

HORIZON 2020  
The Framework Programme for Research and Innovation



Project acronym: VALUECARE  
Grant Agreement Number: 875215  
Project full title: Value-based methodology for integrated care supported by ICT  
Call identifier: H2020-SC1-DTH-11-2019

## D5.1 Agreed-upon pilot sites evaluation framework

Version: 2.0  
Status: Revised version  
Dissemination Level: Public  
Due date of deliverable: 30.09.2020  
Actual submission date: 05.04.2022  
Work Package: WP5 - Formative and summative evaluation of the VALUECARE pilot  
Lead partner for this deliverable: EMC  
Partner(s) contributing: ECHA, FBK, VI, VIDA VO, UVEG, AGE, IFIC and KVC

### Main author(s):

Esmée Bally	EMC		
Amy van Grieken	EMC		
Hein Raat	EMC		

### Contributions made by:

Nhu Tram	AGE		
Tamara Alhambra Borrás	UVEG		
Oscar Mayora	FBK		
Panos Athanasiadis	VIDA VO		
Natalia Allegretti	ECHA		
Karolina Mackiewicz	ECHA		
Maite Ferrando	KVC		

### Internal reviewers:

Vanja Vasiljev	MEDRI		
Mirian Fernández Salido	UVEG		

**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This deliverable contains original unpublished work except where clearly indicated otherwise.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

**History**

Date	Version number*	Change
30.09.2021	1.0	First version D5.1 submitted
22.12.2021	1.01	Version sent to EMC, ECHA, FBK, VI and VIDAVO for revision
20.01.2022	1.02	Version sent to all internal reviewers
05.04-2022	2.0	Revised version D5.1 submitted

## EXECUTIVE SUMMARY

The value-based methodology for integrated care supported by ICT (ValueCare) approach aims to deliver efficient outcome-based integrated health and social care to older people with chronic health conditions, frailty or (mild) cognitive impairment. The project's vision of integrated value-based care will be supported by a robust, secure and scalable digital solution that will be tested and evaluated in 7 large-scale pilots in Europe.

The ValueCare evaluation study combines a formative and summative approach to monitor and evaluate the process of implementation and adoption as well as the impact of the approach among all relevant end-users and stakeholder. The progress and the outcomes of the broad and ongoing evaluation will be frequently discussed within the consortium, with the advisory board of ValueCare and with relevant stakeholders. During the project, lessons learned can be applied in improving ValueCare. The evaluation is needed to support the future implementation and the business exploitation of ValueCare. There will be continuous interaction with the advisory board and with the work package on business exploitation.

A broad array of data is collected continuously in collaboration with partners in the consortium to make use of all resources available, including the technical solution, interviews, self-report, pilot-site visits and administrative data. Analyses will study the acceptability, appropriateness, feasibility and usability of the ValueCare approach as well as the level of fidelity during implementation. Among the people who contribute to the collection of the ValueCare data are older people in both the intervention group and the control group, informal (family) caregivers, professional care providers, IT specialists, care managers and policy makers. In addition, a preliminary cost-effectiveness analysis will be performed.

The comprehensive approach applied in the evaluation study supports the uptake, success and future exploitation of the ValueCare approach for older people, their families, and health and social care providers in different European settings.

## TABLE OF CONTENTS

EXECUTIVE SUMMARY .....	3
1 Introduction to the ValueCare project .....	6
1.1 Objectives of the project .....	6
2 Introduction to the deliverable .....	8
2.1 Deliverable objectives and scope .....	8
2.2 Relation to other WPs and deliverables .....	8
3 Methodology.....	10
3.1 Study design .....	10
3.2 Participants and recruitment.....	10
3.3 Intervention condition and control condition .....	11
3.3.1 Intervention condition: The “ValueCare approach” .....	11
3.3.2 Control condition: ‘care as usual’ .....	12
3.4 Procedures.....	12
3.5 Data collection .....	12
3.5.1 Formative evaluation .....	12
3.5.2 Summative evaluation .....	14
3.5.3 Outcomes .....	14
3.6 Data management and analysis .....	22
3.7 Interdisciplinary collaboration between partners .....	23
4 Findings and conclusions .....	25
5 References .....	27

## LIST OF TABLES

- Table 1** Deliverable 5.1 in relation to other WPs and deliverables
- Table 2** Target group per site
- Table 3** Overview of implementation outcomes assessed among older people
- Table 4** Overview of implementation outcomes assessed among informal care providers
- Table 5** Overview of implementation outcomes assessed among formal care givers
- Table 6** Overview of outcomes from self-report in older people
- Table 7** Overview of additional data from older people in the intervention condition collected via sensors in each pilot site
- Table 8** Overview of outcomes in informal caregivers
- Table 9** Overview of outcomes in health and social care professionals
- Table 10** Overview of cost-effectiveness outcomes in the self-report questionnaires

## LIST OF ABBREVIATIONS

BMI	Body Mass Index
D	Deliverable
HR-QoL	Health Related Quality of Life
ICHOM	International Consortium for Health Outcomes Measurements
IMTA	Institute for Medical Technology Assessment
IPAQ	International Physical Activity Questionnaire
IPCQ	Imta Productivity Costs Questionnaire
ISRCTN	International Standard Randomised Controlled Trial Number
IVICQ	iMTA Valuation of Informal Care Questionnaire
M	Month
MRQ	Medication Risk Questionnaire
PROMIS	Patient Reported Outcomes Measurement Information System
SHARE	Survey of Health, Ageing and Retirement in Europe
SMRC	Self-Management Resource Center
SNAQ	Short Nutritional Assessment Questionnaire
UCLA	University of California, Los Angeles
WP	Work Package

# 1 Introduction to the ValueCare project

Healthy ageing along with independent living have become fundamental challenges for Europe as all EU member states (and virtually every country in the world) are experiencing growth in the number and proportion of older people in their population. Several international organisations (Council of Europe, 2014; International Longevity Centre Brazil, 2014; WHO, 2002) have remarked the importance of the independence, participation and autonomy of older people to remain healthy and, consequently, to ensure their quality of life.

