D8.1 Evaluation framework for SmartCare

Based on the SPIRIT guideline (WP8)

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Document information

Abstract

Contains the scientific protocols for the SmartCare trials.

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D8.1 v1.0 Evaluation framework for SmartCare

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

Executive summary

This deliverable (D8.1) is the scientific protocol for the SmartCare project. The protocol presents descriptions of all relevant information for carrying out an evaluation of ICT supported integrated care.

The protocol is based on the SPIRIT guideline for scientific protocols adapted to cohort studies. It presents the background of the evaluation, objectives, methodologies used for selection of participants, data collection, data management, statistics, monitoring and ethics. The protocol describes the evaluations of pilot sites along with the overall evaluation of SmartCare.

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1. Introduction

1.1 Purpose of this document

In SmartCare, WP8 requires a scientific protocol as a deliverable. This document describes the protocol for the individual pilot sites and in brief for the overall SmartCare project as well.

This document is produced based on the SPIRIT guidelines for scientific protocols (Chan et al. 2013) modified to fit a cohort study design, so only relevant items for cohort studies are considered and presented in this document.

This evaluation framework constituting D8.1 is structured as and intended to become a scientific protocol. Thus, throughout the text, when referring to the current document, it is described as a protocol as opposed to an evaluation framework.

1.2 Structure of document

Most of the headings in the document below include an Item number. These item numbers correspond to the way headings are presented in the SPIRIT guideline.

Section 2 provides background information on the trial, including the trial objectives and trial design

Section 3 describes the participants, interventions and outcomes, including inclusion and exclusion criteria.

Section 4 sets out data collection methods, while sections 5 and 6 cover data management and statistical methods respectively.

Finally, section 7 covers methods monitoring, section 8 ethics and dissemination, and section 9 contains references.

1.3 Glossary

COPD	Chronic Obstructive Pulmonary Disease
CR	Care Recipient
DM	Diabetes Mellitus
EHR	Electronic Healthcare Record
HCP	HealthCare Professional
I/FC	Informal / Family Carers
Meta-analysis	Statistical analysis pooling the results of different studies by pooling odds ratios or relative risks.
QoL	Quality of Life
SCP	Social Care Provider
Stopping rules	Stopping rules should be perceived to belong to the pilot or project level. So, rules for stopping include any indicator used as flag-raising to indicate safety problems related to the interventions.

2. Background information on trial

2.1 Item 6: Background and rationale

2.1.1 Introduction to the MAST model applied to integrated care (MASTATIC)

The most important aspect for the outcome evaluation of SmartCare was fitting the MAST model to be able to encompass the extended complexity of integrated care as opposed to telemedicine. Thus, the MASTATIC model was elaborated.

At the core of integrated care is the integration of social and health care in providing services to end-users. Therefore, the evaluation model needs to include outcomes across service delivery agents. Stakeholders participating in the care of end-users include:

- Health care providers.
- Social care providers.
- Volunteer organisations and/or relatives.

An elaboration of the MAST domains with the different stakeholders in presented in table format below:

Table 1: Extension of MAST to encompass social care and volunteers/relatives domains

MAST domain	Health care	Social care	Volunteers/relatives
1. Health problem and characteristics of application	1. Health problem and characteristics of application	1. Social problem and characteristics of application	1. Health and social problem and characteristics of application
2. Safety	2. Safety	2. Safety	2. Safety
3. Clinical effectiveness	3. Clinical effectiveness	3. Care effectiveness	3. Clinical and care effectiveness
4. Patient perspectives	4. Patient perspectives	4. End-user perspectives	4. End-user perspectives
5. Economic aspects	5. Economic aspects	5. Economic aspects	5. Economic aspects
6. Organisational aspects	6. Organisational aspects	6. Organisational aspects	6. Organisational aspects
7. Socio-cultural, ethical and legal aspects	7. Socio-cultural, ethical and legal aspects	7. Socio-cultural, ethical and legal aspects	7. Socio-cultural, ethical and legal aspects

As the MAST model was originally intended for use in the health care setting using telemedicine, this is reflected in all MAST domains being directly copied into the health care column. In the social care column, a few changes are made in that the problem to be described is the problem related to social care services, and the applications need to be described separately if they differ from applications used in health care. In addition, the third domain concerns the effectiveness of the care services delivered as opposed to clinical effectiveness. Finally, the fourth domain focuses on end-users, who are not necessarily patients. The volunteer/relatives column combines the two approaches, since the viewpoint differs according to the type of support or service provided by volunteers and/or relatives. Therefore, both health and social problems might be relevant along with

descriptions of application characteristics; clinical and care effectiveness might both be relevant, and finally, the fourth domain again views the end-user as not being a patient.

Please note that the elaborations to the MAST model were based on clarification issues in relation to integrated care. Careful reading of the MAST model does already include all the aspects mentioned above. Therefore, the MASTATIC model should not be considered a separate model adding to MAST, but rather a more thorough elaboration on the specific aspects and terminology concerns raised when evaluating integrated care.

The evaluation framework described as D8.1 in SmartCare was developed based on this adapted MAST model, the MASTATIC model.

2.1.2   Item 6a: Description of research question and justification for the trial

Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

The trial will evaluate the functions and impacts of the SmartCare pilot services from the point of view of the different principal roles/stakeholders, such as end users (care recipients), voluntary and non-voluntary informal carers, formal care staff/professionals, managers and fund-holders. Evaluation of integrated care service delivery processes (process evaluation) will improve the current scientifically based knowledge base on barriers and facilitators towards integrated care delivery. Beyond this, scientific knowledge will be generated on outcomes of integrated care service delivery from the perspective of all actors involved. Apart from generating a number of self-standing deliverables, this work package will directly feed into WP9 with a view to support further exploitation of project outcomes beyond the project duration by relevant stakeholders and wider dissemination within the project duration.

2.1.3   Item 6b: Explanation for choice of comparators

Comparators were chosen to be current delivery of health and social care processes, as provided by pilot sites individually. The current health and social care services will be described for the evaluation of SmartCare. The project uses local scenarios as the comparator in order to enable the evidence generated to contribute to local decision making on using the technologies. It was neither possible nor desirable to standardise the usual care in all pilot sites before carrying out the research project. Comparators were running simultaneously to the intervention, in most pilot sites divided by geographical aspects. Thus, the control groups were as similar as possible to the intervention groups. In addition, a number of possible confounding factors were measured for all participants.

2.2   Item 7: Specific objectives or hypotheses

The overall aim of the scientific studies carried out in SmartCare is: To identify the differences induced by implementing ICT supported integrated health and social care.

Any impact that ICT supported integrated health and social care might have on all users will be the subject of analyses according to the framework presented in the MAST model (Kidholm et al. 2012).

In addition, the objectives that will be tested in SmartCare are:

- Difference in number of contacts to health care.

- Difference in number of contacts to social care.

- Differences in use of health care services.

- Differences in use of social care services.

- Differences in costs.

- Differences in organisational aspects caused by implementing ICT supported integrated care.

- Difference in end-user empowerment.

- Difference in end-user satisfaction.

The specific data that will be collected in order to answer the objectives are specified in Item 12 on outcomes (see section 3.7 below).

2.3 Item 8: Description of trial design including type of trial, allocation ratio, and framework

It is important to note, that the overall study design in SmartCare is divided into three phases:
1) First wave pilot sites (cohort)
2) Second wave pilot sites (cohort)
3) Overall SmartCare study (meta-analysis)

This division into phases means that the pilot sites are required to adhere to one study design (controlled cohort studies), which will afterwards be pooled in a meta-analysis.

Data will be collected prospectively and with an allocation ratio of 1:1.

3. Methods; Participants, interventions, outcomes

The set-up of all SmartCare pilot sites is cohort studies, i.e. a group of people with similar characteristics are followed over a period of time. The groups are split into halves, so half of the population receives the intervention, and the other half receives usual care. The two groups run in parallel. The rules of division into groups are allowed to differ between pilot sites; so in some pilots there will be randomisation, whereas in others, geographical aspects decide the groups. Sufficient calculations on possible confounding from geographical division will be carried out. In addition, the overall meta-analysis with subgroups based on sampling will provide knowledge on the measured differences in effect sizes that can be explained by study design.

Intervention

Control

Time
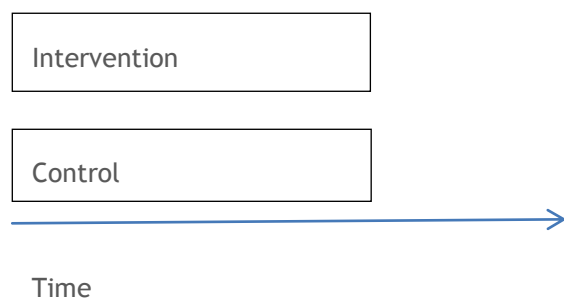
Measurements on primary and secondary outcomes within all MAST domains will be carried out for both groups allowing for comparisons of all outcomes.

3.1 Item 9: Description of study settings and list of countries where data will be collected

Study settings include ten pilot sites and all relevant types of services offered to people enrolled. Services include health and social care provided by public or private institutions, volunteer sector or informal carers.

Regions included in SmartCare as pilot sites are:

- 1st wave:
  - Scotland, UK
  - Region of Southern Denmark, DK
  - Aragon, ES
  - FVG-ASS1, IT

- 2nd wave:
  - Kraljevo, SRB
  - Tallinn, EST
  - South Karelia, FIN
  - Uppsala, SE
  - Attica, GRE
  - North Brabant, NL

Study settings include all settings that are in any way relevant for the provision of care, i.e. hospitals, GP's offices, users' homes and volunteer service providers' offices.

3.2   Item 10: Inclusion and exclusion criteria for participants

Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions.

Inclusion criteria for end users: provided with both health and social care.

Although foci of the individual deployment sites differ in terms of primary or secondary prevention and the frailty of the enrolees, the overall criterion for inclusion is that the person should be provided with both health and social care. Thus, the true implementation population will be reflected in the evaluation approach.

Population samples will be drawn either by randomisation or consecutive inclusion of either intervention or control end-users determined by geographical areas.

3.2.1   Item 11a: Interventions for each group

Interventions for each group with sufficient detail to allow replication, including how and when they will be administered.

Interventions will be provided by a combination of health care, social care, volunteer sector care providers, and informal carers. Thus, the professionals that are involved in providing any type of health and/or social care for the included citizens will be enrolled as intervention performers and as users of the interventions.

Pathways, including thorough descriptions of usual care, are copied from D1.1 Requirements for SmartCare Pathways and Integration Infrastructure, and set out in sections 3.3 to 3.6 below.

3.2.2   Item 11b: Criteria for discontinuing or modifying allocated interventions for a given trial participant

Intervention might be modified according to:
1) End users' wishes of data sharing across involved sectors.
2) End users' possibility to access data through the use of ICT.
3) Other users' possibility to access data through the use of ICT.

There is no strategy for discontinuing allocated interventions, since any additional treatment or admission to hospital is allowed in the study design.

3.2.3   Item 11d: Relevant concomitant care and interventions that are permitted or prohibited during the trial.

None.

3.3   Aragon

3.3.1 Contextualisation of the generic SmartCare pathways

3.3.1.1 Entry points

The starting point of this integrated-care pathway would be when a patient has been suggested to be included on the SmartCare programme, either upon a visit to Primary Care Attention or during a stay at Barbastro's Hospital. There are two ways to identify potential participants. First is during a hospitalisation of a patient. If any healthcare professional supposes that the patient is in social risk of any type, then he notifies the social worker working at the Hospital. This social worker evaluates if the patient is at real risk. The second channel would be when a patient visits a doctor at Primary Care Attention. If the GP suspects a patient to be at risk, then he refers the patient to the SmartCare Evaluation Committee who will evaluate if the user is a potential participant in the programme.

3.3.1.2 Assessment of the service user's needs for integrated care

HCP, either GP or Specialist, will define the medical attention that the patient may need in relation to any home care; the frequency of the needs, his inclusion in a telemonitoring programme, the clinical parameters to monitor, and other assistance services such as adherence to treatment etc. This decision will be made based on the patient information collected from the hospital records and the EHR.

The SCP, either the local SCP or the Hospital social worker, will define the social attention that the patient may need in relation to any home care. In order to identify these needs, the SCP will have an interview with the patient, and will rely on the notes taken by the HCP that identified the risk and recorded it on the SALUD Information Systems at that time.

3.3.1.3 Enrolment into the SmartCare service

A key element on the SmartCare programme is the SmartCare Evaluation Committee. The SmartCare Evaluation Committee will be formed of a representative of every care provider and technical staff. The Evaluation Committee will act as the SmartCare project manager, and will be responsible to manage and coordinate the actions within the SmartCare programme. The procedure of enrolment into the SmartCare programme will be as follows:

- Patients identified by Primary Care. The patient visits the GP at Primary Care. If the doctor supposes the patient to be at risk and could be participant in the SmartCare pilot, then he refers the patient to the SmartCare Evaluation Committee. This Committee will check the clinical criteria; if he is a potential candidate, it will ask for information from the social worker of the local SCP who will evaluate if there is a real risk and a need for social care. If he does, the SmartCare Evaluation Committee will evaluate if the user fulfils the SmartCare inclusion criteria; if that is the case, the patient will be included on the programme.

- Patient identified at the Hospital. During a patient stay at the Hospital, any HCP can suspect the patient to be at risk. In that case, the HCP records the suspicion on the SALUD Information System, and notifies the social worker working at the Hospital who evaluates if the patient is in real need. If he is, he refers the patient

to the SmartCare Evaluation Committee. This SmartCare Evaluation Committee will evaluate if the user fulfils the SmartCare inclusion criteria, and will decide together with the healthcare Specialist in charge of the discharge the inclusion of the patient into the programme.

The criteria from a medical point of view to select patients to be included in the SmartCare programme would be:

- Aged +65.
- Chronic disabled disease (COPD, DM, Myocardial infarction history (MI) + heart failure, cerebrovascular accident (CVA) history).
- Stabilised (for long-term cases).
- Terminal neoplastic or neoplastic illness.
- Dementia and / or psychic handicap.
- Hip fracture.
- Situation of temporal dependence at discharge time.
- Loss of autonomy due to age without pathology.
- Health problems appearing during hospitalisation requiring continuity of care.

The criteria from a social point of view to select patients to be included in the SmartCare programme would be:

- +75 living alone.
- Living with partner, siblings or elder relatives.
- Living with dependent people at home.
- Lack of support at home.
  - o Lack of resources at home;
  - o Main carer at hospital;
  - o Communication problems with immigrants;
  - o Other problematic due to immigrant condition;
  - o Lack of relatives during hospital admission or during the first 2 days.
- Minor at risk.
- Alcoholism.
- Drug dependency.
- Abuse or suspected abuse.

When a patient has been identified as a potential participant, he is informed of the programme either by the GP and local SCP worker or by the Specialist and the Hospital social worker. The patient has to give written signed consent to participate on the pilot.

