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inCASA

Integrated Network for Completely Assisted Senior citizen's Autonomy

All Pilot Installation Report

Jo Fursse

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Executive summary

The main objective of the inCASA project is develop an integrated health and social service model enabled by technology that will support the aging population and facilitate them to stay well within their own homes. The target group for inCASA is frail elderly people who would benefit from the inCASA platform.

Each of the five pilot sites involved in the inCASA project have at their core the aim to integrate service that will support improving quality of life for the end users / patients who are involved in their pilot.

This deliverable presents the pilot installation report for each of the five pilots. This document draws on information contained in the following deliverables.

- D2.5
- D6.1
- D6.2
- D6.4

The deliverable describes the five pilots:

- The aims of the inCASA Solution – Provides an overview of each Pilot inCASA solution including aim and objectives.
- Health and Social Integrated Service Model – Provides a description of the integrated service model
- Telehealth and Telecare Technical Integration – Provides a description of the integrated technical solution used to support the service.
- Pilot Installation Process – A description of each pilot
- Pilot Challenges – Provides information on challenges each pilot has faced during the pilot phase to date.
- Deviations from Pilot Plan – Provides an overview of any deviations from the original pilot plan.

1 Introduction

InCASA aims at developing an integrated health and social service model supported by technology that will support the aging population and facilitate them to stay well at their own homes, by mean of this specific objective:

- Providing elderly people with means to profile their habits, while they are at home,
- Providing elderly people (and patients with special needs) with means to monitor their health conditions outside traditional healthcare environments,
- Providing doctors and health professionals with more comprehensive monitoring data for understanding remote user's social/physical conditions and diagnostics.
- Enabling continuity of care through a wider interaction between elderly people and caretakers, especially including not just health specialists but also relatives or people who has close social relations with the user;
- Integrating home automation in a system permitting remote control of electronic devices in the immediate surroundings.

The table below summarises each pilot sites specific aim.

Partner	Country	Integration	Aim
ATC	Italy	Social / Health	ATC seeks to incorporate the concepts, values and standards of inCASA solution into the organisational structure and culture of the local environment, improving the quality of life of Italian frail elderly people and the quality of work of socio-medical professionals, supporting healthy environments and actively cooperating with the social and healthcare community.
CHC	UK	Primary Care / Social	The Chorleywood pilot aims to develop an integrated service delivery model that will combine health and social care to identify and respond to the needs of frail older people with long term conditions in order to enable them to remain in their own homes for longer.
INSERM	France	Hospital / Social	The INSERM pilot aims to develop a service of technologies for cancer patients focused on their habits in their daily life and the evolution of different physiological parameters that may be affected by the disease and / or treatment. This will result in improved quality of life and patient prognosis through facilitating health care coordination, controlling patient symptoms and enhancing circadian robustness.
KGHNI	Greece	Hospital / Social	The aim of the KGHNI pilot is to integrate social and health services in order to support patients with Congestive Heart Failure and co-morbidities who live in their own home. The integrated KGHNI services are designed to complement the established medical services and aim to provide doctors early signs of a patient's deterioration (clinical) to enhance the patients' quality of life (psychologically, functional-wise in home and in everyday activities).
FHC	Spain	Hospital / Social	The FHC pilots aims to integrate social and health services in order to delay deterioration by promoting and monitoring rehabilitation exercise at home as well as providing additional support for social needs for those patients that live at distance from the hospital.

Table 1 inCASA Pilot Aims

1.1 Integrated Health and Social Service Models

Following the review meeting, all pilots were tasked with revisiting their pilot service model. Where necessary, meetings were arranged with local social services providers and stakeholders to develop linkages and to design service delivery models. Specifically pilots were asked to define the following:

- The existing problem that will be helped by the integrated service
- The stakeholders involved
- The proposed solution to the problem
- The integrated technology solution to support the service
- And to define the overall integrated health and social service model

Pilots have spent significant time over the summer months developing and enhancing their pilots where necessary. This has involved formalising linkages between organisations and developing work paths.

1.2 Summary of inCASA Pilot Status and Progress

The following provides a summary of each of the pilot sites pilot status and installation progress.

Pilot	Start Date of Pre	Start date of Pilot	Status of Pilot Pre / Pilot / on Hold	Total number of Users to be recruited	Number Recruited to date	Number currently using the system	Number of Users Completed
ATC	Oct 2011	March 2012	Pilot	20	20	20	20
CHC	Oct 2011	July 2012	Pilot	25	12 (pre-pilot) 5 pilot	2	12 (pre-pilot)
FHC	N/A	2nd December 2011	Pilot	32	12	6	6
INSERM	Nov 2011	March 2012	Pilot	30	8	6	2
KGHNI	Oct 2011	March 2012	Pilot	25	15	5	10

Table 2 Summary of inCASA Pilot Status and Progress

1.3 Purpose and content of this deliverable

Deliverable 6.3 is an output from WP6, Pilot Use Cases. This deliverable describes the installation of the five inCASA pilots as of August 2012.

It contains and updates information from the following deliverables.

- D2.5
- D6.2

- D6.4

The deliverable does not contain information on the Evaluation of the pilots. This is described in D6.1 and which will be reported in D6.5 and D6.6.

1.4 Outline of this deliverable

Section 2 through of this document reports on each individual Pilot Installation.

These follow under the following heading

- The inCASA Solution
- Integrated Health and Social Services Model
- Telehealth and Telecare Technical Integration
- Description of Stakeholders
- Pilot Status – timetable
- Pre-pilot installation feedback (summary)
- Description of Sample
- Recruitment
- Description of Installation
- Monitoring Process / Protocols
- Challenges
- Deviations from Pilot Plan

2 ATC inCASA Solution

ATC seeks to incorporate the concepts, values and standards of inCASA solution into the organisational structure and culture of the local environment, improving the quality of life of Italian frail elderly people and the quality of work of socio-medical professionals, supporting healthy environments and actively cooperating with the social and healthcare community. It will provide local authorities with an opportunity to contribute to the public health agenda, incorporating health promotion as a daily work activity.

ATC will integrate both health and social territorial services. This will be possible through the direct involvement of local social and healthcare authorities with the mediation of ICT and Innovation local authorities.

The service implemented will profile user habits in order to automatically identify anomalous situations and send alerts to the user, carers and service providers. ATC will monitor both behavioural parameters, e.g. movement, contact and home environment parameters, e.g. gas/water leaks and room temperature as well as health parameters such as blood pressure and weight in order to establish an alert system. The service will also profile user habits. Any significant deviations from the Habits Model will generate an alert that requires a defined action by a designated person (e.g. case manager, clinician or social worker).

For the Italian environment these activities can be an essential part of social and healthcare work, with the increasing prevalence of lifestyle-related and chronic diseases. Profile driven therapeutic education (single case focused), strategies enabling patients to take an active role in chronic disease-management or motivational counselling, can support better healthcare outcomes. Social services involvement will contribute also to the maintenance and the improvement of the social contacts and the social relations between elderly people who will have many opportunities to meet with other persons of their age, and develop various activities and interests, and outcomes will be easily monitored through inCASA integration.

The objectives for the ATC pilot are:

- improving elderly people's quality of life
- promote remote health monitoring
- implement home automation services
- improve relations with neighbours

2.1 Integrated Health and Social Services

ATC will integrate both health and social territorial services. This will be possible through the direct involvement of local social and healthcare authorities with the mediation of ICT and Innovation local authorities...

ATC will be working closely with The Italian Federation of General Practitioners (FIMMG) to provide integrated services. FIMMG is the trade union and national professional association of Primary Care GP's as well as other local physicians. FIMMG is divided into regional federations, Provincial Sections and possibly Unit District

It is hoped that integrating services will also impact on the way the "health organizations" interact with the "social organizations". The service will be enabled by the technological tools provided within the project: the contact centre. These tools will support the communication flow among different professionals, and the monitoring system that will profile user habits according to the data coming from the environment monitoring and the human monitoring in order to intercept variations on the clinical conditions of the elderly people by comparing movement data and weight variations.

The Italian pilot will therefore introduce some healthcare devices:

- Weight scale
- Pulse Oximeter
- Blood pressure monitor

The introduction of health devices will enable clinicians to evaluate some clinical parameters compared with the telecare data (temperature, moisture, movement, activity).

Healthcare and social care professionals (or Case managers joining both roles) will be able to make the right decision and to plan interventions to prevent social and healthcare risks for the single user (Case Management). The upgrades introduced in the ATC pilot will try to perform extended profiles correlating physiological parameters to daily life habits.

Use cases already adopted for the ATC pilot

Use case 1: The front door
Overview: The service will monitor if there is an abnormal opening/closing of the front door of the flat.
Purpose: To show if the door is closed or open, in order to verify if there is an abnormal gap referring to the habits of the tenant.
Procedure: To reveal possible different patterns (user opens/closes the door; user goes out/stays in; user opens the door, goes out and closes the door; user open the door, goes out without closing the door etc.).

Analysis: Evaluation of the time of gap concerning the user's habits.
Data fusion: The data will be sent and processed.
Alerts: If the user forgets to close door, after going out or staying in, a text message/alert will be sent to the neighbour/relative/social worker. If the alert is not responded to an operator will be sent to close the door and to do a survey of the situation.
Feedback to patients and relatives: Patient/relatives will be notified that the situation occurred.
Personalisation: All the users' habits are customized.
Devices: Contact sensor.

Use case 2: Indoor movement (movement sensors)
Overview: Through the data coming from the user's movements indoors, the use case will define a system of alerts. The movement sensors will be placed in strategic and relevant places in order to capture the user's habitual movements.

Purpose: The service will monitor the user's indoor movements in order to identify gaps and anomalies and to send alerts to the appropriate care worker.
Procedure: The user is not moving for several hours (> 50% of usual movement), or is moving abnormally inside his/her home, or is moving during the night when she/he usually sleeps, etc.: the corresponding signals will be processed and send to verify the level of warning.
Analysis: Analysis of the gap between the user's habits and actual monitored movements.
Data fusion: All data are stored in a database connected to the system.
Alerts: Text message sent to the appropriate care worker.
Feedback to user and relatives: Yes.
Personalisation: Personalised to each user.
Devices: Movement sensors.

Use case 3: Comfort of the home (sensors for temperature-humidity)
Overview: Sensors of temperature and humidity will be placed in appropriate locations; the data will be processed and compared with the defined normal parameters.
Purpose: By processing the data coming from the homes it will be possible to assess the comfort level in order to avoid critical situations with potential dangers for user's health (i.e. dehydration during hot summers).
Procedure: It is important to underline that every sensor is set with initial data for temperature and humidity different from each season. The sensors receive the data from the environment and indicate discrepancies from the seasonal average temperature/humidity. The data are received and processed in order to generate alert messages in case there is a difference from normality.
Analysis: The data are analysed by the system using an algorithm that compare the average situation (seasonal) from the day to day pattern.
Data fusion: All data are stored in a database connected to the system.
Alerts: Phone calls, text messages and/or e-mail will be sent to the user and relevant care worker.
Feedback to user/relatives: Yes.
Personalisation: Yes.
Devices: Sensors of temperature and humidity.

Use case 4: Technical emergency
Overview: The service shall provide an automatic set of alerts in case of water leak in order to prevent acute dangerous situations in the tenant/user's home.
Purpose: Domestic accidents caused by forgetting to close the water taps happens quite frequently in elderly people's homes (when living alone). The service will help to avoid severe dangers from developing.
Procedure: If an emergency event is detected (water leak detected) an immediate alert will be sent through to the Call Centre.
Analysis: No.
Data fusion: All data are stored in a database connected to the system.
Alerts: Yes
Feedback to patients and relatives: Yes.
Personalisation: No.
Devices: Specific sensors.

Use cases to implement as soon as possible

After the installation of bed/chair sensor and healthcare sensors scheduled starting from September 2012, the following use cases will be implemented:

Use case 5: Bed/chair permanence
Overview: A contact sensor will be placed in a way to enable it to detect when the user is on the bed/chair and how long.
Purpose: Staying too long in bed/chair or getting up too many times during the night could be a warning of illness or uneasiness that could necessitate an intervention by the social worker.
Procedure: The system will process some inputs such as: the user goes to bed; the user stays in bed/chair; the user gets up from bed; the user doesn't go to bed. These different patterns will be processed in order to generate alert messages.
Analysis: Analysis of the gap between the user's habits and actual monitored movements.
Data fusion: All data are stored in a database connected to the system.
Alerts: Text message sent to the appropriate care worker.
Feedback to user and relatives: Yes.
Personalisation: Yes.
Devices: Contact/movement sensors.

Health and Social Integration scenario
Mario Rossi, a 75 year old male with chronic heart failure, goes to play cards with friends every Tuesday and Thursday afternoon in a Cultural Centre in Turin some minutes far by walk from his house. The inCASA telecare motion and contact sensors detect that he goes out usually between 2:30 and 3:00 pm and returns at about 6:30 pm to have dinner. The inCASA telehealth SpO2 monitor and weight-scale usually give information on the clinical condition and overall health status of Mario.
In May, he doesn't go out of his home on Tuesday and Thursday for one week, but continues to move around his apartment as usual. Telecare motion and contact sensors relay this information to the activity hub and to the inCASA platform, from which SPP detect a change in the habits model and an alert is forwarded to the inCASA Contact Centre Operator.
Minor changes on the weight (750g weight loss) across the last two weeks and 1% decrease of average SpO_2 are not enough to declare a significant clinical condition worsening, even if they triggered some low level alerts on the inCASA platform directed to Dr. Vittorio Verdi, Mario's primary care clinician, who is aware, but continues monitoring the trends through the inCASA interface, waiting for other changes.
Francesca Bianco, Mr. Rossi's Case Manager, knowing his passion for playing cards basing on the analysis of the information, considers there might be some problems. Checking the socio-clinical database Francesca finds also from the notes that Mario has not called his home help for two weeks to buy food and other goods. Combining the information, Francesca gives a call to Mario, and finds he is really tired and depressed. She promptly calls Dr. Verdi to explain her worries. The combination of minor clinical changes and habits changes leads Francesca to schedule a visit to Mario for the next day, according to Dr. Verdi. When she meets him, she notices clear symptoms of fatigue and evidence of worsening of his clinical condition. This prompts a visit of Dr. Verdi, who changes Mario's medication; his condition improves within a few days. He resumes his short walk to the Cultural Centre to play cards again, and avoids hospitalisation.

2.2 Health and Social Technical Integration

The service will be installed and configured in the users' homes with the appropriate devices and infrastructure. ATC plan to adapt the devices not just to the users but to their houses.

For the TC/TH integration ATC will use only one Activity Hub that includes two different modules: Zigbee module for habit sensors and Bluetooth module for healthcare sensors.

Habit sensors (activity, motion or presence sensors, and door and contact sensors) will be used to create a behavioural model of the monitored person. Preferably, the sensors shall be available out of the shelf, as proven hardware is widely available from home automation or smart metering solutions. Amongst these, only standard products shall be regarded providing long-term availability of compatible hardware. To ease the sensors' installation, they are meant to communicate wirelessly.

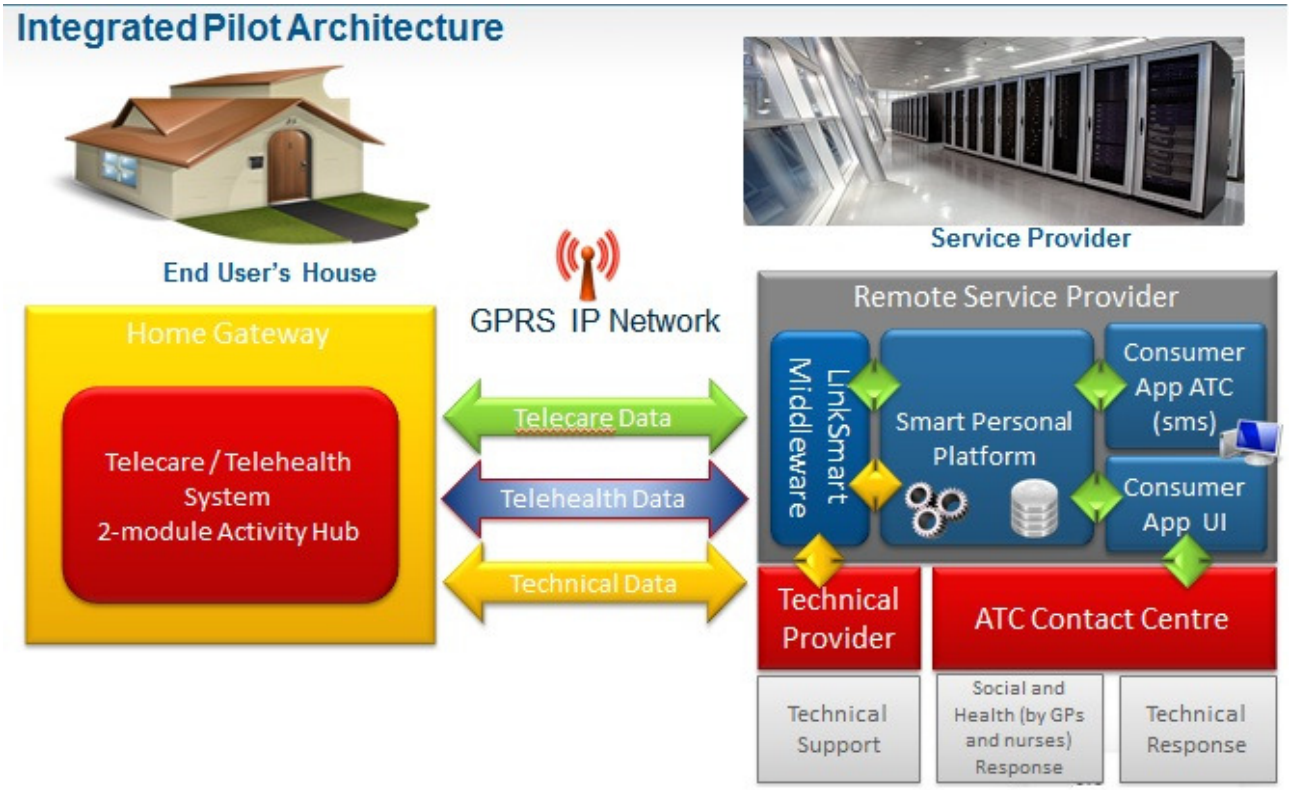

Figure 1 Health and Social Technical Integration

Healthcare sensors (Weight scale, Pulse Oximeter, Blood pressure monitor) will be used to help the clinician to evaluate some clinical parameters compared with the telecare data (temperature, moisture, movement, activity).

Human movements are not to be monitored directly using distance calculation to anchor points, but indirectly, person's activity is measured using environmental sensors. Based on this approach, the modelling has a chance to work even if the monitored person forgets to wear the radio tag. This approach comes with the drawback that identification is not possible, and if there are multiple persons in a household, differentiation and behavioural model creation is a very difficult task. In those cases, sensors that are directly worn may permit the differentiation of different persons in the same environment.

Installation and Tests

A testing session of the real installation is always performed in the laboratory before to install the devices into the users' home. If any tests (also only one of them) are not positive the technicians have to solve the problem and to repeat all tests until they can reach a totally positive outcome.
When the whole sensors' network is working, the technicians will be able to install the specific devices into the users' house and to activate the specific services.
The technicians will demonstrate the system to the user and explain how the service will work.

2.3 Description of Stakeholders

The different user profiles are described in this chapter including what their main roles and responsibilities are.

End-user/resident
The end-user/patient is the person who will have the monitoring equipment in their Social Housing home. The end-user has specifically accepted (through informed consent) that a certain type of his/her movements at home will be monitored and processed as part of the overall aim to improve social care and housing care services. He/she is a senior citizen over 65 with particular home assistance needs and thus receives services provided by the health and care system.

Carer/family member/neighbour/friend
The group of end users is composed by a very heterogeneous mix: some of the end users have a family network while others do not. The family member is the person nominated by the user who may also view user data; assist the user in taking measurements and when doing activities. This user cooperates with social services workers (case and care manager) and receives the alert messages if necessary.

If the family network does not exist we rely on the reference person indicated by the end user. This may be a neighbour or a friend who will cooperate in the same manner as the family member.

Case/care manager
First line Case/Care Manager responsible for user. He/she is a social worker in charge of the end-user or someone who will liaise with the social worker, the carer / family / neighbour / friend, with the admin support, and with the local administrators of ATC who are in charge of residence maintenance, in case of warning messages regarding gas and water leaks.

Social worker
The second line professional responsible for providing social support to the end-user is the social worker employed by Social Services. These social workers may have different professional profiles according to their special work area. The professional profiles of the social staff are:

- Team leaders who employs other professional staff
- Social workers who take care of preliminary interview with the users, and deal directly with complex situations from a social perspective;
- Educators involved in educational projects especially disabled;
- Caring Instructors who care for not self-sufficient elderly people with family network;
- Social care professionals dealing with cases of elderly self-sufficient in a family with a focus perspective to prevention and network ;
- Administrative employees who take care of the economic issues.

The Social Services provide also for a service called “Staying-at-home social services” that comprise:

- At home assistance (OSS or family assistance)
- Tele aid
- Family care
- Day care or residential assistance
- Home delivery of food.

The above indicated duties are provided by the Social workers, the Educators, the Caring Instructors and the Social Care Professionals.

The PAI (Individual Assistance Plan): The Social Services design for each user (over 65) an individual home assistance plan. To resolve the issue of loneliness, the Social Services include in the individual plan a series of collective activities in addition to the ordinary individual interventions. The PAI is the responsibility of the Care Manager / Admin Support.

General Practitioners
The General Practitioners are professionals foreseen by the Italian National Health System; their main task is to guarantee health assistance to each person living in the specific area that the Local Health Authorities have assigned them. So they know the complete health conditions of their patients because they usually follow them for many years.

Installer
The Installer is a professional electrician instructed by an electrical and electronic engineer selected by Reply. The electrician is responsible for the mere installation of the sensors within the dwelling and the electrical engineer is responsible for the correct installation of the sensors, the training of the end users, and the correct transmission of the data to the main system.

Admin Support
Will be responsible for providing support / answering calls from users and support all professional actors. Will be the Case/Care Manager, in the pre-pilot phase, which is in a charge of the ACT call centre during the final implementation phase.

2.4 Pilot Timetable

This Schedule shows the milestones leading to the deployment of the ATC pre-pilot and pilot.

Date	Action
March 2011	Pre-pilot Users’ Home Inspection
July 2011	Follow-up pre-installation and Interviews with Users
July - September 2011	Pre-pilot Training of Multidisciplinary Operations Group
October 2011	Pre-pilot is running

27th October 2011	1st Pre-pilot Installation
3rd November 2011	2nd Pre-pilot Installation
6th December 2011	3rd Pre-pilot Installation
March 2012	Pilot is running
8th – 9th March 2012	5 Pilot installations
26th – 17th March 2012	5 Pilot installations
29th – 30th March 2012	3 Pilot installations
28th – 29th June 2012	4 Pilot installations
July/September 2012	Involvement of General Practitioners and local authorities to identify Healthcare/Social care integrated scenarios
October 2012	Iteration 3 is running
March 2013	Conclusion of Pilot monitoring and final evaluation beginning
April-June 2013	Conclusion of evaluation and of Pilot activities overall

Table 3 Pilot Timetable

2.5 Pre-pilot installation (summary)

The pre-pilot implemented four of the ATC use cases. The selection use cases were based largely on technical and device grounds. The pre-pilot was initiated in October 2011 with the first installation of devices. The pre-pilot ran for three months (October 2011 – December 2011) and involved a total of 3 end-users (homes).

During the pre-pilot stage the protocol monitor is reduced at the core and used to map point by point what happens to the sensors, what and how data are delivered and the monitoring activity is done on a simplified reporting tool made by data extraction from the sensors.