The WHO defines health as "...a state of complete physical, mental and social well-being and not merely the absence of disease". The idea of health as the absence of disease has long been considered insufficiently broad and not covering all aspects of health. Unfortunately, it is at present likely unobtainable for many, particularly with the rise in chronic disease and an aging population, with many people with multi-morbidity and frailty who require a coordinated care plan involving numerous health providers, social and other care services. The concept of health promoted by WHO is also hard to measure, is not tailored to the individual and, according to some authors, of limited use for assessing whether a health system is providing value to citizens. Greater acknowledgment of areas of wellbeing providing wider value to older people and those with chronic illnesses, such as societal participation and coping capacity, may allow for a more practical and thorough assessment of value in healthcare, particularly in high-income countries. Shilton et al. (2011) propose a definition of health focused on giving people the income, education, and power to control their lives, highlighting the role of supportive systems, environments, and policies in enabling health.

In this context, ValueCare's vision of healthy ageing is that any older individual in society can live the best life possible according to what they value, facilitated by access to high quality, person-centred, evidence-based and affordable health and social care services, supported by strong and integrated health and social services. ValueCare partners believe that taking an "enhanced value-based approach" (including not only health but also lifestyle and social care in the concept of value-based care) supported by secure and robust digital technologies will help to achieve this. In addition, the project will also take into account the job satisfaction and the wellbeing of the health and social service providers. Not only satisfying the Triple Aim; i.e. (i) improving the experience of care (including quality and satisfaction); (ii) improving the health of populations; and (iii) containing and potentially reducing, by means of a better use of the available resources, the per capita cost of care, which mainly focuses on the person's side, but taking also into account the care providers and integrating their satisfaction in the job and wellbeing in order to truly optimize ValueCare's performance.

## 1.1 Objectives of the project

ValueCare addresses Horizon 2020 Call: SC1-DTH-2018-2020 – Digital transformation in Health and Care. The project aims to deliver personalised integrated (health and social) care services, better outcomes for citizens, improved care experience, improved staff satisfaction and greater efficiency in the use of resources and coordination of care in a setting that ensures trust of users and policy makers with regard to data access, protection and sharing and which can be replicated and deployed at large scale in other EU countries. In alignment with the above, ValueCare will focus on the following general objectives:

- ▶ Objective 1. To deliver efficient outcome-based integrated (health and social) care to older people suffering from cognitive impairment, frailty and multiple chronic health conditions in order to improve their quality of life (and of their families)
- ▶ Objective 2. To contribute to the sustainability of health and social care systems in Europe
- ▶ Objective 3. To provide a secure, scalable and robust digital solution for integrated care

The progress and the outcomes of the broad and ongoing evaluation will be frequently discussed within the consortium, with the advisory board of ValueCare and with relevant stakeholders. During the project, lessons learned can be applied in improving ValueCare. The evaluation is needed to support the future implementation and the business exploitation of ValueCare. There will be continuous interaction with the advisory board and with the work package on business exploitation.

## 2 Introduction to the deliverable

Work Package (WP) 5 concerns the evaluation of the ValueCare approach in the seven pilot sites. The evaluation study will collect proper evidence for the ValueCare approach to be adopted by health systems, reimbursement bodies, and the market.

This Deliverable 5.1 describes the framework for the evaluation of the ValueCare approach.

- The formative evaluation studies the feasibility, appropriateness, acceptability and usability of the ValueCare approach as well as the implementation of the ValueCare approach: how well is the ValueCare approach adopted and are key elements delivered?
- The summative evaluation studies the benefits of the ValueCare approach with regard to quality of life of end-users (older people and informal and formal caregivers), quality of the working conditions and job satisfaction of health and social care professionals and managers, and cost-effectiveness of the approach.

During the ValueCare project, learnings from the evaluation can be discussed and applied in improving ValueCare. The evaluation is needed to support the future implementation and the business exploitation of ValueCare. There will be continuous interaction with the advisory board and with the work package on business exploitation.

### 2.1 Deliverable objectives and scope

The aim of deliverable 5.1 (D5.1) is to describe the framework of the evaluation of ValueCare in all pilot sites. The evaluation framework combines a formative and summative evaluation study collecting relevant data available among all target groups involved in the ValueCare approach. In this deliverable the framework of the study design, methodology, data collection resources, methods and instruments, analyses and data management is presented. It also presents the structure that supports multidisciplinary collaboration in the consortium and the interlinking of the evaluation study and input and output towards other tasks, ensuring the success and uptake of the ValueCare approach. For this reason, intermediate results will be frequently discussed with the work package on dissemination to promote future implementation, and with the work package on business exploitation.

### 2.2 Relation to other WPs and deliverables

The evaluation study will provide input for scientific output, practical implementation and business exploitation. By using data collected specifically for the evaluation study in combination with data available from the ValueCare technical solutions a comprehensive overview of impact can be generated. This deliverable is strongly linked with the following WPs and deliverables, please see Table 1.