3.3.1.4 Initial integrated home care plan

Next, an initial plan will be defined to provide the home support through SmartCare. First of all, and if the user is included in the telemonitoring programme, the process of taking vital signs will be defined. The patient will be either provided with biomedical devices and

technology, referred to a technology counter owned by a TSCP or I/FC or included on the SCP agenda for home visits. This decision will be taken according to several criteria such as the patient's clinical profile, or if having an active social role or living in dependency situation. A coordinated agenda will be defined between the patient, the HCP, the SCP, the TSCP and/or I/FC that will be agents in providing care to the patient, along with a schedule of actions and personnel responsible for the tasks. The patient will also be provided with a contact point to be able to communicate with his carers when needed. Patients will use this Integrated-Care Coordination point of contact (Contact Centre) to request care needs and to access the programmed agenda. The IC home care plan will coordinate the agents working in the territory and cities involved in the project, these being: Servicio Aragonés de la Salud (Hospital, emergencies, and Primary Care Centres), several councils of the Cruz Roja Española in the area, the regional and local SCP acting in the cities, a Community Pharmacy located in Barbastro, several Patients Associations and the patients relatives.

3.3.1.5 Permanent coordination of integrated care delivery/revision of the initial care plan

When a user is included in the SmartCare programme, he will be provided with a set of services that may not be consumed at the same time or during the whole duration of the pilot. Therefore, there will be an essential continuous revision of the services provided and requested by the patients and the coordination plan. In order to ease this task, a platform will hold all the information and attention provided to the patients. This platform will register the coordinated action plan, the IC agenda and schedule, and agents responsible for providing the care, the services provided and the new services requests. This platform will permit to identify needs, assign responsibilities, coordinate carers and register actions; the information related to the care provided will be registered on this platform. Moreover the HSCP will be supported by the SALUD IS that holds all the patient data, EHR, the clinical activity and the monitoring portal. The SCP will also be supported by the patient's data records. And the contact centre will be able to access a common set of the patient's data provided by the HCP and SCP. The SmartCare Committee will receive all notifications and will evaluate if the user still fulfils the inclusion criteria. If that is the case, the Committee, together with the SCP and HCP, will decide the provision of the services to fulfil the demand, or cancellation if there is no longer need of a service, modify the care plan if needed, and/or review the tasks and responsibilities assigned.

During the life of the pilot, the user may change his needs due to several conditions: enhancement or deterioration of their health, to be no longer in risk situation, in need of more services, etc. Therefore, it is important that the patient has a procedure to communicate with the Pilot to review his requirements. The entry point may be the GP at the Primary Care Centres, or notification by the TSCP or SCP or I/CP or patient to the Contact Centre available through the telephone that will be redirected to the SmartCare Committee. The Contact Centre will be formed of SCP and HCP agents.

Moreover the telemonitoring programme will need a very close coordination of actors, as there may be plenty of changes on the schedule and initial plan due to changes in the clinical status and evolution of the CR. Telemonitoring of users with the aid of social associations and volunteers is a clear example of integrated care that responds to a planned social/health care intervention and that will need constant review.

3.3.1.6 On-site provision of formal social care

According to the clinical profile of the patients, mainly for patients with social needs and or in clear situations of dependency or included on the telemonitoring programme, it may be necessary to provide services at the patients' homes. These tasks can be performed by the SCP, such as taking the vital signs parameters in defined cases, accompaniment at home, home care or home support tasks such as cleaning or helping to get up from bed. From a social point of view, the services that a user may be provided with in accordance with the existing social care system can be those of:

- Accompaniment for administrative purposes.
- Accompaniment to /in hospital.
- Accompaniment at home.
- Administrative tasks.
- Home tasks.
- Shipment of support products.
- Installation of products to reduce energy consumption.
- Follow-up agenda.
- Home care support.
- Home care private support.
- Telecare.
- Orthopaedic support management.
- Travel expenses reimbursement among regions.
- Wheel chair loan.
- Loan of crutch.
- Loan of articulated bed.
- Submission of reports to court in case of gender related or domestic violence.
- CARITAS volunteering service: Accompaniment.
- Translation for foreigners.
- Coordination with CARITAS.
- Support for Impairment recognition applications.
- Other support, information or resources management.
- Coordination Healthcare centre / Hospital.
- Coordination with NGO.

3.3.1.7 On-site provision of formal health care

According to the clinical profile of the patients, mainly for patients with social needs and/or in a clear situation of dependency or included in the telemonitoring programme, it may be necessary to provide services at the patients' homes. Some of the medical tasks to be performed at home for patients with reduced mobility are cure of wounds, participation in educational programmes on health issues through different communication channels,

pain management, and adherence to treatment programmes or GP/nurse visits. From a medical point of view, the services that a user may be provided with in accordance with the existing health care system can be those of:

- Health transportation.

- Emergency transfers.

- GP or nurse home assistance.

- Remote telemonitoring.

- Education programmes on health issues.

- Pain management..

- Wound care.

- Forms filling to detect alert signs

- Adherence to treatment programs.

3.3.1.8 On-site provision of informal care

Informal care tasks provided by informal carers can be to perform telemonitoring tasks such as those of taking vital sign measurements, or those in a contractual relationship with the patient, such as cleaning, cooking and the like.

3.3.1.9 Remote provision of health / social care to the home (telecare, telemonitoring)

One of the main goals of this pilot is not only to provide integrated care to patients, but also the coordination of actors to avoid duplication of the activities provided. Other goals are tracking patient well-being and promoting the empowerment of the users in the management of their own health, making them co-responsible to maintain and keep good practices on health issues. Therefore, some of the services can be provided in a remote manner. Some examples are the self-telemonitoring of vital signs by the patient or IC at home, and the provision of those measurements to the HCP, the reminder of events (such as HCP visits or others) thanks to the shared agenda, calls made by the SCP to know about the CR health status, or alarm calls thanks to push-button devices or geo-positioning devices provided to users.

A telemonitoring service is being piloted and under evaluation in Aragon. Since 2009 there is a telemonitoring pilot implemented thanks to the European project called Dreaming (http://www.dreaming-project.org). This service is oriented to autonomous patients, who actually collect their own vital signs with biomedical devices at home, and send the measurement via DSL to a monitoring portal. This portal creates alarms that are checked by HCPs and reacts to the user's needs when a decompensation occurs giving a response to the need by mobilising resources properly.

A second telemonitoring project is ongoing oriented to dependent users and with the collaboration of the Red Cross. Several Red Cross teams visit the patient at home and collect their vital signs, provide the information to the HCP and respond to medical needs. In SmartCare, these two models will be extended to cover more population, more targeted people, and making technology available to a wider number of users (involving other care agents and bringing technology to other places that elders frequent) This is possible thanks to the unique identification of Aragon's population through the health card.

3.3.1.10 Integrated documentation of home care provided / self-care measures

The central point will be the platform that will hold the information on the services that a user can benefit from, the actions provided, the delegation of tasks to agents, and the coordination between agents. This platform will be managed by the Contact Centre and will provide all the information that is required to provide integrated care. (See section 3.3.1.5 above).

3.3.1.11 Control / reassessment of the home care recipient

Telemonitoring services need of a follow-up of the measures taken, usually in the form of tracking the alerts and alarms. This control will be performed by the HCP who, according to the seriousness of the alert, will evaluate the need to provide special care, new services or emergency services, e.g. ambulance transport. Furthermore, the HCP will review periodically, through the documentation, the conditions of CRs that are benefiting from the telemonitoring service to check whether changes and/or revisions are to be made to the service provided or initial care plan. Similarly, the SCP will also review periodically the documentation to check the use of the services by CRs, and identify if they are really consumed or there are deficiencies that require a reorganisation of the attention provided. If that is the case, the SmartCare Committee will be notified, and will act on on-going coordination of integrated care delivery / revision of initial home care plan

3.3.2 Temporary admission / re-admission to an institutional setting (e.g. hospital, day care centre)

According to changes in the condition of the patient (either social or worsening of the clinical status), there may be an admission to a hospital or social institution. Those cases will be evaluated by the SmartCare Committee, as it may imply the temporary suspension or disenrollment of the patient from the SmartCare project.

3.3.3 Exit point

The end point of this pathway would be when the patient is no longer in need of medical or social attention, or is excluded from the medical programmes, the patient revokes consent or his participation on the programme is closed, the patient is exitus or the pilot causes concerns or bothers patients or relatives.

3.4 Friuli Venetia Giulia

3.4.1 Point of departure: The current service landscape

Friuli-Venezia-Giulia (FVG) is an autonomous Italian region and, as such, has developed, over the years, a coordinated healthcare sector with some pilot implementations of ICT solutions. However, the system is still partially fragmented and shows room for further integration both in terms of ICT and inter/intra-team communication.

The public FVG Health Service is divided into six Health Authorities, two Hospital-University bodies and one Hospital Authority; 20 Districts acting as reference centres for all the services provided by the NHS Authority, besides ensuring the integration between health and social services, and coordination of Social Workers as well as private and volunteer organisations.

Within this framework, GPs and most specialists are an integral part of each District. A spoke hospital may act as the intermediate health reference point of one District. Within the District Services, a District door (Single Access Point) has been established to guarantee access to welfare facilities. This entrance point is being managed by healthcare and social care staff. Home health services are being provided by nurses and rehabilitation therapists in collaboration with GPs, social workers, home assistants, physiotherapists, specialised physicians, volunteers and other medical and social operators.

District medical residential facilities (RSA) for intermediate care provide assistance for the rehabilitation of hospitalised patients suffering from serious multi-pathologies (e.g. orthopaedic, neurological, pneumological, cardiovascular pathologies, etc.) as well as for patients with stable, or temporarily major social problems requiring 'relief' for family members and/or patients with prevailing end-of-life issues, i.e. terminally ill patients. A territorial cardiology service attends to patients discharged from different hospital structures (e.g. ER, Cardiology, 118, etc.).

3.4.2 Contextualised use case scenario for the SmartCare pilot service

3.4.2.1 Overview of local / regional actors involved

Table 2 - Friuli Venetia Giulio: Overview of the client domain

Type of actor	Description of actor	Description of the role	Information handled
CR	Patients age >50 with a chronic disease (cardiovascular, pulmonary, diabetes, orthop. surgery, Parkinson), with high chances of complications and/or instabilisation. Multiple comorbidities are the rule in this population. Inclusion criteria should be multiple (≥ 2) admissions in the last 12 months (included index hospital admission). Dementia and psychiatric conditions are exclusion criteria.	Patient-centred care is the main focus. Depending on the level of patients' self-care capabilities, they will take an active role in their treatment by viewing and entering relevant health data. If the patient cannot take an active role, caregivers may be actively involved.	Patients will be able to access relevant information as well as add further information both in text form, e.g. questionnaires and notes, as well as measurements from home monitoring devices. Information may include diagnosis, measurements taken by professional caregivers, relevant data on lifestyle and social issue, filled out questionnaires, notes, activities, goals, emotional self-monitoring, symptoms and contact persons.
I/FC	Relatives and/or friends of patients/care recipients	Patients will make the choice to include their relatives or friends in their treatment, and may also give them access to the electronic data in the SmartCare platform. Often, the person / family pays a personal private assistant (ca. 1.200 €/month – so called "badante") in order to support the subject	Caregivers will be able to share patients' relevant information as well as add further information, if they deem it necessary, both in text, questionnaires and notes, as well as measurements from home monitoring devices. This will include information regarding the patients' illness such as

Type of actor	Description of actor	Description of the role	Information handled
		24/7 at home.	diagnosis, measurements taken by professional caregivers, relevant data on lifestyle and social factors, filled out questionnaires, notes, activities, emotional self-monitoring, symptoms and additional contact persons.

Table 3 - Overview of service provider domain

Type of actor	Description of actor	Description of the role	Information handled
SCP	Social care workers are employed by municipalities	The social care workers will provide home-based social care such as cleaning, food delivery, bathing, shopping, etc. as well as help in the procedures needed to obtain financial support from the municipality/state.	Social care providers will be able to see relevant and selected information about the patient's disease and self-care capabilities. They will also be able to write down notes, set up goals together with the patient and fill out relevant questionnaires. Data may include notes, plans, goals, questionnaires and activities. They will also be able to see selected information provided by different actors such as patients, hospitals and GPs.
HCP	This group is made up by the multi-disciplinary team (specialists, GPs, nurses, psychologists, physical therapists, etc.)	The healthcare providers play different roles. The hospital is in charge of acute heart problems, specialised treatment as well as discharging. Upon discharge, territorial services take on patient care through the activation of dedicated pathways for a clinical and social integrated patient care. Continuity of care from Hospital towards residential or/and home care with / without GP involvement are more frequent in rural areas.	The actors involved will be able to share data from their individual systems and use the portal to support their workflow across sectors, as well as to view data from all other care providers. The information shared may include lab-results, measurements, notes, symptoms, diagnosis, goals set with the patient, activities, questionnaires, reports and self-care indicators provided by patients.
TSCP	Non-profit organisations, including volunteers,	Trained volunteers from these organisations may provide support to the	Volunteers could provide home-based support such as xample cleaning, food

Type of actor	Description of actor	Description of the role	Information handled
	citizen association, "active citizenship". We consider social cooperatives belonging to the third sector; they are able / allowed to participate in the provision of services, taking in charge some parts of the personal project. They are active members of the local community and they represent a resource for the system.	patients if needed, such as participation in multi-disciplinary meetings, or entering (not accessing) data relevant to patient's holistic well-being (e.g. home support, social support, emotional changes in well-being, etc.) The can have precise expertise and can contribute to the whole comprehensive approach.	delivery, shopping, transportation, etc. They can play an important role in the self-empowerment process, too.

3.4.3 Contextualisation of the generic SmartCare pathways

3.4.3.1 Entry points

Existing procedure

Currently, heart failure patients (NYHA IV) with COPD on continuous oxygen therapy are admitted to hospital ward for worsening of dyspnea due to 5 Kg weight increase in five days. The staff working in the hospital alert the relevant District. The District sends a nurse within 48 hours to meet the patient and his/her relatives; hospital staff start gathering all the relevant information needed on discharge. The SmartCare platform will allow to improve and enrich information about previous healthcare pathways (i.e. identification of previous needs and actors involved in patient's care) so as to activate prompt action upon discharge. This process would help decrease re-hospitalisations rates. The District nurse will carry out a pre-assessment on the basis of the information available. At this time, patients may be asked to sign a pre-enrolment consent form.

3.4.3.2 Discharge from hospital

According to current practice, the patient goes home and usually finds all the needed equipment available (bed, wheelchair, etc.). Follow-up and continuous home care is activated upon discharge as well. The Case Coordinator will provide home-care services according to patient needs. In SmartCare, the multidisciplinary team will be led by a Case Coordinator chosen to meet prevailing needs. Monitoring of vital parameters (BP, HR, weight, SO2, etc.) as well as environmental data or videoconferencing device (only for selected cases) will be made available on a daily basis through external service or integrated platform to all care providers. Questionnaires and notes will add to the clinical information thus providing thorough information.

3.4.3.3 Assessment of the service user's needs for integrated care

Currently, no data collection for shared network system exists. The District nurse activates the relevant healthcare services according to identification of specific clinical and psycho-

social needs. There are different systems for electronic storage of patients' data (clinical and social). In SmartCare, the District Nurse will be in charge of completing the assessment by contacting all parties involved in the multi-disciplinary team approach. Subsequently and according to specific needs, a Case Coordinator will be appointed from among the members of the multidisciplinary team, who will act as the reference person for the home care integrated plan. At this point in time, no SmartCare platform is available. Patient's final consent will have to be signed.