In this phase, was created a multidisciplinary operations group that has involved the following professionals: i) social workers for social intervention and actions as outcome of the habits monitoring activities; ii) technicians who will respond to technical alerts (technical issues/problems) during the extension of the pilot, and iii) General Practitioners who will be involved during the Phase Three (Pilot Extension) of the ATC pilot to perform analysis of the habits monitoring data from a clinical point of view, trying to compare habits data with clinical information about the users in order to plan right decisions and actions.

2.6 Pilot Installation

The following provides an overview of the progress of the pilot.

Pilot	Start Date of Pre	Start date of Pilot	Status of Pilot Pre / Pilot / on Hold	Total number of Users to be recruited	Number Recruited to date	Number currently using the system	Number of Users Completed
ATC	Oct 2011	March 2012	Pilot	20	20	20	0

Table 4 ATC Pilot Progress

2.6.1 Start dates

The ATC Pilot started the 7th of March 2012

2.6.2 Sample Description

A total of 20 end-users will be involved who have been identified to be at risk of loneliness or who have safety or autonomy issues.

The targeted groups of tenants are:

- Senior citizens over 65 self-sufficient that require light support by professional to improve their autonomy in addition to or in replacement of the family network (where absent)
- Senior citizens over 65 partially self-sufficient or non-self-sufficient who require support by professional to improve their autonomy in addition to or in replacement of the family network (where absent)
- Different situations where a coexistence of the matters above is present.

Exclusion criteria:

- Residents who do not require social support
- Residents who do not have chronic health conditions.

2.6.3 Recruitment

ATC has chosen District 1 as the pilot site based on an evaluation of the following factors:

- The demographic conditions
- Good integration with social and health services
- Age of the buildings
- Number of elderly people

District 1 includes over two thousand flats, often situated in old buildings without lifts. The final pilot site will be composed of 20 flats.

2.6.4 Installation

During the first step of implementation, the users are contacted by phone or by direct visit by the Social Services of the Municipality of Turin. A close and direct contact is the best choice instead of sending a letter. This because the specific target of the ATC pilot are elderly people (over 65 year-old) living alone, self-sufficient and not necessarily suffering of a specific disease (Figure 1).

Figure 2 A real user of ATC Pilot at her own home

Usually, this group of users has unexpressed needs and the best choice to achieve their acceptance of any kind of care is to have personal contact with them, i.e. to have a trusted approach. During this first contact the social services present the project, the benefits and the related possible issues to try to have a verbal acceptance (Figure 2).

Figure 3 Social worker presents inCASA Project to the user

On the same day the ATC pilot's team (technical provider with social services support) will demonstrate the service to the user, showing a working demo of the service (Figure 3).

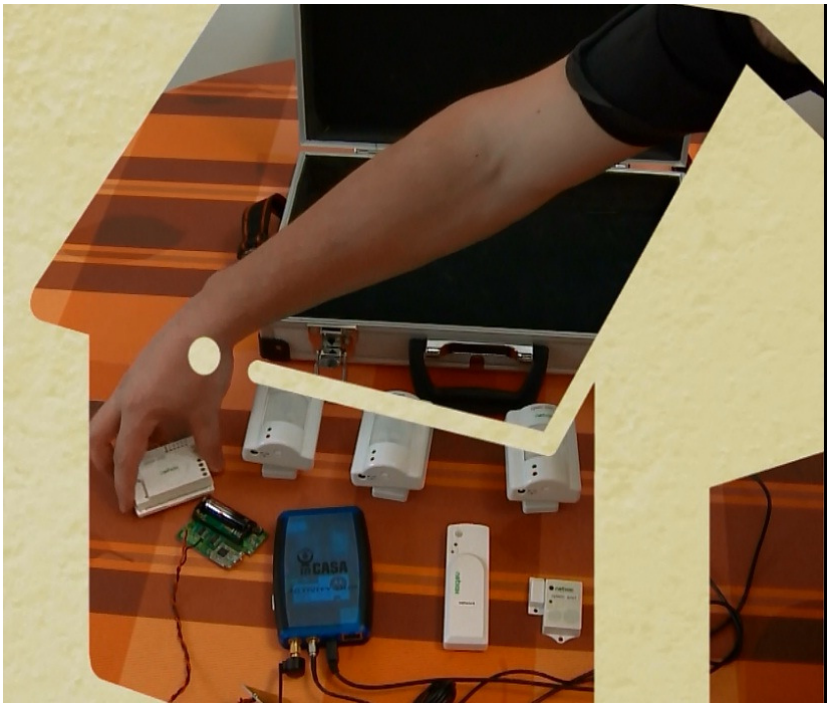

Figure 4 the installer presents the different sensors to the user

The technical provider (who is responsible for supply, installation and management of the devices and sensors) will evaluate the physical environment where the devices and services are going to be installed, and identify any possible issue and constraint. A representative from social services will be present to support the technical inspection and to answer any questions the user might have. This way the user will become more involved which should also help to ensure user acceptance as understanding and trusting the service are prerequisites for acceptance.

Afterwards there will be a follow-up pre-installation where the technician and social services representative will visit the user's houses once more to perform a second assessment of the environment (maybe to do specific laboratory tests) and to interview the user in order to build personal profile, the identification of problems and needs.

Finally, the technical provider will be able to install the sensors at users' home verifying that the whole network is totally working.

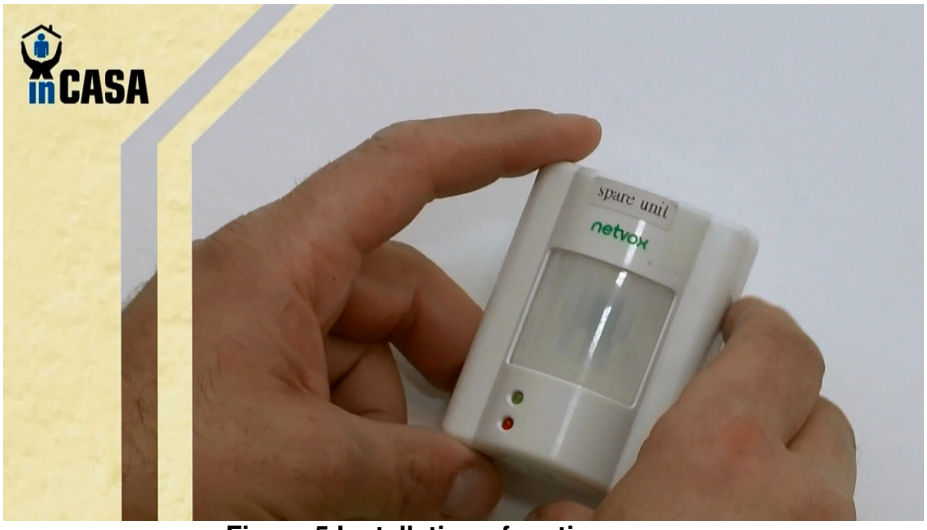

Figure 5 Installation of motion sensor

2.6.4.1 Installation of Equipment

The ATC pilot installations are performed by an external company called IPSA based in Turin. ATC has completed the installations of following telecare sensors for all 20 users involved:

- Door sensor
- Motion sensors
- Temperature/humidity sensor
- TV activity sensor
- Water leak sensor

The installations of sensors above has required around 3 hours for every user.

Starting in September 2012 ATC will complete the Telecare sensors' installations adding the bed/chair sensor for the users and in order to enhance the pilot, in perspective of the healthcare/social care integration, the following telehealth sensors will be added:

- Weight scale
- Pulse Oximeter
- Blood pressure monitor

ATC estimates that every new installation will require around 2 hours for every user involved.

2.6.5 Monitoring Process / Protocols

The following workflow describes the integration process and the stakeholders involved in the ATC pilot.

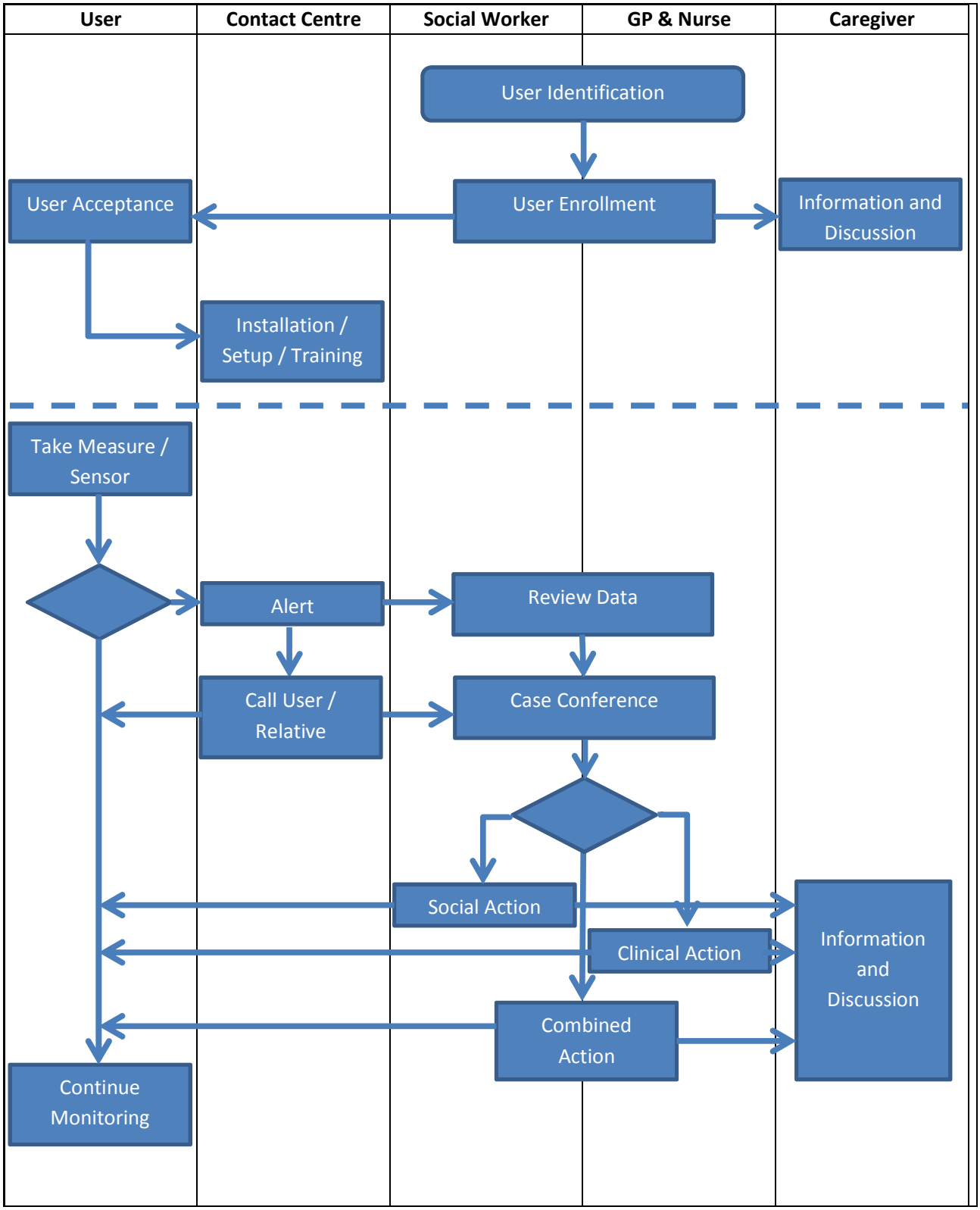

Figure 6 ATC pilot Integrated Workflow

2.7 Challenges

The following section provides a description of some of the challenges that have been faced by ATC during the installation phases of the pilot.

2.7.1 Patient

The main problem of this challenge was the recruitment of the users with the requested requirements for the pilot.

2.7.2 Professional

The biggest challenge was to involve in the pilot different professionals that had to work together; furthermore, after the third review meeting, ATC had to enhance its pilot with new telehealth services, including the general practitioners of the users.

2.7.3 Organisational

Considering that the normal activity of the ATC Call Centre operators regards the tenants' requests for the solution of maintenance problems in their homes, for ATC it was necessary to train them in order to understand how they must act in relation to the different alerts that can be generated by the different use case scenarios of the pilot.

2.7.4 Technical

In order to solve the technical issues had with the SIG Activity Hub that have caused delays in the starting of ATC pilot we had to look for a different supplier to try to manage these technical problems.

2.7.5 Resource

The technical difficulties, above mentioned, generated the need for purchasing the Activity Hubs on the market, with the consequence of bigger expenses, not foreseen, for ATC.

2.8 Deviations from Pilot Plan

In respect to the initial ATC pilot plan, it will not be possible to activate the functionalities of emergency call, because the ATC Call Centre has not been authorized by the Piedmont Region Health System to manage that kind of tasks.

Moreover, even if initially ATC pilot foresaw only telecare services, currently ATC is including the telehealth services involving general practitioners and installing a set of new sensors in order to detect the users 'clinician status (blood pressure, pulse oximeter and weight).

3 CHC inCASA Solution

The Chorleywood pilot has developed an integrated service delivery model that will combine health and social care in responding to the needs of frail older people with long term conditions. This service integration is driven by both health and social care. Information about the patient and data from the remote monitoring will be shared and exchanged between the general practice and social services.

Objectives

- Build the integrated health and social service to deal with the data from both remote patient monitoring and environmental monitoring.

- Evaluate the value of the integrated service to both the frail elderly person and the social and clinical services that care for that person.
- Understand and measure the impact of such a service to a patient's quality of life
- Prevent or delay the eligibility of frail patients for social services
- Prevent or reduce the numbers of unnecessary interventions and hospital admission
- Reduce length of stay and enable early discharge of the frail patient into their own home

3.1 Integrated Health and Social Services

The CHC service model supports the identification and monitoring of those frail patients with chronic disease who are at risk of sudden deterioration so that they can be treated and supported in their own home. The integrated health and social team can monitor, review and respond to the patients' needs as they change by providing comprehensive support covering a range of services. Costly hospital admissions can be avoided and the number of bed days can be reduced and early discharge can be enabled. Appropriate social support can be identified earlier in order to enable the frail older patient to remain safe and independent in their own home.

Currently health and social services are delivered separately. Adult services are organised by Hertfordshire County Council and Chorleywood Health Centre provides primary care to over 6000 residents within the area. While work elsewhere in the county is looking at integrating health and social care, it has not yet been accepted as a model by West Hertfordshire where Chorleywood Health Centre is located. Referral between health and social care is currently carried out by referral letter and by phone. Social workers are then assigned to the patient direct and no further communication between health and social care takes place.

There are two main challenges that impact on the older frail person and the use of social services. Firstly carer breakdown, which is when the informal carer (unpaid carer) can no longer cope with the needs of the person they are caring for. Secondly it is when hospitals choose to discharge elderly frail patients into residential care rather than enable the person to return to their own home.

For health providers the challenge is to identify those of its frail older patients who are at most risk from deteriorating and requiring costly and avoidable admissions to hospital. While there are measures in place such as the Quality Outcome Framework (QOF) which supports the tracking of chronic disease every six months, measures of frailty are not recorded within primary care. However, it is the older frail patients that are at most risk of sudden deterioration and which can go undetected until the condition deteriorates and hospital admission is unavoidable.

A frail older patient will be monitored by a combination of health and habits sensors in their own home (blood pressure, weight, spo2, blood glucose, bed, chair PIR sensors). Sensor data is transferred from the home to the health care team in the general practice and to a key social worker in social services. Data can be viewed on a combined health and social care interface. Aided by algorithms, changes in usual clinical measurements and levels of activity are measured.

Incoming data will be monitored by the health care team at Chorleywood Health Centre. Patterns of behaviour and physiological data, including in-bed restlessness, habits and deviations from habits, toilet visits, eating patterns, rapid weight loss or gain, medication adherence, blood pressure, weight ,spo2 and blood glucose will be assessed to provide decision support for the

health and social care professionals for cases such as loss of autonomy or early detection of clinical deterioration. Responses to the information will be managed by joint case conference between health professionals at Chorleywood Health Centre and social workers from Hertfordshire Adult Social Services. These will be held weekly or sooner if deemed necessary and facilitated by means of video conferencing or teleconferences. Appropriate social and/ or medical interventions can then be determined by the joint team.

Current paper based referrals between health and social care will be supported by the new service model. This integrated service model will support the identification and monitoring of those frail patients with chronic disease who are at risk of sudden deterioration so that they can be treated and supported in their own home.

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3.1.1 Use Cases

The UK Pilot will implement and demonstrate the following use cases:

- In-home pathways habits monitoring through passive motion detection and bed/chair sensing
- Physiological monitoring (blood pressure, glucose, weight and pulse Oximeter depending on underlying disease)
- Medication compliance using medication dispenser

3.1.2 Health and Social Integrated Service Scenario

Mrs Osbourne is 79 years old. She lives alone in a ground floor flat in Chorleywood. She has chronic heart failure, diabetes and hypertension. She has a daughter who lives 209 miles away who visits regularly but otherwise she lives a quiet and independent life. Two months ago, Mrs Osbourne's health deteriorated quite rapidly and she was admitted to hospital due to renal failure. After discharge, she was assessed using the frailty scale by the general practice team. The results indicated that she was becoming frailer but was very keen to maintain her independence. She was offered the opportunity to be monitored using the inCASA solution. She was provided with a weight scale to monitor her weight, a bed sensor and a PIR sensor which was positioned in the hallway near her kitchen.

Each day, data from the sensors was analysed by the system for degrees of change from normal pattern. After 5 weeks, the nurse who was looking at the data was notified by an alert from the system that activity levels in the home had reduced. The health care team continued to monitor closely over the next few days and noticed a slight reduction in weight and then a sudden increase. Mrs Osbourne was contacted by the nurse and said that she had not been feeling very well and had not been feeling well enough to cook and so had not been eating. A visit was made to the patient in her home by a GP who discovered that she was retaining fluid which was why she had been feeling poorly and had not wanted to eat. The patient was provided with diuretic medication to reduce the fluid levels.

Mrs Osbourne's was continued to be monitored and notes were reviewed at the next joint health and social case review. It was suggested that while Mrs Osbourne was determined to remain

independent she may need some short term support in her home such as meals on wheels and home help during the week. The social care team contacted Mrs Osbourne and also her daughter to discuss the options available. A care package was agreed which provided additional social support.

3.2 TC and TH Technical Integration

The integrated platform will analyse data in order to profile user behaviour, implement customised intelligent multilevel alerts/communication services. It will then seek to compare variations in the activity template and the variations in the physiological parameters to identify patterns and to understand if and how environmental monitoring can aid and even predict clinical events and care.

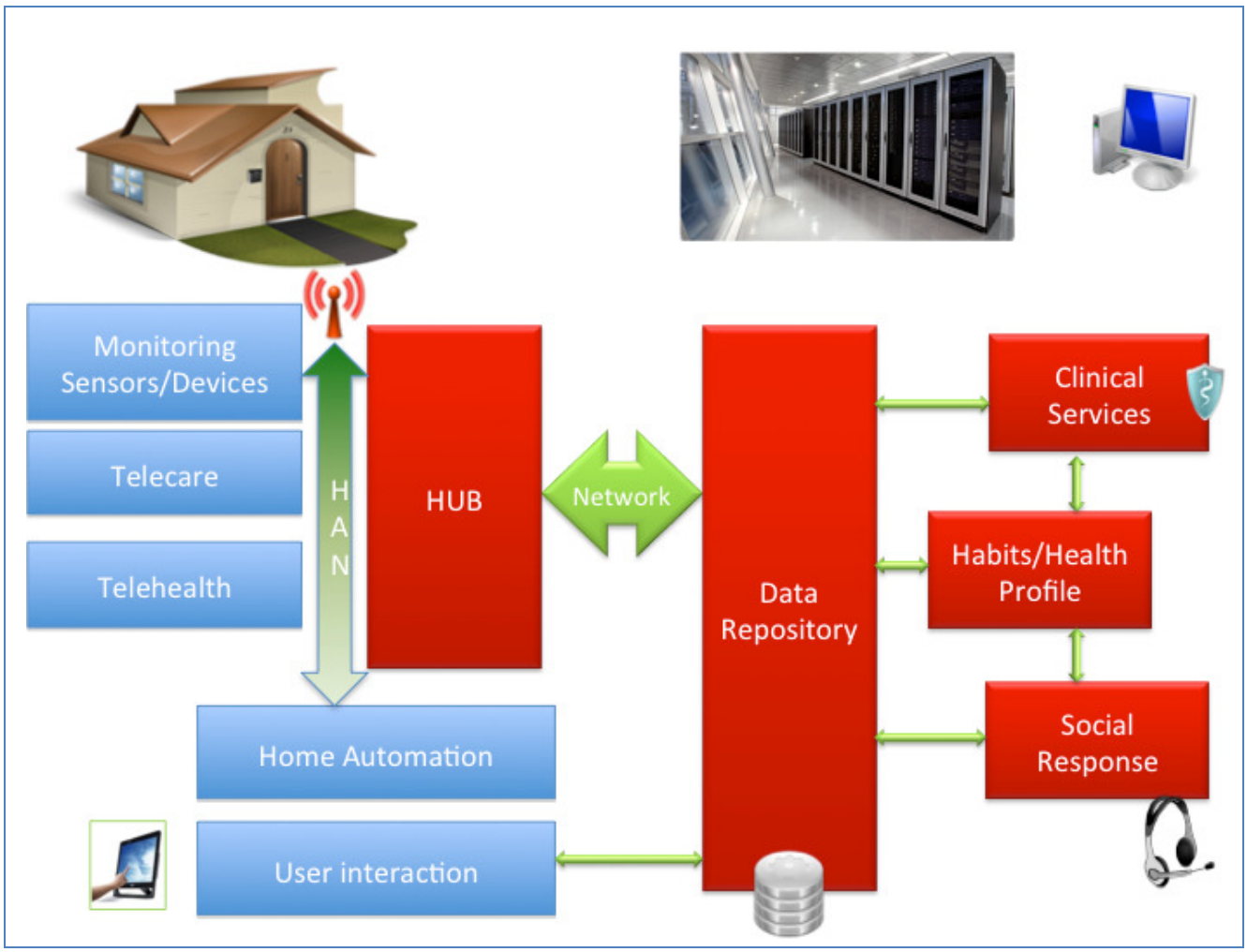


Figure 7 CHC Health and Social Technical Integration

This model will support independent living and respond to the combined clinical and social needs of an older population by extracting patterns of behaviour and physiological data, including

- in-bed restlessness,
- habits and deviations from habits,
- toilet visits,

- eating patterns,
- rapid weight loss or gain,
- medication adherence ,
- blood pressure, weight ,spo2 and blood glucose
- And to discover new knowledge in order to provide decision support for health and social care professions such as Loss of autonomy, Early detection of disease onset.

The platform will be available to both health and social service teams. The devices are Continua and Zigbee Alliance certified. All devices work through a simple to use home gateway that accepts Zigbee ZHCP compliant devices and transmits data over GPRS using IHE-PCD01 standard messages. This will integrate directly to the Reply reasoning engine.

3.3 Description of Stakeholders

Patients: Patients will have the monitoring equipment in their home. They will be asked to take a physiological measurement per day. Both their habits and physiological data sent via the devices in their home will be viewed the health and social team.

Informal Carer: Unpaid carers of the patient such as relative, neighbour or friend. They provide support and care to the patient in their everyday lives and within the patient's home. They may support the patients in using the monitoring devices.

Research Nurses – **Chorleywood Health Centre**: The nurses will be responsible for recruitment, training, installation reviewing data, participating in joint clinical and social case conferences and responding to intervention needs.

Social Workers – Hertfordshire Adult Social Services: Key social workers will be responsible for reviewing data, participating in joint clinical and social case conferences and responding to intervention needs.

General Practitioners: The GP's will be responsible for reviewing data, participating in joint clinical and social case conferences and responding to intervention needs.

