



D7.2 INTERIM PROCESS EVALUATION REPORT - GUIDELINES

WP7 Evaluation

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1. Introduction

1.1 Purpose of the document

This document describes how the analyses should be carried out and presented by pilot sites in the D7.2 Interim Evaluation Report deliverable.

2. Guideline for reporting

The objective of the guideline is to assist the local pilot teams in the analysis of the data they have collected and to make sure that the analysis and reporting of the results are similar and comparable across pilots.

The structure of the reporting guideline follows the MAST structure (see Figure 1)(1). Any changes in the MAST model has been **underlined** and put in *cursive* in the model.

However, since the CareWell is in the beginning of the data collection phase only data on relevant domains will be covered in the D7.2 Interim Evaluation Report. The guideline presents a minimum level of information that all pilots should provide. These data will be the basis for a site by site analysis that will be performed by the evaluation team at Kronikgune. Some pilots may want to specify specific health care, social care or integrated care initiatives or other additional studies and data collection which we encourage. However, these extra analyses and information are generally not described in the guideline.

Each section within this guideline presents a description of the domain and the necessary reporting, which is also presented as questions towards the end of each domain. In addition, a number of tips are provided for further information as well as examples on how others have reported the individual domain.

Finally, a template has been extracted, including the questions that need to be answered within each section. A complete reporting should include answers to all questions within each template.

Preceding consideration

- Purpose of the **integrated care model** and the **ICT** application?
- Relevant alternatives?
- International, national, regional or local level of assessment?
- Maturity of the application?

Multidisciplinary assessment

1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness
4. Patient perspectives
5. Economic aspects
6. Organisational aspects
7. Socio-cultural, ethical and legal aspects

Transferability assessment

- Cross-border
- Scalability
- Generalisability

Any words highlighted and underlined are an addition to the MAST model for the purpose of the CareWell project.

Figure 1: The elements in MAST



2.1 Background

The guideline is based on a number of documents:

- *The Renewing Health Guideline on analysis and reporting of results from the pilots in Renewing Health, September 2013.*
- *MAST-Manual*
The detailed description MAST – Model for Assessment of Telemedicine applications and the 7 domains included in MAST can be found in the MAST-manual (2010), see <http://www.renewinghealth.eu/project-overview/overview/assessment-method>. A short description can be found in Kidholm et al. (2012).
- *Deliverable D7.1 CareWell Evaluation Framework, 2015.*

3. Data cleaning – before analysis of data

It is important to clean the collected end-users data for data errors before uploading it to the central web database and before any analysis is initiated. This means that you should check whether data are missing, whether the recorded values are plausible and rectify errors in the data if needed.

By doing this, we can hope to find the major errors in the dataset. However, it must be acknowledged that we cannot find all transcription and data entry errors. See Altman (1999) for a more detailed description of data cleaning, on which the following description is based (2).

The site will perform its own data cleansing process before submitting data to the central web-based database and before analysing the data. All subjects with missing values, or values that are considered illegal or outliers, must be checked and compared to an alternative reliable data source if such is available. The correct value (the most plausible) should be included in the dataset. However, a note must be made about the alteration of the value.

How can errors occur?

Errors can emerge when the data are originally recorded (often on paper) or when data are typed or entered into a computer. The most frequent errors are:

- Mistakes in the coding of answers (e.g. because data are entered by different persons).
- Confusion over the correct unit of measurement (e.g. misplacing of the decimal point).
- Mistakes in the coding of dates.

What can I do?

We have tried to minimize the risk of errors by setting up rules in the codebook for the data format (see the columns Variable type and Note in the codebook) when uploading to the central database (e.g. specific format for entering dates, ranges for entering clinical data (height, weight, heart rate,...) and specifying the number of decimals when appropriate). Accordingly, three kinds of checks of data should be made: Range checks, consistency checks and check of dates:

Range check is done by examining the distribution of responses to each item or question in your data set, e.g. by producing frequency tables for each variable. In Table 1 below e.g. the value 12 for Height should not be include as a valid observation, but compared to an alternative reliable data source if such is available. Otherwise, the observation should be defined and excluded as a missing value. For categorical variables (with nominal or ordinal data) it is easy to identify these errors, e.g. if more categories for gender are registered. For continuous data like age it is often more difficult to determine which values are plausible and which are not. However, as mentioned before we have tried to specify realistic lower and upper limit for each variable in the codebook when possible to help in this. Values outside of the range stated in the codebook will not be possible to upload to the central web database.

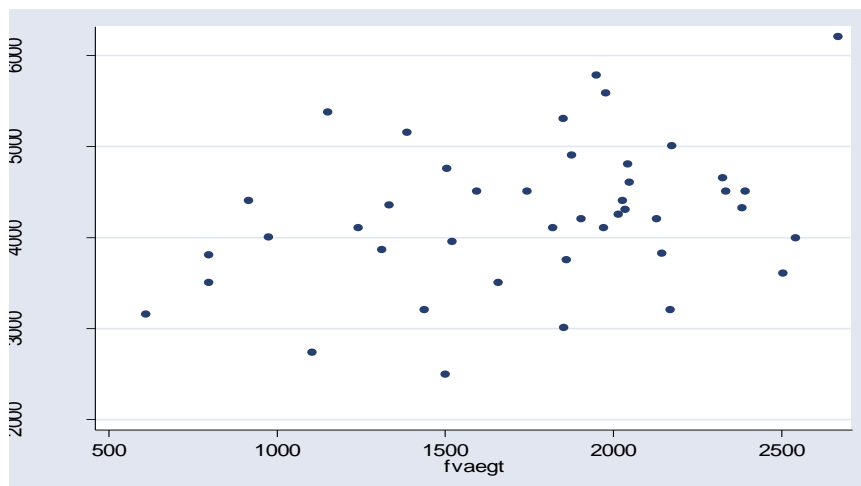
**Table 1: Frequency table of end-user's height**

Patient Id	Height
2000a	165
2005a	174
2006a	160
2008a	194
2011a	12

Notice, that the values outside the range are not necessarily wrong, but should be checked. Only values that are considered impossible (e.g. ages higher than 150 years or height of 12 cm) should be excluded. If suspicious outliers are found, a strategy can be to analyse the data set both including and excluding the outliers in order to identify the effect on the result. If outliers have large impact, a statistical expert should be consulted in order to employ alternative statistical methods, e.g. rank methods.

