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**Final Trial Report - CHF**

**Version 1.3**

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## Abstract

This final trial report describes the key aspects of the Congestive Heart Failure (CHF) arm of the United4Health Project in each of the four deployment sites across Europe, namely Scotland (UK), Slovenia, Northwest Moravia (Czech Republic) and Basque Country (Spain).

## Key Word List

Congestive Heart failure (CHF), telemonitoring, scale-up, implementation.
Executive Summary

This final study report describes the evaluation of the Congestive Heart Failure (CHF) arm of the United4Health (U4H) project in each of the four deployment sites across Europe, namely Scotland, Northwest Moravia, Slovenia and the Basque Country. The evaluation follows the Model for Assessment of Telemedicine framework (MAST).

Strengths & limitations of the evaluation

In accordance with the D3.1 v1.3 U4H Scientific Study Protocols, 3rd December 2013, (section 2.3: Expected measurable final results of the project), the project “is aiming at focusing on the organisational aspects, the efficiency gains, and the economic aspects of the telemedicine interventions” and not on clinical effectiveness. It was agreed that an observational study design would be more appropriate to assess the real life outcomes and to complement the evidence of efficacy demonstrated in several randomised controlled trials (RCTs) (section 3.1 Study design of D3.1). The evaluation of the project was conducted using the MAST multidimensional evaluation framework and was designed taking into consideration the kind of evidence that the various stakeholders need to engage in the roll-out of ICT-supported integrated care services for older people.

Six months before the end of the follow-up, a detailed statistical analysis plan was prepared by the Medical Coordinator, supported by two biostatisticians, and presented to the management team, the WP leaders and the clinical leads. The plan was discussed and revised based on the discussions, suggestions and decisions of the U4H Heart Failure Scientific Committee, chaired by Nekane Murga (Cardiologist, Clinical Lead of the Basque Country and WP8 leader). This plan was completely followed, but extended to include additional regression analyses, because unexpected and significant differences were observed between intervention and comparator group.

- Basque Country, Spain
- Northwest Moravia, Czech Republic
- Scotland, UK
- Carinthia, Slovenia
The pragmatic, observational study approach of the evaluation focused on an assessment of the clinical, organisational and economic impact of telehealth deployments, following best practice wherever possible.

Significant delays in the procurement of necessary infrastructure, coupled with associated organisational changes in some U4H deployment sites, resulted in the total number of patients recruited for telehealth and ‘usual care’ being less than originally planned. This posed a significant challenge to the project evaluation, which was further compounded by a number of issues which also impacted on the data analysis:

- The composition of the comparator groups varied, with some sites including the same patients before the intervention, and others identifying a different prospective group.
- The intervention and comparator groups were significantly different and not matched at baseline, indicating a potential selection bias.
- Significant heterogeneity of healthcare resource use was found among the deployment sites.
- The data was incomplete in a non-random, but systematic way. This lack of data availability made it difficult to arrive at definitive conclusions.

It is acknowledged that the above limitations may have created biases relating to the comparative advantages of telehealth which, as a result, are not fully validated. The reader should take this into account when considering the findings of the evaluation.

Domain 1: Description of the health problem and characteristics of the application

CHF disease has a high prevalence, and is growing with the ageing of populations. Hence it leads to a considerable clinical, societal and economic burden, as it causes a decreased life expectancy, impaired quality of life, and repeated hospitalisations.

Home telemonitoring of CHF can improve the quality of life of patients with CHF and diminish clinical care burden. It provides healthcare professionals with a real-time assessment of patients’ health status and biological parameters, and enables bi-directional communication between patient and professional.
Each deployment site has implemented the above generic model into their local healthcare systems, taking into account local variations and adjusted accordingly. Using telehealth, they have redesigned their routine care management to enable a shift in the care pathways; this has changed the balance between self-management, supported self-management, and specialist supported self-management towards more self-management and supported self-management, and reducing the period of specialist supported self-management, which is the most costly part of the pathway.

**Domain 2 and 3: Safety and Clinical Effectiveness**

The main aim of this project was to test if telemonitoring (TM) can be implemented at scale across different healthcare settings.

In general, patients included in the intervention group have reached better results than the comparator group in nearly all primary and secondary outcomes. In the primary outcome, patients who benefit from telemonitoring have lower mortality and lower hospitalisations.

There are some limitations when considering the findings of the study. The difference between intervention and comparator groups in demographic and clinical baseline data should not be underestimated, although regression analysis has been used to try to eliminate the effect of confounding factors. Patients in the comparator group have worse baseline parameters than the intervention group; these are relevant for CHF management and outcomes.

Although there are long established and studied guidelines on how to treat CHF patients, clinicians agree that there is space for improvement, mainly in aspects such as care coordination, patient empowerment, medication adherence and anticipatory care. This project has shown that telehealth is seen as a good tool to approach most of these dimensions, while yielding effective and secure clinical outcomes.
Domain 4: Patient perspectives

Patients from Scotland, Northwest Moravia, Slovenia and the Basque Country that participated in the U4H CHF deployment have a high acceptability and satisfaction associated with the telemonitoring intervention. They reported that the telemonitoring did not cause privacy or discomfort issues, nor affect the clinician-patient relationship. However, patients did not feel that the telemonitoring should replace routine care completely.

Domain 5: Economic aspects

Based on the observational multicentre study and additional collection of data on costs of the telehealth intervention, the economic analysis shows that:

- The telehealth intervention in the CHF trial reduced the average costs per patient by 329€, mainly because the study in Scotland was able to demonstrate a reduction in costs. In the other three regions, the costs per patient are increasing.

- In some cases, equipment was purchased for the project, in other cases it was already in place from other interventions before the start of the project; finally, some sites have used the patients’ own devices.

- No site found that they saved time using the telehealth solutions instead of offering traditional care to CHF patients.

Domain 6: Organisational aspects

There was overall satisfaction with the telehealth service expressed by both healthcare professionals and patients, although from the professionals’ perspective, a number of issues still needed to be addressed. After some initial problems with the technologies at the beginning of deployment, the telehealth systems worked well and provided the clinicians with beneficial additional data about their patients’ health status.

In the sites where the uploaded telehealth data was filtered by staff in a call centre (alert filtering and validation, as well as resolution of minor technical problems), this was felt to be very advantageous, but roles and responsibilities of all the different people involved needed to be clear.

Patients felt more empowered and secure, as they were better able to self-manage their long term condition, with the technology helping to support and build patient confidence.

Domain 7: Socio-cultural, ethical and legal aspects

The issues encountered by each site were not dissimilar, and were addressed in similar ways, e.g. consent, and the non-availability of WiFi issue resulting in patients being offered landline telehealth technologies. Appropriate measures were taken in relation to ethical committee approval if relevant, but in all cases the telehealth service followed the local codes of practice and disease care management guidelines. No serious ethical issues were found; on the contrary, positive benefits for patients and relatives were reported. Equity was obtained, and no gender issues were identified by the sites.
Transferability assessment

The outcomes of each MAST domain are in some cases to be perceived as transferable, while in other cases they are very specific to the local context. For example, whilst the approaches to stakeholder engagement, clinical outcomes, and organisational structures suggest that telehealth services could be scaled-up in the U4H deployment sites, the differences in the demographic and clinical characteristics between the intervention and comparator groups limits the generalisability of some of the clinical findings. However, U4H has demonstrated that the telemonitoring service can be multi-level and cross-disciplinary, or concentrated in one sector (e.g. hospital department or local GP practices).
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Outstanding Issues
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1 Introduction

1.1 Purpose of this document

This final trial report describes the key aspects of the Congestive Heart Failure (CHF) arm of the United4Health (U4H) project in each of the four trial sites across Europe, namely Scotland, Northwest Moravia, Slovenia and the Basque Country.

This document contains the final report of the CHF trials in the United4Health project.

1.2 Structure of the document

Section 2 contains information for MAST Domain 1: The health problem and the telehealth application.

Section 3 contains information on Domains 2 and 3: Safety and clinical effectiveness.

Section 4 contains information and data on Domain 4: Patient perspectives.

Section 5 contains information and data on Domain 5: Economic aspects.

Section 6 contains information on Domain 6: Organisational aspects.

Section 7 contains information on Domain 7: Socio-cultural, ethical and legal aspects.

Section 8 discusses transferability assessment.

1.3 Glossary

CHF  Congestive Heart Failure
DBP  Diastolic Blood Pressure
EMR  Electronic Medical Record
GP  General Practitioner
HF  Heart Failure
ICT  Information & Communication Technology
NYHA  New York Heart Association
SBP  Systolic Blood Pressure
U4H  United4Health
WSD  Whole System Demonstrator (UK trial)
WTE  Whole Time Equivalents (for staff)
2 Domain 1: Description of the health problem and characteristics of the application

2.1 The health problem of the patients

Congestive Heart Failure (CHF) is a complex syndrome characterised by the inability of the heart to expel sufficient amounts of blood needed for the metabolic requirements of different organs. As a result, the typical symptoms affecting patient with CHF are dyspnoea and fatigue at rest or with reduced physical effort, and loss of appetite, which sometimes appear gradually over days or weeks. In addition, neurohormonal mechanisms produce liquid retention, resulting in a reduction of urine volume (occasionally not perceived by the patient) and the appearance of progressive oedemas, which frequently are not related to the disease by the patients and relatives [1].

The current healthcare model is based on the management of acute destabilisation of chronic patients by hospitalisation, maintenance of a stable health state, and early diagnosis of decompensation [1,2]. Advances in treatment for CHF look for better quality of life, reduced length of hospital stay, and, in some cases, the avoidance of hospital admissions. The demand for home care services increases. The design of new processes that further improve the quality of life of patients with CHF and diminish the clinical care burden is still necessary. These alternative models typically involve ICT, and may include self-monitoring and training delivered via standard telephone or more advanced telemonitoring technology. Home telemonitoring allows the clinical professional to follow up on the health status and biological constants of patients at home using ICTs [3,4,5,6,7].

