



D7.2 INTERIM PROCESS EVALUATION REPORT

WP7 Evaluation

Version 1.0, date 30th November 2015

The CareWell project is co-funded by the European Commission within the ICT Policy Support Programme of the Competitiveness and Innovation Framework Programme (CIP). Grant Agreement No.: 620983

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DOCUMENT INFORMATION

ABSTRACT

This deliverable presents the preliminary results of CareWell on a site by site basis. All sites were requested to provide their current flow chart and input for a table on demographic characteristics of end users.

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DELIVERY DATE

30th November 2015

DISSEMINATION LEVEL

P Public

VERSION HISTORY

Version	Date	Changes made	By
0.1	01/09/2015	Table of contents added and guidelines	Signe Daugbjerg
0.2	10/09/2015	Structure of the document modified	Ane Fullaondo
0.3	20/09/2015		Ane Fullaondo
0.4	01/10/2015	Input of pilot sites for Domain 1	Ane Fullaondo
0.5	25/10/2015	Contribution of pilot sites for Domain 2 and 3	Sara Ponce
0.6	05/11/2015	Inclusion of local analysis of Veneto, Basque Country, Veneto, Puglia and Lower Silesia	Itziar Vergara and Maider Mateo
0.7	15/11/2015	Interpretation of results by each pilot site	Francesco Marchet
0.8	26/11/2015	Results of the analysis of Croatia	Vanessa Bencovic
0.9	27/11/2015	Conclusions	Itziar Vergara
1.0	30/11/2015	First version for issue	John Oates



OUTSTANDING ISSUES

A more comprehensive baseline analysis will be reported in the version 2, due mid-February 2016. This amended document will include the quantitative analysis of the whole sample size and the process evaluation results.

FILENAME

D7.2 v1.0 CareWell First interim evaluation report

STATEMENT OF ORIGINALITY

This deliverable contains original unpublished work except where clearly indicated otherwise.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



Executive Summary

This deliverable presents the preliminary results of CareWell gathered by the means, metrics and instruments defined in the evaluation framework (deliverable D7.1) on a pilot site level.

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1. Introduction

1.1 Purpose of the document

Deliverable D7.2 Interim Evaluation Report describes the preliminary results of CareWell at a local pilot site level.

This first interim report presents the background and first steps of the CareWell project. The MAST evaluation model has used as the framework for the comprehensive evaluation of this project.

A more comprehensive baseline analysis will be reported in the version 2 of this deliverable, due mid-February 2016. This amended document will include the quantitative analysis of the whole sample size and the process evaluation results.

1.2 Structure of the document

The document is presented according to the MAST domains:

- Chapter 2 presents the results of Domain 1 - Description of the health problem and characteristics of the application of the intervention.
- Chapter 3 presents the results of Domain 2 and 3: Safety, clinical and social effectiveness

The guideline for the pilot sites on how the analyses should be carried out and presented in the deliverable are attached as Annex 1

1.3 Glossary

ADA	American Diabetes Association
COPD	Chronic Obstructive Pulmonary Disease
CVD	Cardiovascular Disease
EASD	European Association for the Study of Diabetes
EHR	Electronic Healthcare Record
F2F	Face-to-face
GP	General Practitioner
HIS	Hospital Information System
ICT	Information & Communication Technology
IDF	International Diabetes Federation
LIS	Laboratory Information System
NCD	Non-Communicable Diseases
RIS	Radiology Information System
WHO	World Health Organisation

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

2.1 Description of the health problem

2.1.1 Chronic obstructive pulmonary disease (COPD)

Chronic obstructive pulmonary disease (COPD) is an umbrella term for a number of lung diseases that prevent proper breathing. Three of the most common conditions are emphysema, chronic bronchitis, and chronic asthma that is not fully reversible. These conditions can occur separately or together. The main symptoms are breathlessness, chronic cough and sputum production. Cigarette smokers and ex-smokers are most at risk. COPD used to be more common in men, but the disease is quite evenly spread across the sexes now that women and men smoke in equal numbers. Typically, COPD develops so slowly that the person does not realise their ability to breathe is gradually becoming impaired. The damage done to the lungs can be considerable before the symptoms are severe enough to notice.

Symptoms include: breathlessness after exertion (in severe cases, breathlessness even when at rest); wheezing, coughing, coughing up sputum, fatigue; cyanosis.

A person with COPD is at increased risk of a number of complications, including: chest infections and pneumonia, collapsed lung, heart problems and oedema (fluid retention), hypoxemia, anxiety and depression, risks of sedentary lifestyle and osteoporosis (as side effect of the corticoid treatment).

The 2011 update of the GOLD guidelines¹ acknowledges that acute episodes of exacerbation in patients with COPD constitute a major deleterious factor, negatively modulating several dimensions of the disease, namely: deteriorates patient's quality of life, increases the use of healthcare resources, accelerates COPD progress, and it has a negative impact on patient's prognosis. Moreover, it has been demonstrated that hospital admissions due to severe episodes of COPD exacerbation constitute the most important factor determining the disease burden in the health system. Consequently, early detection and self-management of COPD exacerbations, as well as policies to prevent unplanned hospital admissions of COPD patients due to acute episodes of the disease, seem to constitute the two pivotal priorities in COPD management.

2.1.2 Burden of the disease

COPD is a highly prevalent chronic condition affecting approximately 9% of the adult population (>45 yrs). In Europe, the disease is mainly caused by tobacco smoke in susceptible subjects. It has a high degree of under-diagnosis (approximately 70%), but it shows an elevated degree of heterogeneity. Organisation of healthcare in COPD patients requires a proper assessment of risk and subsequent generation of stratification criteria.

The disease is currently the fourth cause of death worldwide with a trend to increase during the next years. It is estimated that COPD will be the third cause of disease in 2020. The disease burden on the health system is mainly due to hospital admissions and

1 Vestbo J, Hurd SS, Agustí AG, Jones PW, Vogelmeier C, Anzueto A, Barnes PJ, Fabbri LM, Martinez FJ, Nishimura M, Stockley RA, Sin DD, Rodriguez-Roisin R. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. *Am J Respir Crit Care Med.* 2013.15;187(4):347-65



complications associated with frequent co-morbid conditions, including the highly prevalent non-communicable diseases (NCDs) such as cardiovascular disorders and type 2 diabetes mellitus. COPD is part of the main chronic disorders of the WHO's programme for NCDs which is one of the health priority issues at worldwide level, as shown by the United Nations General Assembly devoted to the topic in 2011². A recent update on the high impact of COPD in terms of deaths, years of life lost, years lived with disability and DALY's has recently (2013) been reported in the *New Engl J of Med*³.

2.1.3 Diabetes Mellitus (type 1 and type 2)

Diabetes mellitus type 2 is a metabolic disease characterised by a relative deficit of insulin secretion, that generally increases over time, but never leads to an absolute hormone lack, and that is normally the consequence of a more or less severe insulin resistance on a multifactorial basis. Therefore, diabetes mellitus causes a persistent instability of blood glycaemic level, going from hyperglycaemia (more frequent) to hypoglycaemia.

Diabetes mellitus type 2 represents about 90% of diabetes cases, while the remaining 10% is mainly due to diabetes mellitus type 1 and to gestational diabetes⁴.

First usual symptoms for diabetic patient are polyuria (frequent urination), polydipsia (increased thirst), polyphagia (increased hunger) and weight loss. Other symptoms commonly present at diagnosis are: blurred vision, itch and peripheral neuropathy.

Lots of people are not affected by symptoms in the first years, and the diagnosis is made only through routine tests. In the case of too low or too high glycaemic levels, patients with diabetes mellitus type 2 may suffer from hyperglycaemic hyperosmolar nonketotic coma (e.g. very high level of sugar in blood, associated with a decrease of consciousness and hypotension level).

The clinical diagnosis of diabetes mellitus type 2 is normally anticipated by an asymptomatic phase of about seven years⁵, during which hyperglycaemia causes deleterious effects at target tissues level, so that at the moment of clinical diagnosis the complications of the disease are already present.

The World Health Organisation recognises diabetes (type 1 and type 2) after the detection of high glucose levels and the presence of typical symptoms. Diabetes can be diagnosed through one of the following:

- Glycaemia on fasting ≥ 126 mg/dl (on a sample taken at about 8 a.m. after at least eight hours of fasting).
- Glycaemia ≥ 200 mg/dl two hours after 75 g glucose oral consumption (OGTT)⁵.

In 2009, an international committee of experts, including representatives of ADA, IDF and EASD, recommended a level of HbA1c $\geq 6,5\%$ to be used for diabetes diagnosis. ADA adopted this recommendation in 2010.

² 2011 High Level Meeting on Prevention and Control of Non-Communicable Diseases. General Assembly. New York. 19-20 September 2011. "Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases". Document A/66/L.1. <http://www.un.org/en/ga/ncdmeeting2011/>

³ Murray CJ, Lopez AD. Measuring the global burden of disease. *N Engl J Med*. 2013;369(5):448-57

⁴ WHO 2012

⁵ "Standard italiani per la cura del diabete mellito tipo 2" – Società Italiana di Medicina Generale, Associazione Medici Diabetologici – Società Italiana di Diabetologia – 2011 Infomedica, Formazione & Informazione Medica



Once the pathology is diagnosed, the most important value to monitor the clinical course of diabetes is the glycosylated haemoglobin (HbA1c). The higher the glycaemia is, the higher the glycosylated haemoglobin levels will be. As the haemoglobin is carried into red blood cells having an average life of 120 days, the HbA1c value reflects the control on glucose levels in the three months before the analysis. Generally, a value lower than 6.1% is considered as normal. The typical HbA1c value in diabetic patients is around 7% or even 6.5%⁶.

The persistence over years of moderately high glycaemia levels can in the end cause complications:

- Cardiovascular diseases, for example hypertriglyceridemia and hypertension.
- Diabetic nephropathy that affected 20-40% of diabetic patients; it is the main cause of nephropathy in terminal phase.
- Retinopathy that is strictly correlated to the duration of diabetes and can be considered as the main cause of new cases of blindness in adults aged 20 to 74 years.
- Neuropathy that generally affect distal sensory nerves, altering the perception of vibration, temperature and pain in feet and hands.
- Ulceration that leads to foot amputation.

In-so-far as the disease may lead to the deterioration of other organs, diabetes mellitus type 2 can be considered a chronic disease associated with a life expectancy that is 10 years lower than average.

A certain number of factors correlated to lifestyle are known to be linked to the development of diabetes mellitus type 2, among which are obesity (defined by a body mass index higher or equal to 25 kg/m²), lack of physical exercise, bad diet (consumption of too many sugars or saturated fats), and cardiovascular risk factors. Moreover, there are people predisposed to the development of diabetes mellitus type 2, for example people with a family history of diabetes and women with previous events of gestational diabetes. In addition to this, there are some drugs that may predispose a person to diabetes. These drugs include glucocorticoids, thiazides, beta-blockers, atypical anti-psychotics and statins.

2.1.4 Burden of the disease

In 2010, about 285 million people in the world were estimated to suffer from diabetes mellitus type 2; this represents about 90% of diabetes cases, and about 6% of the world adult population. Traditionally considered as an adult disease, diabetes mellitus type 2 is now being diagnosed more frequently in children, in parallel with higher obesity rates⁷.

Diabetes complications can be extremely disabling, and compromise the functionality of essential organs: heart (myocardial infarction, heart diseases), kidneys (renal failure with the need of dialysis or transplantation), blood vessels (hypertension or other heart diseases, ictus, etc.), eyes (glaucoma, retinopathy, blindness, etc.). Personal and social consequences of diabetes are therefore a progressive loss of personal autonomy and of work skills, reduction of social contacts, more frequent need of assistance at home, and more hospital care. The personal consequences can also include experiences such as: anxiety to get a low blood sugar level; fear of needles; eating disorders in various degrees; depression; anxiety of amputation because of foot ulcers, etc.

⁶ Rossana de Lorenzi, Cristina Gritti, "Verso il primo farmaco ricombinante", European Molecular Biology Laboratory 2007

⁷ International Diabetes Federation Data - 2010

The social consequences may include that the person experiences limitations when dealing with others because of the disease. The person may also experience prejudice from other people and therefore have a need to talk to other people diagnosed with the same disease. Good treatment and control of the disease can reduce both the personal and social consequences for the individual⁸.

2.1.5 Cardiovascular diseases (CVDs)

Cardiovascular diseases are the largest cause of deaths worldwide⁹. Tobacco smoking, physical inactivity, unhealthy diets, and the harmful use of alcohol are the main behavioural risk actors of CVDs. Long-term exposure to behavioural risk factors results in raised blood pressure (hypertension), raised blood sugar (diabetes), raised and abnormal blood lipids (dyslipidaemia) and obesity. CVDs are largely preventable; population-wide measures and improved access to individual healthcare interventions can result in a major reduction in the health and socio-economic burden caused by these diseases and their risk factors. These interventions, which are evidence based and cost effective, are described as best buys¹⁰. Although a large proportion of CVDs are preventable, they continue to rise mainly because preventive measures are inadequate.

2.1.6 Burden of the disease

It is reported that more than 17 million people worldwide died from CVDs in 2008. Of these deaths, more than 3 million occurred before the age of 60, and could have largely been prevented. Out of the 17.3 million cardiovascular deaths in 2008, heart attacks were responsible for 7.3 million, while strokes were responsible for 6.2 million deaths. Premature deaths from CVDs range from 4% in high-income countries to 42% in low-income countries, leading to growing inequalities in the occurrence and outcome of CVDs between countries and populations. Deaths from CVDs have been declining in high-income countries over the past two decades, but have increased at a fast rate in low- and middle-income countries.

Major cardiovascular risk factors such as hypertension and diabetes link CVD to renal disease. Of the 57 million global deaths in 2008, 36 million (63%) were due to NCDs (non-communicable diseases) and 17.3 million (30%) were due to CVDs. Over 80% of cardiovascular and diabetes deaths occur in low- and middle-income countries.

2.2 Current management of the health problem (usual care)

2.2.1 Basque Country

Primary care professionals (GP and GP nurse) are principally responsible for a patient's case management, therapeutic / care plan definition, drug prescription, patient training, home visits, and follow-up when the patient is stable. While the communication between healthcare professionals and patient is mainly via traditional channels (f2f, phone), GP and GP nurse can communicate and share information through the EHR and electronic

⁸ <http://changingdiabetesbarometer.com/docs/Diabetes%20den%20skjutle%20epidemic%20og%20konsekvenserne%20for%20Danmark.pdf>

⁹ WHO, World Heart Federation., & World Stroke Organisation. (2011). Global atlas on cardiovascular diseases prevention and control. Eds: Mendis, S., Puska, P Norrving, B. http://www.who.int/cardiovascular_diseases/publications/atlas_cvd/en/index.html (last checked 4/11)

¹⁰ WHO (2011). Global Status Report on Non-communicable Diseases (NCDs). 2010 ed Alwan, A. http://www.who.int/nmh/publications/ncd_report2010/en/ (last checked 23/11)



prescription. Additionally, healthcare professionals can exchange patient-related documentation by meeting on a periodic-basis, phone or a social EHR.

Once the patient shows worsening symptoms, but is still out of hospital care (unstable stage), additional healthcare actors take part in the care process. The care manager takes charge of case management, and either he/she or the GP refers the patient to a specialist if necessary. Upon a patient's request, the Deputy Health Service can be activated out of hours, and healthcare professionals can visit the patient at home to perform the clinical interventions required.

The roles that have to be highlighted in hospital care are those of reference internist and hospital liaison nurse. The former is responsible for carrying out tests and diagnostics, defining the therapeutic plan, following up the pharmacological plan, coordinating specialists, informing GP on patient's health status, referring the patient to the long-term hospital (if required), and activating hospital social care team. The latter, in turn, supervises patient's hospital discharge by sharing information with GP nurse, and providing patient with information on therapeutic plan and health education.

On hospital discharge, GP and GP nurse perform an intensive follow-up, including home visits, in order to ensure that patient's health status is not worsening. The GP nurse carries out the patient's integrated frailty assessment; depending on the outcomes, community social services can be activated.

2.2.2 Croatia

Delivery of the field nurse service is organised at the level of primary care setting, and within the healthcare centre at the municipal level. GPs provide primary care services to patients during patient visits to the GP's office, while field nurses deliver healthcare services to those elderly patients who are not able to visit the doctor's office; field nurse service is delivered in patients' homes. The GP and field nurse will meet when needed to discuss a patient's health status, and make appropriate changes in therapy. Those meetings take place regularly, at least once per month or more often if needed. Where field nurses identify a patient's need for the intervention of social care services, they will contact social care, requesting them to take appropriate actions.

The GP will refer the patient to the specialist and/or laboratory if any specific patient examination or test is needed. Based on lab results and specialist feedback and recommendation, the GP will refer the patient for any necessary hospital treatment. The GP is also responsible for prescribing medication to the patient, which can be collected from the pharmacy.

The hospital care is performed by in-hospital specialists and dedicated in-hospital nurses, who take care of the patient. At the point of hospital admission, the patient will be assessed by admission staff (initial analysis, referral to appropriate hospital department and in-hospital specialist, referring to other specialist if needed, providing the medication plan). Once the hospital treatment process has been completed, a dedicated in-hospital nurse will write a discharge letter which will be given to the patient. Since a central EHR is not yet in place, the patient needs to take the discharge letter to their GP, who will then copy the relevant data into the patient's healthcare record.

2.2.3 Lower Silesia

Stable patients out of hospital care are not supported by ICT. Only face-to-face communication is currently used within healthcare delivery. Care practitioners (GP, specialist, long-term nurse and informal carers) do not currently have any technology to support the care they provide to their patients. GPs and specialists can communicate on a 1:1 basis by phone and/or paper communication. The GP is responsible for continuity of care for patients, and directs them to specialists when necessary.



Care practitioners (GP, specialist, environmental nurse and informal carers) do not have any technology to support their communication when caring for unstable patients. Emergency is the only exception because of ECG transmission to the hospital. Environmental nurses are responsible for specifying needs of patients and execution of daily care provision.

There is no integration of procedures in hospital care. Care practitioners (specialists, nurses, pharmacists, psychologists, dieticians and rehabilitation staff) have access to HIS and LIS/RIS, but these IT systems are not integrated. There is no one login to the systems. Face-to-face is the major type of communication.

Process of discharge preparation is based on paper documentation. Care practitioners of this process communicate face-to-face.

2.2.4 Veneto

The current model focused on assistance of elderly people has three different ways to access services at home. The patient can need a simple ward assistant (= home care worker) or social care intervention, an intervention from the home nursing service, or a more complex home integrated care service. The three services have a different access pathway.

Access to Social Service and Ward Assistance is activated by a request made by the patients, caregivers or the GP, and it follows the pathway represented below.



Figure 1: Veneto: Social Service and Ward Assistance activated pathway

The Home Nursing Service can be accessed in two different ways, depending on the care setting in which the need arises.

If the need of home nursing care arises in the context of a hospitalisation, the service is activated as follow:

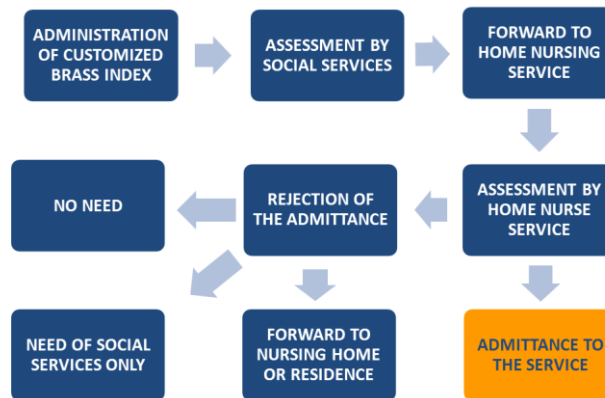


Figure 2: Veneto: Home Nursing Service pathway following hospitalisation

If the need arises for a patient that is at home, the activation of the service proceeds as follows:

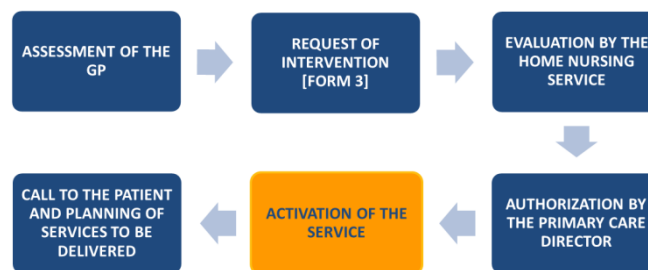


Figure 3: Veneto: Home Nursing Service pathway for patient at home

In the more complex cases where the request is for multidisciplinary intervention at home, the different services involved in the process of care are engaged in an integrated approach called the Multidimensional Assessment Unit, where the multidisciplinary team evaluate the case and decide which services have to be activated to respond to the needs of the patient. In the Multidimensional Assessment Unit, which operates in both primary and hospital care, the team consists of the GP, Director of Primary Care, Home Nursing Service, Social Service, and all the relevant services for each case.