Consistency checks is more complicated and is using the fact that the possible values on a variable for a respondent depend on the values of the respondent on other variables. As an example, if two variables are used to construct another variable, e.g. BMI (height and weight), it should be checked whether the values of the combined variable is reasonable.

If repeated observations or several measurements of the variable are made over time, it should also be examined whether the development over time for each respondent is reasonable, e.g. in measurements of weight or height. In general, all pairs of variables can be checked by producing a scattergram, see example below in Figure 1, from a study of relation between birth weight (X-axis) and weight after 6 weeks (y-axis) for premature babies.

**Figure 2. Example of scattergram**

Check of dates: Variables including information on *dates* often have a large proportion of errors. It should therefore be checked that:

- All dates are within a reasonable time span (e.g. no birth date before 1900 and only 4 digits).
- All dates are valid (e.g. days range from 1 to 31, months from 1 to 12)
- Dates are correctly sequenced (e.g. birth before surgery before death)



- Age and time interval are reasonable (when age and time interval is computed by use of dates)

When a potential error is found, next step is to locate the appropriate source document, e.g. a paper questionnaire, determine which value that should have been entered into the data set and make the necessary corrections.

Missing observations: An important part of the checking and cleaning of data is the identification of missing observations for each variable. As described in the minimum dataset, if a respondent refuse to answer a question or if a question has not been asked, the value 9999 should be used. Thus, it is important that these values are identified as missing values for each variable to the statistical software before analysing the data. However, the way missing values are defined in practise varies from software package to software package. Therefore, you must follow the manual to the software package you use.

4. Analysis and reporting of data within relevant domains

The protocol will evaluate the impact of the new organisational models developed in the framework of CareWell project in order to provide ICT supported integrated healthcare (IHC) to frail elderly patients. The evaluation will be performed covering the needs of the different principal stakeholders, such as end users (care recipients), voluntary and non-voluntary informal carers, formal care staff / professionals, managers, decision-makers, and third-party payers. Evaluation of integrated healthcare service delivery processes (process evaluation) will improve the current scientifically based knowledge base on barriers and facilitators towards integrated healthcare delivery. Beyond this, scientific knowledge will be generated on outcomes of integrated care service delivery from the perspective of all actors involved.

In the following sections the analysis and reporting of data within relevant MAST domains for this time being are described. The structure of each section is the same:

- Introduction - including definition of the domain and relation to the minimum data set
- Guideline for reporting
- Reporting of results – description of the information, tables and results that must be produced within each domain including templates.

5. Domain 1: Description of the health problem and characteristics of the application of the intervention

5.1 Introduction

As the MAST Manual describes, the first domain includes description of the health problem of the end-user and of the application being assessed including description of the current use (1). In CareWell this will include a description of the social needs of the end-user, a description of the integrated care model as well as a description of the information flow between sectors (health / social / end-user / etc.). Thus, the content of this domain serves as a description of the background of and context in which the study is carried out and helps to understand the perspective from which the assessment is performed.

Description of the geographical context and the health and social care setting is relevant for the construction of economic and/or organizational models in order to assess the impact of, for example, the future deployment of the care model under investigation, or the promotion of its implementation, etc. In addition, on a later stage of the assessment, the information provided in this domain could be used for evaluation and discussion of the generalisability of the reported results.

There are three main topics included within Domain 1 (the third topic has been added by the evaluation team in order to include integrated care in the MAST model):

- Description of the target diseases or health problem and its social impact,
- Description of integrated care pathway, including information and work flow between sectors, explaining its current pathways and how this is expected to change with the new service as well as the implemented ICT.

A large part of this information is already included in the Local Operational Protocols and description of pathways, and could be directly used. Nevertheless, at the time of the reporting of the assessment results, the actualization of some data should be considered.

5.2 Guidelines for reporting

The guidance offered here is based on the elements proposed for these topics in the MAST model (1), together with other relevant methodological briefings (3) and adapted to serve the evaluation needs of the CareWell pilots investigating the impact of integrated care models.

Below, a description of the elements that should be reported in this domain is listed, together with some orientation on which questions they answer and the methods for gathering the necessary information.

Some of the elements of this domain might overlap with or be complementary to elements in other domains. Some of these elements are considered OPTIONAL for reporting and it is up to the pilot teams to consider their inclusion in the final assessment report or in scientific publications.

If the description of the health problem, social needs or the integrated care and ICT solution includes references to scientific publications or other kinds of literature, it is important that the source is correctly referenced i.e. by using the APA or Harvard citation styles, within this production, the Harvard style is used. Easy referencing can be facilitated by the use of EndNote or RefMan (the first is free of charge).