By keeping the patient at home, the “white coat effect” is avoided [1], and the real-time assessment of monitored parameters is possible, pushing the patient to interact with the telemonitoring system, promoting self-care and enabling bi-directional communication between patient and professional more frequently than the conventional and periodic follow up. Home telemonitoring is not intended to replace health professional care or visits, but rather to enhance the level of care [6,8,9,10,11].

2.2 Burden of the disease

Epidemiological studies indicate that the prevalence of CHF is considerably high, affecting 10% of the population older than 70 years old [12]. Over the last decade, the annual number of hospitalisations has increased from 800,000 to over a million for HF as a primary diagnosis, and from 2.4 to 3.6 million for HF as a primary or secondary diagnosis [13].

Approximately 50% of HF patients are readmitted to hospital within six months of discharge. With the aging of the population, this trend will continue to rise [14,15]. Due to the ageing population and the increased survival of acute cardiac diseases, CHF is becoming more common, representing a public health problem. As the prevalence of CHF grows with the ageing of populations, it will become increasingly difficult to maintain the quality of care [1]. Recent trials have shown that the patients,
after hospitalisation for HF, present 30-day, 1-year and 5-year mortality rates of 10.4%, 22% and 42.3% respectively[16].

Healthcare costs for CHF are at least two-fold higher than in the general population, mostly due to the high consumption of human resources caused predominantly by repeated and lengthy admissions to hospital[17]. Projections show that by 2030, the total cost of CHF will increase almost 120% (reaching $70 billion for USA)[18]. Despite advances in its treatment, CHF results in poor life expectancy, impaired quality of life, and repeated hospitalisations, so it is a considerable clinical, societal and economic burden[19,20].

2.3 Routine and Telehealth Service Models and Technical Solutions

2.3.1 Scotland

Ambition

The aim of the telehealth service for people living with CHF in Scotland is to support the treatment and management of CHF by enabling earlier detection of deterioration, allowing timely intervention, better care co-ordination, fostering increased patient self-management, and preventing unplanned crisis episodes requiring hospital admission or readmission.

CHF care management – routine care

The routine care for patients living with CHF is provided by specialist nurses working as a key intermediary between patients and other healthcare practitioners, including cardiologists in secondary care and staff in GP practices (see figure below). Patients are reviewed and assessed by specialist Heart Failure (HF) nurses in a variety of settings: outpatient clinics, community clinics, and in their homes, to detect early clinical deterioration or offer additional support post hospital discharge. (Yellow). Patients undertake daily weight monitoring and report any increase (Green) to their main healthcare practitioner. If a patient requires hospitalisation, they will be referred to a home-visiting HF nurse who will visit the patient at home within a week of being discharged. One month after discharge, patients are offered an outpatient consultation with the hospital cardiac team. Patients and families are encouraged to make contact in the event of problems or changes in their condition by telephone, e.g. to specialist HF nurse. Subsequent visits and contacts are determined by individual patient needs. The specialist nurses implement agreed care plan protocols, including any prescription changes, in liaison with the cardiologist; information is sent directly to the GP (Yellow/Red). Most specialist HF nurses also offer facilitation of self-management to practice nurses and GPs.
Figure 1: Scotland: CHF care service model

U4H telehealth enabled CHF care management

Patients are offered a telehealth service as an integral part of their care plan, either on discharge, or shortly after an emergency hospital admission for a crisis episode. Care pathways have been developed in each of the deployment sites: NHS Ayrshire & Arran, NHS Greater Glasgow & Clyde, and NHS Lanarkshire. The telehealth care pathways provide telemonitoring which is co-ordinated by the specialist HF nursing teams based within the community services or on an outreach basis from hospital cardiac departments. For one site, installation and referral co-ordination is supported by a Telehealth Hub (contact centre).

Patients are provided with a monitoring device and peripherals (weight scales, blood pressure cuff) within 24 hours of discharge. The device is installed and training provided by the nursing or Telehealth Team alongside education in self-management principles. The physiological measurements taken by the patient (Green) are uploaded via the telehealth device and made available to the HF nursing team who review the measurements against a set individual clinical parameters, and make any necessary changes to the patient’s medication or care plan. Depending on the status of the readings, the patient can receive a teleconsultation (usually by telephone) from their specialist HF nurse who, if required, will arrange an urgent outpatient appointment or home visit. Throughout the monitoring period, patients using SMS devices will receive motivational health and wellbeing coaching messages from the HF team (Green). Across all sites, patients continue to provide data uploads initially for up to six months, or until their CHF is stable, after which care management is co-ordinated by the GP practice or practice nurses. Patients continue to have outpatient appointments as required with their cardiologist or GP, with A&E or hospital admission as required (Yellow/Red).
Figure 2: Scotland: CHF telehealth enabled care model

Figure 3 below illustrates the CHF telehealth solution configuration and key interactions in Scotland:

2.3.2 Basque Country

Ambition

The aim of the telehealth service for patients living with CHF is to support and improve levels of self-management and achieve equal or better clinical outcomes.
CHF care management – routine care

Patients with CHF in the Basque Country have their CHF care management regularly reviewed and are supported to self-manage by the primary care nurses (Green & Yellow). Between 48-72 hours after hospital discharge following a hospital admission, a patient is contacted by telephone by a nurse from the eHealth centre. The nurse will ask structured, validated questions to elicit up-to-date information on the patient’s health status and how they are coping. The nurse will decide on the appropriate next steps in line with answers given by the patient. These options for further care, support, and/or treatment include the patient being seen by the GP or GP nurse in the health centre within 24-48 hours, 48-72 hours or a week later depending on the severity of the patient’s health status. During the consultation, the GP and/or the GP nurse will assess the patient and determine whether any further tests and investigations are required, as well as agree appropriate self-management and patient empowerment support. One month after hospital discharge, the patient will be offered an outpatient consultation with the cardiologist in the health centre (Red). A medication review will be undertaken, together with any additional laboratory tests and ECG. Once the patient’s condition has stabilised again, they will be reviewed by the GP and GP nurse on a six-monthly and three-monthly basis respectively (Yellow).

![Figure 4: Basque Country: CHF care service model](image)

**Figure 4: Basque Country: CHF care service model**

**U4H telehealth enabled CHF care management**

A patient will follow the routine care model until their telehealth solution has been installed and training given by the Telecare Centre. This period usually covers 5-10 days post discharge. Once a patient has started transmitting their physiological measurements, a cardiologist reviews the data uploaded and adjusts their care plan and medication regime as necessary. During ongoing telemonitoring (Green), an operator from the Telecare Centre monitors the data uploads; if any alerts are generated as a result of readings being outside the patient's parameters, the patient is contacted to verify the uploaded data. If the alerts are corroborated and the patient’s health status has worsened, the call is transferred to a nurse at the eHealth Centre (Yellow). Depending on the severity of the situation, the nurse will follow the
clinical protocol and take the necessary action; this could involve scheduling an appointment with the patient’s GP (face-to-face or phone consultation), a referral for a specialist appointment (face-to-face or phone consultation), or activating an ambulance for transfer to the ED. The cardiologist will also continue to regularly review the telemonitoring data (Red) until the patient is considered stable; responsibility for ongoing CHF care management and proactive follow-up is then transferred to the GP and GP nurse. If the GP or GP nurse has any cause for concern in relation to the patient’s CHF health and wellbeing, they will contact the patient, reassess the care and self-management plan, and revise as necessary.

**Figure 5: Basque Country: CHF telehealth enabled care model**

Figure 6 below illustrates the CHF telehealth solution configuration and key interactions in the Basque Country:

**Figure 6: Basque Country: CHF process workflow**
2.3.3 Northwest Moravia

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with CHF is to support and improve the individual patient’s endeavours to self-manage and lead a lifestyle to reduce their risk of exacerbation and improve their quality of life.

CHF care management – routine care

Routine care for patients living with CHF takes place at the University Hospital Olomouc and follows the Czech Society of Cardiology guidelines for the diagnosis and treatment of heart failure. Patients self-manage (Green) and have scheduled outpatient consultations in accordance with their ongoing health status and disease progression, although most patients are seen every three months by the hospital specialists (Red) in order to review their physiological measurements, and make any adjustments to their medication and treatment. GPs are not funded to provide CHF care management (Yellow).

Figure 7: Northwest Moravia: CHF care service model

U4H technology enabled CHF care management

Patients are provided with a smartphone or tablet, blood pressure meter, pulse oximeter and weight scales, and are given training to use a software application called Medimonitor on the smartphone (Green). The smartphone or tablet acts as a gateway to upload the vital signs readings daily to the telemonitoring centre located in the hospital’s Cardiology Clinic. Doctors, specialist nurses and biomedical engineers access the telehealth portal with the collected data via internet using a web browser with secure login (Red). The Medimonitor system generates alerts in response to:

- A patient’s vital signs readings are outside their threshold parameters. Patients will be contacted by a specialist nurse who will assess the severity of the situation. If the patient’s treatment and self-management plan needs...
adjusting, the cardiologist will contact the patient to make the necessary adjustments and/or invite the patient to attend an unscheduled outpatient appointment.

- If there is missing or incomplete measurement upload twice in a row, a biomedical engineer or nurse will contact the patient by telephone, SMS or Medimonitor message, and provide additional training in the use of the smartphone or tablet if required.

The scheduled outpatient consultations are enhanced through the availability of the telemonitoring information which can also be accessed by hospital specialists if a patient’s symptoms worsen and they are admitted to hospital. The system can also receive data from INR measurements (anticoagulation therapy) using the Medimonitor if required as part of the patient’s care management.