Administrative Support Team: will provide administrative support to the pilot including record keeping and telephone support.

Technical Support Team: Will provide technical support to the pilot including help desk support.

3.4 Pilot Timetable

The CHC pilot is being implemented in three phases. The Pre-pilot introduced telehealth monitoring device to the patient's participating in the pre-pilot phase. Phase two saw the introduction of habits monitoring to the platform as well as a combined clinical and habits monitoring interface. The integrated platform underwent robust and rigorous field tests in order to

ensure reliability and usability by both professional and patient groups. The pre-pilot phase was extended and additional patients were recruited in order to complete the pre-pilot phase

Phase two also saw the introduction of the integrated health and social working practices. Information generated from the devices was shared amongst health and social professionals. Joint working practices and learning were developed in order to react to the data in an appropriate way. The new integrated social and health service model was described and put into practice.
For phase three, a patient tablet will be introduced where it is suitable. This will enable patients to view the data that they are sending each day. Information can also be feedback to the patient. This may include educational and helpful resource information for both health and social care.

As an extension, family and carers could also be given access to the information being collected. The patient portal can be viewed via a URL which can be accessed via any device that has an internet connection. It is envisaged that relatives and or carers would be able to monitor data if they are concerned or live far away.

Date	Action
October 2011	Pre-Pilot Commences
February 2012	D6.2 Pre-Pilot Report - Telehealth
March 2012	Pre-Pilot Extension – New Gateway, Telecare sensors, Combined Clinical Habits
July 2012	Pilot Commences,
September 2012	Integrated and Social Service Model Commences
September 2012	Installation Report
October 2012	Interim Report
March2013	Pilot Ends
June 2013	Evaluation Report

Table 5 CHC Pilot Timetable

3.5 Pre-pilot installation Summary

The original pilot phase began in April 2011. 3 patients were recruited for a period of 3 weeks. Due to technical problems with the equipment, the pre-pilot phase was cancelled. Between April and December of 2012, further development work was undertaken on the equipment. The pre-pilot phase started again in December with a 3 patients. In March 2012, a further 10 patients were recruited to take part in the pre-pilot phase. This phase saw the roll out of the gateway which replaced the smart meter that had been used in the earlier stages.

3.6 Pilot Installation

The following table provides a summary of progress.

Pilot	Start Date of Pre	Start date of Pilot	Status of Pilot Pre / Pilot / on Hold	Total number of Users to be recruited	Number Recruited to date	Number currently using the system	Number of Users Completed
CHC	Oct 2011	July	Pilot	25	12 (pre-	2	12 (pre-

		2012			pilot) 5 pilot		pilot)

Table 6 CHC Pilot Progress

3.6.1 Start dates

The integrated health and social service pilot starts in September 2012. Patients are enrolled in the pilot for 6 months.

3.6.2 Sample Description

A total of 25 patients who meet the following inclusion criteria are taking part in the study. These patients have been selected through joint working with health and social services in order to target those that are deemed to be most in need of support.

- =>65
- Registered at CHC
- Registered as having one or more chronic diseases
- Live Alone
- Identified as being frail as defined by the Edmonton Frail Score
- Identified as in need of social and health support as identified using the Caretrack tool.

The Caretrack tool is a new information sharing tool. It is designed to match health and social resource usage for individual patients and can help determine those that are at increased risk of deterioration.

3.6.3 Recruitment

The patients meeting the inclusion criteria are sent a letter of invitation, a demonstration information Form and the inCASA press release, which describes the project.

Follow up phone calls are made to discuss the project with the patient. The call is used to:

- Further explain the demonstration
- Describe what the impact will be on the patient e.g. time / disruption during installation as well as monitoring requirements
- Answer patients questions
- Confirm whether the patient is willing to participate and can attend the demonstration induction meeting.

Each patient is asked to read and sign a consent form. This form ensures that the patient is aware of why they are participating in the project and how their participation in the project will impact on them. This includes – understanding what the project is about, understanding the correct use of the technology e.g. not emergency devices and to inform them that they have the right to withdraw at any time.

Figure 8 CHC Patient Induction

3.6.4 Installation

Once the patient agrees to participate in the pilot a mutually agreed time and date for installation is agreed. Installations are normally carried out within the hours of 9am and 5pm, Monday - Friday, however when there is a specific requirement, out of hours installation will take place. The time scheduled for installations is kept flexible in order to account for the patient's age and frailty as well as their unfamiliarity with the technology.

Installations are carried out by the nurses who follow a pre-defined installation process. This process always starts by an explanation of the project and ensuring that the patient understands fully their participation. A consent form is always completed prior to the installation of equipment.

The following tasks are completed during the installation.
:

- Ensure the patient is aware that the equipment is not an emergency device and if they feel unwell during the time they are being monitored they should contact their GP or dial 999 in an emergency as per usual
- Carry out a site inspection to ensure a suitable location is found for the medical devices e.g. scales and the habits monitoring devices e.g. chair, bed sensor.
- Install the monitoring devices as required
- Train the patient on using the monitoring devices
- Watch the patient use the monitoring devices
- Carry out further training if required
- Provide the patient with a monitoring device user guide
- Provide the patient with contact information
- Send a test transmission and confirm receipt either via laptop with mobile internet connection or contact CHC and confirm with one of the research team
- Complete the installation form and ask the patient to sign

- Return installation form to CHC.

3.6.5 Installation of Equipment

Prior to the installation of the equipment, a patient is registered onto the inCASA web interface.

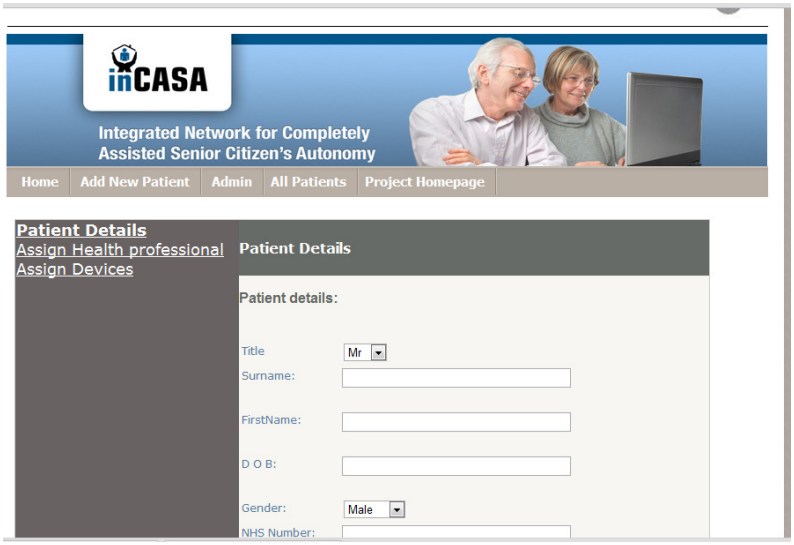


Figure 9 inCASA CHC Web Interface

Dependent on the patient's clinical and social need a combination of telehealth and telecare devices can be installed. This combination is agreed upon during joint consultation between health and social services. This combination of devices can be changed dependent on the patients changing needs.

User Group	BP	Weight	Spo2	Chair Sensor	Bed Sensor	PIR	Hub
CHF		X		X	X	X	X
COPD			X	X	X	X	X
Dementia	X			X	X	X	X
Hypertension	X			X	X	X	X

Figure 10 inCASA CHC Devices

All devices have been modified to use Zigbee communication. The devices are pre-paired with the gateway, so that during installation batteries just need to be inserted and they are ready to use. This makes the process simple and quick for both the nurse doing the installation and the patient doing the measurements.

Figure 11 inCASA CHC Patient Kit

3.6.6 Monitoring Process / Protocols

All patients are asked to take their physiological measurements once per day, 7 days per week and to take the measurement before 12pm. The habits monitoring data is collected automatically 24 hours per day. Data is monitored for the following:

Parameter	Reason	Frequency	Monitoring for	Outcome Measure
Blood Pressure	Hypertension	Daily	Trend – variance from defined targets - 140/80	Stability / Change from Day 1 to Day N / Improvement
Spo2	COPD	Daily	Trend – variance from defined targets - < 85%	Stability / Improvement
Weight	CHF	Daily	Change of >1kg in 24 hours or 1.4kg over 3 days	Stability
Motion Sensor	Habits Monitoring	Continuous	Trend Movement	Stability and change from "normal"
Chair Sensor	Habits Monitoring	Continuous	Avg time spent sitting	Stability and change from "normal"
Chair Sensor	Habits Monitoring	Continuous	Avg time spent sitting	Stability and change from "normal"

Table 7 CHC Monitoring Outcome Measures

The clinical team at CHC review the data each day. Aided by algorithms, changes in usual clinical measurements and levels of activity are measured. Responses to the information are managed by joint case conference and appropriate social and medical interventions can be determined. Decisions to intervene on care, both social and medical, will be based on physiological monitoring, any significant variations in patient behaviour revealed by movement monitoring, and clinical events to which the primary healthcare team would usually respond. Patient data will be reviewed by a multi-professional primary healthcare and social services team along with their electronic patient record when patient data lies outside pre-determined data limits. Calls and visits are made to the patient and details recorded on the clinical portal and in the patients' health and social records.

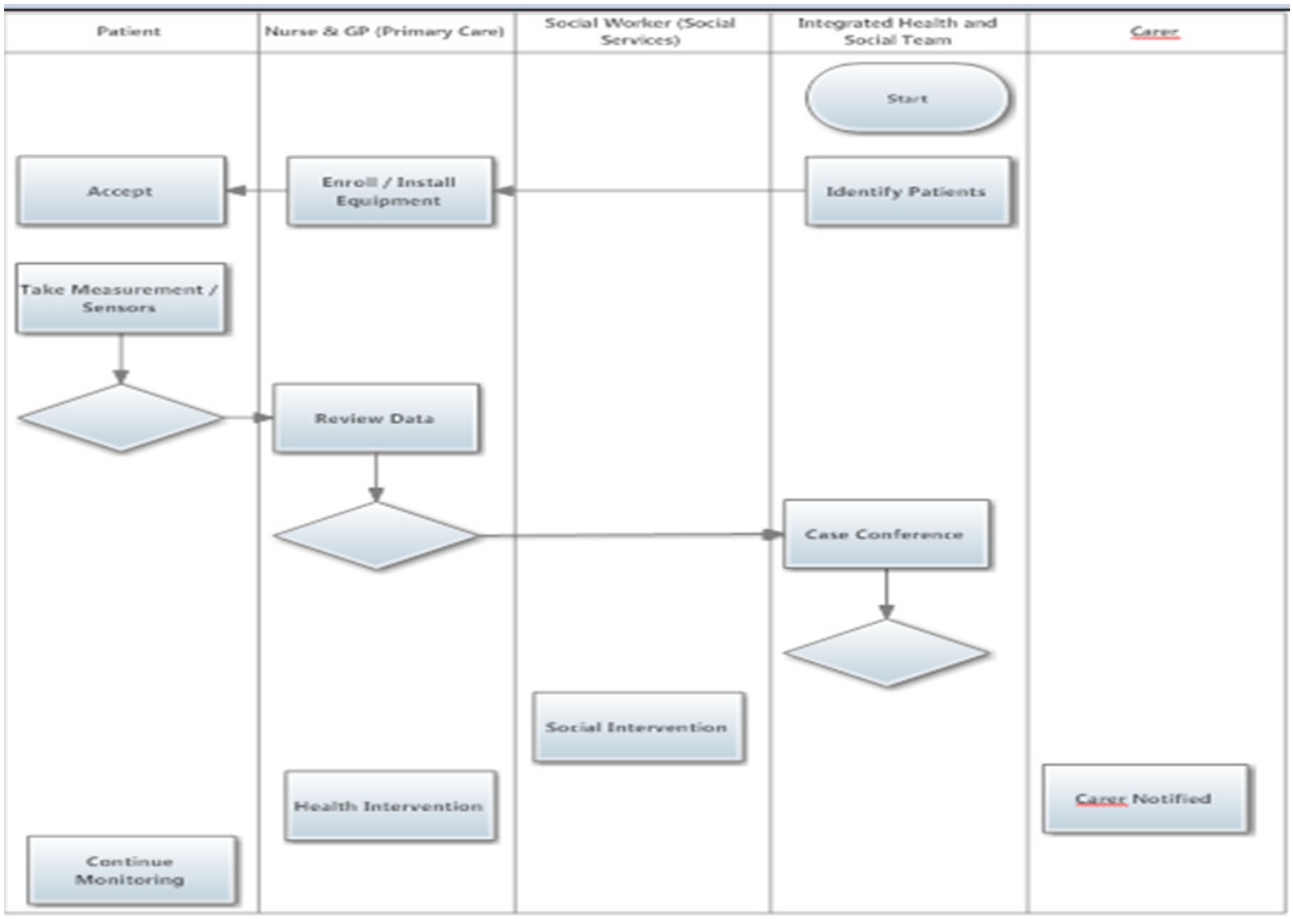
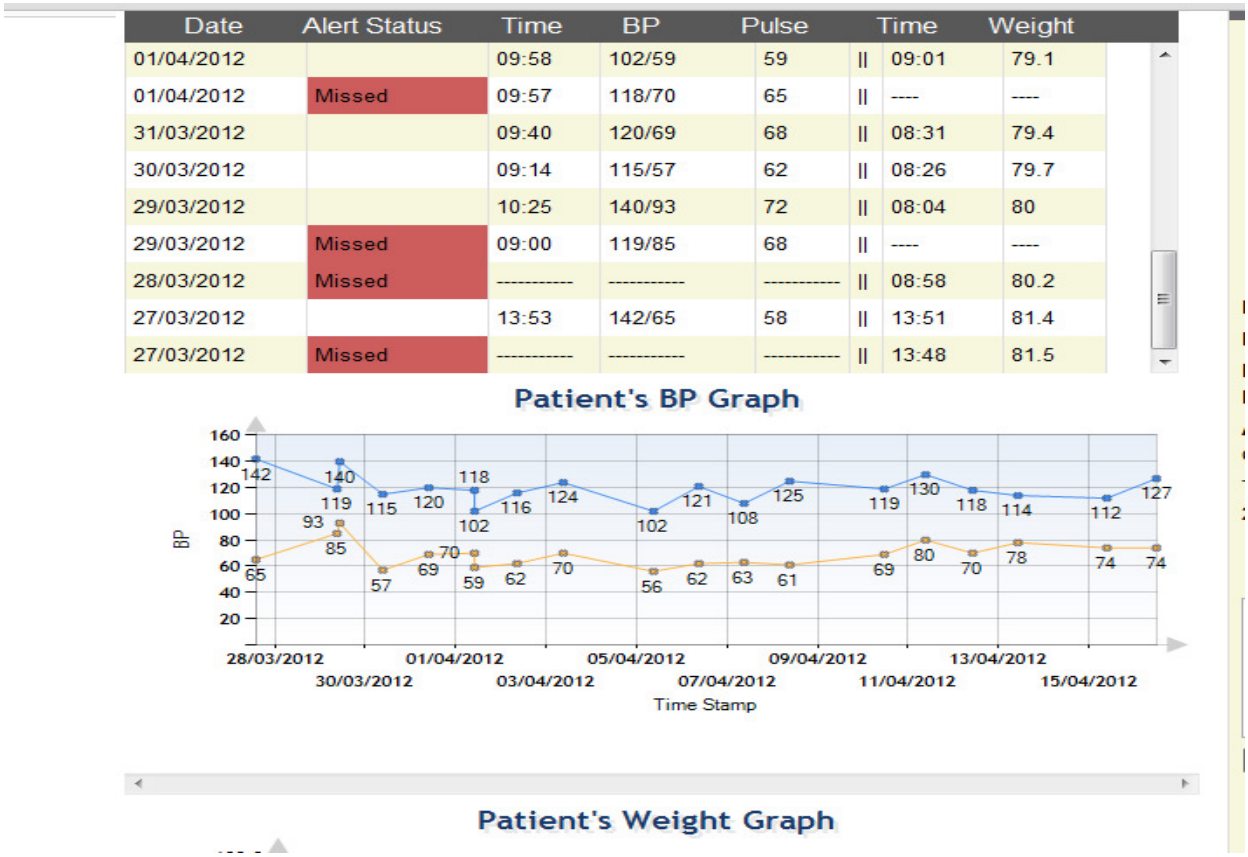


Figure 12 CHC Integrated Workflow

Significant and sudden variations indicating acute exacerbations and the need for immediate clinical responses will be sought for at daily reviews of patient data. Trends that indicate the need for clinical or social interventions will be considered by two weekly clinical meetings.

Figure 13 Nurse reviewing patient data



Date	Alert Status	Time	BP	Pulse		Time	Weight
01/04/2012		09:58	102/59	59	||	09:01	79.1
01/04/2012	Missed	09:57	118/70	65	||	----	----
31/03/2012		09:40	120/69	68	||	08:31	79.4
30/03/2012		09:14	115/57	62	||	08:26	79.7
29/03/2012		10:25	140/93	72	||	08:04	80
29/03/2012	Missed	09:00	119/85	68	||	----	----
28/03/2012	Missed	----------	----------	----------	||	08:58	80.2
27/03/2012		13:53	142/65	58	||	13:51	81.4
27/03/2012	Missed	----------	----------	----------	||	13:48	81.5

Figure 14 Patient Data displayed of inCASA web portal

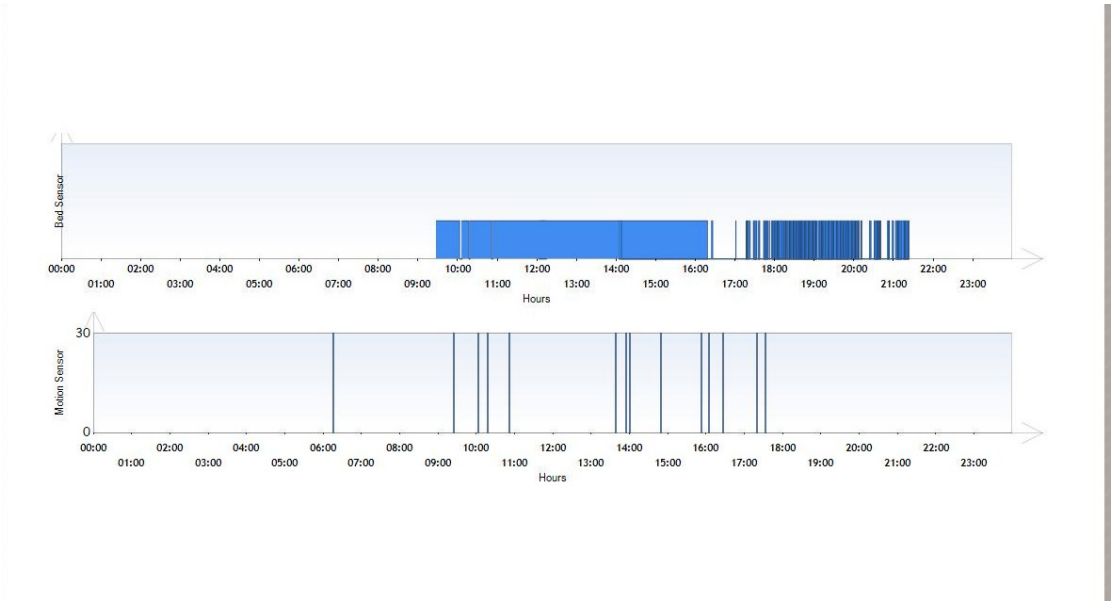


Figure 15 Habits monitoring data displayed on inCASA web portal

3.7 Challenges

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3.7.1 Patient

A continuing challenge to the pilot is that of patient recruitment. As reported in the pre-pilot report, continuing delays to technology have meant that patient lists have had to be re-run on a number of occasions.

We have also found this targeting this age range of patient that are of particular frailty requires more time in installation and support. When we have come across technical difficulties we have had to make home visits as opposed to being able to provide support via the phone.

3.7.2 Professional

The introduction of the service means a steep learning curve for the professionals involved. The team at CHC have previous experience of telehealth monitoring and are following familiar monitoring pathways, while the team at Hertfordshire Social Services are familiar with telecare monitoring. However neither team has experience of both. Developing close working relationships has been essential in order to share experiences and support the service during the early stages of the pilot.

3.7.3 Organisational

One of the main obstacles of developing the CHC inCASA pilot has been in creating formalised linkages between health and social care. There are many competing interests and some wariness between the two organisations.

There has been much discussion as to the inclusion criteria for the study between the health and social organisations. Each organisation has outcomes that they would like to achieve via the study and these do not necessarily target the same patient group. As a result of these discussions we have incorporated a tool which helps identify patients based on certain health and social resource usage criteria. It also incorporates a risk analysis tool.

3.7.4 Technical

While the platform has become more stable and less prone to technical faults, there are still issues that need to be addressed before the pilot can commence in earnest. Much work has gone into improving battery life and reliability in Zigbee pairing which has made transmission of data more reliable and robust. However there are still some reoccurring issues with the software which are creating failures in devices. All problems are reported to the technical team via an action log which is reviewed and updated.

Mobile Connectivity – The gateway loses GSM signal and data cannot be sent. This results in missing data on the clinical portal and calls having to be made to the patients to determine if they have taken their measurements.

Gateway Lock up - The home gateway has on a number of occasions locked up and stopped working. This requires a power cycle of the gateway, which in some cased requires a nurse to make home visits to the patient if the patient is unable to do these themselves.

3.7.5 Resource

Ensuring sufficient resources are available at each stage of the pilot is challenging. The two biggest impacts have been on:

- Providing increased support to frail patients as compared to other groups that we have monitored in the past. We are tracking the numbers of support calls and time taken to manage each in order to provide

- Technology problems result in additional time having to be spent on home visits when something does not work as expected.

3.8 Deviations from Pilot Plan

Then main deviation from the original pilot plan has been in the start date of the pilot. The CHC delay has been predominantly due to availability of technology that would be suitable to use within the pilot phases. Despite the delay in the initial user requirement collection, CHC had a clear understanding the technology that would be required to deliver the integrated service however it became clear during the 1st year that we were not able to find a supplier of the required technology.

During the early planning of the pilot, talks were held with one of the technology partners to provide the technology. The requirements were clear in that we needed a system that would integrate both telecare and telehealth. Despite numerous attempts we were not able to secure agreement that integration would be possible. A further meeting with a UK telecare supplier was also unsuccessful in finding a solution that would be support the pilot.

As a result it was decided to work with our technology partner, Brunel University who had been developing standards based system in another project and that would enable the integration of the sensors that would ultimately support the system.

The pre-pilot initially began in April 2011 but had to be cancelled due to a number of reliability problems with the technology. The pre-pilot phase started again in October 2011 with a subset of telehealth devices and using an existing Smart Meter gateway to transmit data. This was reported in D6.2. The pre-pilot phase was extended in order to include and test the final inCASA integrated health and care sensor solution.

CHC is now testing the final solution with patients from the user group. It has been demonstrated to Hertfordshire Adult Social Services who will be partnering with us in the social and health integration phase.

4 FHC inCASA Solution

FHC pilot goal is to integrate health and social services for patients with chronic obstructive pulmonary disease (COPD) attended by hospital.

Patients with COPD often decrease their physical activity because exercise can aggravate dyspnoea. The progressive physical deterioration associated with inactivity initiates a vicious cycle, with dyspnoea becoming problematic at increasingly lower physical demands. This pilot program aims to break this vicious cycle by promoting and monitoring rehabilitation exercise at home as this will improve patients' quality of life. The patient's clinical condition is also strongly influenced by their lifestyle and environment. Their lifestyle (daily activity degree, autonomy, healthiness of the environment, diet guidelines, social life, etc.) is a determinant factor both in the appearance and in the evolution of COPD. By integrating social and health services the FHC pilot aims to delay deterioration by promoting and monitoring rehabilitation exercise at home as well as providing additional support for social needs.