5.3 Reporting of results

5.3.1 Description of the health and social problem

As a starting point a short overview of the disease or health problem for which the integrated care model has been designed and is used for in the current study must be provided, including:

- its definition and naming according to a relevant classification system (e.g. ICD-9 or 10);
- underlying mechanism(s) and symptoms of the health problem, as well as characteristics which allow a precise diagnostic;
- the natural course of the health problem and the different stages in the disease evolution, which may be object of different interventions; if relevant – e.g. when the technology does not target the whole clinical condition – a description of subgroups or special indications within the disease should be included;
- disease prognosis and consequences of the disease for the individual (e.g. pain, disability, etc)
- known risk factors for acquiring the health problem (OPTIONAL)
- social needs associated with the health problem (OPTIONAL)

The overview should include answers to the following questions:

- Which disease/health problems (including ICD-9 or 10) are targeted?
- What are the symptoms of the diseases?
- What is the natural course of the health problem and its clinical stages?
- What are the possible consequences of the condition and the burden of the disease for the patient?
- Which are the known risk factors for acquiring the diseases? (OPTIONAL)
- Which social needs are associated with the health problem?
- What are the social consequences associated with the health problem?

Tips to identity information

The information necessary to describe the elements considered here can be found in the medical and social science literature and in scientific publications.

5.3.2 Quantification of the burden of the disease/health problem

You have to describe the epidemiology of the health and social problem in order to quantify the burden for the society and for the healthcare system. For this, you will have to describe the incidence (rate of occurrence of new cases per year) and prevalence (the proportion of cases in the population at a given time) of the targeted health problem, as well as the incidence and/or prevalence of the consequences of the disease (i.e. mortality, disability or disabling symptoms, sickness leave, retirement, social isolation, etc.).

Questions to be answered:

- How many people belong (or will belong) to the specific target group having the health problem at the moment?
- What is the burden of the disease in terms of mortality, disability, life years lost, personal and social consequences, etc?



Tips to identity information

To identify the information needed, an effective approach can be to use the evidence from existing systematic reviews (cohort studies, cross-sectional surveys) and/or primary data sources, such as routinely collected statistics and registers. Depending on the disease these data may vary between different geographical contexts, and, accordingly, it is important, when possible, to give comparative information on both, local and international level. Also, who.org often has information on prevalence, incidence and consequences of different health conditions.

5.3.3 Current management of the health and social problem (usual care)

This topic is focused on a description of how the disease is being managed in the current clinical practice (usual care) in the local context of the pilot and, whether this practice reflects the recommendations of evidence-based clinical practice guidelines. Since CareWell is focusing on integrated care a description is required of how the disease currently is being managed in the health sector and, if any, how the integration between care levels works. In addition, if family members are involved in the care it should be described in this section. In case there are regional or national guidelines or programs, you should references to these. If any, these guidelines should be specified. If relevant for the concrete pilot study, the existing differences in the clinical management of different end-user subgroups could be described (OPTIONAL).

Other potential comparators for the ICT solution assessed in the project should be described if possible.

The existing alternatives for managing the health problem (or the specific end-user subgroups) could be described here.

Questions to be answered:

- How is the disease/health problem and social needs currently being managed? In accordance with which (if any) practice guidelines/recommendations?
- Which are the differences (if any) in the management of the different stages of the disease? (OPTIONAL)
- What are the other evidence-based alternatives in the disease management, if any? (OPTIONAL)
- Which integrated service, if any, is offered to people with this health problem?
- How are family members being involved in the care of this health problem? (OPTIONAL)

Tips to identity information

Information sources to support the description of these issues might be results (published or not) of surveys, utilization reviews and audits, or alternatively, expert interviews can be carried out. In most cases, the clinicians participating in the pilots will be able to contribute with important information to this topic. In addition, an overview of guidelines should be given, synthesizing relevant recommendations.

5.3.4 The ICT solution including any telemedicine application (technology)

A description of the purpose of the ICT solution, how it supports integrated care, and its current use in the study (intervention) should be made.

The ICT (technology) should be described in a manner that is detailed enough to separate it from related systems, using concepts that allow for a person unfamiliar with the application to get an overall understanding of its functioning and use.

The introduction of the ICT application in the healthcare and social care continuum and its use may target one specific aspect of the burden of the health problem - for example, disability but not mortality; or healthcare cost but not symptomatology. In this part of the report it is important to explain for what purpose(s) the application was designed and how it is used in the provision of integrated care.

This part is closely related to the main objective and hypotheses of the study. Further, the intervention under assessment is introduced. It is necessary to describe the level(s) of health care (primary, secondary, tertiary care, emergency unit, home care, etc) where the new ICT-based service is introduced and/or links, as well as the professional profiles involved. Figures or diagrams as visual presentation might be useful in improving the understanding of the existing relations between actors and processes.

The description of the organizational setting presented in this domain can be used as introductory information to the issues discussed in the Organizational domain.

Questions to be answered:

- Which aspects of the problem with integrated service are targeted by the ICT solution, i.e. are expected to be improved by its use?
- How is the ICT solution used to provide integrated care?
- At which level(s) of healthcare and by which type(s) of professionals and end-user is the application used?

5.3.5 Technical characteristics of the application

In this part, the report may refer to a technical description provided elsewhere, but data regarding the model and the manufacturer of the system used for the provision of the ICT-based service, has to be provided. Short technical description of the type of device(s), operations, software and hardware, imaging and other available features can be useful. For example, you should specify the type of information that is managed by the application (end-user demographic data, clinical outcomes registers, care plans, questionnaires, drug orders, etc.) and the clinical or other tasks supported by the system (referrals, follow-up visits schedule, data exchange with EHR, etc).

Another issue, which has to be dealt with, is the life cycle of the technology and the level of maturity of the technology, as well as the actual market situation, e.g. how robust and diverse are the providers in the market. Knowing who manufactures the technology is relevant in order to identify potential sources of information (e.g. ongoing developments, price changes, etc).