**Table 1** Deliverable 5.1 in relation to other WPs and deliverables

WP	Deliverable	Link
WP2	D2.2	Identify data needed – start term



WP3	Task 3.1	VALUECARE Digital Solution Architecture Definition and Design (Leader: VIDAVO)
	Task 3.2	Definition and development of ML/AI algorithms for VALUECARE implementation and Prediction modelling techniques in pilot sites (Leader: FBK)
	Task 3.3	ValueCare digital solution back-end development (leader: FBK)
	Task 3.4	Development of the ValueCare digital solution front-end to enable the ValueCare methodology implementation in pilot sites (leader: VI)
WP4	Task 4.1	General framework for the pilots' implementation (leader: EMC)
	Task 4.3	ValueCare implementation (leader: MEDRI)
WP7	D7.1	Innovation management
	Task 7.2	Business models and corresponding feasibility studies (leader: ECHA)
	Task 7.5	Standardisation activities (leader: KVC)
WP8	Task 8.1	Ethics management (Leader: UVEG)
	Task 8.3	Data gathering, saving and sharing (Leader: FBK)
WP9	D 9.5	POPD - Requirement No. 11 (Leader: EMC)

## 3 Methodology

### 3.1 Study design

Seven countries participate in the ValueCare evaluation study. In each of these countries the ValueCare approach is implemented. In a pilot site there will be services implementing the ValueCare approach (intervention sites) and services implementing care as usual (control sites). The ValueCare evaluation study will run parallel to implementation of the ValueCare approach. Data is collected from all resources available, including the technical solution, interviews with older people, informal and formal caregivers, self-reported data, pilot site visits and administrative data. All participants provide consent to participate in the ValueCare evaluation study and data collection. Multidisciplinary collaboration between work packages in the consortium ensures that the activities as part of the evaluation study contribute to the success, uptake and exploitation of the ValueCare approach.

### 3.2 Participants and recruitment

The ValueCare approach targets older people with medical conditions and/or disabilities (e.g. cardiovascular diseases, diabetes), and/or frailty and/or (mild) cognitive impairment, their families (e.g. informal carers) and health and social care professionals. All three target groups are invited to join the ValueCare evaluation study. The inclusion and exclusion criteria for each target group are described in D4.1, and more specifically for each site in D9.1. Each pilot site defined the specific target group of older people for their intervention (Table 2).

**Table 2** Target group per site

Site	Target group of older people
Athens (Greece)	Type II Diabetes Mellitus and hypertension as comorbidity, living independently in the community.
Coimbra (Portugal)	Patients/clients with no or mild cognitive impairment, and two or more chronic conditions, and a lack of social or familiar support.
Cork/Kerry (Ireland)	Older people ( $\geq 75$ years old) with mild to moderate frailty.
Rijeka (Croatia)	Patients who had a myocardial infarction, with inclusion after the clinical phase of rehabilitation.
Rotterdam (the Netherlands)	Patients who had an ischemic stroke.
Treviso (Italy)	Mild cognitive impairment and/or frailty, in combination with hypertension, or diabetes or cardiovascular diseases.
Valencia (Spain)	Mild to moderate frailty.

Study enrolment is planned to be conducted between the end of 2021 and summer 2022. Older people will be recruited with the support of health and social care providers. In each site, older people participating are asked whether they have an informal caregiver, and who is/are the most relevant formal caregiver(s). These informal and formal caregivers will be approached (with the permission of the participant) and invited to participate in the study. More information about the recruitment strategy in each pilot sites is described in D9.1.

In order to have adequate power (see below) to detect meaningful impact on health-related quality of life (summative evaluation) 1680 older people (i.e. patients, clients) in total (120 participants in the intervention group and 120 participants in the control group in each site) are included. In each of the seven sites, we aim to enrol 50-70 informal caregivers (e.g., relatives, friends) and 30-40 health and social care professionals who work with older people having the targeted condition. All participants provide informed consent to participate in the evaluation study and data collection.

### Power considerations

In each of the seven sites, 120 participants will be included in the intervention group and 120 participants in the control group. Assuming a 20% participant loss to follow-up between T<sub>0</sub> and T<sub>1</sub> (e.g., due to disability, rehousing, mortality, study withdrawal), we expect to get complete data from 672 participants in the intervention group and 672 participants in the control group of all sites at follow-up; in total n=1344 study participants. We assume equal standard deviations in the intervention group and the control group, alpha of 0.05 and power of 0.80. Thus, given seven participating study sites each with an intervention group and control group, we applied a correction factor to account for the cluster design, assuming an average cluster size of 96 older citizens (1344/14) and an intra-class correlation coefficient of 0.02. For this expected overall sample size and assumptions, regarding the continuous outcome measures, a difference of 0.23 SD between the intervention and the control group can be detected at follow-up. This means that both at the European level and within each individual site, small differences regarding the outcomes in the intervention group compared to the control group can be shown (Middel et al., 2002).

## 3.3 Intervention condition and control condition

Prior to the start of the intervention, in ValueCare, older people, their informal caregivers, health and social care professionals, as well as other stakeholders (e.g., policymakers, managers) are progressively involved in co-design sessions to develop the ValueCare approach. In this regard, co-design ensures the technical solution is tailored to the needs and preferences of end-users regarding feasibility, appropriateness, acceptability and usability. The co-design sessions are organized in two rounds between April 2020 and the end of 2021. More information about the methodology and results of the co-design sessions can be found in the deliverables D2.4, D2.6 and D2.7. A third round of co-design activities is planned in 2022. The co-design findings are also used in the continuous process of evaluation in order to improve the ValueCare solutions, during the project. The results of the third round of co-design will also be used to improve the ValueCare solutions for integrated care and to improve the final versions of the ValueCare digital solutions by using the input and experiences from the users.

### 3.3.1 Intervention condition: The “ValueCare approach”

In the intervention condition, the ‘ValueCare approach’ will be applied. For details on the ValueCare approach we refer to D4.1 General framework for the pilots’ implementation and D4.2 ValueCare adaptation to pilot sites, where pilot-specific intervention plans are described. In summary, the ValueCare approach entails:

- ▶ Self-reported questionnaires to assess ‘outcomes’/‘values’ that are relevant to older people (i.e. patients, clients);

- ▶ A consultation between the patient (client) and care provider to discuss the results of the self-reported questionnaires;
- ▶ A personalised care plan that is co-produced by the patient (client), their informal caregiver (if applicable) and care provider;
- ▶ Technical solutions to support the personalised care plan of the patient (client), their informal caregiver and health and social care professionals;
- ▶ Monitoring of the personalised care plan by informal and formal caregivers (with permission of the participant).

