in the WP9, along with the disease-specific health parameters, satisfaction and working conditions, health services utilization, and economic variables. The project aims to achieve quantified gains in patient health status by means of slowing down clinical and functional deterioration and improving PROs. PROMs, as a key element of the Assessment Scales based Clinical Decision Support Services (CDSS) developed in WP6 and implemented in WP5, help to monitor the clinical status and to indicate decline, functioning and dependency of ADLIFE patients.

Finally, Task 7.1 "Patient-reported outcomes measurements" is a means of verification of Milestone MS5 "ADLIFE guidelines, scales and PROMs final selection", along with Task 6.2 "Decision support". The main output of Task 7.1 is this deliverable, due by Month 13, while MS5 is due by Month 21. In this interim period between the two delivery dates, the pilots will review the most adequate assessment scales — including PROMs —, as well as evidence clinical guidelines to provide recommendations to be incorporated as CDSS. This extended period of research may result in the proposal of new PROMs that had not been considered after the analysis performed in task 7.1 and their subsequent inclusion into the definitive list of PROMs (Month 21) to be used in ADLIFE. Any update in this regard will be reported in D6.1. "ADLIFE Decision Support Modules Scope and Content" (Month 21).

2.3 Approach and scope of the deliverable

ADLIFE aims to provide a personalized integrated care to improvethe health situation, deliver more appropriate targeted and timely care for patients over 55 years old with Advanced Chronic Diseases.. ADLIFE's technology innovations will be deployed, used, and evaluated in seven healthcare environments in Spain, UK, Sweden, Germany, Poland, Denmark, and Israel.

The scope of this deliverable encompasses the design of the ADLIFE conceptual framework and the definition and selection of the PROMs to be used in the project.

The conceptual framework developed during this phase of the project allows the organization and categorization of the different health outcomes that must be measured in the targeted patients to fulfill the ADLIFE project needs. This framework will not only be used to identify and organize the PROMs needed to evaluate each outcome, but it will also be considered for the evaluation of the care plan in the last phase of the project.

PROMs will be used in the ADLIFE toolbox (Personalized Care Plan Management Platform [PCPMP], CDSS, and PEP) to reinforce patient-centered care. PROMs will provide patient-based information about health status, illness, and the effects of the treatment or other interventions, which will be used as inputs to guide and make decisions aimed at improving the quality of life of senior people with advanced chronic diseases. According to this, the intelligent tools for clinical decision-making support will detect health changes or undesired events and will adapt to patients' changing conditions and context and just-in-time adaptive interventions (JITAI) will be delivered to the patients. Finally, by the end of the project, PROMs will help to measure gains in patient health status as a consequence of the personalized care plan.

To make the ADLIFE's purposes possible, the chosen PROMs have been selected to accurately assess the health status of the patient, provide enough information to develop the care plan, and must be responsive to the interventions and activities conducted during the plan. Therefore, the selection of the PROMs to be used in ADLIFE constitutes one of the crucial tasks of the project. For this reason, this part of the project involved multiple healthcare professionals from the seven pilot sites who reviewed, analyzed and proposed the most suitable PROMs to be used in ADLIFE after a thorough and iterative process, as will be described in the next sections.

3 Definition of the health outcomes framework in ADLIFE

The ADLIFE project has been created with the ambition to produce gains in health outcomes and positively impact the health status and the quality of life of chronic patients. To that end, the project aims to provide patients, healthcare professionals, and caregivers with a digital solution to help to create and follow up personalized care plans. The ADLIFE personalized care plan is expected to have a dual impact, both on the patient and on clinical decision-making. From a patient-centered perspective, the personalized care plan will improve patients' knowledge about their disease and will promote patient engagement to self-care and treatment, which will finally result in health status improvement. Moreover, from the project perspective, the generation of integrated care plans will provide objective and measurable evidence in order to deploy the most appropriate clinical interventions according to the patients' needs.

For decades, health services provision planning and evaluation has been driven by the goal of achieving high-quality services at the lowest possible cost. However, the results obtained so far are not positive and performance in these organizations is not always highly rated[11]. Since the beginning of this century, a new perspective of value-based services has arisen, proposing that the evaluation of health services should not be based on the measurement of performed services, but on the outcomes they achieve[12]. Furthermore, these outcomes have to be relevant for the patients receiving the services. In this context, the patients' role shifts from a passive service receiver to an active decision-making one. These new services' design and evaluation paradigm are called the 'patient-centered approach' and is based on valuable health outcomes measurement. Patient-centered care in healthcare is defined as care provision that is consistent with the values, needs, and desires of patients, and it is achieved when clinicians involve patients in healthcare discussions and decisions[13].

Despite the interest in this new paradigm, patient-centered care has not been massively implemented in actual health service planning and evaluation[14], and its key elements are not always taken into consideration. In order to help change this situation, Professor Michael Porter of Harvard University, the Boston Consulting Group, and Sweden's Karolinska Institute founded the International Consortium for Health Outcomes Measurement (ICHOM) in 2012. This non-profit organization aims to provide a guide for the implementation of these new health services planning and evaluation paradigm[15]. One of the main tasks conducted by this organization is the definition and standardization of the outcomes based on patients' priorities to ensure that they remain at the center of their care. To do so, multidisciplinary groups constituted by patient representatives, clinician leaders, and registry leaders from all over the world work together to develop these sets of outcomes in a collaborative process. Thus, ICHOM's goal is to promote standardize outcomes measurement in the clinical practice, which will allow clinicians to compare to their peers worldwide and to learn from each other, and will improve the care for specific medical conditions. To date, 39 standard sets of outcome measures have been developed, covering a wide variety of medical conditions and patient populations[16]. Furthermore, focused on patient-centered results, ICHOM proposes internationally-agreed upon methods to measure each outcome.

As an example, the ICHOM standard sets for older persons and for heart failure are shown in Figure 1. The standard sets include several health outcome areas (outer ring), each of which comprises multiple dimensions (inner ring). The information that needs to be registered to evaluate each dimension can be collected using different tools and sources, such as clinical measurements, questionnaires, electronic health records (EHR), administrative databases, etc. To facilitate comparisons, measurements are case-mix adjusted, which means that they are adjusted using demographic and clinical variables.

Figure 1 - ICHOM standard sets for older person (left) and heart failure (right)[17,18].

Considering the patient-centered approach of ADLIFE, the ICHOM standard sets represent a valuable tool to define the health outcomes that need to be assessed for the purposes of this project. Thus, as part of the ADLIFE project, the original ICHOM standard sets for older people and heart failure disease have been reviewed to cover the study target population, which is represented by people over 55 years old with severe heart failure and/or COPD. This task has been conducted by a working group of ADLIFE members constituted by professionals with a wide background, including physicians, and outcome evaluation researchers. Following ICHOM methodology, this working group worked over a period of seven months on the definition of a comprehensive minimum set of outcomes. The areas finally selected for the ADLIFE project corresponded with the six areas defined in the ICHOM standard set for older person, which are the following ones:

- Disutility of care
- Symptoms, functioning quality of life
- Care
- Healthcare responsiveness
- Clinical status
- Quality of death

As previously described for ICHOM standard sets, each one of these areas includes several dimensions. In this project, in addition to the dimensions that are already comprised in the ICHOM standard sets for both older person and heart failure, new dimensions were considered to fit our target population. Table 2 summarizes the areas and dimensions included in the ADLIFE project as well as their correspondence with the areas defined for the respective ICHOM standard sets.

Table 2: ADLIFE health outcomes set. Those dimensions that were already described in the ICHOM standard sets are highlighted in green. The sign "✓" in the third and/or fourth columns indicates whether the dimension was included in the ICHOM standard set for heart failure and/or for older person. When any of the ICHOM dimensions were renamed in the ADLIFE project, the third and fourth columns show the original name as it appeared in the ICHOM standard sets.

ADLIFE Areas	ADLIFE Dimensions	Heart failure ICHOM dimensions	Older person ICHOM dimensions
Symptoms, functioning quality of life	Autonomy, control	✓ Independence	✓
	Symptom control	✓	
	Mood and emotional health	✓ Psychosocial health	✓
	Social context		✓ Loneliness and isolation
	Activities of daily living	✓	✓
Disutility of care	Polypharmacy		✓
	Appropriateness		
Quality of death	Place of death		✓
	Advance directives		
Clinical status	Patient attention time	✓ Hospital visits	✓ Time spent in hospital
	Survival (quality adjusted)		✓
	Complications (i.e. hurdle, severity)	✓	
	Side effects	✓	
Healthcare responsiveness	Participation		✓ Participation and decision making
	Continuity of care		
Care	Satisfaction		
	Carer Burden		✓

The adequacy of these health outcomes in relation to ADLIFE purposes was reviewed by a multidisciplinary team, which will be referred to in this project as the 'Clinical Reference Group'. This group is constituted by health professionals with representatives from the seven pilot sites that provide expert advice, support, and guidance throughout the project. The proposal was successfully accepted as the project's framework by the Clinical Reference Group, who

agreed that the selected areas and dimensions achieved a good balance between feasibility and comprehensiveness. The final conceptual framework approved for the ADLIFE project is represented in Figure 2.

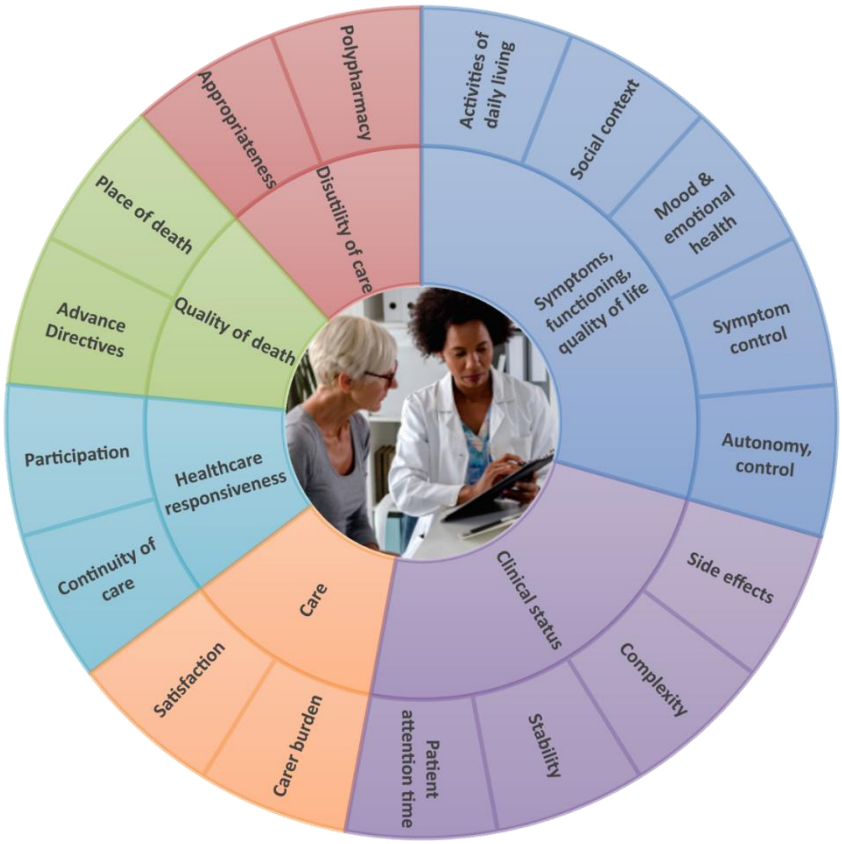

Figure 2 – ADLIFE approved health outcome set. The covered areas are presented in the inner ring and the dimensions comprised in each area are represented in the outer ring.

Once the ADLIFE health outcomes have been defined, clinical information needs to be collected from patients in order to evaluate these outcomes throughout the project.

The first step requires the identification of patients who match the eligibility criteria for the ADLIFE study. Patients will be recruited at the seven participating sites and will be classified into control (who will not receive the personalized care plan) and intervention (who will receive the personalized care plan) groups.

Then, their clinical information will be collected using different tools and sources (clinical measurements, questionnaires, EHR logs, administrative databases, etc.) at different phases of the project. Data collection will be made under ethics committee approval and subject to approved safeguards and will be differentially collected depending on the study group:

- Thus, the clinical data from the control group will be retrospectively recorded from the EHR, so only the information already available in local databases can be used for the analysis. Since no consent form will be obtained from the control group, their data will only be used anonymously.
- Regarding the intervention group, data will be retrospectively recorded, but also on a regular prospective basis as the study evolves. For these patients, informed consent will be obtained for the use of their health data, as they will also receive care that is supported by ADLIFE innovations.

The information recorded form patients will be helpful for the following purposes:

- Design the components of the digital solution developed by ADLIFE. The information provided by patients that has an impact on health outcomes will be considered to develop the digital solution.
- Personalize and adapt the care plan. The information obtained from each patient will be used by the digital solution to provide individualized recommendations depending on his/her changing condition and specific needs.
- Evaluate the benefit of the ADLIFE care plan for patients and health systems. After the digital solution is implemented, the information provided by patients will be useful to assess whether the care plan produces an improvement in health status. This evaluation will be carried out through a large-scale pilot and trial in a future phase of the ADLIFE project.

Therefore, as outlined in Figure 3, there will be a continuous flow of information between the patient and the digital solution that provides the care plan. Briefly, the care plan starts with an initial assessment of the baseline patient health status. From this point, the care team, with the support of the digital solution, will select the short- and long-term care goals that must be attained to improve the health status of the patient (i.e. dyspnea, oxygen saturation, weight loss, etc.). In order to achieve these goals, patients will be encouraged to carry out specific activities, which can be either manually designed or selected from a list of recommendations proposed by the digital solution. Patients will play an active role in the development of the care plan since they will be asked about their preferences for the details of the proposed activities (i. e., appointment schedule, type of exercise or diet, treatment, etc.). As it is conceived as an adaptive care plan, the healthcare team and the patient will follow up and review it regularly to check the goal's progress and update it as the disease evolve. Thus, patient information will be used to feed the digital solution and so, to promote personalized and adapted interventions. By the end of the process, the information will be used to measure health outcomes and compare them with the baseline status of the patient, which will allow assessing the performance of the personalized care plan.