This service could offer great value for patients connected to FHC due to the long distance between many patients' homes and the hospital (FHC is placed in a rural area with small-to medium size villages, some of them 50 km far from hospital facilities). Moreover, a general shortage of staff means that by offering at home and self-monitoring patients' needs can be met more efficiently. A specific training program will be built for every patient. Portable pedal machines, weight scales, pulse Oximeter and a touch screen device will be provided. Parameters that will be monitored include fatigue perception (not to be gathered but to be estimated by the patient himself according to previous training at hospital gym by using the Borj dyspnoea scale), blood oxygen saturation and heart rate. Breathing exercises will be also included to improve the muscles involved in the process of breathing. The patient will also receive education about their disease and its symptoms and the different ways to deal with them. FHC's social worker will be the coordinator between the health professionals of FHC and the social workers at both primary care level and municipalities, according to each patient's arising needs during the execution of the in-home training period.

Objectives:

- Improved Clinical Outcomes.
- Improved quality of life or, at least, maintained, given the constant deterioration of the illness being treated.
- More appropriate clinical interventions.
- Reduced Hospital Admissions – visits to Hospital Emergency unit.
- Increased independence.
- Provide additional social support.

4.1 Integrated Health and Social Services

During the development of the pilot at FHC pilot site, a significant number of preselected patients did not complete the programme initially prescribed:

- Some of them did not want to participate in the initial interview with the clinicians due to different reasons such as feeling depressed , due to the chronic character of their condition; it often causes a lack of interest to the effort required by the program for the changes in the

habits of living, and other unknown social determinants (social environmental pressures, acknowledge of the determinants of their own illness)

- Other patients have declined the invitation to participate because they or their relatives did not want to do the prescribed exercises, which required them to undergo to pre-tests (spirometers, Body Mass Index calculation, tobacco withdrawal, etc.).
- Despite of their willingness to take part in the pilot, some patients have no way of transport to the hospital or no one to accompany them regularly during the period of pre-training (one hour for two or three sessions per week, in a continuous period from two to four weeks). Thus, factors such as isolation, solitude, place and conditions of residence (for example, living too far from hospital, lack of own home, no transportation alternatives, etc.) made it impossible for them to participate.
- Finally, in some cases patient's health status made it unadvisable for them to do the exercises initially proposed. This was caused either because they are too elderly or because the comorbidity related to their condition could not guarantee that the treatment would result in more benefits than inconveniencies to their state of health (in one case the patient had completed the initial phase of training at the FHC gym but he died just before he could continue with the home treatment due to his complex clinic status).

From a general point of view, it is evident, that both groups of patients –those who decide to participate in the treatment and those who decline to do it- are influenced by their clinical condition, life habits and possibly by their social environment, too. Their life style (daily activity degree, autonomy, healthiness of the environment, diet guidelines, social life, etc.) is a determinant factor both in the appearance and in the evolution of the illness (chronic obstruction pulmonary disease).

Consequently, it has been determined that the initial design of the pilot must be changed in order to include a higher determination in the offered service to the patients' those aspects related specifically with both care and social issues that can influence in their medical status. The availability of alternatives has been checked by health professionals directly involved in the project; regional authorities in charge of providing both social and health services have also been asked about related issues.

Main conclusion arise after completing the review of the initial design of the pilot is the need of a new role within the pilot, name "social worker", that would be in charge of attending those needs related to social issues.

One major difficulty for this purpose (inclusion of new role) is that FHC is a county hospital oriented to specialized assistance for acute patients, mainly consisting of outpatient surgery. Therefore, FHC suffers from the lack of pre-existing integrated services that combine both social and health aspects. The redefinition of the organizational aspects of the FHC pilot requires the acquisition of an initial minimum level of expertise in social issues.

In order to achieve this goal, FHC has decided to establish cooperation guidelines with the units that are in charge of providing social services within the regional public organization. Secondly, FHC has decided to redefine the roles for some of their staff whose tasks nowadays are mainly focused on patients and users' claims and who only occasionally carries out social tasks. They will play an active role within the pilot.

Social services at FHC's regional level are public ones. They are integrated into the "Consejería de Salud y Servicios Sociales del Gobierno de La Rioja", that is, the Health and Social Issues public regional organization at La Rioja - Spain (in Spain, national health systemn is completely decentralised so that each region is in charge of developing and sustaining its own health service).

FHC, as a public county hospital, is also integrated inside the same "Consejería de Salud y Servicios Sociales..." but is not formerly linked to the autonomous organization in charge of health related issues (named SERIS, that is, "Servicio Riojano de Salud): in each region, there are one "Consejería" and one "Health service"; first one designs health policies and second one provides health services under agreed basis with the "Consejería". The regional Health Service at La Rioja (SERIS)includes not only secondary level health organizations, such as one general hospital placed at the regional capital (50 km far from FHC), but also primary care level organizations as well as emergency units, physciatric units, clinical R&D facilities, etc.; SERIS has created recently a unit integrated by social workers in charge of social issues raised inside regional "health" organizations (this means both primary and secondary level organizations within the region);

Measures to be taken according to previous explanation are:

1. The introduction of ”social worker” role must be characterized for the following notes:

- Execution of evaluation reports regarding patient’s status from a social perspective, to be done by the professionals who are formerly qualified in this particular field (social workers).
  - There is a chance to use the current health management system of FHC, which is common to the rest of the regional health care system (”Selene”, powered by Siemens &Telefónica) to prescribe a specific”social status valuing” report.
  - The execution of this report will be responsibility of the social worker attached to FHC or of those social workers that are currently developing their activity in the primary attention level (FHC belongs to the second attention level –specialized services to be offered by hospital organizations-).
  - The total number of patients estimated to pass the social report activity in the period from August 2012 to December 2012 is 42, according to this distribution:
    - 32 patients who have completed the telerehabilitation program, or are carrying out it or could do it in the future.
    - 4 patients that only do the treatment at hospital’s gym (control group).
    - 3 patients who initially did not want to participate into then in-home training programme..
    - 1 patient who has been excluded because he does not live in a private home but in a nursing home for elderly people.
    - 2 patients excluded due to comorbidity risks (Charlson index >3 –dementia-).
- FHC’s social worker will be the interlocutor between the health professionals working at FHC and the social workers working at primary care level, and will also coordinate the execution of these reports (see flow chart below).
- Patients’ monitoring during the execution of the treatment at home will be under surveillance by social worker and it will consist of:
  - Control phone calls twice a month during the period of six weeks while the patient does prescribed exercises at home (this period of in-home treatment can eventually be repeated in case it is needed, according to clinical evaluation of each patient’s status)

  - Visits to patients' homes under demand (depending on development: hourly availability, ways of transport, etc.).

- Coordination between the physiotherapist in charge of home care assistance and the social worker in charge of the evaluation activity previously described is required. The inclusion of the social worker role can demand the introduction of changes for other involved professionals, too (e.g. the technical team, health care professionals, social workers of city councils and primary care level). Nowadays the physiotherapist is the one who rules contacts with patients, for example by warning when there are technical problems which may require a visit to any particular home. From now on, it could be assumed and developed by FHC social worker.
- Another point to be attended is the inclusion of any kind of remote monitoring of the physical activity carried out by the patient, in substitution of the monitoring of the execution of the prescribe exercises, due to the lack of capability to do prescribed exercises because of patient's bad health conditions. It could also be a way to understand better the implications and results of the execution of those exercises, by storing information related to the regular level of activity before and after the in-home training period. The use of an actigraph has being added for this particular purpose, thanks to the availability of INSERM's expertise as they have developed an use case within the In-casa project which involves this device for similar purposes.

The flow chart below describes the Healthcare/Social care service integration for FHC pilot:

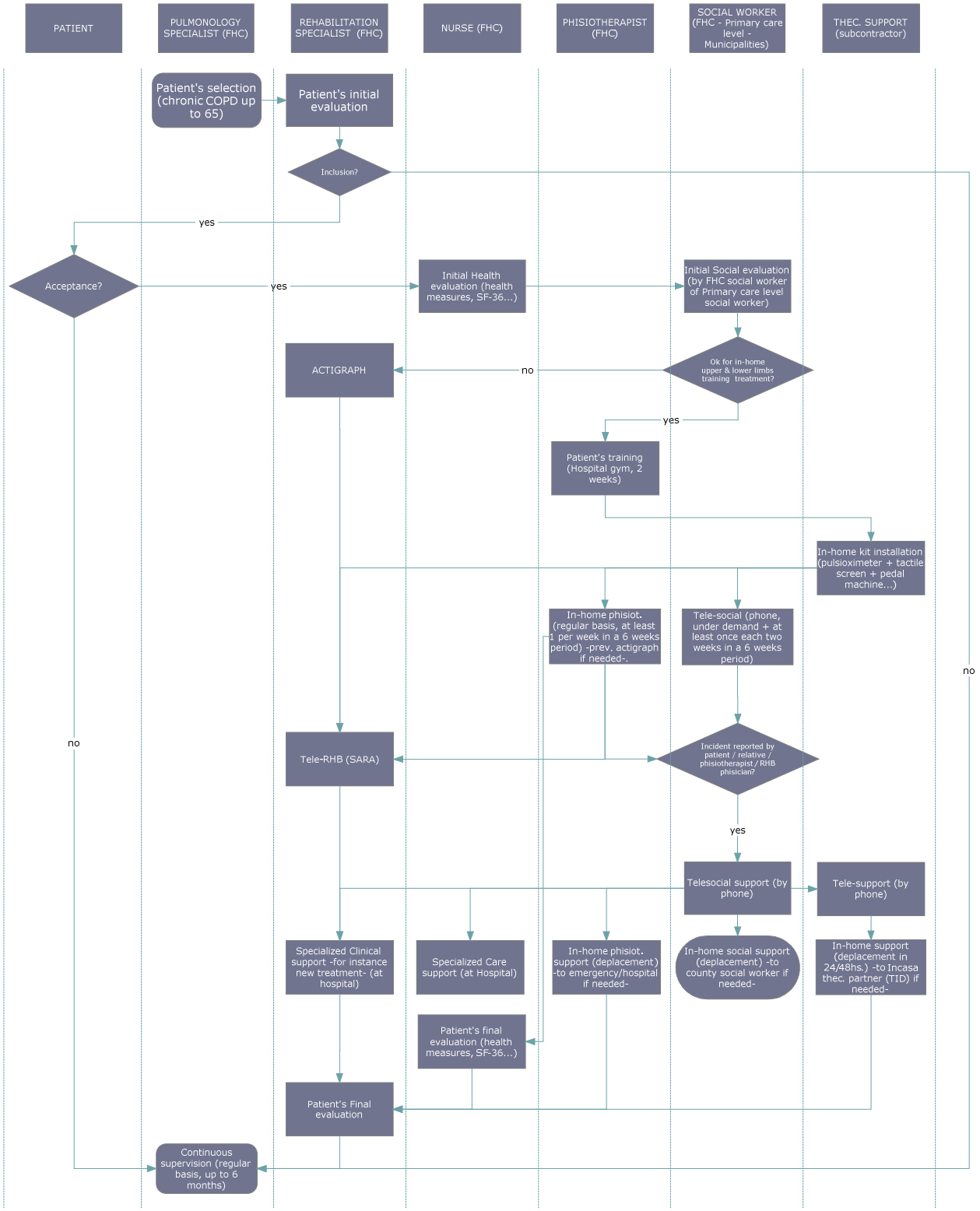

Figure 16 FHC Health and Social Integrated Pathway

4.2 TC and TH Technical Integration

In order to complete the TC and TH Technical Integration an actigraph will be used. It allows compilation and transmission of relevant information related to the daily physical activity carried out by the patient in significant periods of time. Two possible scenarios have been defined:

- Patients who cannot complete the training plan at home: These patients will use the actigraph during a continuous period of five-to-ten days to obtain information about his/her behavioural habits, which will allow healthcare staff to design a treatment plan accordingly.
- Patients who can complete the training plan at home: These patients will use the actigraph during a period of four-to-five days prior to the execution of the exercises at home, plus another four-to-five days after having completed it all to check the possible degree of influence of the treatment prescribed according to the life style of the patient.

The patient is using a pulse oximeter that communicates automatically and constantly (every 30 or 60 seconds) via Bluetooth with a tablet PC where both SARA and a Linksmart Client Agent are installed. The use of an actigraph at the FHC pilot site in accordance with INSERM and TID was decided, too. Its aim is to get a better understanding of the activity patterns of those patients who cannot do the in-home care initially prescribed due to different reasons (please see below paragraph 7.4).

Then, SARA uses specific Web Services to send information to the server, where it is saved through the Telehealth platform services.

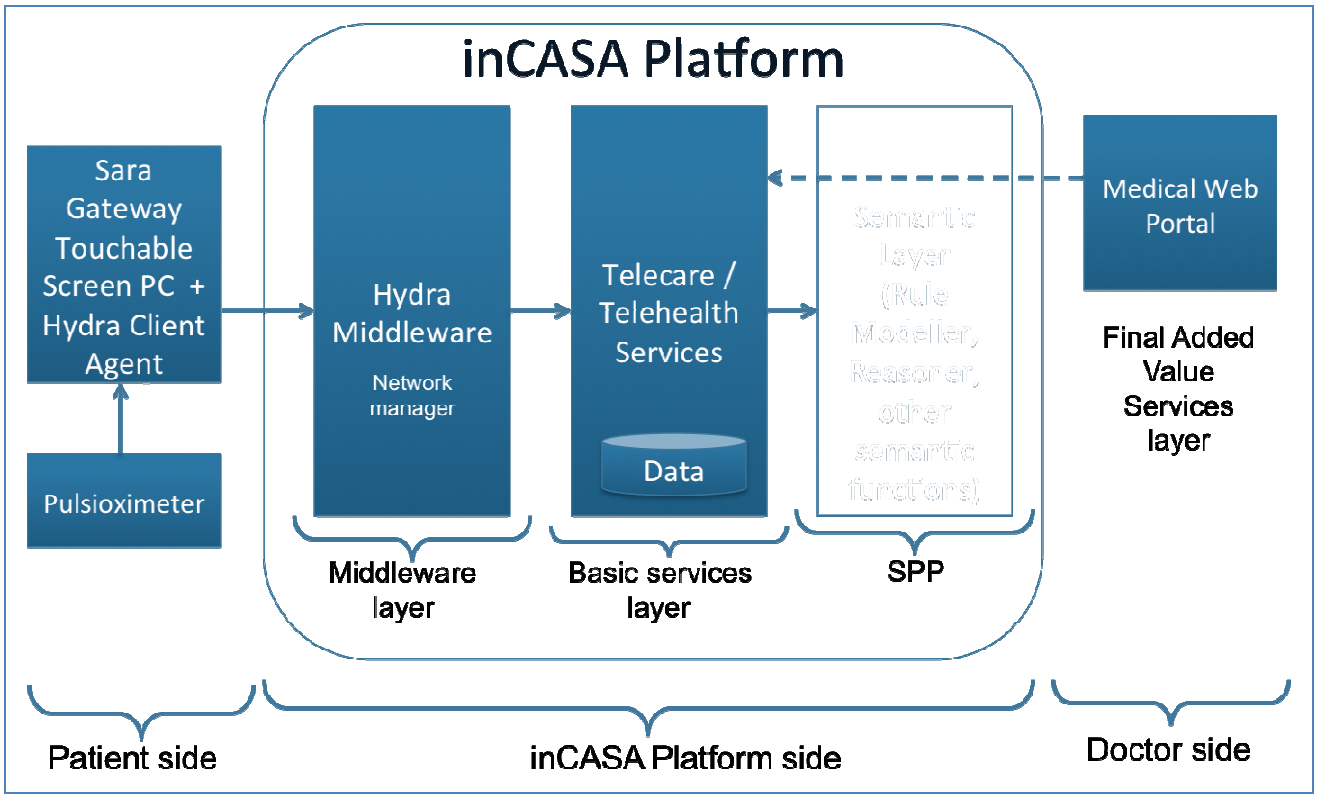

Figure 17 FHC Health and Social Technical Integration

FHC has a borrowed one actigraph and a touchable screen authorized to send the data of the actigraph online. To be able to do this, it was necessary to transfer part of the investment initially obtained by FHC in the inCASA project (1PM) to TID. Interoperability is necessary between the actigraph and the touchable screen, and the remote delivery of data for this query from FHC is a prerequisite in order to be able to complete the remote monitoring in a successful way.

4.3 Description of Stakeholders

Patients: The number of patients who are expected to be included in the project is 30, all of them suffering COPD disease. Their age is below 65 years-old and they live in different villages within the surrounding area. Most of them will complete an in-home treatment by using portable pedal machines plus touchable screens, weights and Pulse Oximeter. Some of them will take part only into activities to be developed at hospital gym, acting as control group, and some of them will use only actigraph instead of Pulse Oximeter and weights, as previously explained.

Caregivers: Relatives of the patient, neighbours, nurses, etc., that is, people who take care of the patient at home.

Clinician: Responsible for the clinical care of the patients within the project.

Care/Case Manager: made up for two pulmologists who are selecting the COPD patients and collaborating with the rehabilitation specialist in the diagnosis of the patient, and a RHB specialist

Physiotherapist: in charge of the measurement of the physical capability of each patient in order to establish the exercises to be done and is also responsible for teaching patients how to do the exercises properly and for modifying them if necessary.

Social worker: will coordinate activities related to social issues within the project, such as the execution of the social evaluation questionnaires and the control phone calls and visits to patients, as well as the coordination with local services in charge of social issues if required.

Nurse: attached to the rehabilitation unit responsible for care and clinical activities such as the competition of questionnaires and related issues prior to physicians' intervention.

4.4 Pilot Timetable

Date	Action
31.05.2011	Project ethics approved by the Committee for Ethics in Clinical Research in La Rioja (CEICLAR)
30.09.2011	Equipment acquisition and parameterisation completed
13.01.2012	Group 1 pilot started
03.05.2012	Group 2 pilot started
06.08.2012	Group 3 pilot started
03.09.2012	Group 4 pilot started
01.10.2012	Group 5 pilot started
05.11.2012	Group 6 pilot started

Table 8 FHC Pilot Timetable

4.5 Pre-pilot installation Summary

FHC didn´t undergo a pre-pilot phase and entered the project by the second iteration (2nd phase) of inCASA User Requirements consolidation and prioritisation due to internal issues.

Because of the nature of the FHC participation, with only one patient in the early phase to start the studies with, this entity decided to begin directly with the pilot phase. This is the reason why FHC wasn´t include on the D6.2 document, because FHC didn´t run a pre-pilot.

From the very beginning of the pilot the main objective of FHC has been to develop a design of the services for the patients as much simple and solid as possible, based on the previous experience of FHC in the attention of patients at home thanks to the Home Health Care Unit created in February 2005. Under these conditions, it was considered that it wasn´t necessary to delay the real beginning of the pilot to avoid putting in risk it´s correct execution. According to the financing initially given it was decided to acquire five kits to be used sequentially with six groups of patients of different cities following the planning of the execution of the project sent by the end of the second semester of 2011. On February 2012 four patients had begun the tele-rehabilitation treatment at home with the following numbers of clinic history (NHC):

- Zero patient: 11999 (13/01/2012)
- 56995 (27/02/2012)
- 32194 (27/02/2012)
- 40727 (16/02/2012)

The reason for giving priority to begin as soon as possible with the pilot was the necessity to execute a training phase with the patients in order to help them to familiarize with the exercises that they should do at home with the higher and lower limbs without the direct supervision of a professional the most part of the time (a physiotherapist visits the patient once a week), and to teach them how to use properly the technology used (touchable screen, pulse oximeter, pedal and weight).

Initially, the length of the first phase of gym training was estimated in four weeks. The phase has now being reduced to two weeks and the period of exercise execution at home has being increased from four to six weeks, according to the recommendations made by the Spanish Rehabilitation Society. The Society gave advice to the medical professionals of the FHC during its journeys celebrated in Madrid on January 2012 when Dr. Jariod, doctor in charge of the FHC clinical-medical pilot part presented the preliminary results. The length of the rehabilitation program was established according to the scientific evidences available detailed a couple of times during the project.

It was decided that the pre-pilot activities would be done only with that patient, parallel to the beginning of the pre-selection of 40-50 patients that fulfil the requirements of the project (more than 65 years old, etc.) by the pulmonologists.

In November 2011 a series of test were performed to test the kit exercises that are part of the tele-rehabilitation program with the zero patient. It enabled adjustments to be undertaken in the design and in the design and development. It was also found that there was a need to include mobile trolley bases for the equipment to enable it to more movable...

In December 2011 the zero patients was arranged to meet in the Hospital to start the first phase of the pilot with the training in the gym of the Hospital on the 5th December 2011.

Previously, on November 2011 several kits had been installed in the gym of the Hospital. Each kit includes a touchable screen and a pulse oximeter connected by Bluetooth acquire by the Hospital end deliver by the supplier.

4.6 Installation description

Pilot	Start Date of Pre	Start date of Pilot	Status of Pilot Pre / Pilot / on Hold	Total number of Users to be recruited	Number Recruited to date	Number currently using the system	Number of Users Completed
FHC	N/A	2nd December 2011	Pilot	32	12	6	6

Table 9 FHC Pilot Progress

4.6.1 Start dates

A “0” patient was the first selected patient to take part in FHC pilot; he was also the first one that tested the kit by doing exercises at Hospital under direct supervision by RHB specialist and also the one who provided a first feedback about the performance of the devices under real conditions.

On January 2012 the first “kit”, including pc with touchscreen, pulse oximeter and related devices, was installed at patient’s home by local specialized partners.

4.6.2 Sample Description

Elderly patients suffering COPD -stage II or III- self dependant and living in their own homes are to be included in the pilot. They enter the service via a referral from the Respiratory Medicine Department of FHC.

4.6.3 Recruitment

Patients are sent from the Respiratory Medicine Department and evaluated in advance by the rehabilitation unit, taking into account their clinical status. Scientist evidences related to COPD patients’ evolution after completing training activities for upper and lower limbs are the basis for the treatment to be offered to each patient[1].

Patients are able to freely choose whether they want to participate or not (and may withdraw at any time), and it will be made clear that should they refuse to participate then there will be no impact on their existent care plan. Patients have to sign the form provided by the project before they actively participate in the pilot.

1 For further information please take into account previous documents, a general overview –in Spanish- is affordable at: Hernandez MT, Rubio TM, Ruiz FO, Riera HS, Gil RS, Gomez JC. “Results of a homebased training program for patients with COPD”. Chest 2000;118(1):106-114. Puente-Maestu L, Sanz ML, Sanz P, Ruiz de Ona JM, Rodriguez-Hermosa JL, Whipp BJ. “Effects of two types of training on pulmonary and cardiac responses to moderate exercise in patients with COPD”. Eur Respir J 2000;15(6):1026-1032.

Nevertheless, recruiting process will be kept open during the project in order to include more patients in case it is needed.

4.6.4 Installation

4.6.4.1 Training at hospital gym.

Selected patients who accept to take part in the treatment are trained at hospital gym under direct supervision by physiotherapist for a period of two weeks. They receive detailed instructions about how to use the devices (pulse oximeter, portable pedal machine, weights, touchable screen), too, and information related to the perception of fatigue according to the Borj dyspnoea scale.