3.4.3.4 Enrolment into the SmartCare service

No ICT-based enrolment procedure currently exists. At present, pre-discharge individuation of case and provisional clinical and social risk stratification allow to send to the District the request for "protected discharge". In SmartCare, during the first meeting at the hospital if the patient is deemed eligible for SmartCare enrolment, the District Nurse will ask consent to enter patient's data and to share them with other relevant actors within the SmartCare platform. She/he will also provide the patient and/or caregiver with all the basic information on the SmartCare platform, and the possibility to access it directly from home. The nurse will also evaluate the patient's ability to perform home monitoring; if deemed eligible, they will be given the opportunity to receive home monitoring equipment. An order will subsequently be sent to the dedicated Service, who will send their employees to set up the devices at the patient's home while simultaneously introducing the relatives to their use. Through regional Registry of Birth, the nurses will collect available information (health and social) from different databases. After collecting and entering the available information, the nurse will update the disease information and relevant health and social care data.

3.4.3.5 Initial integrated home care plan

Today, on discharge a discharge plan is prepared by the District Nurse, or the Case Coordinator who will complete the ValGraft multidisciplinary, multidimensional, longitudinal assessment and evaluation form. In SmartCare, the ValGraft assessment will be planned to be subsequently shared with all the participating actors who will be able to proactively start a planned and individualised healthcare integrated care plan. This plan will be periodically reassessed and adjusted by the multidisciplinary team. Depending of clinical and social needs, and according to the Integrated Home care plan, for any case there will be specific target and priority of care (health care i.e. hemodynamic stability for heart failure etc; social care: i.e. food delivery, preparing meals, home sensors, etc.).

3.4.3.6 Permanent coordination of integrated care delivery / revision of the initial care plan

A multidisciplinary team will be activated, led by a Case Coordinator. Data and information will be constantly shared among the different parties. Goals and needs will be adjusted accordingly.

3.4.3.7 Coordinated delivery of integrated care at point of care / revision of the initial care plan

The district nurse (case-manager of CR) coordinates home-care. He/she supports the GP (and/or specialists) in delivering health care, and keeps in touch with social workers,

family and volunteers for other needs. District nurse activates different care providers in presence of unmet or urgent needs of CR/family.

3.4.3.8 On-site provision of formal social care

Today, social care is being activated upon request from the District nurse. In SmartCare, social care actors will be able to access and update SmartCare platform. Depending on social needs and according to the integrated home care plan, for any case there will be specific target and priority of care (i.e. food delivery, preparing meals, home sensors, etc.).

3.4.3.9 On-site provision of formal health care

At the moment, the patient's Case Manager arranges for and provides formal healthcare. In SmartCare, healthcare actors will be able to access and update SmartCare platform. Depending of clinical needs and according to the Integrated Home care plan, for any case there will be specific target and priority of care (i.e. hemodynamic stability for heart failure etc.).

3.4.3.10   On-site provision of informal care

Even though the caregiver's presence and collaboration is vital for the patient's care, at present, caregivers (family members, or friends) play a secondary role within the care plan and do not have access to the patient's information, nor are they able to help adjust the care plan, unless through individual contacts with physicians, or nurses. The family is directly and formally involved only in the case of meetings aimed at establishing need and eligibility for economic support. Through SmartCare, family members and/or friends will be able, upon patient's request, to access the system and share information on their loved one. This will allow them to feel more secure, less isolated and will provide them with better tools to monitor and contribute to the patient's maintenance of health and QoL and be more directly involved in the provision of services.

3.4.3.11   Remote provision of health / social care to the home (telecare, telemonitoring)

For the whole FVG region, remote Home health and social care services will be provided by an external company with ad hoc 24/7 Call Centre. SmartCare services will provide full support to cooperative delivery of care, integrated with self-care and across organisational silos, including essential coordination tools such as shared data access, care pathway design and execution as well as real time communication support to care teams and multi-organisation access to home platforms.

3.4.3.12   Integrated documentation of home care provided / self-care measures

Any intervention made by the various parties are documented in the ICT SmartCare system and made available to other parties. Depending of Home care plan (targets, criticisms, needs, intensity of monitoring) the case coordinator plans periodic meetings with the District Team. Daily update from CR and home monitoring (clinical and environmental) will be provided as well as periodic update by care team according to care priorities, CR needs, roles of actors.

3.4.3.13   Control / reassessment of the home care recipient

Integration of data into care planning and management processes will be updated at three months to decide whether to end Home care plan or prolong it up to six months. Sharing and analysis of clinical, scheduling, monitoring information will continue.

3.4.3.14   Temporary admission / re-admission to an institutional setting

An Integrated Care Record will allow sharing of updated clinical information of in-hospital and out-of-hospital care. Updated information provided in emergency situations by a Call Centre will be available through a pre-defined printed version. Exit of patient from Smart Care platform will be evaluated at the time of readmission according to specific parameters.

3.4.3.15   Exit point

At the end of programme, the District Team, on the baise of global review of persistent CR needs and results obtained with ICT programme, will decide about exit from SmartCare pathway.

3.5   Scotland

3.5.1   Point of departure: The current service landscape

Scotland intends to use the prevention and management of falls as the focus for our SmartCare pilot across seven local health and care partnership areas. With an ageing population, falls and the consequences of falls are a major and growing concern for older people and health and social care providers. Recurrent falls are associated with increased mortality, increased rates of hospitalisation, curtailment of daily living activities and higher rates of institutionalisation (ref Dept of Health Economic Evaluation, 2009). Falls are the leading cause of accident related death in older people (ref WHO, Europe 2004). Falls are a common problem amongst older people with long term conditions, including dementia.

Falls and fractures, in people aged 65 and over, account for over 18,000 unplanned hospital admissions and 390,500 hospital bed days each year in Scotland. Average lengths of stay for falls and hip fracture admissions exceed those for other emergency admissions in the same age groups: average lengths of stay for falls and hip fractures in the 75+ population are 25 days and 36 days respectively (compared to an average stay of 13 days for a COPD admission in the same age group) (2010/11 data provided by ISD Scotland).

Department of Health (DH) data (2009) reports that 30% of the population aged 65–79 years and 45% of those aged 80 years and over fall annually. Applying these assumptions to the Scottish population gives an absolute risk of 0.34 falls per person for those aged 65 years and over.

Around 1% of falls result in hip fracture (ref Cumming, Neville and Cummings 1997); although the percentage is low, this amounts to over 6,000 hip fractures in Scotland each year. The acute management of hip fracture alone costs NHS Scotland in excess of £73 million each year. Twenty percent of older people who sustain a hip fracture die within six months (ref: SIGN 2009); approximately half will never be 'functional' walkers again (ref: WHO, 2004).

In addition, in the over 65 population, falls cases are the largest single presentation to the Scottish Ambulance Service (over 35,000 presentation each year), one of the leading causes of Emergency Department attendance, and are implicated in over 40% of Care Home admissions (ref: American Geriatrics Society, British Geriatrics Society, 2001). Post - fall syndrome, a combination of fear of falling, anxiety, loss of confidence and depression is prevalent, leading in many to an inability to carry out day to day activities and social withdrawal and isolation.

Despite these statistics, falls are not an inevitable consequence of old age. An individual's risk of falling or fracturing is determined by a complex interaction of multiple risk factors relating to the ageing process, the presence of long term conditions, lifestyle choices, risk-taking behaviours and the surrounding environment. Well-organised services delivering evidence-based care can help to prevent future falls. Recognising and modifying an individual's risk factors is crucial in preventing falls and injuries, including fractures. In many cases early identification of risk and timely intervention can prevent falls and fractures and improve outcomes for older people, retaining or restoring independence and reducing health and social care needs.

Prior to SmartCare being introduced, Scotland has in place a National Falls Programme to support local health and social care partnerships to implement a co-ordinated, evidence-based and person-centred approach to falls and fracture prevention as described in the 2010 NHSQIS resource, Up and About. A national Programme Manager is in place who currently works with a network of mainly health staff e.g. local Falls Leads, Rehabilitation Co-ordinators, AHP Directors/Leads and other key stakeholders to support the development of local falls and fracture prevention care pathways in the community setting. Partners in this work have already included the National Telecare Development Programme.

Scotland also has a national eHealth Strategy and a National Delivery Plan for Telehealth and Telecare. We have an established Scottish Centre for Telehealth and Telecare (SCTT) which will support SmartCare activities and the expanded use of telehealthcare and ICT within integrated care and to support informal carers.

Currently within the majority of Health Boards in Scotland, falls prevention and management is provided by generalist assessment and rehabilitation services for older people, such as community multidisciplinary teams and day hospitals for older people. Even where dedicated falls services exist, other members of the health and social care team have an important role to play in falls and fracture prevention and management. It is essential that a more integrated approach to care is developed which address the key components of the Up and About resource and other related good practice guidance such as "Telehealthcare and Falls".

A national mapping exercise of local arrangements for falls prevention and management and fracture prevention for older people was undertaken in 2011, which aimed to:

- Identify the extent to which recommended practices to prevent and manage falls and fragility fractures are built-in to the wider systems of care for older people in Scotland.

- Capture good and promising practice as well as common gaps in service organisation and provision, and where possible, identify developments and changes since a previous mapping in 2009/10.

- Inform recommendations for the improvement of services in Scotland.

A 100% response rate was achieved, with all 35 CH(C) Ps in Scotland participating. The findings of this exercise were published in May 2012 and identified that in some areas modest steps have been taken since a previous mapping in 2009/10 and that there is much improvement work in progress. However, the findings also showed that there is still unacceptable variation in service provision and quality, and in some localities services remain poorly developed. Scotland still has much to do to provide older people with equitable, high quality services for fall and fracture prevention.

The aim of SmartCare in Scotland is to focus the current activity on falls prevention / management and ICT development, and to use this to develop more robust local pathways which support integrated care across health, social care and informal carers. SmartCare in Scotland will focus on improving data sharing, co-ordination and communication and will involve:

- Building on evidenced good practice and local mapping to implement four care bundles for secondary falls prevention in the community. This approach is based on an approach first developed and introduced in Wales. The bundles aim to ensure that falls prevention and management activity is clearly aligned with the two high level SmartCare pathways, and that appropriate assessment and interventions are delivered consistently and in line with current guidance. The introduction of the bundles, in combination with a Model for Improvement, a local measurement framework, and the SmartCare evaluation will help services to systematically monitor, evaluate and improve the quality and effectiveness of the care they provide.

- Expanding the use of telehealthcare technologies and other ICT systems to support efficient delivery of effective and integrated care pathways for falls prevention and management across different organisations and locations. This will improve access to home based technology solutions, assist with the early identification of people who are at risk of falling, support self care and self management, enable effective responses to those who do fall, and improve care co-ordination, communication and service planning.

- By joining these elements up and by expanding the care pathways and interventions to a large scale population, we anticipate positive impacts on our organisational resources, and the health and well-being of our citizens.

In summary, falls prevention and management has been identified by Scotland as the focus for SmartCare:

- This activity area is already clearly recognised as an important area for integrated care in Scotland at an individual, local and national level i.e. there is a common desire for improvement across all the key stakeholders and willingness to be involved in achieving shared benefits. The project will be used to inform and refine a roll out of robust falls prevention and management activity right across Scotland.

- There has been significant good practice developed around care pathways, care bundles and the effective use of technology services within Falls prevention and management in Scotland which can be built upon and expanded to evidence quality integrated care.

- It will provide an 'added value' contribution to the EIP on AHA Action Groups on Integrated Care (B3) and Personalised Health Management starting with a Falls Prevention Initiative (A2).

3.5.2 Contextualised use case scenario for the SmartCare pilot service

3.5.2.1 Overview of local / regional actors involved

Table 4 – Scotland: Overview of client domain

Type of actor	Description of actor	Description of the role	Information handled
CR	Care recipient who has a history of falls or who is at significant risk of falling, who live in the identified geographic areas and who are aged 50+	These people will be the main beneficiaries of the service and will be consulted and involved in the service redesign	Information from telecare/community alarm services Assessment and care co-ordination/planning Access to generic self management and self care information.
I/FC	Family members, neighbours and friends of the CR who provide care and support.	The informal carers will be involved in the service pathways. They may also be responders or key holders of telecare service.	Information on care co-ordination with consent of CR which will enable them to play key role. Access to generic self-management and self care information.

Table 5 – Scotland: Overview of service provider domain

Type of actor	Description of actor	Description of the role	Information handled
SCP	Social workers, care assistants, Occupational Therapists, home care and care home providers, telecare staff involved with people who fall or who are at risk of falling. Part of multi-disciplinary teams where established. Staff involved in ICT services.	Assessment of care, care co-ordination, care planning and care delivery. Delivery of advice, front line care services and care co-ordination. Telecare and ICT service support.	Communication and co-ordination of assessment, care and risk management plans (electronic or paper), data from telecare services and response services. Cross organisational referral for services. Provide access to self management/self care information and resources.
HCP	NHS 24, specialist and multidisciplinary teams, falls leads, GPs, Allied health Professionals community nursing (other community health services), Scottish Ambulance Service.	Diagnosis and treatment of fall related issues. Prevention and assessment activities. Care integration, data processing and specialist advice/support/care service provision.	Communication and co-ordination of assessment, care and risk management plans. Cross organisational referral. Provide access to self management/self care information and resources.
TSCP	Third sector voluntary and independent sector providers delivering care and support to people who fall or are at risk of falling.	Delivery of advice, support and care services. Input to care reviews.	Agree intervention, outcome, review and discharge plan or ongoing care management responsibility where required.

3.5.3 Contextualisation of generic SmartCare pathways

3.5.3.1 Entry points

SmartCare in Scotland involves seven local health and care partnerships who have developed different local services and pathways, and there is not a robust baseline of 'fallers' currently in place. A key challenge will be to secure robust engagement across such a complex and large group of stakeholders, and establish a clear baseline from which progress can be evidenced. SmartCare will identify common elements where a positive contribution can be made across all of the partners and each of the different geographies. In terms of the Entry Point, a challenge will be to ensure that all referrers are aware of SmartCare pathway and that relevant parties have access to data or are notified of CR needs and follow up requirements. Another challenge will be the CRs being agreeable to receiving and paying for service elements. Integrated or shared ICT will be the most significant challenge to identifying and managing service recipients.

To identify potential care recipients, the entry point for SmartCare will integrate into mainstream assessment and referrals processes across health and social care. To support this, SmartCare will:

- Undertake awareness raising and training: some of which will be enabled via electronic means. An existing Telehealthcare learning portal is in place in partnership with NHS National Education Scotland and the Scottish Social Services Council which will help support professional activity in this area.

- Establish a baseline of number of fallers in each area to inform 'before and after' considerations, this will require information to be collated consistently from similar data producing areas e.g. telecare monitoring centre information.

- Develop a common minimum data set for people who fall or who are at significant risk of falling. This will be used to identify the target population within local systems. (Note: This may support the development of a comprehensive register of fallers.).

Using this minimum data set, Health and Care professionals will identify the target population (Stage 2 of *Up and About* Pathway) via a range of means:

- Reactively when they present either at GP surgery, hospital or via the emergency services with a fall or an injury due to a fall ('Trigger' care bundle implementation).

- Opportunistically by health and social care practitioners e.g. osteoporosis clinics, home care visit, during implementation of a care package, mainstream assessment processes.