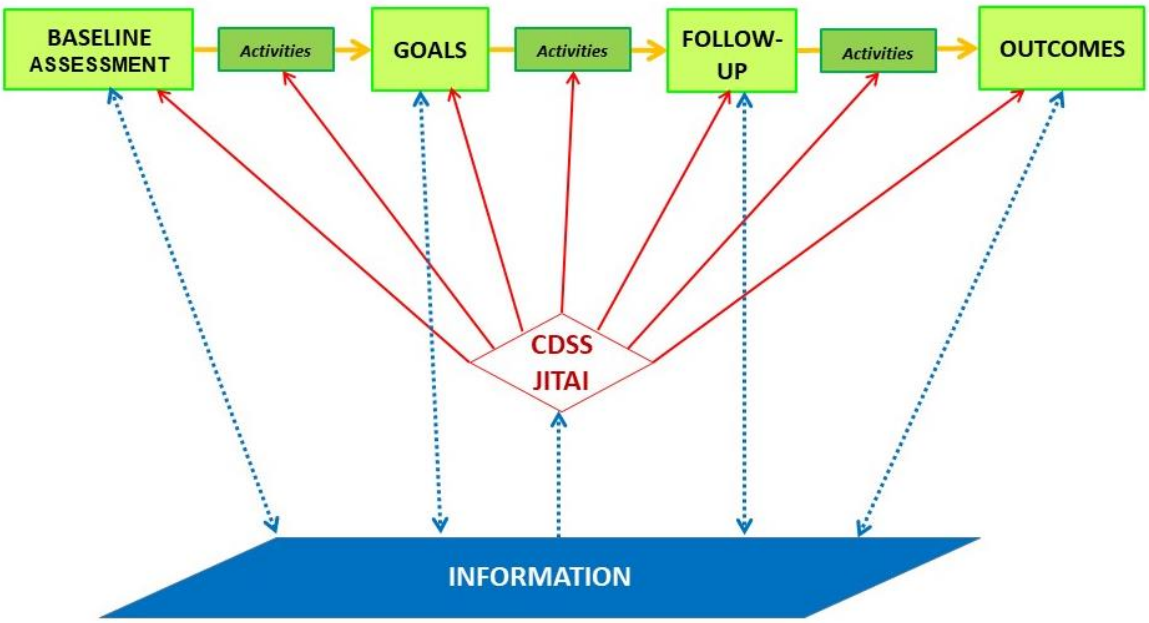

Figure 3 – ADLIFE care plan concept. Patient information will feed over time the care plan created in the digital solution and will also trigger the decision support modules within the digital solution.

More specifically, and as outlined in Figure 4, the information collected from the patient at all care plan stages (creation, follow-up and evaluation) will be used to:

- set the baseline evaluation and follow-up of patients as in a standard operation mode (without our digital solution),
- guide the definition of care plan goals and activities,
- identify the early warning signs on the disease progression,
- provide personalized recommendations based on clinical guidelines and scale scores, and
- deliver JITAIs in a personalized manner.

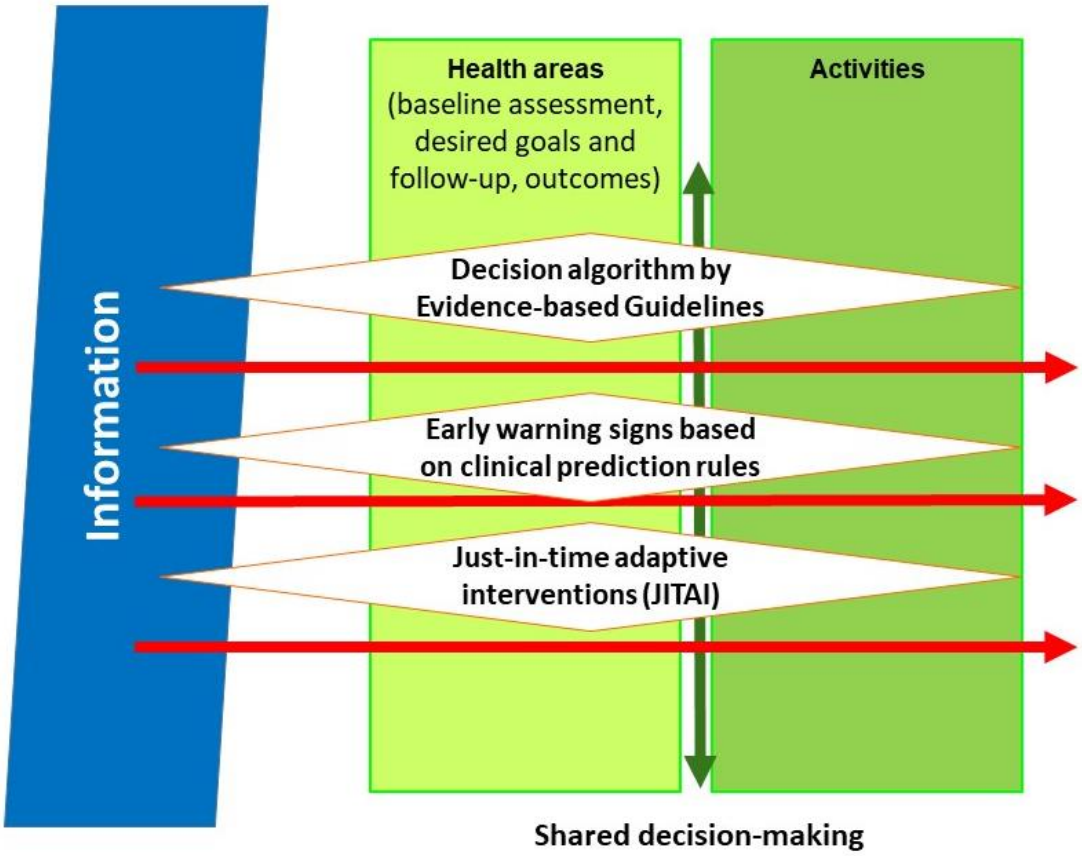

Figure 4 – ADLIFE information needs. In order to optimize the resources provided by the digital solution in all health areas, patient-centred information must drive the care plan design and incorporate shared decision-making strategies for patients, caregivers, and multidisciplinary teams.

Each one of the health outcomes considered in the ADLIFE framework is expected to be responsive to a specific care plan component. In other words, each goal or activity proposed by the care plan should have an effect on the health outcome. To ensure this responsiveness, both health professionals and patients will have the chance to review the outcome set and jointly choose the most suitable activity, objective, or goal that boosts the desired outcome. A technical solution is being developed to help to trace health outcomes and associate them with the appropriate goal or activity. ADLIFE has set a clinical data repository based on the standardized Fast Healthcare Interoperability Resources (FHIR)[19]. The Health Level Seven (HL7) FHIR Repository (open source onFHIR.io FHIR Repository) serves as a common data repository that enables reliable and secure storage and exchange of clinical data between

local EHRs, chronic disease management platforms, and patient platforms. All the components that constitute the care plan (goals, activities, observations, referrals, procedures, etc.) will be incorporated into the repository as a FHIR resource. Each one of them will be associated with the health outcome they influence by codifying the health outcome as an element or attribute of the FHIR resource. This approach facilitates the identification of the appropriate methods needed to assess each health outcome and offers a mechanism to record their evolution. A timeline for assessing the changes in the health outcomes will be scheduled to regularly update the health outcome status. In this way, a link of measurable traceability between the goals/activities and the measurable health outcomes could be created.

The collected information throughout the follow-up of the care plan will allow observing the change in each health outcome over time, which constitutes a crucial part of this project's end results. Finally, by comparing the variations observed for each outcome between those who receive the personalized care plan (intervention group) and those who do not (control group), we will be able to demonstrate that the ADLIFE intelligent personalized care model has a relevant impact on achieving the health care goals.

Among all the collected information that can be used to measure health outcomes, PROMs are the focus of this document. The next sections will focus on the definition and development of the set of the most suitable PROMs for the ADLIFE project.

4 PROMs

4.1 How do PROMs measure health?

Over the course of several decades, clinical, health services, and social sciences researchers have produced thousands of validated instruments that facilitate consistent and reliable measurement of patient-reported health[20]. Patient perspectives on their health outcomes can now be measured in most clinical areas[20].

PROMs are tools for capturing the patient's perspective on the outcomes of their own treatment and care[6]. There is a plethora of different PROM questionnaires or instruments, differing in terms of the wording and nature of the questions asked, the number of questions asked, and how the answers are scored or summed up[20]. The quality of these instruments, in terms of their reliability and validity, also varies considerably[20]. It is important to use valid, reliable, and appropriate instruments when selecting PROMs and minimize the burden on patients and healthcare teams in data collection.

Depending on the target, PROMs can be generic, disease-specific, or condition-specific[6]. The advantage of generic PROMs is that they allow comparison of outcomes across conditions[21]. There are larger number of disease-specific PROMs, but they can only be completed by those with the specific disease. When used together, generic and disease-specific PROMs can provide complementary information[6].

Advances in data science have contributed to the development of computerized adaptive testing, a predictive model that identifies the correct subset of questions selected from the full questionnaire to ask each patient based on his/her previous responses[22]. This approach of administering a questionnaire minimizes the time and effort required by the respondents to complete a test[6]. Being available in both computerized adaptive testing and traditional versions, PROMs can help to evaluate and improve the quality of healthcare services[6].

4.1.1 Generic PROMs

Generic PROMs usually measure either single aspects of health (e.g. pain) or cover multiple dimensions of health status[6]. These multidimensional questionnaires generally include items on physical functioning, role functioning, psychological symptoms, and pain[6]. Some questionnaires extend to additional domains such as sleep, social functioning, and sexual functioning[23].

If the goal of using a generic PROM is to estimate relative costs and benefits of different treatments, as in comparative effectiveness research, a range of multidimensional indices (also known as multiattribute utility measures) is available[23]. These are short health questionnaires designed to generate a single index value for the health state being measured[6]. This single index or number can then be used to derive quality-adjusted life years (QALYs) with which costs data can be associated. There are a number of recent reviews that provide guidance on selecting a generic PROM instrument that is fit for purpose[23,24].

As PROMs are often used to measure changes in function for a cohort of patients following treatment[25] or variation among patients receiving different treatments, sensitivity to small differences is an important psychometric characteristic of these instruments[6].

4.1.2 Disease-specific PROMs

Disease-specific PROMs (e.g. for a type of cancer) measure patient-reported health in a way that is particular to a disease, a set of conditions, or part of the body[20]. These have been called condition-specific measures (they are sometimes also referred to as disease-specific measures)[20]. The questions in these instruments measure the severity of a particular condition or some specific aspect of health, as viewed by the patient[20]. The questions focus on the

particular sorts of limitations or problems that people can experience as a result of a very specific condition, or a wider set of conditions that affect a body part[20].

Disease-specific PROMs are used with other disease-specific indicators, which include clinical and physiological measures (e.g. blood pressure, serum cholesterol) and outcome-related performance indicators (e.g. time to receive treatment variables, complications, and adverse events)[6].

Compared with generic instruments, disease-specific PROMs provide far more detailed information about a patient's experience of key symptoms across the trajectory of treatment and recovery for the disease. They are often adopted by disease-specific clinical registries[6]. Some of these instruments incorporate generic elements such as perceived health status or health-related quality of life[6]. Although this may seem an efficient approach, measurement errors can result from including both types of measures in one instrument (e.g. inadequate item representation on generic domains) and valid comparisons across conditions cannot then be made. Increasingly, such 'blended' instruments are being displaced by modular packages, which combine a general health profile and a complementary disease-specific instrument as well as relevant clinical indicators and information such as demographics and comorbidities[23].

4.1.3 Condition-specific PROMs

Condition-specific instruments are relevant to patients who suffer, or are suspected of suffering, from health problems[20]. They are not usually used in population health surveys. Condition-specific PROMs do not focus on a particular disease but on a broader health condition or state[6]. They include a range of functional status or disability measures used to assess the health of a particular population group such as the elderly or those with mental health problems[6,23]. Thus, 'condition-specific' apply to a service sector, such as rehabilitation or mental health services or a population segment such as the elderly. The European Heart Failure Self-Care Behaviour Scale[26] is an example of a condition-specific PROMs for measuring the behaviour of heart failure patients to maintain life, healthy functioning, and well-being.

4.1.4 Outcome measurement suites

Recently, outcome measurement suites have been developed for conditions (e.g. chronic disease management, dementia, incontinence conditions, mental health, assessment and monitoring of the elderly and asthma) and for particular situations (e.g. assessment and monitoring in primary and community care)[6]. These are collections of PROMs and other items that are seen as relevant for the outcomes monitoring of these conditions. They usually contain patient information, medical history, medication use, service use, clinical indicators, and generic and disease or condition-specific measures[23]. It is the case of the standardized datasets of ICHOM for health outcomes measurement across a range of diseases for population groups.

5 Definition and identification of PROMs in ADLIFE

As described in the previous section, PROMs are questionnaires completed by patients to ascertain perceptions of their health status, level of impairment, disability and health-related quality of life[9]. They allow the measurement of outcomes in relation to clinical interventions from the patients' perspective and represent a means of assessing clinical effectiveness and safety[10,27]. Since ADLIFE will follow an outcome-based and patient-centered approach, PROMs represent an especially valuable tool to evaluate the outcomes addressed in this project.

The outcomes that will be evaluated in the project have already been defined in section 3 of the present deliverable. The proposed conceptual framework and the categorization of health outcomes into the corresponding areas and dimensions (outlined in Figure 2) allow for an easier identification of the variables — including PROMs — that need to be considered to measure each one of these outcomes.

In ADLIFE, PROs will be used for both care improvement and/or personalized care plans assessment. PROMs will allow evaluating the most recent patients' clinical context, constituting a supportive tool for the health status assessment, the decision-making process, and the definition of care goals and activities according to the patients' specific needs.

The definition of the specific PROMs that will be relevant for ADLIFE (i.e. PROMs that will be useful to measure the health outcomes described in the ADLIFE conceptual framework) is a crucial step of this project. The selection process and the list of PROMs initially chosen for outcome measurement in the ADLIFE project will be described in depth in sections 5.1 and 5.2.

5.1 Proposed PROMs in ADLIFE

The aim of this part of the project was the selection of health-related quality of life PROMs relevant either for health outcome evaluation and/or for clinical management.

The process has been conducted by seven working teams, each one of them constituted by members of a multidisciplinary group of health professionals (hereinafter referred to as the 'Local Clinical Reference Group') and local project teams from each one of the seven participating pilot sites. These working groups have contributed to defining the PROMs that should be collected according to the ADLIFE functional requirements and needs. Thus, each one of the selected PROMs should provide useful information to assist either in the evaluation of the patients' health status and/or in the clinical decision process.