**Figure 8: Northwest Moravia: CHF telehealth enabled care model**

Figure 9 below illustrates the CHF telehealth solution configuration and key interactions in Northwest Moravia.
2.3.4 Slovenia

Ambition

The aim of the telehealth service for patients living with CHF is to promote self-management and enable bi-directional communication, as required, between the patient and specialist more frequently than the routine care periodic follow-up schedule. In addition, the service has been designed to enhance the level of care provided, and improve clinical outcomes, quality of life and be cost effective.

CHF care management – routine care

Patients with CHF implement their self-management plan (Green) and have regular (six-monthly if stable) specialist consultations in hospital outpatient clinics and health centres in the Koroška region (Yellow/Red). Routine care management aims to achieve personalised goals in relation to their blood pressure, weight and blood oxygen levels. Patients enter their measurements in a booklet; this information is reviewed by the specialist at regular scheduled consultations. All patients are given personalised advice in relation to their diet according to their blood pressure and weight. If their physiological measurements are not well controlled (Yellow/Red) they are reviewed in the hospital outpatient clinic or regional health centre more frequently than every six months.
U4H telehealth enabled CHF care management

The telehealth service is provided by the Telemedicine Service Centre CEZAR from the Slovenj Gradec regional hospital. Using physiological measurement devices (blood pressure meter, pulse oximeter, weight scales), patients take their measurements daily at home. The readings are transmitted via Bluetooth to a smartphone provided by U4H and subsequently uploaded to the CEZAR centre at the hospital (Green). An alert is generated when, according to the clinical protocol, the telehealth system detects that one or more readings are outside the patient’s set parameters. In such case, an eHealth coordinator from the CEZAR centre contacts the patient by phone to check the data upload (Red). If the data is correct, the coordinator contacts a hospital cardiac specialist to seek advice on further action, e.g. change in therapy or unscheduled hospital consultation. Any changes are communicated to the patient by phone, and followed up by a paper report sent by postal mail. The coordinator may need to communicate with the patient’s GP and/or home-visiting nurse if there are changes, for example, to the patient’s medication regime (Yellow). In addition, cardiologists and specialist nurses periodically review all patients on telehealth to determine whether any changes to their care and self-management plan are required; if this is the case, a paper report is once again sent to the patient.

Figure 10: Slovenia: CHF care service model
Figure 11: Slovenia: CHF telehealth enabled care model

Figure 12 below illustrates the diabetes telehealth solution configuration and key interactions in Slovenia:

Figure 12: Slovenia: Diabetes process workflow
3 Domain 2 and 3: Safety and clinical effectiveness

3.1 Methods: Trial design

Renewing Health has demonstrated the efficacy of the interventions in randomised controlled trials. Thus the clinical impact has been demonstrated in studies with a high degree of internal validity and in experimental conditions.

However, real life effectiveness of these interventions has not been demonstrated yet. As described in Hendy et al. (2012) [21] in a study of the implementation of the WSD, the randomised design may result in a number of practical problems for the organisations which carry out the study and perform the data collection. For example, the knowledge and experiences gained during the trial cannot be used to improve the intervention during the study, because the service must remain constant during the latter.

Therefore, U4H has studied the effectiveness of the interventions in an observational design by comparing a control group treated before the implementation of the telehealth interventions with an intervention group treated after the implementation of telehealth. The strengths of this study design are complementary to the evidence demonstrated in several efficacy trials [22], and are based on:

1. Long follow-up period which allows for registering and monitoring long-term clinical effects and safety data [23].
2. Big sample size representative of the general population, which allows for stratification analysis and identification of patient subgroups that benefit the most from the intervention [24].
3. Real-life data about impact on costs and organisation (structure and processes) which allows the identification of barriers and facilitators for a wider service implementation [25].

In addition, from an ethical perspective, the service that is proved to be efficacious should be offered to all potential healthcare users. This type of study design assesses the real-life effectiveness of the trialled services with a high degree of external validity and generalisability of the results. Due to inclusion of patients from many European countries, this study is able to provide to other regions in Europe a valid estimate of the expected impact of the interventions.

The observational study uses as a comparator group the total population of patients fulfilling the eligibility criteria who have been treated and followed for at least one year before the implementation of the telehealth service, in the same health units as the intervention group, and whose data are available through EMR or other databases (retrospective collection of data regarding demographics, clinical and economic outcomes for the comparator group). Additional data regarding the costs of the telehealth service, patient perception and organisational aspects has been collected for the intervention group.
3.2 **Methods: Participants**

**Eligibility criteria:**

Hospitalisation or Emergency Department (ED) visit for decompensated HF (with need and administration of diuretics) in the previous six months, and at least one of the following three conditions:

- LVEF < 45% (at least once during the last year or in the last echocardiogram if older).
- LVEF > 45% but BNP > 400 (or plus NT-proBNP>1500) (at least once during the last year).
- Confirmed diagnosis of CHF by a cardiologist.

Deviation from the general criteria are described below.

### 3.2.1 Scotland

None.

### 3.2.2 Basque Country

None.

### 3.2.3 Northwest Moravia

None.

### 3.2.4 Slovenia

At SB-SG hospital, a small proportion of CHF patients (20%) involved in the comparator group do not meet a criterion set by the U4H consortium on hospitalisation or ED visit (i.e. hospitalisation or ED visit for decompensated HF in the previous six months). All of them have been hospitalised within the last 12 months before inclusion into the comparator group for telemonitoring, or have been invited to the centre for decompensated heart within the hospital where they have been treated for cardiac decompensation with Edemid Forte 250-500 mg (PO, not intravenously). Those patients have been involved in telemonitoring as the service empowers their self-treatment at home, and because they fulfil all the other inclusion criteria.

3.3 **Methods: Interventions**

Refer to domain 1.

3.4 **Methods: Outcomes**

**Primary clinical outcome:** HF related hospitalisations (readmissions).
**Secondary outcomes**: total days hospitalised for HF, all-cause admissions, ED visits, cardiovascular mortality, all-cause mortality, visits to GPs or primary healthcare.

Demographic characteristics are collected during recruitment according to the common protocol, and include:

- Year of birth.
- Gender.
- Smoking.
- Date of last hospitalisation/ED visit due to decompensated HF.
- If there is a carer (formal/informal), optional.
- Reason for non-participation, if not.
- Region/study site.
- Assessment of comorbidity using the ICD-10 International Classification of Diseases (including CHF aetiology, diabetes, COPD).

The selected clinical indicators and the time for assessment are:

- Heart rate: at recruitment and end of the study, and through telemonitoring.
- Oxygen saturation: at recruitment and the end of the study, and through telemonitoring.
- Blood pressure: at recruitment and the end of the study, and through telemonitoring.
- Weight: at recruitment and the end of the study, and through telemonitoring.
- Height: at recruitment.
- Left ventricular ejection fraction: at least once every 12 months.
- BNP or NT-proBNP and other laboratory exams, e.g. creatinine, urea, sodium etc. are optional.

For treatment and follow-up of patients and evaluation of the provided services, the participating sites have the flexibility to monitor additional indicators, adjusted to the local needs and experiences. These are:

- Scotland
  No additional indicators.
- Basque Country
  Laboratory examination and clinical examination.
- Northwest Moravia
  No additional indicators.
- Slovenia
  No additional indicators.

Data were collected at intervention initiation and end. For the sub-population with extended monitoring, there was an assessment at study start, 12 months and 18 months.
The outcome measures included are described in detail in the protocol, D3.1 dated 31st March 2014.

3.5 Methods: Sample size

The total population included in the four sites deploying the telehealth solutions for CHF in the U4H Project was 1,106: 358 in Scotland, 131 in Northwest Moravia (CZ), 360 in Slovenia, and 257 in the Basque Country. These patients are distributed in several categories (intervention, comparators and deployment groups). See Table 1 in the section 3.7 below for details. The United4Health Evaluation dataset (U4H-E) consists of all intervention and comparator group patients followed for a minimum follow-up of six months. The United4Health Deployment dataset (U4H-D) consists of all patients receiving the U4H services and the total number of patients used as comparator group, who cannot be included in the U4H-E dataset because of a shorter period than accepted in the protocol follow-up.

Enrolment of patients in the intervention group started on 1st January 2014 and continued until 15th March 2015, or until they recruited the target population (whichever occurred first). The study duration for an individual participant was 12 months. Due to the different organisational and deployment events reported elsewhere, not all patients could be followed for 12 months. All evaluated patients have been followed for at least six months. More patients were recruited after 15th March 2015, but they have not been included in the U4H-E dataset. Participants were selected by screening electronic healthcare records or/and hospital databases or/and hospitalised patients. Candidates were informed about the nature and the objectives of the intervention. Once candidates had signed the informed consent form, they received the telemonitoring devices and the appropriate training.

Retrospective collection of data for the patients in the comparator group started on 1st November 2013 and continued until 31st December 2013 through EMR or other databases. The monitoring duration for an individual participant was 12 months.

Intervention group:

The number of patients finally evaluated in the intervention group was:

- Scotland: 70 patients
- Basque Country: 64 patients
- Northwest Moravia: 22 patients
- Slovenia: 121 patients

Comparator group:

The total population of patients fulfilling the eligibility criteria who have been treated and followed for at least one year before the implementation of the telehealth service, in the same health units as the intervention group, and whose data are available through EMR or other databases have been 334. See Table 1 in the section 3.7 below for the distribution amongst sites.
3.6 **Methods: Statistical methods**

Analysis of the results will be done in accordance with the STROBE guideline for reporting of observational studies.\(^{26}\)

First, the patient characteristics of the intervention and comparator group are compared and tested for statistically significant differences by use of t-test and chi-square test (or non-parametric tests). Thereafter unadjusted differences in primary and secondary outcomes in the two groups are compared by use of the same statistical tests. Finally, adjustment for differences between the patient groups with regard to age and severity of illness of the patients is made by multiple regression analyses. The length of follow-up of clinical outcomes (days) (LFUc) was calculated for each patient who has not left the study, and separately for each patient who left the study or deceased. The primary and secondary outcomes are presented as raw data, but they are also adjusted for the length of follow-up (per patient year) for each individual patient. This is particularly important taking into consideration the differences in the length of follow-up between the intervention and comparator group.