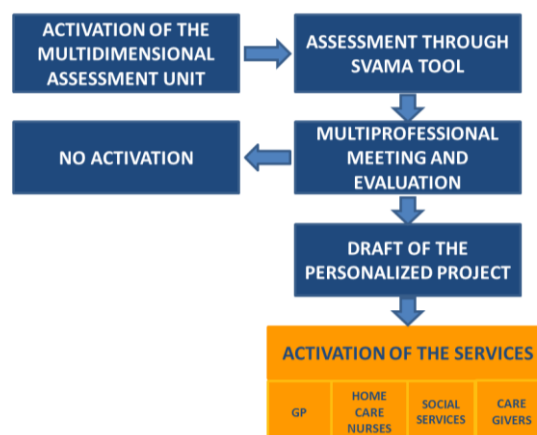


Figure 4: Veneto: Complex home integrated care service

2.2.5 Puglia

According to the guidelines now universally recognised, the Regional Healthcare Agency with the *CARE Program Puglia* is going to take action for the whole Region proposing, with the necessary adaptations, a new model of care based on the Chronic Care Model.



The CARE Puglia Model, implemented since the beginning of 2012, is based on taking care of the patient and their chronic health problems according to the Chronic Care Model with the involvement of all stakeholders, and the introduction of a new professional, a specialised nurse called Care Manager (CM).

CMs provide the patient with tools for self-management of their disease(s). They use a web based decision support system (Information System CARE Puglia Project), and work closely with the patient, GP and specialist, who work as a team (Care Team), to develop an individual care plan to address the problems identified.

A fundamental characteristic of the model is the strong focus on patient / user empowerment which features in all the different phases of treatment, and is supported by appropriate educational processes and coaching. Currently, proactive care is provided for patients with diabetes, heart failure, COPD, cardiovascular disease (CVD) and people at risk of CVD.

Information is shared among healthcare practitioners using a specific web application. This software works by creating specific networking between the practitioners, facilitating the circulation and sharing of the care plan through the creation and dissemination of electronic patient files. This software is being developed to introduce an additional vertical framework - one for each chronic disease.

2.2.6 Powys

Stable patient out of hospital care

If the patient is stable, his/her (and the carer's) contacts with GP / community or specialist nurse are mainly face-to-face or via the telephone. Patients use ICT to access NHS direct, either through the web, or by phone. E-prescription is passed via the GP practice to the community pharmacy where medication is collected in person by the patient or their carer. Patients have contact with social care teams through face-to-face communications or via the call centre.

GPs and nurses liaise to discuss patient care via face-to-face contact, phone or email. ICT is used for electronic referrals from the GP into secondary care via the Welsh Clinical Communication Gateway (WCCG), although its use is still limited, and only in place at some practices. GPs also use the clinical portal to communicate with hospitals.

For the unstable patient out of hospital care, the tool of communication is either face-to-face or via the phone. No ICT is included in this model.

In preparation for the patient's discharge from hospital, the Care Transfer Co-ordinator (CTC) is the key actor in this model. The ward nurse, hospital doctor or discharge liaison nurse meet face-to-face with the CTC to assess and co-ordinate discharge of the patient. The CTC liaises with the social care team to prepare the patient's care package; there is also phone contact with the community hospital during discharge preparation. The CTC has mainly phone contact with GPs, community nurses, community specialist nurses and the reablement team.

There is face-to-face contact between GPs and community nurses (arranging home visits); there is also face-to-face contact between community therapy teams, specialist nurses and reablement teams. Social care teams link with reablement teams regarding care packages and home based reablement.

ICT is used by GPs to send e-referrals via WCCG to the hospital.

2.3 Revised management of the health problem (new care)

2.3.1 Basque Country

Stable patients – out of hospital care

The current service model will be enhanced in a number of ways:

- Wider deployment of the reference internist and hospital liaison nurse into other hospitals in the region.
- Follow-up phone calls by the GP practice nurse on a monthly basis to monitor patient's health status, using a validated clinical questionnaire.
- Further develop the care pathways for frail older people to extend the eHealth Centre to provide improved follow-up / response calls out-of-hours.
- Provide symptom management questionnaires in the Personal Health Folder to further support self-care and self-management.
- Rolling out the electronic prescription to additional healthcare professionals including pharmacists.
- Development of a structured and standard empowerment programme (Kronik ON) for frail elderly patients and caregivers.
- Provision of self-care and self-management educational material through the Personal Health Folder and Osakidetza web portal.

Unstable Patients – out of hospital care

In addition to the above service model enhancement for the 'stable' patient, healthcare professionals will have improved access to near-time information to assist with decision-making when a patient's health status deteriorates. The enhanced role of the eHealth Centre will enable easier continued follow-up of the patient during their recovery period, thus reducing the need for F2F visits.

Inpatient - hospital care

Healthcare professionals in the hospitals will have richer information to understand the nature of a patient's deterioration leading up to their emergency admission, including symptom management questionnaire responses. It is likely that the acuity of patients requiring hospital admission will increase as more patients are able to be managed remotely (by phone calls) and supported in their own homes for minor exacerbations.

Inpatient – hospital discharge preparation

The information on hospital discharge entered into the EHR by the hospital liaison nurse will be able to be viewed by all healthcare practitioners involved in a patient's care team; this will provide a much improved, streamlined and safer service model.

Tailoring self-care and self-management information and education to the individual patient will be facilitated through defining educational material provided to the patient and their family / informal care givers through the Personal Health Folder or Osakidetza's web portal.



2.3.2 Croatia

Stable Patients – out of hospital care

The service model will predominantly be enhanced through the deployment of new ICT, and resultant new ways of working between the GPs and field nurses, social workers (if such need occurs) and patients in the following ways:

- Adaptation and implementation of the Ericsson Mobile Health (EMH) system for support in patient care, used by the field nurses to record the care services that they provide to patients. This information will be immediately available to the GP if necessary.
- The implementation of the EMH system will enable GPs to review a patient's care, and provide advice or a change in a patient's care plan or medication regime through the system rather than having to meet the nurse F2F.
- Field nurses will be able to communicate with the social care workers through the EMH system.
- Patient information to support self-care and self-management will be developed and made available through the EMH system for the nurses to pass on to the patient. This should ensure consistent quality of educational content, and enable information to be updated easily within the system, and new knowledge to be shared.

Unstable Patients – out of hospital care

The EMH system will facilitate the field nurses obtaining additional support and advice from the patient's GP practice if they become 'unstable'; a patient's care plan will be optimised to manage the "deterioration" quicker than is the case currently. The nurses will also be able to provide the patient with additional educational material to help them self-care and self-manage their health and wellbeing during the period when they are considered unstable but not requiring hospital admission.

Inpatient - hospital care

If a patient does have to be admitted to hospital, the GP will be able to provide the hospital with up-to-date information to support the admission and medical history of the patient.

Inpatient – hospital discharge preparation

The introduction of the EMH system will facilitate the discharge of patients, as hospital healthcare professionals will be aware that patients can be more closely monitored in their own homes and be better supported to self-care and self-manage.

2.3.3 Lower Silesia

Stable Patients – out of hospital care

The implementation of the CareWell integrated pathway enables the following developments to the service model:

- Better understanding of the roles and responsibilities of the different care practitioners involved in delivering services and interventions within the care pathway.
- Integrating the hospitalisation of those patients who require it as part of the care pathway to provide better patient care transition experiences across the different sectors and professionals.
- Introduction of telemonitoring for patients who require this service.



- Easier access to healthcare response service for patients through the platform.
- ECR will provide an improved communication mechanism through the email box, and thus enhance the co-ordination of a patient's care.
- The platform will provide a directory of services for patients, family members and informal care givers, as well as professionals, to search for appropriate quality assured health and wellbeing services that are available.

Unstable Patients – out of hospital care

The above enhancement for the stable patient will also be relevant for the unstable patient. In addition, virtual consultations will be able to be activated, if necessary, between the hospital specialists, nurses and GPs via the email box when a patient's health and wellbeing deteriorates.

Inpatient - hospital care

The hospital information system (HIS) is integrated into the ECR; healthcare professionals will have access to the information (anonymised) in the platform if a patient gets admitted. Selected doctors involved in CareWell have access not only to the information in the HIS, but also to the LSV CareWell platform. If the doctor is interested in the information uploaded by the patient, they ask permission from the patient to look at this data. This should provide improved information on the patient's medical history, and the events and care leading up to the hospital admission.

The educational platform in this phase of the project is not targeted at hospital doctors, but they will be able to access the information in the platform if they are interested in it.

Inpatient – hospital discharge preparation

The hospital is able to refer the patient for telemonitoring if they are not already receiving the intervention according to the defined CareWell criteria, and determine their physiological parameters and frequency accordingly. In addition, patients will be signposted to appropriate patient empowerment services and educational content through the platform.

For patients who were receiving telemonitoring prior to their admission, it is expected that they will return to receive the telemonitoring service upon discharge from the hospital.

2.3.4 Veneto

Stable Patients – out of hospital care

The service model underpinning the multi-disciplinary care pathways already implemented in Veneto will be further enhanced in the following ways through CareWell:

- An online patient's 'dashboard' will be created; it will bring together the relevant information from health and social care records, home-care service records, and hospital records. This 'dashboard' will be accessible to all care practitioners involved in a patient's care through a role-based access model.
- The care pathway data collection that informs the multi-dimensional assessment will be enhanced through the patient dashboard.
- Home-care nurses will provide a monitoring service to patients; the information will be shared with relevant healthcare practitioners via the Territorial ICT system.
- The home-care nurses will provide a telemonitoring service, responding to patients entering their physiological measurements and symptom management questionnaire answers into the system.



- The home-care nurses' monitoring systems will include educational material and interventions to assist the patient to self-care and self-manage.
- In addition to the educational material available in the monitoring system, web-based material will be available through the ULSS 2 authority website.
- Patients will be able to access the interactive portal within the ULSS 2 website, where they will be able to provide and receive information about their health and wellbeing, search for some information in their health reports, download results of tests and investigations, and book appointments.
- The Territorial ICT system will facilitate the sharing of information, care plans, patient monitoring measurements and self-management materials with all those in the care team.

Unstable Patients – out of hospital care

All the above functionality and enhancement to the service model will be available for the unstable patient. It should be possible to respond more appropriately to any deterioration in the patient's condition, as there will be much greater near-time information available to the relevant care practitioners. In addition, the Territorial ICT system will allow GPs to ask for and to receive teleconsultation on patients with the specialist if necessary.

Inpatient - hospital care

Hospital healthcare professionals will have access to the patient dashboard; this should improve the information supporting decision-making in assessing and drawing up the care plan for the patient.

Inpatient – hospital discharge preparation

The availability of the home-care nurses monitoring will facilitate the hospital discharge of a patient. In addition, the continuity of care across the different care sectors will be improved through the implementation of the patient dashboard, together with improved consistency in education material to support the patient to self-care and self-manage.

2.3.5 Puglia

From February 2015, the new organisational model will be put in place and the 100 patients will be followed by integrated healthcare services:

- A Care Team coordinated by a Care Manager will be assigned.
- Therapeutic-individualised care plans will be defined and shared for a better interaction and coordination between GPs, specialists, nurses.
- Care Manager will be responsible for the proper application of the therapeutic-care plan individualised for each patient.
- Care Team operators will rely on the support of Apulia Care Information System for recording, browsing, real-time monitoring and remote consultation of all the health information of the patients enrolled.
- Remote telemonitoring services (for the acquisition and remote transmission of blood pressure, weight, blood glucose, pulse oximetry) will be set up at patient's home by a specific installation team (clinical data will flow into the EHR).
- Specific protocols for vital sign measure and registration will be established and shared with patients to power home data coming from remote monitoring.

CareWell will facilitate the development and implementation of additional care pathways for chronic diseases.



Stable Patients – out of hospital care

CareWell will facilitate the development and implementation of additional services for chronic diseases. Therapeutic recall to improve adherence will be provided together with educational services that can be accessed by patients from a web based platform (Nardino enhancement). Patients will be cared for in a more integrated way by their GP in collaboration with nurses and specialists in outpatient clinics who can share information through the EHR. Specialists will be involved in sharing information through EHR, and to consult and update patient's information in EHR. Messaging and picture sending service (8 a.m. – 8 p.m.) between informal care giver and Care Manager will be put in place according to a protocol. This can be useful to support the patient in self-care and self-management, particularly in relation to recognising symptom deterioration or improvement, clarification on medications, etc., as well as e.g. monitoring wound healing in a diabetic ulcer.

Unstable Patients – out of hospital care

As with the stable patient, a patient considered to be unstable is cared for by the same team, and benefits from the same new services mentioned above, with an increased frequency of delivery, needing additional monitoring and assessments, frequent adjustments of therapy, or additional counselling. In addition, additional services specified below will be implemented:

- Each health professional involved in delivering the care and support of the care plan, thanks to his own log-in profile, can join a virtual community of health professionals using the online platform to discuss specific clinical problems of their patients.
- Each professional engaged in a patient's clinical management will participate in periodic and planned briefings via videoconference to assess the general clinical status of patients, according to a specific protocol agreed with the quality team.
- Home monitoring will be introduced to measure blood pressure, weight, oxygen and glucose in blood, from devices used by the patients in their homes, interfaced to the Nardino software. All clinical measurements will be uploaded to the EHR.
- Additional consultations / advice through the EHR will be provided according to a defined protocol in response to alerts generated from the telemonitoring technologies.

Inpatient - hospital care

When an unstable patient is unable to be managed at home through the integrated care pathway in primary care, the GP or specialist will refer the patient to the hospital for an admission. When a patient is admitted to a reference hospital, the EHR information will be available to the healthcare practitioners involved in CareWell; this should improve decision making and inform the assessment and care planning process. The integrated care pathway will be enhanced with a more active specialist participation (even the hospital specialist). They will be able to refer a patient who has been admitted to hospital inappropriately to the primary care team, suggesting home telemonitoring, as this has the potential to increase the patient's confidence to self-care and self-manage, and provide the primary care team with additional information for decision support in the event of a patient reporting deteriorating symptoms.

Inpatient – hospital discharge preparation

The stabilised patient is discharged from hospital back to his home. Hospital specialist entrusts the patient to territorial Care Manager, and clinical information for the territorial care team is provided by the EHR. Services for stable patient as above will be provided.

2.3.6 Powys

Stable Patients – out of hospital care

The care pathway and service model for stable patients living with complex needs will be enhanced through the following ICT functionality and associated new ways of working:

- MSDi case finding tool to target CareWell service at patients most likely to benefit.
- Access to the Individual Health Record (IHR) for community nursing and therapy staff through TotalMobile.
- Videoconferencing communication within the community nursing team through Microsoft Lync.
- Community nursing team able to access the GP EHR to record contacts, measurements taken, and care given.
- Comprehensive directory of health and wellbeing services available for patients in Powys through the Info Engine.
- Community nursing team will provide a telemonitoring service in response to patients taking and uploading their own physiological measurements at home.
- GP practice websites to include chronic conditions management educational content to support patients to self-care and self-manage.
- Patients will have access to My Health Online where they will be able to view a subset of their GP EHR, book GP practice consultations, order repeat prescriptions, and update their demographic details if necessary.

Unstable Patients – out of hospital care

All of the above functionality will be available to support improved team working and response services for patients who experience deterioration in their health and wellbeing.

Inpatient - hospital care

Healthcare professionals in the community hospitals will have richer information to understand the nature of a patient's deterioration leading up to their emergency admission, including telemonitoring information and any symptom management questionnaire responses. It is likely that the acuity of patients requiring hospital admission will increase, as more patients are able to be managed by telemonitoring and support in their own homes for minor exacerbations.

The use of TotalMobile and Microsoft Lync by the community nursing team will facilitate improved communication between the team and community hospital staff.

Inpatient – hospital discharge preparation

The availability of the community nursing team's telemonitoring service will facilitate the hospital discharge of a patient. In addition, the patient will be signposted to the relevant chronic conditions management educational content on the GP practice website, and any additional support services available from searching the Info Engine.

2.4 Technical characteristics of the application

Full details of the CareWell ICT-enabled service specification and IT architectures can be found in deliverable D4.1 Pilot level Service Specification for CareWell service. The following section provides an overview for each site.



2.4.1 Basque Country

The Basque Country has made a number of changes to improve their services:

- Integration of hospital pharmacy data into the EHR.
- Integration of systems to provide the EHR in a single system for both care sectors (primary and secondary care).
- Integration of the clinical information from the CareWell chronic programmes into the EHR.
- Improve the Business Intelligence to provide new functionalities for patient stratification.
- Development of an educational web platform for patients.

The new systems or functionalities are:

Integration of hospital pharmacy data into the EHR

The e-Prescription service in secondary care will be extended to include primary care with a shared database. This will be achieved through the deployment of several web services designed to recover and upload data to the central e-Prescription database irrespective of whether the prescription request is made from the module in the primary or secondary care IT system.

System integrated of both primary and secondary care EHRs

The interface of the application integrating both EHRs is equal to that used in secondary care. The major challenge, therefore, is the implementation of this application in primary care, where practitioners can be reluctant to use new applications. In order to avoid this situation, a contingency measure has been established which defines a progressive functional adaptation for primary care users. This plan outlines how the functional modules only present in the primary care EHR can be gradually added to the new application, although the interface visualisation will be slightly different.

Development and standardisation of the data collection to automate the risk stratification score calculation

The independent variables needed to calculate the risk stratification score developed in the Basque Country come from several administrative and clinical databases (hospitalisation, emergency visits, consultation, prescription, diagnosis, demographic data, etc). All this data needs to be linked at patient level. During the CareWell project, a Data Business Warehouse has been developed which allows data to be collected from several databases in a standardised way.

Through this data collection process, the prediction risk algorithm is applied manually, and the outcome of the risk stratification at patient level is uploaded into the EHR.

The risk stratification score is used in the CareWell pathway to identify patients with high complex needs who are most likely to benefit from the CareWell pathways and services.

Develop a new educational web

New educational materials and documentation have been added to the Basque Health Service's web portal. There is a specific section in the portal called 'Health School' where distinct content aiming to foster patient / caregiver empowerment are described:

- Actions in case patient health worsened.
- Healthy lifestyles.
- Information about your disease.

2.4.2 Croatia

The main challenge for Croatia pilot during CareWell has been to develop and deploy the architecture required to deliver the patient empowerment and home-support services pathway. The core of this architecture is Ericsson Mobile Health system for support in patient care.

For this activity, the EMH has several adapters and viewers that enable it to run on several platforms such as tablet, PC or TV (Smart TV).

The Croatian pilot focused on the following technological developments:

- To adapt and deploy to a pilot population the EMH system consisting of a number of modules to support chronic conditions management and the provision of digital educational tools for patients.
- To integrate the telemonitoring data from the EMH into the GP patient record within the GP application (G2).
- Develop and implement the Home Health Smart TV viewer to enable patients and informal caregivers to access the telemonitoring data collected by the field nurses using EMH.

Ericsson Mobile Health system for support in patient care

This is a platform to provide remote health services, applicable for various use cases in healthcare, self-care and wellbeing, to be implemented for the purpose of CareWell project. EMH will receive input from physiological measurement devices and record the data into the PHR, which will be viewable on the android application running on a tablet or Home Health Smart TV. This data will also be sent to G2 (GP office applications).