Based on their expertise and after thorough research to identify the most suitable tools to measure the health outcomes addressed in this project, the Local Clinical Reference Groups reached a consensus and agreed to include the following PROMs:

- The 5-level EQ-5D version (EQ-5D-5L),
- The COPD Assessment Test (CAT),
- The Modified Medical Research Council Dyspnea Scale (mMRC),
- The Shared decision-making: "ask 3 questions",
- The Person-centered Climate Questionnaire – patient version (PCQ-P)
- The Zarit Burden Interview: 12-item version (ZBI-12)
- A generic wellbeing questionnaire

All these PROMs have been categorized following the structure of the ADLIFE conceptual framework. Thus, each variable (PROM) has been selected to provide the information needed to cover each specific dimension included inside the corresponding health-related area. The association between PROMs, dimensions, and areas is shown in Table 3.

Table 3: Initial list of proposed PROMs in the ADLIFE project.

ADLIFE areas	ADLIFE dimensions	PROMs
Symptoms, functioning quality of life	Autonomy, control	EQ-5D-5L
	Symptom control	EQ-5D-5L
	Mood and emotional health	EQ-5D-5L
	Social context	EQ-5D-5L
	Activities of daily living	EQ-5D-5L
Clinical status	Complexity (i.e. hurdle, severity)	CAT, mMRC
Healthcare responsiveness	Participation	Shared decision-making: “ask 3 questions”
Care	Satisfaction	PCQ-P
	Carer burden	ZBI-12, Wellbeing questionnaire

Briefly, the selected PROMs address four of the six ADLIFE health-related areas, which are as follows:

- Symptoms, functioning quality of life
- Clinical status
- Healthcare responsiveness
- Care

Regarding the area “Symptoms, functioning quality of life”, the EQ-5D-5L has been selected to cover all the dimensions comprised in this area, namely “Autonomy, control”, “Symptom control”, “Mood and emotional health”, “Social context” and “Activities of daily living”. The CAT and the mMRC have been proposed to cover the dimension “Complexity”, which is part of the “Clinical status” health-related area. The Shared decision-making: “ask 3 questions” was the PROM proposed to assess the dimension “Participation”, which is included in the “Healthcare responsiveness” area. Finally, regarding the “Care” area, the PCQ-P was selected to evaluate the “Satisfaction” dimension, while the ZBI-12 and the generic wellbeing questionnaire were selected for the “Care Burden” dimension.

5.2 Description of PROMs

This section provides an in-depth description of the PROMs initially proposed in the ADLIFE project. Each one of the PROM descriptions includes a brief summary of the questionnaire, the authorship, its intended use, its format and number of questions, availability of translations, evidence of its validation, conditions of use, and a reference to an annex with the complete questionnaire in English. The wellbeing questionnaire will not be described in this section since at this stage of the project as no specific version had been chosen. The selection of the specific test that should be included was done in a later phase and so, it will be described in section 7.

5.2.1 Zarit Burden Interview: 12-item version (ZBI-12)

5.2.1.1 Summary of the questionnaire

ZBI is a questionnaire aimed to assess the level of burden experienced by the caregivers of older people with senile dementia and disabled patients[28].

Feeling burdened or distressed by the demands of caregiving is the most frequently reported outcome associated with caregiving[29]. A wide range of caregiving effects have been described in the literature, such as disruption of family routines, psychological distress, and psychological and physical morbidity including mortality, financial hardship, and work-related problems[29].

Although there is a moderate relationship between the level of patient disability and psychological stress of the caregiver, the caregivers' burden can be affected by many other factors, such as economic or social support, personality attributes, or coping strategies, among others[29]. Thus, the use of a caregiver burden screening instrument may be more effective in identifying problems than unstructured clinical questioning[30].

ZBI can be used for different purposes: screening caregivers to identify those people at higher risk; comparing disease burden in different groups or populations, tracking changes over time, and planning or evaluating the outcomes of treatment[31].

5.2.1.2 Author

Dr. Steven H. Zarit, a pioneer in the study of family caregivers, developed the first version of the questionnaire in 1980, which then comprised 29 items[32]. In recent years, several short forms of the ZBI have been published in the literature, with the advantage of reducing the time needed to complete the questionnaire. The 12-item version proposed to be used in ADLIFE was developed in 2001 by Bédard et al[33].

5.2.1.3 Intended use

The ZBI is one of the most commonly used instruments to assess caregiving burden in clinical and research settings. The ZBI was originally developed to assess the burden among caregivers of community-dwelling persons with dementia. It can help to identify signs of caregiver collapse among people looking after chronic patients with severe conditions (such as COPD and/or heart failure)[34]. The short 12-item test serves as a screening version of the ZBI suitable for caregivers of cognitively impaired older adults[33].

5.2.1.4 Format and number of questions

ZBI can be either completed by caregivers themselves or administered as an interview by a health professional. The questionnaire focuses on the subjective experience of the caregiver in order to assess the impact that providing assistance to chronic patients has on their lives[31]. Care burden can be influenced by multiple factors, including psychological, social, and financial resources and the caregiver's relationship to the care receiver[31]. The ZBI-12 comprises 12 questions spanning the most relevant dimensions about the impact of the

patient's disabilities on the caregivers' lives[31]. For each item, caregivers are asked to indicate how often they have felt that way: never, rarely, sometimes, quite frequently, or nearly always. All items are scored on a 5-point scale ranging from 0 to 4. The ZBI can be considered as a cumulative risk measure in which higher scores indicate that caregiving has a greater impact on the caregiver's life[31].

5.2.1.5 Validation

ZBI has been widely validated, and their items have demonstrated to be relevant and acceptable to caregivers from many different countries and cultures[31]. Very short forms (4 to 7 items) often do not correlate well with full or longer versions, while 12- or 14-item versions are comparable to the full scale and have good psychometric properties[31,35].

5.2.1.6 Translations

The questionnaire was developed in English and has been translated into many languages, including Polish, Swedish, Spanish or German[28]. However, there are not translated versions for Hebrew or Danish.

5.2.1.7 Licensing / Conditions of use

Students, physicians, clinical practice, non-funded academic users may access available translations of the questionnaire directly. For funded academic users, healthcare organizations, commercial users, and information and technology companies, fees may be applied[28].

5.2.1.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.1.

5.2.2 Person-centered Climate Questionnaire – patient version (PCQ-P)

5.2.2.1 Summary of the questionnaire

The PCQ is one of the most well-documented and widely tested scales available for evaluating the person-centered quality of the care environment within institutional settings[36]. The questionnaire measures how the climate care setting is perceived as person-centered[37,38]. The development of this test was based on the theory that care environments that provide a person-centered climate may represent places that maintain and protect the personhood of individuals with cognitive decline[36,38].

5.2.2.2 Author

David Edvarsson developed two versions of this test: one designed for patients (PCQ-P)[37] and another one for staff members (PCQ-S)[38].

5.2.2.3 Intended use

The PCQ-P is the version used as a PROM in ADLIFE to measure to what extent the atmosphere of the healthcare setting is experienced as person-centered by patients[39].This scale was designed to facilitate comparing the patients' perception of different units; identifying units which may require interventions; evaluating the effects of interventions on the perceived person-centered outcomes and exploring the correlation between levels of person-centeredness and measures of wellbeing[37].

5.2.2.4 Format and number of questions

The PCQ-P comprises 17 statements about the climate of the unit, considering these three dimensions: a climate of safety, a climate of everydayness, and a climate of hospitality[37].

Respondents must score each sentence according to their agreement on a 7-point Likert scale (1 = No, I disagree completely, to 7 = Yes, I agree completely)[37].

5.2.2.5 Validation

The PCQ-P has been validated in populations from different countries and characteristics[39–41].

5.2.2.6 Translations

The original PCQ-P was developed in Swedish, but it has been translated into English, and other languages such as Persian[39,42], but it is not available in all the languages spoken by the pilot sites.

5.2.2.7 Licensing / Conditions of use

The conditions of use of the PCQ-P are, at this moment, under investigation. The authors have been asked, but their answer is still pending.

5.2.2.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.2.

5.2.3 The COPD Assessment Test (CAT)

5.2.3.1 Summary of the questionnaire

The CAT is a questionnaire developed for its use in clinical practice to measure the impact of COPD on the patients' health status[43]. It is a complement to other existing instruments used to assess COPD, such as the forced expiratory volume in 1 second (FEV_1). It was designed through a rigorous scientific development process, to provide a simple and reliable measure of health status in COPD as a supportive instrument to evaluate patients and enhance the communication between patients and clinicians[44].

5.2.3.2 Author

The CAT was designed by a multidisciplinary group constituted by pulmonary specialists, primary care physicians, experts in the development of PROMs, and representatives from patient associations, supported and funded by GlaxoSmithKline (GSK)[45].

The use and further development of the CAT are overseen by a Governance Board, constituted by members from the Global Initiative for Chronic Obstructive Lung Disease (GOLD), COPD Foundation (COPDF), representatives from the research in industry and academia, and a scientific adviser with expertise in the development and use of PROs[45].

5.2.3.3 Intended use

CAT is a simple and reliable tool that allows the quantification of the impact of COPD on the patients' health. It also helps to identify where COPD has the greatest effect on the patient's health and daily life. As a result, it provides support in the assessment of the health status, promotes the communication between patients and clinicians, and contributes to a better understanding of the disease's impact. All these features make the CAT questionnaire a valuable instrument to help both clinicians and patients to manage their condition (through shared decision-making) and to reduce the burden of disease as much as possible[45].

5.2.3.4 Format and number of questions

The CAT comprises eight questions to be completed by the patients. Despite the small number of components, the test covers a broad range of effects of COPD on patients' health, represented by the following items[43]:

- Cough
- Phlegm
- Chest tightness
- Breathlessness going up hills/stairs
- Activity limitation at home
- Confidence leaving home
- Sleep
- Energy

Patients must score each question on a 6-point scale (ranging from 0 to 5) depending on how much they agree with the statement[43]. The sum of the individual items results in a final score in which higher values mean a higher impact.

5.2.3.5 Validation

The CAT was initially validated in prospective studies conducted in the USA, Europe, and China. Since these questionnaire was launched, further validation studies have been conducted around the world showing that the CAT is globally applicable[45].

It has been shown that the CAT's performance is comparable to much more complex health status questionnaires (such as the St. George's Respiratory Questionnaire), and that it is responsive to changes in the treatment and exacerbations[45]. Moreover, since 2013 it has been incorporated as the preferred measure of the symptomatic impact of COPD into clinical assessment schemes, it is included in the COPDF guide[45] and it is also recommended by GOLD Guidelines.

5.2.3.6 Translations

The CAT was originally developed in English, but, to date, nearly one hundred validated translations have been made, included those to be used by the seven ADLIFE pilot sites. The available translations can be accessed at the CAT website[44].

5.2.3.7 Licensing / Conditions of use

The CAT can be used and reproduced for personal use, clinical practice, academic research purposes, and commercial research purposes[46].

5.2.3.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.3.

5.2.4 Modified Medical Research Council Dyspnea Scale (mMRC)

5.2.4.1 Summary of the questionnaire

The mMRC is a questionnaire used to quantify the disability attributable to dyspnea in patients with respiratory diseases[47]. Thus it is useful to measure how breathlessness impacts the daily activities of the patients and helps to characterize dyspnea[47].

5.2.4.2 Author

Dr. Donald A. Mahler developed this assessment tool in 1988, based on a previous test named Medical Research Council scale[48].

5.2.4.3 Intended use

This questionnaire is an easy-to-use and efficient tool to assess the baseline functional impairment due to dyspnea and shows a good correlation with other dyspnea indicators and

with the quality of life and morbimortality of patients with respiratory diseases (particularly COPD)[47].

5.2.4.4 Format and number of questions

In order to measure the severity of the dyspnea-associated symptoms, the mMRC presents five different routine situations in which the patient may feel breathless. Patients must choose the situation that best fits with the symptoms they experience and, depending on their selection, they will receive a score ranging from 0 to 4. Higher scores indicate higher severity of the symptoms and, in turn, a higher degree of dyspnea[47].

5.2.4.5 Validation

This questionnaire has been used for more than two decades in multiple and heterogeneous populations, showing a higher inter-rater reliability[47]. Validation studies of this test have demonstrated a good correlation with other dyspnea indexes, such as the baseline dyspnea index (BDI) and the oxygen cost diagram (OCD)[49]. However, the correlation with spirometric measurements is poor and it is not accurately responsive to the treatment of COPD.

5.2.4.6 Translations

The mMRC has been translated into 12 languages[50].

5.2.4.7 Licensing / Conditions of use

The conditions of use of the mMRC are still under investigation by the ADLIFE members.

5.2.4.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.4.

5.2.5 Shared decision-making: "Ask 3 questions"

5.2.5.1 Summary of the questionnaire

“Ask 3 questions” is part of a campaign launched to encourage patients to participate in the decision-making process by asking three questions to their clinicians[51]. This short questionnaire represents the conversation that takes place between a patient and his/her health professional to reach a healthcare choice together. This approach improves the quality of the information received by patients, helps physicians to make better decisions, strengthens patient-physician communication, and improves safety and quality of care[52].

5.2.5.2 Author

The campaign was released by The Health Foundation’s MAGIC programme[51] and was based on a trial conducted by Heather L. Shepherd to promote patient involvement in shared decision-making[52].

5.2.5.3 Intended use

This questionnaire enhances patients’ awareness of shared decision-making and encourages them to think about what’s important to them when choosing a treatment or intervention, ensuring that the patient’s preferences are considered and discussed with the physician[51].

5.2.5.4 Format and number of questions

The questionnaire is composed by these three questions[51]:

- What are my options?
- What are the pros and cons of each option for me?
- How do I get the support to help me make a decision that is right for me?

5.2.5.5 Validation

The generic nature of the questions allows the use of the test for most healthcare decisions, regardless of the medical condition or the patient's characteristics[51].

5.2.5.6 Translations

The use of the questionnaire is free and can be translated into any language.

5.2.5.7 Licensing / Conditions of use

This questionnaire can be freely used.

5.2.5.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.5.

5.2.6 EQ-5D-5L (COPD & CHF)

5.2.6.1 Summary of the questionnaire

The EQ-5D-5L is a standardized instrument for examining the health-related quality of life, introduced by the EuroQol Group in 2009 to improve the instrument's sensitivity and to reduce ceiling effects of their previous test (EQ-5D-3L)[53].

The EQ-5D family of instruments has been designed to describe the health status across a wide range of disease areas. Each tool comprises a short questionnaire that provides a simple descriptive profile of the patient's health status, and a visual scale in which the patient rates his perceived current health[54].

5.2.6.2 Author

The EQ-5D-5L was developed by the EuroQol Group, which comprises an international network of multidisciplinary researchers dedicated to the evaluation of health status. The EuroQol Group Association was originally constituted by members from the United Kingdom, Finland, the Netherlands, Norway, and Sweden, but, to date, more than 100 members from all over the world are included[54].