Normality plots and tests assess the normality of distributions of variables: Shapiro-Wilk test was used for sample sizes less than 50 and Kolmogorov-Smirnov test was used for sample sizes more than 50. Transformations (square root, natural log, square, and inverse) were undertaken to normalise data before starting the analysis, and boxplots helped to identify outliers.

The type of analysis was based on the type of variables (categorical or continuous) and their distribution (normal or not). More precisely, continuous variables were compared between two groups by t-test or between three (or more) groups by Analysis of Variance (ANOVA) test, when normally distributed, and by Mann-Whitney U-test or Kruskal-Wallis test, respectively, in other cases. Categorical variables were compared by the Chi-square ($X^2$) test, while the statistical significance was assessed by Pearson's correlation coefficient.

To estimate the adjusted differences between the intervention and the comparator group, to identify potential confounders, and to determine the effect of several variables on primary and secondary outcomes, linear and logistic regression models were conducted, after removing outliers.

Analyses were performed per patient group (intervention versus comparator). All p-values less than 0.05 were considered statistically significant. All tests were two-sided. All statistical analyses were carried out using IBM SPSS Statistics, Version 22.0 (IBM Corp., Armonk, NY, USA).

3.7 **Results: Participants**

Altogether 1,378 patients were assessed for eligibility. However, 272 did not participate due to several reasons; amongst them, patient refusal (193) was the main reason, the others being professionals' clinical judgment and logistic reasons.
Table 1: Participant numbers

<table>
<thead>
<tr>
<th></th>
<th>SC</th>
<th>CZ</th>
<th>SL</th>
<th>ES</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessed for eligibility</td>
<td>437</td>
<td>131</td>
<td>360</td>
<td>450</td>
<td>1378</td>
</tr>
<tr>
<td>Evaluation</td>
<td>140</td>
<td>22</td>
<td>292</td>
<td>157</td>
<td>611</td>
</tr>
<tr>
<td>Intervention group</td>
<td>70</td>
<td>22</td>
<td>121</td>
<td>64</td>
<td>277</td>
</tr>
<tr>
<td>Comparator group</td>
<td>70</td>
<td>0</td>
<td>171</td>
<td>93</td>
<td>334</td>
</tr>
<tr>
<td>Same patients before</td>
<td>0</td>
<td>0</td>
<td>119</td>
<td>0</td>
<td>119</td>
</tr>
<tr>
<td>Other, retrospective</td>
<td>0</td>
<td>0</td>
<td>52</td>
<td>93</td>
<td>145</td>
</tr>
<tr>
<td>Parallel group</td>
<td>70</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>70</td>
</tr>
<tr>
<td>Deployment</td>
<td>218</td>
<td>109</td>
<td>68</td>
<td>100</td>
<td>495</td>
</tr>
<tr>
<td>Shorter Follow-Up</td>
<td>80</td>
<td>38</td>
<td>39</td>
<td>97</td>
<td>254</td>
</tr>
<tr>
<td>No Follow-Up</td>
<td>138</td>
<td>71</td>
<td>29</td>
<td>3</td>
<td>241</td>
</tr>
<tr>
<td>Total U4H population</td>
<td>358</td>
<td>131</td>
<td>360</td>
<td>257</td>
<td>1106</td>
</tr>
</tbody>
</table>

3.8 Results: Baseline data

A total of the 611 patients were enrolled; of these, 277 were assigned to the intervention group (IG) and 334 to the comparator group (CG). Baseline demographic characteristics are statistically different in terms of age, sex and smoking.

The average age of the intervention group is 72 years, compared with 76 for the comparator group (Table 2), and the intervention group has a higher percentage of males (71% vs. 56%). The differences between sites were bigger. The average age range was from 59.86 years in Northwest Moravia to 81.13 in the Basque Country, and nearly 72 in Scotland and 74 in Slovenia.

Table 2: Baseline demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th></th>
<th></th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention (n=277)</td>
<td>Comparator (n=334)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.45 (11.06)</td>
<td>76.66 (10.29)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Age groups (n, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years old</td>
<td>58 (20.9%)</td>
<td>42 (12.6%)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>65-75 years old</td>
<td>102 (36.8%)</td>
<td>94 (28.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;75 years old</td>
<td>117 (42.2%)</td>
<td>198 (59.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n, %)</td>
<td>197 (71.1%)</td>
<td>189 (56.6%)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Smoking (n, %)</td>
<td>251</td>
<td>308</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Yes</td>
<td>18 (7.2%)</td>
<td>21 (6.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>188 (74.9%)</td>
<td>271 (88.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>45 (17.9%)</td>
<td>16 (5.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assisted at home (n, %)</td>
<td>61 (96.8%)</td>
<td>87 (93.5%)</td>
<td>0.363</td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Baseline clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Comparator</td>
</tr>
<tr>
<td>Days from last hospitalisation</td>
<td>219.45 (282.49)</td>
<td>133.24 (229.40)</td>
</tr>
<tr>
<td>Days from last ED visit</td>
<td>133.42 (280.49)</td>
<td>54.3 (212.3)</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>82.07 (18.79)</td>
<td>79.23 (18.38)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>167.62 (10.62)</td>
<td>165.27 (9.56)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.14 (6.25)</td>
<td>28.77 (6.01)</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>76.08 (15.56)</td>
<td>80.04 (18.83)</td>
</tr>
<tr>
<td>Oxygen saturation (%)</td>
<td>94.52 (5.86)</td>
<td>95.49 (2.92)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>130.85 (22.5)</td>
<td>137.67 (22.24)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>76.34 (13.61)</td>
<td>79.02 (14.35)</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>40.03 (13.57)</td>
<td>42.45 (12.68)</td>
</tr>
<tr>
<td>Number of years with CHF</td>
<td>4.28 (3.53)</td>
<td>5.02 (3.36)</td>
</tr>
</tbody>
</table>

On the other hand, there are also relevant differences in other clinical baseline aspects:

- The intervention group had a longer time since last hospitalisation and since the last ED visit.
- The intervention group had a lower heart rate (76 vs 80),
- The intervention group had lower SBP and DBP (130/76 vs 137/79).
- Ejection fraction was also lower in the intervention group (42.4 vs 40).
- The intervention group had less time to disease progression (4.2 vs 5 years),
- The intervention group had lower number of years with CHF (4.28 vs 5.02)

There is a lack of data collected in some covariates such as education level or patients’ familiarity with the use of technology, which prevented adjustment for these factors in subsequent analyses.

There was no significant difference between Charlson Comorbidity Index (CCI) of the intervention (2.7) and control (2.49) groups, even if adjusted for age (6.16 in the IG and 6.15 in the CG). There was no difference in the number of co morbidities (3.62 in IG and 3.47 in CG).

### 3.9 Results: Estimate of outcomes

Table 4 presents the clinical data at the end of the follow up period (for the patients included in the Evaluation dataset) and compares them with the comparator group.
Table 4: Clinical data at the end of follow-up

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Comparator</td>
</tr>
<tr>
<td>Mean length of follow up (days) (LFUc)</td>
<td>283.62 (79)</td>
<td>383.65 (148.09)</td>
</tr>
<tr>
<td>Lost-to-follow-up</td>
<td>81 (29.2%)</td>
<td>95 (28.4%)</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>82.41 (18.79)</td>
<td>78.98 (18.58)</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>71.66 (13.17)</td>
<td>80.58 (18.25)</td>
</tr>
<tr>
<td>Oxygen saturation (%)</td>
<td>94.4 (6.17)</td>
<td>95.49 (2.39)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>127.38 (20.2)</td>
<td>134.6 (21.94)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>73.8 (11.54)</td>
<td>76.81 (14.07)</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>43.41 (12.87)</td>
<td>43.22 (12.98)</td>
</tr>
</tbody>
</table>

Statistically significant differences persist between the two groups in heart rate and systolic blood pressure. No differences appear in LVEF.

Table 5: Clinical outcomes / differences (unadjusted)

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Comparator</td>
</tr>
<tr>
<td>Clinical/Echo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>0.33 (6)</td>
<td>-0.15 (4.69)</td>
</tr>
<tr>
<td>BMI(kg/m2)</td>
<td>0.14 (2.25)</td>
<td>-0.07 (1.76)</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>-4.28 (15.62)</td>
<td>0.6 (21.1)</td>
</tr>
<tr>
<td>Oxygen saturation (%)</td>
<td>0.09 (2.85)</td>
<td>0.07 (3.36)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>-3.75 (21.42)</td>
<td>-2.94 (22.89)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>-2.56 (13.29)</td>
<td>-2.17 (16.99)</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>2.21 (10.43)</td>
<td>-0.75 (11.05)</td>
</tr>
</tbody>
</table>

Comparing before and after values in the intervention and comparator groups, statistically significant differences in their changes appear in heart rate (-4.28), and increase in LVEF (2.21). A reduction of blood pressure, higher reduction of heart rate and a higher increase in LVEF means an improved overall health status in the intervention group.
### Table 6: Primary and secondary outcomes analyses