Questions to be answered:

- Which are the technical characteristics of the application tested?
- Is the technology fully developed or in its early stages?
- How is the solution integrated with other applications and the IT-infrastructure?
- Is there previous evidence or experience on the use of the ICT solution and the telemedicine application in the target health problem, or in other clinical conditions? (OPTIONAL)

5.3.6 Requirements for the use of the ICT solution

The part is focused on describing the requirements for successful use of the ICT solution.



Firstly, all material investments necessary for the functioning of the system have to be defined as this gives important reference regarding the need for back-up investment to cover for breakdowns in use. This includes all those tools and parts of the system that need to be purchased (and installed) – i.e. devices, machinery, computer programs, etc.; as well as clear description of necessary facilities either in the clinical setting or in the end-user's home (e.g. independent room for teleconsultations, broadband connection, etc).

Further, issues like the need for common infrastructure and interoperability should be discussed. Interoperability refers to the integration needs with regard to other clinical and administrative systems, e.g. electronic health record, patient administrative systems, clinical databases or other applications. The assessment must also include a description of the need of user support (call center), help desk functions and back-up systems and procedures.

If any, existing registers and records for monitoring the application's use should be specified (OPTIONAL). These may be collecting data about the use of the application regarding care processes, professionals involved, end-users and their health outcomes.

Training of professionals and end-users:

The next element of this topic is to briefly describe the needs of training for health care and professionals and end-users. Notice that the description of training is a major part of the organisational domain. If the technology requires a specific skill that is developed over a period of time using it (learning curve) it should be estimated how long a period a professional needs to use the ICT system in order to reach acceptable quality.

Questions to be answered:

- What kind of special premises are needed to use the ICT system?
- What equipment and supplies are needed to use the ICT system?
- What kind of data needs to be collected to monitor the use of the application? (OPTIONAL)
- What kind of training is needed for the users (personnel and end-users) of the ICT solution?

Tips to identity information

The information concerning most of the mentioned issues regarding the technology may be obtained from the manufacturers, interviews with clinical and/or technical experts in the use of the technology, user surveys, but also from the literature (i.e. descriptive publications, applicability studies).

5.3.7 Requirements for Integrated Care Model implementation

The final part of this domain is focused on describing the requirements for successful use of the Integrated Care Model.

Firstly, all material and structural investments necessary for the implementation of the Integrated Care Model have to be defined. This includes all those tools and parts of the model that need to be purchased (and installed) – i.e. devices, machinery, computer programs, etc.; as well as clear description of necessary facilities either in the clinical setting or in the end-user's home (e.g. independent room for teleconsultations, broadband connection, etc).

Training of professionals and end-users:

The next element of this topic is to briefly describe the needs of training for health care, social care professionals and end-users. Notice that the description of training is a major part of the organisational domain.

Questions to be answered:

- What kind of special premises are needed to implement the Integrated Care Model?
- What kind of training is needed for the users (personnel and end-users) of the Integrated Care Model?

5.4 Template for Domain 1

Description of the health and social problem:

- Which disease/health problem (including ICD-9 or 10) and social problems are targeted?
- What are the symptoms of the diseases?
- What is the natural course of the health problem and its clinical stages?
- What are the possible consequences of the condition and the burden of the disease for the patient?
- Which are the known risk factors for acquiring the diseases? (OPTIONAL)
- Which social needs are associated with the health problem?
- What are the social consequences associated with the health problem?

Quantification of the burden of disease/health problem and social problem:

- How many people belong (or will belong) to the specific target group having the health problem at the moment?
- How large a proportion of the specific target group have social needs?
- What is the burden of the disease in terms of mortality, disability, life years lost, personal and social consequences, etc?

Current management of the health and social problems (Usual care):

- How is the disease/health problem and social problem currently being managed? In accordance to which (if any) practice guidelines/recommendations?
- Which are the differences (if any) in the management of the different stages of the disease? (OPTIONAL)
- What are the other evidence-based alternatives in the disease management, if any? (OPTIONAL)
- What social assistance is being offered to people with this health problem?
- Which integrated service, if any, is offered to people with this health problem?
- How is family members or volunteers being involved in the care of this health problem?

Description of the ICT solution (technology):

- Which aspects of the problem with integrated service are targeted by the ICT solution, i.e. are expected to be improved by its use?
- How is the ICT solution used to provide integrated care?
- At which level(s) of healthcare and social care and by which type(s) of professionals, volunteers and end-user is the application used?

Technical characteristics of the application

- Which are the technical characteristics of the application tested?
- Is the technology fully developed or in its early stages?
- How is the solution integrated with other applications and the IT-infrastructure?
- Is there previous evidence or experience on the use of the ICT solution and the telemedicine application in the target health problem, or in other clinical conditions? (OPTIONAL)

Requirements for use of the ICT solution



- What kind of special premises are needed to use the ICT system?
- What equipment and supplies are needed to use the ICT system?
- What kind of data needs to be collected to monitor the use of the application? (OPTIONAL)
- What kind of training is needed for the users (personnel and end-users) of the ICT solution?

Description of the Integrated Care Model

- What are the components of the integrated care model?
- How the ICT solution fits on it?
- What professional roles are involved in the Integrated Care Model and what's the role they play?

Requirements for the Integrated Care Model implementation

- What kind of special premises are needed to implement the Integrated Care Model?
- What kind of training is needed for the users (personnel and end-users) of the Integrated Care Model?

6. Domain 2 and 3: Safety, clinical and social effectiveness

Domain 2 and 3 in MAST concerns the safety, clinical and social effectiveness of the Integrated Care Model.

6.1 Guideline for reporting

Since most of the pilot sites have only just started recruiting participants in the CareWell project, the reporting from Domain 2&3 will focus on:

- End-users
- Objectives
- End-user flow and recruitment
- Baseline characteristics

6.1.1 End-users

In this section information about the eligibility criteria for the patients and the settings and the locations where the data are collected should be described.