5.2.6.3 Intended use

The EQ-5D-5L questionnaire is a generic instrument useful to measure health-related quality of life as an indicator of patients' physical, psychological and social life, which is influenced by experience, beliefs, perceptions, and expectations, and measures the subjective perspective of the patient himself.

5.2.6.4 Format and number of questions

The EQ-5D-5L is designed for self-completion by respondents. It basically consists of two pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ-VAS)[54,55]:

- The descriptive system is a preference-based health-related quality of life measure with one question for each of the five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each one of these dimensions has five severity levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. EQ-5D-5L health states can be summarized using a 5-digit code or represented by a single summary number (index value), which

reflects how good or bad a health state is according to the preferences of the general population of a country/region. An EQ-5D summary index is derived by applying a formula that attaches values (weights) to each of the levels in each dimension[54].

- The EQ-VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labeled "The best health you can imagine" and "The worst health you can imagine". The EQ-VAS can be used as a quantitative measure of the health outcome at the specific point of time that reflects the patient's own judgment.

Data collected using EQ-5D-5L can be presented in various ways[54]:

- Presenting results from the EQ-5D-5L descriptive system as a health profile.
- Presenting results of the EQ-VAS as a measure of overall self-rated health status.
- Presenting results from the EQ-5D-5L index value.

The way results can be presented is determined both by the data and by what message the researcher wish to convey to his/her audience.

5.2.6.5 Validation

These questionnaires are widely used around the world in clinical trials, population studies, and real-world clinical settings[54]. The EQ-5D has been used in a multitude of health conditions[56], has good test-retest reliability[57], and has been validated for many diseases.

There is growing evidence on the comparative psychometric performance of the EQ-5D-3L and EQ-5D-5L descriptive systems[58]. A recent systematic review found that the 5-level version performed better, or at least the same in terms of measurement properties when compared to the 3-level version, so the EQ-5D-5L is to be preferred[59]. The EQ-5D-5L is a valid and responsive measure of health status in COPD[60,61] and quality of life assessment in patients with heart failure[62].

5.2.6.6 Translations

EQ-5D-5L is available in more than 150 languages (including those to be used in ADLIFE), which have been generated using a standardized translation protocol that conforms to internationally recognized guidelines[54].

5.2.6.7 Licensing / Conditions of use

No license fee will be charged if the EQ-5D is used for a non-commercial purpose. A license fee will be charged for commercial use of the EQ-5D[63].

5.2.6.8 Complete questionnaire

The complete questionnaire can be found in Appendix 1.6.

6 Validation of PROMs by pilot sites

Once the most appropriate and suitable PROMs have been identified for the project's patient segments, each pilot site reviewed the proposed PROMs and evaluated their adequacy and coherence with the project in terms of the intended use, relevance, and feasibility.

In this way, we could be aware of the real scope of the PROMs' impact on the ADLIFE study and know to what extent they constitute relevant tools for the development and later evaluation of the personalized plan.

6.1 Methodology

To do that, the initial draft of the PROMs to be assessed in the ADLIFE project was provided to all pilot sites, where the local project teams and local staff carried out the review of each PROM.

The template was a spreadsheet divided into columns in which the proposed PROMs were listed and categorized according to their corresponding dimension and area described in the ADLIFE conceptual framework. The spreadsheet contained additional columns to collect the information required from each pilot site. Each site received their specific pilot sheet and was asked to review it, according to the following criteria:

- Intended use of the PROM. Pilot sites indicated if the corresponding PROM would be used for the control and/or the intervention group of patients. In this way, if the PROM was not routinely collected in the clinical setting, since the information from the control group can only be retrospectively recorded, the PROM was considered only for intervention patients. If a variable was collected in the site, although not always, then it was considered for both intervention and control patients.
- Relevance of the PROM in the site. Each site indicated if the PROM was considered as a relevant tool at the site, regardless of whether it was collected or not.
- Existence of an alternative tool on the site to the proposed PROM. In this case, the pilot site indicated the alternative tool used to collect the specific information.
- Confirmation whether the PROM was routinely collected in the site or not.
- Source of the site where the PROM result could be retrieved (i.e. EHR, national databases, etc.)
- Comments and/or observations of interest related to the activity that the pilot site considered of interest.

6.2 Results

Each pilot site completed their specific template and sent them back for their analysis. The results obtained for each site will be described in the next subsections.

6.2.1 Poland (FALKHOSP Lower Silesia)

The A. Falkiewicz Specialist Hospital (FALK) is a leading center in Lower Silesia (Poland) in the field of care for the elderly. It has a geriatrics and internal diseases ward. The Hospital is a provider of healthcare services/facilities and professionals for the implementation of the Polish pilot site of the CareWell Project. It has created the Geriatric Competence Centre. This is why the Hospital is participating in one more project undertaken by the Lower Silesian Voivodeship Marshal Office – TITTAN (Interreg Europe). It will also take part in the eCare project (H2020 PCP), and is also participating in a project for youth – UPRIGHT (H2020). FALK, within his geriatrics and internal diseases ward activity, has experience and competences in the area of supportive care and chronic diseases as well as in telemonitoring of life parameters. The Hospital is ready to integrate its HIS system and telemonitoring system as well as the Project's platform.

FALK considered all the proposed PROMs as relevant except the PCQ-P and the CAT. All the proposed PROMs were routinely collected in their EHR (although the PCQ-P and the mMRC were not registered for all patients), except the CAT and the "Ask 3 questions". Those recorded in the EHR could be easily retrieved for their use in ADLIFE. Regarding the intended use, the proposal of the FALK pilot was to use all the proposed PROMs both for intervention and control patients, except the "Ask 3 questions", the wellbeing questionnaire and the PCQ-P, which would be used only for the monitoring and assessment of intervention patients. Finally, the FALK pilot proposed the inclusion of two additional questionnaires for their use in ADLIFE: the Barthel Index and the Lawton Instrumental Activities of Daily Living Scale (IADL), both for the assessment of the "Care burden" dimension. The complete sheet is shown in Figure 5.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I/C	YES	Barthel Index	YES	EHR (AMMS)	
Care	Carer burden	Wellbeing questionnaire	I	YES	IADL	YES	EHR (AMMS)	
Care	Satisfaction	PCQ-P	I	NO		YES*	EHR (AMMS)	*Not registered for all patients
Clinical status	Complexity (i.e hurdle, severity)	CAT	I	NO		NO		
Clinical status	Stability (undesired events)	mMRC	I/C	YES		YES*	EHR (AMMS)	*Not registered for all patients
Healthcare responsiveness	Participation	Ask 3 questions	I			NO		
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I/C	YES		YES	EHR (AMMS)	

Figure 5 – Sheet completed by FALK. I: intervention, C: control.

6.2.2 United Kingdom (NHS Lanarkshire)

The University of Strathclyde (USTRAT) is one of the United Kingdom's leading technological universities with a world-class research profile and a reputation for excellence in teaching and

research. They have a world-leading reputation for their work with businesses and organizations, and their areas of expertise include energy, future cities, manufacturing, and health.

USTRAT will collaborate with clinicians from primary, secondary, and tertiary care that are responsible for delivering healthcare services in NHS Lanarkshire. The NHSL Lanarkshire, as part of the team of STRATHCLYDE in the project, will provide the access to 3 Acute Hospitals and over 100 sites in the region.

USTRAT considered that the CAT, the mMRC, the "Ask 3 questions", and the EQ-5D-5L were relevant PROMs for ADLIFE, while they expressed some doubts about the relevance of the ZBI, the wellbeing questionnaire, and the PCQ-P. Only the CAT and the mMRC were routinely collected and recorded in their EHR. USTRAT proposed the use of the EQ-5D-3L as an alternative tool to the EQ-5D-5L since this PROM was routinely collected and registered in their EHR. Thus, the CAT, the mMRC, and the newly proposed EQ-5D-3L could be easily retrieved during the development of the ADLIFE project and so, USTRAT proposed their use both for control and intervention groups. Therefore, the rest of the PROMs included in the set list could be used only for the intervention group. The complete sheet is shown in Figure 6.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I	Doubts	No immediate suggestion	NO	Questionnaire	
Care	Carer burden	Wellbeing questionnaire	I	Doubts	No immediate suggestion	NO	Questionnaire	
Care	Satisfaction	PCQ-P	I	Doubts	No immediate suggestion	NO	Questionnaire	
Clinical status	Complexity (i.e hurdle, severity)	CAT	I/C	YES	NO	YES	EHR	
Clinical status	Stability (undesired events)	mMRC	I/C	YES	NO	YES	EHR	
Healthcare responsiveness	Participation	Ask 3 questions	I	YES	NO	NO		
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I/C	YES	EQ-5D-3L	NO	EHR	

Figure 6 – Sheet completed by USTRAT. I: intervention, C: control.

6.2.3 Sweden – RJH (Region Jämtland Härjedalen)

Region Jämtland Härjedalen (RJH) is a County Council in Sweden. The main responsibility of RJH is primary and secondary healthcare, preventative measures, and dentistry as well as regional development in a region of approximately 130,000 inhabitants. Secondary healthcare is carried out at the sole hospital in the only town of the region, Östersund Hospital, with 416 beds and 51 outpatient clinics. Primary healthcare is carried out in 28 locations, while home and social care are the responsibilities of its eight municipalities. There are roughly 4,000 employees in 100 different professions in RJH.

As part of RJH, the Research & Development unit oversees education, including parts of the training for all medical personnel. Research & Development is responsible for and collaborates mainly within EU developmental projects and has a special emphasis on the promotion and enhancement of e-Health. The Research & Development unit functions as a resource to internal and external project partners, and also acts as a networking resource in that takes project results onto a larger marketplace.

RJH identified the ZBI-12, the CAT, and the mMRC as relevant tools for their use in ADLIFE, while they expressed some doubts about the relevance of the wellbeing questionnaire and recognized that they were not familiar with the use of the "Ask 3 questions". None of the proposed PROMs were systematically collected. Nonetheless, the information from the EQ-5D-5L was recorded in some patients, and the CAT might have been recorded at the lung clinic and some healthcare centers, while the mMRC might have been available in pulmonary centers. When collected, the CAT and the mMRC were registered in the EHR, while the EQ-5D-5L was registered in an online database, which can be accessed at https://palliativregistret.se/. The information corresponding to these three PROMs (CAT, mMRC, and EQ-5D-5L) could be easily retrieved to be used in the ADLIFE project. Thus, the intended use for these three PROMs involved both the control and the intervention patients, while the other PROMs could only be used for the intervention group. The complete sheet is shown in Figure 7.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I	YES		NO	Questionnaire	Important area, have not used a tool though
Care	Carer burden	Wellbeing questionnaire	I	Doubts		NO	Questionnaire	
Care	Satisfaction	PCQ-P	I	NO		NO	Questionnaire	
Clinical status	Complexity (i.e hurdle, severity)	CAT	I/C	YES		YES*	EHR	*Not always. Maybe at the lung clinic and some health care centers
Clinical status	Stability (undesired events)	mMRC	I/C	YES		YES*	EHR	*Not always. Available in pulmonary clinic. Primary care level does not use it regularly.
Healthcare responsiveness	Participation	Ask 3 questions	I	Not familiar with		NO		
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I/C			YES*	https://palliativregistret.se/	Not always collected

Figure 7– Sheet completed by RJH. I: intervention, C: control.

6.2.4 Israel (Assuta Ashdod Hospital together with Maccabi Healthcare Services Southern Region)

Samson Assuta Ashdod University Hospital (AMCA) is Israel's newest public hospital. The unique mission of the new not-for-profit University Hospital is to create a fully integrated care system that links the hospital staff, community health care providers, social services, community support services, the patient and the patient's family by reengineering the care

process supported by information and communication technologies, a process that is being conducted in collaboration with the Health Plans and the Municipality.

Maccabi Healthcare Services, the owner of ASSUTA, is the second largest health plan in Israel and provides comprehensive primary and secondary community healthcare services to over 2 million people. Maccabi is AMCA's key partner in developing the model for integrating hospital and community care in Assuta Ashdod University Hospital and in the ADLIFE project.

The Assuta Ashdod Hospital is one of the pilot sites in which ADLIFE will be implemented, in close collaboration with Maccabi Healthcare Services primary and secondary care services in the community in the Ashdod area.

AMCA stated that all the PROMs considered in the original set list were relevant, except the PCQ-P and the “Ask 3 questions”, which were indeed unfamiliar to the interviewed members of the pilot site. AMCA also stated that there were many wellbeing questionnaires, and so, its relevance and availability would depend on which specific questionnaire was being proposed. None of the proposed PROMs were routinely collected, although AMCA recognized that they would have used the ZBI-12 if they had it in Hebrew. Since none of these PROMs were available at any record or database, all the PROMs were proposed only for the assessment and evaluation of intervention patients. Finally, AMCA proposed the EQ-5D and the 12-Item Short Form Survey as additional tools to evaluate the “Carer burden” dimension. The complete sheet is shown in Figure 8.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I	YES		NO		We have used it have it in Hebrew
Care	Carer burden	Wellbeing questionnaire	I	YES	EQ5D, SF12	NO		There are a lot wellbeing questionnaires. We need to concrete which one.
Care	Satisfaction	PCQ-P	I	Doubts				Not familiar with. Need to see it.
Clinical status	Complexity (i.e hurdle, severity)	CAT	I	YES		NO		
Clinical status	Stability (undesired events)	mMRC	I	YES		NO		We can do this for the Interventio group. Not sure how accurate it would be for the control group
Healthcare responsiveness	Participation	Ask 3 questions	I	Not familiar with		NO		
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I	YES		NO		

Figure 8 – Sheet completed by AMCA. I: intervention, C: control.

6.2.5 Basque Country (Osakidetza)

Kronikgune is an Institute for Health Services Research that promotes and carries out management and organization research on health and socio-health services. Its scientific research program is aligned with the policies of the Basque Department of Health, which pursue the continuous adaptation of the health system by keeping people at the center and addressing the challenges derived from aging, chronicity, and dependency.

Kronikgune will work with healthcare professionals of Osakidetza to deploy the large-scale pilot. Osakidetza is the public healthcare service of the Basque Country, a region located in the north of Spain. Osakidetza was created by the Health Department of the Basque Government in 1983. All the public hospitals and primary care centers of the Basque Region are under this organization. The Basque Health System includes 14 hospitals, more than 100 primary care clinics organized through four different geographical areas, apart from the Mental Health Centers, Emergencies, and Basque Transfusion and Human Tissue Centre. More than 30,000 professionals work for Osakidetza, which could be considered the biggest organization in the Basque Country.