The roles able to use EMH will be GP/Nurse, Field Nurse, Social Care Worker, Caregiver, and Patient.

FER Home Health Smart TV

FER Home Health Smart TV provides easy access to the valuable EMH data to patients. The system consists of two main components:

- FER Home Health TV application.
- Adapter service

Using the carefully designed application, patients and their caregivers can access and view their medical data such as medical measurements, warnings and messages, and educational materials provided by medical experts. For the purpose of Croatia pilot, FER Home Health TV will enable only one role – patient. In order to improve the interoperability of FER Home Health TV system, the adapter service is designed and integrated. The advantage of adapter service is that it would be easily installed in other CareWell pilot sites if there was interest.

2.4.3 Lower Silesia

As Lower Silesia currently does not have many IT systems implemented to support the delivery of care or share information, both CareWell pathways will be significantly improved with the proposed ICT-enabled services and functionality. The LSV telecare procedure concerns patients aged between 65-85 years with at least two chronic diseases including hypertension (ICD I10), diabetes (ICD E 11), COPD (ICD J44) or heart failure (ICD J50).

The development of a platform to provide interoperability between the different IT systems used in primary and secondary care will enable information to be shared

between the different care practitioners and patients. The new systems or functionalities are:

- Registration of patient referrals for home care telemedicine (TOP). This is the first task in the process of LSV teleCare.
- Registration of performed patient results in HIS Portal.
- GPs access to EHR and their own tasks supporting the process of LSV teleCare procedure.
- Nurses access to the EHR, and their task or process that supports the LSV teleCare procedure.
- Patients access to their own PHR tasks supports the process of LSV teleCare procedure.
- Implementation e-Prescription in SIM (P1) during the LSV teleCare procedure.
- Call Centre staff access their own tasks supporting the LSV teleCare procedure process. Receive e-mail and SMS alerts.
- Doctor, nurse and patient access the Information and Education Portal.
- Call Centre staff access the Information and Education Portal.
- Some of the developments and changes will revolve around the new interoperability platform Integratis.

2.4.4 Veneto

The most important challenge for Veneto pilot during CareWell is the evolution and the integration the EHR in primary and secondary care. This integration is possible due to extending the use of Territorial Information System to secondary care and to GPs.

This challenge is not only the number of users; this challenge represents others problems to resolve such as:

- To implement new roles of users.
- To implement the functionalities foreseen within CareWell.
- To share information among services and levels of care.
- To develop new interoperability connections.
- Major risk of data duplication and incremental cost of support and management.

The Territorial ICT System has been upgraded and enhanced with new tools and modules. It has mainly involved:

- Development of the patient dashboard that collects and aggregates the information about the patients relevant for the integrated care delivery. The dashboard called "Fascicolo Territoriale" contains data such as services, assessments, diagnoses, evaluations, and other relevant information.
- The creation of an assessment module in which has been inserted the complete electronic workflow for all the professionals involved in the multidisciplinary assessment of the patient (GP, Director of Primary Care District, home care nurse, social worker, specialist if required).
- The enhancement of the Home Care module with the development of new features such as the telemonitoring for nurses and GPs and the teleconsultation between GPs and specialists.
- Development of the mobile app used by the nurse during service delivery at the patient home.

The patient empowerment and home-support services pathway includes the following IT architecture developments:

- Develop interactive functionalities such as search for some information in their health reports, download results of tests and investigations, and book appointments.
- Develop educational materials to be shared in the web site.

The activation / deployment of the services foreseen in CareWell have led to changes to the architecture of the Territorial ICT System.

2.4.5 Puglia

The new systems or new functionalities are:

- During the CareWell implementation, the CARE Puglia Program platform will be enhanced to support new service delivery, and will undergo many technical adaptations.
- A new clinical profile will be created to allow specialists to access the EHR and share information with the Care Manager and GP. A new user role will be defined giving them the possibility to update information on patients and consult information uploaded from other members of the care plan. The platform is fully compliant with DICOM 3.0 standard, so CARE Puglia software will integrate with PACS for management of all forms of diagnostic imaging to implement specific work flow or process a second opinion, or in general, to support specialised activities.
- Technological adaptation will be provided to create an interface between the telemonitoring device hub software (at patient's home) and Care Puglia software, and to create conditions for the platform to receive clinical parameters from home monitoring; platform adaptations are also necessary, and they will be provided to send therapeutic recalls toward Hub; it will also be enhanced to support the release of educational tools for patients and their informal caregiver (by their own PC), and to upload images coming from messaging service between patients and Care Manager. Technical interventions both on platform and Hub software will be set to create a warning on the platform for out-of-range clinical parameters revealed by home devices.

2.4.6 Powys

The most significant changes in the IT architecture are those to deliver the patient empowerment and home-support services pathway. The services and ICT solutions that will be deployed and utilised to support the delivery of these integrated care pathways are shown in the diagram below, which represents an update to that presented in deliverable D4.1.

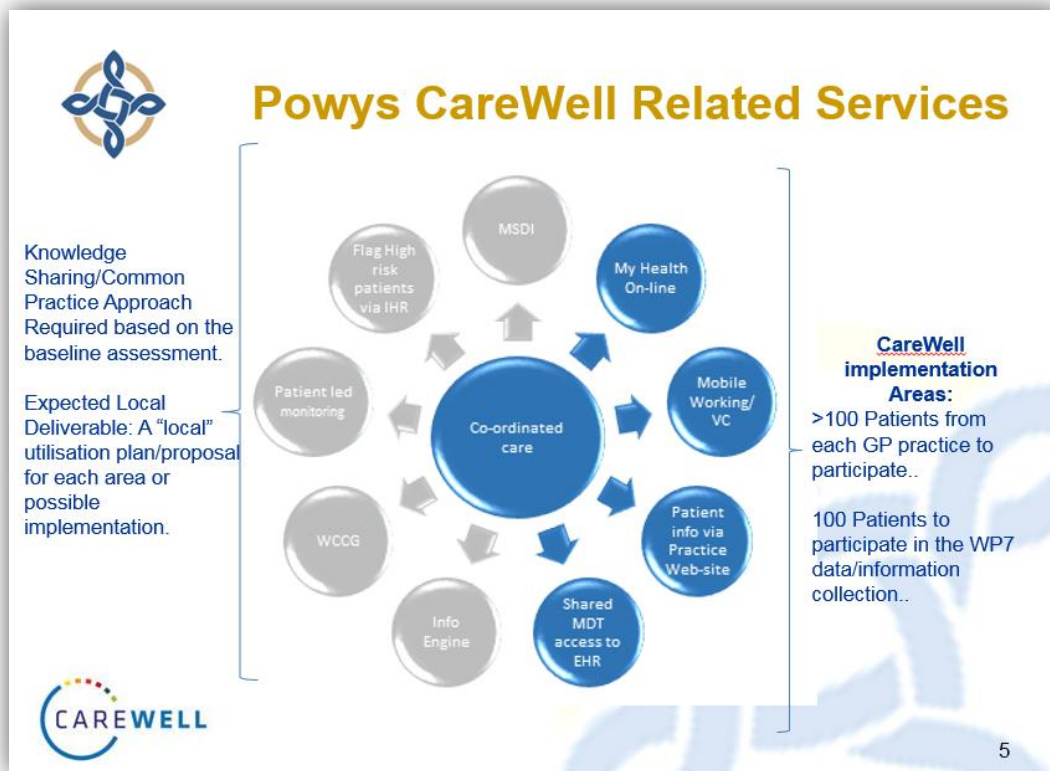


Figure 13: Services and ICT solutions deploy in Powys

Changes or new systems (pathway empowerment and home support):

- Mobile app to access EHR: The current and newly developed systems will be adapted to run on mobile devices such as Smartphones and tablets for the district and specialist nurses to use when they make visits to patients' homes.
- Implement a telemonitoring service.
- Develop a single database with social and clinical information for community services which is currently undergoing a national procurement.
- Educational materials and information available on GP practice websites.

The integrated and coordination services pathway will be enhanced in the following ways:

- Implement inter-consultation message (referrals) through EHR between clinicians.
- Implement live communication tool between community nurses and GP.
- Implement videoconference.

2.5 Requirements for the use of the ICT solution

2.5.1 Basque Country

The Basque Country's ICT system has been improved with new services to achieve a better coordination among healthcare professionals and provide patients and caregivers with clinically validated educational material for self-management.

The introduction of these services has required distinct training sessions for the healthcare professionals involved in CareWell. The training has included information on:



- Clinical aspects of the different pathologies frail elderly patients can suffer from (diagnosis, symptoms, management etc).
- The clinical questionnaire GP practice nurses have to ask patients on a monthly basis.
- Description of the extended roles of the reference internist, hospital liaison nurse and eHealth centre nursing.
- The content and methodology of the new structured empowerment programme.
- Handling the educational platform embedded in the web portal.
- Procedures to gather and register all the information required for the project evaluation.

2.5.2 Croatia

To run the ICT solution needed for the delivery of the CareWell service in Croatian pilot site, the following requirements need to be satisfied:

1. Application server h/w and s/w configuration.
 - HW -> min. 2 CPU-a i, 4GB RAM-a, 1GB HDD.
 - SW -> Linux OS, MySQL database SW licence (standard edition subscription).
2. Ericsson Mobile Health system s/w licences:
 - EMH Backend system s/w licence.
 - EMH Patient licence.
 - EMH Android application s/w licence.
3. Communication link:
 - wired broadband connection link, 1 Mbit upload and download.
4. Healthcare staff equipment:
 - GP office PC with broadband internet connection.
 - Android based tablet for field nurses.
 - Android based Smartphones for patients.
 - SIM cards with mobile data plans for tablets and smartphones (512MB monthly plan).
 - Bluetooth enabled medical devices for field nurses, one set per nurse: blood pressure monitor, pulse oximeter, spirometer, 12-Lead ECG.
 - Consumables for medical devices: ECG electrodes, personal filters for spirometer, 1.5V batteries.

Apart from the basic requirements to run the system, EMH system must be integrated with the standard GP office application:

- to secure the interoperability;
- to simplify the field nurse created data analysis process;
- for the GPs to use one application in everyday work instead of two.

Training is needed for the following actors to secure the service delivery quality:

1. EMH System administrator:
 - Knowledge transfer on how to administrate all parts of EMH system (Backend and Android).
2. GP:
 - Explain the new service flow introduced within the CareWell.



- EMH Web application training for data access (backup option) and how to access the CareWell data through their standard GP application.
3. Field nurse:
- Explain the new service flow introduced within the CareWell.
 - EMH web application training for data access.
 - EMH Android app training (tablet and smartphone).
 - FER Home Health smart TV application.
4. Patient and caregiver (training provided by field nurses):
- Explain the new service flow introduced within the CareWell.
 - EMH Android app training (smartphone).
 - FER Home Health smart TV application.

According to the experience from the first four months of the operational pilot phase, we have learned that 60% of field nurses included in the pilot have adapted to the use of the ICT in the four months of operational pilot phase. Our expectation is that by the mid-term we will have the 100% adaptation of field nurses to the use of ICT.

2.5.3 Lower Silesia

It is important to enable patients to benefit from telecare services in a safe way that they can understand. Facing the problem of an aging population and the fight against social exclusion, it becomes increasingly important to educate the public, and create the opportunity for people to learn about and understand the model of telecare and the benefits it brings. The most important task, as well as the most difficult one, is to educate patients to make them aware that the use of telecare increases their safety and a quality of life. Confronted with the standard model of healthcare, telecare give them more benefits. Social portal functionality also means to patients an easy access to their care history (of the disease), the possibility of being kept informed with their results, and the feeling of having more control over the process of healthcare.

2.5.4 Veneto

In order to deploy the services described and forecast in CareWell the ICT infrastructure had to be updated and upgraded.

The Territorial ICT System has been upgraded and enhanced with new tools and modules. The system is web-based, and therefore does not require any special premises or installation, neither for GPs nor for the other professionals involved.

It has been necessary to replace old palm held devices with smartphones, and acquire the devices used by nurses to measure and monitor clinical parameters. The devices are:

- Sphygmomanometers;
- Pulsoximeters;
- Glucometers;
- Coagulometers;
- Weight scale.

2.5.5 Puglia

Training sessions for patients, formal and informal care givers will be carried out on use of devices, according to the protocols.

ICT components to be procured are digital and wireless devices such as:



- Glucometers.
- Medical weight scales.
- Sphygmomanometers.
- Pulse oximeters.

2.5.6 Powys

The services that are being deployed under this integrated care pathway are being done so through the deployment and utilisation of existing and available ICT software solutions to NHS Wales. Therefore the requirements for use of these services are broken down into two distinct categories:

- NHS Wales (Internal Hardware/Resources): This is inclusive of the service / operational model that has been deployed across NHS Wales and is not solely used / available to Powys THB but to all NHS bodies (where applicable). The use and utilisation of this hardware, specifically in terms of the integrated Care Pathways and services being deployed are "built" into existing support arrangements between NHS Wales (inclusive of Powys THB), NWIS and local ICT directorates.
- Requirements for use by "End Users" i.e. patients: This relates to the ICT requirements for end users / patients to access the ICT related services detailed in section 2.3.6 above being deployed to patients to support our Integrated Care Co-ordination and Patient Empowerment. The services that Powys Teaching Health Board are/will be deploying to patients (i.e. those that are accessible to patients) will all have a web enabled user interface. On that basis the ICT requirements of the users are limited to access to the World Wide Web, web browser and device that supports the use of internet access/web applications (e.g. Desktop PC, Laptop, Tablet, Mobile Device).

2.6 Requirements for Integrated Care Model implementation

2.6.1 Basque Country

In the case of the Basque Country, the new pathway has been designed by the managers and clinicians of both the hospitals and the primary care centres involved in the programme. This is essential for the implementation of the model in a proper way, meaning that all stakeholders' perspectives have been taken into account, and a clear methodology in the design the intervention has been carried on (analysis of current model, detection of improvement areas, prioritise actions and define the new care pathway). Moreover, the objectives of the CareWell project are totally aligned with the strategic plan of the central organisation of the Basque Country health system (Osakidetza).

The new model has been presented in several meetings to the GPs, nurses and specialists who are principally responsible for patients' case management. The professionals from primary care and secondary care now have new and better channels of communication to share information about the patient before, during and after delivering their services.

Since primary care nurses are the ones responsible for the empowerment of the patients, some nurses in charge of chronic patient have developed the new educational material for the educational platform. After all the material and the methodology were developed, these nurses trained their colleagues in peer training.



2.6.2 Croatia

Since the new, adapted service provided in CareWell project is mostly based on the existing field nurse service, we will not have the need to introduce new premises for the implementation of the integrated care model.

The service is taking place in two settings, GP office and patient home. Field nurses are doing patient visits in their home during which certain activities are being performed: collecting patient data (questionnaires and medical measurements), and educating patients on healthy living and prevention methods for the specific disease area.

All training needed for GPs, nurses and patients / caregivers, are described in section 2.5.2.

2.6.3 Lower Silesia

The first step in implementation of telecare is suitable qualification of patients, and then, depending on its outcome, configuration of the appropriate telecare procedure. This is important because the process of telecare which is implemented in the system, described crucial flow of information and tasks, but does not define how various steps have to be performed by individual patient.

The telecare process of the Lower Silesia CareWell System assumes that at fixed intervals a patient will perform life parameters measurements at home and the results will be transferred to a healthcare unit. In contrast to the old style home care, the telecare results have to be checked by a doctor who has to determine what specific tests and at what intervals the patient should do them. During the process, there may be a need to change some details such as measurement intervals.

The results of the patient's measurements flow into the central system, where algorithms analyse the results and examine whether they exceed thresholds, and check if their behaviour is similar to that expected. If there is a departure from the norm, a task appears in the system for hospital staff, in our case a nurse, to analyse these results. Her task is to verify whether the test was carried out in a correct way, whether the patient may have taken any medicine responsible for the distortion of the results, or if his behaviour affected their values (e.g. increased physical activity). When the observed anomaly is an erroneous measurement or it is caused by human error, the patient is recommended to repeat the test. If it is a worrying signal which may endanger the patient's health, a nurse can contact a doctor or intervene immediately by calling an ambulance to the patient.

Another phenomenon in telecare procedure is an intervention, which we understand as a situation caused by an undesired phenomenon (e.g. accident) or is a significant deviation from the standard implementation of the procedure. The incident may be reported by the patient in two ways. First, the patient can use the supplied phone number to call the Call Centre (in the hospital conducting this procedure), where he can obtain help from a nurse; in some situations, a nurse may consult with a doctor; she can also arrange a home visit earlier, or in special situations call an ambulance to the patient. Second, the patient calls the emergency room directly; then he is admitted to hospital following standard procedures; after discharge, the patient record is supplemented with an extract from hospital.

In the course of the procedure there are also anticipated periodic visits by a nurse in the patient home. Normally this is done once a month. Although in case of incidents appearance, their frequency can be increased.

Once the telecare goal is reached, a patient visits a doctor, who may decide to continue the treatment or end the procedure. In the case of telecare procedure termination, there

is generated an automatically record of results and doctor prepares a detailed report for the whole period covered by telecare.

2.6.4 Veneto

In the case of Veneto Region's Local Health and Social Authority nr.2 of Feltre, the most significant part of the change has related to the technological infrastructure: these changes have therefore led to modifications to the organisational model underlying the delivery of integrated care.

The professionals now have new and better channels of communication (other than paper, fax or phone) for sharing information about a patient before, during and after delivering their services:

- New channel of communication will improve and enhance the team work of the GP, nurses and other professionals involved in a single case.
- The specialist will devote part of his time to new ways of consulting with GPs and assessing the patients.
- GPs will be able to monitor their patients, especially those in not stable conditions at home, in cooperation with the Home Care nurse.
- Nurses will have new tools and ways to assist the patient at home, and will play a fundamental role in the coordination and exchange of information. This will also strengthen the relations between nurse and GP and vice versa.

To do this, it is absolutely important to give proper training to all the professionals.

The training is carried out starting with meetings dedicated to single professional categories, in order to show and acquaint them with the new system. After this first stage, a second wave of meetings for multidisciplinary teams is carried out.

2.6.5 Puglia

In Puglia, an integrated approach to patients with complex needs has existed since 2012 (Care Program).

GPs and Care Managers are involved in populating the EHR, and using it for inter-consultations. The Care Manager has an important role in pathway coordination and support patients empowerment.

ICT tools are available to support integrated approach: the Care Program software – Regional health information system.

The patient is selected for enrolment in the CareWell programme by either a GP or specialist after a complete medical examination. During the examination, the clinician informs the patient about the Disease and Care Management programme, with explanations of the pathway, the advantages / disadvantages, and the envisaged holistic approach. The patient is then asked to sign an informed consent form for inclusion in the programme and use of their data. The patient is then referred to the Care Manager (CM specialised nurse) to be formally enrolled.

After enrolment, the CM completes the initial assessment in a face-to-face interview, using information already present in the GP's / specialist's data base, and answers given by the patient; software supports the CM in collecting information about the patient by opening specific interfaces containing questionnaire on lifestyle and socio-economic condition. Based on the initial assessment, the GP / specialist and the CM define the patient's care plan, and share it with the patient so the patient can provide input. The GP / specialist identify the degree of complexity of the patient in terms of care load required, and then tailor / focus interventions. The care plan is then used to plan the workflow of

all relevant healthcare professionals. The GP has access to all documents of the patient through CarePuglia. Where necessary, specialist consultations are requested using specific and dedicated booking systems to ensure the patient receives tests / examinations in line with an appropriate schedule which is defined according to the related protocols. The CM coordinates the whole care management process, ensures the care plan is carried out, and through direct interaction with the patient constantly monitors adherence to care plan and therapy. The CM is also responsible for delivering coaching activities which seek to provide:

- Information.
- Motivation.
- Support / empowerment.
- Health education and self-management.

Therefore the patient becomes empowered, learns how to cope with his own condition, becomes pro-active and responsible, and is aware of how his involvement and commitment in managing his condition can improve his overall clinical condition and his quality of life.

Each step of the Disease and Care Management process is registered in the EHR via the digital platform. Information uploaded via the digital platform is included in a database which is at the disposal of the entire care team, and can be used to better orient care processes and the patient's coaching.