The eligibility criteria include information on disease, social needs, age limits, restrictions on co-morbidities etc. The description of usual care, the integrated care model and the ICT intervention include thorough descriptions of what happens to the end-user, when they are included in the CareWell project, what kind of care they are offered, who provides the care, how often and what does 'care' mean for the exact type of end-user (health care). It needs to be elaborated to the point that anybody – also non-clinicians – will understand every detail that the end-user experiences and even the parts that the end-user do not experience, but that somebody does in their care.

The main reason for describing this information is that readers should be able to see to which degree the study includes typical end-users and typical providers, institutions and settings of care.

In the textbox below an example of the description of participants and the interventions is presented.

To evaluate whether the introduction of a short-term telemonitoring program for COPD patients discharged from the hospital after disease exacerbation produces benefits in terms of a reduction in hospital readmissions and health related quality of life. In addition the trials evaluate the economical and organisational impact of the services and examine their acceptability by patients and health professionals.

Textbox 1. Example of description of participants

3000 patients with exacerbation of COPD according to the GOLD guidelines were admitted to the department at Odense University Hospital during the period of uptake between 2009 and 2011. All were assessed for eligibility (based on the criteria described) and 300 included. The department is serving patients from five municipalities including a population of 250.000 persons. The department has 25 beds and has 1700 inpatients and 20.000 outpatient visits annually.

6.1.2 Objectives

The objectives of the study should be included in the pilot protocol. As an example the objective can be described as below.

The overall aim of the evaluation carried out in CareWell is to identify the differences introduced by implementing ICT supported integrated healthcare in different domains according to the MAST evaluation framework, including safety and clinical outcomes, resource use and cost of care, user/carer experience and organisational changes.

The main focus of the evaluation will be the impact of so called “vertical” integration, that is the integration of services delivered between primary healthcare, secondary healthcare and the third sector (voluntary sector), and changing organisational models for the frail elderly patient.

6.1.3 End-user flow and recruitment

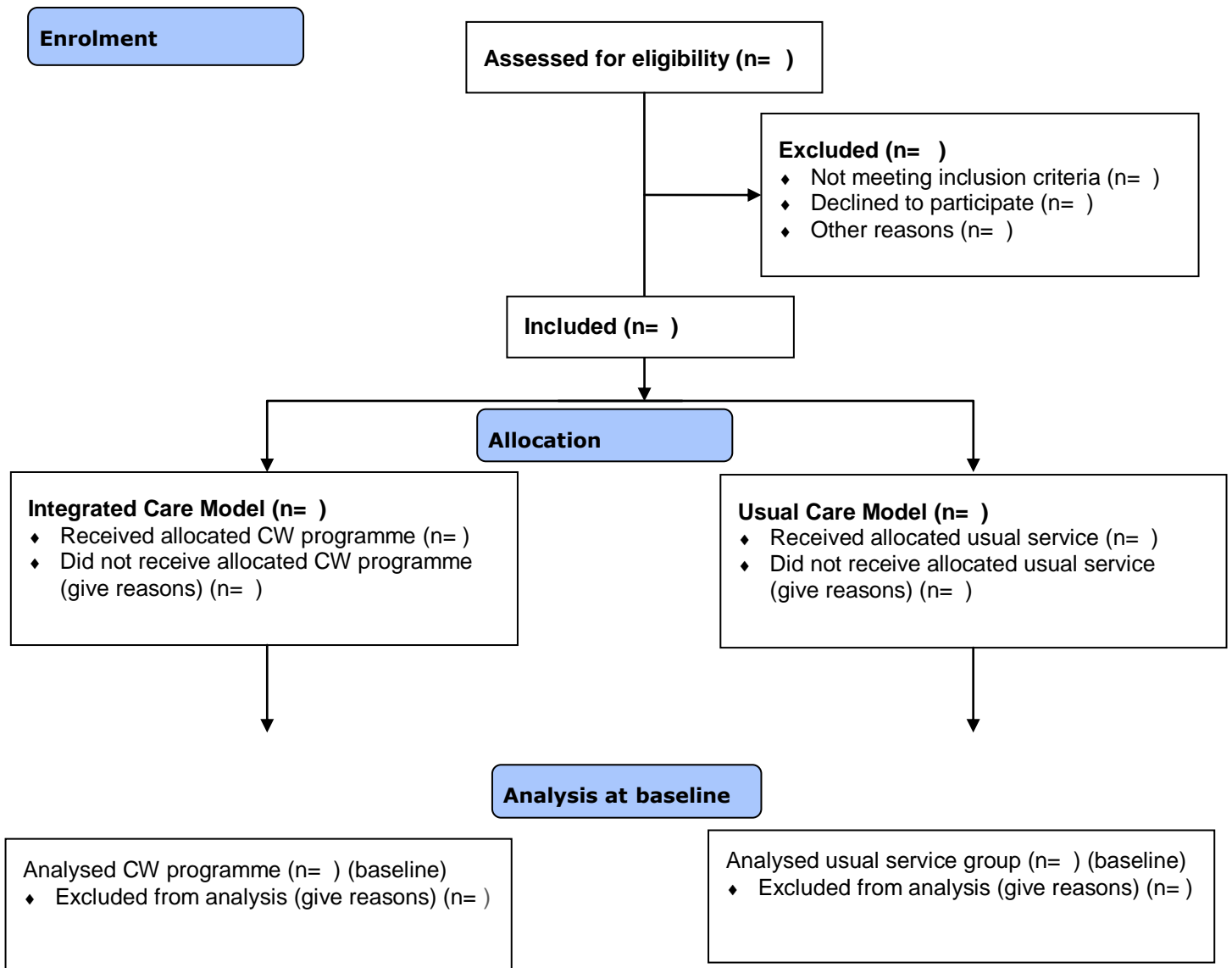
A flow chart of end-users paths throughout the CareWell has to be presented for each pilot site. In D7.2 Interim Evaluation Report the figure should account for all end-users:

- Tested for eligibility
- Found eligible
- Included – according to group
- Provided with service – according to group
- Included in baseline analyses – according to group

In relation to the figure, the elements need to be described in detail also, e.g. with presentation of the reasons for non-participation, if possible, since this could affect the external validity (validity of generalized). If you do not have all the information required in the chart, please indicate this with a question mark (?) in the relevant box. If possible, the number of people assessed for eligibility should also be reported. This can be difficult for some pilots, but it is very important for the assessment of the external validity of the study because the numbers indicate whether the end-users were likely to be representative of all eligible possible users.

In relation to the description of the participant flow, a description should also be made of the timing of the study: At which dates was recruitment being carried out?

The chart below is based on the CONSORT statement (4). Please note that the flow chart has been adjusted, since the CONSORT statement is a guideline aimed at randomised controlled trials. An explanation of what goes into each box can be found after the chart.



Please note: n is the number of people.

Figure 3: Flow chart of end-users paths throughout the CareWell project

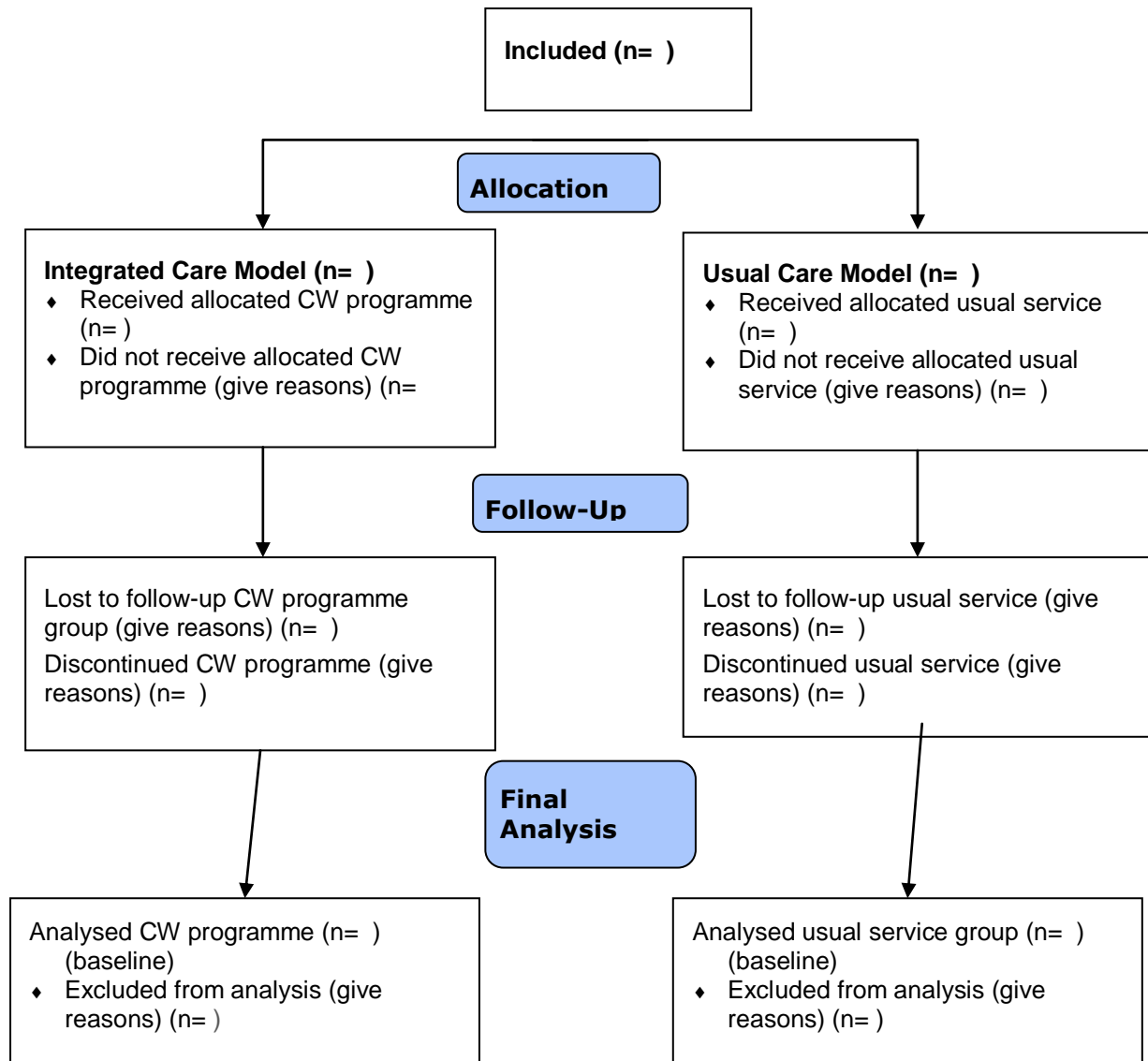


Figure 4: Flow chart of end-users paths throughout the CareWell project

Assessed for eligibility: The number of people that were considered as subjects for inclusion in the study. This number should include the total number of people, disregarding whether they were included or not.

Excluded: This is the number of people that ended up NOT being included into the study. It is further specified into categories describing the cause of each individual to not be included. The pre-specified categories are:

Patient refuses the use of devices

- 1) Felt overwhelmed with the amount of information they needed to provide.
- 2) Did not want to participate for health reasons.
- 3) Did not find the subject of the study relevant for their own situation.
- 4) Refuses participation in studies in general.