Kronikgune considered that all the initially proposed PROMs were relevant, except the CAT and the "Ask 3 questions". The ZBI-12, the CAT, the mMRC, and the EQ-5D-5L were routinely collected, although not recorded for all the patients. When registered, the data were available from the EHR (named OBI), and so, they could be easily accessed. The ZBI, the CAT, the mMRC and the EQ-5D-5L were used both for control and intervention patients. The complete sheet is shown in Figure 9.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I/C	YES		YES*	EHR (OBI)	*Not registered for all patients
Care	Carer burden	Wellbeing questionnaire	I	YES		NO		Not identiffied in EHR
Care	Satisfaction	PCQ-P	I	YES		NO		Not identiffied in EHR
Clinical status	Complexity (i.e hurdle, severity)	CAT	I/C			YES*	EHR (OBI)	*Not registered for all patients
Clinical status	Stability (undesired events)	mMRC	I/C	YES		YES*	EHR (OBI)	*Not registered for all patients
Healthcare responsiveness	Participation	Ask 3 questions	I					
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I/C	YES		YES*	EHR (OBI)	*Not registered for all patients

Figure 9 – Sheet completed by Kronikgune. I: intervention, C: control.

6.2.6 Denmark (Odense University Hospital – Region of Southern Denmark)

Odense University Hospital (OUH) operates four academic and community hospitals located in the Region of Southern Denmark. OUH research activities involve the development of digital solutions by combining research and science with practical implementation and technological development.

A 1,000+ bed medical center, OUH annually has more than 100,000 inpatient admissions and handles more than of 1.1 million outpatient visits in 50 different clinical departments. The hospital has a budget of €870 million and employs more than 8,700 people. In Denmark, 16 specialized care pathways are offered only at OUH, and the hospital serves patients from

across Denmark, as well as from abroad. The hospital has an organization-wide, distinct patient-centered culture where the patients' and their relatives' benefit and experience are of the highest importance. At all times, this core value is reflected in every aspect of the work done at OUH by every member of staff.

OUH indicated that the ZBI-12, the CAT, the mMRC, and the "Ask 3 questions" were relevant PROMs for ADLIFE. However, none of them were routinely collected at their site, and only the CAT and the mMRC were occasionally recorded in some of the patients. Although they did not register the EQ-5D-5L, they used other surveys to collect the same data. When collected, the information was registered in the EHR, and thus, it could be easily collected for ADLIFE. Only the CAT and the mMRC, were proposed as PROMs to be used both for control (when available) and intervention groups, while the rest of the proposed PROMs could only be used for the intervention group. The complete sheet is shown in Figure 10.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I	YES		NO		
Care	Carer burden	Wellbeing questionnaire	I	NO		NO		
Care	Satisfaction	PCQ-P	I	NO		NO		
Clinical status	Complexity (i.e hurdle, severity)	CAT	I/C	YES		YES*	EHR	*Not always routinely collected. Maybe not for all patients
Clinical status	Stability (undesired events)	mMRC	I/C	YES		YES*	EHR	*Not always routinely collected. Maybe not for all patients
Healthcare responsiveness	Participation	Ask 3 questions	I	YES		NO	EHR**	**Only for intervention patients
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I	NO		NO		The same data is collected from other surveys

Figure 10 – Sheet completed by OUH. I: intervention, C: control.

6.2.7 Germany (Werra-Meißner Kreis)

The OptiMedis AG (OM) is a management and health data analytics company registered in Germany. Its core business is to develop and manage regional integrated care delivery systems together with physician networks and other providers. OM's approach to transforming health care systems has frequently been recognized by the EU, multiple EU research projects, the Commonwealth Fund, Duke Margolis Centre for Health Policy, WHO, the World Bank, and others. Using interventions based on good health science, an excellent network of doctors and therapists, and patient motivation, OM improves the health condition of the population and creates health benefits for the entire region. At the same time, it drops health insurance expenses.

Gesunder Werra-Meißner-Kreis (Healthy Werra-Meißner-Kreis) is one of the regional health networks managed by OM. It is located in the northern Hessian district of Werra-Meißner. In May 2018, OM and the regional health insurance BKK Werra-Meissner concluded a long-term,

performance-related agreement with partial assumption of budget responsibility in accordance with § 140 a SGB V (German Social Code). Together with the administrative district, health care professionals, social institutions, and the office for economic development, a regional integrator company, Gesunder Werra-Meißner-Kreis GmbH, has set up a comprehensive health network since the end of 2018.

OM considered that all the PROMs originally suggested were relevant. However, they stated that, at that moment, PROMs were not being generally collected. However, it is expected that mMRC and CAT start to be routinely collected by 2022 and recorded at their EHR. Thus, if these two PROMs were finally available before the intervention, they could be used both for control and intervention patients. The rest of the unregistered PROMs could only be used for intervention patients. OM proposed the use of the EQ-5D-3L as an alternative to the EQ-5D-5L, since this PROM is registered at the site and, in turn, it could also be used for control patients. Moreover, OM suggested an additional PROM to assess the "Satisfaction" dimension: the Teamwork Assessment Survey. The complete sheet is shown in Figure 11.

Area	Dimension	Tool	I/C	Relevant tool?	Alternative or additional tool?	Routinely collected?	Available in the site from:	Comments
Care	Carer burden	ZBI-12	I	YES	No *ad hoc* suggestion	NO		/
Care	Carer burden	Wellbeing questionnaire	I	YES	No *ad hoc* suggestion	NO		/
Care	Satisfaction	PCQ-P	I	YES	Teamwork Assessment Survey (Shortell, Rodrigues, CHOIR (2015)	NO		/
Clinical status	Complexity (i.e hurdle, severity)	CAT	I/C*	YES	NO	YES*	EHR*	*Not collected at the moment in our EHR (Epa). The access to the EHR is expected by the begining of 2022, before the intervention. If routinely assessd by that moment, it will be possible to collect it for control patients
Clinical status	Stability (undesired events)	mMRC	I/C*	YES	NO	YES*	EHR*	*Not collected at the moment in our EHR (Epa). The access to the EHR is expected by the begining of 2022, before the intervention. If routinely assessd by that moment, it will be possible to collect it for control patients
Healthcare responsiveness	Participation	Ask 3 questions	I	YES	NO	NO		/
Symptoms, functioning, quality of life	ALL	EQ-5D-5L	I/C	YES	EQ-5D-3L	NO		For control group: reference data for the German population of the EQ-5D exists

Figure 11 – Sheet completed by OM. I: intervention, C: control.

7 Common list of PROMs

7.1 Analysis of the feedback received from the pilot sites

The data provided from the pilot sites was analyzed in order to select the final list of PROMs to be measured in ADLIFE. Figure 12 summarizes the feedback received for each PROM in terms of relevance, availability, and intended use (i.e. intervention or control patients).

Regarding the relevance for the ADLIFE project, two of the proposed PROMs were considered relevant tools by all seven pilot sites: the ZBI-12 and the mMRC. However, they were not routinely collected in all pilot sites. Thus, only FALK collected ZBI-12 on a regular basis, while the rest of the pilots either did not collect it at all (USTRAT, RJH, AMCA, OUH and OM), or in case they did it, the collection was not conducted for all patients (Kronikgune). Similarly, the mMRC was only routinely collected by USTRAT, while the other sites did not register it at all (AMCA) or not recorded it for all patients (FALK, RJH, AMCA, Kronikgune, OUH). When OM was asked, they were not collecting the mMRC, but by the time of the intervention it is expected they will do it (to date, they are in a development phase).

There was no unanimity regarding the relevance neither the availability of the rest of the PROMs. The two remaining PROMs proposed to evaluate the “Care” area — the wellbeing questionnaire and the PCQ-P — were only systematically collected by FALK. The CAT was routinely collected in USTRAT and expected to be collected by OM by the time of the intervention, whereas in RJH, OUH, Kronikgune, it was recorded, but not for all patients. The PROM selected to measure the area “Symptoms, functioning quality of life” — the EQ-5D-5L — was routinely registered in FALK, occasionally recorded in RJH, and Kronikgune, and not recorded at all in the rest of the pilot sites., the PROM “Ask 3 questions” was not collected in any of the pilot sites. It must be highlighted that it is yet a novel PROM for shared decision-making that will be included during the ADLIFE intervention as part of the care plan designed for the included patients.

Whether the PROMs were collected on a regular basis or not affects their intended use. As stated in previous sections, the information from the control group will only be retrospectively collected. Thus, only those PROMs that are routinely collected and recorded can be used for the evaluation of both the control and the intervention groups. Considering this limitation and according to the answers received form the pilot sites, all the proposed PROMs will be used for the evaluation of intervention patients, while only two PROMs — the CAT and the mMRC — will also be used for the evaluation of control patients, but only in the pilot sites where these PROMs have been collected and only when they have been registered and so, can be retrieved from the EHR, databases or similar sources.

Area	Dimension	Variable / Tool	For all pilot sites		FALKIEWICZ	USTRAT	RJH	OUH	AMCA	Kronikgune	OM
			Intended use	Relevant	Collected	Collected	Collected	Collected	Collected	Collected	Collected
Care	Carer burden	Zarit	I		Yes	No	No	No	No	Not always	No
Care	Carer burden	Wellbeing questionnaire	I	Doubts	Yes	No	No	No	No	No	No
Care	Satisfaction	Person-centred Climate Questionnaire – PCQ-P	I	Doubts	Yes	No	No	No	No	No	No
Clinical status	Complexity (i.e hurdle, severity)	CAT (COPD Assessment Test)	I/C (when available)	Doubts	No	Yes	Not always	Not always	No	Not always	Yes*
Clinical status	Stability (undesired events)	Dyspnea (mMRC)	I/C (when available)		Not always	Yes	Not always	Not always	No	Not always	Yes*
Healthcare responsiveness	Participation	"Ask 3 questions"	I	Doubts	No	No	No	No	No	No	No
Symptoms, functioning, quality of life	ALL	EQ-5D-5L (COPD & CHF)	I	Doubts	Yes	No	Not always	No	No	Not always	No

Figure 12 – Summary of the feedback received on the relevance, availability, and intended use for the evaluation of intervention (I) and/or control (C) patients. “Yes*” means that the PROM was not being routinely collected when the pilot site was asked, but it is expected to be collected by 2022, before the start of the intervention.

7.2 Update of the proposed list of PROMs

The target patients for the ADLIFE project are old people with advanced chronic diseases (COPD and/or heart failure). Slowing down clinical and functional deterioration and improving PROs is crucial for improving the quality of their lives. The analysis of the relevance, feasibility, and intended use of the initial list of proposed PROMs, revealed a lack of information regarding certain key aspects of the health outcomes reported by patients that could be improved. Therefore, the list of PROMs was further updated to match with new patient needs identified during the pilot analysis and feedback phases. The main updates in comparison to the previous list were:

- Incorporation of four additional PROMs to address dimensions of the ADLIFE framework not fully covered in the previous version.
- Redefining the version of the ZBI that should be included based on the author's recommendations and considering the availability of validated translations for its use in the ADLIFE pilot sites.
- Definition of the specific PROM that should be used as the wellbeing questionnaire.

The sites identified some key dimensions which were not fully covered by the proposed list of PROMs and suggested additional tools that were not included in the initial set list. Overall, four new PROMs were proposed:

- The Barthel Index
- The Lawton IADL
- The Kansas City Cardiomyopathy Questionnaire (KCCQ)
- The Hospital Anxiety and Depression Scale (HADS)

As had been done with the other tools, the new PROMs were categorized according to the ADLIFE conceptual framework.

All of them covered the already included "Symptoms, functioning quality of life" health-related area, albeit different dimensions. Three of them were proposed to assess the dimension "Activities of daily living", which was previously measured only with the EQ-5D-5L. This dimension refers to the basic self-care tasks of everyday life, such as dressing, bathing, and toileting. "Instrumental activities of daily life" go beyond this concept and include tasks that an individual needs to carry out to live independently in the community, for example, using the telephone, managing money, and preparing meals. The assessment of both activities and instrumental activities of daily life provides a general picture of a person's self-care abilities. Considering the relevance of these measurements in older and chronic patients, the ADLIFE conceptual framework was updated and included specific PROMs to further address the dimension "Activities of daily living". Two of them, the Barthel Index and the Lawton IADL, are generic PROMs that can be used in any disease population, while KCCQ is a disease-specific questionnaire to address health outcomes in patients with heart failure. The fourth PROM — the HADS — was included to address the "Mood and emotional health" dimension which was being covered only by the EQ-5D-5L. HADS is a reliable instrument for the detection of states of depression and anxiety in the clinical setting and for the management of emotional disorders in patients in medical and surgical departments.

Apart from the inclusion of new PROMs, the already included ZBI was reviewed and updated. The original set of PROMs proposed the use of the 12-item version of the questionnaire, which revealed important limitations after the analysis. On the one hand, the versions clearly recommended by the author (Dr. Zarit) are the 22-item and the 29-item questionnaires[28]. On the other hand, the 12-item version has not been translated into Danish or Hebrew, two of the languages used by the ADLIFE pilot sites. In contrast, the 22-item test has been translated

into a wide variety of languages, including those used by the seven pilot sites. Considering the author's recommendation and the availability of translations, the 22-item was selected for the final list of PROMs.

In addition to the ZBI, the original list of PROMs proposed the use of another generic wellbeing questionnaire to address the "Carer burden" dimension. Since there is a wide variety of tests that can be used to evaluate the patients' wellbeing, it should be specified which one to use in the ADLIFE project. Thus, the Warwick-Edinburgh Mental Wellbeing scale (WEMWBS) was selected to be included in the final list of PROMs.

Finally, the inclusion of additional instruments to address the dimension "Autonomy and control" was discussed. The PROM Patient Assessment of Chronic Illness Care (PACIC) as well as the evaluation of other lifestyle activities (such as the number of walked steps and other activities that may act as indicators of mental health, including cooking, reading, etc.) might seem suitable and appropriate for the ADLIFE patients' needs. However, one of the objectives of the consortium has been to achieve the minimum and sufficient set of PROMs to be reported by patients. This set should, on the one hand, comply with the information needed in physical/biological, psychological, social, spiritual, practical, and overall empowerment dimensions. On the other hand, the set should not overwhelm ADLIFE patients with a large number of questionnaires to be completed. In other words, the amount of information that should be collected from patients to fulfill the ADLIFE's needs has to be commensurate with the declined health of the targeted patients. For this reason, only those PROMs that were closely related to the ADLIFE study population were finally included, and so, PACIC or other lifestyle activities have not been included in the common list of PROMs to be reported by patients.