The ValueCare technical solution will enhance the assessment and the monitoring of the personalised care plan by: 1) a mobile application for older people, 2) (wearable) sensors, and 3) a web application for informal and formal caregivers. The mobile application uses a motivational and goal-setting approach, including a “Virtual Assistant” that will act as a conversational agent to help participants accomplish their personal goals. Furthermore, (wearable) sensors, including fitness trackers can be added as part of the ValueCare technical solution for monitoring and motivation of the participant. Moreover, informal caregivers, and health and social care professionals can have access to a web application, where progress and data of the patient is presented and the care plan can be defined. In D3.3 more information can be found on the technical solutions used in ValueCare.

### 3.3.2 Control condition: ‘care as usual’

In the control condition, participants will receive ‘care as usual’.

## 3.4 Procedures

The study protocol is registered as a clinical trial under ISRCTN registry number 250 891 86 (<https://www.isrctn.com/ISRCTN25089186>). The date of trial registration is 16/11/2021. Before the implementation of the ValueCare approach, pilot sites will work on some preparatory activities including applying for medical ethical approval. All preparatory activities are described in D4.1.

## 3.5 Data collection

Data collection entails the input and output the evaluation study will deliver in the project. The structure set up (see 2.7) ensures multidisciplinary collaboration and the collection of proper evidence for access to the market. Data collection takes place using several complementary methods and resources.

### 3.5.1 Formative evaluation

The formative evaluation study concerns the feasibility, appropriateness, acceptability and usability of the ValueCare approach as well as the evaluation of fidelity (i.e. how well is the approach adopted and is the implementation as intended) (Proctor et al., 2011). The formative evaluation has a specific focus on the usability of the ValueCare technical solution and Virtual Assistant (see 2.3.1). Therefore, the four concept of the ISO TS 82304-2 (healthy and safe, easy to use, secure data, and robust build) are taken as perspective. Taking this standard serves market purposes. The following sections describe the methods for data collection as part of the formative evaluation..

## Interviews

During the first and second round of co-design the implementation of ValueCare was targeted and information was collected about feasibility, appropriateness, acceptability and usability. During a third round of co-design (WP2, WP3) planned in 2022 the opportunity is taken to collect in-depth insights on these aspects and specifically the usability of the ValueCare app among older people.

In each pilot site regular debriefing interviews will be organised with end-users during implementation. These debriefing interviews serve to evaluate the usability of the ValueCare approach and determine whether implementation is going as intended. These interviews thus feed the ValueCare approach implementation as well as evaluation.

Focus groups and/or interviews will be held with target groups 9 to 12 months after baseline, and at the end of the intervention period. At least 2 focus groups will be held in each site with n=8-12 participants per focus group. Participants will be asked to share their experiences, for example, regarding shared-decision making, satisfaction with care, perceived fit and barriers and facilitators to use the ValueCare approach. It will also assess the usability of and compliance to the ValueCare web and ValueCare app, and specifically the validation of the Virtual Assistant.

Every year pilot site visits take place. In these visits interviews are planned with all end-users and local stakeholders to evaluate usability of the ValueCare approach and whether implementation is going as intended (fidelity).

## Self-report

In a self-report questionnaire at follow-up  $T_1$  (after 12 months) and  $T_2$  (after 18 months) among all end-users, questions address the coordination of care older people experienced, acceptability, appropriateness and feasibility of the ValueCare approach. Following the four dimensions of usability and quality of health apps, additional questions will be asked about aspects of healthy and safe, easy to use, secure data, and robust build with regard to the ValueCare technical solution. More specifically, the Virtual Assistant will pose questions to assess its usability and validity.

## Technical solution

The ValueCare technical solution consists of a mobile application for older people (the ValueCare app), (wearable) sensors (including smartwatches, activity trackers and bluetooth devices), and a web application for informal and formal caregivers. The ValueCare technical solution only collects data among end-users in the intervention condition.

Individual level and aggregated data is collected to gain insight in the fidelity of the technical solution. For example, the app functions used by the older person or the modules activated based on care plan in the web application (e.g. number of downloads, number of logins, number of interactions/views).

## Administrative data

Administrative data provides information on fidelity, it includes the information collected on study and ValueCare activities such as enrolment rates, participation in training sessions, use and evaluation of training material, and other relevant (file-) administrative information.

### 3.5.2 Summative evaluation

The summative evaluation concerns an analysis of benefits of the ValueCare approach with regard to quality of life of the end-users, quality of the working conditions of the health and social care professionals and cost-effectiveness of the intervention. Findings are directly linked and discussed with the work of other WPs (see 2.7) to feed the ValueCare solution and support eventual exploitation.

#### Self-report

In both the intervention and control condition data is collected using self-reported questionnaires at baseline  $T_0$ , at follow-up  $T_1$  (after 12 months) and  $T_2$  (after 18 months). Assistance to fill in the questionnaire will be provided, if necessary. The questionnaires can be completed on paper or digitally through a secured web-based application.

The instruments used are based on the Standard Set for Older Person (ICHOM, 2016; Akpan et al., 2018) developed by the International Consortium for Health Outcomes Measurements (ICHOM). Additional instruments are added, for example to capture lifestyle behaviours. The general outcome measures are described in 2.5.3. Moreover, pilot sites can add specific outcome measurements from for example the ICHOM Stroke Set or the ICHOM Diabetes Set. For details see D2.2. The instruments for which no validated translations are available are translated (forward and backward translations). Before the start of the study, pilot sites have the possibility to test the questionnaires to assure its user-friendliness in terms of appropriateness, comprehensibility and length.

#### Clinical registration data

With permission of the participant, data will be collected from clinical sources. For details see also D2.2.

#### Technical solution

Individual level data to assess impact is available for 1) participants in the intervention condition, b) participants that use this aspects of the technical solution, and 3) a limited period of time with expected high numbers of missing data. Individual level data (with consent of the participant) is collected with regard to the sensors (e.g. number of steps per week) or via the web application (e.g. food diaries). For details on additional data available per pilot site we refer to D2.2.