- Proactively via existing databases e.g. Scottish Patients at Risk of Readmission or Admission (SPARRA) database can usefully identify some high risk fallers, along with information from telecare/community alarm databases (e.g. 3,000 fallers identified in Lanarkshire), social care and health databases.

Once identified, SmartCare will support the implementation of a simple, common referral process at a local level which links all access points to a single point of contact for Falls Prevention & Management. This will include people who wish to self-refer or their carers, voluntary sector, Scottish Ambulance Service, fire service, A&E. In summary, the process will follow a number of general principles as follows:

- Concept: "Push a button to report a fall and get referral into system".

- Process for referral by healthcare professional: Referral form completed. New referral routed through Single Point of Access. If already known, pass to existing case / care manager. If not known, pass to identified local contact for completion of mini screening process.

- Process for referral by social care professional: Referral form completed. New referral routed through Single Point of Access. If already known, pass to existing case / care manager. If not known, pass to identified local contact for completion of mini screening process.

- Process for self referral: Self referrals or carers referrals will be encouraged to the Single Point of Access via a range of means e.g. local information and advertising. Self referrals can be made by telephone or by completion of referral form available on local websites. If already known, the CR will be passed to existing case/care manager. If not known, pass to identified local contact point for completion of mini screening process.

3.5.3.2 Discharge from hospital

SmartCare will need to effectively integrate with (and perhaps adjust) existing hospital discharge procedures. These are likely to differ between hospitals.

3.5.3.3 Assessment of the service user's needs for integrated care

There are current challenges around resource requirements and waiting times for assessment. There is a need to ensure that SmartCare does not inadvertently push everyone down a formal statutory care assessment route which will compound existing issues by increasing demand within additional resources to respond. Once the referral is received by the Single Point of Access, it should be confirmed that the SmartCare project would be of benefit to the individual and that they meet the eligibility criteria (this should have been done previously at entry point, but will be confirmed at this stage). At this stage, open eligibility criteria are envisaged to be applied as follows:

- Age 50+ (banding into 50-64, 65-74, 75 – 84, 85+) and living in the identified Clyde Valley and Ayrshire area.

- People with history of falls (defined as: evidence of at least one fall in the past year, SPARRA risk score).

- People at significant risk of falling (defined as: concern expressed by user / patient / carer, via mainstream assessment processes in health and care).

- Carer of someone with a history of falls or at significant risk of falling.

- Involvement in the SmartCare project would bring benefit to the individual or their carer and would cause no harm.

Contact will then be made with the potential CR and a mini screening will be undertaken to identify the key contributory risk factors to their falling. (Note: SmartCare will investigate the potential for the mini screening to be undertaken electronically, remotely and by non-professionals). SmartCare will develop a common approach to mini screening to provide consistent, good quality initial assessment within and across the seven local partnership areas. The mini screening will identify if there is a need to:

- refer on for a full multifactorial assessment (Level 2 – URGENT or Non-URGENT).

- notify senior colleague / onward referral for other reason.

- recommend common sense precautions, provide information and advice.

As part of this initial introduction to SmartCare, CR and I/FC will be introduced to a range of Information and Self Management resources which will:

- Enable access to 'trusted' information and advice: e.g. National Falls Training Pack for Care Homes. It is anticipated that this will be provided via the Living it Up Portal which will be able to record contacts achieved via the SmartCare project.

- Develop single point of information to support falls prevention and self management. Also to be used for dissemination of training, awareness raising of referral routes. Data hub which could be fed into and accessed by all services. One single repository that enables other systems to feed information in. Could include a database of simple technology, equipment, share experiences and services available to healthcare providers to use as part of patient care e.g. telehealthcare, befriending services etc. It is anticipated that this will be provided via the Living it Up Portal.

- Promote access to healthy activity: Get up and Go, Invigor8 (700 people participating in exercise classes), partnerships with leisure services (50 week courses), Seniors Together Group, Active Lanarkshire, makinglifeeasier website. It is anticipated that this will be provided via the Living it Up Portal.

Care recipients and their carers will have opportunities to engage in health promotion and lifelong learning around health improvement and minimising falls and fracture risk e.g. build information on Slips and Trips, South Ayrshire pack for sheltered housing. They will also have opportunities to access appropriate services and organisations, e.g. local falls and telecare services, which aim to support the maintenance of health and well-being, a safe home environment and a safer community environment. (Stage 1 of the *Up and About* Pathway / Level 1 SmartCare) Information, advice, peer support groups and access to appropriate services will be enabled as part of SmartCare and are likely to be provided within the Living it Up ICT portal (which will link to a range of resources and information sources) and other appropriate formats.

3.5.3.4 Enrolment into the SmartCare service

Only those CR requiring a multifactorial assessment will be formally enrolled into the next level of the SmartCare project (Level 2). This is likely to include people who require more tailored and specific interventions or investigations, and who are likely to require services from both health and social care. The mini-screening will identify if the need for the multifactorial assessment is:

- URGENT or
- NON- URGENT

The multifactorial assessment will be used to identify specific risk factors for falling; this will include a comprehensive falls history (data from telecare and other ICT systems), medication review, fracture risk assessment and assessment of gait and balance, assessment of their home environment, postural hypotension, vision, cognition and feet / footwear ('Assessment' care bundle implementation). Where appropriate, and with the consent of the care recipient, communication and exchange of relevant data will take place between secondary and primary care, social work, and informal carer; it is likely to be paper based initially, or facilitated by telephone/email contacts.

The multifactorial assessment will be completed and stored (note: Further clarification will be required on access, storage, consent to share), and will be used to guide tailored interventions for the CR. (Note: Common KPI to be agreed for the completion of the multifactorial assessment.)

Following the multifactorial assessment, the individual and/or their carer will be provided with detailed information about the SmartCare project, e.g. via leaflets/discussions with healthcare professionals and voluntary sector providers. (Note: Style and language of information to increase potential uptake and minimise concerns will be carefully considered). Benefits of the SmartCare Project will be explained, discussed and agreed with the individual and his/her carers, and any decision to decline involvement will be respected. Where they wish to participate, the care recipient will be enrolled onto Level 2 of the SmartCare project, along with their informal carer if agreed.

At this point, where appropriate an assessor or co-ordinator / case manager will be provided from either health or social care to co-ordinate the elements of any care package. This will help support co-ordinated management including specialist assessment (Stage 4 of the *Up and About* pathway). A summary of relevant care recipient information and the multifactorial assessment will be provided as background to the project with the prior consent of the care recipient.

3.5.3.5 Initial integrated home care plan

Although there is ad hoc communications and many examples of good practice, there are no integrated care plans today for people who fall or who are at significant risk of falling. Once the multifactorial assessment is completed and the CR has agreed to be enrolled into the SmartCare project, they will then be put forward for an individualised, multifactorial programme, i.e. the integrated care plan or personal plan ('Intervention' care bundle implementation). This will be integrated where appropriate with other mainstream care planning processes, and will aim to identify and then minimise an individual's risk factors for falling and sustaining a fracture. The Personal Plan will consider the role of any informal / family carers (I/FC) and is aimed at:

- minimising the identified risks for falling and/or sustaining a fracture;
- promoting independence via a self management and self care programme;
- improving physical and psychological function.

This may include e.g. strength and balance exercises, telecare / community alarm service provision, telehealth home monitoring, interventions to mitigate home hazards and promote the safe performance of daily activities, self management coaching, information, peer groups and support via the Living it Up portal.

Prior consent from the CR and I/FC will be obtained to enable the Personal Plan to be shared as necessary, and appropriate elements are anticipated to be integrated with the care recipient's Key Information Summary (KIS is an electronic record which is currently being rolled out across Scotland and captures important information on an individual's care needs and situation) and any individualised Anticipatory Care Plans (ACPs).

SmartCare will identify opportunities and mechanisms to support better communication and share relevant data more effectively (e.g. care diaries such as Ayrshire system for Children Services, falls summary Anticipatory Care Plan, Key Information Summary). The Scottish Ambulance Service has identified that they would benefit from a system for when they attend a fall and the person is not transported to hospital that provides reassurance

that the person is not left unmonitored. Referral/Links to local social/leisure services will also be further considered at this stage.

3.5.3.6 Permanent coordination of integrated care delivery/revision of the initial care plan

Input from the key stakeholders will inform the delivery and revision of the Care Plan for Level 2 SmartCare CRs. At every stage, accurate and relevant data will be collected and shared where appropriate to support direct care and provide information for service and resource evaluation, planning and improvement ('Monitoring' care bundle implementation). This will identify any hospital admissions / readmissions or significant care incidents. The best mechanisms for this have yet to be agreed across the partnerships along with the timescales for the review / reassessment of the care recipient. However, the care diaries mechanism may be one means of doing this, e.g. East Renf's IT Manager and Carenet Manager developing a mandatory field for fallers which will support data integration.

Local health and social care stakeholders have already agreed that at all points where local pathways might connect with the high level pathway, the best service can only be achieved with adequate communication and data sharing between the teams and between health and social care organisations. This view is also likely to be shared by informal carers.

3.5.3.7 On-site provision of formal social care

The Care Plan (and potentially the care diaries) will provide detailed information on the on-site social care provision. This will include mainstream social care services such as home care which are identified and commissioned via the care planning process.

3.5.3.8 On-site provision of formal health care

The Care Plan (and potentially the care diaries) will provide detailed information on the on-site health care provision.

3.5.3.9 On-site provision of informal care

The Care Plan (and potentially the care diaries) will provide detailed information on the on-site informal care provision.

3.5.3.10 Remote provision of health / social care to the home (telecare, telemonitoring)

Improved access will be provided to home based technologies to support early identification of fallers, self management and care, and enable effective and timely responses to those who fall. The technologies and their associated data will be investigated to identify how best they can improve care co-ordination, communication and service planning, e.g. NHS 24 can investigate the extent to which home health monitoring information should be included within the Key Information Summary.

3.5.3.11   Integrated documentation of home care provided / self-care measures

Currently there is a limited awareness around remote provision of telecare and telemonitoring services, and how these can be accessed. SmartCare will provide a great opportunity to address this. The pilot service will support improved access to home based technologies which can provide early identification of fallers, support self management and care, and enable effective and timely responses to those who fall. The technologies and their associated data will be investigated to identify how best they can improve care co-ordination, communication and service planning, e.g. NHS 24 will investigate the extent to which home health monitoring information can be included within the Key Information Summary. Referrals to telecare services and telemonitoring services will be enabled. For example, hospital discharge with a home pod may enable patient / carers access to support for assessment / case management over a short time frame. Current telecare monitoring stations or NHS 24 could be utilised as part of this programme to ensure outwith 9-5pm coverage. A common KPI will be identified to facilitate early installations for URGENT cases e.g. hospital discharge. Low intensity CBT trail via pods could be used to support confidence and activity for those in fear of falling.

3.5.3.12   Control / reassessment of the home care recipient

Today, there is a statutory requirement to formally review care packages within social care in Scotland. However, for the large number of small care packages this can be undertaken from an administrative perspective due to resource issues and pressure on assessments and care planning. In SmartCare, health staff will utilise additional information from telecare and telemonitoring and link these in to inform the mainstream reassessment / review processes.

3.5.3.13   Temporary admission / re-admission to institutional setting

Today, care providers are not often aware when a service user/patient is admitted by another provider to an institutional setting for a short period of time. Improved communication and co-ordination could help to address this. SmartCare will identify a mechanism to record known short stays in institutional settings.

3.5.3.14   Exit point

After formal review, the care recipient will either continue in the 'At Home Service' with appropriate adjustments or exit from the service with a self management plan where it no longer meets care recipient needs or preferences. SmartCare will identify common outcome measures for individual and system. IoRN could be adapted for this purpose and measured at entry and exit. The Talking Points Personal Outcomes Framework is envisaged to be included.

3.6   Region South Denmark (RSD)

3.6.1   Point of departure: The current service landscape

In many ways, Denmark is a front-runner when it comes to ICT solutions and coordinated

care in the health sector. However, the Danish healthcare system today is similar to many other systems with many actors, i.e. a partly fragmented one. There are three major care deliverers; the hospitals managed by the regions, the general practitioners, and the municipalities, each with their own organisation and IT systems. For patients with a chronic disease or patients with many contacts in the three sectors, this means that they experience a somewhat fragmented treatment. Even though the Danish
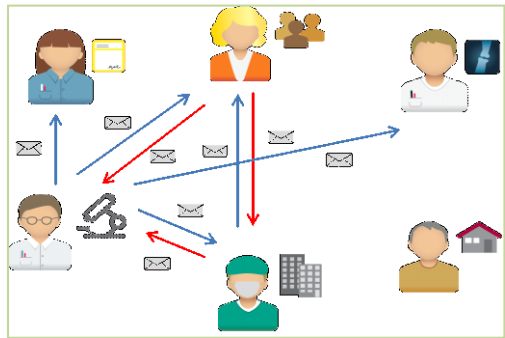
healthcare system has a well-established system of electronic messages, each actor typically has their own IT system and not all are able to share and see relevant patient data. In particular, the municipalities are large organisations with difficulties in communicating across departments even though they share the same patients.

The patients can be roughly divided into two groups. Patients with low self-care ability or issues of both physical and social character have many contacts in the three sectors and have to carry
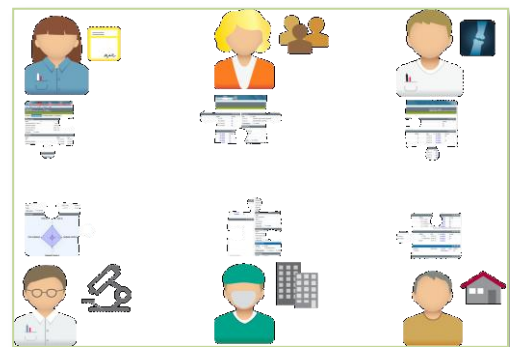
much of the information themselves. The second group, patients with high self-care ability are expected to take an active part in their disease and treatment and need access to information in order to do that.

A strong ICT infrastructure in the Region of South Denmark (RSD) creates the foundation for interoperability in health and social care, as 65.000 standardised electronic messages are transmitted daily in RSD. In order to IT-support the care of the patient and the cross-sectoral cooperation, the transfer of information, and aggregation of data, standardisation is required. This is based on the nationally adopted standards and wherever possible on internationally recognised standards.

The electronic communication today consists mainly of the secure Danish Health Data Network, where standardised electronic messages are shared according to a joint agreement based on the patients flow between the three major actors. Examples of such messages are:

- Message of admittance to the hospital sent to the GP and the municipality.

- Report sent from the municipality to the hospital with additional and relevant information on the patient.

- Rehabilitation plan send to the municipality when the patient is discharged.

- Prescription sent from the GP to the pharmacy.

In addition to this messaging system, there are a wide array of national databases and standards for exchanging data between systems. At the same time, there are a number of national initiatives such as the newly implemented shared medical record, where the patients' medicine is kept updated and shared to the actors centrally, in order to make sure that only updated medical information is available to the actors. Patients today have access to parts of their health data through the public web portal Sundhed.dk, where they can see appointments, test results and other information.