Excluded is a highly important category, for transferability purposes. So please read the section carefully, and contact WP8 lead if you have any questions



- 5) Did not believe that data protection was ensured.
- 6) Did not want to explain their decision.
- 7) Other reason. This category gives the opportunity to give other reasons. These reasons should be specified. So, if one end-user gives the reason "I have not internet connection", that should be stated as an option, and each number of end-users that give that reason should be counted and registered as such. So, this is the field to note the possible, and highly important, reasons for declining that might not be related to the criteria for inclusion, i.e. "Cannot afford equipment", "No equipment available", etc.

Please note that in some settings it may be illegal to ask end-users to explain why they did not want to participate. So, if you are allowed to ask the question, feel free to do so. It can definitely provide interesting information, but it is not a mandatory measure.

Included: Is the number of end-users that were chosen for inclusion in the CareWell service, and who entered the study as end-user. So, the numbers should add up (Excluded + Included = Assessed).

Allocation: Describes the way in which the total sample was divided into the two groups of intervention and control. It is not described within the figure, but is clearly described in the "Methods" section (see below).

Allocation to CareWell programme: Includes the number of end-users that were allocated to (=put into) the CW programme group. In practice, this means the number of end-users that were meant to receive the CareWell service. As a subsection, it needs to be specified how many end-users did receive the CareWell service. This is necessary due to the fact that reality does not always reflect the plans. If no end-users ended up NOT receiving the CW programme, the number should be equal to the overall category of "Allocation to intervention". The second subgroup "Did not receive allocated CW programme" is for the number of end-users that did not receive the service although they should have. There can be multiple reasons for this, and it is important to register the reasons so that if the causes are practical, these can be sorted out at a later stage. Sometimes end-users do not receive the service because they die in the meantime. Sometimes they do not receive the service because something went wrong with the message that they should receive it. Sometimes other things cause the end-users to not receive the intended service. If this does not happen at the local deployment site, the category should include "n=0". Thus, it will be clear to readers that it was registered whether or not people received the CW programme, but that they did if they were allocated to receive it. Please note that the numbers should add up (Received allocated CareWell service + did not receive allocated CareWell service = Allocation to CareWell service).

Allocation to usual service: Includes the number of end-users that were allocated to (= put into) the usual service group. It needs to be specified as a subsection, how many of the end-users did receive the usual service intervention and how many that did not receive the usual service intervention. The purposes are similar to those of the category above "Allocation to intervention".

Analysis: This is not a section that needs to be explained within the figure. Instead, it should be clearly described within the "Methods" section (see below).

Analysis intervention group: This describes the number of end-users that were included in the final analyses. If some were excluded, it should be stated how many, and why, in the sub-group "Excluded from analysis intervention group". It might be that there is a rule that only end-users with > 50% of observations available are included in analyses, or there might be other reasons that a few individuals are excluded from the analyses, e.g. another severe disease was identified during the study period.

Analysis control group: As for the “Analysis intervention group”, it is important to take note of any end-users that were excluded from the analyses, including the reasons for this decision. Reasons should be similar for both intervention and control groups.

Follow-up: This is a category that does not need description within the figure. Instead, it should be described within the “Methods” section, how and when the end-users were followed up.

Please note that if you have decided to have multiple follow-ups for each group (i.e. at three months and at six months), the follow-up part of the figure should be repeated for each additional follow up, since it is likely that with time, more end-users leave the study. It might be a valuable finding, if there are trends in the pattern of leaving the study, so one follow-up section of the figure is necessary for one follow-up in real life.

Lost to follow up intervention group: Within the intervention group it might happen that some end-users are lost during the follow-up, and that they cannot be identified, so their follow-up data are unavailable for analysis. This can be caused by people moving to other geographic areas or other reasons. Please keep a record of the reasons that some people are lost to follow-up. As a sub-group, some people are lost to follow-up because they choose to withdraw their informed consent. If it is legal within your setting, please keep a record of the reasons for wanting to leave the study. If it is not legal, please just keep note of how many end-users decide to leave the study.

Lost to follow up control group: This section is just like the “Lost to follow up intervention group”, except that it concerns end-users within the control group.

6.1.4 Baseline characteristics

Baseline characteristics will be presented for each pilot site. Baseline distribution for both control and intervention groups, and the p-value for the difference, in order to assure the comparability of them, should be performed.

When calculating, the type and distribution of each variable determines how it should be presented. **Numerical** variables, also known as “counts” should be presented with a **mean** and **standard deviation** (SD). **Categorical** variable (a variable where you cannot assume that there is a rank between the categories, e.g. gender and marital status), should be presented with the **absolute value** and a **percentage** (%).

Measurement	Intervention	Control	Difference (p)	Missing
Sample size (n)	Number	Number		Number
Age	Mean (SD)	Mean (SD)		
Gender				
Male	Number (%)	Number (%)		
Female	Number (%)	Number (%)		
Marital status				
Never married	Number (%)	Number (%)		
Currently married	Number (%)	Number (%)		
Separated	Number (%)	Number (%)		
Divorced	Number (%)	Number (%)		
Widowed	Number (%)	Number (%)		
Cohabiting	Number (%)	Number (%)		
Education				
Less than primary school	Number (%)	Number (%)		