4.6.4.2 Installation of Equipment

The Kit used by each patient has been specifically designed according to pilot purposes and it includes:

- USB Bluetooth to connect pulse oximeter and touchable screen. Provided computers have no Bluetooth connectivity pre-installed.
- Internet 3g usb to get access to the internet (it is hidden behind the screen to avoid its manipulation). Access to internet services in some villages is not good or it suffers shutdowns. Many patients' homes have no per-installed internet access.
- Tactile screen: patient must push it only once to start and once again to switch it off.
- SAI: to avoid electrical failure and data missing.
- Borj scale printed in colors to provide the patients ease information about effort during exercising activity. An scale was also included into the sSARA software to be deployed at the screen but some problems have arisen when it started to be used under real conditions: each time the patient touches the screen for gathering purposes, the scale disappears. The size of the screen is too small to include at same time info related to heath indicators (hearth rate plus oxygen saturation) so it is not affordable to shown it to patients while he/she is doing prescribed exercises in front of the touchable screen.
- Graphical instructions about how to use tactile screen, pulse oximeter and software.
- Mobile base: it allows to move or to transport the kit, it acts also as a base to connect all devices in an easier way and, last but not least, it allows adjustment for each patient's.

Local partners services (UPICAL) have been hired to develop the installation of the kits and to solve technical issues related to kits 'deployment. They provide also with feedback about the project evolution thanks to their experience in the field.

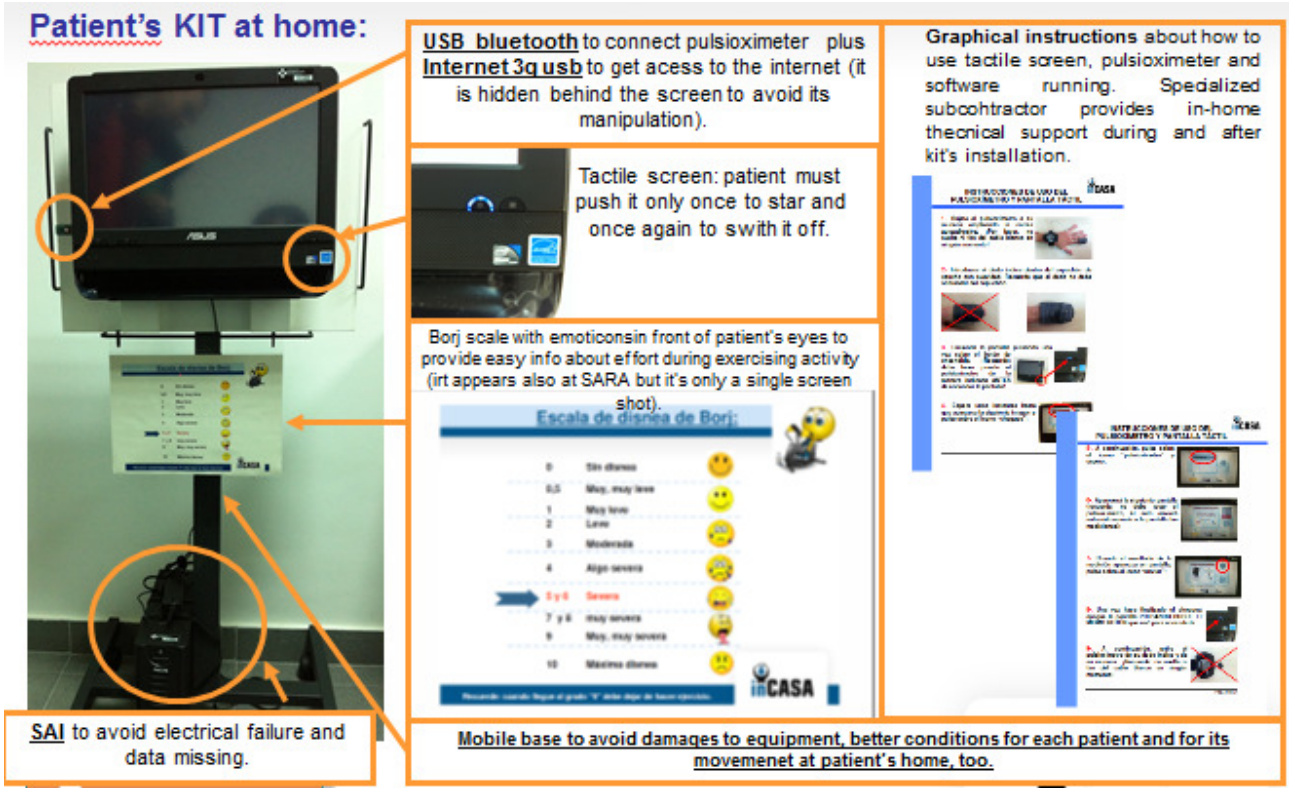

Figure 18 FHC Patient kit

4.6.5 Monitoring Process / Protocols

The patients who participate in the project have been organized into different groups which are completing sequentially the phases of the treatment:

- **Patient evaluation (4 weeks)**

Involves the agreement between the Internal Medicine Unit and the Physiatry Unit about patients to be included in the pilot, first medical consultation with the physiatrist, general information for the patient and informed consent.

- **Training at the hospital (2 weeks)**

Includes specific training in the exercises that will be performed and the devices that the patient will use at home. This phase was cut down from originally four weeks to two weeks period due to advices given by the colleagues of a FHC rehabilitation specialist at a meeting held in Madrid (Spain) on January 2012 where inCASA project (FHC pilot site) was presented.

- **SARA evaluation from home (6 weeks)**

This phase includes transportation and installation of the monitoring devices and, of course, the remote monitoring of exercise for at least 4 weeks, withdrawal of the equipment after finishing the pilot and (very important) patient supervision by home care professionals to guarantee the implementation of activities that ultimately are agreed according to pilot results.

- **Psychiatric Evaluation (1 week)**

Final evaluation by the physiatrist through standardised and ad hoc questionnaires (SF-36, St. George, BODE index). The Edmonton frailty scale was also included in response to conclusions

made at the pilots' meeting held at INSERM on September 2011. A FHC Neumologist specialist will also be involved during the monitoring of a post-phase at the end of the IinCASA project for patients due to their needs as chronic patients (it will include the monitoring of FEV1 levels)

All of the steps defined above will be repeated for each group of 5 patients subsequently. A control group was added to get data gathered from patients who are not attended to in their own homes but only at the hospital gym. They will use the same inCASA kits as patients doing prescribed training exercises at home. The aim for this particular activity was mentioned in one of the pilot meeting held during the development of the pilot phase and it is expected to strength the quality of clinical evaluation at the end of FHC pilot site.

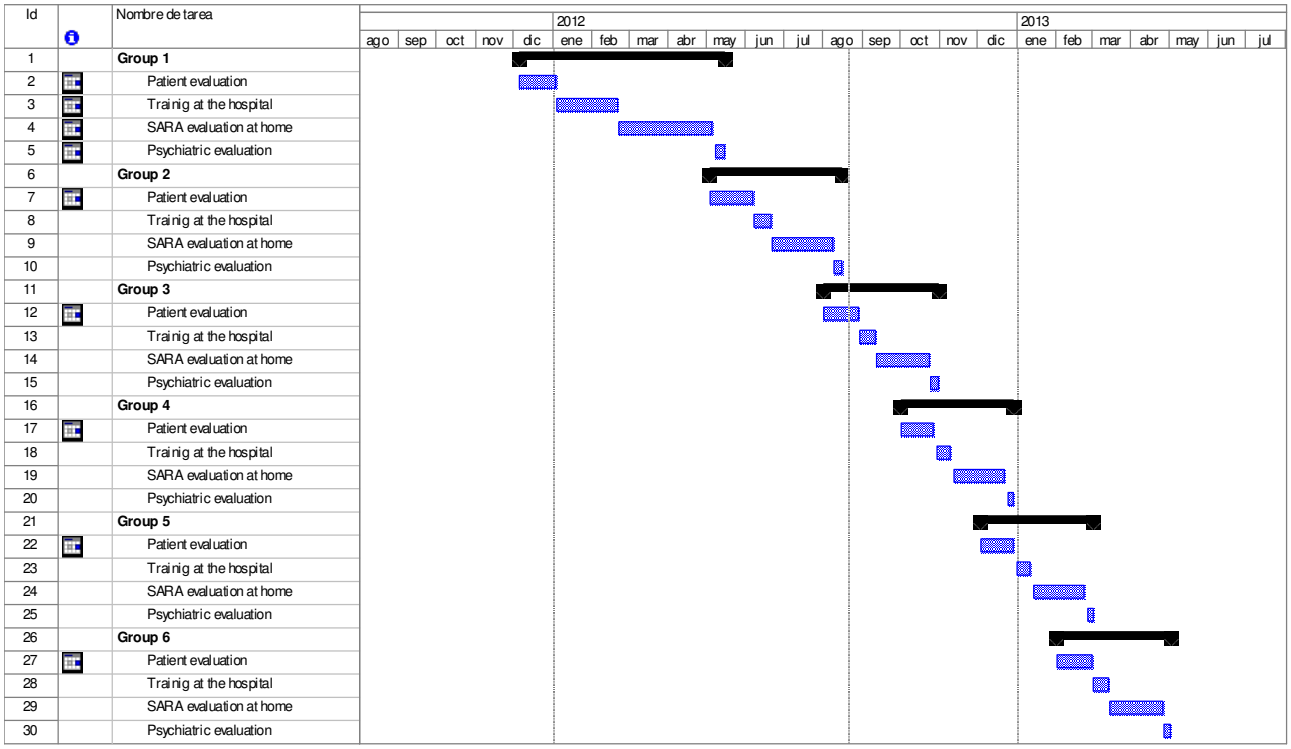

Figure 19 FHC Monitoring Timetable

Clinical data is included at FHC's clinical ERP on regular basis. Clinical protocols are included too.

Main issue is that Rehabilitation specialist can see relevant data for clinical purposes gathered via SARA on remote basis continuously. Physiotherapists can see them if necessary, too. In case some deviation occurs, treatment programme can be reviewed and adapted to patient's needs immediately.

4.7 Challenges

4.7.1 Patient

Due to social and health conditions some patients refuse to participate in the pilot for different reasons such as:

- Some patients living far from hospital have no relatives available to bring them there three times per week during four weeks for completing their 1st training period and sometimes there is no disposal of alternative mobile services such as ambulances.

- Some patients' relatives don't want patients making exercises for different reasons (they think they are too old to do so, etc.).
- At least one patient is in social exclusion situation (alcoholism, living alone) and cannot start the program.
- One patient cannot do exercises at home without supervision due to some type of minor level of dementia, although he could complete 1st period at hospital gym.
- Two patients died before starting in-home training due to comorbidity, one of them the day before the kit was going to be installed at his home. Another 2 pre-selected patients have recently died too.

4.7.2 Professional

Iteration between pulmonologists and rehabilitation specialist has been improved in benefit of patients (previously there was a lack of continuity of care for some patients with no alternatives to be offered to face their chronic disease in long-term conditions). IT dept. has faced the need to be pro-active in the implementation of new technologies (tele-medicine). Administrative staff has included new reporting and cost-calculation related issues due to the development of the project. Language skills have been developed too as a pre-condition to participate within the project, according to reporting needs derived from InCASA project.

4.7.3 Organisational

Facing social issues has been a major issue, as FHC is a small-size hospital with no previous experience in dealing with non-health needs of chronic patients. New roles are being developed due to project's needs, such as "social worker" one, as well as closer interaction with other service providers within the regional social and health organization.

4.7.4 Technical

During the pilot some of the technical problems detected have been:

- Access to internet via 3g can be a problem sometimes due to local coverture failure.
- Sometimes connection between pulse oximeter and tactile screen fails for different reasons. A subcontracted company offered support to solve it but sometimes it arises new problems that need to be solved in place.
- Using tactile screens is hard for elderly people without minimal acquired abilities. From time to time during their exercises they must touch the screen and eventually they must watch the Borj Scale emoticons too. Exercising can be bored for some of them.
- Using devices without direct supervision can be a problem as they are not intended to be used by patients but for skilled professionals. For example, Bluetooth pulse oximeters were not intended originally to be manipulated by elderly patients by connecting /disconnecting cables (at least one pulse oximeter has been damaged due to inappropriate usage).
- On the other hand, at least one patient (2^{nd} one indeed) said he would like immediate feedback referred to data gathered at tactile screen as he could see data at pulse oximeter wrist screen on real time too. Patients are using more devices not connected to any pc (pedalled, light weights) so there is no chance of colleting those data to offer immediate feedback to patients.

- Lack of continuous remote assessment for technical problems related to software malfunction.

4.7.5 Resource

Initially expected investment in Durable Equipment has been altered as the pilot is being developed, due to new problems derived from technical devices and unexpected needs (enable equipment to be mobile, internet access at patients' homes, actigraph inclusion).

Expected level of personnel costs have increased also due to the inclusion of new roles within the pilot and the complexity of the administrative tasks related to the reporting requisites directly associated to the project (cost calculation, monitoring of investments, etc.).

4.8 Deviations from Pilot Plan

The most important deviation from the pilot plan has been the delay from the initial calendar. The day when the first group of patients involved in the pilot started was delayed due to the final date of competition of the acquisition of required kits (for example, 1 of the pulse oximeter had to be changed due to malfunction). Secondly, as per the observation of first "patient zero" iteration with the real kit at FHC facility held on November 2011, it was established that a mobile base was needed to put the tactile screen in the proper way to complete the prescribed exercises –the patient needs to touch the screen every 60 seconds approximately while he/she is doing the prescribed exercises, but TID expressed the impossibility of developing an automatic interface between the pulse Oximeter and the tactile screen to avoid this step, while FHC clinicians stated that the continuous monitoring of SPO2 was not an option but an specific requirement for the success of the treatment-; an specific model of mobile base was designed with the help of subcontracted technicians in charge of installation of the equipment at patients' homes (it was studied how to adjust the length and height parameters for each patient in an easy and safe way, for example); then, the first two of them were built-up as soon as possible and they were tested at Hospital gym by installing two kits onto them. Finally, first complete equipment was installed successfully at first patient's home on January 2012 (previously, the patient had to complete a four weeks training period at hospital gym by using the same kit).

Second main reason for observed delays was caused by different problems, both technical and ethical ones. Technical problems are mainly related to failure of connection between wrist pulse Oximeter and tactile screen, as there are three different devices involved in the data gathering activity: tactile screen (with no Bluetooth capability), Bluetooth device connected to tactile screen and wrist pulse Oximeter (finally it was discovered that the reason was the interaction between these devices just after the iniziallating phase –the patient must push the on/off button of the tactile screen before making the exercises) . Internet connection was expected to be a problem due to low range of internet services coverture within the region (it is a rural area with small-to medium sized villages spread over a square with a radio of 30-to40 kilometres), but finally it has not been the most important one. Unexpected power shutdown due to local restraints has happened but has been solved by adding a specific device to InCASA kits to avoid data missing, too. One more kit was acquired to complete scheduled activities (two kits are installed at hospital gym, while four more kits are installed-desinstalled and installed again every 6 weeks according to patients' needs –date of finishing of training period at hospital gym, absences due to displacements, etc.-), as well as to include actigraph within the FHC pilot sites activities, as it was established with the rest of the partners (TID), although it was not ready to use till April 2012. Ethical problems have raised the need of redesigning the pilot in order to include both social and care issues in a better way.

5 INSERM inCASA Solution

Cancer is a chronic disease with a high impact on patient's quality of life, health and wellbeing. The treatment proposed by the Chronotherapy Unit of the Paul Brousse Hospital in Villejuif is a chrono-modulated chemotherapy delivered at home. Chronomodulated chemotherapy (chronotherapy) aims at the reduction of treatment-related symptoms through the adjustment of chemotherapy delivery to the circadian timing system which rhythmically regulates cellular metabolism and proliferation. Cancer chronotherapy is delivered at home using programmable pumps, and avoid familial and social disruption. Since cancer is a complex disease associated with co-morbidities, many health and social care providers are involved. This leads to a large burden on the health care system as well as a complex situation for patients and their family. By integrating social and medical care and using telehealth monitoring, patients can be supported on more than one level in efficient ways.

The goals of the pilot involve:

- Improvement of care for cancer patients, which currently is handled by several social and medical care providers who usually interact separately with the patient.
- early detection of drug-related adverse events or disease exacerbations through close monitoring of the health condition in order to prompt relevant intervention thus reduce hospitalization. This approach includes the daily self-rating of the symptoms which reflect impaired behavioural or biological functions, as well as body weight and circadian rest-activity pattern through non-invasive rest-activity monitoring.

This will result in improved quality of life and patient prognosis through facilitating health care coordination, controlling patient symptoms and enhancing circadian robustness.

The telemonitoring system is composed of an electronic platform with the SARA software, a weight scale, an electronic internationally validated symptoms questionnaire and an actigraph watch. This system provides relevant and online daily information about the body weight, the symptoms severity and their interference with daily life, as well as the rest-activity and sleeping patterns of the patients. This data is checked daily by the hospital nurses, with action following when appropriate.

The nurses are the primary access point who directly interact with the patient and if necessary signal the health problems at an early stage to the oncologist, the GP, the local nurse, other relevant healthcare professional or the "helper" relative. Early detection of worsening of cancer or early detection of adverse events on chronotherapy at home followed by immediate appropriate action could prevent health deterioration, hospitalisation and/or death. Pending upon the type of deteriorated item (symptom, body weight, rest-activity...), as indicated with reference to pre-set thresholds eventually completed with patient interview , the nurse refers the patient to the relevant health professional (oncologist, geriatrist, general practitioner, psychologist, dietician, physical therapist or social worker). The patients can then check the appointments with healthcare or social care professional directly on the diary displayed on the electronic platform at his or her home. When a patient has medical questions or needs with arranging social services, the nurses can be contacted by phone during office hours.

5.1 Integrated Health and Social Services

The main objectives of the INSERM pilot is to develop a service of technologies for cancer patients (with a sufficient level of independence and living at home) focused on their habits in their daily life and the evolution of different physiological parameters that may be affected by the disease and / or treatment (rest-activity rhythm, body weight, symptoms score evaluated by the MDASI scale). This will result in improved quality of life and patient prognosis through facilitating health care coordination, controlling patient symptoms and enhancing circadian robustness.

By integrating health and social services a network of social and medical professionals is built around the patient. This will result in the most appropriate care being delivered in the shortest time possible and minimising also the burden on informal carers (mostly partners or family of the patient).

The social services aspect will be coordinated by LVL medical (http://www.lvl-medical.com/) and the oncology network of Val-de-Marne Onco94 (http://www.onco94.org/site/index.php). LVL medical is a homecare company which involve social workers, home helps or homecare nurses. Onco94 is a regional oncology network which provides counselling and social activities and involves patient associations

INSERM will involve the hospital nurses as a primary access point for the patients. They will directly interact with the patient and point out any health problems at an early stage to the oncologist, the GP, the local nurse and/or other relevant healthcare professionals. Depending on the type of deteriorated monitored parameter (symptom, body weight, rest-activity etc.), as indicated by a level below a pre-set threshold and her interview of the patient, the nurse will refer the patient to the relevant health professional (oncologist, geriatrist, general practitioner, homecare nurse, psychologist, dietician, physical therapist or social worker)..

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Use case 1 – Chronotherapy delivery at home

Michel is followed by his oncologist at Paul Brousse hospital in Villejuif for metastatic colorectal cancer. He is treated with three-drug chronotherapy delivered at home using programmable pumps four days every three weeks. Michel is relieved because with such treatment modality he can stay at home with his wife despite the complexity of the chemotherapy protocol. Yet he is also anxious about the pump operation and the follow-up of his health condition during chemotherapy delivery because of the risk of side effects.

A SARA platform is installed at his own home in order to collect his own data. For this purpose, Michel weighs himself every morning on a Bluetooth weight scale and scores his symptoms himself on an electronic version of a widely used worldwide questionnaire about health and quality of life for cancer patients using touch screen. His rest-activity pattern is automatically recorded by an Actigraph worn in the wrist like a watch. He simply sends the recorded data once a day using infrared communication by pressing a button on the Actigraph and on the SARA platform. Michel feels safer with this equipment as he knows that his health status is monitored and that the hospital nurses who check the data daily will be able to react promptly if his health condition worsens. He also knows that he may contact the nurses at any time for social needs or medical or technical assistance.

When Michel attends hospital for a medical consultation with his oncologist every three weeks, Sandrine, the hospital nurse, programs a pump in order to deliver the drugs as described in the medical prescription. She connects the pump to the implanted venous access port of the patient. Sandrine makes sure that Michel is visited whenever needed by a nurse involved in a homecare company so as to properly and quickly alleviate symptoms, handle technical issues and check that the pump is operating well. Upon treatment course completion, the nurse removes the pump from the implantable port and administers the required care.

All the appointments are reported by Sandrine on the web portal and Michel can see his diary updated directly on the SARA platform. He can call the hospital nurse if any change is required.
Michel is happy that everything has been arranged for him. He feels comfortable to be at home when he knows he is being monitored while on intensive chronotherapy, and has one central point that he can call if he needs either medical or social support.

Use case 2 – Medication adjustment
During the second day of her chronotherapy, Catherine rates her pain at 8 over 10 on the MDASI scale whereas she rated the pain below 3 the previous days. Sandrine the hospital nurse is alerted and calls Catherine who confirms that her pain and fatigue have suddenly increased. Sandrine contacts the oncologist who decides to prescribe painkillers. Then, Sandrine faxes the prescription to the local pharmacy and calls Catherine that the pharmacy will deliver the medicine at her home.
Over the next day, the score of pain rated by Catherine decreases back to its baseline level. Catherine feels much better and she is grateful to Sandrine and the pharmacist that they could react so promptly.

During the next medical consultation, her oncologist checks the data on the web portal and he realizes that Catherine had pain and fatigue exacerbations during the previous chronotherapy course and that she also had lost 4 kg within two weeks. Then, he decides to reduce the dose of the drugs delivered by the pump in order to decrease the side effects and increase tolerability.

Use case 3 – Preventing hospitalization
When checking the data on the web portal, Sandrine is alerted that several functions recorded for François are out of range. She looks into the medical record of François. She finds out that he has been followed by the hospital for 6 months for his cancer and that he received his last chronotherapy course last week. She notices that the weight of François has decreased by 6% within one week and that his rest-activity rhythm is severely altered. She decides to call the GP.
The GP also looks at the data on the web portal and decides that a home visit is needed. Sandrine calls François to let him know that the GP will make a home visit and update his diary. The wife of François answers the phone and she confirms that François's condition is getting worse. He has no appetite and has difficulties to sleep.

The GP visits François, who is really in trouble, as a result of a complete lack of appetite for the past week. The GP prescribes parenteral nutrition at home for three days and decides that no hospitalization is needed. He informs the home care company of his prescription using the inCASA web services. Later the home care company implements the prescription at François's home and informs Sandrine on the same way. François's wife calls the hospital nurse on the next day to inform her that François is doing better and he is well taken care of at home.

When the GP makes the home visit three days later they discuss the condition of François, which is improving. However the wife of François tells the GP that François is often feeling down and worried. The GP, François and his wife discuss this thoroughly and François agrees that he feels depressed and would need counselling. Together they call the hospital nurse. She takes action and makes an appointment for François with a psychologist and updates the diary.
After a few months, the home care nurse makes regular visits at François. She founds him in a good condition. The evolution of his cancer is stable and François and his wife confirm that he is in much higher spirits lately. He has obviously accepted his condition and is complying with his medicine.

5.2 TC and TH Technical Integration

The elements integrated into the French pilot are:

- Web services for the exchange of user information and clinical data.
- SARA platform installed at the patients' home for data collection and visualization of the appointments

The web portal provides an interface for professional users to access and share patient information such as user name, ID, gender, date of birth, phone number, user's current medication, diseases and allergies, etc.. And clinical data collected by the SARA platform such as body weight measured with a Bluetooth weight scale, symptoms self-assessed following the M.D. Anderson Symptom Inventory Scale and rest-activity rhythm continuously recorded with an Actigraph (wrist-watch accelerometer).
The web portal also allows scheduling appointments of the patients with healthcare or social care professionals. The diary of the patient displayed on the SARA platform is then updated with the time, date and details of the appointments

The user interface on the touch screen computer is managed by the SARA software which allows the patients not familiar with technology to easily send their medical data and see their diary.