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>Absolute Difference</th>
<th>Relative Difference (Delta, %)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Comparator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF-related hospitalisations</td>
<td>0.38 (0.96)</td>
<td>0.61 (1.13)</td>
<td>-0.23</td>
<td>-37.7%</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF-related days hospitalised</td>
<td>2.22 (6.97)</td>
<td>4.58 (12.37)</td>
<td>-2.36</td>
<td>-51.5%</td>
</tr>
<tr>
<td>Number of CHF-related ED visits</td>
<td>2.59 (2.1)</td>
<td>0.99 (2.15)</td>
<td>1.6</td>
<td>161.6%</td>
</tr>
<tr>
<td>Patients with CHF-related hospitalisations within 30 days</td>
<td>4 (1.86%)</td>
<td>6 (1.71%)</td>
<td>0.1%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Days until first CHF-related admission</td>
<td>163.59 (137.1)</td>
<td>193.29 (155.09)</td>
<td>-29.7</td>
<td>-15.4%</td>
</tr>
<tr>
<td>Days until first CHF-related ED visit</td>
<td>174.6 (124.37)</td>
<td>191.66 (122.18)</td>
<td>-17.06</td>
<td>-8.9%</td>
</tr>
<tr>
<td>Patients with CHF-related hospitalisation</td>
<td>78 (36.23%)</td>
<td>139 (39.59%)</td>
<td>-3.36%</td>
<td>-8.48%</td>
</tr>
<tr>
<td>Patients with CHF-related ED visits</td>
<td>95 (44.13%)</td>
<td>158 (45.01%)</td>
<td>-0.87%</td>
<td>-1.94%</td>
</tr>
<tr>
<td>Other clinical outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of hospital admissions</td>
<td>0.83 (2.03)</td>
<td>1.15 (2.09)</td>
<td>-0.32</td>
<td>-27.8%</td>
</tr>
<tr>
<td>Number of days hospitalised</td>
<td>3.94 (9.68)</td>
<td>7.71 (16.95)</td>
<td>-3.77</td>
<td>-48.9%</td>
</tr>
<tr>
<td>Number of visits to the emergency department</td>
<td>1.05 (2.03)</td>
<td>1.25 (2.46)</td>
<td>-0.2</td>
<td>-16.0%</td>
</tr>
<tr>
<td>Number of face-to-face contacts with GP or cardiologist</td>
<td>26.31 (28.39)</td>
<td>17.98 (29.56)</td>
<td>8.4</td>
<td>46.9%</td>
</tr>
<tr>
<td>All primary care contacts</td>
<td>34.07 (42.74)</td>
<td>20.84 (35.62)</td>
<td>13.23</td>
<td>63.5%</td>
</tr>
<tr>
<td>Days out of hospital and alive (actual)</td>
<td>359 (11.42)</td>
<td>354.02 (19.26)</td>
<td>4.98</td>
<td>1.4%</td>
</tr>
</tbody>
</table>
Primary outcome measure

The predefined primary outcome adjusted for length of follow-up has shown a significant reduction of CHF-related hospitalisations by 37.7% for the intervention group.

Secondary outcomes and other clinical outcomes

A statistically significant reduction of 51.5% of CHF-related days hospitalised was found in the intervention group, as well as a reduction in the number of hospital admissions, number of days hospitalised, and days out of hospital and alive. The number of face-to-face contacts with GP or cardiologist and primary care contacts was higher in the intervention group. The number of CHF-related ED visits was lower in the comparator group. On the other hand, the intervention group achieved better control heart rate and reduced blood pressure.

No significant difference was seen between the two groups for CHF-related hospitalisations within 30 days, days until first CHF-related admission, days until first CHF-related ED visit, CHF-related mortality, or number of visits to the emergency department.

There is a significant difference in the number of CHF-related ED visits of 1.6 per patient and, at the same time, a difference in the number of patients who had CHF-related ED visits of -0.87% between intervention and comparator group.

To estimate the adjusted differences between the intervention and the comparator group, to identify potential confounders and to determine the effect of several variables on primary and secondary outcomes, multiple logistic regression and linear regression models have been performed.

For CHF-related hospitalisations adjusted for length of follow-up, we used logistic regression analysis, since a high percentage of cases (72.39%) have zero values.

Table 7: CHF-related hospitalisations adjusted for length of follow-up

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP</td>
<td>1.531</td>
<td>0.274</td>
<td>31.106</td>
<td>1</td>
<td>0.000</td>
<td>4.622</td>
<td>2.699</td>
<td>7.916</td>
</tr>
<tr>
<td>GENDER</td>
<td>-0.549</td>
<td>0.301</td>
<td>3.328</td>
<td>1</td>
<td>0.068</td>
<td>0.577</td>
<td>0.320</td>
<td>1.042</td>
</tr>
<tr>
<td>CCI_code2</td>
<td>-0.775</td>
<td>0.369</td>
<td>4.415</td>
<td>1</td>
<td>0.036</td>
<td>0.461</td>
<td>0.223</td>
<td>0.949</td>
</tr>
<tr>
<td>REGION</td>
<td>25.688</td>
<td>3</td>
<td>0.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REGION(1)</td>
<td>-1.557</td>
<td>0.606</td>
<td>6.593</td>
<td>1</td>
<td>0.010</td>
<td>0.211</td>
<td>0.064</td>
<td>0.692</td>
</tr>
<tr>
<td>REGION(2)</td>
<td>0.094</td>
<td>0.771</td>
<td>0.015</td>
<td>1</td>
<td>0.903</td>
<td>1.099</td>
<td>0.242</td>
<td>4.983</td>
</tr>
<tr>
<td>REGION(3)</td>
<td>1.111</td>
<td>0.341</td>
<td>10.625</td>
<td>1</td>
<td>0.001</td>
<td>3.037</td>
<td>1.557</td>
<td>5.923</td>
</tr>
<tr>
<td>AGE</td>
<td>0.011</td>
<td>0.015</td>
<td>0.571</td>
<td>1</td>
<td>0.450</td>
<td>1.012</td>
<td>0.982</td>
<td>1.042</td>
</tr>
<tr>
<td>LVEF</td>
<td>-0.022</td>
<td>0.010</td>
<td>4.642</td>
<td>1</td>
<td>0.031</td>
<td>0.978</td>
<td>0.958</td>
<td>0.998</td>
</tr>
<tr>
<td>BMI</td>
<td>0.026</td>
<td>0.023</td>
<td>1.290</td>
<td>1</td>
<td>0.256</td>
<td>1.027</td>
<td>0.981</td>
<td>1.074</td>
</tr>
<tr>
<td>SBP_NEW</td>
<td>-0.016</td>
<td>0.007</td>
<td>5.704</td>
<td>1</td>
<td>0.017</td>
<td>0.984</td>
<td>0.971</td>
<td>0.997</td>
</tr>
<tr>
<td>DBP_NEW</td>
<td>0.023</td>
<td>0.011</td>
<td>4.402</td>
<td>1</td>
<td>0.036</td>
<td>1.023</td>
<td>1.001</td>
<td>1.045</td>
</tr>
<tr>
<td>SO2</td>
<td>-0.066</td>
<td>0.040</td>
<td>2.739</td>
<td>1</td>
<td>0.098</td>
<td>0.936</td>
<td>0.865</td>
<td>1.012</td>
</tr>
<tr>
<td>Constant</td>
<td>4.480</td>
<td>4.343</td>
<td>1.064</td>
<td>1</td>
<td>0.302</td>
<td>88.245</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GROUP is a dichotomous variable that is coded so that patients with the higher numeric value were patients who belonged to the comparator group. The effect of GROUP is significant and positive, indicating that comparator patients are more likely to have CHF-related hospitalisations than intervention patients. The OR (Exp(B)) tells us they are 4.622 times more likely to have CHF-related hospitalisations than the others. In the same way, patients with Charlton Coefficient Index (CCI) 1 or 2 are 0.461 times more likely to be hospitalised than patients with CCI 3 or 4. Some variables, such as education, symptoms or NYHA, were not included in the analysis as there were not enough cases.

Table 8: CHF-related days hospitalised adjusted for length of follow-up

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP</td>
<td>1.653</td>
<td>0.293</td>
<td>31.907</td>
<td>1</td>
<td>0.000</td>
<td>5.222</td>
<td>2.943</td>
<td>9.267</td>
</tr>
<tr>
<td>GENDER</td>
<td>-0.516</td>
<td>0.325</td>
<td>2.523</td>
<td>1</td>
<td>0.112</td>
<td>0.597</td>
<td>0.316</td>
<td>1.128</td>
</tr>
<tr>
<td>CCI_code2</td>
<td>-0.789</td>
<td>0.400</td>
<td>3.882</td>
<td>1</td>
<td>0.049</td>
<td>0.454</td>
<td>0.207</td>
<td>0.996</td>
</tr>
<tr>
<td>SMOKE</td>
<td>2.031</td>
<td>2</td>
<td>0.362</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMOKE(1)</td>
<td>1.072</td>
<td>0.760</td>
<td>1.988</td>
<td>1</td>
<td>0.159</td>
<td>2.920</td>
<td>0.658</td>
<td>12.957</td>
</tr>
<tr>
<td>SMOKE(2)</td>
<td>0.595</td>
<td>0.687</td>
<td>0.748</td>
<td>1</td>
<td>0.387</td>
<td>1.812</td>
<td>0.471</td>
<td>6.971</td>
</tr>
<tr>
<td>REGION</td>
<td>23.098</td>
<td>3</td>
<td>0.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REGION(1)</td>
<td>-1.529</td>
<td>0.699</td>
<td>4.776</td>
<td>1</td>
<td>0.029</td>
<td>0.217</td>
<td>0.055</td>
<td>0.854</td>
</tr>
<tr>
<td>REGION(2)</td>
<td>-0.038</td>
<td>0.922</td>
<td>0.002</td>
<td>1</td>
<td>0.967</td>
<td>0.962</td>
<td>0.158</td>
<td>5.858</td>
</tr>
<tr>
<td>REGION(3)</td>
<td>1.279</td>
<td>0.422</td>
<td>9.181</td>
<td>1</td>
<td>0.002</td>
<td>3.592</td>
<td>1.571</td>
<td>8.215</td>
</tr>
<tr>
<td>AGE</td>
<td>0.015</td>
<td>0.016</td>
<td>0.837</td>
<td>1</td>
<td>0.360</td>
<td>1.015</td>
<td>0.983</td>
<td>1.047</td>
</tr>
<tr>
<td>LVEF</td>
<td>-0.019</td>
<td>0.011</td>
<td>3.013</td>
<td>1</td>
<td>0.083</td>
<td>0.981</td>
<td>0.960</td>
<td>1.002</td>
</tr>
<tr>
<td>BMI</td>
<td>0.031</td>
<td>0.025</td>
<td>1.597</td>
<td>1</td>
<td>0.206</td>
<td>1.032</td>
<td>0.983</td>
<td>1.082</td>
</tr>
<tr>
<td>SBP_NEW</td>
<td>-0.015</td>
<td>0.007</td>
<td>4.474</td>
<td>1</td>
<td>0.034</td>
<td>0.985</td>
<td>0.971</td>
<td>0.999</td>
</tr>
<tr>
<td>DBP_NEW</td>
<td>0.023</td>
<td>0.011</td>
<td>4.051</td>
<td>1</td>
<td>0.044</td>
<td>1.023</td>
<td>1.001</td>
<td>1.046</td>
</tr>
<tr>
<td>SO2</td>
<td>-0.085</td>
<td>0.042</td>
<td>4.138</td>
<td>1</td>
<td>0.042</td>
<td>0.919</td>
<td>0.847</td>
<td>0.997</td>
</tr>
<tr>
<td>Constant</td>
<td>4.723</td>
<td>4.498</td>
<td>1.103</td>
<td>1</td>
<td>0.294</td>
<td>112.514</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The effect of GROUP is significant and positive, indicating that the comparator patients are more likely to have more CHF-related days hospitalised than the intervention patients. The OR (Exp(B)) tells us they are 5.222 times more likely to have more CHF-related days hospitalised. In the same way, patients with CCI 1 or 2 are 0.454 times more likely to have more CHF-related days hospitalised than patients with CCI 3 or 4.