7.3 New PROMs added

7.3.1 Kansas City Cardiomyopathy Questionnaire (KCCQ)

7.3.1.1 Summary of the questionnaire

The KCCQ is a questionnaire designed to measure the health status perceived by patients with heart failure. To do so, this tool quantifies, in a disease-specific fashion, physical function, heart failure symptoms (frequency, severity, and recent change), impact on social function, self-efficacy and knowledge, and quality of life[64–66]. The concepts quantified in the KCCQ are designed to be relevant and appreciable by all heart failure patients specified in the qualified context of use.

7.3.1.2 Author

The KCCQ was developed and validated by John Spertus, Director of Cardiovascular Education and Outcomes Research at the Mid America Heart Institute, and Professor of Medicine at the University of Missouri[64,66].

7.3.1.3 Intended use

The questionnaire has been developed to provide a better description of health-related quality of life in patients with congestive heart failure and may serve as a clinically meaningful outcome measure in cardiovascular research, patient management, and quality assessment[66]. It can be used in feasibility and pivotal studies of patients with symptomatic heart failure and for the evaluation of safety and effectiveness for heart failure medical devices[65].

7.3.1.4 Format and number of questions:

The questionnaire must be completed by patients and includes 23 items used to quantify the following six domains and two summary scores[65]:

- Symptom Domain quantifies the frequency and burden of clinical symptoms attributable to heart failure, including fatigue, shortness of breath, paroxysmal nocturnal dyspnea and patients' edema/swelling.
- Physical Function Domain measures to what extent the heart failure symptoms experienced by patients limit the performance of routine activities.
- Quality of Life Domain evaluates the patients' assessment of their quality of life considering the current status of their heart failure.
- Social Limitation Domain quantifies the extent to which heart failure symptoms impair patients' ability to interact in social activities.
- Self-efficacy Domain quantifies patients' perceptions of how to prevent heart failure exacerbations and manage complications when they arise.
- Symptom Stability Domain measures recent changes in patients' symptoms by comparing the patients' frequency of heart failure symptoms at the time of completing the KCCQ with their frequency 2 weeks before.
- Clinical Summary Score includes total symptom and physical function scores to correspond with the New York Heart Association (NYHA) Classification.
- Overall Summary Score includes the total symptom, physical function, social limitations, and quality of life scores.

Patients must rate each item on a scale continuum with equal spacing from worst to best. Scores are transformed to a range of 0-100, in which higher scores reflect better health status[64].

7.3.1.5 Validation

The KCCQ is the most sensitive, specific, and responsive health-related quality of life measure for heart failure[64]. Validity, reliability, responsiveness, and interpretability support the use of this instrument to measure health-related quality of life in patients with heart-failure[64].

7.3.1.6 Translations:

The questionnaire was originally developed in English and it has been translated into 96 languages, including those to be used in ADLIFE[67,68].

7.3.1.7 Licensing / Conditions of use

The license can be obtained through a registration form in which information about the organization and intended use must be provided[68].

7.3.1.8 Complete questionnaire

The complete questionnaire can be found in Appendix A.1.7.

7.3.2 Lawton Instrumental Activities of Daily Living Scale (IADL)

7.3.2.1 Summary of the questionnaire

The Lawton IADL evaluates the ability of patients to perform tasks that are required to live independently in the community, such as using a phone, shopping, or cooking[69,70].

Aging, worsening chronic illnesses, and hospitalization usually contribute to a decline in the ability to perform this kind of activities[70]. The functional assessment of patients helps to identify their needs and to provide personalized care[70]. The Lawton IADL can be used to assess independent living skills and to detect early signals of functional decline that need further assessment[70,71].

7.3.2.2 Author

The questionnaire was developed by M. Powell Lawton and Elaine M. Brody in 1969 to assess the more complex instrumental activities of daily living necessary for living in the community[69,71].

7.3.2.3 Intended use

The Lawton IADL is used to assess the everyday functional competence of patients[72]. This instrument is designed to be used among older adults, and may be used in community, clinic, or hospital settings, but not for institutionalized older adults[70]. It may be used as a baseline assessment tool or to observe the changes in functional decline over time[70].

7.3.2.4 Format and number of questions

The questionnaire covers eight domains of function[70]:

- Ability to use the telephone
- Shopping
- Food preparation
- Housekeeping
- Laundry
- Mode of transportation
- Responsibility for own medications
- Ability to handle finances

Patients are scored according to their highest level of functioning in each category, with a total score ranging from 0 (low function, dependent) to 8 (high function, independent)[70].

7.3.2.5 Validation

This assessment tool has been widely used both in research and clinical practice. The original study tested its reliability and found a good correlation with other scales that measure domains of functional status[70].

7.3.2.6 Translations

The test was originally developed in English and has been translated into some of the languages to be used by the pilot sites, including Hebrew, Spanish, German, or an adapted version of Swedish[73–76].

7.3.2.7 Licensing / Conditions of use

Permission is granted to reproduce, post, download, and/or distribute the questionnaire in its entirety for not-for-profit educational purposes only, provided that The Hartford Institute for Geriatric Nursing, New York University, Rory Meyers College of Nursing is cited as the source[70].

7.3.2.8 Complete questionnaire

The complete questionnaire can be found in Appendix A.1.8.

7.3.3 Barthel Index

7.3.3.1 Summary of the questionnaire

The Barthel Index is a scale used to measure the capability to perform basic activities in daily life, reflecting the ability to function independently[77]. The questionnaire measures the degree

of assistance required by an individual by asking about mobility and self-care activities[77]. Time taken and physical assistance required to perform each activity are used to assess the independence of the patient[77].

7.3.3.2 Author

The Barthel Index was developed by Mahoney and Barthel in 1965, although many additional versions have been developed after its initial design[78,79].

7.3.3.3 Intended use

The objective of the Barthel Index is to assess an individual's daily functioning regarding the activities of daily living and the mobility[79].

7.3.3.4 Format and number of questions

The questionnaire includes ten items related to the following personal and basic activities of daily life[77]:

- Feeding
- Personal toileting
- Bathing
- Dressing and undressing
- Getting on and off a toilet
- Controlling bladder
- Controlling bowel
- Moving from wheelchair to bed and returning
- Walking on level surface (or propelling a wheelchair if unable to walk)
- Ascending and descending stairs.

Patients must rate each item depending on whether they can perform the activity on their own or need assistance. Each item is scored on a 3-point scale (0 = unable, 1 = needs help, 2 = independent) and the final result is expressed as a percentage, with lower values meaning a higher degree of dependency[77].

7.3.3.5 Validation

The Barthel Index is an easy-to-apply method that has widely demonstrated its reliability, validity, and capability to detect changes. Moreover, it is easy to interpret and can be easily adapted to different cultural environment[80].

7.3.3.6 Translations

It has been translated into many languages, including those needed for each pilot site[79].

7.3.3.7 Licensing / Conditions of use

Students, physicians, clinical practice, not-funded academic users may access available translations of the questionnaire directly. For funded academic users, healthcare organizations, commercial users, and information and technology companies, fees may be applied[79].

7.3.3.8 Complete questionnaire

The complete questionnaire can be found in Appendix A.1.9.

7.3.4 Hospital Anxiety and Depression Scale (HADS)

7.3.4.1 Summary of the questionnaire:

HADS is a generic PROM that assesses both anxiety and depression, which commonly coexist. Anxiety is poorly recognized by clinicians, and it often precedes depression in response to stressors[81]. The anxiety and depression subscales are also useful to measure the severity of the emotional disorder[82]. HADS focuses on non-physical symptoms, avoiding somatic symptoms of illness, such as fatigue and insomnia or hypersomnia. Thus, it can be used for the detection of anxiety and depression in people with physical health problems, including old and chronic patients[82]. However, HADS does not include all of the diagnostic criteria of depression or all those required by the Health and Work Development Unit National Depression and Long Term Sickness Absence Screening Audit. For this reason, additional questions on appetite, sleep and self-harm/suicidal thoughts have to be asked[81].

7.3.4.2 Author:

The HADS was developed by R. P. Zigmond and A. S. Snaith in 1983 to measure anxiety and depression in the setting of a hospital medical outpatient clinic[82].

7.3.4.3 Intended use

This questionnaire is a reliable tool to detect states of depression and anxiety in medical and surgical departments[82]. This instrument contributes to facilitating the detection and management of emotional disorders in patients under investigation or treatment[82].

7.3.4.4 Format and number of questions:

The HADS is a 14-item questionnaire that includes two subscales: a 7-item subscale to assess anxiety, and another 7-item subscale for depression.

Although the anxiety and depression questions are interspersed within the questionnaire, they must be scored separately[81]. Each item on the questionnaire is scored from 0 to 3 depending on the frequency or severity of the feelings experienced by the patient[81]. The total score ranges from 0 to 21 for either anxiety or depression.

7.3.4.5 Validation:

The HADS questionnaire has been widely validated in many languages, countries, and settings including general practice and community settings[81]. It is one of the National Institute for Health and Care Excellence (NICE) recommended tools for the diagnosis of depression and anxiety[81]. Apart from diagnosing, it can also be used to follow up the progression of the psychological symptoms[81].

7.3.4.6 Translations:

The HADS has been translated into many languages, including those to be used by the ADLIFE pilot sites[83].

7.3.4.7 Licensing / Conditions of use

The use of the questionnaire is licensed by GL Assessment. A license agreement must be completed beforehand and a user fee is required for all uses (commercial, healthcare organizations and academic users)[83].

7.3.4.8 Complete questionnaire

The complete questionnaire can be found in Appendix A.1.10.

7.3.5 Zarit Burden Interview: 22-item version (ZBI-22)

7.3.5.1 Summary of the questionnaire

As described in section 5.2.1, the different versions of the ZBI are questionnaires designed to evaluate the burden experienced by the caregivers of patients with severe conditions[28].

7.3.5.2 Author

With the 29-item questionnaire as a starting point, Dr. Steven H. Zarit developed a shorter version that included 22 items, generating the most used version of the questionnaire[84].

7.3.5.3 Intended use

The objective of this questionnaire is exactly the same described for the shorter version: to assess caregiving burden in clinical and research settings[28].

7.3.5.4 Format and number of questions

Caregivers are asked to answer 22 questions about the impact of the patient's disabilities on their lives[31]. These questions cover the following dimensions[31]:

- Burden in the relationship (6 items)
- Caregiver's emotional wellbeing (7 items)
- Social and family life (4 items)
- Finances (1 item)
- Loss of control over one's life (4 items)

For each item, caregivers are asked to indicate how often they have felt that way: never, rarely, sometimes, quite frequently, or nearly always. All items are scored on a 5-point scale ranging from 0 to 4. A total score is computed by summing the 22 items. The ZBI can be considered as a cumulative risk measure in which higher scores indicate that caregiving has a greater impact on the caregiver's life[31].

7.3.5.5 Validation

ZBI-22 has been widely validated, and their items have demonstrated to be relevant and acceptable to caregivers from many different countries and cultures[31].

7.3.5.6 Translations

The questionnaire has been translated into many languages, including those to be used in the ADLIFE project[28].

7.3.5.7 Licensing / Conditions of use

Students, physicians, clinical practice, not-funded academic users may access available translations of the questionnaire directly. For funded academic users, healthcare organizations, commercial users, and information and technology companies, fees may be applied[28].

7.3.5.8 Complete questionnaire

The complete questionnaire can be found in Annex 1.11.

7.3.6 Wellbeing questionnaire (WEMWBS)

7.3.6.1 Summary of the questionnaire

The WEMWBS was designed to monitor the mental wellbeing of the general population and for the evaluation of projects, programs, and policies that aim to improve mental wellbeing[85].

The WEMWBS was developed as part of the Scottish Executive's National Programme for Improving Mental Health and Wellbeing in Scotland and was funded by the NHS Health Scotland[85]. The development of WEMWBS involved the review of concepts of mental wellbeing and existing scales as well as a discussion with a panel of experts. The final questionnaire was based on a previous test, the Affectometer 2, which had been identified as one of the most promising measures of mental wellbeing, but which accounted for important limitations[86]. Taking this scale as a starting point, new items were developed, discussed, and iterated until the final questionnaire was resolved for testing[86].

A shorter version of the WEMWBS (the SWEMWBS) was later developed, showing robust measurement properties[87].

7.3.6.2 Author

The WEMWBS was developed by a panel of experts led by Professor Sarah Stewart-Brown and supported by Professor Stephen Platt from the University of Edinburgh[85]. Dr. Ruth Tennant played an important role in the original study, and so, she is the first author of the paper that presents the results from the study[86].

7.3.6.3 Intended use

All the items included in the scale inquire about positive aspects of mental health and the questionnaire supports positively focused interventions. As a result, the WEMWBS is well received by study participants, service users, and practitioners[85].

The WEMWBS is useful to indicate the overall level of mental wellbeing, to measure the effect of interventions aimed at improving mental wellbeing, and contributes to a better understanding of mental wellbeing, both from the patient's and the institutions' perspective. Moreover, it can be used either with the general population or with targeted groups[85].

Feedback from mental health service users and carers demonstrates a preference for WEMWBS over other mental health scales[85].

7.3.6.4 Format and number of questions

The original WEMWBS is a 14-item scale, while the SWEMWBS comprises 7 items. The former has been validated in more studies and is preferred in situations where it is valuable to give study participants a picture of their mental wellbeing, so it will be used in the ADLIFE project[88].

The WEMWBS scales have been designed to be self-completed. The 14 items are all worded positively and cover both feeling and functioning aspects of mental wellbeing, which makes the test more accessible[85]. Each one of the statements included in the test must be scored on a 5-point-scale depending on the frequency that the feeling is experienced (1 = None of the time, 5 = All of the time). The overall score for the WEMWBS is calculated by summing the individual scores, resulting in a total score ranging from 14 to 70. A higher WEMWBS score indicates a higher level of mental wellbeing[86].

The total score gives an overall estimation of the individual wellbeing. Moreover, the change in the score measured at two different times can detect improvement or deterioration in many different situations. A threshold of 3 points can be taken to represent 'meaningful change' between measurement points in individuals[88].

7.3.6.5 Validation:

WEMWBS was initially tested with students in England and Scotland and with a large representative sample of the general population in Scotland with positive results[86].

The scales have been validated for use in a wide variety of geographical locations, languages, and cultures and at many different settings, such as the workplace, schools, clinical settings, and community wellbeing projects[89].