The purpose of the SmartCare service in the Region of Southern Denmark is to supplement the existing system with the Shared Care platform. The platform's purpose is to gather all the relevant data into one overview, to support the health agreements on how to share treatment of patients with a chronic disease, and to make data available at any time to as many actors as possible, including the patient. It is designed for those patients that are in need of more than what the existing system is able to provide. The platform is highly focused on integration with the existing systems and databases, so that information only should be entered once, but shared with more people. So the Shared Care platform offers an opportunity to collect data from the patients' homes and to involve the patient and their relatives more in the care and collaboration between the parties. It is also a way to share data more dynamically between organisations, such as municipalities regardless of their other IT-systems. The schemas presented above illustrate the existing data, the need for the SmartCare platform and the role of the Shared Care platform. SmartCare will allow for coordination to become more fluent and will be based more on the patient's needs than on the standardised agreements. It will also allow care professionals to see a more complete picture of the patient across multiple diseases, as these are all collected in the Shared Care platform. Today many electronic messages are sent between the caregivers, however not including the patients themselves. This means that each actor has their own part of information in the entire puzzle of information about the patient.

The Danish healthcare system is tax-based and builds on the welfare state. As the Regions cannot collect taxes themselves, the health expenses of the Region are financed through subsidies from the state and the municipalities of the Region:

- Block subsidy from the state: 75%.

- Payment by the state – depending on the activity: 5%.

- Basic contributions from the local authorities: approx. 10%.

- Local authority payment – depending on consumption: approx. 10%.

The economic framework for the Regions is decided on in the yearly financial agreement between the government and Danish Regions. The provision of care is divided between the regions and the local municipalities. The Region is responsible for the hospitals (including psychiatry and social services) and the practices (GPs and dentists) of the region. Also, the Region prioritises the various areas of treatment, and establishes principles for the management of hospitals, quality assurance, service levels, etc. It has the responsibility for the working relationship between the hospitals and private medical practices. On account of their responsibility for prevention, rehabilitation and subsequent care at home, and their share in the joint financing system, the local authorities (municipalities) are key partners in the area of health. The Region advises the local authorities on prevention.

Further to this, the Danish health and social care system can be characterised by the following features:

Governance: The development of the healthcare system in Denmark has always been a collaborative effort between all parties involved. In 2010, the Danish Regions and the Danish Government agreed on a number of changes in the organisational set-up in the field of eHealth. The main focus of the agreement is to ensure a clearer division of labour between all parties involved, including the Ministry of Health and the five regions. The agreement states that the Ministry is responsible for overall development and national coordination and prioritisation. Within this framework, the regions are responsible for investments in and the implementation of specific eHealth solutions.

Primary care: Most primary care in Denmark is provided by GPs, who are paid on a combined capitation and fee-for-service basis. The regions determine the number and location of GPs; their fees and working conditions are negotiated centrally between the physicians' union and the government. The municipal health services provide health visitors, home nurses and school health care.

Secondary care: Hospital care is mainly provided by hospitals owned and run by the regions. There are also private hospital providers in Denmark, but these are only used to a very limited extent.

Central government role: The central government's main functions are to regulate, coordinate and provide advice, and its main responsibilities are to establishing goals for national health policy, determining national health legislation, formulating regulation, promoting cooperation between different health care actors, providing guidelines for the health sector, providing health and health care-related information, promoting quality, and tackling patient complaints.

- **Regulatory framework:** As a part of the structural reform in 2005, the Health Act was established. The Act regulates the responsibilities for treatment, prevention, and health promotion in the Danish healthcare system.

- **Guidelines for the treatment of chronic diseases:** In 2008, an agreement was signed between healthcare and social care professionals (the region and the municipalities) in the Region of Southern Denmark in the area of chronic conditions, which is considered to be one of the largest groups of patients. This agreement ensured development of pathways and a consistent workflow for each disease defined as a chronic condition.

- **The chronic care pathways support a unified process. Included in this is a generic model, which stems from SAM:BO** that describes how a unified cross-sectoral, cross-disciplinary, and coordinated health effort is crucial. The pathways support integrated care and the cooperation between the different healthcare and social care sectors and the patient.

- **SAM:BO** is based on the need to introduce programmes for continuity of care for the patient groups that enter the hospital, and when leaving need services from home care. In addition, there is a need to support patients' ability to care for themselves in their own home. The chronic care pathways have been developed to ensure coherence between the different health-related interventions in the course of a disease. Thus, the pathways aim at achieving high quality interventions and patient safety in the entire course of the disease as well as an appropriate utilisation of resources.

Health outcomes are improved through cooperation between the different sectors of the healthcare system. This cooperation is enabled through the IT-infrastructure of the Region. The infrastructure is described below, and is a huge factor when it comes to standardised electronic communication and interoperability. All players in the healthcare sector use ICT as a tool of their trade; a large proportion communicate electronically via the health data network: 98% of laboratory orders and resorts are electronic; 89% of all prescriptions are electronic. The five Danish regions are responsible for regional IT solutions. A number of public-sector IT organisations develop joint solutions nationally, which the decentralised players undertake to implement. ICT is very commonly used throughout all branches of the Danish health service, and today IT supports a great many work processes, including processes that reach across organisations and sectors. This has also helped to make a large number of services available for citizens and healthcare professionals alike.

Alongside personal contact with the GP, the web portal sundhed.dk (sundhed = health) is the citizen's most important interface with the healthcare sector. Here citizens have direct access to knowledge and advice about their own condition and treatment, and about illnesses and health in general. Digital services to citizens are based on the fact that a considerable amount of communication between healthcare professionals – hospital wards, GPs, specialist doctors, laboratories, pharmacies, and physiotherapists – has become digital over the past 15 years.

It began with electronic exchange of messages between healthcare professionals via
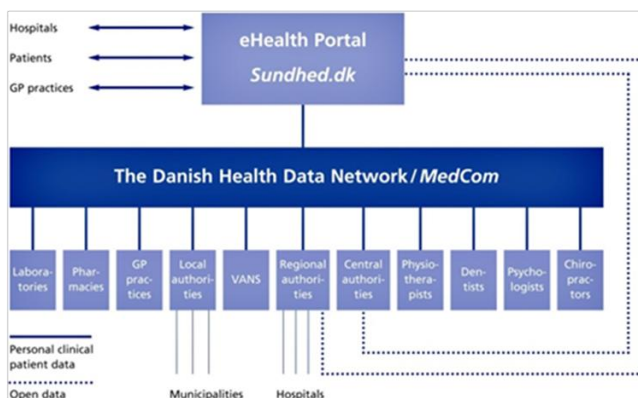
MedCom standards, nationally agreed upon standards (www.medcom.dk). Communications such as prescriptions, referrals, laboratory orders and responses, etc., are exchanged daily. In the month of January 2010, more than 5 million communications were exchanged. Over the years, the repertoire of communications has expanded considerably, and the infrastructure has been extended to include more and more aspects of the healthcare services. Concurrent with this, Internet technology has been adopted, so now communications also include web services, and telemedicine solutions are rapidly being developed. Throughout the development process, efforts have remained focused on giving healthcare professionals access to flexible knowledge searches and internal communications, and, at the same time, enhancing the quality of the services that the healthcare sector is able to offer to citizens.

The history of MedCom - the Danish Health Data Network (DHDN) - goes back to the late 1980s, when interest in electronic communication among healthcare providers grew. It is a long-term project that enables effective data transfer between several actors of the health service, including stakeholders of the community-based social care system. This national network allows fast information flow in the form of reliable data exchange of EDIFACT or XML-based messages among the respective software systems of the participating healthcare providers. Agreements on interface specifications as well as certification of software compliance with agreed upon standards and syntax allow for optimal interoperability. Data transfer begins at the point of care for patients and GPs. From there, services that citizens may need access to include pharmacists, diagnostic services and specialist consultation at hospitals, referral to and discharge from a hospital, and transfer to home care and residential care services. Effective access to these by citizens depends on the efficient exchange of messages between health and social care

providers and other actors. One of the main prerequisites for establishing a coherent and cooperating healthcare system is to ensure that all healthcare professionals dealing with a patient have easy access to relevant patient information where and when it is needed. This strengthens the base for decision making and enhances patient safety.

Digitalisation is the key element in achieving this goal by giving healthcare professionals access to data and examination results across the entire health sector. eHealth is also vital for leveraging secure, efficient work processes, high productivity, and high standards of healthcare delivery. The Region used this as a back-drop to invent and to innovate new services, such as the collaboration agreements SAM:BO and the Shared Care solution.

In order to give the best patient care and to ensure a high quality of life for the citizens in the Region of Southern Denmark, the Region has implemented SAM:BO, which is an agreement on collaboration between all players in health and social care, based on new innovative ways of providing services and new ways of communicating electronically. The goal of the regional cooperation is to ensure consistent citizen / patient care pathways between health sectors in the region, and thus achieve higher quality, efficiency, and patient satisfaction with the health services provided. It is also to strengthen the cooperation between GPs, local authorities, and hospitals regarding the individual citizen / patient and his/her progress through the healthcare system, and ensure dialogue and coordination between them and with the greatest possible involvement of patients and relatives.

SAM:BO entails requirements and expectations concerning content and timing of the electronic communication sent between the municipality and hospital during a patients' hospitalisation. The overall objective of this exchange of information is to optimise hospitalisation with a particular focus on discharge, enabling continuity once the patient is discharged and the municipality / home care takes over the care.

The citizen must experience consistency from the very beginning in the process where the GP is contacted, to the diagnosis and treatment at the hospital and until the citizen is back in his/her own home for the follow-up rehabilitation therapy. The starting point is the individual's needs, so that treatment is offered on a needs basis.

For the complex patients with one or several chronic diseases, the Region of Southern Denmark is in the midst of implementing an innovative solution that runs on the backbone of SAM:BO. This solution supports the integrated approach as outlined and is established on the basis of the chronic care guidelines that have been issued both nationally and internationally. The Shared Care system is an ICT system that supports the Danish "programmes for the continuity of care" and thereby also supports the cross-sectoral collaboration (communication and sharing of data) for patients with chronic diseases.
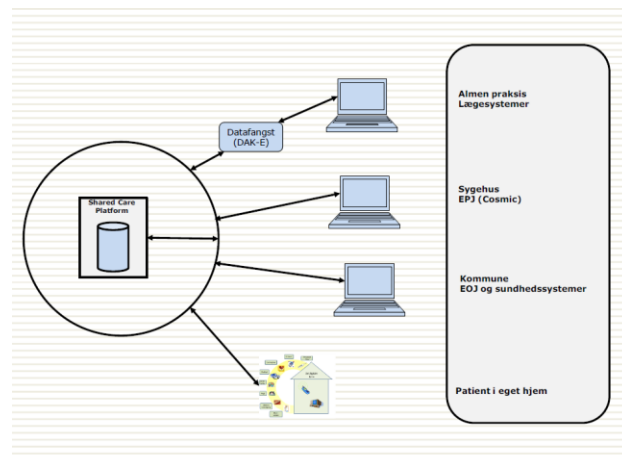
The Danish National Board of Health has issued "chronic care guidelines" to support a unified process for patients with a chronic disease. Included in these is a generic model that describes how a unified cross-sectoral, cross-disciplinary, and coordinated health effort is crucial. Therefore, a process has begun to underpin this model with electronic communication and shared care records, thus connecting all the stakeholders in the health and social care continuum in a

collaborative effort to secure that the right information is available for authorised caregivers anywhere and anytime. This is what Shared Care supports. The process involves the primary care sector, the regional hospital sector, the municipal social care sector, and the patients themselves.

The solution thereby supports the integrated care approach and adopts the common and nationally agreed upon dataset standard for citizens with a chronic disease. In addition, the solution utilises the existing national infrastructure and optimises the workflows among the players in the healthcare sector, and care service delivery processes.

3.6.2 Contextualised use case scenario for the SmartCare pilot service

The following is based on patients with a chronic heart condition, as this is the patient group we have focused on as the pilot group. To clarify the existing system (Sam:Bo) and the new system (SmartCare) we have divided the use-case into two subsections when relevant under each headline.

3.6.2.1 Overview of local / regional actors

Table 6 – South Denmark: Overview of the client domain

Type of actor	Name of actor	Description of the role	Information handled
CR	Patients with a chronic heart disease and over the age of 18. Patients who are in need of both health and social care elements on a long term basis.	The patients are the main focus of the delivery. They are at the centre of the care and depending on their level of self care abilities they will be able to take an active role in their treatment by viewing and entering important health data.	The patient can see relevant information and also add information in both text, such as questionnaires and notes, and measurements from home monitoring devices. Information regarding the patients disease such as diagnosis, measurements taken by the professional carers, relevant data on lifestyle and social factors, filled out questionnaires, goals, notes, activities, symptoms and contact persons.
I/FC	Relatives to patients/care recipients	It will be the patient themselves that include the relatives in the treatment and may also give them access to the electronic data in the SmartCare platform. They will serve as a support for the patients themselves.	The relatives will have the same rights as the patients themselves, and can see relevant information and also add information in both text, such as questionnaires and notes, and measurements from home monitoring devices. Information regarding the patients disease such as diagnosis, measurements taken by the professional carers, relevant data on lifestyle and social factors, filled out questionnaires, goals, notes, activities, symptoms and contact persons.

Table 7 – South Denmark: Overview of the service provider domain

Type of actor	Name of actor	Description of the role	Information handled
SCP	Home care department, care coordinators and the health centres in the municipalities	The social carers will deliver care elements such as education in lifestyle, including diet, exercise, alcohol and smoking in healthcare centres in the local communities. There will also be a number of the patients that will receive social care in the home such as cleaning, food delivery, bathing, shopping and other daily tasks. Finally, some of the patients will have a care coordinator from the municipality, who helps the patient navigate the system and helps them to implement lifestyle changes where necessary.	Social carers will be able to see relevant information about the patient's disease and self-care ability. They will also be able to write notes, set up goals with the patient and fill out relevant questionnaires with the patient. Data that can includes notes, plans, goals, questionnaires and activities. They will also be able to see the information provided by the different actors, such as patients, hospitals and GPs.
HCP	This group primarily consists of hospitals and GPs, however some health care services are also provided by the municipalities, including physical therapy and home nurses helping with measurements and nursing care.	The healthcare providers have different roles. The hospital is in charge of acute heart problems, specialised treatment as well as discharging and following up on the patient after discharge for a period of typically a year. The GP is responsible for the long term check-ups yearly and the general communication with the patient about their health. The municipality is responsible for rehabilitating physical therapy, education in lifestyle factors and homecare activities related to healthcare.	Care professionals from the different relevant clinics in the hospitals as well as staff in the general practitioners offices and selected staff from the municipalities will be able to share data from their individual systems, use the portal to support their workflow across sectors and to view data from the different caregivers. Information shared from the hospitals and GPs could be lab-results, measurements, notes, symptoms, diagnosis, goals set with the patient, activities, questionnaires, reports and self-care indicators. They will also be able to see the information provided by the different actors such as patients and municipalities.
TSCP	Non-profit organisations	The organisations may provide support and counselling to the patients if needed, such as joining them in meetings or accessing the data of the patient if the patient allows them to.	Their role remains unidentified at this point – it is not yet clear if these organisations will have access to the portal.