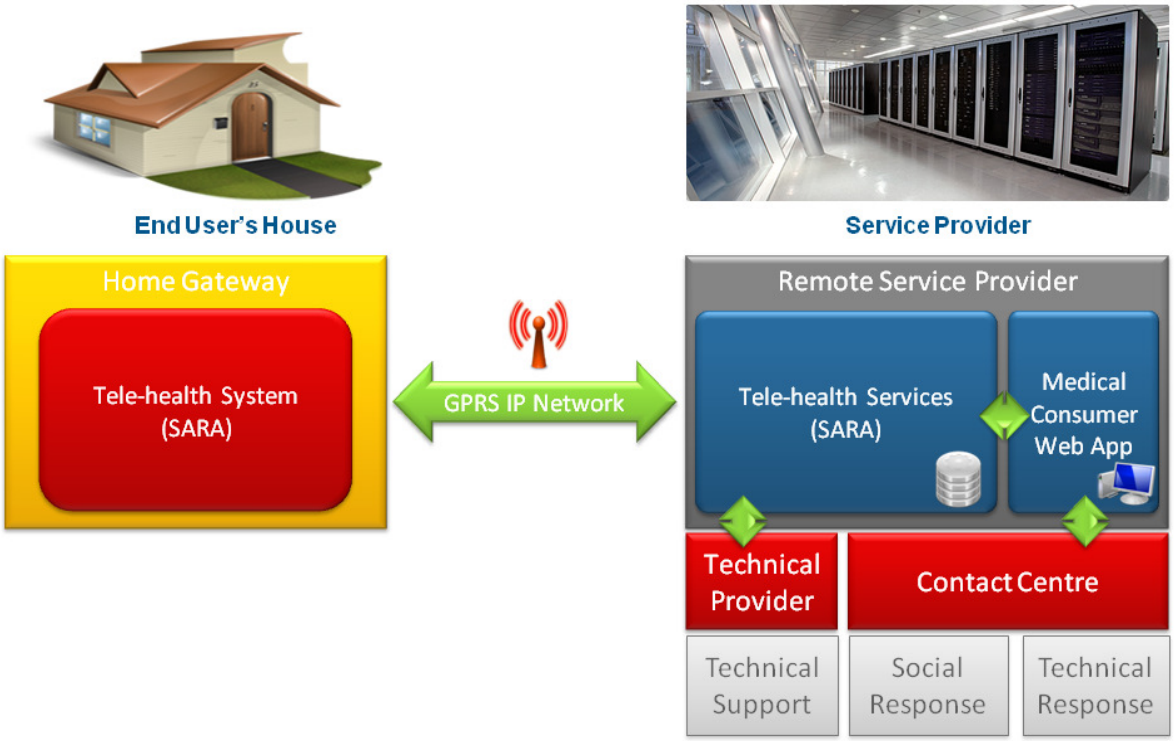

Figure 20 INSERM Health and Social Integration

5.3 Description of Stakeholders

Patients

The outpatients of the Chronotherapy Unit of the Medical Oncology Department of the Paul Brousse Hospital (Villejuif) are the end-users. They suffer from cancer and are treated at home with chrono-modulated chemotherapy using programmable pumps. They come back to the hospital every two or three weeks for a medical oncology consultation. They are usually accompanied and helped by relatives.

Oncologist

The oncologist is responsible for the patients' selection, initial evaluation and follow up. He prescribes the treatment and is alerted by the nurses if a patient's health condition is deteriorating in order to adjust the treatment or prescribe other drugs.

Hospital nurses

The hospital nurses program and prepare the drug delivery chronopump that will administer chronomodulated chemotherapy. They interview the patient before the oncology consultation. They check the data sent by the patients daily through the InCASA platform and can be contacted by phone at any time. They alert the oncologist, other healthcare professional, social care professional or the case manager or the "helper" relative if an incident is detected.

Healthcare professional

The healthcare professional can be the General Practitioner, a homecare nurse, a geriatrist, a physiotherapist, etc..., alerted by the hospital nurse depending on the health problem detected.

Social care professional
The social care professional can be a psychologist, a dietician, a social worker, a home help, etc..., alerted by the hospital nurse, depending on the social needs of the patients.

Case manager
The case manager is responsible for the enrolment of the patients in the study, the equipment installation at home and provides a technical support if necessary

5.4 Pilot timetable

Date	Action
20.05.2011	Project ethic approval by the French ethical committee
04.07.2011	Equipment acquisition and parameterisation
07.07.2011	Information meeting in Paul Brousse hospital about the inCASA solution to all the hospital staff
October 2011	Selection of patient and patient acceptance signature
November 2011	Pre-pilot starts
November 2011 – February 2012	Equipment installation (PC platform and weight scale), data collection and evaluation
March 2012	Pre-pilot end- Pilot activities start
September 2012	Deployment of integrated Telecare/Telehealth services
March 2013	Conclusion of Pilot monitoring and final evaluation beginning
June 2013	Conclusion of evaluation and of Pilot activities overall

Table 10 INSERM Pilot Timetable

5.5 Pre-pilot installation Summary

Five patients were involved in the pre-pilot phase. The study included a daily monitoring of the weight and symptoms using a Bluetooth weight scale and the M.D. Anderson Symptom Inventory questionnaire to be filled in a SARA platform. The patients were very positive about this study, so that the data were successfully collected despite minor technical issues. However the nurses were not involved in the pre-pilot phase because the web portal didn't allow an easy visualization of changes in the health condition of the patients. Some additional requirements were requested to the technical partners in order to improve the web portal for health professional users.
Several patients had no internet access at home which prevented the installation and raised an issue for equal access to care. So a 3G USB key was bought in order to recruit patients without internet access at home into the pilot phase.

5.6 Installation description

Start Date of Pre Pilot	Start date of Pilot	Status of Pilot Pre / Pilot / on Hold	Total number of Users to be recruited	Number Recruited to date	Number currently using the system	Number of Users Completed

Nov 2011	March 2012	Pilot	30	10	5	5

Table 11 INSERM Pilot Progress

5.6.1 Start dates

The pilot phase started on March 1st. The pilot extension with the deployment of integrated telecare and telehealth services will start in September 2012 for a six-month evaluation period.

- .

5.6.2 Sample Description

30 patients who are over the age of 18 with a diagnosis of cancer and who are attending the Paul Brousse Hospital in Villejuif will be recruited to take part in the pilot.

5.6.3 Recruitment

Patients are recruited from the outpatient Chronotherapy Unit of the Department of Medical Oncology (Dr Francis Lévi) at Paul Brousse Hospital (Villejuif) and are followed as outpatients.
If selected patients meet the eligibility criteria and if they agree to be enrolled in the study and to use the system at home, an appointment is made for the installation.

Pilot inclusion criteria:

- Male or Female
- Suffering from cancer (any type of cancer)
- Age : > 18 years
- Ambulatory
- Living at home (alone or with spouse)
- Affiliated to a social security system
- Written consent to participate in the study signed and dated

The demographic characteristics correspond to the common demographic dataset.

Clinical baseline characteristics:

- Current treatment (sleep inducer, pain killer, antidepressant, beta blockers, corticoids, or other specific treatments).
- Primary tumour (date of first diagnosis, histological type, date of first metastasis).
- Chemotherapy/radiotherapy before the inclusion to the inCASA study.
- Clinical symptoms, grade at inclusion according to NCI CTCAE v. 3.0 (nausea, vomiting, sensory neuropathy, anorexia, fatigue, diarrhoea, constipation, pain).
- Chemotherapy/radiotherapy during the inclusion to the inCASA study.

5.6.4 Installation

5.6.4.1 Installation of Equipment

The first step before the installation at the patient's home is the configuration of the platform. The profile of the user is created on the web portal and associated with a protocol and a kit number. The SARA platform is configured using the kit number which corresponds to the new patient.

Figure 21 Creation of a new patient's profile on the web portal

Then the equipment is installed at patient's home by the case manager at the beginning of the inclusion period of minimum six weeks. The patient is asked to use it every day for body weight measurement, symptoms self-assessment through the M.D. Anderson Symptom Inventory questionnaire and rest-activity rhythm recording. Patients are trained during the installation of the platform at home to use the equipment. The installation and training last about one hour in average.

The equipment provided to the patients is composed of an electronic Bluetooth weight scale, an infrared Actigraph (wrist-watch accelerometer) and an all-in-one PC with a touch screen and with the SARA application installed. The computer is connected to the internet through the WiFi or 3G network if no internet connection is available at home.

Figure 22 Equipment: SARA platform, weight scale, Actigraph

Each platform is configured to be used by patients and one reference number is assigned to each equipment. A list is established to manage available and assigned equipment.

Figure 23 Patient using the platform for body weight measurement and symptoms self-assessment

5.6.5 Monitoring Process / Protocols

All data sent by patients are stored on a server located in TID's premises and can be viewed through a web portal using a web browser. Authentication with login and password is required to access to the web portal due to privacy protection.

The home page of the Tracking part displays the list of the patients enrolled in the study. The Biomeasures tab presents the results of the last measurement performed by the selected patient and the changes over time in weight and symptoms through graphs. A button called "Actigraph" allows opening a new window with the list of the Actigraph files transmitted by the patients.

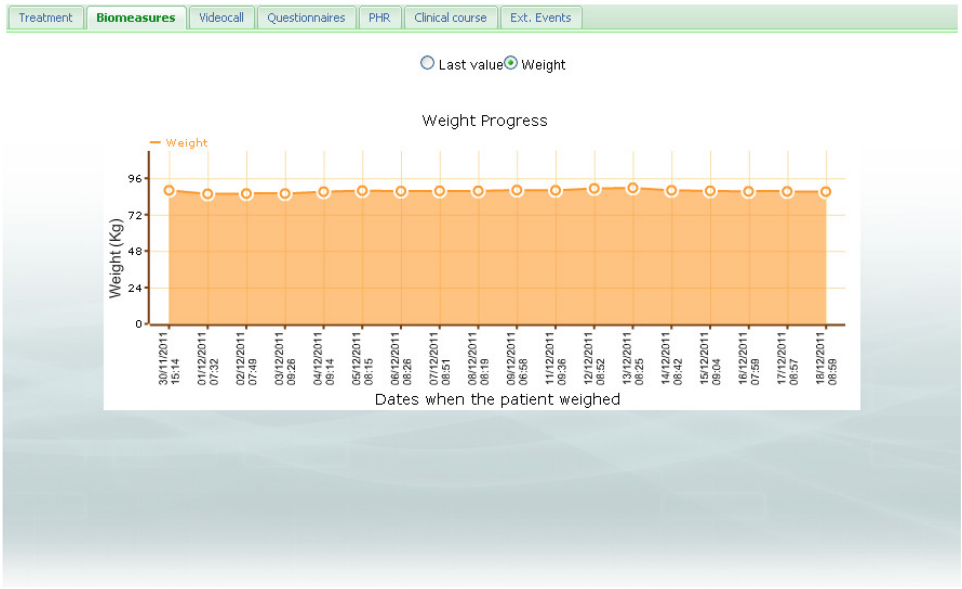

Figure 24 Weight Progress

The symptoms are organized by clusters to facilitate a quick visualization of changes over time.
Five clusters of symptoms have been defined from the core symptoms of the M.D. Anderson Symptom Inventory:

- Gastro-intestinal: nausea + vomiting + anorexia
- Pain and neurosensory: pain + numbness
- Rest-activity: fatigue + disturbed sleep + drowsiness
- Emotion: distress + sadness
- Others: shortness of breath + dry mouth + memory

The last six items of the questionnaire correspond to the interference with life (quality of life)
If a high score or an increase in a cluster of symptoms' score is detected, the details of the progress of each symptom are displayed in a separate graph.

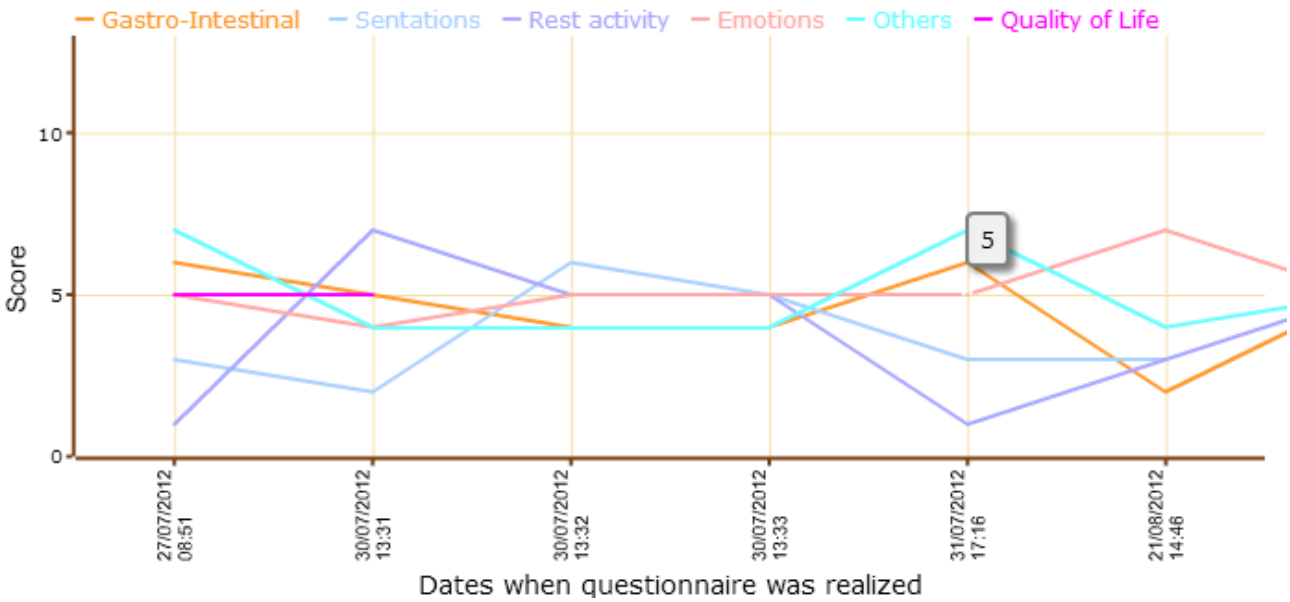

Figure 25 Clusters of symptoms

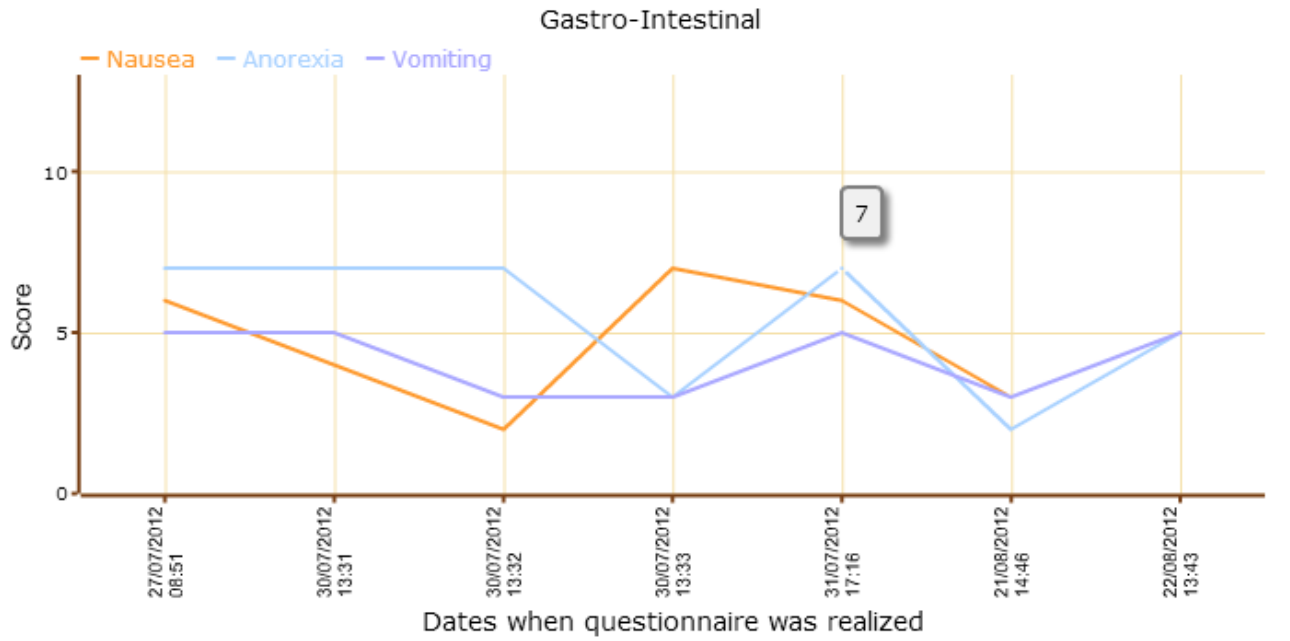

Figure 26 Details of symptoms in the Gastro-intestinal cluster

After downloading the 24-h-long Actigraph files from the web portal, the first step to analyze the rest-activity rhythm of the patient is to manually merge the files using the software provided by the manufacturer. The next step is the selection of periods where the patient is in bed. These periods can be identified with a lower activity level. The software calculates the dichotomy index called "I<O" which represents the amount of median activity out of bed compared to the activity in bed and which provide an indication on the quality of the rest-activity pattern. The rhythm is considered as altered if I<O if lower than 97.5%.

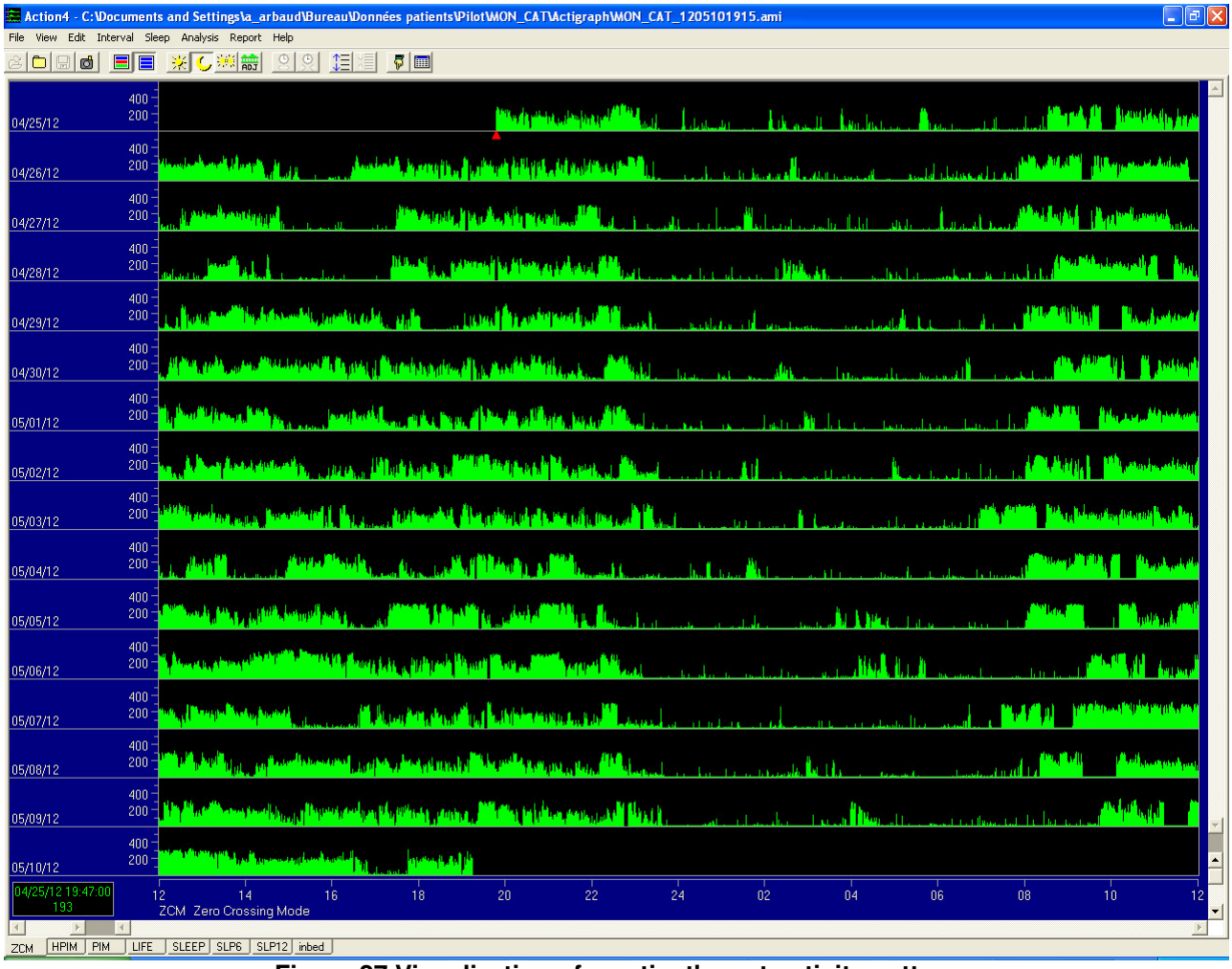

Figure 27 Visualization of a patient's rest-activity pattern

As described in the following diagram, after patient's selection, user acceptance, equipment installation and training, the hospital nurses ensure data monitoring. As soon as an incident is detected and confirmed, they alert the adequate professional who provides the required care.

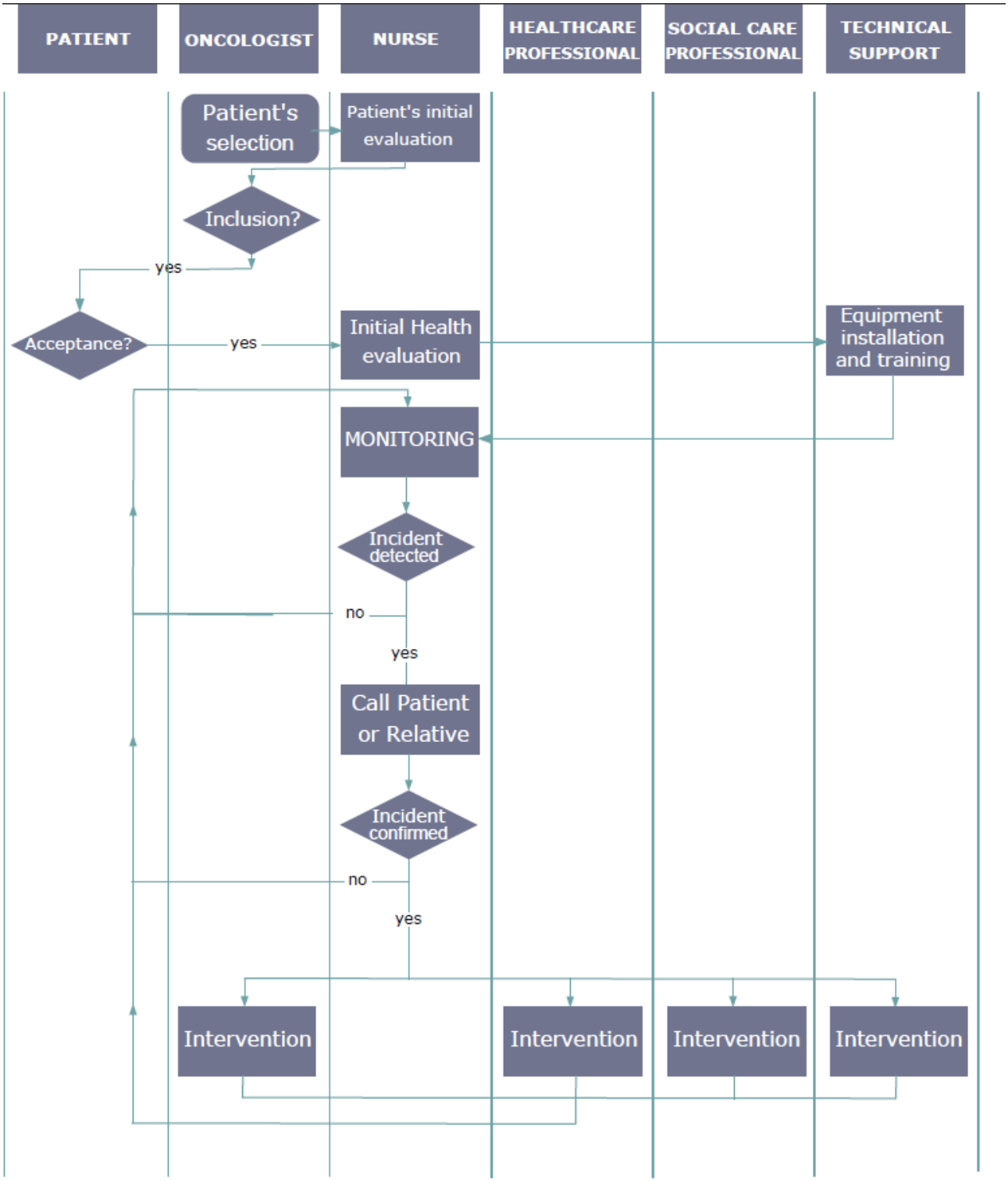

Figure 28 FHC Integrated workflow

5.7 Challenges

5.7.1 Patient

Most patients followed at the Chronotherapy unit at the Paul Brousse Hospital in Villejuif are less than 65 years of age. However their frailty due to cancer and cancer treatments is making them eligible for the study.
In general the patients react very positively to the inCASA platform project, yet some patients who are not familiar with using a personal computer can display anxiety reactions.