WEMWBS has been extensively validated in adult populations, young people, minority populations, and users of mental health services and their carers[90–92]. All of them share the opinion that WEMWBS is easy to complete and provides a credible picture of mental wellbeing.

7.3.6.6 Translations:

The 14-item scale and the 7-item scale WEMWBS have been translated into many languages including those to be used in ADLIFE[93]. However, the available translations in Danish, German, Hebrew, and Polish have not been validated in the literature[93].

7.3.6.7 Licensing / Conditions of use

The questionnaire is protected by copyright, so one of the following licenses is needed to use it[94]:

- Non-commercial use, available for organizations whose main purpose is not directed towards commercial advantage or monetary compensation.
- Commercial use, for other kind of organizations.

7.3.6.8 Complete questionnaire

The complete questionnaire can be found in Annex 1.12.

7.4 PROMs researched and considered but not included

7.4.1 Patient Assessment of Chronic Illness Care (PACIC)

7.4.1.1 Summary of the questionnaire

The PACIC is a questionnaire designed to provide the patients' perspective about the care received in relation to their chronic illnesses[95]. This scale is based on the key elements of modern self-management support (e.g., collaborative goal settings, problem-solving, and follow-up) and planned, proactive, and population-based care.

7.4.1.2 Author

The PACIC was developed and validated in the study published by Glasgow *et al*.[95] and the authorship of the test is attributed to The MacColl Center[95].

7.4.1.3 Intended use

The PACIC collects patient reports of the extent to which they have received specific actions and attention that are congruent with the 'Chronic Care Model', an approach designed to improve chronic illness care[95]. It can be used in a variety of health care settings and applied to adult patients having one or more of many different chronic illnesses[95].

7.4.1.4 Format and number of questions

There are two versions of the PACIC questionnaire: the 20-item PACIC[95] and the 26-item PACIC+[96].

The PACIC measures specific actions or qualities of care that patients experienced in the healthcare system. The comprised items are categorized in the following subscales:

- Patient activation (3 items)
- Delivery system design/decision support (3 items)
- Goal setting (5 items)

- Problem-solving/contextual counseling (4 items)
- Follow-up/coordination (5 items)

Each item must be scored on a 5-point scale (0 = Almost never, 5 = Almost always) according to the frequency of the care received[95].

The PACIC+ includes 26 items: the same 20 items from the PACIC, and six additional items. These new items are derived from the '5As' model (ask, advise, agree, assist, and arrange), a patient-centered model of behavioral counseling congruent with the Chronic Care Model and frequently used to enhance self-management support and linkages to community resources[95].

7.4.1.5 Validation

The PACIC was validated in the original study by Glasgow *et al*.[95] for patients with a variety of chronic diseases. The PACIC+ was also validated for patients with diabetes type 2[96].

Psychometric performance has been further explored in a wide variety of studies in different countries[97]. The PACIC has been proposed as one of the most promising tools to measure the quality of the integrated chronic care received by patients[98].

7.4.1.6 Translations

Many teams across the world have translated and adapted the PACIC, including Dutch, Spanish, Danish, French, and German[99–102].

7.4.1.7 Licensing / Conditions of use

Individuals interested in using the PACIC in non-commercial quality improvement work or research are free to do so. No permission is needed for personal or non-commercial use. Commercial use of the PACIC requires a written license from Kaiser Permanente (formerly Group Health Cooperative)[103].

7.4.1.8 Complete questionnaire

The complete questionnaires can be found in Annex 1.13 and Annex 1.14.

7.5 Updated list of PROMs

All the above analysis has helped to improve and refine the current list of PROMs to be used in the ADLIFE project.

Table 4 summarizes the included PROMs, categorized according to the ADLIFE conceptual framework.

Table 4: Updated list of PROMs to be used in the ADLIFE project. PROMs that have been modified from the previous version or newly incorporated are shown in boldface type.

ADLIFE areas	ADLIFE dimensions	PROMs
Symptoms, functioning quality of life	Autonomy, control	EQ-5D-5L
	Symptom control	EQ-5D-5L
	Mood and emotional health	EQ-5D-5L, **HADS**
	Social context	EQ-5D-5L
	Activities of daily living	EQ-5D-5L, **Lawton IADL**, **Barthel Index**
Clinical status	Complexity (i.e. hurdle, severity)	CAT, mMRC
Healthcare responsiveness	Participation	Shared decision making: “ask 3 questions”
Care	Satisfaction	PCQ-P
	Carer burden	**ZBI-22**, **WEMWBS**

8 Conclusions and next steps

This section outlines some of the main observations and issues from this deliverable and also proposes further work based on the research developed in PROMs within Task 7.1.

The D7.1 explains the work developed in Task 7.1 for the identification and selection of the PROMs that are necessary for fulfilling the ADLIFE needs and requirements, according to the expertise and research conducted by the pilot sites and the clinical experts that have participated in this project. These elected PROMs will allow:

- collecting feedback from patients that will later feed the care plan in real-time, and
- gathering information on the effectiveness of care delivered to patients during the intervention as perceived by the patients themselves.

This document provides the specific collection of PROMs for the project with the aim of capturing feedback from patients about the outcome measures and monitoring risk factors. The process and the results have been described in the previous sections of the deliverable and associated details are provided in Appendix A.

Considering the high prevalence of comorbidities among the elderly, it is likely that ADLIFE patients have other chronic conditions, such as diabetes, chronic renal failure, chronic liver disease, stroke, or mild cognitive impairment, in addition to COPD or heart failure, the inclusion criteria. The project has provided PROMs not only for the two target conditions (disease-specific PROMs, such as the CAT or the KCCQ), but also generic PROMs for measuring the wellbeing of patients within certain dimensions such as physical function, social function, pain, and depression or anxiety. The combined use of both disease-specific and generic PROMs will help to provide a general overview of the patients' health status.

One of the challenges of this task was to identify and select PROMs that were available in the different languages spoken by each of the pilot sites. Most of the selected PROMs included in the final set list are available in the languages which patients are expected to speak in each site, although in some cases there is uncertainty about their validation.

To ensure the effectiveness and reliability of PROMs, patients and caregivers should answer the questionnaires as recommended in each case, and healthcare professionals should supply the PROMs to their patients as activities of their personalized plans. The ADLIFE solution will record the levels of usage so this variable can be checked as part of the evaluation.

The next steps can be summarized as follows:

- The final decision on the definitive list of PROMs will be extended until the work in other areas of the project is completed. The updated list of PROMs shown in this deliverable has been shared with the Clinical Reference Group for their acceptance, but, by the time of the submission of this deliverable, their review has not been completed. The confirmation of the Clinical Reference Group on the proposed PROMs is crucial to ensure the integrated care model of the project supported by the ADLIFE toolbox. Considering the exhaustive process conducted for the development of the current list, no major modifications on the proposed list is expected, but there may be a requirement to provide additional PROMs. During the development of Task 7.1, the reference guidelines to be used as CDSS were still being reviewed, analyzed and reconciled in Task 6.2, which means that this information was not available and so, could not be used to guide the selection and identification of the ADLIFE PROMs. Once finished, this analysis is not expected to result in the elimination of any of the PROMs included in the current proposed list. However, the analysis may identify new PROMs as relevant for the needs of the clinical decision support system, which would justify

their inclusion into the definitive list. Therefore, the definitive PROMs to be used in ADLIFE will be reported, as part of MS5 “ADLIFE guidelines, scales and PROMs final selection”, by month 21 of the project (September 2021).

- In ADLIFE, patients will access PROMs through PEP. PEP is the online platform that allows patients to see and review their personalized care and to fill in the PROMs and other questionnaires. PROMs collected in PEP will feed PCPMP and CDSS. PEP supporting PROMS will be available by M24 (December 2021), by means of D4.1 “ADLIFE Patient Empowerment Platform supporting PROMs”.
- The ADLIFE intervention will demonstrate the acceptability and user friendliness of the list of PROMs to be used in ADLIFE with patients and caregivers after the intervention, as a subset of evaluation. This qualitative analysis will allow seeing to what extent the selected PROMs are useful and acceptable for patients and will help to identify the best way or approach to provide them. This evaluation will help to assess the issues found and make recommendations on how they should be tackled. The results of this assessment will be reported in D9.2 “Final evaluation report, including predictive algorithms validation and economic impact of the intervention” (M54, June 2024).

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Appendix A

A.1 Appendix

A.1.1 Zarit Burden Interview: 12-item version (ZBI)[104]

Short Form Zarit Burden Interview (ZBI-12)

	"Never" (0)	"Rarely" (1)	"Sometimes" (2)	"Quite frequently" (3)	"Nearly always" (4)
Do you feel…?					
That because of the time you spend with your relative that you don't have enough time for yourself?					
Stressed between caring for your relative and trying to meet other responsibilities (work/family)?					
Angry when you are around your relative?					
That your relative currently affects your relationship with family members or friends in a negative way?					
Strained when you are around your relative?					
That your health has suffered because of your involvement with your relative?					
That you don't have as much privacy as you would like because of your relative?					
That your social life has suffered because you are caring for your relative?					
That you have lost control of your life since your relative's illness?					
Uncertain about what to do about your relative?					
You should be doing more for your relative?					
You could do a better job in caring for your relative?					

A.1.2 Person-centered Climate Questionnaire – patient version (PCQ-P)[39]

The English Language Person-Centered Climate Questionnaire–Patient Version

I experience this unit as:
1. A place where the staff is knowledgeable.
2. A place where I rely on receiving the best care.
3. A place where I feel in safe hands.
4. A place where I feel welcome.
5. A place where it is easy to talk to the staff.
6. A place where the staff take notice of what I say.
7. A place where the staff come quickly when I need help.
8. A place where the staff use language I can understand.
9. A place which is neat and clean.
10. A place where the staff have time for the patients.
11. A place where there is something nice to look at.
12. A place which feels homely even though I am in an institution.
13. A place where it is possible to get unpleasant thoughts out of your head.
14. A place where people talk about ordinary things, not just illness.
15. A place where the staff make a little extra effort on my behalf.
16. A place where I have choices, for example, what to wear.
17. A place where I can get "that little bit extra."

Note: The response options used are: no, I disagree completely; no, I disagree; no, I partly disagree; yes, I partly agree; yes, I agree; yes, I agree completely.

A.1.3 COPD Assessment Test (CAT)[105]

Your name:

Today's date:

CAT
COPD Assessment Test™

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	
		TOTAL SCORE	

A.1.4 Modified Medical Research Council Dyspnea Scale (mMRC)[106]

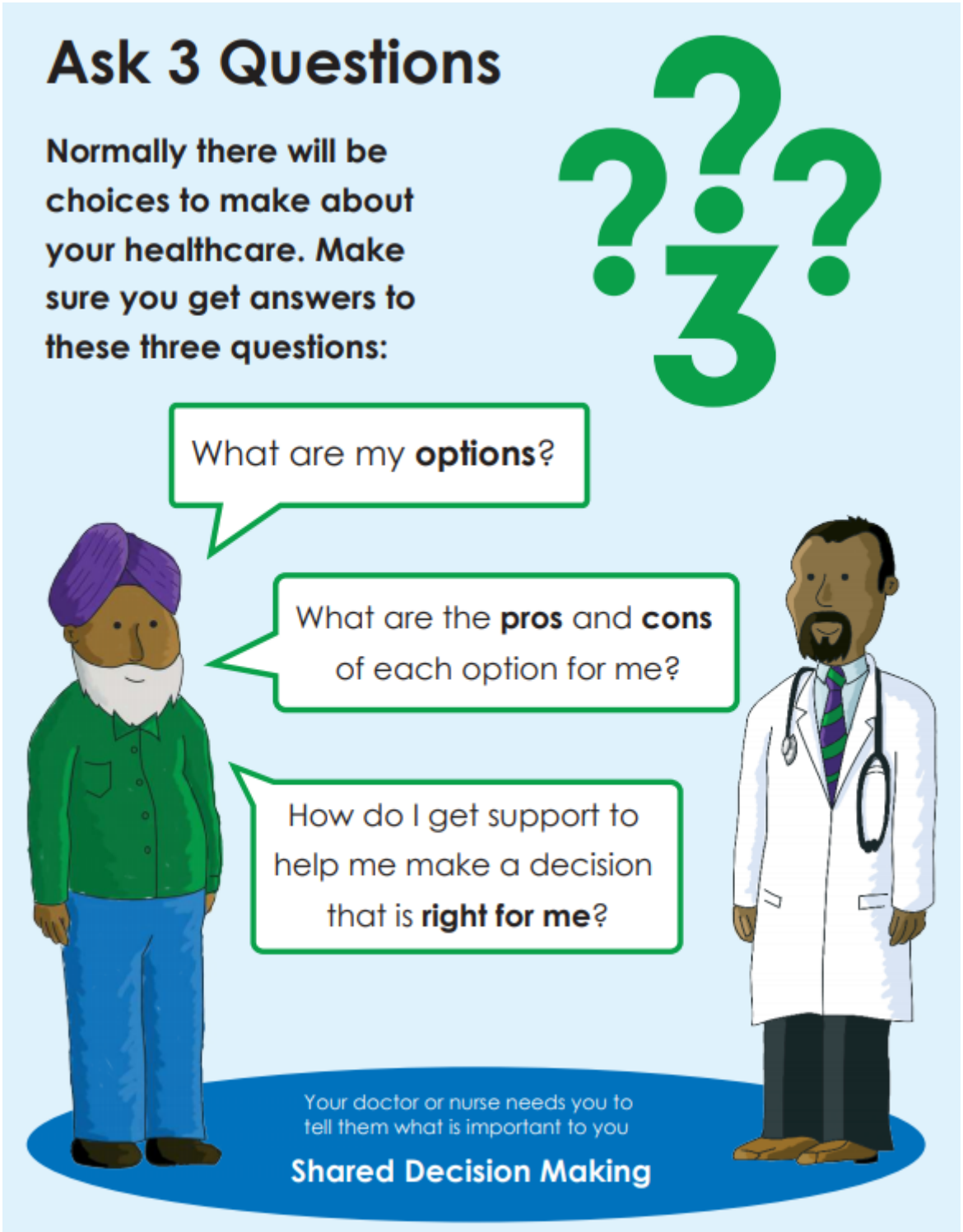
Bronchiectasis Toolbox

Modified Medical Research Council Dyspnoea Scale

0	"I only get breathless with strenuous exercise"
1	"I get short of breath when hurrying on the level or walking up a slight hill"
2	"I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level"
3	"I stop for breath after walking about 100 yards or after a few minutes on the level"
4	"I am too breathless to leave the house" or "I am breathless when dressing"

Doherty DE et al. COPD: Consensus Recommendations for early diagnosis and treatment. Journal of Family Practice, Nov 2006

A.1.5 Shared decision-making: "Ask 3 questions"[107]



A.1.6 EQ-5D-5L[54]

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

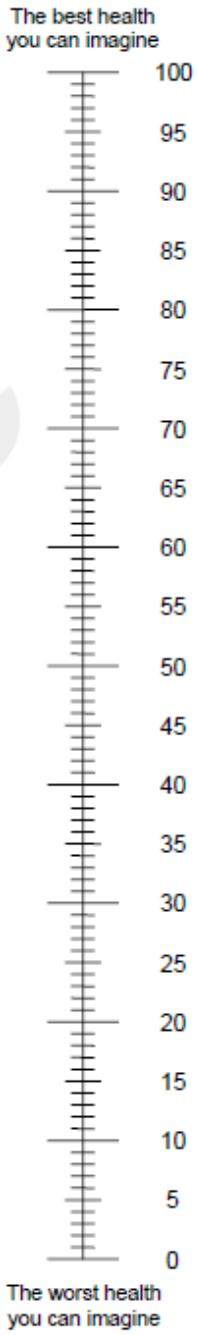
- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



3

A.1.7 Kansas City Cardiomyopathy Questionnaire (KCCQ)[66]

THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE:

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Place an **X** in one box on each line

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
Dressing yourself	❑	❑	❑	❑	❑	❑
Showering/Bathing	❑	❑	❑	❑	❑	❑
Walking 1 block on level ground	❑	❑	❑	❑	❑	❑
Doing yardwork, housework or carrying groceries	❑	❑	❑	❑	❑	❑
Climbing a flight of stairs without stopping	❑	❑	❑	❑	❑	❑
Hurrying or jogging (as if to catch a bus)	❑	❑	❑	❑	❑	❑

2. Compared with 2 weeks ago, have your symptoms of **heart failure** (shortness of breath, fatigue or ankle swelling) changed?