### 3.5.3 Outcomes

#### Formative evaluation

The formative evaluation uses all resources available to gain insight in the acceptability, appropriateness, feasibility and usability as well as the implementation of the ValueCare approach (fidelity). Table 8 provides an overview of indicators that are assessed among end-users.

**Table 3** Overview of implementation outcomes assessed among older people

Outcome	Outcome measures	Methods and instruments
Acceptability: willingness to receive the service offered (ValueCare Approach); satisfaction with various aspects of the approach e.g. content, complexity, delivery.	Satisfaction with various aspects of the ValueCare approach	Co-design sessions Focus groups/interviews after 9 to 12 months and at the end of the intervention period Debriefing interviews Pilot site visits Administrative data (e.g. evaluation of training material)
	Perceived acceptability	4-item Acceptability of Intervention Measure (AIM) scale on self-report questionnaires at follow-up
	Enrolment rates (%)	Enrolment rates in the study, the ValueCare personalised plan, app, etc.
	Attrition/retention rate (%)	Descriptive statistics and reasons for non-consent to the study, if available
Appropriateness: perceived fit, relevance and compatibility of the service	Relevance, perceived fit and compatibility of the service	Co-design sessions Focus groups Debriefing interviews Pilot site visits
	Perceived fit	4-item Intervention Appropriateness Measure (IAM) scale on self-report questionnaire at follow-up
Feasibility: actual fit or utility, suitability for everyday use	Perceptions of barriers and facilitators to everyday use	Co-design sessions Focus groups Debriefing interviews Pilot site visits
	Perceived feasibility of the approach	4-item Feasibility of Intervention Measure (FIM) scale self-report at follow-up
	Training of end-users	Evaluation of training materials and training sessions using debriefing interviews

	Perceived quality of the delivery	Co-design sessions Focus groups Debriefing interviews Pilot site visits
Usability	Perceived usability	Co-design sessions Focus groups Debriefing interviews Pilot site visits Self-report questions in the technical solution and in the follow-up questionnaires

**Table 4** Overview of implementation outcomes assessed among informal care providers

Outcome	Outcome measure(s)	Methods and instruments
	Satisfaction with various aspects of the ValueCare approach	
Acceptability: willingness to receive the service offered (ValueCare Approach); satisfaction with various aspects of the approach e.g. content, complexity, delivery.	Enrolment rate (%)	Comparison of reported enrolment rates and targets set for the study
	Attrition/retention rate (%)	Descriptive statistics and reasons for non-consent
	Perceived acceptability	4-item Acceptability of Intervention Measure (AIM) scale self-report at follow-up  Co-design sessions Focus groups Debriefing interviews Pilot site visits Administrative data
Appropriateness: perceived fit, relevance and compatibility of the service	Perceived fit	4-item Intervention Appropriateness Measure (IAM) scale self-report at follow-up
		Co-design sessions Focus groups Debriefing interviews Pilot site visits



Feasibility: actual fit or utility, suitability for everyday use	Perceived delivery of the program	4-item Feasibility of Intervention Measure (FIM) scale self-report at follow-up
	Perceptions of barriers and facilitators	Co-design sessions Focus groups Debriefing interviews Pilot site visits
Usability	Perceived usability	Co-design sessions Focus groups Debriefing interviews Pilot site visits Self-report questions in the follow-up questionnaires

**Table 5** Overview of implementation outcomes assessed among formal care givers

Outcome	Outcome measure(s)	Methods and instruments
Acceptability: willingness to receive the service offered (ValueCare Approach); satisfaction with various aspects of the approach e.g. content, complexity, delivery.	Satisfaction with various aspects of the ValueCare approach	Co-design sessions Focus groups Debriefing interviews Pilot site visits Administrative data (e.g. evaluation of training material)
	Perceived acceptability	4-item Acceptability of Intervention Measure (AIM) scale self-report at follow-up
	Attrition/retention rate (%)	Descriptive statistics and reasons for non-consent to the study if available
Appropriateness: perceived fit, relevance and compatibility of the service	Perceived fit	4-item Intervention Appropriateness Measure (IAM) scale self-report at follow-up
		Co-design sessions Focus groups Debriefing interviews Pilot site visits

		Administrative data (e.g. evaluation of training material)
Feasibility: actual fit or utility, suitability for everyday use	Perceived delivery of the program	4-item Feasibility of Intervention Measure (FIM) scale self-report at follow-up
	Perceptions of barriers and facilitators	Co-design sessions Focus groups Debriefing interviews Pilot site visits
Usability	Perceived usability	Co-design sessions Focus groups Debriefing interviews Pilot site visits Self-report questions in the follow-up questionnaire
Adoption: uptake, utilization, intention to try	Uptake and utilization	File analysis and questions in the follow-up questionnaire: presence of care plan, app functions used, number of (digital) interactions between patients and care team. Focus groups \ Pilot site visits Administrative data
Fidelity: extent to which the service was implemented as prescribed in the original protocol	Dose delivered (completeness)	File analysis and questions in the follow-up questionnaire: presence of care plan, app functions used, number of (digital) interactions between patients and care team.
		Co-design sessions Focus groups Debriefing interviews Pilot site visits
	Quality of the delivery	Pilot site visit observations and interviews

## Summative evaluation

In the tables below we provide an overview of the outcomes and data sources to assess health and well-being as part of the summative evaluation. For all target groups (older people, their informal caregivers, and health and social care professionals) socio-demographic characteristics are assessed such as, age, gender, country of birth, level of education and living status. The self-reported questionnaires provide information on health and wellbeing outcomes to compare intervention and control group participants. Other data is collected among intervention group participants only. More details on the data collected in pilot sites is available in D2.2. Table 6 and 7 presents data collected among older people, table 8 among informal care providers and table 9 among health and social care professionals.