The CM conducts periodic questionnaires in face-to-face interviews with the patient to update the assessment of the patient's condition. From this the care plan is modified accordingly. Coaching of the patient will then be updated to reflect these changes; if necessary, an appointment is made with the GP or the specialist in order to modify the therapeutic plan.

The CM will also collect patient measurements such as their weight, the size of their waist, etc. These measurements are collected every six months, and are used to follow the development / improvement of the patient's health status. Over time, the number of assessments will decrease if the care plan is effective and the patient's measurements / health status improves.

2.6.6 Powys

The CareWell Integrated Care Model for Powys Teaching Health Board has been designed based on use of ICT and services that already exist within Wales, and is aimed at deploying these services to patients of Powys via health professionals in general practices and primary care. The model has been presented to all stakeholders in various forums within the organisation, and specifically to the project board and team who report to senior directors and executives within the organisation. We have also communicated to patients via GPs and via telephone and written communications; we have plans in Powys to hold user group forums with our cohort in the new year.

Training of stakeholders in the use and development of these chosen services is carried out in a number of ways: by the service providers, healthcare professionals and the project team. It is supported by (at this stage) hard copy training materials, with a view to producing e-learning materials if the need increases as expected.

The services being deployed will be used either at the GP practice, at the patient's home, or through mobile devices / tablets made available to the healthcare professionals. The services being deployed in Powys are (in the majority of cases) web based, and therefore are accessible from any location with a valid internet connection and web browser enabled device.



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

3.1 End Users

3.1.1 Basque Country

In the Basque Country, the population is stratified using a risk assessment method based on John Hopkins ACG PM (Adjusted Clinical Groups Predictive Model). The tool included several risk factors: demographics, clinical diagnoses (Dx coding), medication utilisation (Rx coding), and prior healthcare costs. The output of the risk assessment is a risk score (IPR: Risk Prediction Index) that is used to allocate patients into four different strata: 'case management', 'disease management', 'self-management support' and 'prevention and promotion'.

According to the stratification tool, 32.000 patients are identified as patients with multiple comorbidities ('frailty'). Following the stratification tool results and the inclusion criteria of CareWell project, 200 patients have been identified and recruited by their GP in five different integrated healthcare organisations of the Basque Country: OSI Bilbao-Basurto, OSI Uribe-Cruces, OSI Tolosaldea, OSI Galdakao-Barrualde, and HUA.

3.1.2 Croatia

The recruitment of patients was undertaken at primary healthcare polyclinic Zagreb City Centre.

The Polyclinic covers 350.000 patients of the city of Zagreb, which makes around 300.000 primary healthcare examinations and 200.000 secondary healthcare examinations. Although the Polyclinic is of primary healthcare, secondary healthcare is also available such as pulmonology, cardiology, women's health.

The plan was to recruit around 50-60 patients for control and for intervention group.

For the purpose, six GPs were selected based on their coverage of patients, and among them patients were recruited based on the study protocol (indications, presence of care giver, etc.).

3.1.3 Lower Silesia

In Lower Silesia, 100 patients were selected based on Clinical Guidelines. All patients assessed for eligibility are current patients of A. Falkiewicz Hospital (for integrated care model) and Outpatient Clinic (for usual care model). The average number of patients is similar to data from 2014.

In 2014, the following were admitted to the A. Falkiewicz Specialist Hospital (45 geriatric beds):

- 168 Diabetics patients.
- 35 COPD patients.
- 416 Hypertension patients.
- 231 Heart failure patients.

The Hospital serves patients as a one of five municipal hospitals in Wroclaw City, with a population of 600.000 inhabitants.

In 2014, cooperating outpatient clinic had patients:

- 655 Diabetics patients.
- 40 COPD patients.
- 2.268 Hypertension patients.
- 47 Heart failure patients.

3.1.4 Veneto

Regione Veneto has been deploying in the Local Health and Social Authorities the Johns Hopkins University ACG System for the stratification of the population since 2013. This tool assesses the health status and risk of the population and individuals using socio-demographic data, clinical diagnoses, drugs prescription and consumption, information on hospitalisation, emergency room admissions, outpatient visits, and other services delivered; in addition, it takes into account the consumption of resources.

The ACG analysis is carried out on an annual basis; it allows stratification the population and identification of patients with high risk; it is used by the Local Health and Social Authorities to plan actions and interventions on specific target sub-populations according to different conditions and needs.

For the CareWell project, the stratification of the population at 31st December 2014 has been used in the Local Health and Social Authority nr. 2 of Feltre to identify eligible patients according to the inclusion criteria defined in WP7 (n=3.893). From this sub-population, a cohort of frail patients who have already received at least one home care intervention during 2014 has been identified (n=726). The lists of patients were handed to GPs for recruitment in order to reach the planned sample in the intervention group (n=80) and control group (n=80).

3.1.5 Puglia

The inclusion criteria are:

- ≥ 65 years old.
- Two or more chronic diseases included in the Charlson Comorbidity Index. At least one of the comorbidity conditions should be: COPD, heart failure, or diabetes mellitus (both insulin dependent and non-insulin dependent).
- Patient must meet the local, national or international frailty criteria: complex healthcare needs, a high risk of hospitalisation or home care, increase in vulnerability.
- The patients who are going to be provided with telemonitoring devices must be able to use them (by themselves, or with their caregivers).

Exclusion criteria:

- Subjects who have either been registered with an active cancer diagnosis under treatment, have undergone an organ transplant, or are undergoing dialysis prior to enrolment.
- Subjects who are candidates for palliative care (with life expectancy less than one year, clinically evaluated).

The GP or the Care Manager / GP nurse will review the EHR of their patients in order to identify candidates who meet the inclusion criteria. If a potential candidate is identified, an appointment with the GP will be organised. The GP or the Care Manager / GP nurse will explain the intervention to the patient. If the patient accepts, he/she will have to sign

the informed consent form. Patient recruitment started in February 2015, and ended in September 2015).

The service added to the CareWell organisational model performed in Puglia implied the remote monitoring of vital signs / parameters.

3.1.6 Powys

Patients participating in the CareWell project in Powys all meet the criteria set in D6.1: they are aged 65 or over, and suffer from a chronic disease along with other conditions set in the evaluation. Only those patients meeting the criteria have been approached in Powys. We have a variety of information systems available in NHS Wales and Powys; these have allowed us to narrow down the patients that we identify and approach to those specifically meeting the criteria set. That however does not negate some patients who have declined to take part, nor those who have since deceased (see above enrolment process).

The patients in Powys can expect direct access to three distinct services as part of our delivery model:

- Website information: this will provide them with “trusted” sources of information and support mechanisms in relation to their condition.
- MS Lync: this will provide GP practices with the ability and added functionality to hold and participate in mobile working.
- Video Conferencing facilities between care providers, My Health Online: this will enable patients to manage their healthcare information online linked to GP systems, and enable them to manage their repeat prescriptions and appointment bookings online.

The scope of the use of My Health Online has been restricted to these two key aspects of functionality; however, there is a continuous development cycle for this product, and future features may be used post the CareWell project. Patients can also expect to benefit from six other areas identified through the local project, but these will not be “front” facing solutions that the patients can access, and therefore their benefits will be indirect.

The care will be deployed and implemented by the project team with ultimate care being provided through existing pathways, general practices, and care providers in Powys and Wales.

Access to these services will vary dependent on which of the three is used by the patients: My Health Online and the website information will be available 24/7. However the use of MS Lync will be determined for use by the GP practices as they see fit and suitable for each case.

3.2 Objectives

The overall aim of the evaluation carried out in CareWell is to identify the differences introduced by implementing ICT supported integrated healthcare in different domains according to the MAST evaluation framework [2], including safety and clinical outcomes, resource use and cost of care, user/carer experience, and organisational changes.

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

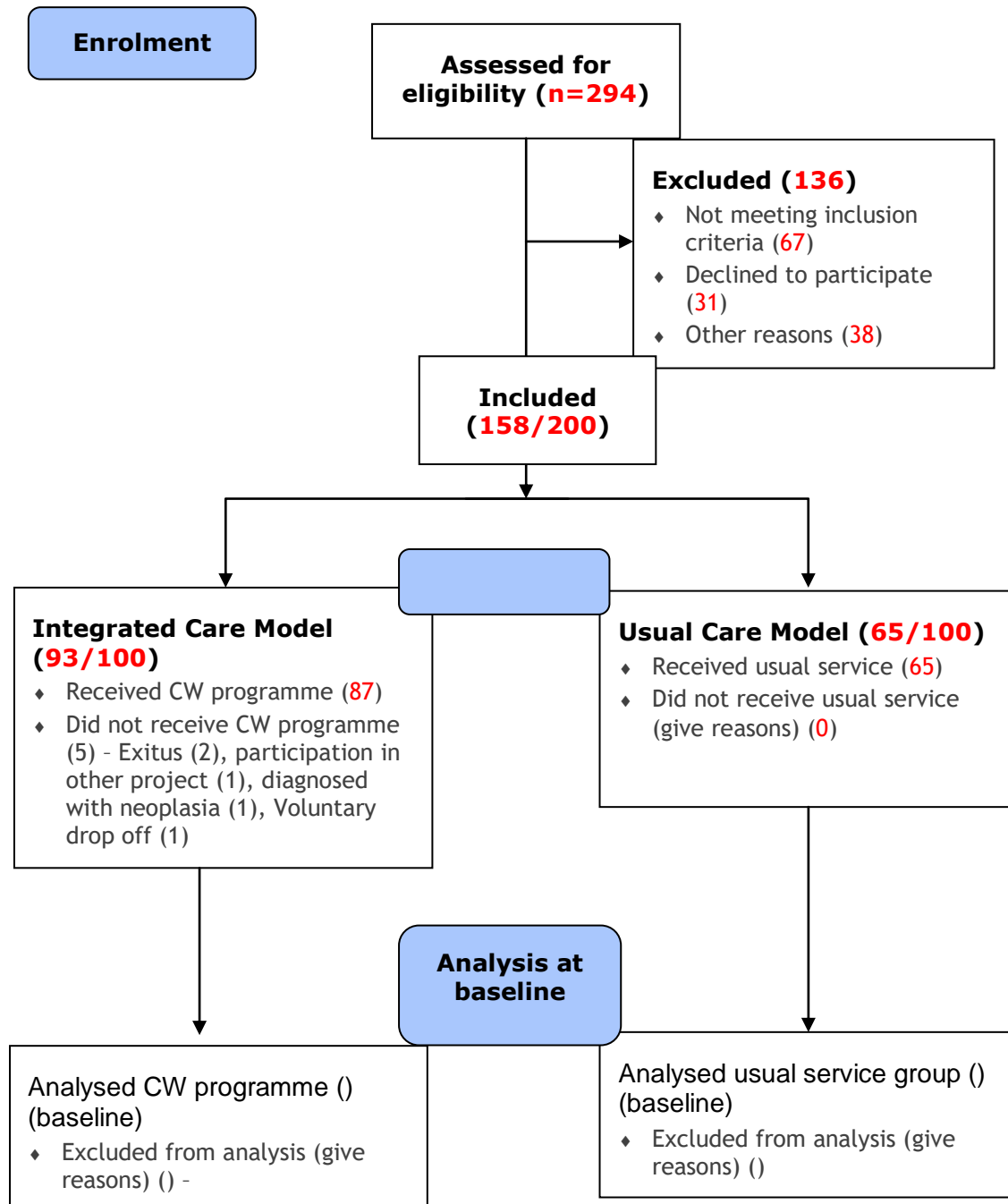
3.3 Enrolment flow charts

3.3.1 Basque Country

Flow-chart has being filled out: November 2015.

The recruitment has been carried out: From June 2015.

Professionals in charge of the recruitment: GPs.

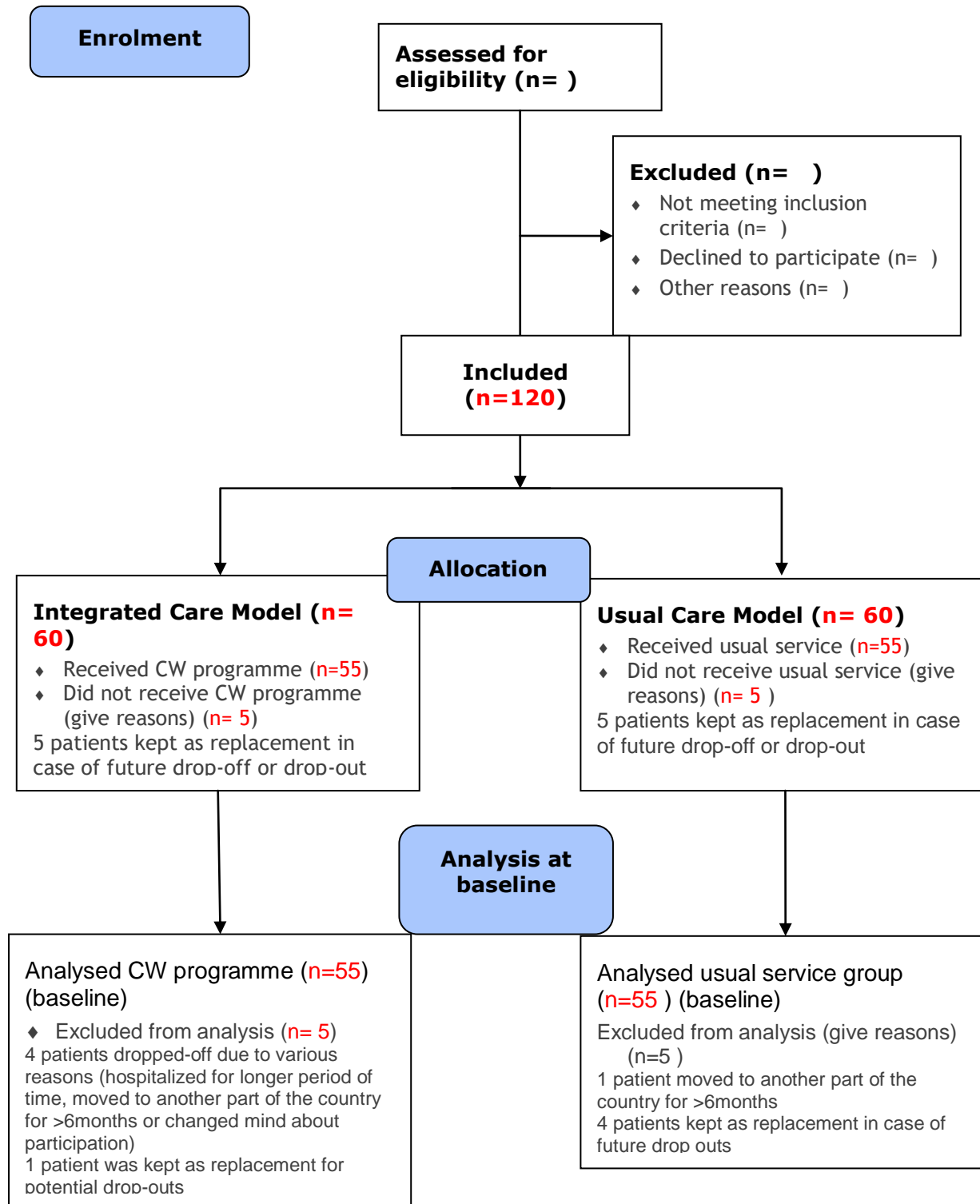


3.3.2 Croatia

Flow-chart has being filled out: November 2015

The recruitment has been carried out: January-May 2015

Professionals in charge of the recruitment: GPs



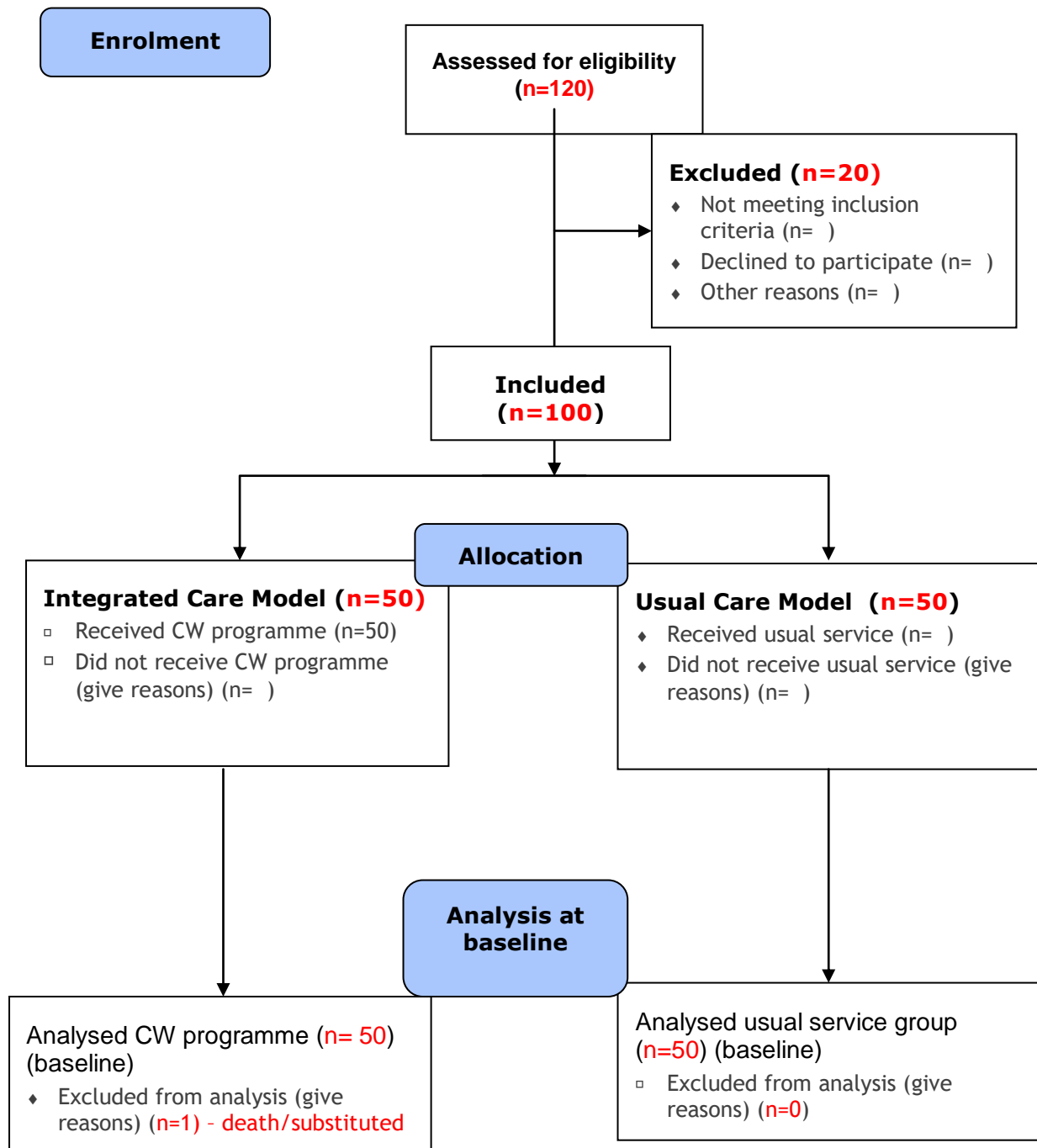
3.3.3 Lower Silesia

Flow-chart has being filled out:

November, 2015

The recruitment has been carried out: 21st September and will be finished 27th November

Professionals in charge of the recruitment: GPs



3.3.4 Veneto

Flow-chart has being filled out:

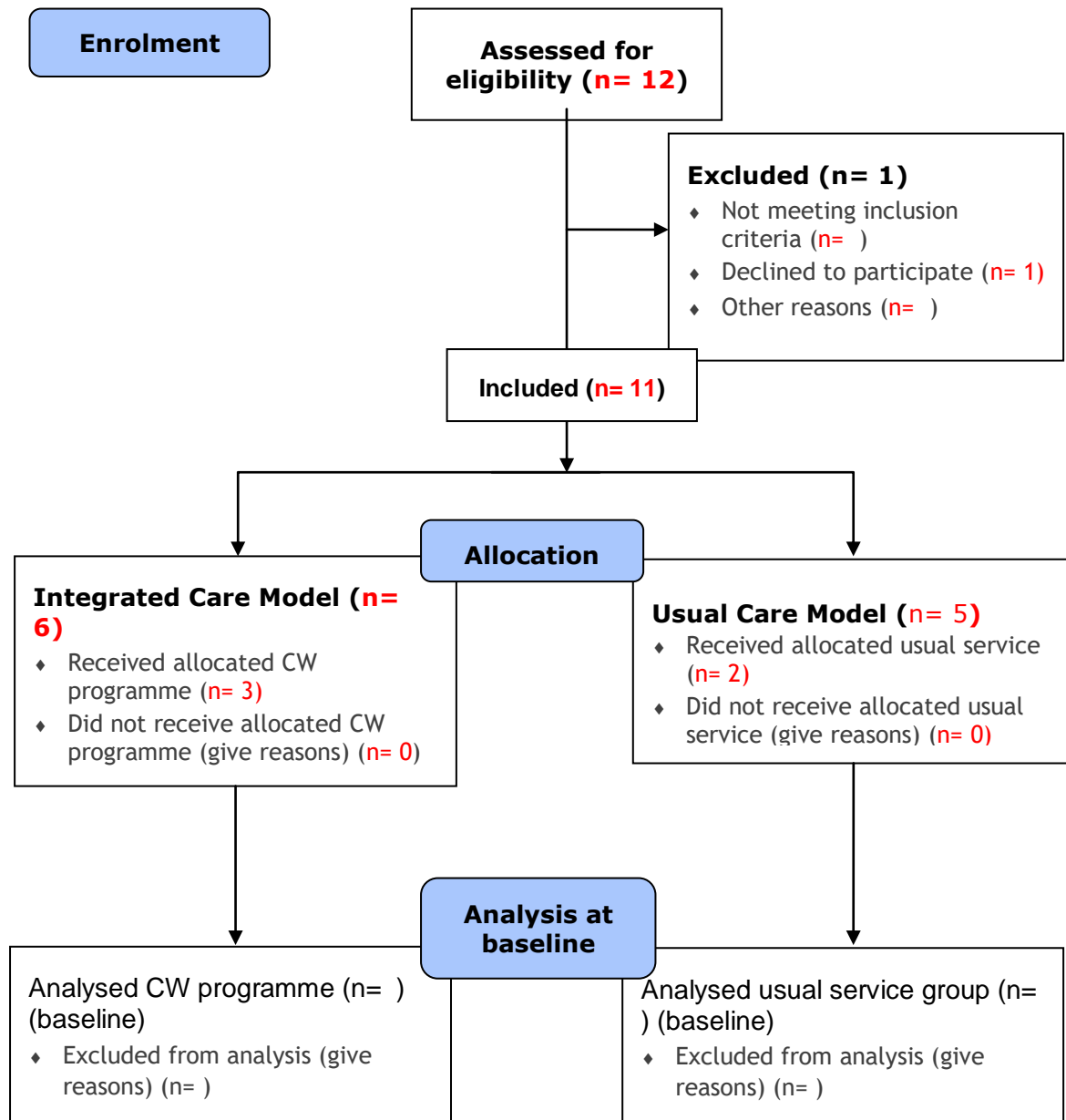
November 2015

The recruitment has been carried out:

From September 2015 (still ongoing)

Professionals in charge of the recruitment:

GPs

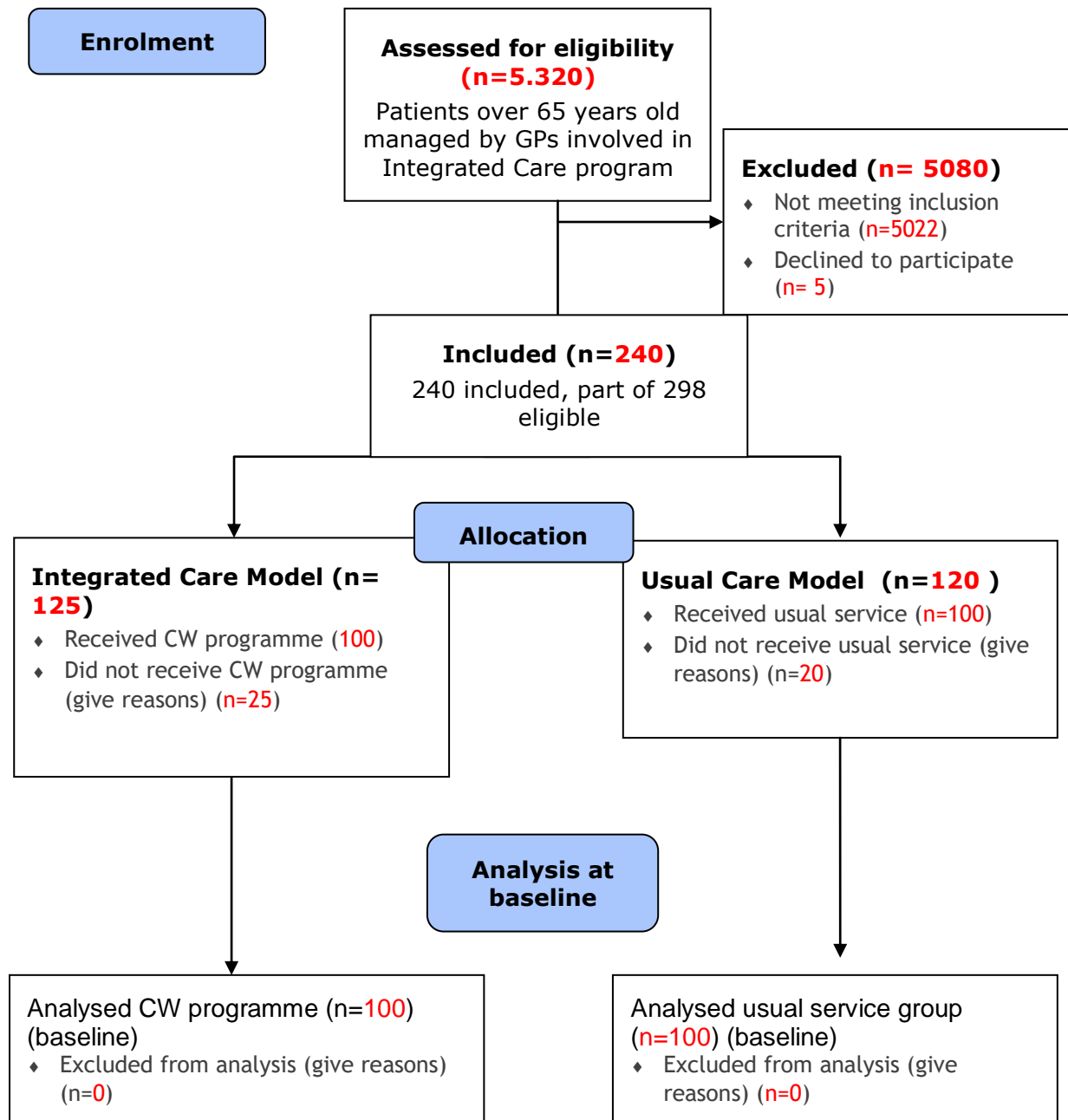


3.3.5 Puglia

The flow-chart has being filled out: November, 2015

The recruitment has been carried out: February 2015-30th June. 2015

Professionals in charge of the recruitment: The GP or the Care Manager / GP nurse

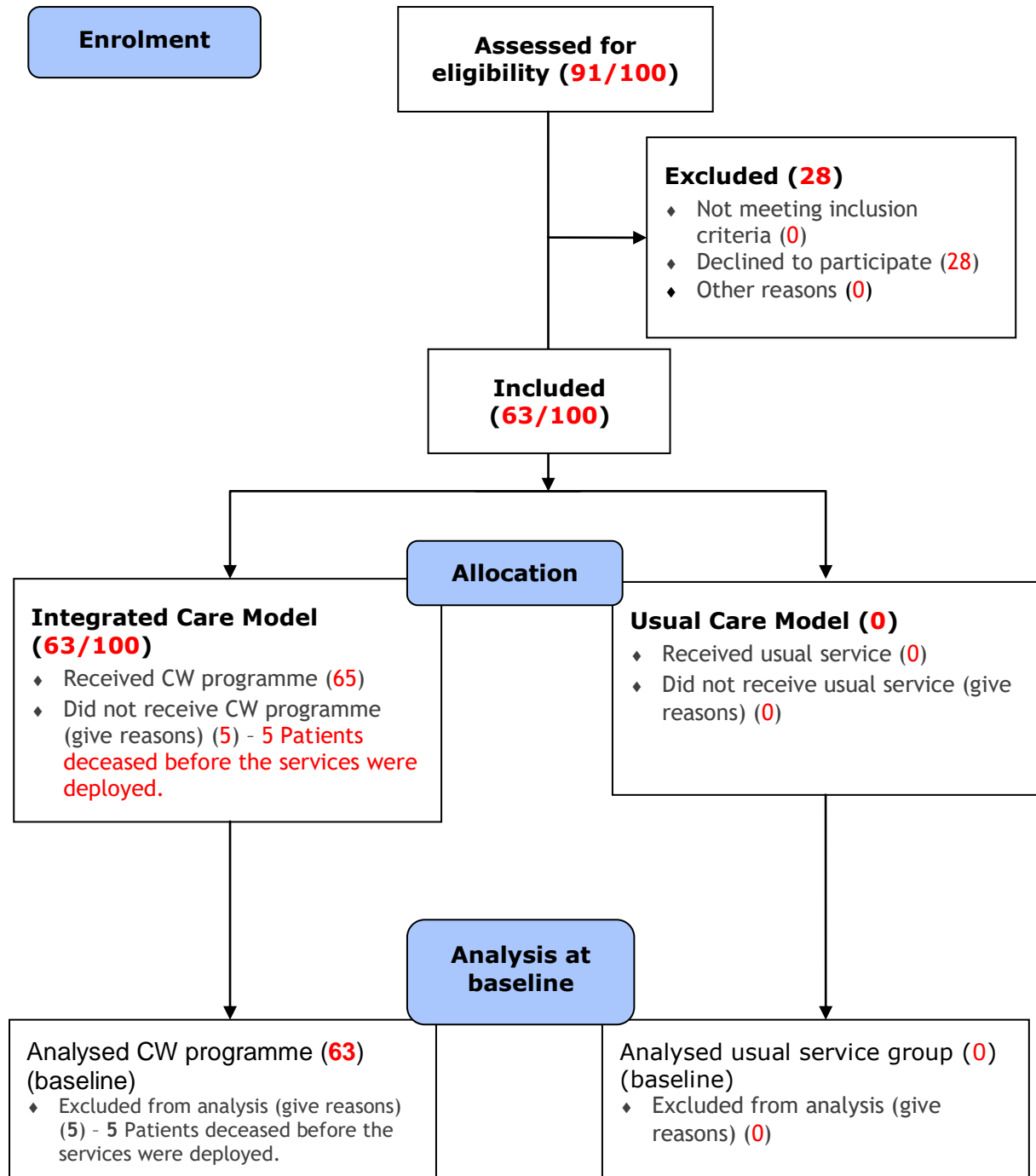


3.3.6 Powys

The flow chart has being filled out: November, 2015

The recruitment has been carried out: Start in April 2015 and continues beyond November 2015

Professionals in charge of the recruitment: The general practices in Powys were viewed as best placed and responsible for the recruitment of patients, the management of which is co-ordinated by the local Project Team.



3.4 Baseline analysis

This section presents the results of the baseline analysis performed for each pilot site, and also for the total of recruited patients across all the sites. It is very important to note that some discrepancies will be found between the figures indicated in the flow charts above, and the figures the baseline analysis has been performed on. This is due to the complex process of data uploading, reviewing and cleansing, and the conditions and time schedules to upload and access data both for the pilot sites' data managers as well as for the evaluation team. All these conditions and procedures are necessary in order to guarantee the quality and safety procedures of a research project with these characteristics. This situation has its maximum impact for two sites, Powys and Lower Silesia. Both are recruiting according to their objectives and timescales, but circumstances related to the data uploading requirements and follow up have made it impossible for this data to be included in the overall analysis. These issues have been resolved and their site specific results as well as the global analysis with these data included will be provided in the next version of this deliverable.

For each pilot site, two tables are presented and discussed;

- The first table presents the baseline characteristics of the evaluation population: age, gender and other socioeconomic measures, clinical description and comorbidities, as well as functional status. This information is presented separately for the intervention and control groups, and the statistical significance of any difference is provided. This assessment is relevant in order to state the comparability of the groups.
- The second table presents an analysis of the answers to the PIRU Questionnaire. This enables an approach, from a preliminary quantitative perspective, how the care process is perceived and valued by the participants.

These are the baseline results for each site.

3.4.1 Basque Country

Table 1: Basque Country: Baseline characteristics by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>Sample size (n)</i>	82	22		
Age	79.85 (6.73)	78.27 (6.36)	0.316	2
Gender			1	2
Female	27 (33.8%)	7 (31.8%)		
Male	53 (66.2%)	15 (68.2%)		
Marital status			0.441	4
Never married	7 (9%)	2 (9.1%)		
Currently married	53 (67.9%)	12 (54.5%)		
Separated				
Divorced				
Widowed	18 (23.1%)	8 (36.4%)		
Cohabiting				
Education			0.272	4
Less than primary school	13 (16.7%)	7 (31.8%)		
Primary school	47 (60.3%)	9 (40.9%)		
Secondary school				
High school	12 (15.4%)	5 (22.7%)		
College/University	6 (7.7%)	1 (4.5%)		
Post graduate degree				
Longest held occupation			0.32	5
Manual				
Non manual				
Unemployed (but able to work)				
Unemployed (unable to work)	65 (84.4%)	21 (95.5%)		

Measurement	Intervention	Control	Difference (p-value)	Missing values
Homemaker	12 (15.6%)	1 (4.5%)		
Household income (euro/year)			0.81	9
0-6.999				
7.000-13.999	57 (77%)	15 (71.4%)		
14.000-19.999				
20.000 or more	17 (23%)	6 (28.6%)		
Housing tenure			1	7
Owners	65 (85.5%)	18 (85.7%)		
Renters	11 (14.5%)	3 (14.3%)		
People older than 18 living in household				
Mobile use (Yes)	48 (61.5%)	15 (68.2%)	0.749	4
PC use (Yes)	11 (14.1%)	2 (9.1%)	0.796	4
Alcohol			0.838	13
None	40 (54.8%)	12 (66.7%)		
Less than 1/week	5 (6.8%)	1 (5.6%)		
1-7/week	5 (6.8%)	1 (5.6%)		
8-14/week	23 (31.5%)	4 (22.2%)		
15-21/week				
More than 21/week				
Tobacco use			0.482	4
Never	47 (60.3%)	15 (68.2%)		
Former	25 (32.1%)	5 (22.7%)		
Current smoker	3 (3.8%)	2 (9.1%)		
e-cigarette				
Other	3 (3.8%)	0 (0%)		
Height (cm)	161.8 (9.19)	164.36 (10.68)	0.315	6
Weight (kg)	83.52 (18.09)	79.97 (18.91)	0.439	5
Heart rate (bpm)	73.39 (11.41)	72.73 (7.13)	0.742	5
Systolic blood pressure (mmHg)	130.79 (15.33)	140.55 (14.59)	0.01	4
Diastolic blood pressure (mmHg)	70.03 (9.7)	69.73 (9.39)	0.897	4
Oxygen saturation (%)	95.76 (2.1)	94.41 (3.91)	0.132	6
Blood glucose (mg/dl)	126.91 (46.99)	133 (36.13)	0.783	88
HbA1c (%)	7.13 (1.43)	6.05 (0.21)	0.058	93
Creatinine (mg/dl)	1.15 (0.41)	1.01 (0.29)	0.503	89
Primary disease				
Primary disease CHF				
Primary disease COPD				
Primary disease DIABETES				
Secondary disease				
Secondary disease CHF				
Secondary disease COPD				
Secondary disease DIABETES				
Comorbidity ICD-10 codes				
Myocardial infarct				
Congestive heart failure				
Peripheral vascular disease				
Cerebrovascular disease				
Dementia				
Chronic pulmonary disease				
Rheumatic disease				
Peptic ulcer disease				
Mild liver disease				
Diabetes without chronic complication				
Diabetes with chronic complication				
Hemiplegia or paraplegia				
Renal disease				
Any malignancy				
Moderate or severe liver disease				
Metastatic solid tumour				
Barthel index - 100	86.46 (22.31)	88.86 (13.97)	0.537	0
GDS - Geriatric Depression Scale (Short Form)	3.5 (2.81)	4.95 (2.42)	0.021	0

Quantitative data presented as mean (SD) and qualitative data presented as frequencies (%).

At this time, a total of 104 patients have been recruited in the Basque Country; 82 patients have been assigned to the intervention group, and 22 to the control group. Over the last few weeks, the number of controls recruited has increased exponentially, getting close to the intervention group. However, these data are not included in this report due to the timing issues and processes referred to above.

Participants have a mean age of 78.5 years, being a bit older in the intervention group, but without statistics significance. Regarding gender distribution, 67% are men without differences between groups. Education level is also comparable, with most participants having completed primary school education, and also comparable is the household income level. The low number of missing answers to this question is interesting; it tends to be avoided by participants of this age.

More surprising are the absence of differences in mobile and PC use between groups and the high percentage of subjects familiar with the phone and low with PCs.

With regard to health related live habits, most of the participants present a moderate pattern of alcohol consumption. Most participants have never smoked nor are former smokers, without differences between groups.

When clinical control parameters are assessed, it is interesting to find that mean blood pressure categorises as hypertension; but no differences can be found between control and intervention group. The high number of missing values for HbA1c and creatinine levels is due to the inclusion of the control of these parameters among the ones that need to be reviewed in order to control each diseases, for example, HbA1c could only be assessed for patients with diabetes mellitus, and has no clinical meaning for patients with other diseases. All the assessed parameters are close to good control measures.

Information about primary and secondary diseases is not currently available, but these variables will be presented and discussed in the next version of this document.

Another significant characteristic of participants is their level of functional dependence, measured by Barthel Index. In this case there are no differences between the intervention and the control groups and all present a mean below 90, indicating moderate dependence.

Regarding baseline mental health, both groups present mean values corresponding to normality, though close to depression.