5.7.2 Professional

One of the main challenges of the pilot phase is the involvement of the nurses and other healthcare or social care professionals. After a period of training, the nurses will have to change their habits in order to check the data daily and if necessary alert adequate professionals.

5.7.3 Organisational

The inCASA solution will induce a new organisation for hospital nurses and should enhance the cooperation between healthcare professionals and social care professionals.

5.7.4 Technical

Several known technical issues (Bluetooth connectivity problems, SARA time outs, Actigraph data transmission) still may affect the SARA platform and prevent data collection from users. Prompt technical assistance is necessary until the resolution of problems.

The SARA software will be updated with the new DLL provided by Ambulatory Monitoring in order to make the Actigraph data transmission become more user-friendly for the patients and in order to automatically merge daily time series files to be analyzed by the professional users.

5.7.5 Resource

We have estimated to 45 minutes the time needed for a nurse to screen the InCASA cancer data and make a decision of action for 10 monitored patients. The procedure could last up to an additional 30 min in case a complex action is required. This time should counterbalance that spent in case of unexpected emergency call from the patient and/or his/her helper relative or nurse or GP.

5.8 Deviations from Pilot Plan

No deviation from Pilot plan.

6 KGHNI inCASA Solution

Several epidemiological studies conducted in the USA and Europe concludes that both incidence and prevalence of cardiovascular diseases (CVDs) in elderly are increasing. The same prevalence patterns have been reported in Greece for this specific age group. Nearly two thirds of all deaths in women and men aged ≥ 65 years are associated to cardiovascular diseases. The increasing burden of cardiovascular diseases in the ageing population poses a substantial economic burden on societies and their health care systems. Early diagnosis, prevention, detection, therapy and prognosis of cardiovascular diseases in the elderly can enhance both the quality and the quantity of their lives.

The inCASA infrastructure will give the healthcare professionals at the Department of Cardiology of KGHNI the opportunity to have a close follow-up of the Congestive Heart Failure patients; estimate the efficacy and safety of the medical treatment; make the appropriate regulation of the medication dose; detect acute changes in the patient's situation; and instigate early treatment of acute problems with either clinical or social means.

In parallel, our target through the project is to demonstrate substantial prolongation of the time elderly people can continue to be at home, as well as the resulting increased efficiency of the social and health care systems. Through continuous monitoring, we will ensure best medical compliance for patients after discharge while staying at home. One step beyond stands the improvement of medical therapy if needed, the decrease of re-hospitalization need, the improvement of the quality of life for the patients and the improvement of quality and cost effectiveness of delivered health care services. Last not but least, a close follow-up of the social and psychological status of the patients through the participation into the project of KGHNI's social workers and expert psychologists will allow behaviour monitoring and early detect problematic situations, like depression; it is widely known that depression and Congestive Heart Failure are strongly correlated [1].

The main pilot objectives can be summarized as follows:

- improving the speed of delivery and the quality of the provided healthcare services while at the same time reducing costs;
- reducing the medical risks for the patients due to their continuous monitoring,
- reducing patients' anxiety about their medical condition;
- understanding the health condition of CHF patients in their real life at home by analysing the pilot results;
- discovering correlations between the patients' medical condition and everyday habits thus enabling the consolidation of the latter as early indicators of worsening clinical status;
- demonstrating that the active involvement of relatives and the assistance provided by social workers contribute to the patients' overall quality of life;
- prolong elderly patients independence by supporting them in their own home;
- enable early discharge of patients;
- Improve medical therapy in order to decrease the risk of hospital readmission.
- Detect and/or prevent depression.
- Manage an organizational cooperation between the participating units of the hospital into the project: The Cardiology Clinic, the Psychiatric Clinic and the Social Service.

6.1 Integrated Health and Social Services

The aim of the KGHNI pilot is to integrate social and health services in order to enhance the support offered to patients with Congestive Heart Failure and co-morbidities who live in their own home. The integrated services are designed to complement the established KGHNI pilot's medical services and aim to provide doctors early signs of a patient's deterioration (clinical) and to enhance the patients' quality of life (psychologically, functional-wise in home and in everyday activities).

Both components contribute to better CHF patients' prognosis while effectively reducing the risk of re-hospitalization and averting non-required visits to the hospital's out-patient clinic. To this end,

additionally to the clinical measurements, the activity of CHF patients in-home will also be monitored (habits model), since they generally suffer from reduced mobility. A reduction in their average daily mobility or change in their habits is a strong indicator of a worsening clinical status. Another explanation for this reduced activity could be the onset of depression, something very common in this particular patient group.

Specifically, depression is a common comorbid condition in heart failure and the two conditions have been shown to share similar underlying physiologic mechanisms [1]. The prevalence of depression in patients increases sharply with the severity of heart failure symptoms, an important consideration when confronting patients with worsening failure. A 2006 meta-analysis of 27 studies found a 21% incidence of clinically significant depression in patients with heart failure [2] additionally, depression leads to poorer outcomes in patients with heart failure, including increased risk of hospital readmission and death [3-5]. HF patients who have depressive symptoms are more than twice as likely to die or experience a cardiac event compared to other patients; major depression is a stronger predictor of mortality than is minor depression. Moreover, depression has a negative impact on every dimension of health-related quality of life for HF patients, including physical-social functioning and mental health [6]. Depression is also costly: in a 3-year retrospective study of community-based patients following a first hospitalization for heart failure, it was found that annualized adjusted total costs were nearly 30% greater for depressive patients and that inpatient and outpatient service utilization was also greater [7].

For the above reasons the KGHNI integrated social and health services are targeted towards a) mitigating health-related risks by employing combined Telehealth/Telecare views to assist doctors in identifying early on the deterioration of individual patients b) supporting the patients' everyday life, particularly in cases where their physical/social/in-home activities are also impaired by their psychological condition and/or other societal circumstances.

To achieve the first target, the inCASA TH and TC data monitoring facilities have been deeply integrated on the platform level to support unified modes of messages' exchange, reasoning on measured data and against automatically built - personalized habit profiles, and result alerts forwarding to involved actors and professional end-users (see following section). The Greek pilot will focus, during the extension period (Phase III), on establishing common views that will materially help clinicians to detect trends and possibly observe any correlation between changes in usual habits and any decline in physical health. This is an ambitious goal set towards meeting deficiencies in chronic CHF patients' treatment and follow-up; specifically empirical data indicates that sometimes a chronic patient's condition is getting worse for no apparent (at the time) reason or that people close to the patient often fail to recognize signs of deterioration (usually able to identify such signs in retrospect, after a serious incident has taken place – often dismissing too easily complaints from the elderly patient). The capitalization on the contextual TC data (personalized habits models) is expected to bring added-value to the delivered care, emphasizing the prevention of possibly life threating incidents and the reduction of re-hospitalizations, while at the same time reinforcing the sense of security of the patients and the people close to them.

Identified risks of the proposed approach are a) building effective combined TH/TC data and alerts views[2], b) the ability of professional users to identify correlations between the patients' health

[2] Presentation guidelines at present – subject to change: the clinical team should be able to open the clinical user interface and see both clinical and habits monitoring data visualized in tabular and graphical format;

condition and possible changes in their habits, c) failing to deliver appropriate response if other societal or psychological factors have been found to interfere with the daily activities and habits of the monitored patients. Regarding the first identified risk an effort will be made to better align with the professional users (doctors, nurses) requirements and suggestions during the pilot extension period. The second risk is expected to be partially mitigated by the lessons learnt during the combined services delivery period, while also a subsequent evaluation of the pilot findings will be conducted to see if “hard data” supports the empirically identified correlations between habits changes and clinical status of the patients. Furthermore, at this phase, changes or additions to the monitored TC parameters used to build the personalized habits model will be proposed; currently planned monitored parameters for the Greek pilot include TV usage, chair permanence and motion sensors all installed in the living-room of the patient’s home.

The third identified risk is actually more tangible and special provisions have been made at the service level to bring enhanced psychological and social support to the patients participating in the Greek pilot (second target). The use of the inCASA technical facilities can be viewed as a starting point for triggering Social Care services (internal or external to the hospital) and Psychology Clinic resources to offer additional assistance to these patients. In greater detail the organizational units directly involved in the delivery of the KGHNI health and social care integrated service are:

- Cardiology clinic. The KGHNI pilot is coordinated by the Cardiology clinic of the hospital. The appointed cardiologists and nurses who participate in the project will have the overall case management for every CHF patient monitored via the inCASA solution. Some of their tasks are: measurements monitoring, trend analysis, alerts management, interventions, medication change decisions etc.
- Social services: KGHNI social workers will have an active role in the framework of the inCASA project. They are responsible for the communication with patients and for making them feel that the inCASA solution as user-friendly as possible. The social workers may call the patient asking him/her to come to the hospital if doctors judge so. Moreover, they are asked to perform conferences with the patients in order to determine their psychological status and alert the doctors / psychologists if there is a need to. The latter will be achieved via the usage of specific questions, produced by experts from the Psychiatric Clinic, which will make it possible to extract useful information about the patient's mental and social well-being.
- Psychiatric clinic: KGHNI psychiatrists / psychologists define the questions posed to the patients by the social workers during their conference. These questions are formed with respect to the scientific standards of this domain. Moreover, KGHNI psychiatrists / psychologists are part of the inCASA chain, in terms of patient's psychological status evaluation through the analysis of the inCASA platform data. Last but not least, they perform face-to-face interviews with patients who are considered to face non-negligible social and psychological difficulties.

The following pathway exemplifies the different levels of intervention required when new health-related symptoms are consolidated from observed deviations in the patient’s habits or additional psychological/social factors are deduced to have a detrimental influence in their quality of life and everyday activities:

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patients should be prioritised in order of clinical need on the screen based on pre-defined rules; the data should be viewable for each individual patient.

1. Habits change detected: case of reduced mobility / activity of the monitored elderly patient at home (TV usage and chair permanence increase over a short period of time while motion detector indicating reduced mobility in the premises).
2. The system automatically produces an alert and the KGHNI professional user (Doctor / Nurse) monitoring the inCASA Portal acknowledges it.
3. The assigned Doctor checks if the patient's monitored health parameters (BP, Oxygen Saturation, Weight, Pulse) have also changed:
    a. The trends over monitored parameters indicate that the patient's medical condition may be deteriorating, but at a rate that didn't result in the automatic triggering of the health-related alerts by the inCASA platform.
    b. Monitored health parameters seem largely unchanged and the habit's change cannot be safely attributed to changes in medication or other registered interventions (if any recent).
4. Both cases require the Doctor to ask the patient to visit the outpatient clinic for further examinations (possibly expediting an already scheduled appointment with the patient).
5. The Doctor interviews the patient regarding his daily life (i.e. feeling depressed or isolated, increasingly in need for assistance for initiating/completing everyday functions), activities (i.e. loss of interest or pleasure), level of comfort or discomfort (i.e. during sleep or movement) to properly assess if new health-related symptoms have emerged and their relevance to his/her current condition (i.e. an increase in weight not rapid enough to be attributed to diuretics dosage but that can be related to reduced physical activity) or other societal/psychological factors may have also come into play. This informal interview is crucial in helping the doctor to determine whether:
    a. further medical examinations should be ordered for the patient and/or the medication should be adjusted,
    b. The patient should (also) be referred to the psychological/social services internal to the hospital.
6. In the first case, a thorough evaluation of the medical condition of the patient warrants that the risk of a future medical emergency or need for re-hospitalization is reduced.
7. If the latter case is also applicable, a Social Worker makes the first approach to the patient (as a result of the Doctor referral) and fixes an appointment for the patient with a Psychologist in the hospital.
8. The Psychologist reviews the patient case having also access to the medical records of the patient and recommendations provided by the Doctor along with the Telecare data accessible through the inCASA Consumer Applications. The Psychologist interviews the patient and employs standardized questionnaires or other methods to identify the underlying mental condition (if present) with greater specificity (i.e. depression - not to be confused with adjustment disorders; additional disorder examples: anxiety, phobias, and compulsive behaviours).
9.
    a. If the Psychologist can provide a solution (psychological support during a number of sessions, medication) then he/she can proceed with it. In the specific case where a depressive episode is diagnosed, the Psychologist may apply non-pharmacological interventions, such as cognitive behaviour therapy (CBT), or prescribe anti-depression medication after consulting the assigned cardiology Doctor to minimize the risk of side-effects from medication.
    b. Effective treatment of a psychological condition, such as depression, may also help mitigate the risk of associated conditions like sleep apnoea syndromes or low heart rate variability (HRV); both conditions have adverse prognostic implications in heart failure patients.
    c. If the psychological condition diagnosed constitutes a barrier to effective heart failure self-care, increases the risk of patient non-compliance with prescribed medication, or induces impairments in one or more important areas of functioning

(social, occupational etc.) the Psychologist may consider complementing the patient's treatment with assistance offered by social services and/or educate people that are close to the patient (i.e. family, informal carers, etc.).

d. Even if no psychological condition is diagnosed, the Psychologist may nevertheless seek the assistance of Social Services, especially if the patient has been proven to have significant social problems (poor and/or frail and/or without strong familiar support).

10. The most appropriate level of social care intervention is decided in coordination with the Hospital Social Care service: i.e. direct assistance to the patient may be better accommodated by referring patients to nation-wide or regional social services such as "Help at Home" (http://old.50plus.gr/en/helpathome) rather than employing the comparatively constrained resources of the hospital internal services.

11. In the latter case, the social services of the hospital help elderly patients to prepare their inclusion application (eligibility criteria, notifying external social service), and communicates the pertinent details to the external services.

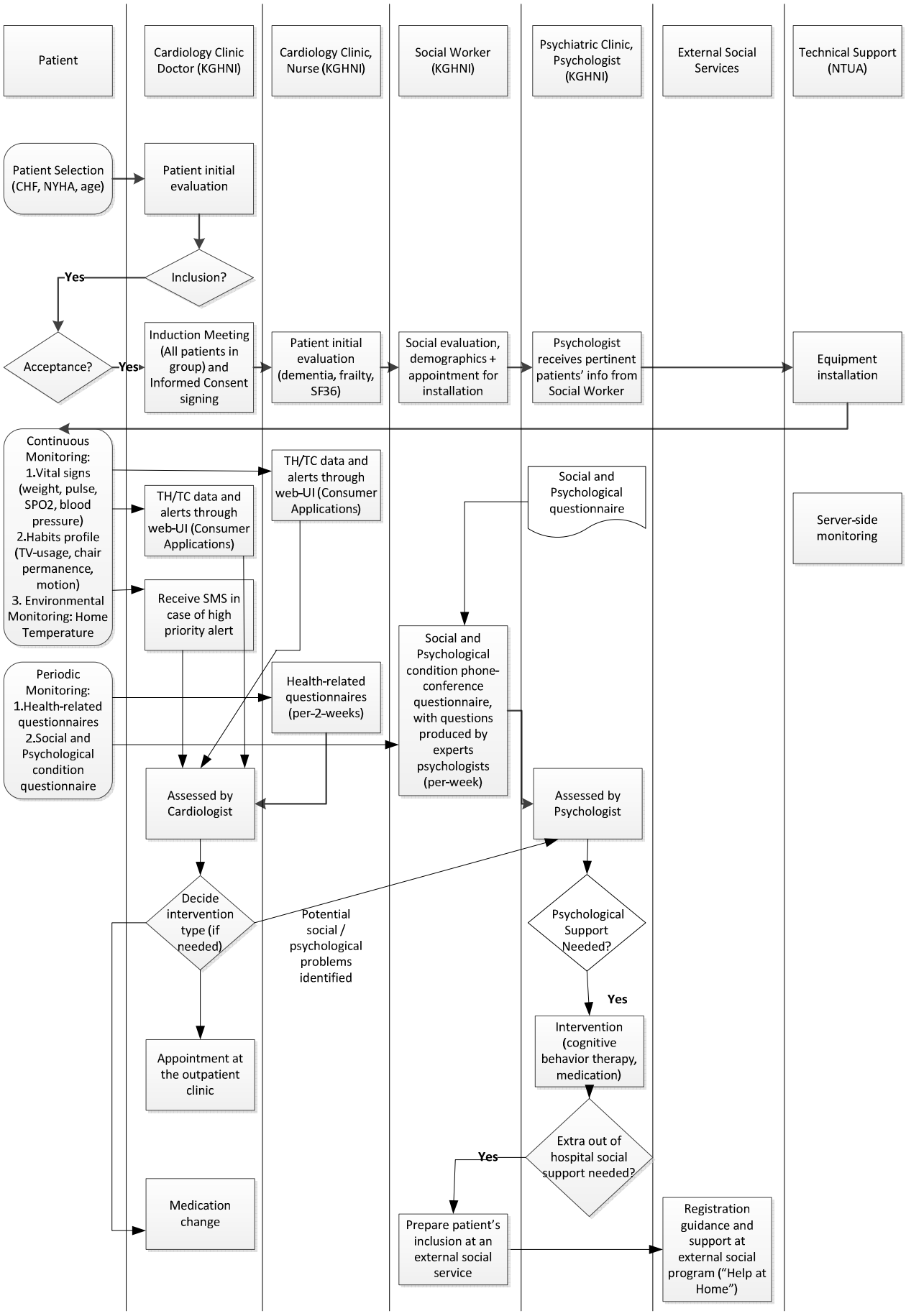
Patient
Cardiology Clinic Doctor (KGHNI)
Cardiology Clinic, Nurse (KGHNI)
Social Worker (KGHNI)
Psychiatric Clinic, Psychologist (KGHNI)
External Social Services
Technical Support (NTUA)
Patient Selection (CHF, NYHA, age)
Patient initial evaluation
Inclusion?
Yes
Acceptance?
Yes
Induction Meeting (All patients in group) and Informed Consent signing
Patient initial evaluation (dementia, frailty, SF36)
Social evaluation, demographics + appointment for installation
Psychologist receives pertinent patients' info from Social Worker
Equipment installation
Continuous Monitoring: 1.Vital signs (weight, pulse, SPO2, blood pressure) 2.Habits profile (TV-usage, chair permanence, motion) 3. Environmental Monitoring: Home Temperature
TH/TC data and alerts through web-UI (Consumer Applications)
TH/TC data and alerts through web-UI (Consumer Applications)
Social and Psychological questionnaire
Server-side monitoring
Receive SMS in case of high priority alert
Social and Psychological condition phone-conference questionnaire, with questions produced by experts psychologists (per-week)
Periodic Monitoring: 1.Health-related questionnaires 2.Social and Psychological condition questionnaire
Health-related questionnaires (per-2-weeks)
Assessed by Cardiologist
Assessed by Psychologist
Decide intervention type (if needed)
Potential social / psychological problems identified
Psychological Support Needed?
Yes
Intervention (cognitive behavior therapy, medication)
Appointment at the outpatient clinic
Extra out of hospital social support needed?
Yes
Medication change
Prepare patient's inclusion at an external social service
Registration guidance and support at external social program ("Help at Home")

Figure 29 KGHNI Integrated Workflow

6.2 TC and TH Technical Integration

One of the major KGHNI's goals in the framework of the inCASA project is to provide integrated Telecare - Telehealth services. In order for this to be feasible, a relevant integration of the two fields at a technical level is required. NTUA is the associated technical partner of KGHNI, responsible for its technical integration design and deployment.

KGHNI makes use of the inCASA reference architecture, as it is analysed in WP3 deliverables. More specifically, the architecture scheme that adapts to KGHNI Pilot needs is depicted below.

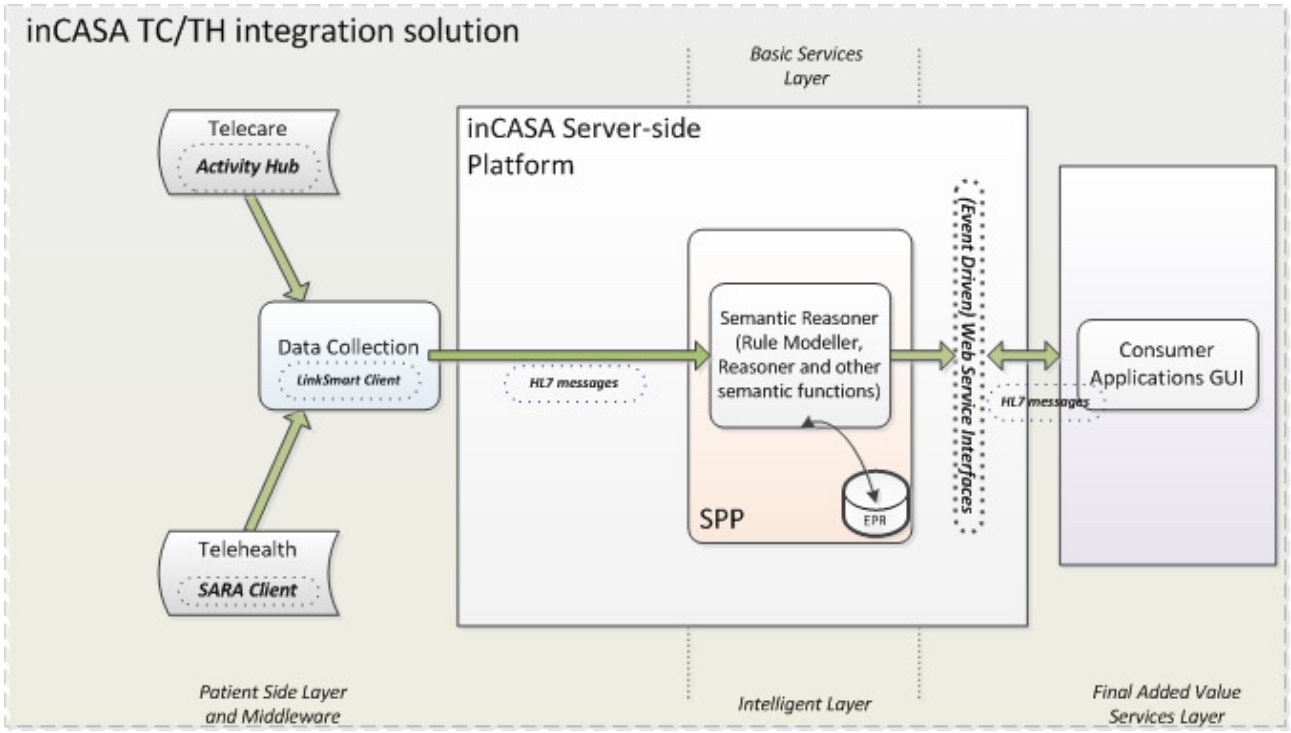

Figure 30 KGHNI Health and Social Technical Integration

The high-level description of the system components used follows:

- The Activity Hub, provided by SIG, stands as the Telecare Gateway. The Hub is installed at every patient's home and receives wirelessly the data produced by the Telecare sensors, which in our case are temperature, motion, chair and TV usage sensors.
- The SARA software, provided by TID, stands as the Telehealth Gateway. SARA is installed at every all-in-one PC that is set up for every patient. It offers the appropriate user interfaces that enable patients to perform health measurements which are collected by SARA via Bluetooth communication with the corresponding medical device, namely Blood pressure monitor, Pulse Oximeter and Weight scale.
- The LinkSmart Middleware, provided by CNET, is the software part, installed at patient's PC, that receives both Telecare and Telehealth data from the aforementioned gateways. It is responsible for data collection, aggregation, transformation into standard HL7 messages and finally transmission to the server side of the platform - to the SPP.
- The SPP, provided by Reply, is a server-side component that stands as the master inCASA repository of all collected data. Meanwhile, it encompasses the needed intelligence for

profiling user habits and alarming while detecting divergence from the "built" profile. It is also the master component for all alerts produced in the inCASA system.