Measurement	Intervention	Control	Difference (p)	Missing
Primary school	Number (%)	Number (%)		
Secondary school	Number (%)	Number (%)		
High school	Number (%)	Number (%)		
College/University	Number (%)	Number (%)		
Post graduate degree	Number (%)	Number (%)		
Longest held occupation				
Manual	Number (%)	Number (%)		
Non manual	Number (%)	Number (%)		
Self-employed	Number (%)	Number (%)		
Unemployed (but able to work)	Number (%)	Number (%)		
Unemployed (unable to work)	Number (%)	Number (%)		
Homemaker	Number (%)	Number (%)		
Household income (euro/year)				
0-6.999	Number (%)	Number (%)		
7.000-13.999	Number (%)	Number (%)		
14.000-19.999	Number (%)	Number (%)		
20.000 or more	Number (%)	Number (%)		
Housing tenure				
Owners	Number (%)	Number (%)		
Renters	Number (%)	Number (%)		
People older than 18 living in household	Mean (SD)	Mean (SD)		
Mobile use (Yes)	Number (%)	Number (%)		
PC use (Yes)	Number (%)	Number (%)		
Alcohol				
None	Number (%)	Number (%)		
Less than 1/week	Number (%)	Number (%)		
1-7/week	Number (%)	Number (%)		
8-14/week	Number (%)	Number (%)		
15-21/week	Number (%)	Number (%)		
More than 21/week	Number (%)	Number (%)		
Tobacco use				
Never	Number (%)	Number (%)		
Former	Number (%)	Number (%)		
Current smoker	Number (%)	Number (%)		
e-cigarette	Number (%)	Number (%)		
Other	Number (%)	Number (%)		
Height (cm)	Mean (SD)	Mean (SD)		
Weight (kg)	Mean (SD)	Mean (SD)		
Primary disease				
Primary disease CHF	Number (%)	Number (%)		
Primary disease COPD	Number (%)	Number (%)		
Primary disease DIABETES	Number (%)	Number (%)		

Measurement	Intervention	Control	Difference (p)	Missing
Secondary disease				
Secondary disease CHF	Number (%)	Number (%)		
Secondary disease COPD	Number (%)	Number (%)		
Secondary disease DIABETES	Number (%)	Number (%)		
Comorbidity ICD-10 codes				
Myocardial infarct	Number (%)	Number (%)		
Congestive heart failure	Number (%)	Number (%)		
Peripheral vascular disease	Number (%)	Number (%)		
Cerebrovascular disease	Number (%)	Number (%)		
Dementia	Number (%)	Number (%)		
Chronic pulmonary disease	Number (%)	Number (%)		
Rheumatic disease	Number (%)	Number (%)		
Peptic ulcer disease	Number (%)	Number (%)		
Mild liver disease	Number (%)	Number (%)		
Diabetes without chronic complication	Number (%)	Number (%)		
Diabetes with chronic complication	Number (%)	Number (%)		
Hemiplegia or paraplegia	Number (%)	Number (%)		
Renal disease	Number (%)	Number (%)		
Any malignancy	Number (%)	Number (%)		
Moderate or severe liver disease	Number (%)	Number (%)		
Metastatic solid tumour	Number (%)	Number (%)		
Barthel index - 100	Mean (SD)	Mean (SD)		
Instrumental activity of daily living (IADL)	Mean (SD)	Mean (SD)		
GDS - Geriatric Depression Scale (Short Form)	Mean (SD)	Mean (SD)		
PIRU questionnaire on user experience of Integrated Care	Mean (SD)	Mean (SD)		
eCCIS - eCare Client Impact Survey				
No, I usually have to give only once	Number (%)	Number (%)		
I sometimes have to repeat	Number (%)	Number (%)		
I have to repeat quite frequently	Number (%)	Number (%)		
Yes, I have to keep repeating	Number (%)	Number (%)		
Refuse to answer	Number (%)	Number (%)		

6.2 Template for domain 2&3

End-users

- Describe the eligibility criteria for participating. Include any deviations from the criteria set in D6.1 Evaluation protocol.
- What service/care will an end-user in the CareWell project receive (new care)? Include both health and social care.
- Who will provide the care (doctors, nurses, social workers ec.)
- How often will the end-user receive care?
- What service/care will an end-user **not** included in the CareWell project receive (usual care)?



- Who will provide the care for usual care (doctors, nurses, social workers ec.)
- How often will the end-user receive care (usual care)?

Objectives

- What are the objectives of the CareWell project

End-user flow and recruitment

- At which date was the flow-chart filled out?
- At which dates was recruitment being carried out?
- Who was in charge of the recruitment (profession)?
- How many was tested for eligibility?
- How many was found eligible?
- How many was included – according to groups?
- How many was provided with service – according to groups?

Baseline characteristics

- At which date was the baseline table being filled out?
- How many was included in the baseline analyses - according to groups?
- Describe the mean age and gender distribution – according to groups?
- Describe the distribution of primary and secondary disease – according to groups.
- Describe social support according to groups.
- Describe significant differences between the groups ($p < 0.05$).



References

- 1) Kidholm K, Pedersen CD, Jensen LK, Ekeland AG, Bowes A, Flottorp S, Bech M. A model for assessment of telemedicine applications – MAST. *International Journal of Technology Assessment in Health Care*, 28:1, January 2012, 44-51.
- 2) Altman DG. *Practical statistics for medical research*. Chapman & Hall, London, 1999.
- 3) Zia Agha, Ralph M. Schapira, and Azmaira H. Maker. Cost Effectiveness of Telemedicine for the Delivery of Outpatient Pulmonary Care to a Rural Population. *Telemedicine Journal and e-Health*. September 2002, 8(3): 281-291.
- 4) Zwarenstein [M](#), [Treweek S](#), [Gagnier JJ](#), [Altman DG](#), [Tunis S](#), [Haynes B](#), [Oxman AD](#), [Moher D](#); CONSORT_group; [Pragmatic Trials in Healthcare \(Practihc\) group](#). Improving the reporting of pragmatic trials: an extension of the CONSORT statement. [BMJ](#). 2008 Nov 11;337:a2390