3.10 Results: Adverse events

There is no significant difference between groups in CHF-related mortality. The results indicate a significant decrease in overall mortality (by 57.1%) but this finding has to be interpreted with caution because of the significant differences between the two groups.
Table 9: Adverse events

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>Absolute Difference</th>
<th>Relative Difference (Delta, %)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Comparator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse events:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF-related</td>
<td>3 (1.39%)</td>
<td>8 (2.28%)</td>
<td>-0.9%</td>
<td>-38.8%</td>
</tr>
<tr>
<td>Total mortality</td>
<td>5 (2.32%)</td>
<td>19 (5.41%)</td>
<td>-3.1%</td>
<td>-57.1%</td>
</tr>
</tbody>
</table>

3.11 Discussion of clinical findings

The clinical findings should be considered in the context of routine care delivery for patients living with CHF and how remote monitoring can be embedded into the CHF care management pathway as outlined below:

3.11.1 CHF routine care management

Patients living with CHF are offered planned care, treatment, support and personalised education services as part of their CHF disease management, monitoring and review in accordance with their disease severity (New York Heart Association functional classification considered), capacity and capability to self manage. As a minimum, all deployment sites offer patients an annual review during which the following is usually assessed and recorded in the patient’s health record:

- Clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of pulse), cognitive status and nutritional status.
- Review of medication, including need for changes and possible side effects.
- Serum urea, electrolytes, creatinine and eGFR.

In addition, patients are offered an annual vaccination against influenza and pneumococcal disease.

Patients whose CHF is unstable or severe are usually offered regular planned specialist follow-up / review consultations.

3.11.2 CHF telehealth care

The remote monitoring service implemented in each region centred on the regular taking and uploading of pulse rate, oxygen saturation, blood pressure and weight. Any adjustments to the patient’s medication and care plan were made either through the telehealth system or through a phone call with the patient. The measurements were available to the clinicians involved in the planned and unplanned CHF disease management consultations, and provided trend data which assisted in the ongoing care planning and management. The remote monitoring service was not designed as a substitute for the annual review consultations, but where a patient’s care plan included more frequent review / follow-up consultations, some regions’ ambition was that these consultations, as well as any emergency admissions to hospital, could be reduced.
3.11.3 Discussion – scalability and clinical system architecture

The main aim of this project was to test if telemonitoring (TM) can be implemented at scale across different healthcare settings. For patients with CHF immediately following hospital admission or ED visit, the result was positive. Although the actual versus predicted patients in the intervention group evaluated was 24.8% (277 out of 1,116), this is explained by initial launch and implementation issues that delayed and slowed the recruitment rate during the first months of the project. They include procurement procedures, integration and interoperability issues, agreements on clinical governance and pathways, training and others. Altogether though, the TM service was deployed to 772 patients (69% of the target). This sets the ground for further analyses at global and local level.

The study design is an observational one, not a randomised clinical study. Comparing with a historical cohort has some inherent design faults, and the differences between Groups regarding important clinical factors. Although the inclusion criteria for the intervention and comparator groups were well defined in the protocol, overall the intervention and control groups are quite heterogeneous, both in demographic terms and clinical baseline data. Most probably this is due to the weight of the Slovenian comparator group in the total sample. The differences between the sites and in the period observed may have also contributed. These no doubt influence some of the outcome data.

Slovenians were recruited by invitation at the centre for decompensated heart to adjust the diuretic treatment, rather than after discharge or visit to the Emergency Department. The characteristics of CHF patients attending a health centre to adjust treatment and CHF patients after discharge or visit to the Emergency Department are demographically and clinically different. Slovenia may have enrolled more stable patients.

Referring to baseline clinical data, systolic blood pressure, diastolic blood pressure and LVEF values could suggest that the comparator group may have had a higher ratio of hypertensive cardiac disease, which has a better prognostic. However, it is also possible that the intervention group’s lower blood pressure was associated with a more adjusted hypertension treatment or the latest stage of the CHF disease. Regarding number of years with CHF, the control group has a longer CHF evolution that is usually associated with a worse clinical status.

Referring to clinical data at the end of follow-up, there are statistically significant differences between the two groups in heart rate and systolic blood pressure; but no differences appear in LVEF. Comparing before and after values in the intervention and comparator groups, statistically significant differences in their changes appear in heart rate (-4.28), and increase in LVEF (2.21). A reduction of blood pressure, higher reduction of heart rate and a higher increase in LVEF means an improved overall health status in the intervention group. The intervention group seems to have had a greater improved overall hemodynamic status with a higher increase in LVEF. Also remarkable is the intervention group’s higher reduction of heart rate that suggests a benefit of the treatment, and is a predictor of a better prognostic. Those differences in hemodynamic evolution have demonstrable consequences in expected clinical development. Knowing the ratio of baseline CHF aetiology (hypertensive or ischemic) of both groups would have help to explain clinical evolution and outcomes.

In general, patients included in the intervention group have reached better results than the comparator group in nearly all primary and secondary outcomes. In the primary outcome, patients who benefit from telemonitoring have lower mortality and
lower hospitalisations. CHF-related hospitalisations decreased 37.7% in the intervention group when adjusted for length of follow-up between both groups. Previous observed differences when adjusted for length of follow-up in outcomes regarding CHF-related hospitalisations remain after adjusting for gender, Charlson Comorbidity index, region, age, LVEF, BMI, systolic and diastolic blood pressure and SO2. With the regression analysis, patients in the intervention group were 4.62 times less likely to have a heart failure related hospitalisation, and 5.22 times fewer hospitalisation days than the patients included in the comparator group.

On the secondary outcomes, there is a significant difference in number of CHF-related ED visits of 1.6 and, at the same time, a difference of patients with CHF-related ED visits of -0.87% between intervention and comparator group. It may indicate that in the intervention group there are a small number of patients that have a high use of ED visits. This suggests that the intervention may not be suitable for some specific patients.

However, to analyse this lower percentage of hospitalisations and mortality in the intervention group, we have to take into account that this group has a longer time since the last hospitalisation (except ES group), more frequent GP visits during the follow-up period (hence earlier hospitalisations), and it presents better kidney function and better cognitive function (to perform the activities required by telemonitoring).

All in all, the intervention group presents a lower risk; the intervention group is younger, has a shorter course of the disease, better renal function, lower heart rate and better haemoglobin levels. All these aspects are indicative of better prognosis in heart failure. Another aspect that may also influence the results is that the intervention group presents a close-fitting drug treatment according to clinical guidelines.

With respect to secondary outcomes, the telemonitored group has a decrease in CHF related days hospitalised, total mortality and number of hospital admissions. As was expected, the number of primary health contacts and CHF-related ED visits are higher in the intervention group than in the comparator group. On the other hand, we have not found differences in CHF-related mortality and in the global number of ED visits. This can, at least partly, be explained by the low number of deaths related to CHF that we have found in the present study, as well as by the low number of visits to the ED apart from those related to the primary disease, CHF. As expected, the number of face-to-face contacts with GP or cardiologist and primary care contacts was higher in the intervention group. However, the number of CHF-related ED visits was lower in the comparator group.

The differences in mortality and hospitalisations are remarkable, and could be explained by the intervention along with the baseline differences between the groups being compared.

There are some limitations when taking the findings of the study into consideration. The difference between intervention and comparator groups in demographic and clinical baseline data should not be underestimated. Patients in the comparator group have worse baseline parameters than the intervention group; these are relevant for CHF management and outcomes. So the findings have to be taken with care and further analysed, both between sites but also within sites.

Although there are long established and studied guidelines on how to treat CHF patients, clinicians agree that there is space for improvement, mainly in aspects such as care coordination, patient empowerment, medication adherence and
anticipatory care. This project has shown that telehealth is seen as a good tool to approach most of these dimensions, while yielding effective and secure clinical outcomes.

### 3.12 Limitations, bias and constraints

In accordance with the D3.1 v1.3 U4H Scientific Study Protocols, 3rd December 2013, (section 2.3: Expected measurable final results of the project), the project “is aiming at focusing on the organisational aspects, the efficiency gains, and the economic aspects of the telemedicine interventions” and not on clinical effectiveness. It was agreed that an observational study design would be more appropriate to assess the real life outcomes, and to complement the evidence of efficacy demonstrated in several randomised controlled trials (RCTs) (section 3.1 Study design of D3.1). The evaluation of the project was conducted using the MAST multidimensional evaluation framework, and was designed taking into consideration the kind of evidence that the various stakeholders need to engage in the roll-out of ICT-supported integrated care services for older people.