My symptoms of **heart failure** have become . . .

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
❑	❑	❑	❑	❑	❑

3. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
❑	❑	❑	❑	❑

4. Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you?

It has been . . .

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
❑	❑	❑	❑	❑	❑

5. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you want?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times per week	Less than once a week	Never over the past 2 weeks
❑	❑	❑	❑	❑	❑	❑

6. Over the past 2 weeks, how much has your **fatigue** bothered you?

It has been . . .

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
❑	❑	❑	❑	❑	❑

7. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times per week	Less than once a week	Never over the past 2 weeks
❑	❑	❑	❑	❑	❑	❑

8. Over the past 2 weeks, how much has your **shortness of breath** bothered you?

It has been . . .

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
❑	❑	❑	❑	❑	❑

9. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
❑	❑	❑	❑	❑

10. **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
❑	❑	❑	❑	❑

11. How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse? (for example, weighing yourself, eating a low salt diet, etc.)

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
❑	❑	❑	❑	❑

12. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
❑	❑	❑	❑	❑

13. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
❑	❑	❑	❑	❑

14. Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
❑	❑	❑	❑	❑

15. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Please place an **X** in one box on each line

Activity	**Severely** limited	Limited **quite a bit**	**Moderately** limited	**Slightly** limited	**Did not** limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities	❑	❑	❑	❑	❑	❑
Working or doing household chores	❑	❑	❑	❑	❑	❑
Visiting family or friends out of your home	❑	❑	❑	❑	❑	❑
Intimate relationships with loved ones	❑	❑	❑	❑	❑	❑

A.1.8 Lawton Instrumental Activities of Daily Living Scale (IADL)[70]

The Lawton Instrumental Activities of Daily Living Scale

Ability to Use Telephone

1. Operates telephone on own initiative; looks up and dials numbers 1
2. Dials a few well-known numbers 1
3. Answers telephone, but does not dial 1
4. Does not use telephone at all 0

Shopping

1. Takes care of all shopping needs independently 1
2. Shops independently for small purchases 0
3. Needs to be accompanied on any shopping trip 0
4. Completely unable to shop 0

Food Preparation

1. Plans, prepares, and serves adequate meals independently 1
2. Prepares adequate meals if supplied with ingredients 0
3. Heats and serves prepared meals or prepares meals but does not maintain adequate diet 0
4. Needs to have meals prepared and served 0

Housekeeping

1. Maintains house alone with occasion assistance (heavy work) 1
2. Performs light daily tasks such as dishwashing, bed making 1
3. Performs light daily tasks, but cannot maintain acceptable level of cleanliness 1
4. Needs help with all home maintenance tasks 1
5. Does not participate in any housekeeping tasks 0

Laundry

1. Does personal laundry completely 1
2. Launders small items, rinses socks, stockings, etc. 1
3. All laundry must be done by others 0

Mode of Transportation

1. Travels independently on public transportation or drives own car 1
2. Arranges own travel via taxi, but does not otherwise use public transportation 1
3. Travels on public transportation when assisted or accompanied by another 1
4. Travel limited to taxi or automobile with assistance of another 0
5. Does not travel at all 0

Responsibility for Own Medications

1. Is responsible for taking medication in correct dosages at correct time 1
2. Takes responsibility if medication is prepared in advance in separate dosages 0
3. Is not capable of dispensing own medication 0

Ability to Handle Finances

1. Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income 1
2. Manages day-to-day purchases, but needs help with banking, major purchases, etc 1
3. Incapable of handling money 0

Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).

Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. *The Gerontologist*, *9*(3), 179-186.

A.1.9 Barthel index[108]

The Barthel Index

Bowels
0 = incontinent (or needs to be given enemata)
1 = occasional accident (once/week)
2 = continent
Patient's Score: _____

Bladder
0 = incontinent, or catheterized and unable to manage
1 = occasional accident (max. once per 24 hours)
2 = continent (for over 7 days)
Patient's Score: _____

Grooming
0 = needs help with personal care
1 = independent face/hair/teeth/shaving (implements provided)
Patient's Score: _____

Toilet use
0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)
Patient's Score: _____

Feeding
0 = unable
1 = needs help cutting, spreading butter, etc.
2 = independent (food provided within reach)
Patient's Score: _____

(Collin et al., 1988)

Transfer
0 = unable – no sitting balance
1 = major help (one or two people, physical), can sit
2 = minor help (verbal or physical)
3 = independent
Patient's Score: _____

Mobility
0 = immobile
1 = wheelchair independent, including corners, etc.
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid, e.g., stick)
Patient's Score: _____

Dressing
0 = dependent
1 = needs help, but can do about half unaided
2 = independent (including buttons, zips, laces, etc.)
Patient's Score: _____

Stairs
0 = unable
1 = needs help (verbal, physical, carrying aid)
2 = independent up and down
Patient's Score: _____

Bathing
0 = dependent
1 = independent (or in shower)
Patient's Score: _____

Total Score: _____

A.1.10 Hospital Anxiety and Depression Scale (HADS)[109]

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

A.1.11 Zarit Burden Interview: 22-item version (ZBI)[110]

The Zarit Burden Interview

Circle the response that best describes how you feel.

	Never	*Rarely*	*Sometimes*	*Quite frequently*	*Nearly always*
1. Do you feel that your relative asks for more help than he/she needs?	0	1	2	3	4
2. Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4
4. Do you feel embarrassed over your relative's behavior?	0	1	2	3	4
5. Do you feel angry when you are around your relative?	0	1	2	3	4
6. Do you feel that your relative currently affects your relationships with other family members or friends in a negative way?	0	1	2	3	4
7. Are you afraid what the future holds for your relative?	0	1	2	3	4
8. Do you feel your relative is dependent on you?	0	1	2	3	4
9. Do you feel strained when you are around your relative?	0	1	2	3	4
10. Do you feel your health has suffered because of your involvement with your relative?	0	1	2	3	4
11. Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4
12. Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
13. Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4
14. Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on?	0	1	2	3	4
15. Do you feel that you don't have enough money to take care of your relative in addition to the rest of your expenses?	0	1	2	3	4
16. Do you feel that you will be unable to take care of your relative much longer?	0	1	2	3	4
17. Do you feel you have lost control of your life since your relative's illness?	0	1	2	3	4
18. Do you wish you could leave the care of your relative to someone else?	0	1	2	3	4
19. Do you feel uncertain about what to do about your relative?	0	1	2	3	4
20. Do you feel you should be doing more for your relative?	0	1	2	3	4
21. Do you feel you could do a better job in caring for your relative?	0	1	2	3	4
22. Overall, how burdened do you feel in caring for your relative?	0	1	2	3	4

Instructions for caregiver: The questions above reflect how persons sometimes feel when they are taking care of another person. After each statement, circle the word that best describes how often you feel that way. There are no right or wrong answers.

Scoring instructions: Add the scores for the 22 questions. The total score ranges from 0 to 88. A high score correlates with higher level of burden.

A.1.12 Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)[111]

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Below are some statements about feelings and thoughts.

Please tick the box that best describes your experience of each over the last 2 weeks

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

A.1.13 Patient Assessment Of Chronic Illness Care (PACIC)[112]

Over the past 6 months, when I received care for my chronic conditions, I was:

	None of the time	A Little of the Time	Some of the Time	Most of the Time	Always
1. Asked for my ideas when we made a treatment plan.	☐1	☐2	☐3	☐4	☐5
2. Given choices about treatment to think about.	☐1	☐2	☐3	☐4	☐5
3. Asked to talk about any problems with my medicines or their effects.	☐1	☐2	☐3	☐4	☐5
4. Given a written list of things I should do to improve my health.	☐1	☐2	☐3	☐4	☐5
5. Satisfied that my care was well organized.	☐1	☐2	☐3	☐4	☐5
6. Shown how what I did to take care of myself influenced my condition.	☐1	☐2	☐3	☐4	☐5
7. Asked to talk about my goals in caring for my condition.	☐1	☐2	☐3	☐4	☐5
8. Helped to set specific goals to improve my eating or exercise.	☐1	☐2	☐3	☐4	☐5
9. Given a copy of my treatment plan.	☐1	☐2	☐3	☐4	☐5
10. Encouraged to go to a specific group or class to help me cope with my chronic condition.	☐1	☐2	☐3	☐4	☐5
11. Asked questions, either directly or on a survey, about my health habits.	☐1	☐2	☐3	☐4	☐5

Over the past 6 months, when I received care for my chronic conditions, I was:	None of the time	A Little of the Time	Some of the Time	Most of the Time	Always
12. Sure that my doctor or nurse thought about my values, beliefs, and traditions when they recommended treatments to me.	☐1	☐2	☐3	☐4	☐5
13. Helped to make a treatment plan that I could carry out in my daily life.	☐1	☐2	☐3	☐4	☐5
14. Helped to plan ahead so I could take care of my condition even in hard times.	☐1	☐2	☐3	☐4	☐5
15. Asked how my chronic condition affects my life.	☐1	☐2	☐3	☐4	☐5
16. Contacted after a visit to see how things were going.	☐1	☐2	☐3	☐4	☐5
17. Encouraged to attend programs in the community that could help me.	☐1	☐2	☐3	☐4	☐5
18. Referred to a dietitian, health educator, or counselor.	☐1	☐2	☐3	☐4	☐5
19. Told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment.	☐1	☐2	☐3	☐4	☐5
20. Asked how my visits with other doctors were going.	☐1	☐2	☐3	☐4	☐5

A.1.14 Patient Assessment Of Chronic Illness Care Plus (PACIC+)[113]

Think about the health care you've received for your diabetes over the past 6 months. (If it's been more than 6 months since you've seen your doctor or nurse, think about your most recent visit.)

Over the past 6 months, when receiving medical care for my diabetes, I was:

	Almost Never	Generally Not	Sometimes	Most of the Time	Almost Always
1. Asked for my ideas when we made a treatment plan.	☐1	☐2	☐3	☐4	☐5
2. Given choices about treatment to think about.	☐1	☐2	☐3	☐4	☐5
3. Asked to talk about any problems with my medicines or their effects.	☐1	☐2	☐3	☐4	☐5
4. Given a written list of things I should do to improve my health.	☐1	☐2	☐3	☐4	☐5
5. Satisfied that my care was well organized.	☐1	☐2	☐3	☐4	☐5
6. Shown how what I did to take care of my illness influenced my condition.	☐1	☐2	☐3	☐4	☐5
7. Asked to talk about my goals in caring for my illness.	☐1	☐2	☐3	☐4	☐5

	Almost Never	Generally Not	Sometimes	Most of the Time	Almost Always
8. Helped to set specific goals to improve my eating or exercise.	☐1	☐2	☐3	☐4	☐5
9. Given a copy of my treatment plan.	☐1	☐2	☐3	☐4	☐5
10. Encouraged to go to a specific group or class to help me cope with my chronic illness.	☐1	☐2	☐3	☐4	☐5
11. Asked questions, either directly or on a survey, about my health habits.	☐1	☐2	☐3	☐4	☐5
12. Sure that my doctor or nurse thought about my values and my traditions when they recommended treatments to me.	☐1	☐2	☐3	☐4	☐5
13. Helped to make a treatment plan that I could do in my daily life.	☐1	☐2	☐3	☐4	☐5
14. Helped to plan ahead so I could take care of my illness even in hard times.	☐1	☐2	☐3	☐4	☐5
15. Asked how my chronic illness affects my life.	☐1	☐2	☐3	☐4	☐5
16. Contacted after a visit to see how things were going.	☐1	☐2	☐3	☐4	☐5

	Almost Never	Generally Not	Sometimes	Most of the Time	Almost Always
17. Encouraged to attend programs in the community that could help me.	☐1	☐2	☐3	☐4	☐5
18. Referred to a dietitian, health educator, or counselor.	☐1	☐2	☐3	☐4	☐5
19. Told how my visits with other types of doctors, like the eye doctor or surgeon, helped my treatment.	☐1	☐2	☐3	☐4	☐5
20. Asked how my visits with other doctors were going.	☐1	☐2	☐3	☐4	☐5
21. Asked what I would like to discuss about my illness at that visit.	☐1	☐2	☐3	☐4	☐5
22. Asked how my work, family, or social situation related to taking care of my illness.	☐1	☐2	☐3	☐4	☐5
23. Helped to make plans for how to get support from my friends, family or community.	☐1	☐2	☐3	☐4	☐5
24. Told how important the things I do to take care of my illness (e.g., exercise) were for my health.	☐1	☐2	☐3	☐4	☐5
25. Set a goal together with my team for what I could do to manage my condition.	☐1	☐2	☐3	☐4	☐5
26. Given a book or monitoring log in which to record the progress I am making.	☐1	☐2	☐3	☐4	☐5