Table 1.1: Basque Country: Baseline PIRU questionnaire by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
PIRU questionnaire on user experience of Integrated Care				
Have all your needs been assessed?			0	0
<i>All of my needs have been assessed</i>	74 (90.2%)	12 (54.5%)		
<i>Some of my needs have been assessed</i>	8 (9.8%)	10 (45.5%)		
<i>None of my needs have been assessed</i>				
<i>Don't know/can't remember</i>				
Were you involved as much as you wanted to be in decisions about your care and support?			0.001	0
<i>Yes, definitely</i>	75 (91.5%)	13 (59.1%)		
<i>Yes, to some extent</i>	7 (8.5%)	9 (40.9%)		
<i>No</i>				

Measurement	Intervention	Control	Difference (p-value)	Missing values
Were you involved as much as you wanted to be in decisions about your treatment? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i>	 73 (89%) 9 (11%)	 11 (50%) 11 (50%)	 0	 0
Were your family or carer involved in decisions about your care and support as much as you wanted them to be? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i> <i>There were no family or carers available to be involved</i> <i>I didn't want my family or carer to be involved in decisions about my care and support</i>	 71 (86.6%) 2 (2.4%) 2 (2.4%) 6 (7.3%) 1 (1.2%)	 16 (72.7%) 4 (18.2%) 0 (0%) 0 (0%) 2 (9.1%)	 0.008	 0
Were your family or carer involved in decisions about your treatment as much as you wanted them to be? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i> <i>There were no family or carers available to be involved</i> <i>I didn't want my family or carer to be involved in decisions about my treatment and support</i>	 71 (86.6%) 2 (2.4%) 2 (2.4%) 6 (7.3%) 1 (1.2%)	 13 (59.1%) 5 (22.7%) 0 (0%) 1 (4.5%) 3 (13.6%)	 0.001	 0
Overall, do you feel that your carer/family has had as much support from health and social services as they needed? <i>Yes, they have had as much support as they needed</i> <i>They have had some support but not as much as they needed</i> <i>No, they have had little or no support</i> <i>They did not want/need support</i> <i>There are no family members or carers to support</i>	 55 (67.1%) 11 (13.4%) 4 (4.9%) 10 (12.2%) 2 (2.4%)	 6 (27.3%) 2 (9.1%) 2 (9.1%) 11 (50%) 1 (4.5%)	 0.001	 0
To what extent do you agree or disagree with the following statement... 'Health and social care staff always tell me what will happen next' <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 63 (76.8%) 5 (6.1%) 5 (6.1%) 9 (11%) 0 (0%)	 15 (68.2%) 2 (9.1%) 2 (9.1%) 2 (9.1%) 1 (4.5%)	 0.352	 0
When health or social care staff plan care or treatment for you, does it happen? <i>Yes, it happens all of the time</i> <i>It happens most of the time</i> <i>It happens some of the time</i> <i>No</i>	 74 (90.2%) 3 (3.7%) 1 (1.2%) 4 (4.9%)	 11 (50%) 7 (31.8%) 4 (18.2%) 0 (0%)	 0	 0

Measurement	Intervention	Control	Difference (p-value)	Missing values
To what extent do you agree or disagree with the following statement...‘My care and support is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 72 (87.8%) 3 (3.7%) 3 (3.7%) 3 (3.7%) 1 (1.2%)	 15 (68.2%) 3 (13.6%) 3 (13.6%) 1 (4.5%) 0 (0%)	0.131	0
To what extent do you agree or disagree with the following statement...‘My treatment is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 73 (89%) 4 (4.9%) 1 (1.2%) 3 (3.7%) 1 (1.2%)	 15 (68.2%) 4 (18.2%) 2 (9.1%) 0 (0%) 1 (4.5%)	0.034	0
To what extent do you agree or disagree with the following statement...‘My medicines are thoroughly reviewed as often as they should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 59 (72%) 5 (6.1%) 11 (13.4%) 6 (7.3%) 1 (1.2%)	 14 (63.6%) 4 (18.2%) 2 (9.1%) 1 (4.5%) 1 (4.5%)	0.336	0
Do you have a named health or social care professional who co-ordinates your care and support? <i>Yes</i> <i>No, I co-ordinate my own care and support</i> <i>Don't know/not sure</i>	 82 (100%) 0 (0%) 0 (0%)	 19 (86.4%) 2 (9.1%) 1 (4.5%)	0.003	0
If you have questions, when can you contact the people treating and caring for you? Please tick ALL that apply <i>During normal working hours</i> <i>During the evening</i> <i>During the night</i> <i>Weekends</i> <i>Don't know/not sure</i>	 72 (87.8%) 8 (9.8%) 2 (2.4%)	 22 (100%) 0 (0%) 0 (0%)	0.227	0
Do you feel this person understands about you and your condition? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i>	 76 (92.7%) 5 (6.1%) 1 (1.2%)	 19 (86.4%) 3 (13.6%) 0 (0%)	0.444	0
Do all the different people treating and caring for you work well together to give you the best possible care and support? <i>Yes, all of them work well together</i> <i>Most of them work well together</i>	 73 (89%) 3 (3.7%)	 17 (77.3%) 4 (18.2%)	0.052	0

Measurement	Intervention	Control	Difference (p-value)	Missing values
Some of them work well together No, they do not work well together Don't know/not sure	6 (7.3%)	1 (4.5%)		
Do health and social care services help you live the life you want as far as possible? Yes, definitely Yes, to some extent No	53 (64.6%) 20 (24.4%) 9 (11%)	4 (18.2%) 18 (81.8%) 0 (0%)	0	0
To what extent do you agree or disagree with the following statement... 'In the last 12 months, health and social care staff have given me information about other services that are available to someone in my circumstances, including support organisations' Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree	16 (19.5%) 0 (0%) 0 (0%) 66 (80.5%)	2 (9.1%) 6 (27.3%) 9 (40.9%) 5 (22.7%)	0	0
Data presented as frequencies (%)				

Significant differences can be found between intervention and control groups in almost all the questions, with the intervention group, in general, being more satisfied with the usual received care. The presence of this difference is probably unavoidable at this point; so, the discussion of the results and analysis for PIRU questionnaire should be based on the differences found between pre and post values in order to avoid the introduction of bias.

Considering the questions of the PIRU questionnaire in individually, it is interesting to note that the first set of questions that explore the perceived involvement of the patients and the carers in the decision making process related to the care provision is very positive, and more so among the subjects in the intervention group. When information and treatment review is explored, satisfaction is still very high, but lower for controls. And finally, when access to care and to other services is explored, results are variable, again tending to high satisfaction and low when availability of other services is explored.

3.4.2 Croatia

Table 2: Croatia: Baseline characteristics by group

Measurement	Intervention	Control	Difference (p)	Missing
Sample size (n)	52	52		0
Age	76,85 (6,60)	78,24 (7,23)	0,325	5
Gender				
Male	27 (55,1%)	30 (60,0%)	0,622	5
Female	22 (44,9%)	20 (40,0%)		
Marital status				
Never married	1 (2,0%)	1 (2,0%)	0,234	5
Currently married	35 (71,5%)	25 (50,0%)		
Separated	0	0		
Divorced	2 (4,1%)	2 (4,0%)		
Widowed	10 (20,4%)	21 (42,0%)		
Cohabiting	1 (2,0%)	1 (2,0%)		
Education				
Less than primary school	5 (10,2%)	2 (4,0%)		5
Primary school	4 (8,2%)	8 (16,0%)		

Measurement	Intervention	Control	Difference (p)	Missing
Secondary school	3 (6,1%)	7 (14,0%)	0,181	
High school	23 (47,0%)	20 (40,0%)		
College/University	11 (22,4%)	13 (26,0%)		
Post graduate degree	3 (6,1%)	0		
Longest held occupation			0,635	12
Manual	17 (38,6%)	19 (39,6%)		
Non manual	24 (54,6%)	23 (47,9%)		
Self-employed	0 (0)	0 (0)		
Unemployed (but able to work)	0	1 (2,1%)		
Unemployed (unable to work)	0 (0)	0 (0)		
Homemaker	3 (6,8%)	5 (10,4%)		
Household income (euro/year)				104
0-6.999	0 (0)	0 (0)		
7.000-13.999	0 (0)	0 (0)		
14.000-19.999	0 (0)	0 (0)		
20.000 or more	0 (0)	0 (0)		
Housing tenure			0,543	13
Owners	43 (93,5%)	44 (97,8%)		
Renters	3 (6,5%)	1 (2,2%)		
People older than 18 living in household	2,88 (1,79)	2,40 (1,11)	0,112	5
Mobile use (Yes)	31 (63,3%)	38 (76,0%)	0,168	5
PC use (Yes)	15 (30,6%)	11 (22,0%)	0,330	5
Alcohol				104
None	0 (0)	0 (0)		
Less than 1/week	0 (0)	0 (0)		
1-7/week	0 (0)	0 (0)		
8-14/week	0 (0)	0 (0)		
15-21/week	0 (0)	0 (0)		
More than 21/week	0 (0)	0 (0)		
Tobacco use			0,765	1
Never	33 (63,5%)	30 (58,8%)		
Former	14 (26,9%)	17 (33,3%)		
Current smoker	5 (9,6%)	4 (7,9%)		
e-cigarette	0 (0)	0 (0)		
Other	0 (0)	0 (0)		
Height (cm)	161,87 (15,84)	159,92 (14,26)	0,513	0
Weight (kg)	71,12 (29,082)	65,94 (19,515)	0,289	0
Primary disease			0,673	6
Primary disease CHF	18 (36,0%)	16 (34,0%)		
Primary disease COPD	21 (42,0%)	21 (44,7%)		
Primary disease DIABETES	11 (22,0%)	10 (21,3%)	0,685	6
Secondary disease			0,514	6
Secondary disease CHF	30 (60,0%)	25 (52,1%)		
Secondary disease COPD	5 (10,0%)	9 (18,8%)		
Secondary disease DIABETES	12 (24,0%)	7 (14,6%)	0,327	6
Secondary disease DIABETES			0,351	6
Comorbidity ICD-10 codes			0,830	4
Myocardial infarct	15 (29,4%)	14 (28,6%)		
Congestive heart failure	33 (67,3%)	22 (47,8%)		
Peripheral vascular disease	37 (75,5%)	35 (71,4%)		
Cerebrovascular disease	29 (58,0%)	21 (44,7%)		
Dementia	15 (28,8%)	9 (18,4%)		
Chronic pulmonary disease	19 (36,5%)	21 (41,2%)		
Rheumatic disease	17 (32,7%)	19 (39,6%)		
Peptic ulcer disease	6 (11,8%)	7 (15,2%)		
Mild liver disease	5 (9,6%)	3 (6,1%)		
Diabetes without chronic complication	40 (76,9%)	35 (68,6%)		
Diabetes with chronic complication	21 (41,2%)	12 (23,5%)		
Hemiplegia or paraplegia	4 (7,7%)	3 (5,9%)		
Renal disease	10 (20,0%)	4 (8,2%)		
Any malignacy	4 (8,5%)	2 (4,5%)		
Moderate or severe liver disease	4 (8,3%)	3 (6,1%)		
Metastatic solid tumor	2 (4,5%)	0		

Measurement	Intervention	Control	Difference (p)	Missing
Barthel index - 100	88,17 (19,93)	91,27 (13,56)	0,359	0
GDS - Geriatric Depression Scale (Short Form)	3,81 (3,21)	4,36 (3,29)	0,407	0

At the baseline enrolment, Croatian pilot site had equal sample patient distribution in intervention and control group. Average age was 76,85 for the intervention group and 78,24 for the control group. Gender was equally distributed: in intervention group there were 55,1% male patients versus 60% in the control group. Regarding other socio demographic characteristics, in both groups most patients are married (71,5% in intervention vs. 50,0% in control group); concerning education, most of the patients finished high school (47,0% vs. 40,0%); most of them through their life worked a non manual job (54,6% vs. 47,9%).

Surprisingly, all of the enrolled patients declined to answer about their income, which may partly be explained by the fact that they were giving answers to a person they know. Almost all of the patients own their houses/apartments (93,5% vs. 97,8%). Average number of people above 18 years old living in the household is 2,88 (intervention) and 2,40 (control). More than half of them use mobile phone (63,3% vs 76,0%), whereas a smaller number of patients know how to use personal computer (30,6% vs. 22,0%). As with the household income, no patient wanted to respond regarding drinking alcohol. More than half of them never smoked tobacco, but a few of them still do smoke (9,6% vs. 7,9%). Average height was 161,87cm vs 159,92cm for controls. Weight was also similar in both groups (71,12kg vs 65,94kg). Most of the patients have COPD for primary chronic disease in both groups, and CHF for secondary chronic disease. COPD had 42% and 44,7% respectively, while CHF as a secondary disease had 60,0% and 52,1%. Regarding comorbidity, most of the patients had peripheral vascular disease (75,5% vs 71,4% controls) and diabetes without chronic complication (76,9% vs 68,6% control).

The interpretation of Barthel index shows us that patients from the intervention group, based by their scoring, are moderately dependent (average score of 88,17) while patients from control group are only slightly dependent (average of 91,27). The GDS scale analysis in both groups led to the conclusion that both patient groups did not have suggestive depression – average score was 3,81 vs 4,36 for controls.

For the data analysis we have used student's t-test for quantitative variables and χ^2 test for qualitative variables. In these baseline characteristics, no statistically significant differences between groups were found in any of the variables (no significance was less than or equal to 0.05 in confidence interval of 95%).

Table 2.1: Croatia: Baseline PIRU questionnaire by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
PIRU questionnaire on user experience of Integrated Care				
Have all your needs been assessed?				
<i>All of my needs have been assessed</i>	36 (72,0%)	39 (81,2%)		
<i>Some of my needs have been assessed</i>	11 (22,0%)	7 (14,6%)	0,160	3
<i>None of my needs have been assessed</i>	2 (4,0%)	1 (2,1%)		
<i>Don't know/can't remember</i>	1 (2,0%)	1 (2,1%)		
Were you involved as much as you wanted to be in decisions about your care and support?				
<i>Yes, definitely</i>	31 (62,0%)	33 (66,0%)	0,874	1
<i>Yes, to some extent</i>	16 (32,0%)	13 (26,0%)		



Measurement	Intervention	Control	Difference (p-value)	Missing values
No	3 (6,0%)	4 (8,0%)		
Were you involved as much as you wanted to be in decisions about your treatment?				
Yes, definitely	31 (62,0%)	33 (66,0%)	0,743	1
Yes, to some extent	16 (32,0%)	14 (28,0%)		
No	3 (6,0%)	3 (6,0%)		
Were your family or carer involved in decisions about your care and support as much as you wanted them to be?				
Yes, definitely	37 (74,0%)	33 (66,0%)		
Yes, to some extent	10 (20,0%)	5 (10,0%)		
No	2 (4,0%)	5 (10,0%)	0,052	1
There were no family or carers available to be involved	0	5 (10,0%)		
I didn't want my family or carer to be involved in decisions about my care and support	1 (2,0%)	2 (4,0%)		
Were your family or carer involved in decisions about your treatment as much as you wanted them to be?				
Yes, definitely	39 (78,0%)	31 (62,0%)		
Yes, to some extent	9 (18,0%)	7 (14,0%)		
No	1 (2,0%)	4 (8,0%)		
There were no family or carers available to be involved	0	5 (10,0%)	0,540	1
I didn't want my family or carer to be involved in decisions about my treatment and support	1 (2,0%)	3 (6,0%)	0,011	
Overall, do you feel that your carer/family has had as much support from health and social services as they needed?				
Yes, they have had as much support as they needed	43 (86,0%)	32 (66,6%)		
They have had some support but not as much as they needed	4 (8,0%)	9 (18,8%)	0,159	3
No, they have had little or no support	2 (4,0%)	1 (2,1%)		
They did not want/need support	1 (2,0%)	1 (2,1%)		
There are no family members or carers to support	0	5 (10,4%)		
To what extent do you agree or disagree with the following statement... 'Health and social care staff always tell me what will happen next'				
Strongly agree	12 (24,5%)	13 (26,5%)	0,934	3
Agree	20 (40,8%)	19 (38,8%)		
Neither agree nor disagree	15 (30,6%)	10 (20,4%)		
Disagree	2 (4,1%)	7 (14,3%)		
Strongly disagree	0	0		
When health or social care staff plan care or treatment for you, does it happen?				
Yes, it happens all of the time	29 (61,7%)	30 (62,4%)	0,747	6
It happens most of the time	16 (34,0%)	15 (31,3%)		
It happens some of the time	2 (4,3%)	2 (4,2%)		
No	0	1 (2,1%)		

Measurement	Intervention	Control	Difference (p-value)	Missing values
To what extent do you agree or disagree with the following statement...‘My care and support is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	20 (40,0%) 23 (46,0%) 6 (12,0%) 1 (2,0%) 0	19 (39,6%) 19 (39,6%) 8 (16,6%) 2 (4,2%) 0	0,160	3
To what extent do you agree or disagree with the following statement...‘My treatment is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	21 (42,0%) 21 (42,0%) 8 (16,0%) 0 0	21 (42,8%) 19 (38,8%) 7 (14,3%) 2 (4,1%) 0	0,322	2
To what extent do you agree or disagree with the following statement...‘My medicines are thoroughly reviewed as often as they should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	17 (34,0%) 22 (44,0%) 9 (18,0%) 2 (4,0%) 0	22 (44,0%) 15 (30,0%) 12 (24,0%) 1 (2,0%) 0	0,638	1
Do you have a named health or social care professional who co-ordinates your care and support? <i>Yes</i> <i>No, I co-ordinate my own care and support</i> <i>Don't know/not sure</i>	42 (85,7%) 5 (10,2%) 2 (4,1%)	43 (86,0%) 5 (10,0%) 2 (4,0%)	0,322	2
If you have questions, when can you contact the people treating and caring for you? Please tick ALL the apply <i>During normal working hours</i> <i>During the evening</i> <i>During the night</i> <i>Weekends</i> <i>Don't know/not sure</i>	46 (95,8%) 0 (0) 0 (0) 0 (0) 2 (4,2%)	46 (97,9%) 0 (0) 0 (0) 0 (0) 1 (2,1%)	0,636	6
Do you feel this person understands about you and your condition? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i>	43 (89,6%) 5 (10,4%) 0	40 (85,1%) 6 (12,8%) 1 (2,1%)	0,681	6
Do all the different people treating and caring for you work well together to give you the best possible care and support? <i>Yes, all of them work well together</i> <i>Most of them work well together</i>	35 (71,4%) 9 (18,4%)	32 (72,7%) 8 (18,2%)	0,054	8

Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>Some of them work well together</i>	1 (2,0%)	3 (6,8%)		
<i>No, they do not work well together</i>	0	1 (2,3%)		
<i>Don't know/not sure</i>	4 (8,2%)	0		
Do health and social care services help you live the life you want as far as possible?				
<i>Yes, definitely</i>	28 (58,3%)	29 (60,4%)	0,954	5
<i>Yes, to some extent</i>	18 (37,5%)	15 (31,3%)		
<i>No</i>	2 (4,2%)	4 (8,3%)		
To what extent do you agree or disagree with the following statement... 'In the last 12 months, health and social care staff have given me information about other services that are available to someone in my circumstances, including support organisations'				
<i>Strongly agree</i>	14 (28,0%)	16 (32,7%)	0,322	2
<i>Agree</i>	22 (44,0%)	11 (22,4%)		
<i>Neither agree nor disagree</i>	10 (20,0%)	16 (32,7%)		
<i>Disagree</i>	4 (8,0%)	6 (12,2%)		
<i>Strongly disagree</i>	0 (0)	0 (0)		

Regarding baseline PIRU questionnaire, most of the patients from both groups were very satisfied with involvement of themselves or their carers and family in their care, and expressing the opinion that all of their needs were assessed (72% intervention vs, 81,2% controls). Patients demonstrated awareness of connectivity between social care and medical care staff, concluding that these staff work together and that they are receiving good care. Almost every patient thinks that the healthcare professional who co-ordinates and supports their care understands them and understand their condition (89,6% vs 85,4% in control group). Patients have found their care, support, treatment and medicine is reviewed regularly.

Again, for this analysis we have used student's t-test for quantitative variables and χ^2 test for qualitative variables. Regarding statistical differences lower than 0.05, there was only one showing $p=0.011$; this was variable "Were your family or carers involved in decisions about your treatment as much as you wanted them to be?". Results demonstrated that patients in the control group experienced less participation of family members and carers in their treatment than patients in the intervention group.

3.4.3 Lower Silesia

The baseline analysis from Lower Silesia is not available for this first version of the document. Although patients have been recruited, and the information has been compiled, several problems with the usual data processing occurred, impeding the corresponding analysis. The results of the baseline analysis and the corresponding interpretation of findings will be included in the version 2 of this D7.2 due mid-February 2016.