**Table 6** Overview of outcomes from self-report in older people

Outcome	Outcome measure(s)	Methods and instruments
Health, wellbeing and quality of life (HR-QoL)	Physical HR-QoL	PROMIS-10
	Mental HR-QoL	
	Frailty	Tilburg Frailty Indicator
	Comorbidities	ICHOM Older Person Set
	Loneliness	UCLA 3-Item Loneliness Scale
	Activities of daily living	Modified 10-item Barthel Index
	Falls	Visual Analogue Scale for Fear of Falling Number of falls
Lifestyle behavior	BMI	ICHOM Older Person Set
	Smoking status	ICHOM Older Person Set
	Alcohol consumption	ICHOM Older Person Set
	Physical activity	One item of the SHARE-Frailty One item of the Internal Physical Activity Questionnaire (IPAQ)
	Nutrition and undernutrition	SNAQ65+
	Medication intake	Medication Risk Questionnaire (MRQ-10)
	Care use	Care utilization

**Table 7** Overview of additional data from older people in the intervention condition collected via sensors in each pilot site

Pilot site	Sensor	Offered to number of participants	Time period used	Data collected to support the personal care plan
<b>Athens</b>	Smart watch	120	During the intervention period (12 months)	<ol style="list-style-type: none"> <li>1. Steps count</li> <li>2. Calories burned</li> <li>3. Distance</li> <li>4. Heart rate</li> <li>5. Type of activity</li> </ol>
<b>Coimbra</b>	Not applicable	Not applicable	Not applicable	
<b>Cork/Kerry</b>	Not applicable	Not Applicable	Not Applicable	
<b>Rijeka</b>	Smart watch	40	During the intervention period (12 months)	<ol style="list-style-type: none"> <li>1. Steps count</li> <li>2. Calories burned</li> <li>3. Distance</li> <li>4. Sleep quality</li> <li>5. Heart rate</li> <li>6. Sedentary behaviour</li> <li>7. Type of activity</li> </ol>
<b>Rotterdam</b>	Smart watch	40-60	Approximately 8 weeks (or can be longer, depending what the participant prefers)	<ol style="list-style-type: none"> <li>1. Steps count</li> <li>2. Calories burned</li> <li>3. Distance</li> <li>4. Heart rate</li> <li>5. Sedentary behaviour</li> <li>6. Type of activity</li> </ol>
<b>Treviso</b>	Smart watch	120	During the intervention period (12 months)	<ol style="list-style-type: none"> <li>1. Sleep quality and its phases</li> <li>2. Steps count and movement</li> <li>3. Calories burned</li> <li>4. Heart rate</li> </ol>
<b>Valencia</b>	Smart watch	30	During the intervention period (12 months)	<ol style="list-style-type: none"> <li>1. Steps count</li> <li>2. Distance</li> <li>3. Sedentary behaviour</li> </ol>

**Table 8** Overview of outcomes in informal caregivers

Outcome	Outcome measure(s)	Methods and instruments
Wellbeing	Mental HR-QoL	PROMIS-10
	Physical HR-QoL	
Perceived burden	Carer burden	iMTA Valuation of Informal Care Questionnaire (iVICQ)
		Zarit Burden Interview 4-item
	Autonomy and control	Adult Social Care Outcomes Toolkit

**Table 9** Overview of outcomes in health and social care professionals

Outcome	Outcome measure(s)	Methods and instruments
Job satisfaction	Working conditions	Culture of Care Barometer
	Satisfaction	Minnesota Satisfaction Questionnaire
	Work-related burn-out	Copenhagen Burnout Inventory

In order to collect data for the evaluation on cost-effectiveness, we have specific instruments to the questionnaires for the end-users (see table 10), and collect information from the other resources.

**Table 10** Overview of cost-effectiveness outcomes in the self-report questionnaires

Target group	Outcome measure(s)	Methods and instruments
Older people	Quality of life to calculate QALYs	EQ-5D-5L
	Care use	SMRC Health Care Utilization questionnaire
	Productivity losses	iMTA Productivity Cost Questionnaire (iPCQ)
Informal caregivers	Productivity losses	iMTA Productivity Cost Questionnaire (iPCQ)

## 3.6 Data management and analysis

To conduct the evaluation, data from all resources and all pilot sites is combined. Analyses are done at Erasmus MC. All data is handled confidentially and scientific data is stored, compliant with national and European regulations. Details on the data management is described in deliverable D8.7 and subsequent versions of the Data Management Plan (D8.8, D8.9 and D8.10).

### a. Formative evaluation

The formative evaluation studies the acceptability, appropriateness, feasibility and usability as well as the implementation of the ValueCare approach (fidelity). Data is combined from interviews, self-report, technical solution, and pilot site visits to summarize the impact of the ValueCare approach. In line with the stakeholder analyses and exploitation plans as part of WP7, the formative evaluation supports future implementation in differential health systems.

Qualitative data (interviews) are transcribed and analysed using Nvivo software to identify key themes that emerged during the interviews with regard to acceptability, appropriateness and feasibility.

Descriptive statistics are used to present quantitative insight in the acceptability, appropriateness and feasibility of the ValueCare approach stemming from the self-report questions, the attention/retention rates and the data from the technical solution. For example, participation rate by evaluating the number of people being offered the ValueCare App, the number of people using wearables, the existence of a care plan and the number of modules activated. Usability is also evaluated using self-report in the Virtual Assistant and as part of the qualitative assessments described above. Scores are presented as means (standard deviations) and range, or percentages. Quantitative data also provide insight in the dose delivered, which is also used in the summative evaluation (see b.)

### b. Summative evaluation

The summative evaluation concerns the benefits of the ValueCare approach with regard to quality of life of the end-users (older citizen and families), quality of the working conditions of the health and social care professionals and managers, and cost-effectiveness of the approach.