- The Consumer Applications, provided by NTUA, stand as the Professional's Web Portal that is the single point of access to the inCASA data. The developed Web Portal provides role-based access to the different professionals (Doctors, nurses, socials workers, operators) and, basically, presents patient's data and alerts at a user friendly manner accompanied with useful graphical representations. Moreover, the Consumer Applications include logic to trigger the Doctors when appropriate, e.g. send SMS in case of a high-priority alert.

For all these components to work smoothly together, a long testing and bug fixing period was needed. Finally, KGHNI is able to deploy this integrated solution within September 2012.
For sure, the previous phase of the Pilot helped significantly in identifying and solving problems concerning the Telehealth part of the solution. Concerning the Telecare part, lots of simulations and tests during June - August 2012, performed mainly by the NTUA team, were needed in order for the overall solution to be ready for deployment.

6.3 Description of Stakeholders

The professional stakeholders involved in the project are depicted in the following table, where their role is also summarized.

Job Title	Number from this category involved	Role summary
KGHNI cardiologists	5	They coordinate the Pilot activities. Responsible for patient's recruitment, data monitoring, alerts processing, interventions and pilot evaluation. As they coordinate all activities, they should also report any raised ethical issue to the hospital's ethical committee and to the inCASA ethical board too.
KGHNI Social workers	2	Responsible for the communication with the patients (appointment fixing etc). Also responsible for carrying out via phone calls with the patients the depression questionnaires that will be included in the final phase (Telecare / Telehealth integration)
KGHNI Psychologists	2	Responsible for the psychological status assessment and for the habits change alarms assessment. They are the ones to form the psychological status monitoring questionnaires, like the depression diagnosis questionnaire, and to score them.
NTUA	4	The NTUA technicians designed

technicians		the whole KGHNI Pilot architecture and customized the inCASA reference architecture in order to fit KGHNI's needs. Their role includes equipment installation and de-installation, system deployment, administration and technical support.

Table 12 KGHNI Stakeholders

6.4 Pilot timetable

The Greek pilot started on March 2012 with its Telehealth phase, after a successful conclusion of the pre-pilot and its evaluation, and is planned to be concluded by June 2013, when the evaluation of the pilot activities will also have been completed. So far, 15 out of the projected total of 25 CHF patients have been included in the Pilot, 5 of them (3rd group) are currently active while the remaining 10 have already ended their participation in the program. Sept. 2012 is the next milestone for pilot activities since Telehealth phase will come to an end and the combined Social-Health services phase will be introduced. The latter will stand as the final solution provided by KGHNI in the framework of the inCASA project.

The detailed timetable of the pilot activities is presented in the following table.

Date	Action
March 2012	Pilot Start - Telehealth Pilot phase
1st week of March 2012	Pilot Users' Home Inspection and Consent Forms (1st group of 5 patients)
2nd week of March 2012	Pilot Equipment Installation, Training and Testing
3rd and 4th week March 2012	Patient Questionnaires / Patients started taking measurements
April 2012	End of participation for 1st group
May 2012	2nd group initiated
3rd and 4th week of June	End of participation for 2nd group
July 2012	3rd group initiated (on-going)
August 2012	Testing Integrated Telehealth/Telecare inCASA platform (1 patient)
3rd and 4th week of August	End of participation for 3rd group
4th week of August	Evaluation of Telehealth Pilot phase
September 2012	Pilot with Integrated Telehealth/Telecare services begins 4th group is initiated
End of November 2012	End of participation for 4th group
December 2012	5th and final group is initiated
April 2012	Conclusion of Pilot monitoring and final evaluation beginning
May-June 2013	Conclusion of evaluation and of Pilot activities overall

Table 13 KGHNI Pilot Timetable

6.5 Pre-pilot installation Summary

KGHNI implemented one of the use cases (Body weight) in the Pre-Pilot phase. Body weight measurement was selected as it is the most common use-case among the inCASA pilots in order to give to the project a common basic layer in this first phase. The Pre-Pilot phase was finally initiated on October 2011 and was concluded on December 2011. Three patients participated in that phase. They all already had good rapport with the doctors and were willing to provide feedback.

The deployment of the pre-pilot was based on the SARA platform and supported by TID (software) and NTUA (installations), as stated into D6.2 "Pre-Pilot Installation Reports" . KGHNI tested the platform with the use of body weight scales and user-friendly touch screen PCs supporting the operation of SARA platform. The feedback provided by doctors and patients helped to propose enhancements regarding deployment and the usability of the client measurements software. Also, the experiences gathered and lessons learned during the pre-pilot were internalized in the KGHNI cardiology department and enabled the specification of more robust operational procedures for the main pilot phase. No ethical issue was raised during the Pre-pilot period.

6.6 Pilot Installation

6.6.1 Start dates

The Greek pilot started on March 2012 when the first installations also took place. These first installations included the following deployment list at a patient's house:

- All-in-one PC with touch screen
- Weight scale
- Blood pressure monitor
- Pulse Oximeter

Starting from September 2012, the deployment list also includes the following extra system components that allow the simultaneous Telehealth / Telecare monitoring:

- Activity Hub
- Motion / Temperature Sensor
- TV usage sensor
- Chair contact sensor

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6.6.2 Sample Description

The pilot will include 25 patients who are 60 years and over who have a primary diagnosis of Chronic Heart Failure and are followed by the Cardiology clinic of KGHNI. Patients may also have co-morbidities, like diabetes mellitus.

The various characteristics of the sample follow in summary:

- They are all diagnosed with CHF
- They all have low or medium income

- ~90% are men and ~10% women
- Their average age is 66
- They are all citizens of Athens and their homes are less than 5Km away from the hospital.

6.6.3 Recruitment

The recruitment process is described in more detail into D2.5 "National Pilot Blue Print". Concerning the recruitment status, 20 out of a target total of 25 patients have been already recruited for the inCASA pilot participation. From this set of 20 patients, 15 have been already included in the program. The remaining not yet recruited patients form the last group of 5 patients that will be included into the program in December 2012. Their recruitment is planned to have been finished by mid November 2012.

6.6.4 Installation

For every installation, some actions should take place prior to the on-site equipment installation. These include:

- Patient (User) creation at the server side of the platform - this is done by NTUA technicians having as input the patient's data provided by the cardiologists.
- Patient's "Kit" configuration at the server side of the platform - this is again done by NTUA technicians.
- Appointment fixing for equipment installation after specific communication with the patients managed by the social workers team.

The above preparatory work is estimated overall at 2 working hours.

The actual on-site installation is an approximately 3 hour’s process that contains the following actions:

- All-in-one PC setup and installation of inCASA software
- Activity Hub setup
- Sensors set-up and medical devices provisioning
- Informed consent signing from the part of the patient. This consent form has already been communicated and explained to the patient via the initial phone conference with the social worker or via the face to face inclusion meeting with the doctor. The patient should have declared its willingness to sign it. Otherwise, he/she could not be chosen for inclusion. The consent form that is used by KGHNI pilot can be found at the **Errore. L'origine riferimento non è stata trovata.** of this document.
- Hard copies of questionnaires to be filled in at the beginning and at the end of the study (inCASA common questionnaires, Kansas City Cardiomyopathy Questionnaire, EQ-5D health outcome test (Euroqol)). It should be noted that, in the final phase of KGHNI pilot, during the patient's monitoring period it is planned to include depression diagnosis questionnaires as already stated in this document. These questionnaires will be managed

via phone conferences with the social workers team and they will not be delivered as hard copies to the patients.

6.6.4.1 Installation of Equipment

The equipment installation is an approximately 3 hours process that, in more detail than previously stated, is spitted into the following technical tasks, all performed by the NTUA technicians team:

- Telecare sensors installation
  - **Motion Detection** / **Temperature Sensor** - Netvox Z-B01C
  - **Chair sensor -** Funkstuhl Transmitting Chair
  - **TV usage sensor** (Power Socket with Power Consumption Monitoring) - Netvox Z-800
- Activity Hub (Telecare gateway) deployment and connection with patient's PC
- Telehealth devices pairing with patient's PC
  - **Weight Scale** - A&D Medical UC-321-PBT
  - **Blood Pressure Monitor** - A&D Medical UA-767-PBT
  - **Pulse Oximeter** - Nonin Onyx II 9560
- SARA software (Telehealth gateway) installation into patient's PC
- LinkSmart middleware installation
- LinkSmart configuration for server-side communication

The above tasks are supposed to take place to support the Telehealth / Telecare integrated platform and are a super set of the required tasks to support the Telehealth solution. For the Telehealth solution to run independently, as done in the previous phase of the Pilot, only the following steps are required:

- Telehealth devices pairing with patient's PC
- SARA software (Telehealth gateway) installation into patient's PC

All "real" installations till now (15), support only the Telehealth solution. The remaining 10 installations will be done in order to support the Telehealth / Telecare integrated platform.

Below, there are shown pictures from the installation process of the combined Telehealth / Telecare solution. These pictures are taken from the test patient's environment; these tests towards the combined Telehealth / Telecare integrated platform deployment run during August 2012, as shown in the Pilot schedule.

Figure 31 Activity Hub connection with ADSL router

Figure 32 Chair sensor placement

Figure 33 Motion sensor placement

Figure 34 TV usage sensor connection

Concerning the medical devices, no specific connection is required. The only limitation is that they should not be in such distance away from the PC where the Bluetooth connection between the device and the PC cannot be established. Pictures of the medical devices used in the KGHNI pilot can be found below:

Figure 35 Blood pressure monitor

Figure 36 Weight scale

Figure 37 Pulse Oximeter

After installation is completed, NTUA technicians perform a test suite in order to assure well-functioning of the platform. This test suite includes numerous sub-tests; as a representative example, technicians may check the system logs after a blood pressure measurement and check that the correct HL7 message is generated by the middleware (LinkSmart). Such log may look like the following:

```
Xml file received: systolic     NR: 1
Xml file received: diastolic    NR: 2
Xml file received: pulse        NR: 3
Logger enabled
Measurement logger enabled

Initializing the TIL
MedicalObservationService_SetEquipmentID(00A096FFFE0D3BA2)
Systolic: 125
Unit:
Diastolic: 80
Unit:
Timestamp: 20120904131101+0300

DIM parser initializeMedicalObservationService_GetObservation()
ORUR01 message sent to WS
MSH|^~\&|SPP||LINKSMART||20120904131102+0300||ACK^R01^ACK|188|P|2.6|||NE|AL||885
MSA|AA|477BDB0F4B4139E PCD^1.3.6.1.4.1.19376.1.6.1.1^ISO
```

Figure 38 Middleware log after a blood pressure measurement

6.6.5 Monitoring Process / Protocols

With respect to the Telehealth domain, several clinical parameters are monitored during the pilot phase:

1. *Body weight*: An increase weight i.e. 1 kilo per day over maximum 2 days is an indication of body fluid retention i.e. worsening of condition, which needs proper intervention of a doctor.
2. *Blood pressure*: With the measurement of systolic, diastolic and average blood pressure of patients doctors can estimate the efficacy of the medications and the appropriate dosage.
3. *Pulse oximetry*: Trends of the values of oxygen saturation (SO2) can predict if the patient is deteriorating. Doctors can then increase the medication or ask the patient to come to the hospital before the situation becomes critical.
4. *Heart rate*: When a divergence in heart rate is observed, it may mean alteration of the clinical status of the patient.

These clinical parameters and their historical trends are continuously monitored by the assigned personnel at the KGHNI Operator Centre. The measurements and the corresponding medical alerts will be displayed through the Consumer Applications web interface.

The clinical protocols specified for handling emergencies may require the intervention of hospital personnel, relatives/neighbours and social workers (involved actors) depending on their escalation. Herein is presented a generic clinical protocol for handling all types of medical emergencies that can be further customized in accordance to:

- Generic thresholds or normalcy ranges for the specific measurements that may be further personalized for each patient (i.e. patients with concomitant problems).
- Alerting that may be triggered based on the current measurement or by a specific trend automatically detected by the inCASA platform.
- Cardiologist doctor response to the specific alert, based on its severity that may require either the adjustment of medications or may require the visit of the patient to the clinic for further examinations.
- The patient response to the suggested action by the doctor.

The following table summarizes the conditions specified for the individual clinical measurement types that may require the intervention of the operators' personnel and the doctors.

Alerts for	Consistent increasing OR decreasing[1]	Unexpected levels of change over defined time scale[1]	Away from optimal OR expected values[2]	Outside normal limits[2]
Body weight	X	X	X	
Pulse oximetry		X	X	
Blood pressure			X	X
Heart rate				X

Table 14 KGHNI Intervention Protocol
[1] *Related to trend;* [2] *Related to current measurement*

The generic clinical protocol for the Greek pilot use-cases is presented in the following picture:

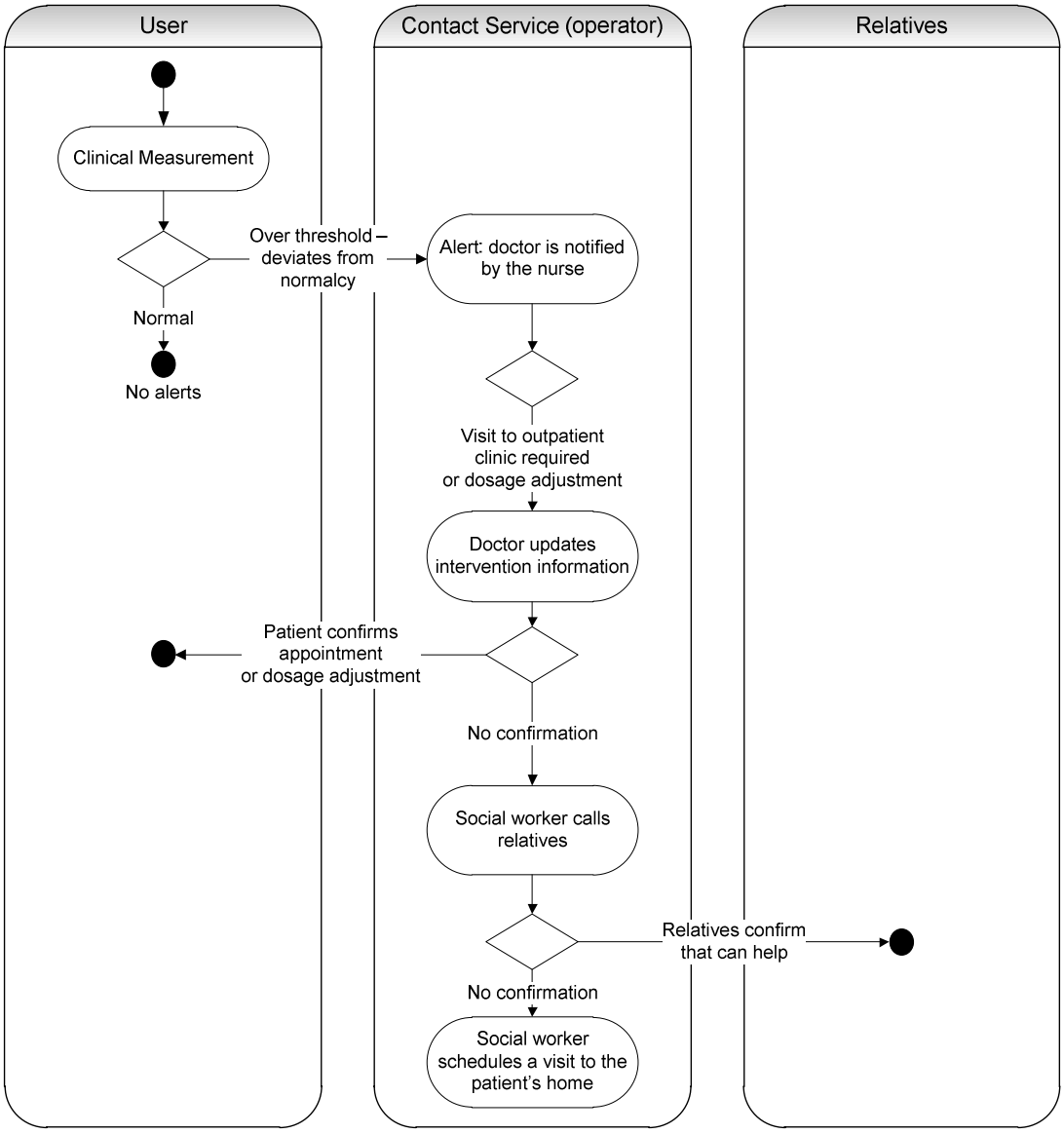

Figure 39 KGHNI Protocol for Clinical Measurements

When the clinical measurement deviates from normalcy, after taking into consideration personalized thresholds or if the patient suffers from a concomitant condition, then:

1. The operator (nurse) at KGHNI is informed of the pertinent alert, displayed in the Consumer Application.
2. The KGHNI nurse notifies the cardiologist.
3. The cardiologist assesses whether there should be an adjustment to the patient medication or the patient should visit the outpatient clinic for further physical examinations.
4. The doctor notifies the patient accordingly through the Consumer Application interface. Practically, an SMS is generated and forwarded to the patient cell-phone describing the medication change required or notifying him/her to visit the clinic, as soon as this activity is registered. Alternatively the doctor contacts the patient by phone.
5. If the patient doesn't confirm the appointment or the medication change, then the nurse notifies the assigned social worker to communicate with the patient's relatives.
6. The operator can write a note associated to the alert, and mark it as "handled" or "forwarded to" in case the alert is forwarded to the social services.

7. When the clinical measurement returns to normalcy, the personnel in KGHNI are notified through the Consumer Application interface.

The integrated KGHNI social-health services are designed to complement the established medical services and aim to provide doctors early-on signs of patient's deterioration (clinical) and to enhance the patients' quality of life (psychologically, functional-wise in home and in everyday activities). Both components contribute to better CHF patients' prognosis while effectively reducing the risk of re-hospitalization and averting non-required visits to the hospital's out-patient clinic.

The synergies between the different KGHNI pilot actors and the result cascading interventions over both the Health and Social care domains have already been described.

6.7 Challenges

6.7.1 Patient

A major challenge identified during the Pilot life till now, is the usual complete lack of PC usage skills from the part of the patients. Taking into consideration their age which is usually more than 65 years, this may sound logical. Of course the inCASA platform is not technology skills demanding and this was one of its main design principles. However, manual actions like restarting the all-in-one PC after a blackout cannot be avoided and some patients have shown difficulties in accomplishing them. It is proven, in fact, that the presence of a familiar younger person is quite useful for the elderly people in order for them to adapt to the new technologies usage; until this moment, the KGHNI inCASA patients that have not complained at all about the platform's usage are the ones that live together with their son(s) or daughter(s).
It is worth mentioning that none of the patients has shown some inconvenience from the daily usage of medical devices, such as the blood pressure monitor. This can be justified by the fact that CHF patients are well familiarized with such devices and know that this monitoring may help them to live more and better.

6.7.2 Professional

A challenge identified until now in the KGHNI pilot life, has to do with the nature of the Cardiologist profession. There are some times when the Cardiologist Case Manager has planned to cross-check the inCASA platform's data but this was not finally manageable due to some external urgency, e.g. a new urgent incident inside the Cardiology Clinic. This challenge is judged as minor and it can be over-passed with better team organization.

6.7.3 Organisational

Organisational challenges are quite important in the framework of the KGHNI pilot. The Pilot requires a close synergy between the Cardiology Clinic, the Social Service and the Psychiatric Clinic. These units were, till now, not much correlated and cooperation between them was more or less non-existent inside the hospital. The inCASA project brought them working together and this is a challenge by itself.
An even bigger challenge would rise if there would be a need for close synergy between a KGHNI internal and an external unit, like an external social service.

6.7.4 Technical

Technical challenges may be summarized as follows:

- Create an always up and running platform with as less as possible patient's intervention.
- Challenging to configure the various software programs to run as services in order to manage their automatic start up.
- Manage to resubmit automatically to the server all failed messages due to temporary Internet connection loss from the patient's home side (Client side)

A key factor remains the effective combination of Telehealth and Telecare data representation (i.e. tabbed views & unified alerts view) which is currently an open research topic; consequently a trial and error approach will be followed during the Greek pilot.

6.7.5 Resource

Obviously, KGHNI, as all other hospitals, has limited resources in terms of human personnel. It is thus challenging to manage to run a project like inCASA which is innovative for the Greek state - so a few previous experiences exists - and demanding as it requires close follow-up, deep and correlated data analysis and not delayed interventions.

6.8 Deviations from Pilot Plan

The following table summarize the major deviations from the initial Pilot Plan:

Deviation	Description	Corrective Action
Delays in procurement for TH equipment in Pilot	One month delay in the equipment procurement due to administrative reasons caused the Pilot to start at the beginning of March 2012.	Procedures established hereafter allow for the early planning of devices/equipment procurement.
Changes introduced to Use Cases in Pilot	During the 2nd update and consolidation of the user requirement, implementation and other risks were weighted against the contribution of each use-case to the pilot objectives: 1. UC-KGHNI-5 Heart Rhythm: high equipment cost, limited availability (only one device), not controlled measurement environment, patients' reluctance to wear a device 24 hours a day, high implementation risk in interfacing the inCASA platform with the specialized KGHNI cardiology clinic software. 2. UC-KGHNI-6 Blood Glucose: limited applicability; so far no patients were recruited that also suffer from diabetes mellitus. 3. UC-KGHNI-7 INR: superseded by	It was decided that the enlisted use cases (Heart Rhythm, Blood Glucose, INR, Movement), originally planned to be gradually introduced during the pilot, will not be implemented. Specifically, the motion sensor will be used in the combined Telehealth / Telecare service deployment to complement the other TC data feeds.

	other more accurate clinical measurements. 4. UC-KGHNI-8 Movement: limited sensor accuracy; implementation risks in automating the NYHA classification.	
Technical challenges prior to final Pilot Phase (Telehealth / Telecare integration)	The planned transition from an all SARA platform deployment to an integrated Telehealth/Telecare inCASA solution required testing of the new components to be deployed (Linksmart, Consumer Applications, SPP).	The transition to an integrated social-health care delivery model was preceded by a pilot installation of the related inCASA services for a single test user throughout August 2012. The remaining scheduled groups of patients (September 2012 until pilot conclusion) will see the deployment of the fully integrated inCASA services.

Table 15 Deviations from Pilot Plan

7 References

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