Six months before the end of the follow-up, a detailed statistical analysis plan was prepared by the Medical Coordinator, supported by two biostatisticians, and presented to the management team, the WP leaders and the clinical leads. The plan was discussed and revised based on the discussions, suggestions and decisions of the U4H Heart Failure Scientific Committee, chaired by Nekane Murga (Cardiologist, Clinical Lead of the Basque Country and WP8 leader). This plan was completely followed, but extended to include additional regression analyses because unexpected and significant differences were observed between intervention and comparator group.

The pragmatic, observational study approach of the evaluation focused on an assessment of the clinical, organisational and economic impact of telehealth deployments, following best practice wherever possible.

Significant delays in the procurement of necessary infrastructure, coupled with associated organisational changes in some U4H deployment sites, resulted in the total number of patients recruited for telehealth and ‘usual care’ being less than originally planned. This posed a significant challenge to the project evaluation, which was further compounded by a number of issues which also impacted on the data analysis:

- The composition of the comparator groups varied, with some sites including the same patients before the intervention, and others identifying a different prospective group.
- The intervention and comparator groups were significantly different and not matched at baseline, indicating a potential selection bias.
- Significant heterogeneity of healthcare resource use was found among the deployment sites.
- The data was incomplete in a non-random, but systematic way. This lack of data availability made it difficult to arrive at definitive conclusions.

It is acknowledged that the above limitations may have created biases relating to the comparative advantages of telehealth and the reader should take this into account when considering the findings of the evaluation.
deployment and not of clinical effectiveness, as well as the significant delays in the procurement of necessary infrastructure and the organisational changes, resulted in significant delays in recruitment of the study population, and in the following limitations of the evaluation:

1. Significantly lower sample population than originally planned
2. Comparator group included same patients before intervention as well as prospective group
3. Intervention and comparator groups significantly different (selection bias?)
4. Heterogeneity and lack of normality of data
5. Missing data for some indicators and questionnaires

These limitations constitute the biggest challenge for the evaluation, since it was unclear if the differences observed in the outcomes were the results of the U4H services or the differences in patient characteristics.

3.12.1 Multiple Regression Analysis

Multiple regression analysis is a statistical technique that allows the researcher to examine how multiple independent variables are related to a dependent variable. Once you have identified how these multiple variables relate to your dependent variable, you can take information about all of the independent variables, and use it to make much more powerful and accurate predictions about why things are the way they are. Multiple regression examines the relationship between a single outcome measure and several predictors or independent variables[27].

Since Cohen’s seminal article[28], multiple regression has become increasingly popular in both basic and applied research journals. It has been noted in the research that multiple regression is currently a major form of data analysis. The correct use of the multiple regression model requires that several critical assumptions are satisfied in order to apply the model and establish validity[29].

The assumptions of multiple regression are:

- **Linearity:** Residual plots show the standardised residuals vs. the predicted values, and are very useful in detecting violations in linearity[30]. Often we can “straighten” a nonlinear relationship by transforming one or both of the variables. Transformations usually fix the problem. The most common transformations are the logarithmic transformation, the power transformation, the inverse transformation, and the root transformation. When transformations fail to remedy these problems, another option is to use some other analyses. If the number of zero values in the dependent variable is large enough (more than 60%), we can use logistic regression[30].

- **Independence of errors:** In order to diagnose violations of this assumption, the researcher has to study the boxplots of the residuals[31].

- **Homoscedasticity:** This assumption can be checked by examine the plot of the standardised residuals by the regression standardised predicted value[32].

- **Normality:** This assumption can be checked through data plots, skew, kurtosis, and P-P Plots.

- **Multicollinearity:** One way to prevent multicollinearity is to combine overlapping variables in the analysis, and avoid including multiple measures of the same construct in a regression
The above assumptions and recommendations have been taken into account; in accordance with the previously mentioned literature, the following techniques have been applied:

i. Logistic regression for the variable “Number of hospital admissions, because of HF exacerbation, adjusted for length of follow-up (A_ADM_NO_NEW_RECODE)”. For this variable, a high percentage of cases (82.43%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

ii. Logistic regression for the variable “Days of hospital admissions, because of HF exacerbation, adjusted for length of follow-up (A_ADM_DAYS_NEW_RECODE)”. For this variable, a high percentage of cases (77.81%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

iii. Logistic regression for the variable “Number of total ED visits because of HF exacerbation, adjusted for length of follow-up (A_ED_NO_NEW_RECODE)”. For this variable, a high percentage of cases (82.43%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

iv. Logistic regression for the variable “Number of hospital admissions (any reason) adjusted for length of follow-up (A_ADMIT_NO_NEW_RECODE)”. For this variable, a high percentage of cases (66.92%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

v. Logistic regression for the variable “Days of hospital admissions for any reason, adjusted for length of follow-up (A_ADMIT_DAYS_NEW_RECODE)”. For this variable, a high percentage of cases (68.06%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

vi. Logistic regression for the variable “Number of total ED visits for any reason, adjusted for length of follow-up (A_ED_NO_ECON_NEW_RECODE)”. For this variable, a high percentage of cases (75.55%) had zero values. This is why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentized residuals bigger than 2.

vii. Multiple regression analysis for the variable “Number of Outpatients clinic visits, adjusted for length of follow-up (A_OUT_NO_NEW)”. For this variable, the assumptions of linearity, independence of errors, normality, homoscedasticity and multicollinearity were not violated. In addition, we removed the outliers, that is, cases with absolute values in standardised residuals bigger than 3. We also recoded the qualitative variables into dummy variables.
4 Domain 4: Patient perspectives

4.1 Aim of the study and the instruments used

The aim of the analysis is to assess patients’ perspectives regarding the acceptability of telehealth in the intervention groups of the Congestive Heart Failure (CHF) study protocol.

Patient perception is assessed by use of a patient acceptability questionnaire from a large telehealth and telecare study, the NHS England Whole System Demonstrator (WSD) programme. Stevenson et al. (2012) gives a first presentation of the results of the WSD programme.

The arguments for this solution were that use of a common questionnaire will increase the possibilities for comparison of the results between the sites and comparison with the WSD programme. At the same time, the results from U4H will, together with the collaboration with the WSD programme, provide an important basis for the development of a validated and well tested patient perception questionnaire in studies of telehealth in Europe.

Researchers under the leadership of Professor Stanton Newman at University College of London developed a patient acceptability questionnaire, called Service User Technology Acceptability Questionnaire or SUTAQ. This was based on a literature review and testing in qualitative studies. The questionnaire is used in WSD pilots including approximately 3,000 patients. The questionnaire can be self-completed by the patients. The wording of the questions does not include “NHS-terms” or any references to NHS and similar, and thus can be used in other countries. The wording of the 22 items (statements) in the Likert scale questionnaire are both positive and negative and this reduces the risk of bias.

The topics include questions on:

- Utility of the 'kit'.
- Effect on health status.
- Effects on access to care.
- Effect on healthcare / social care.
- Privacy.
- Suitability of the kit.
- Satisfaction with the kit.

The development of the WSD patient acceptability questionnaire, the content and the results from the first test of validity of the questionnaire will be described in Hirani et al. (2016 - forthcoming).

4.2 Data collection

The measurement was carried out on a 6-point Likert scale. As is typical in the literature, this symmetrical scale was treated as an interval, rather than ordinal, and therefore values from 1 to 6 were assigned to responses. The wording of these items (statements) in the Likert scale questionnaire is both positive and negative;
this reduces the risk of bias in the results. However, this means that caution is required in order to recode certain items if necessary.

The most important aspects of survey administration in the various regions are given in Table 10. Regions adopted various methods of questionnaire administration. All modes have their strengths and weaknesses; hence a combination of methods might be seen as preferable. In all regions, the survey took place in 2015. The response rates varied across regions.

**Table 10: Data collection across regions**

<table>
<thead>
<tr>
<th>Region</th>
<th>Mode of Administration</th>
<th>Sampling Method</th>
<th>Study Period</th>
<th>Response Ratea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland</td>
<td>Postal at patient’s home</td>
<td>According to site, first 100 or 27 selected or all in arm</td>
<td>3.4.15-5.10.15</td>
<td>In the three sites: 100%, 37%, 42.2%</td>
</tr>
<tr>
<td>NW Moravia</td>
<td>Paper or electronic questionnaire at hospital or home</td>
<td>All patients in intervention arm</td>
<td>1.7.15-30.9.15</td>
<td>53.8%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Telephone at patient’s home</td>
<td>Patients with longest follow-up chosen (&gt;3 months follow up in any case)</td>
<td>Mid-August to End-August</td>
<td>100%</td>
</tr>
<tr>
<td>Basque Country</td>
<td>Telephone at patient’s home</td>
<td>Patients with longest follow-up chosen (&gt;3 months follow up in any case)</td>
<td>Mid-August to End-August</td>
<td>100%</td>
</tr>
</tbody>
</table>

a. These are response rates self-reported by regions and hence are only indicative since they might have used different definitions.

In the overall CHF sample, observations from the regions participating in the telemonitoring intervention were combined: 51 respondents from Scotland, 27 from Northwest Moravia, 107 from Slovenia and 74 from the Basque country. A total of 259 patients were thus analysed.