Participant socio-demographic characteristics and health outcomes will be evaluated at baseline between the intervention and control group in the total study population and in each pilot site separately by means of chi-square tests for categorical variables and one-way ANOVA for continuous variables. These analyses provide insight in the comparability of the participants in both conditions and whether statistical correction for certain characteristics in the analyses is needed.

Main effects at follow-up will be evaluated for the total study population, as per "intention to treat", using a multilevel modelling approach. Clustering effects at study site-level will be taken into account. Multilevel linear regression analyses will be conducted for continuous outcome variables with group (intervention or control) as independent variable. Multilevel logistic regression will be performed for dichotomous outcome variables. We correct effect estimates of multilevel analyses for covariates, based on literature (Metzelthin et al., 2013); age, sex, living situation, education level and the baseline status of the outcome variable. We will assess interactions between intervention condition and study site, gender, age and education level in the association between intervention condition and all outcomes (Fransen et al., 2017). We consider a

P-value of 0.05 or lower to be statistically significant. The main intervention effects are evaluated using comparable analyses stratified per pilot site.

Depending on valid data, number of participants, and follow-up time, data of wearables and the impact of the ValueCare app (only applicable for a limited number of pilot sites) is analysed to study intervention impact in the intervention group only. For example, step counts will be available in multiple pilot sites. These data can be combined, depending on time used etc., to evaluate the mean change in the intervention group.

A per protocol analyses is performed, evaluating the impact on participant-groups. To do this, we will also combine information from the formative and summative information. For example, participants who received a higher dose of the intervention compared to the control group participants. To estimate dose the presence of a care plan and activation of modules in the app is used. If available, follow-up monitoring, is used to develop a variable that assesses dose delivered (e.g. care plan set, care plan set and modules activated, care plan set + modules activated + follow-up monitoring record). A specific per protocol analyses could also study the impact of using wearables in addition to setting up a personal care plan (only applicable for a limited number of pilot sites).

#### c. Cost-effectiveness

Using the baseline measurement as control group, a preliminary cost-effectiveness analysis will be performed from a societal and healthcare perspective and with a time horizon of 6 months. Healthcare costs for individual participants will be determined by multiplying resource use (doctor appointments, hospital emergency rooms and hospital admissions) with corresponding unit prices. Productivity losses for individual participants (lost productivity at paid work due to absenteeism and lost productivity at unpaid work) will follow from the PCQ. Quality-Adjusted Life Years are calculated using the EQ5D HR-QoL measure.

In dialogue with the work package on business exploitation, a 'Social Return on Investment' ('SROI') approach will also be used to strengthen the development of future business exploitation.. The economic ROI and the forecasted cash flow will be estimated; the distribution of cost between public and private organisations will also be considered as well as its potential utilisation. Then the social and health outcomes for older citizens, caregivers and workers will be added (SROI). Consequently, all positive and negative outcomes will be considered from a financial, economic, quality of life, and working conditions point of view.

### 3.7 Interdisciplinary collaboration between partners

The whole consortium will work closely with the evaluation WP to support success and uptake of the eventual solution. There is a strong interlinking of evaluation inputs and outputs towards other tasks in the project. During the project the intermediate results will be frequently discussed with the work packages on the digital solutions to improve the ValueCare technology, and with the work package on dissemination to promote future implementation, and with the work package on business exploitation to collaboratively develop the future exploitation of the results.

There are several structures in place to ensure the evaluation work serves the purposes of the project and guidance and inspiration between WPs is shared. Regular meetings between WP2, WP3, WP4 and WP5 ensure interlinking the evaluation to co-creation, technical solution, implementation and pilot sites. With regard to acceptability, appropriateness, feasibility, usability and fidelity, exchange between WP3 and WP5 will take place with regard to data collection and interpretation, also serving WP7 exploitation opportunities.

Close collaboration by regular meetings between WP5 and WP7 align the evaluation study with the input needed for eventual ValueCare exploitation and the access to market. Proper evidence is collected to support successful adoption by health systems, reimbursement bodies and the market. The feasibility study (Task 7.2) directly connects to data collected as part of the evaluation study. It will consider the information gathered from pilot sites (costs, benefits, potential investors, funding, target, etc.) and, as described in the methodology section, budget impact, health outcomes (QALYs, HRQoL) and indirect care costs.

An External Advisory Board consists of a group of 8 experts and representatives of stakeholders with complementary profiles and consolidated expertise. The Advisory Board provides critical suggestions and comments to the Evaluation study. Every 4 to 6 weeks the Advisory Board of the ValueCare project meets and the progress and collaboration in relation to the evaluation is a standard discussion topic.

The communication and dissemination strategy will be developed in WP6. As part of the communication strategy, scientific project results will be disseminated through publications in scientific peer-reviewed journals and conferences. In addition, social media and the website (<https://projectvaluecare.eu/>) provide a platform to further disseminate key findings of our project to all stakeholders. Key findings from the evaluation study are communicated to WP6 and translated in communication messages.



## 4 Findings and conclusions

In the evaluation study data from all resources is collected, combined and evaluated to demonstrate impact and support successful uptake and exploitation of the ValueCare approach. The ValueCare evaluation study is a continuing collaboration between partners in the consortium aiming to study all aspects of the implementation and impact of the ValueCare approach to provide meaningful and usable insights for exploitation in science, tech and in practice. The evaluation study combines different methodologies, data and analyses to provide in depth insight in both the acceptability, appropriateness, feasibility and usability of the ValueCare approach. The ValueCare approach is compared with 'usual care' practice in terms of benefits in multiple domains of health and wellbeing among older people, their caregivers and health and social care professionals.