3.6.3 Contextualisation of generic SmartCare pathways

3.6.3.1 Entry points

Today, a heart failure patient's typical first contact with the healthcare system is when he or she has an acute heart problem that needs admission into the hospital. Either that, or the patient expresses their symptoms and their concerns to their general practitioner. In that case the GP sends an electronic admission referral to the hospital. When a patient is admitted to the hospital the system sends a message to the patient's municipality informing them of the admission. Today, the municipality's system sends back a message containing detailed information on the patient. In SmartCare, either the social care professionals or the GP or the hospital staff may choose to enter the patient into the SmartCare platform at any given time. All these actors will evaluate the patient and see whether or not he or she is a candidate for sharing information in the platform between the actors. This will be relevant if the patient receives both healthcare and social care services. If the patient already has a heart plan, with specific goals and appointments, this will also be entered into the platform by the caregiver entering the patient into the SmartCare platform. Typically the patient will be entered into the SmartCare platform at discharge from the hospital.

3.6.3.2 Discharge from hospital

According to current practice, the patient is discharged and the hospital nurse sends a discharge report to the municipality stating the patient's needs in terms of home care and a notice to the GP. She also sends a rehabilitation plan to the municipality for physical rehabilitation. She gives the patient a paper-based edition of the heart plan after the first check-up meeting. With SmartCare, instead of filling out the heart plan in paper, she fills it out in the SmartCare platform. As the heart plan is available in the platform, adjustments are easily made at any point in time and shared with the other involved caregivers and the patient. Seeing that the patient has access to the information and can add measurements and notes, revisions can be made more on a need-basis rather than on a plan-basis. She can also give the patient access to home monitoring and videoconference possibilities making some of the visits to and from care professionals unnecessary. This also means that she has the opportunity to discharge the patient earlier and keep contact via telemonitoring / telecare services in the patient's home.

3.6.3.3 Assessment of the service user's needs for integrated care

Currently, all patients with a heart failure are included in the Sam:Bo system automatically. When the patient is ready to be discharged ,the responsible nurse fills out a discharge report in the hospital's IT-system, which she sends to the homecare department in the municipality. In this report she includes information such as:

- General information on the patient and their relatives contact information.

- Information on the cause of the admittance and the treatment delivered while in the hospital.

- The patients current need for further treatment and medicine.

- An evaluation of the patient's functional level and a description of the social care elements that need to be put in place in the patients home.

Today, a distinction is made on how significant is the change to the patient's functional level. If there is a significant change, the hospital is urged to host a videoconference between the hospital professionals, the GP, the municipality and the patient. In the conference, a coordinated plan for the level of care after discharge should be made and the responsibility between the caregivers is divided. If the change is not significant, it is the hospital nurse who evaluates the need for home care, and sends this in the abovementioned report. So in this phase, the hospital nurse decides which care services the patient needs when discharged from the hospital, both healthcare and social care services. She also sends an electronic report to the GP with relevant information on the patient's treatment. The hospital nurse also sends a plan for physical rehabilitation to the training facility at the municipality, where she describes the patient's need for training. These messages are all automatically sent to the specific IT-systems in the different sectors.

With SmartCare, if the patient is already entered into the SmartCare platform at the time of the assessment, the hospital nurse will be able to see the information when assessing the need for home-care based on the history of the patient. She will also be able to see the contacts in the municipality and the GP, and so will be able to contact them for further information if needed. She will also be able to take into account the possibility for the caregivers to follow the patient closely through the platform combined with the possibility for home monitoring – this might have an impact on the assessment and might make the patient more independent.

3.6.3.4 Enrolment into the SmartCare service

Currently Sam:Bo is agreed and accepted as the way to communicate electronically between the actors; patients are automatically enrolled into the existing pathway when they are admitted. With SmartCare, at the first meeting in the clinic, the nurse will ask consent to enter the patients data and to share it with other relevant actors surrounding the patient's treatment in the SmartCare platform. She will also give the patient information on the SmartCare platform and the possibilities for getting access themselves. The nurse also evaluates the patient's ability to perform home monitoring; if they are considered eligible, they are given the opportunity to get home monitoring equipment. This is then ordered at the Region, where employees set up the devices at the patient's home, and at the same time introduce the patient to their use. The nurse simply enters the patients CPR (personal security number) and the SmartCare platform retrieves the basic information on the patient from the national database. After entering the basic information, she chooses the disease and follows the predefined form to enter relevant data together with the patient.

3.6.3.5 Initial integrated home care plan

Today with Sam:Bo, at the point of discharge a rehabilitation plan is made by the hospital staff where the patient's needs are described. The information needed in this plan includes:

- Full name and address of the patient.
- The rehabilitation plan has to include a description of the patient's ability to function just before the event/disease that led to the current hospital treatment. The plan also includes a description of the patient's usual ability to function related to body function, activity and level of participation.

- The rehabilitation plan has to include a description of the patients' ability to function when discharged which includes the patient's current ability to function related to body function, activity and participation that can involve both the patient's resources and limitations.

- The rehabilitation plan has to include a description of the patient's need of rehabilitation at the time of discharge. The description has to include a clarification of which limitations rehabilitation should focus on. Furthermore, this description has to consider the patient's disabilities and possible limitations regarding participation in activities and the rehabilitation in general.

- The rehabilitation plan has to state if the patient needs rehabilitation in the hospital after being discharged.

- The rehabilitation plan has to state the timeframe within which the municipality of residence has the first contact with the patient with a view to plan the course of rehabilitation. This also includes the patient's right to be guided regarding the possibility to choose between different rehabilitation offers. In cases where the patient needs specialised rehabilitation in the hospital after being discharged, the rehabilitation plan has to state a timeframe within which the hospital has to have the first contact with the patient.

- The rehabilitation plan has to include information about how the region of residence and the municipality of residence can be contacted.

The nurse also sends a discharge report stating the patient's treatment, discharge date, functional level and need for assistance including medication and need for personal remedies to the municipality. From this report the municipality can assess the patient's need for social care.

With SmartCare, when the patient returns to the hospital after a discharge, the nurse fills out a personal heart plan in the SmartCare platform. This heart plan is a questionnaire developed in collaboration with the municipalities, and is the patient's tool for setting goals and keeping track with the agreed treatment. If the patient is not yet included in the SmartCare platform, she enters the patient's social security number and chooses the patient's condition. This enables her to fill out the heart plan in the platform with the patient after they have given their consent. Afterwards they fill out the questionnaire together setting goals, entering measurements and scheduling check-ups after three, six and 12 months.

3.6.3.6 Permanent coordination of integrated care delivery / revision of the initial care plan

At each point of contact with a care professional, the patient or the care professional has the opportunity to revise the needs of the patient and the services accordingly. In the existing system, however, this revision is only made by request from the patients themselves or at planned contacts with caregivers. The heart plan is paper-based, which makes it hard to revise. As the heart plan is available in the SmartCare platform, adjustments are easily made at any point in time and shared with the other involved caregivers and the patient. Seeing that the patient has access to the information and can add measurements and notes, revisions can be made more on a need-basis rather than on a plan-basis. The SmartCare platform has an alarm mechanism that allows the care professionals to be alerted when a measurement exceeds an agreed value. This means that the care professionals have an opportunity to intervene faster than in the existing system.

3.6.3.7 On-site provision of formal social care

Today, when the patient returns home, social care is waiting according to the message / report sent by the hospital nurse via Sam:Bo. This could typically be a home care professional from the municipality which provides services such as cleaning, bringing food, bathing, dressing and helping the patient to bed. These services depend on the needs described by the hospital nurse. The patients are also offered an individual conversation with a coordinating social care professional if they are expected to have low self-care ability. The patients are also offered a group-based educational programme of six weeks at a local facility, regarding lifestyle factors such as diet and exercise according to their condition.

With SmartCare, when the patient is discharged, the local rehabilitation centre in the municipality contacts the patient either by telephone or personally for a follow-up meeting on the treatment so far, and the planned rehabilitation course (typically six weeks of training and education in lifestyle elements). Depending on the level of selfcare ability, the patient either has a range of meetings or just the one. In the meeting the rehabilitation worker fills out a list of information in addition to the heart plan, where personal goals and expectations are elaborated. This is entered directly into the SmartCare platform. He or she may also determine which information is to be shared in the platform, such as guides for the patient, activities and notes. He or she will also look at the measurements taken at the hospital or from home.

3.6.3.8 On-site provision of formal healthcare

Today the on-site provision of healthcare may include physical rehabilitation, medication or treatment of wounds and check-ups at the GP. All these services are assessed at the time of discharge; the patient's needs are re-evaluated before starting e.g. physical rehabilitation. Here a six weeks long programme is made according to the individual's needs – either in groups or individually. The patient sees their local GP for annual check-ups after the first year after discharge. If there is a need for rehabilitation, this can either be performed at a local training facility, or at the patient's home depending on the patient's ability to transport themselves.

With SmartCare, the caregivers in this category will find great value in seeing information from the other actors in the treatment as well as benefiting from possible home-monitoring or videoconferencing functions. For heart patients the time for adjustment of medication has shown to be cut in more than a half when using videoconferencing. Also the GP and the hospital clinic will be able to see the patient's measurements and notes before the scheduled check-ups, and some of these check-ups might be able to be replaced by home-monitoring or videoconferencing. The caregivers will enter relevant information such as measurements or goal status either in the SmartCare platform or in their own IT-system, which is then shared between the two systems.

3.6.3.9 On-site provision of informal care

This section is very limited in the Danish system, however relatives will be able to see the information in the SmartCare platform as the same way the patient does. This allows them to support and monitor their loved ones.

3.6.3.10 Remote provision of health / social care to the home (telecare, telemonitoring)

There is not a wide-spread use of telecare and telemonitoring possibilities today. There are however a number of projects that show the relevance of these elements. In the SmartCare platform, the patient is able to enter data from devices into the platform themselves or connect devices that automatically update the platform. The measurements are stamped with the point of origin so that the care professionals are able to see where the measurements are coming from. Videoconferencing will also be made available in this service in a complementary system, not yet defined. These possibilities may replace physical meetings in the hospital or at the GP, and will also supplement the measurements taken at the scheduled check-ups.

3.6.3.11 Integrated documentation of home care provided / self-care measures

In the currently existing system, each caregiver organisation is able to get an overview of defined variables from their own systems. There is also a possibility to see statistical data on the type and amount of electronic messages sent between the parties. The relevant data is stored in the individual systems of the caregivers, and national databases regularly collect information to get an overview across systems. In the SmartCare platform, it is also possible to get reports based on the data entered. There is a very flexible configuration which allows users to set up their own report templates with selected information from the platform. This is only limited by the access and rights of the individual ordering the report. In addition, the entire platform is based on presenting relevant and updated information on the screen, so that caregivers or patient will not need to search around in the system after it. The screen set-up can be customised to suit the individual user's needs. It is also easy to see historic data and get them presented in a visual and user-friendly way.

3.6.3.12 Control / reassessment of the home care recipient

Currently, the patient attends check-ups at three, six and 12 months after discharge from the hospital clinic. The patient is called in for a check-up at their own GP after the first year of check-ups at the hospital. Depending on the level of functionality and self-care ability, home care may be reduced, and the hospital passes the responsibility of check-ups and monitoring measurements made from home to the GP. The GP may also refer the patient to additional patient educational activities in the municipality by sending them a referral. It is the GP's responsibility to be the main responsible caregiver on a long term basis, including evaluating the patient's needs at a regular basis. However the municipality will also assess the patient's needs for home care services on a regular basis, as they are the ones that deliver the services.

With SmartCare, in between check-ups the patient is able to see and enter relevant information from home giving the caregivers a better insight into the patient's needs. The involved caregivers are able to access the SmartCare platform to see and enter relevant information to be shared. Also, the GP will be able to see the patient's measurements and notes before scheduled check-ups, and some of these check-ups might be able to be replaced by home-monitoring or videoconferencing. This also means that the care professionals are better able to evaluate the patient's needs on a regular basis rather than only on scheduled visits.

3.6.3.13   Temporary admission / re-admission to institutional setting

Today, the procedure of a temporary admission / re-admission is the same as described under the previous headlines – so the process simply starts over. With SmartCare, the only difference in the process here will be that the patient is already entered into the common platform and the involved caregivers are able to see the historic data and include this in their decision making.

3.6.3.14   Exit point

The need for care is reassessed by the social caregivers and the GP on a regular basis and services are adjusted accordingly. The patient will probably remain in the SmartCare platform until they are deceased or wishes to be taken out of the system.

3.7   Item 12: Primary, secondary, and other outcomes

Primary, secondary, and other outcomes, including the specific measurement variables, analysis metric, method of aggregation, and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.

All outcomes are presented in Table 8: Outcomes, metrics, timing and explanation for variables below, along with identification of variable, analysis metric, time point and explanation for inclusion of each variable. Also, the table indicates whether each variable can be included on a voluntary basis by pilot sites, or if they are required to collect data. The mandatory variables are defined by the study aim and objectives, and will be used in the final analyses of the study.

The methods of aggregation depend on the scaling of the variable (numeric, categoric, binary) and the distribution (normally or not normally distributed).

Table 8: Outcomes, metrics, timing and explanation for variables

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
1. Overall service effectiveness and specific outcome measures							
Number of contacts, healthcare services	Citizen / client / carer	Individual level	Number	M	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites.
Unplanned contacts, healthcare services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
Number of contacts, social care services	Citizen / client / carer	Individual level	Number	M	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites
Unplanned contacts, social care services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
Number of contacts, volunteer sector services	Citizen / client / carer	Individual level	Number	M, if relevant in setting	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites
Unplanned contacts, volunteer sector services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
1.a Disease specific health status measures							
Blood pressure	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status
Blood glucose	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status (diabetics only)

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
Cholesterol	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status
Anxiety	Citizen / client	Individual level	Scale	V	Questionnaire or interview	Baseline / mid-term / exit	Indicator for health status
Status/severity of primary condition	Citizen / client	Individual level	Scale or number	V	Registries	Baseline / mid-term / exit	Predictor of health outcome
1.b Generic health related / functional quality of life							
SF 36 v2	Citizen / client	Individual level	Scale	V	Questionnaire or interview	Baseline / exit	Might be affected by the intervention
Barthel	Citizen / client	Individual level	Scale	V	Clinical measurement	Baseline / exit	Indicator for health status
Timed up & go	Citizen / client	Individual level	Number	V	Clinical measurement	Baseline / exit	Indicator for health status
CASP-19 family carer QoL	Carers	Individual level	Scale	V	Questionnaire or interview	Baseline / exit	CASP-19 is used to specifically measure QoL of family carers. The measure has four domains: control, autonomy, pleasure and self-realisation. The scale contains 19 items. The domains have Cronbach's αs between 0.60 and 0.80. Correlations between the four domains range from 0.40 to 0.70. Concurrent validity has been assessed using the Life Satisfaction Index – Wellbeing. A strong and positive association was found between the two scales.
1.c Psychological measures							
Anxiety and depression according to HADS	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The HADS is used to determine the levels of anxiety and depression in end users. It is a 14-item scale. Seven of the items relate to anxiety and seven related to depression.
Depression according to GDS	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The Geriatric Depression Scale-15 (GDS-15) is a short, 15-item instrument specifically designed to assess depression in geriatric populations. Its items require a yes/no response. The Geriatric Depression Scale was first introduced by Yesavage et al. in 1983, and the short form (GDS-15) was developed by Sheikh and Yesavage in 1986.
Isolation according to Perceived Isolation Questionnaire	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	Previous research has identified a wide range of indicators of social isolation that pose health risks, including living alone, having a small social network, infrequent participation in social activities, and feelings of loneliness. However, multiple forms of isolation are rarely studied together, making it difficult to determine which aspects of isolation are most harmful to health. Cornwell and Waite (2009) used population-based data from the National Social Life, Health, and Aging Project to generate questions combining

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
							multiple indicators of social isolation into scales assessing social disconnectedness (e.g. small social network, infrequent participation in social activities) and perceived isolation (e.g. loneliness, perceived lack of social support). These questions can be ascribed numerical values so that, when repeated, they provide a way for people to self-rate whether they are more or less socially disconnected and isolated from others than at the previous time of measurement.
Carer burden according to ZBI (short version)	Carers	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The Zarit Burden Interview was developed to measure subjective burden among family carers of adults with dementia. Items were generated based on clinical experience with family carers and previous research, resulting in a 22-item self-report inventory that examines burden associated with functional or behavioural impairments and the home care situation. Most researchers use the 22-item version of the ZBI. However, the length of the instrument may be a deterrent to its use in clinical and research environments. Bédard et al produced a short version consisting of 12 items, with results comparable to the full version. Cronbach's α for the 12-item version is 0.88.
Carer burden according to CADI-CASI-CAMI suite	Carers	Individual level	Number	V	Questionnaire or interview	Baseline / exit	Carers are also assessed for difficulties, satisfaction and management in caring using the CADI-CASI-CAMI suite. The CADI-CASI-CAMI suite is a collection of three instruments used to assess family carers' perceptions of difficulty, satisfaction and management (coping strategies). The Carer Assessment of Difficulty Index (CADI) is a 30-item index and contains a series of statements which carers have made about the difficulties they face. Carers are asked to tick the box next to each statement that applies to them the most from the following options: 'this does not apply to me', 'not stressful', 'stressful', and 'very stressful'. The Carer Assessment of Satisfaction Index (CASI) is also a 30-item index and contains a series of statements about the satisfaction carers' experience. The Carer Assessment of Management Index (CAMI) is a 38-item questionnaire and contains a series of statements about the coping strategies used by family carers.