3.4.4 Veneto

Table 3: Veneto: Baseline characteristics by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>Sample size (n)</i>	6	5		
Age	85.33 (6.8)	87 (9.49)	0.752	0



Measurement	Intervention	Control	Difference (p-value)	Missing values
Gender			1	0
Female	3 (50%)	2 (40%)		
Male	3 (50%)	3 (60%)		
Marital status			0.632	0
Never married	1 (16.7%)	0 (0%)		
Currently married	2 (33.3%)	2 (40%)		
Separated				
Divorced				
Widowed	3 (50%)	3 (60%)		
Cohabiting				
Education			0.329	0
Less than primary school	1 (16.7%)	0 (0%)		
Primary school	5 (83.3%)	3 (60%)		
Secondary school	0 (0%)	1 (20%)		
High school	0 (0%)	1 (20%)		
College/University				
Post graduate degree				
Longest held occupation			0.946	0
Manual	3 (50%)	2 (40%)		
Non manual	2 (33.3%)	2 (40%)		
Unemployed (but able to work)				
Unemployed (unable to work)				
Homemaker	1 (16.7%)	1 (20%)		
Household income (euro/year)				
0-6.999				
7.000-13.999				
14.000-19.999				
20.000 or more				
Housing tenure			0.83	1
Owners	6 (100%)	3 (75%)		
Renters	0 (0%)	1 (25%)		
People older than 18 living in household	1 (0.63)	1 (1.22)	1	0
Mobile use (Yes)	2 (33.3%)	3 (60%)	0.782	0
PC use (Yes)	0 (0%)	0 (0%)	0.763	0
Alcohol			0.176	0
None	2 (33.3%)	3 (60%)		
Less than 1/week	1 (16.7%)	2 (40%)		
1-7/week	3 (50%)	0 (0%)		
8-14/week				
15-21/week				
More than 21/week				
Tobacco use			1	0
Never	5 (83.3%)	4 (80%)		
Former	1 (16.7%)	1 (20%)		
Current smoker				
e-cigarette				
Other				
Height (cm)	165.67 (5.89)	167.6 (7.54)	0.654	0
Weight (kg)	69 (16.3)	72.8 (13.2)	0.679	0
Heart rate (bpm)	71 (11.58)	75.6 (5.37)	0.413	0
Systolic blood pressure (mmHg)	131.67 (11.69)	126 (16.73)	0.544	0
Diastolic blood pressure (mmHg)	75.83 (6.65)	72 (8.37)	0.432	0
Oxygen saturation (%)	95.25 (2.36)	96.2 (3.63)	0.651	2
Blood glucose (mg/dl)	111.2 (36)	142.5 (54.05)	0.365	2
HbA1c (%)	6.95 (0.92)	8.3 (0.42)	0.25	7
Creatinine (mg/dl)	2 (33.3%)	3 (60%)	0.782	0
NYHA Funcional Clasification			0.152	0
Cardiac disease-no symptoms	0 (0%)	3 (60%)		
Mild symptoms	3 (50%)	1 (20%)		
Marked limitation due to symptoms	2 (33.3%)	1 (20%)		
Severe symptoms	1 (16.7%)	0 (0%)		
NIHSS			0.924	0



Measurement	Intervention	Control	Difference (p-value)	Missing values
No stroke symptoms	6 (100%)	4 (80%)		
Minor Stroke	0 (0%)	1 (20%)		
Moderate Stroke				
Moderate to Severe Stroke				
Severe Stroke				
Primary disease				
Primary disease CHF	1 (16.7%)	1 (20%)	1	0
Primary disease COPD	2 (33.3%)	2 (40%)	1	0
Primary disease DIABETES	3 (50%)	2 (40%)	1	0
Secondary disease				
Secondary disease CHF	3 (50%)	2 (40%)	1	0
Secondary disease COPD	0 (0%)	0 (0%)	0.763	0
Secondary disease DIABETES	1 (16.7%)	0 (0%)	1	0
Comorbidity ICD-10 codes				
Myocardial infarct	2 (33.3%)	0 (0%)	0.521	0
Congestive heart failure	3 (50%)	2 (40%)	1	0
Peripheral vascular disease	1 (16.7%)	2 (40%)	0.853	0
Cerebrovascular disease	0 (0%)	2 (40%)	0.354	0
Dementia	0 (0%)	0 (0%)	0.763	0
Chronic pulmonary disease	3 (50%)	2 (40%)	1	0
Rheumatic disease	0 (0%)	0 (0%)	0.763	0
Peptic ulcer disease	1 (16.7%)	1 (20%)	1	0
Mild liver disease	0 (0%)	0 (0%)	0.763	0
Diabetes without chronic complication	0 (0%)	0 (0%)	0.763	0
Diabetes with chronic complication	3 (50%)	2 (40%)	1	0
Hemiplegia or paraplegia	0 (0%)	0 (0%)	0.763	0
Renal disease	1 (16.7%)	0 (0%)	1	0
Any malignancy	1 (16.7%)	0 (0%)	1	0
Moderate or severe liver disease	0 (0%)	0 (0%)	0.763	0
Metastatic solid tumor	0 (0%)	0 (0%)	0.763	0
Barthel index - 100	77.5 (11.73)	72 (23.08)	0.647	0
GDS - Geriatric Depression Scale (Short Form)	2.83 (1.17)	1.8 (1.1)	0.166	0

Quantitative data presented as mean (SD) and qualitative data presented as frequencies (%).

The analysis of this data refers to a provisional sample of 11 patients in Veneto. Baseline characteristics of these patients are similar between the two groups, as set out in Table 3.

In relation to socio-demographic data, the intervention group is composed of six patients, three male and three female, with an average age of 85, while the comparator group is composed by five patients, two male and three female, with an average age of 87.

The majority of patients are widowed, but they lived in household with one person older than 18. Almost all are owners of their house.

Both intervention and comparator group are characterised by low educational attainment (primary school), and the longest held occupation is manual. None of them are able to use a PC, but 33.3% of the intervention group and the 60% of the comparator group are able to use a mobile phone.

With regard to the clinical data, the main differences is with the NYHA Functional classification. The majority of the patients of the intervention group present cardiac disease, but no symptoms and no limitations to ordinary physical activity (e.g. no shortness of breath when walking, climbing stairs) while most of the control group show mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

The majority of patients have diabetes as primary disease (50% in the intervention group and 40% in the control group) and cardiac heart failure (CHF) as secondary disease (50% in the intervention group and 40% in the control group). Among the comorbidities

are CHF (50% vs. 40%), COPD (50% vs. 40%) and diabetes with chronic complications (50% vs. 40% in the control group).

The ability to perform daily activities is evaluated using the Barthel Index: the intervention group achieved a higher mean score than the control group (77.5 vs. 72); this means that on average the patients in the intervention group are more independent than those in the control group in performing daily activities. Both groups report low values of the GDS's score (< 5) so none show depressive symptoms.

The analyses of the data obtained by the PIRU questionnaires do not demonstrate statistically significant differences. Table 3.1 shows that the majority of patients declare that all their needs are assessed and they (and their families or carers) are involved in their treatment, care and support.

Table 3.1: Veneto: Baseline PIRU questionnaire by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
PIRU questionnaire on user experience of Integrated Care				
Have all your needs been assessed?			0.924	0
<i>All of my needs have been assessed</i>	6 (100%)	4 (80%)		
<i>Some of my needs have been assessed</i>	0 (0%)	1 (20%)		
<i>None of my needs have been assessed</i>				
<i>Don't know/can't remember</i>				
Were you involved as much as you wanted to be in decisions about your care and support?			0.763	0
<i>Yes, definitely</i>	6 (100%)	5 (100%)		
<i>Yes, to some extent</i>				
<i>No</i>				
Were you involved as much as you wanted to be in decisions about your treatment?			1	0
<i>Yes, definitely</i>	5 (83.3%)	5 (100%)		
<i>Yes, to some extent</i>	1 (16.7%)	0 (0%)		
<i>No</i>	0	0		
Were your family or carer involved in decisions about your care and support as much as you wanted them to be?			0.924	0
<i>Yes, definitely</i>	6 (100%)	4 (80%)		
<i>Yes, to some extent</i>				
<i>No</i>	0 (0%)	1 (20%)		
<i>There were no family or carers available to be involved</i>				
<i>I didn't want my family or carer to be involved in decisions about my care and support</i>				
Were your family or carer involved in decisions about your treatment as much as you wanted them to be?			0.924	0
<i>Yes, definitely</i>	6 (100%)	4 (80%)		
<i>Yes, to some extent</i>				
<i>No</i>	0 (0%)	1 (20%)		
<i>There were no family or carers available to be involved</i>				



Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>I didn't want my family or carer to be involved in decisions about my treatment and support</i>				
Overall, do you feel that your carer/family has had as much support from health and social services as they needed?			1	0
<i>Yes, they have had as much support as they needed</i>	5 (83.3%)	5 (100%)		
<i>They have had some support but not as much as they needed</i>	1 (16.7%)	0 (0%)		
<i>No, they have had little or no support</i>				
<i>They did not want/need support</i>				
<i>There are no family members or carers to support</i>				
To what extent do you agree or disagree with the following statement... 'Health and social care staff always tell me what will happen next'			0.231	0
<i>Strongly agree</i>	4 (66.7%)	4 (80%)		
<i>Agree</i>	2 (33.3%)	0 (0%)		
<i>Neither agree nor disagree</i>	0 (0%)	1 (20%)		
<i>Disagree</i>				
<i>Strongly disagree</i>				
When health or social care staff plan care or treatment for you, does it happen?			0.924	0
<i>Yes, it happens all of the time</i>	6 (100%)	4 (80%)		
<i>It happens most of the time</i>	0 (0%)	1 (20%)		
<i>It happens some of the time</i>				
<i>No</i>				
To what extent do you agree or disagree with the following statement... 'My care and support is reviewed as often as it should be'			1	0
<i>Strongly agree</i>	5 (83.3%)	4 (80%)		
<i>Agree</i>	1 (16.7%)	1 (20%)		
<i>Neither agree nor disagree</i>				
<i>Disagree</i>				
<i>Strongly disagree</i>				
To what extent do you agree or disagree with the following statement... 'My treatment is reviewed as often as it should be'			1	0
<i>Strongly agree</i>	4 (66.7%)	4 (80%)		
<i>Agree</i>	2 (33.3%)	1 (20%)		
<i>Neither agree nor disagree</i>				
<i>Disagree</i>				
<i>Strongly disagree</i>				
To what extent do you agree or disagree with the following statement... 'My medicines are thoroughly reviewed as often as they should be'			0.924	0
<i>Strongly agree</i>	6 (100%)	4 (80%)		
<i>Agree</i>	0 (0%)	1 (20%)		
<i>Neither agree nor disagree</i>				
<i>Disagree</i>				



Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>Strongly disagree</i>				
Do you have a named health or social care professional who co-ordinates your care and support?			1	0
<i>Yes</i>	2 (33.3%)	2 (40%)		
<i>No, I co-ordinate my own care and support</i>	4 (66.7%)	3 (60%)		
<i>Don't know/not sure</i>				
If you have questions, when can you contact the people treating and caring for you? Please tick ALL the apply			0.763	0
<i>During normal working hours</i>	6 (100%)	5 (100%)		
<i>During the evening</i>				
<i>During the night</i>				
<i>Weekends</i>				
<i>Don't know/not sure</i>				
Do you feel this person understands about you and your condition?			0.231	0
<i>Yes, definitely</i>	6 (100%)	3 (60%)		
<i>Yes, to some extent</i>	0 (0%)	1 (20%)		
<i>No</i>	0 (0%)	1 (20%)		
Do all the different people treating and caring for you work well together to give you the best possible care and support?			1	0
<i>Yes, all of them work well together</i>	5 (83.3%)	5 (100%)		
<i>Most of them work well together</i>	1 (16.7%)	0 (0%)		
<i>Some of them work well together</i>				
<i>No, they do not work well together</i>				
<i>Don't know/not sure</i>				
Do health and social care services help you live the life you want as far as possible?			0.853	0
<i>Yes, definitely</i>	5 (83.3%)	3 (60%)		
<i>Yes, to some extent</i>	1 (16.7%)	2 (40%)		
<i>No</i>				
To what extent do you agree or disagree with the following statement... 'In the last 12 months, health and social care staff have given me information about other services that are available to someone in my circumstances, including support organisations'			1	0
<i>Strongly agree</i>	5 (83.3%)	4 (80%)		
<i>Agree</i>	1 (16.7%)	1 (20%)		
<i>Neither agree nor disagree</i>				
<i>Disagree</i>				
<i>Strongly disagree</i>				
Data presented as frequencies (%)				

3.4.5 Puglia

Table 4: Puglia: Baseline characteristics by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
Sample size (n)	100	94		
Age	75.49 (6.51)	73.68 (6.9)	0.062	0
Gender			0.914	0
Female	45 (45%)	44 (46.8%)		
Male	55 (55%)	50 (53.2%)		
Marital status			0.77	0
Never married	2 (2%)	3 (3.2%)		
Currently married	77 (77%)	69 (73.4%)		
Separated	0 (0%)	1 (1.1%)		
Divorced	1 (1%)	2 (2.1%)		
Widowed	20 (20%)	19 (20.2%)		
Cohabiting				
Education			0.04	2
Less than primary school	26 (26.5%)	25 (26.6%)		
Primary school	54 (55.1%)	34 (36.2%)		
Secondary school	9 (9.2%)	18 (19.1%)		
High school	7 (7.1%)	14 (14.9%)		
College/University	2 (2%)	3 (3.2%)		
Post graduate degree				
Longest held occupation			0.326	163
Manual	0 (0%)	9 (33.3%)		
Non manual	1 (25%)	7 (25.9%)		
Unemployed (but able to work)				
Unemployed (unable to work)	3 (75%)	11 (40.7%)		
Homemaker				
Household income (euro/year)				
0-6.999				
7.000-13.999				
14.000-19.999				
20.000 or more				
Housing tenure			0.643	6
Owners	94 (95.9%)	84 (93.3%)		
Renters	4 (4.1%)	6 (6.7%)		
People older than 18 living in household	1.52 (0.86)	0.21 (0.58)	0	0
Mobile use (Yes)	76 (76%)	68 (72.3%)	0.676	0
PC use (Yes)	8 (8.3%)	16 (17%)	0.113	4
Alcohol			0	25
None	0 (0%)	35 (38%)		
Less than 1/week	26 (33.8%)	6 (6.5%)		
1-7/week	5 (6.5%)	8 (8.7%)		
8-14/week	6 (7.8%)	0 (0%)		
15-21/week	0 (0%)	2 (2.2%)		
More than 21/week	40 (51.9%)	41 (44.6%)		
Tobacco use			0.84	3
Never	54 (55.7%)	56 (59.6%)		
Former	39 (40.2%)	35 (37.2%)		
Current smoker	4 (4.1%)	3 (3.2%)		
e-cigarette				
Other				
Height (cm)	161.98 (8.32)	157.99 (9.62)	0.002	0
Weight (kg)	80.22 (16.95)	75.32 (12.76)	0.024	0
Heart rate (bpm)	70.48 (12.4)	76.56 (12.48)	0.001	1
Systolic blood pressure (mmHg)	128.16 (22.16)	136.17 (19.61)	0.008	0
Diastolic blood pressure (mmHg)	69.56 (12.71)	77.04 (8.99)	0	0
Oxygen saturation (%)	95.75 (2.75)	97.12 (1.7)	0	4
Blood glucose (mg/dl)	142.9 (48.21)	133.2 (38.38)	0.124	2
HbA1c (%)	7.27 (0.96)	6.73 (0.91)	0.001	57



Measurement	Intervention	Control	Difference (p-value)	Missing values
Creatinine (mg/dl)	1.12 (0.93)	0.96 (0.31)	0.121	13
Primary disease				
Primary disease CHF	28 (28%)	3 (3.2%)	0	0
Primary disease COPD	35 (35%)	9 (9.6%)	0	0
Primary disease DIABETES	57 (57%)	79 (84%)	0	0
Secondary disease				
Secondary disease CHF	24 (24%)	4 (4.3%)	0	0
Secondary disease COPD	30 (30%)	11 (11.7%)	0.003	0
Secondary disease DIABETES	58 (58%)	73 (77.7%)	0.006	0
Comorbidity ICD-10 codes				
Myocardial infarct	29 (29%)	12 (13.3%)	0.015	4
Congestive heart failure	37 (37.4%)	5 (5.5%)	0	4
Peripheral vascular disease	51 (52%)	7 (7.6%)	0	4
Cerebrovascular disease	22 (22%)	8 (8.6%)	0.018	1
Dementia	5 (5.1%)	1 (1.1%)	0.254	6
Chronic pulmonary disease	47 (47%)	11 (11.8%)	0	1
Rheumatic disease	6 (6%)	0 (0%)	0.047	1
Peptic ulcer disease	6 (6%)	0 (0%)	0.047	1
Mild liver disease	10 (10%)	0 (0%)	0.005	1
Diabetes without chronic complication	54 (54%)	0 (0%)	0	1
Diabetes with chronic complication	29 (29%)	38 (42.7%)	0.07	5
Hemiplegia or paraplegia	2 (2%)	1 (1.1%)	1	2
Renal disease	9 (9%)	0 (0%)	0.009	2
Any malignancy	17 (17%)	0 (0%)	0	1
Moderate or severe liver disease	5 (5%)	3 (3.3%)	0.81	2
Metastatic solid tumor	100 (100%)	93 (100%)	0.614	1
Barthel index - 100	83.94 (23.62)	98.01 (8.18)	0	12
GDS - Geriatric Depression Scale (Short Form)	5.56 (3.48)	3.46 (2.99)	0	3

Quantitative data presented as mean (SD) and qualitative data presented as frequencies (%).

No significant differences were found in age, sex and marital status between the two groups (intervention and controls). Regarding the educational level: the mean differences were in primary school (55.1% vs 36.2%) and in secondary/high school (16.3% vs 34.0%).

95.9% of intervention group and 93.3% of control group own their house, with no statistically significant differences. There are no subjects aged 18 or below, who lived with patients. 76% of intervention group and 72.3% of controls were used to using a mobile phone, while only 8.3% vs. 17% were used to use a PC.

The apparent difference in alcohol consumption between the two groups was not clinically relevant, while the tobacco use is not different in the two cohorts.

The average values of height, weight, heart rate, blood pressure (systolic and diastolic), glucose, oxygen saturation, glycated hemoglobin and creatinine were significantly different; an analysis with a categorisation of the same variables is needed.

The analysis of primary, secondary pathology and comorbidities reveals the absence of homogeneity between interventions and controls.

The Barthel Index, the score that measures the quality of life analysing aspects such as self-sufficiency and motor skills, revealed an average value equal to 83.94 in intervention group, with a high standard deviation that denotes lack of homogeneity between the data, compared with a higher index and more homogeneous in controls, equal to 98.01, with a very significant p-value. The GDS, the indicator that measures the severity of depressive symptoms, showed results on average higher in the intervention group, 5.56 vs. 3.46. The clinical significance needed a better qualification according to introduction of well-defined cut-offs.

With regard to the PIRU integrated care questionnaire (see table below), a comparison between the two groups was not possible due to the differences in sample size (18 subjects in control group vs 100 in intervention group).