We expect to encounter some challenges in the study. Firstly, previous research has indicated that recruiting and retaining older people with chronic conditions in research studies can be difficult due to for example reduced vision and hearing, the severity of health problems, or fatigue (Dibartolo et al., 2011). For that reason, the recruitment strategy seeks to encourage the participation of this population by providing a fair opportunity for them to participate and to ensure we reach our target sample size. Furthermore, capacity building activities including training sessions and regular communication with health and social care professionals will be put in place by local study teams to reduce recruitment challenges and increase the adherence to the study. Furthermore, it is possible that some elements of the technical solution may not be used by older people, family members or professionals due to the lack of interest or an unfriendly interface design (Nikou et al., 2019). To encounter these challenges, the research team developed the intervention implementing a key co-design process of the ValueCare approach and technology solution. Moreover, training activities are expected to facilitate the implementation of the intervention and the use of the new technology, increasing the adherence to the ValueCare intervention and use of the technical solutions by the target groups (Sanz et al., 2021).

Moreover, this study has several strengths which are important to stress. First of all, the ValueCare evaluation study combines a formative and summative evaluation. Moreover, all available data resources are used and combined to study the impact of the ValueCare approach among end-users. This comprehensive approach to evaluation will help to understand the complexity of the interactions between many contextual factors, and therefore contributes to reducing the research-to-practice gap, uptake of the solution and successful access to the market (Curran et al., 2012). Second, this study explores the ValueCare approach among a diverse older adult populations in seven different European settings which generates contextual information on its acceptability, appropriateness, feasibility and usability. By utilising a complementary set of methods and data resources, a cohesive evaluation will be applied.

In summary, the evaluation study is underpinned by a multidisciplinary collaboration that ensures that the outcomes will serve exploitation in the scientific, technological and professional domain. A broad array of data is collected continuously in collaboration with partners in the consortium to make use of all resources available, including the technical solution, interviews, self-report, pilot-site visits and administrative data. Analyses will study the acceptability, appropriateness, feasibility and usability of the ValueCare approach as well as the level of fidelity during implementation. Among the people who contribute to the collection of the ValueCare data are older people in both the intervention group and

the control group, informal (family) caregivers, professional care providers, IT specialists, care managers and policy makers. In addition, a preliminary cost-effectiveness analysis will be performed.

The progress and the outcomes of the broad and ongoing evaluation will be frequently discussed within the consortium, with the advisory board of ValueCare and with relevant stakeholders. During the project, lessons learned can be applied in improving ValueCare. The evaluation is needed to support the future implementation and the business exploitation of ValueCare. There will be continuous interaction with the advisory board and with the work package on dissemination and business exploitation.

In conclusion, the combination of a broad, ongoing formative and summative evaluation, using all available data and resources, will improve the ValueCare solutions during the course of the project, and will subsequently demonstrate the impact and conditions for successful uptake and business exploitation of the ValueCare approach.

## 5 References

Akpan, A., Roberts, C., Bandeen-Roche, K., Batty, B., Bausewein, C., Bell, D., Bramley, D., Bynum, J., Cameron, I. D., Chen, L. K., Ekdahl, A., Fertig, A., Gentry, T., Harkes, M., Haslehurst, D., Hope, J., Hurtado, D. R., Lyndon, H., Lynn, J., Martin, M., ... Banerjee, J. (2018). Standard set of health outcome measures for older persons. *BMC geriatrics*, 18(1), 36. <https://doi.org/10.1186/s12877-017-0701-3>

Council of Europe (2014). Recomendación CM/Rec(2014)2 del Comité de Ministros a los Estados miembros sobre la promoción de los derechos humanos de las personas mayores. Retrieved from: <https://goo.gl/xFDLwR>

Curran GM, Bauer M, Mittman B, et al. Effectiveness- implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012; 50: 217–226.

Dibartolo, M.C. & McCrone, S. (2003). Recruitment of rural communitydwelling older people: Barriers, challenges, and strategies, *Aging & Mental Health*, 7:2, 75-82, DOI: 10.1080/1360786031000072295

Franse, C. B., Voorham, A. J., Van Staveren, R., Koppelaar, E., Martijn, R., Valía-Cotanda, E., ... & Raat, H. (2017). Evaluation design of urban health Centres Europe (UHCE): preventive integrated health and social care for community-dwelling older persons in five European cities. *BMC geriatrics*, 17(1), 1-8.

ICHOM (2016). Elderly Standard Set. Retrieved June 5, 2020, from: [www.ichom.org](http://www.ichom.org)

International Longevity Centre Brazil (2015). Active Ageing: A Policy Framework in Response to the Longevity Revolution. Rio de Janeiro: ILCB. Retrieved from: <https://goo.gl/YfVQUH>

Metzelthin SF, van Rossum E, de Witte LP, Ambergen AW, Hobma SO, Sipers W, Kempen GI. Effectiveness of interdisciplinary primary care approach to reduce disability in community dwelling frail older people: cluster randomised controlled trial. *BMJ*. 2013;347:f5264.

Middel B, & van Sonderen, E. (2002). Statistical significant change versus relevant or important change in (quasi) experimental design. *Int J Integr Care*, 2:e15.

Nikou, S., Agahari, W., Keijzer-Broers, W., & de Reuver, M. (2020). Digital healthcare technology adoption by elderly people: A capability approach model. *Telematics and Informatics*, 53, 101315.

Proctor, E, Silmere, H, Raghavan, R. et al. (2011). Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*, 38:65-76.

Sanz, MF, Acha, BV, & García, MF. (2021). Co-Design for People-Centred Care Digital Solutions: A Literature Review. *Int J of Integr Care*, 21(2): 16.

Shilton, T., Sparks, M., McQueen, D., Lamarre, M. C., Jackson, S., & executive committee of the International Union for Health Promotion and Education-IUHPE (2011). Proposal for new definition of health. *BMJ (Clinical research ed.)*, 343, d5359. <https://doi.org/10.1136/bmj.d5359>

WHO (2002). Active Ageing: A Policy Framework. Geneva: World Health Organisation. Retrieved from: [https://apps.who.int/iris/bitstream/handle/10665/67215/WHO\\_NMH\\_NPH\\_02.8.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/67215/WHO_NMH_NPH_02.8.pdf?sequence=1&isAllowed=y)