2. Safety

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
Deaths	Citizen / client	Individual level	Yes/no (dichotomous)	M	Registries	Exit	Easy to establish, common as adverse outcome

3. End user / client / carer perspectives

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
End user / client / carer empowerment	Citizen / client / carer	Individual level	Scale for each question	M	Questionnaire	Exit	Reflects the aim of SmartCare

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
End user / client /carer satisfaction	Citizen / client / carer	Individual level	Scale for each question	M	Questionnaire, IFIC	Exit	This would be based on the eCare Client Impact Survey developed in CommonWell and INDEPENDENT in response to a lack of instruments measuring impacts on older end-users and informal carers beyond clinical outcomes and with particular focus on impacts occurring from combined social and health care.
End user perception of integration	End-users	Individual level	One question with visual scale? Ingo, please correct me if this is wrong	M	Questionnaire	Exit	? Ingo?
4. Economic measures							
Efforts related to service development & implementation	Citizen / client / carer / Service providers	Individual or organisational level	Number	M	Various	Exit Implementation and pilot phase	To support the design and implementation of viable and sustainable services. To produce supportive economic for internal decision making processes. To allow for an overall, post-hoc assessment of socio-economic impacts.
Efforts related to service operation or use	Citizen / client / carer / Service providers	Individual or organisational level	Number	M	Various	Exit Implementation and pilot phase	As above.
Equipment cost	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Service effectiveness benefits	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Service efficiency benefits	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Revenue streams	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Willingness to pay	Citizen / client / carer	Individual level	Scale	V	Questionnaire	Exit	Relevant if a service fee payable by end user / client /carer is considered to become part of the revenue model.

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
5. Organisational impact measures							
Impacts on staff	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	Key measures to understand the organisational changes caused by the new service, as well as to get a better understanding of what was actually achieved through the integration of different service silos. Can also capture where staff members and organisational decision makers are (still) not satisfied with the result.
Impacts on organisations	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
Service integration aspects	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
Mainstreaming potential and sustainability	Service providers: key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
6. Possible confounders / control variables							
Date of birth	Citizen / client / carer	Individual level	YYYY-MM-DD	M	Registries or interview	Inclusion	Age is a strong predictor of any health outcome
Gender	Citizen / client / carer	Individual level	Male/female	M	Registries or interview	Inclusion	Gender is very often related to health outcomes
Level of education	Citizen / client / carer	Individual level	Categories	M	Registries or interview	Inclusion	Level of education is a strong predictor of any health outcome. Generally, it is said that one Euro given to education increases the level of health more than one Euro given to health care. Categories are important and have to be used in a similar way throughout pilots

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
Marital status	Citizen / client / carer	Individual level	Categories	M	Registries or interview	Inclusion	Marital status is a strong predictor of health outcomes. It is better to be married than being single. Categories are important and have to be used in a similar way throughout pilots
Ethnicity	Citizen / client / carer	Individual level	Categories	V	Questionnaire or interview	Inclusion	Ethnicity is strongly related to health outcomes
Main work status (last 12 months)	Citizen / client / carer	Individual level	Categories	V	Questionnaire or interview	Inclusion	Work status is being recognised as a strong indicator of health outcome. It turns out that people belong to the social group in which they work rather than the one in which they are educated. Categories are important and have to be used in a similar way throughout pilots
People older than 18 living in household	Citizen / client / carer	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for the level of informal care received
Household income	Citizen / client / carer	Individual level	Number	V	Questionnaire or interview	Inclusion	Necessary if willingness-to-pay is analysed.
Daily tobacco use	Citizen / client	Individual level	Dichotomous	V	Questionnaire or interview	Inclusion	Indicator for health status
Frequency of alcohol (12 months)	Citizen / client	Individual level	Categories	V	Questionnaire or interview	Inclusion	Indicator for health status
Height (CM)	Citizen / client	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for health status
Weight (Kg)	Citizen / client	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for health status
Co-morbidity	Citizen / client	Individual level	ICD-10 codes	V	Questionnaire or interview	Inclusion	Indicator for health status, highly relevant for the usability of results after finishing pilots

3.8 Item 13: Time schedule of enrolment, interventions, etc. & Item 15: Strategies for achieving adequate participant enrolment

Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants & Item 15: Strategies for achieving adequate participant enrolment to reach target sample size.

Table 9: Enrolment of end users per pilot site

Expected date of first enrolee	Expected number enrolled per week	Expected finishing date of enrolling	Strategy to increase inclusion rate (1)	Strategy to increase inclusion rate (2)
Region of Southern Denmark				
May 2013	15	August 2014	Additional project management resources in the project group.	Putting pressure on leaders in the different organisations.
Aragon				
March 2014	There will be a massive inclusion of participants in three periods to ensure their participation in the project at least for 6 months.	March 2015 Living process for Discharge Pathway with a non-ending final enrolling date Living process for LTC-Pathway with a non-ending final enrolment date to cover drop-outs.	Involvement of new healthcare centres in more cities.	Involvement of new third parties associations and promotion of these services among their visitors.
Scotland				
May 2014	A detailed weekly enrolment programme has not yet been defined, although it can be extrapolated from PID document.		Accelerate contacts with and from 7 local health social care and vol providers as part of contractual requirements. Local Partnerships are responsible for participant inclusion.	Direct marketing to targeted population and their locations of interest e.g. churches, libraries as part of Communications and Dissemination Plan.

3.8.1 Further details per site

3.8.1.1 Region of Southern Denmark

In the remaining pilot phase, which runs until January 2013, the aim is to make sure that all the different types of participants are using the platform to ensure that the platform is ready for large scale implementation. The goal is to have at least 10 participants from the hospital, 3 participants from 3 different municipalities, 25 active end users and 5 different general practitioners clinics by 2014. Afterwards, the platform will be implemented more widely in the region both for heart end users in all 5 hospitals and connecting clinics and municipalities and for other relevant conditions.

The end users are asked to participate when they attend their first check-up at the hospital after discharge. Here they are both asked to participate in the research part and in using the SmartCare platform actively. All end users will be a part of the research part regardless of their use of the platform itself. The nurse in charge of the check-up is prepared to inform the end user in order for them to give their consent. She will register this consent into the SmartCare platform.

It will be the Region of Southern Denmark and the Department of Health Innovation that will be in charge of the implementation overall. In 2013 it will be the staff from both the Shared Care and the SmartCare project group; from 2014 a permanent centre is planned to be established. This centre will be in charge of support and implementation.

The participants will be divided into the intervention and control groups based on their geographic location. To make sure we have enough end users in the control group, we have selected the largest hospital in the Region (the University Hospital of Odense). This means that all heart end users in that hospital will be asked to be in the control group for six months, and afterwards be offered to be entered into the SmartCare platform.

3.8.1.2 Aragon

The starting point of this integrated-care pathway would be when an end user has been suggested to be included into the SmartCare programme, either upon a visit to Primary Care Attention or during a stay at Barbastro's Hospital.

Enrolment in ST-Pathway (Early-Discharge)

There are two ways to identify potential participants. First is during a hospitalisation of an end user. If any healthcare professional suspects that the end user is exposed to social risks of any type, then he notifies the social worker working at the Hospital. This social worker evaluates if the end user is in a real threat situation.

Enrolment in Long Term Care Pathway

Second channel would be when an end user visits a doctor at Primary Care Attention. If the GP suspects an end user to be at risk, then he refers the end user to the SmartCare Evaluation Committee who will evaluate if the user is a potential participant in the programme.

The SmartCare Evaluation Committee is the body responsible for the inclusion of participants. It is made up of SmartCare project management team (J. Coll, Dromero, ER Doctor) + 1 specialist (geriatrician) + 1 GP + 1 PC nurse + Barbastro's Hospital Social worker. It decides upon inclusion criteria (health + social needs) of the potential candidates and other requirements. This committee asks for opinions from other specialists (in charge of the end user). Local SCP will interview the end user to evaluate the social need and requirements. Acceptance by care recipient (consent form) is required.

Classification into groups

Upon identification, enrolment and acceptance, the classification of users into the control or intervention groups will be decided randomly.

3.9   Item 14: Estimated number of participants

Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.

Sample sizes were calculated in order to avoid consequences of including more end-users than necessary into the full evaluation. Thus, the number of end-users presented in the original proposal will be reached by each participating region, whereas the evaluation will be carried out on a restricted number of end-users. This decision was primarily based on the ethical considerations of providing end-users with the 'usual care' solution after documenting the expected effectiveness of the intervention. In addition, resources are required in terms of time and money to collect and analyse data. And with enough data to establish statistical significance, further data collection would imply waste of resources related to the evaluation purposes.

3.9.1   Background: Sample size calculations in cohort studies

In randomised trials, the risk of bias due to differences in the samples receiving the intervention versus not receiving the intervention is limited due to the randomisation. The hypothesis is that randomisation ensures all possible confounding characteristics to be equally distributed in the groups of participants, and thus does not influence the results of the study (Liberati et al., 2009).

In non-randomised studies this is not the case. Therefore, a higher number of people need to be enrolled, and the calculation of sample size is more complex (Liberati et al., 2009).

In a calculation of required sample size for a cohort study, the variables include:
- α = Accepted level of significance.
- ß = Accepted level of power.
- SD = Expected standard deviation.
- Estimated change in outcome.

In order to obtain a scientifically sound estimate of outcome, a literature search was carried out in electronic bibliographic databases and in previous European projects. The search yielded a limited number of results, and there were no references focusing on integrated care which was supported by ICT. Only integration of care or ICT were identified as interventions separately.

That left two options, of which the second was chosen:
1) Make an educated guess on the change in outcome.
2) Reverse the calculations of sample size.

So, instead of assuming any undocumented change in outcome, it was decided to estimate which level of change would be acceptable in order to provide decision makers with sufficient information to decide whether or not to implement the services at a large scale.

3.9.2   Calculations

Sample size calculations were carried out for comparing two independent means with α=0.05 (level of statistical significance) and ß=0.8 (power) for two-tailed analyses (not restricting the direction of effect to be either positive or negative).

If usual care for citizens receiving services from both health and social care includes one contact per week, an average reduction of 3.6 contacts per end user for 1,000 people over

a six month period will suffice. In that sense, the outcome change is treated as the dependent variable and the number of end users as the independent.

As one strategy to determine the practical consequences of a reduction in contacts, the Danish pilot was used as a case. Since most of the staff involved in providing health and social care in Denmark are nurses, the average nurse's hourly salary (48 €) was used as the costs of one contact. 4,000 end users are considered eligible on a yearly basis for RSD and with an average reduction in contacts of 3.5, the yearly reduction in costs would be 336,000 €. An extrapolation of these results to the entire SmartCare population of 7,000 end-users would yield a total saving of 6,270,000 € annually.

With these assumptions on costs and possible savings, the calculated outcome changes were considered acceptable for decision makers.

Sensitivity analyses were carried out for varying population sizes

Table 10: Sensitivity analysis of necessary outcome for different population sizes

Sample size (including 25 % dropouts)	1000 (1250)	750 (938)	500 (625)	250 (313)
Mean contacts control group	24	24	24	24
Mean contacts intervention group	20,45	19,90	18,98	16,88
Necessary reduction in contacts	3,55	4,10	5,02	7,12

Please note: the model assumes a six month follow up and a baseline mean number of contacts during that period to be 24.

The analyses above were based on an assumption of a weekly contact during six months in the control group. In any case, the absolute necessary number of reduction in contacts does not change, if the assumed mean of contacts for control group is changed. So, if the assumption is that one contact per fortnight in the control group (=12 contacts), the necessary reduction for 1250 end users is still 3.55, for 938 end users it is 4.10 etc. It should be born in mind that the factors taken into account largely depend on the context in each individual pilot sites, so that for instance cost structures may vary from site to site.

In conclusion, all pilot sites would generally be allowed to include any number of end users, only depending on the strength of the effect to be generated. If, for example, 313 end users is the acceptable number for the pilot site, the consequence is that a reduction in contacts must reach 7.12, so that has to be a reasonable assumption in the local setting. It is also possible to calculate the specific number of end users based on what has been provided in the contract with the Commission (i.e. for 400 end users or 800 end users). Or pilots can choose to stop inclusion at 1250 or 938 end users if it is reasonable to assume a reduction of 3.55 or 4.10 contacts over the period of time.

So one aspect that pilot sites need to consider is whether it is reasonable to assume the calculated reduction in number of contacts for the number of end users eligible in the local setting.

A second aspect is that sample sizes should be high enough to allow for meaningful break-down analyses using the control variables listed in the table above. Examples would be break-downs by age group, household income or level of educational attainment. Following for example ISCED[1] for educational attainment and EUROSTAT's practice of presenting

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[1] ISCED - the International Standard Classification of Education - UNESCO 1997

educational attainment levels (lower secondary = ISCED 2; upper secondary = ISCED 3c long, ISCED 3 a, b and ISCED 4; tertiary = ISCED levels 5 and 6), at least three break-down groups must be possible without n going below meaningful thresholds (~40).

Thirdly, all pilots have to agree on a similar length of time to follow up the individual end users included in order to measure the number of contacts similarly across pilot sites. This document suggests six months, which fits the SmartCare project plan nicely (six months follow up leaves six months to reach the necessary sample size). 18 months of follow-up for the first wave, and 12 months follow up for the second wave.

4. Data collection methods

4.1 Item 18a: Plans for assessment and collection of outcome, baseline, and other trial data

Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.