Table 4.1: Puglia: Baseline PIRU questionnaire by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
PIRU questionnaire on user experience of Integrated Care				
Have all your needs been assessed?			0	76
<i>All of my needs have been assessed</i>	31 (31%)	18 (100%)		
<i>Some of my needs have been assessed</i>	67 (67%)	0 (0%)		
<i>None of my needs have been assessed</i>				
<i>Don't know/can't remember</i>	2 (2%)	0 (0%)		
Were you involved as much as you wanted to be in decisions about your care and support?			0	76
<i>Yes, definitely</i>	33 (33%)	18 (100%)		
<i>Yes, to some extent</i>	65 (65%)	0 (0%)		
<i>No</i>	2 (2%)	0 (0%)		
Were you involved as much as you wanted to be in decisions about your treatment?			0	76
<i>Yes, definitely</i>	38 (38%)	18 (100%)		
<i>Yes, to some extent</i>	60 (60%)	0 (0%)		
<i>No</i>	2 (2%)	0 (0%)		
Were your family or carer involved in decisions about your care and support as much as you wanted them to be?			0	76
<i>Yes, definitely</i>	43 (43%)	16 (88.9%)		
<i>Yes, to some extent</i>	54 (54%)	1 (5.6%)		
<i>No</i>	3 (3%)	0 (0%)		
<i>There were no family or carers available to be involved</i>	0 (0%)	1 (5.6%)		
<i>I didn't want my family or carer to be involved in decisions about my care and support</i>				
Were your family or carer involved in decisions about your treatment as much as you wanted them to be?			0.001	76
<i>Yes, definitely</i>	43 (43%)	16 (88.9%)		
<i>Yes, to some extent</i>	54 (54%)	1 (5.6%)		
<i>No</i>	2 (2%)	0 (0%)		
<i>There were no family or carers available to be involved</i>	1 (1%)	1 (5.6%)		
<i>I didn't want my family or carer to be involved in decisions about my treatment and support</i>				
Overall, do you feel that your carer/family has had as much support from health and social services as they needed?			0	76
<i>Yes, they have had as much support as they needed</i>	15 (15%)	16 (88.9%)		
<i>They have had some support but not as much as they needed</i>	69 (69%)	1 (5.6%)		
<i>No, they have had little or no support</i>	10 (10%)	0 (0%)		
<i>They did not want/need support</i>	5 (5%)	0 (0%)		
<i>There are no family members or carers to support</i>	1 (1%)	1 (5.6%)		



Measurement	Intervention	Control	Difference (p-value)	Missing values
To what extent do you agree or disagree with the following statement...‘Health and social care staff always tell me what will happen next’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	4 (4%) 66 (66%) 28 (28%) 2 (2%)	15 (83.3%) 3 (16.7%) 0 (0%) 0 (0%)	0	76
When health or social care staff plan care or treatment for you, does it happen? <i>Yes, it happens all of the time</i> <i>It happens most of the time</i> <i>It happens some of the time</i> <i>No</i>	15 (15%) 70 (70%) 15 (15%)	17 (94.4%) 0 (0%) 1 (5.6%)	0	76
To what extent do you agree or disagree with the following statement...‘My care and support is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	9 (9%) 86 (86%) 5 (5%)	17 (94.4%) 1 (5.6%) 0 (0%)	0	76
To what extent do you agree or disagree with the following statement...‘My treatment is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	6 (6%) 90 (90%) 4 (4%)	17 (94.4%) 1 (5.6%) 0 (0%)	0	76
To what extent do you agree or disagree with the following statement...‘My medicines are thoroughly reviewed as often as they should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	16 (16%) 82 (82%) 1 (1%) 1 (1%)	16 (88.9%) 2 (11.1%) 0 (0%) 0 (0%)	0	76
Do you have a named health or social care professional who co-ordinates your care and support? <i>Yes</i> <i>No, I co-ordinate my own care and support</i> <i>Don't know/not sure</i>	57 (57%) 34 (34%) 9 (9%)	18 (100%) 0 (0%) 0 (0%)	0.002	76
If you have questions, when can you contact the people treating and caring for you? Please tick ALL the apply <i>During normal working hours</i>	93 (93%)	18 (100%)	0.538	76

Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>During the evening</i> <i>During the night</i> <i>Weekends</i> <i>Don't know/not sure</i>	7 (7%)	0 (0%)		
Do you feel this person understands about you and your condition? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i>	31 (31%) 69 (69%)	18 (100%) 0 (0%)	0	76
Do all the different people treating and caring for you work well together to give you the best possible care and support? <i>Yes, all of them work well together</i> <i>Most of them work well together</i> <i>Some of them work well together</i> <i>No, they do not work well together</i> <i>Don't know/not sure</i>	7 (7%) 69 (69%) 23 (23%) 1 (1%)	16 (88.9%) 2 (11.1%) 0 (0%) 0 (0%)	0	76
Do health and social care services help you live the life you want as far as possible? <i>Yes, definitely</i> <i>Yes, to some extent</i> <i>No</i>	4 (4%) 90 (90%) 6 (6%)	15 (83.3%) 3 (16.7%) 0 (0%)	0	76
To what extent do you agree or disagree with the following statement... 'In the last 12 months, health and social care staff have given me information about other services that are available to someone in my circumstances, including support organisations' <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	3 (3%) 76 (76%) 15 (15%) 6 (6%)	13 (72.2%) 5 (27.8%) 0 (0%) 0 (0%)	0	76
Data presented as frequencies (%)				

3.4.6 Powys

The baseline analysis from Powys is not available in this first version of the document. Although patients have been recruited and the information has been compiled, several problems with the data processing impeded the corresponding analysis. The results of the baseline analysis and the corresponding interpretation of findings will be included in the version 2 of this D7.2 due mid-February 2016.

3.4.7 Global

Table 5: Global: Baseline characteristics by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
<i>Sample size (n)</i>	235	170		
Age	77.53 (6.97)	76.08 (7.49)	0.048	2



Measurement	Intervention	Control	Difference (p-value)	Missing values
Gender			0.897	2
Female	96 (41.2%)	72 (42.4%)		
Male	137 (58.8%)	98 (57.6%)		
Marital status			0.238	4
Never married	11 (4.8%)	6 (3.5%)		
Currently married	166 (71.9%)	108 (63.5%)		
Separated	0 (0%)	1 (0.6%)		
Divorced	3 (1.3%)	4 (2.4%)		
Widowed	50 (21.6%)	51 (30%)		
Cohabiting	1 (0.4%)	0 (0%)		
Education			0.001	6
Less than primary school	44 (19.2%)	34 (20%)		
Primary school	110 (48%)	54 (31.8%)		
Secondary school	12 (5.2%)	26 (15.3%)		
High school	41 (17.9%)	39 (22.9%)		
College/University	19 (8.3%)	17 (10%)		
Post graduate degree	3 (1.3%)	0 (0%)		
Longest held occupation			0	175
Manual	20 (15.5%)	29 (28.7%)		
Non manual	25 (19.4%)	32 (31.7%)		
Unemployed (but able to work)	0 (0%)	1 (1%)		
Unemployed (unable to work)	65 (50.4%)	21 (20.8%)		
Homemaker	19 (14.7%)	18 (17.8%)		
Household income (euro/year)			0.81	310
0-6.999				
7.000-13.999	57 (77%)	15 (71.4%)		
14.000-19.999				
20.000 or more	17 (23%)	6 (28.6%)		
Housing tenure			0.819	310
Owners	206 (92%)	149 (93.1%)		
Renters	18 (8%)	11 (6.9%)		
People older than 18 living in household	1.93 (1.39)	0.96 (1.3)	0	104
Mobile use (Yes)	156 (67.5%)	123 (72.4%)	0.354	4
PC use (Yes)	32 (14.1%)	28 (16.5%)	0.609	8
Alcohol			0	134
None	42 (26.9%)	50 (43.5%)		
Less than 1/week	32 (20.5%)	9 (7.8%)		
1-7/week	13 (8.3%)	9 (7.8%)		
8-14/week	29 (18.6%)	4 (3.5%)		
15-21/week	0 (0%)	2 (1.7%)		
More than 21/week	40 (25.6%)	41 (35.7%)		
Tobacco use	79	55	0.501	7
Never				
Former	135 (59.2%)	104 (61.2%)		
Current smoker	78 (34.2%)	58 (34.1%)		
e-cigarette	12 (5.3%)	8 (4.7%)		
Other				
Height (cm)	3 (1.3%)	0 (0%)		
Weight (kg)	80.02 (19.93)	73.16 (15.95)	0	5
Heart rate (bpm)	72.15 (12.03)	75.48 (11.64)	0.008	40
Systolic blood pressure (mmHg)	129.41 (19.25)	135.04 (19.35)	0.005	24
Diastolic blood pressure (mmHg)	70.87 (11.43)	74.94 (9.5)	0	24
Oxygen saturation (%)	95.89 (2.46)	96.6 (2.47)	0.009	65
Blood glucose (mg/dl)	143.45 (58.66)	132.32 (37.75)	0.053	112
HbA1c (%)	7.25 (1.02)	6.75 (0.93)	0.002	253
Creatinine (mg/dl)	1.12 (0.88)	0.96 (0.31)	0.078	204
Primary disease				
Primary disease CHF	45 (29.8%)	20 (13.9%)	0.002	110
Primary disease COPD	57 (37.7%)	31 (21.5%)	0.004	110
Primary disease DIABETES	69 (45.7%)	90 (62.5%)	0.005	110
Secondary disease				
Secondary disease CHF	54 (35.8%)	30 (20.8%)	0.007	110



Measurement	Intervention	Control	Difference (p-value)	Missing values
Secondary disease COPD	34 (22.5%)	19 (13.2%)	0.053	110
Secondary disease DIABETES	70 (46.4%)	80 (55.6%)	0.143	110
Comorbidity ICD-10 codes				
Myocardial infarct	45 (19.4%)	26 (15.9%)	0.44	9
Congestive heart failure	88 (38.3%)	29 (17.9%)	0	13
Peripheral vascular disease	93 (40.8%)	46 (27.7%)	0.01	11
Cerebrovascular disease	50 (21.6%)	32 (19.4%)	0.675	9
Dementia	18 (7.8%)	9 (5.5%)	0.489	10
Chronic pulmonary disease	146 (62.7%)	54 (32%)	0	3
Rheumatic disease	24 (10.3%)	19 (11.4%)	0.842	6
Peptic ulcer disease	12 (5.2%)	9 (5.5%)	1	9
Mild liver disease	18 (7.7%)	4 (2.4%)	0.037	5
Diabetes without chronic complication	102 (43.8%)	37 (21.9%)	0	3
Diabetes with chronic complication	53 (22.8%)	53 (32.1%)	0.052	8
Hemiplegia or paraplegia	5 (2.1%)	5 (3%)	0.84	4
Renal disease	99 (42.9%)	26 (15.7%)	0	8
Any malignacy	30 (13.2%)	3 (1.9%)	0	15
Moderate or severe liver disease	19 (8.2%)	10 (6%)	0.525	8
Metastatic solid tumor	2 (0.9%)	0 (0%)	0.625	17
Barthel index - 100	85.81 (21.69)	93.87 (12.62)	0	12
GDS - Geriatric Depression Scale (Short Form)	4.45 (3.32)	3.87 (3.05)	0.074	8
Quantitative data presented as mean (SD) and qualitative data presented as frequencies (%).				

At this time, a total of 405 patients have been recruited across all the sites; 235 patients have been assigned to the intervention group and 170 to the control group. These figures will tend to increase and converge, considering that the recruitment process is still ongoing, and that the recruitment of controls is more complicated in some sites.

Participants have a mean age of 76.5 years, being a bit older in the intervention group. Regarding gender distribution, 58% are men without differences between groups. It is interesting to note the education level of participants and the differences between groups, showing higher levels of education in the patients in the intervention group. The observed difference can be found in similar studies when taking part in an innovative care experience is demanded of patients and their families.

More surprising are the absence of differences in mobile and PC use between groups, and the high percentage of subjects familiar with these devices.

Regarding health related living habits, most of the participants present a moderate pattern of alcohol consumption, though 25.6% of the intervention group and 35.7% of controls declare they have a high level of weekly alcohol intake. Most participants are smokers or former smokers, without differences between groups.

When clinical control parameters are assessed, mean blood pressure is at the limit of good control and hypertension. Considering the primary and secondary diseases presented, differences can be found between control and intervention group, subjects in the intervention group being better controlled than controls. The high number of missing values for HbA1c and creatinine levels is due to the inclusion of these parameters among the ones that need to be reviewed in order to control each diseases; for example, HbA1c should be only assessed for patients with diabetes mellitus, and has no clinical meaning in patients with other diseases.

As expected, the most frequent disease among participants is diabetes mellitus, considered the primary disease for 45.7% of subjects in the intervention group and 62.5% for the controls; this difference is statistically significant. Diabetes is also the most frequent secondary disease for both intervention and control group. The second most frequent primary disease is COPD for both intervention and control group, and finally congestive heart failure. There are a considerable number of missing values for this

description of variables. Most of these are due to a specific site where information about this variable will be fully collected during the next data entry process.

Another remarkable characteristic of participants is their level of functional dependence, measured by Barthel Index. In this case there is a considerable difference between intervention and control group, with subjects in the intervention group having a mean of 85, considered moderate dependence, and 95 for the controls, being classified as mild dependence.

Regarding baseline mental health, both groups present mean values corresponding to normality, though close to depression.

Table 5.1: Global: Baseline PIRU questionnaire by group

Measurement	Intervention	Control	Difference (p-value)	Missing values
PIRU questionnaire on user experience of Integrated Care				
Have all your needs been assessed?			0.038	83
<i>All of my needs have been assessed</i>	142 (61.5%)	71 (78%)		
<i>Some of my needs have been assessed</i>	84 (36.4%)	18 (19.8%)		
<i>None of my needs have been assessed</i>	2 (0.9%)	1 (1.1%)		
<i>Don't know/can't remember</i>	3 (1.3%)	1 (1.1%)		
Were you involved as much as you wanted to be in decisions about your care and support?			0.036	81
<i>Yes, definitely</i>	144 (62.3%)	68 (73.1%)		
<i>Yes, to some extent</i>	83 (35.9%)	21 (22.6%)		
<i>No</i>	4 (1.7%)	4 (4.3%)		
Were you involved as much as you wanted to be in decisions about your treatment?			0.37	81
<i>Yes, definitely</i>	146 (63.2%)	65 (69.9%)		
<i>Yes, to some extent</i>	80 (34.6%)	25 (26.9%)		
<i>No</i>	5 (2.2%)	3 (3.2%)		
Were your family or carer involved in decisions about your care and support as much as you wanted them to be?			0	81
<i>Yes, definitely</i>	152 (65.8%)	68 (73.1%)		
<i>Yes, to some extent</i>	66 (28.6%)	9 (9.7%)		
<i>No</i>	5 (2.2%)	6 (6.5%)		
<i>There were no family or carers available to be involved</i>	6 (2.6%)	6 (6.5%)		
<i>I didn't want my family or carer to be involved in decisions about my care and support</i>	2 (0.9%)	4 (4.3%)		
Were your family or carer involved in decisions about your treatment as much as you wanted them to be?			0.001	81
<i>Yes, definitely</i>	154 (66.7%)	63 (67.7%)		
<i>Yes, to some extent</i>	63 (27.3%)	12 (12.9%)		
<i>No</i>	5 (2.2%)	5 (5.4%)		
<i>There were no family or carers available to be involved</i>	7 (3%)	7 (7.5%)		
<i>I didn't want my family or carer to be involved in decisions about my treatment and support</i>	2 (0.9%)	6 (6.5%)		

Measurement	Intervention	Control	Difference (p-value)	Missing values
Overall, do you feel that your carer/family has had as much support from health and social services as they needed? <i>Yes, they have had as much support as they needed</i> <i>They have had some support but not as much as they needed</i> <i>No, they have had little or no support</i> <i>They did not want/need support</i> <i>There are no family members or carers to support</i>	 112 (48.5%) 84 (36.4%) 16 (6.9%) 16 (6.9%) 3 (1.3%)	 58 (63.7%) 11 (12.1%) 3 (3.3%) 12 (13.2%) 7 (7.7%)	 0	 83
To what extent do you agree or disagree with the following statement...‘Health and social care staff always tell me what will happen next’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 82 (35.7%) 91 (39.6%) 44 (19.1%) 13 (5.7%) 0 (0%)	 47 (51.1%) 23 (25%) 12 (13%) 9 (9.8%) 1 (1.1%)	 0.01	 83
When health or social care staff plan care or treatment for you, does it happen? <i>Yes, it happens all of the time</i> <i>It happens most of the time</i> <i>It happens some of the time</i> <i>No</i>	 122 (53.5%) 84 (36.8%) 18 (7.9%) 4 (1.8%)	 62 (68.1%) 21 (23.1%) 7 (7.7%) 1 (1.1%)	 0.096	 86
To what extent do you agree or disagree with the following statement...‘My care and support is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 102 (44.2%) 111 (48.1%) 13 (5.6%) 4 (1.7%) 1 (0.4%)	 55 (60.4%) 22 (24.2%) 11 (12.1%) 3 (3.3%) 0 (0%)	 0.002	 83
To what extent do you agree or disagree with the following statement...‘My treatment is reviewed as often as it should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 101 (43.7%) 113 (48.9%) 13 (5.6%) 3 (1.3%) 1 (0.4%)	 57 (62%) 24 (26.1%) 8 (8.7%) 2 (2.2%) 1 (1.1%)	 0.006	 82
To what extent do you agree or disagree with the following statement...‘My medicines are thoroughly reviewed as often as they should be’ <i>Strongly agree</i> <i>Agree</i> <i>Neither agree nor disagree</i> <i>Disagree</i> <i>Strongly disagree</i>	 97 (42%) 104 (45%) 20 (8.7%) 9 (3.9%) 1 (0.4%)	 56 (60.2%) 21 (22.6%) 13 (14%) 2 (2.2%) 1 (1.1%)	 0.003	 81

Measurement	Intervention	Control	Difference (p-value)	Missing values
Do you have a named health or social care professional who co-ordinates your care and support?			0.16	82
Yes	176 (76.5%)	80 (86%)		
No, I co-ordinate my own care and support	43 (18.7%)	10 (10.8%)		
Don't know/not sure	11 (4.8%)	3 (3.2%)		
If you have questions, when can you contact the people treating and caring for you? Please tick ALL the apply			0.054	86
During normal working hours	210 (91.7%)	89 (98.9%)		
During the evening	8 (3.5%)	0 (0%)		
During the night				
Weekends				
Don't know/not sure	11 (4.8%)	1 (1.1%)		
Do you feel this person understands about you and your condition?			0	86
Yes, definitely	149 (65.1%)	78 (86.7%)		
Yes, to some extent	79 (34.5%)	10 (11.1%)		
No	1 (0.4%)	2 (2.2%)		
Do all the different people treating and caring for you work well together to give you the best possible care and support?			0	88
Yes, all of them work well together	116 (50.4%)	69 (79.3%)		
Most of them work well together	79 (34.3%)	13 (14.9%)		
Some of them work well together	30 (13%)	4 (4.6%)		
No, they do not work well together	0 (0%)	1 (1.1%)		
Don't know/not sure	5 (2.2%)	0 (0%)		
Do health and social care services help you live the life you want as far as possible?			0.03	85
Yes, definitely	89 (38.9%)	50 (54.9%)		
Yes, to some extent	123 (53.7%)	37 (40.7%)		
No	17 (7.4%)	4 (4.4%)		
To what extent do you agree or disagree with the following statement... 'In the last 12 months, health and social care staff have given me information about other services that are available to someone in my circumstances, including support organisations'			0	82
Strongly agree	38 (16.5%)	34 (37%)		
Agree	95 (41.1%)	23 (25%)		
Neither agree nor disagree	22 (9.5%)	24 (26.1%)		
Disagree	76 (32.9%)	11 (12%)		
Strongly disagree				
Data presented as frequencies (%)				

For this group of patients, a total of around 80 missing values are observed. This data collection will be improved in the next version of this document.

Significant differences can be found between intervention and control groups in almost all the questions, with controls, in general (except for Basque Country), being more satisfied



with the usual received care. The presence of this difference is probably unavoidable at this point; so, it has to be considered in the discussion of the results regarding PIRU questionnaire. If a bias was introduced, this would reduce the size of the difference of the effect of the intervention between intervention and control group. So, any positive result will be present in spite of the potential bias.

Considering the questions of the PIRU questionnaire individually, the first set of questions that explore the perceived involvement of the patients and carers in the decision making process related to the care provision is very positive, more so among the controls. When information and treatment review is explored, satisfaction is not so high and is lower for intervention patients. And finally, when access to care and to other services is explored, results are variable, tending to medium satisfaction, again lower for intervention patients.



4. Process evaluation

An evaluation of processes related to the implementation of CareWell services is planned alongside the outcome evaluation described in deliverable D7.1. The aim of the process evaluation is to collect data to enable understanding of the barriers and facilitators for implementing ICT-supported integrated care.

Both the guidelines followed by pilot sites and the results of the qualitative analysis performed will be included in the version 2 of the D7.2 deliverable due mid-February 2016.



5. Predictive modelling

Results of the predictive modelling obtained during the year 2015 will be included in version 2 of this D7.2 due mid-February 2016.



6. Conclusions

The MAST evaluation model has used as the framework for the comprehensive evaluation of this project.

The six pilot sites present, under Domain 1, their integrated care proposals explaining the main components and the key element necessary for their implementation.

Domains 2 & 3 are directed to the assessment of the impact of the programme implementation. First, recruitment flow chart for each pilot each is presented. The pace of recruitment is adequate, even though various difficulties have been overcome. The upcoming months should be see the correct completion of this task.

Also, a first baseline analysis is presented. In the next version of this document, this analysis will be completed, and will include all the patients that have been recruited. Patients included to date match the proposed target population, and could be defined as an aged, multimorbid population with complex health and social needs, that is satisfied with several aspect of the usual care, but that expresses the need to participate more in the decision making process regarding their care.



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