There will be no safety measures for the data collection.

CRFs [2] will be elaborated for the common data set and common questionnaire on empowerment. Any voluntary additional measures will be recorded in local CRFs.

4.2 Item 18b: Plans to promote participant retention

Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols.

No incentives are provided for citizens or carers included in this study. End users are allowed to withdraw at any time, and will not be asked to give reasons for such decisions. (It requires specific ethical approval to ask for reasons for not wanting to participate or withdraw.) A drop-out rate of 25% has been included in the sample size calculations.

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[2] Case Report Form, elaborated in section 5 for Item 19

5. Data management

5.1 Item 19: Plans for data entry, coding, security, and storage

Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.

A case report form (CRF) will be developed in Excel for the common dataset including variables identifying pilot site. Thus, all data should be inputted similarly throughout SmartCare. All data will be submitted to preliminary analyses before being used in statistical analyses by a predetermined strategy for missing values, odd ranges and outliers.

Security and Back-Up of Data

All data will be securely stored and backed up according to the rules and procedures followed by the respective CRF holders.

Study status reports

Status reports will be provided only after data have been collected, but on a wave basis. Thus, according to the descriptions of WP8 in SmartCare Description of Work, status reports will be provided as deliverables in work package 8 (deliverable D8.2, D8.3 and D8.4).

6. Statistical methods

6.1 Item 20a: Statistical methods for analysing primary and secondary outcomes

Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol.

6.1.1 Pilot sites

Data analyses will be carried out on the basis of each pilot site. Those analyses are described in this section.

Regression analyses will be used for the primary and secondary outcomes in analyses at local pilot site level. The types of regressions will depend on the distribution of variables being normal or not normal.

In general, the analyses will follow the principles outlined below.

The type of analyses depends on two issues:

1. The types of variables that are investigated for relationship (dichotomous, categorical or numerical); and
2. The distribution of scores for each variable (i.e. normally distributed or not).

The table below shows which kind of analyses to carry out, based on type and distribution of variables.

Table 11: Matrix of analyses (comparing groups)

Independent variable	Dependent variable	Parametric statistic	Non-parametric statistic	Essential feature
One dichotomous	One dichotomous	None	Chi-square	Identifies number of people in each category
One dichotomous	One continuous	Paired samples t-test	Wilcoxon Signed-Rank test	Same people on two different occasions
One categorical	One continuous	One-way ANOVA	Kruskal-Wallis	Three or more groups – different people in each group
One categorical	One continuous	One-way repeated ANOVA	Friedman Test	Three or more groups – same people on different occasions
Two categorical	One continuous	Two-way between groups	none	Two or more groups for each independent variable – different people in each group
One between-groups independent AND one within-groups independent	One continuous	Mixed between-within ANOVA	None	Two or more groups with different people in each group, each measured on two or more occasions
One or more dichotomous or categorical	Two or more related continuous	Multivariate ANOVA (MANOVA)	None	
One or more dichotomous or categorical AND one continuous covariate variable	One continuous	Analysis of covariance (ANCOVA)	None	

Note: The matrix is inspired by Pallant (2007; 116-117)

The table below shows the types of analyses to use when the analyses are aimed at exploring relationships among data.

Table 12: Matrix of analyses (exploring relationships)

Independent variable	Dependent variable	Parametric statistic	Non-parametric statistic	Essential feature
One dichotomous	One dichotomous	None	Chi-square	Number of cases in each category is considered
Two continuous	None	Person product-moment correlation coefficient (r)	Spearman's Rank Oder Correlation (rho)	One sample with scores on two different measures or same measure at two occasions
Two continuous and one continuous for which to control for	None	Partial correlation	None	One sample with scores on two different measures or same measure at two occasions
Set of two or more continuous	One continuous	Multiple regression	None	One sample with scores on all measures
Set of related continuous	None	Factor analysis	None	One sample multiple measures

Note: Inspired by Pallant (2007;116-117)

A final detailed strategy for analyses will be elaborated before analysing data.

6.1.2 Overall analyses

In addition to the analyses for pilot sites, a number of meta-analyses will be carried out for the primary and secondary outcomes.

The meta-analyses will be carried out as far as they are meaningful. Therefore, first the pilot sites that have similar populations will be analysed together in a meta-analysis. Next, an overall meta-analysis including the primary outcome for all pilot sites carried out in one. The current trend in scientific literature on telemedicine and telecare is presenting combined analyses across populations. For instance, WSD recently published an article presenting results of a study combining outcomes for diabetics, COPD patients and heart failure patients. Therefore, in the SmartCare project, an overall analysis will be carried out as well. The meaningfulness of this will then be discussed based on the level of heterogeneity presented in the meta-analysis.

6.1.2.1 Reporting of meta-analyses

Tables will be provided for all results, along with a graph presenting the forest plot. The interpretation of the overall effects will thus be presented in two different ways.

In addition, the I^2 (along with the designated p-value) will be reported. That is an indication of the between-study variance (heterogeneity). As a rule of thumb, if the I^2 is below 50, the studies are quite homogenous, and a fixed effects meta-analysis will be used. If the value is above 50, a random effects model will be used due to heterogeneity between studies. Although the random effects model does NOT adjust for heterogeneity, it allows the presence of it, and is thus the relevant output to present. If the heterogeneity is above 80, there is reason to discuss the appropriateness of carrying out the meta-analysis at all. Also, in these cases, a meta regression will be carried out to investigate the causes of heterogeneity.

The presentation of meta-analysis will be presented in the format of a table looking like the example below:

```
         Study      |    RR    [95% Conf. Interval]    % Weight
--------------------+---------------------------------------------------
RSD                 |  0.783     0.645     0.950         34.10
Trikala             |  0.708     0.582     0.863         33.12
Catalonia           |  0.818     0.671     0.997         32.78
--------------------+---------------------------------------------------
D+L pooled RR       |  0.768     0.686     0.861        100.00
--------------------+---------------------------------------------------


  Heterogeneity chi-squared =   1.08 (d.f. = 2) p = 0.584
  I-squared (variation in RR attributable to heterogeneity) =   0.0%
  Estimate of between-study variance Tau-squared =  0.0000


  Test of RR=1 : z=   4.56 p = 0.000
```

So, what the output describes is the relative risks (RR) for each setting, 95% confidence intervals (CI) and the % weight given to each study. In this simple and constructed example, all studies have positive effects, i.e. the intervention protects the patients from having an event. All effects are statistically significant. The text below the table describes the level of heterogeneity, i.e. the level of variance between the studies. The I^2 is usually reported along with the p-value. In this case, I^2 = 0.0%, p=0.5, indicating no heterogeneity (or complete homogeneity) and the homogeneity is statistically significant.

In addition to the table and explanatory text, a graph will be presented, looking like this:
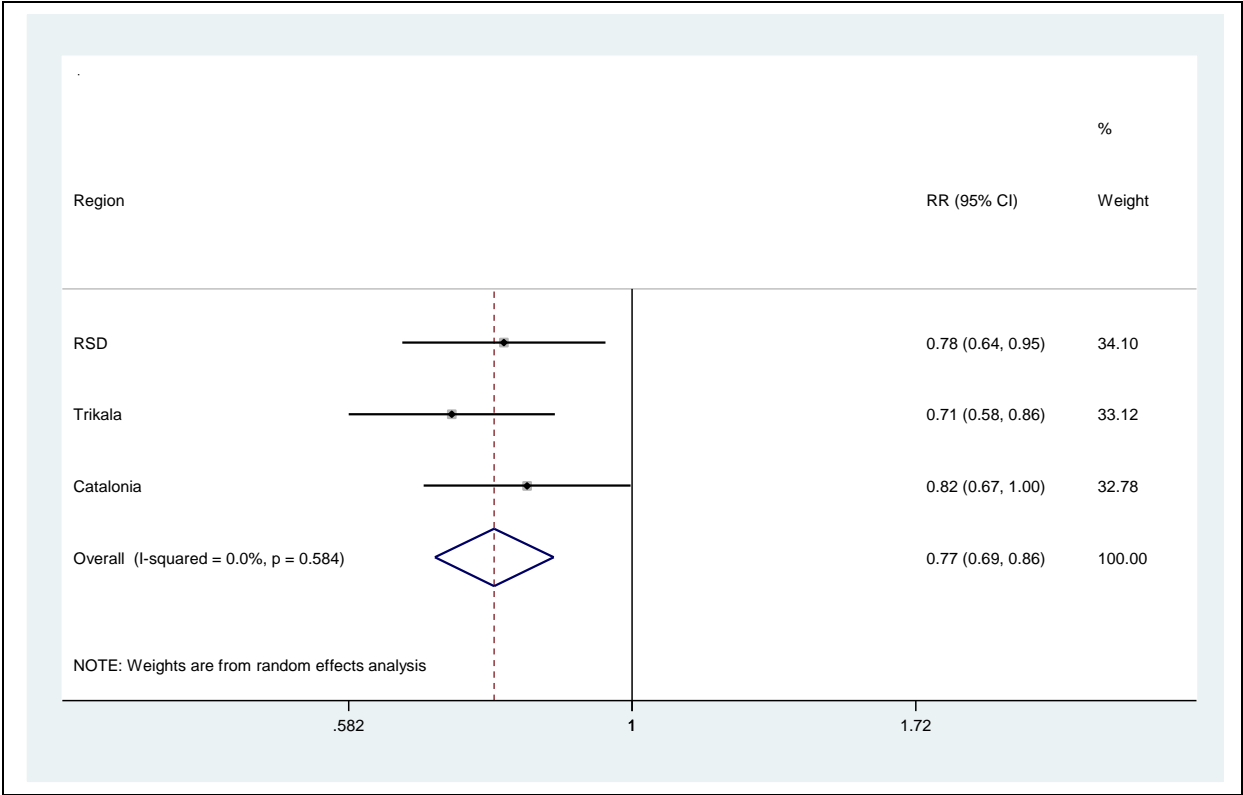
For each region, the RR and confidence intervals are presented graphically. The size of the box on each horizontal line depicts the weight given to each study. Since the studies in this example are of similar size, the weights are close to equal and the boxes are of similar size. The diamond below the horizontal lines is the summary measure, i.e. the result of the meta-analysis combining the individual pilot site results. The width represents the

overall confidence interval, and the corners of the height indicate the point of the summary estimate.

6.2 Item 20b: Methods for any additional analyses

Two different approaches are planned for the overall meta-analyses. First, the pilot sites with common populations in terms of disease, frailty or other factors, will be combined in meta-analyses. Secondly, the overall meta-analysis combining results from all pilot sites will be investigated for subgroup impacts with the subgroups being based on similarities among populations.

The heterogeneity of the overall meta-analysis is expected to be high due to the differences between pilot sites. Thus, meta regressions are planned to determine whether a number of characteristics have an underlying impact on the results. Characteristics that will be used in regressions are predefined to include:

- Level of integration of services.

- Level of ICT utilisation.

- Baseline level of integration.

- Baseline level of ICT utilisation.

- Population frailty.

- Health and social care reimbursement system (level of individual payment, level of volunteer involvement).

6.3 Item 20c: Definition of analysis population

Definition of analysis population relating to protocol non-adherence (e.g. as randomised analysis), and any statistical methods to handle missing data (e.g. multiple imputation).

All analyses will be carried out on an intention to treat basis.

6.3.1 Procedure for data handling

Data cleansing requires a strategy that is clear and consistently followed in order to maintain clarity of methods. A strategy has been developed for handling errors in the data set.

Please note: Access to a codebook or description of variables in the dataset is essential for being able to perform the following process.

6.3.1.1 Categorical variables

- All observations must relate to the allowed categories.
    o If not, register the value as missing.

- The frequency distribution must make sense.
    o If not, discussion should solve issues.

6.3.1.2 Numerical variables

Missing values

- If one subject has <50% missing values, the remaining values are allowed in analyses.
  - Analyses that require some of the missing data will be run without the values, and reporting will present the total number of subjects in all analyses.
- If one subject has >50% missing values, the subject is removed from all analyses.

Outliers (histogram)

- If a value is considered to be an outlier, but the value is possible, the value will remain unchanged. In further analysis, however, sensitivity analysis will be carried out to investigate the impact of the outliers.

- If a value is an outlier, and the value is impossible, the value will be re-coded as missing.

Range check

- A value is considered illegal if it is not registered within the min-max range of possible values.
  - Illegal values are re-coded as missing.

When the described process of data cleansing has been carried out by two independent researchers, the distributions of each variable will be checked again and compared between the researchers to ensure similar results of the process. In cases of discrepancy, discussion will be reported along with chosen solution.

7. Methods monitoring

7.1.1   Item 21b: Description of any interim analyses and stopping guidelines

Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial.

No stopping rules defined. Since the SmartCare project involves only integration of services and supporting services or integration by ICT equipment, there will be no fundamental changes in the individual clinical interventions provided to people.

8. Ethics and dissemination

8.1 Item 24: Plans for seeking research approval

Plans for seeking research ethics committee/institutional review board (REC/IRB) approval.

Table 13: Ethics

Ethical considerations	Description
Plans for seeking research ethics committee/instituti onal review board (REC/IRB) approval.	**Region of Southern Denmark**: All end users are offered to be a part of the SmartCare platform if they are considered able to use the internet. Afterwards, a subset is extracted for evaluation purposes. The end users in the control group are offered to be entered into the SmartCare platform after six months. **Aragon**: Upon inclusion criteria **Scotland**: We will produce information and consent sheets based on the good practice guidelines above as part of the implementation process. We do not anticipate any concerns associated with these as they represent standard practice for our health and social care practitioners.
Informed consent	**Region of Southern Denmark**: The end users are offered oral and written information before giving their consent both as regards to the SmartCare platform and the SmartCare evaluation (research part). They are free to withdraw that consent at any time. The project follows the abovementioned procedures. **Aragon**: Participants are provided with an information sheet explaining the SmartCare project, its implication, what might happen etc. This information document is handled to participants by healthcare professional before their enrolment in the project. The healthcare professional will hand this document to the potential participants and/or relatives at the first meeting when proposing the inclusion, and will answer any potential question. This document is signed by the healthcare professional. Upon acceptance by the user, the end user has to hand-sign a consent document. This document reflects the user authorisation to participate in the project, and the consent to use the data for evaluation purposes. It also describes that the user can revoke consent, at any time and for any reason. Both information and consent documents are carefully written and approved by the Clinic Research Ethics Committee **Scotland**: As above.
Approval from committees	**Region of Southern Denmark**: After receiving the overall protocol, the project will be submitted to the national ethics committee. **Aragon**: Clinic Research Ethics Committee of Aragon (CEICA). **Scotland**: As we are implementing a service redesign we do not anticipate requiring Ethics Committee approval.

8.1.1 Item 31a: Plans for investigators and sponsor to communicate trial results

Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions.

8.1.2   Item 31b: Authorship guidelines

Authorship eligibility guidelines and any intended use of professional writers.

Authorship will follow the Vancouver protocol.

Currently there is no intention to use professional writers.

9. References

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Pallant J. 2007. *SPSS Survival manual. A step by step guide to data analysis using SPSS*. Allen & Unwin: Australia

Vancouver protocol: http://www.research.mq.edu.au/about/research_@_macquarie/policies,_procedures_and_conduct/documents/Vancouver.pdf, visited on September 3rd 2013.