### 4.3 Sub-scales

Data were screened to identify and correct implausible values: e.g. implausible age for study participants; implausible / negative values for time from telehealth initiation to date of survey administration; implausible SUTAQ item scores outside the 1-6 range. Since coding is fundamental for the valid analysis of the data, we asked for confirmation by each region to check that the same coding indicated by the CHF codebook was indeed followed. In this way we ensured that increasing values for each item would signify a positive attitude / perception regarding telemonitoring, or at least a less negative one, and vice versa. The coding reflected Strong – Moderate - Mild Agreement and Strong – Moderate – Mild Disagreement. The codebook had positively stated items following 1=Strongly Disagree to 6=Strongly Agree, and negatively worded items having 1=Strongly Agree to 6=Strongly Disagree. After we ensured that all regions followed the codebook, values higher than 3.5 can be interpreted to imply agreement with a positive statement and disagreement with a negative one; i.e. it signifies a positive view on the specific aspect of telemonitoring measured by an item (or even a subscale).

Items 16 and 20 were not considered to be relevant in the case of Slovenia and were thus missing values in the overall analysis of CHF data. Item 16 refers to whether the kit can be a replacement for regular health or social care. Item 20 asks whether the kit has interfered with the continuity of care the patient receives. In
Slovenia, it was thought that continuity of care has not been affected by the telemonitoring service and that a patient should not consider the new service or kit as an attempt to replace regular care.

Results were obtained with SPSS v.20, SPSS Amos v.15 and STATA v.13. The primary analysis was based on the subscales (i.e. summed or multi-item scales) derived by the UK research team that developed the WSD questionnaire by means of Exploratory Factor Analysis and psychometric testing. Scale scores were calculated as the arithmetic means of the scores of the items identified by this prior work as belonging to each scale. The scales and respective items comprising them were the following:

- Enhanced care (based on items 10, 11, 13, 15 and 17);
- Increased accessibility (based on items 1, 3, 4, 19);
- Privacy and discomfort scale (based on items 2, 5, 8, 12);
- Care personnel concerns (based on items: 9, 20, 21);
- Kit as substitution (based on items 16, 18, 22);
- Satisfaction (based on items: 6, 7, 14).

Subscales, in general, are considered more reliable and valid than the original items, and also allow for their psychometric properties to be tested. Since, however, a questionnaire might not perform equally well when translated and culturally adapted in a foreign language, we tested for internal consistency reliability and construct validity by means of Cronbach’s alpha coefficients, multi-trait analysis, and Confirmatory Factor Analysis. Ceiling effects were also examined. This work will help us decide on the relative confidence that we can place on individual as well as overall SUTAQ results.

Initially, we assessed the missing values in the 22 items. Then we performed normality tests (since patient satisfaction studies typically show skewness in similar survey data) and computed appropriate descriptive statistics for the six subscale scores. We also computed confidence intervals for the medians by dividing subscale scores by unity and then employing ratio statistics (namely, confidence intervals for medians of ratios) in SPSS. Next, we performed regression analysis after assessing the normality of the estimated residuals (with normal P-P plots) and homoscedasticity of variances (with the Breusch-Pagan test) assumptions of the OLS model. When the homoscedasticity assumption was violated, heteroscedasticity-consistent estimators were computed rather than OLS.

### 4.4 Scale estimation from sample data

Missing data should not exceed 10% according to the literature if respondents find the questions clear and there are no other reasons for not answering them. In the CHF sample, the highest percentage of missing values for an item was 3% and the values were in fact much lower for almost all other items. However, Q16 and Q20 had much higher rates of missing values only because in Slovenia it was decided that the two questions were irrelevant to their intervention.

Evidence from the Renewing Health project has shown that deviations from normality might be the case for SUTAQ data. Indeed, skewness and kurtosis statistics (not reported here) indicated departures from normality in most individual items. The Kolmogorov-Smirnov and Shapiro-Wilk tests were thus employed here for the six calculated scale scores.
Table 11: Tests of normality

<table>
<thead>
<tr>
<th>Sub-scale</th>
<th>Kolmogorov-Smirnof(^a)</th>
<th>Shapiro–Wilk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic(^b)</td>
<td>p-value</td>
</tr>
<tr>
<td>Enhanced care</td>
<td>0.179</td>
<td>0.000</td>
</tr>
<tr>
<td>Increased accessibility</td>
<td>0.184</td>
<td>0.000</td>
</tr>
<tr>
<td>Privacy and discomfort</td>
<td>0.158</td>
<td>0.000</td>
</tr>
<tr>
<td>Care personnel concerns</td>
<td>0.197</td>
<td>0.000</td>
</tr>
<tr>
<td>Kit as substitution</td>
<td>0.121</td>
<td>0.000</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>0.237</td>
<td>0.000</td>
</tr>
</tbody>
</table>

\(^a\) Lilliefors significance correction. \(^b\) df = 251.

It is evident from Table 11 that distributions are non-normal. We therefore employed appropriate measures such as medians, interquartile ranges, Spearman correlation coefficients, Kruskal-Wallis and Mann-Whitney tests that were suitable for such data, throughout the analyses that follow.

Table 12: Subscale descriptive statistics for the overall sample

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Mdn</th>
<th>CI (95%)</th>
<th>IQR</th>
<th>% Positive Views(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced care</td>
<td>5.60</td>
<td>5.40 – 5.60</td>
<td>1.00</td>
<td>98.1</td>
</tr>
<tr>
<td>Increased accessibility</td>
<td>5.50</td>
<td>5.25 – 5.50</td>
<td>1.00</td>
<td>93.1</td>
</tr>
<tr>
<td>Privacy and discomfort</td>
<td>5.00</td>
<td>5.00 – 5.00</td>
<td>1.50</td>
<td>85.7</td>
</tr>
<tr>
<td>Care personnel concerns</td>
<td>5.00</td>
<td>5.00 – 5.00</td>
<td>1.33</td>
<td>85.8</td>
</tr>
<tr>
<td>Kit as substitution</td>
<td>4.33</td>
<td>4.00 – 4.50</td>
<td>1.67</td>
<td>64.2</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>5.66</td>
<td>5.66 – 6.00</td>
<td>0.67</td>
<td>96.5</td>
</tr>
</tbody>
</table>

\(^a\) % of patients with subscale scores ≥ 4.

Next, we present the medians, 95% confidence intervals for the medians, interquartile ranges, and percentage of patients with a positive view about the particular aspect of telehealth. The latter is the percentage of patients that have a score in the subscale that is greater than 4. One could in principle employ scores greater than 3.5, since this is the value in the centre between 1 and 6. However, scores close to 3.5 were taken to imply indifference, and were excluded from the calculated percentage, which can therefore be interpreted as the % of patients with a mild, moderate or strong positive view regarding telemonitoring in the specific dimension under study. This is hence a conservative measurement of the positive views of CHF patients.

It is apparent from Table 12 that overall almost all patients agreed, admittedly, to various degrees, that telemonitoring increased the healthcare they received, increased accessibility, and were overall satisfied with the kit. In addition, more than 8 out of 10 CHF patients thought that telemonitoring did not cause privacy or discomfort issues, and did not create problems related to the personnel that provided the new intervention. There was also mild agreement that the kit could act as a substitute to standard care.
The median values gave a similar picture. There was moderate to strong agreement among CHF patients that telemonitoring enhanced the care they received from the healthcare system. According to the content of individual items embodied in the “enhanced care” subscale, this means that they believed that the kit was a good addition to their regular healthcare, it allowed them to be less concerned about their healthcare, and therefore should be recommended to others with similar conditions. It has also made them more actively involved in their health, and has allowed their carers to better monitor them and their condition. This more detailed analysis of a SUTAQ subscale score should be treated with some caution, since it is based on an average of individual question scores, which, although positively correlated (see Cronbach values below), might diverge from each other.

There was moderate to strong agreement that telemonitoring increased accessibility to healthcare services. It thus made it easier to get in touch with a health professional; it saved time by limiting visits to physicians; improved their health; and increased their access to healthcare.

There was also moderate agreement that the kit did not create problems with the privacy of the study participants nor caused them any discomfort. It seems that the median CHF patient believes that the kit has not interfered with his everyday routine, nor has it invaded his privacy. It has not made him feel uncomfortable, and the patient did not believe it made him worried about the confidentiality of the private information exchanged through it.

Similarly, CHF patients moderately agreed that they had no concerns about the personnel associated with their care. In fact, they did not believe that the kit obstructed the continuity of care, nor that the person who monitored their health status had inadequate information about their personal healthcare history or had an inadequate level of expertise.

Unsurprisingly, given the above positive views on specific characteristics and dimensions of the telemonitoring experience, results indicate a very high overall satisfaction. In fact, CHF patients moderately-to-strongly agreed that they were satisfied with the kit. In particular, they felt knowledgeable about the kit, which they seemed to trust, and hence were satisfied with it.

Nevertheless, they were not fully convinced that the kit could act as a substitute to usual care. Specifically, they mildly agreed that it could substitute their regular face-to-face consultations with the healthcare professionals. According to patient preferences, telemonitoring might be as suitable as face-to-face consultations, and the kit might make them less concerned about their health status. As already said, however, they had rather mild preferences.

Summing up, results indicated a high acceptability and satisfaction among CHF patients associated with the telemonitoring intervention. Although they did have a positive view about substituting established care with the kit, they were not fully convinced.

In passing, it might be the case that opinions differ to some extent across different regions. Regions that participated in the U4H CHF overall sample of patients were Scotland, Northwest Moravia, Slovenia and the Basque Country. Median tests suggest that the median levels of each and every subscale differed across regions (p<0.01). Kruskal-Wallis tests of whether the distribution of the subscales were the same across regions corroborate the previous finding (p<0.01). It is therefore interesting to see for the “Satisfaction” subscale which region(s) depart from the others.
Figure 13: Median "Satisfaction" across regions

Figure 13 shows that patients in Northwest Moravia and the Basque Country might have different views on how satisfied with the kit they really felt. Mann-Whitney pairwise tests with Bonferroni corrections for multiple comparisons are thus presented in Table 13.

Table 13: Mann-Whitney pairwise tests with Bonferroni corrections for "Satisfaction" scale

<table>
<thead>
<tr>
<th>Sample 1 – Sample 2</th>
<th>Test Statistic</th>
<th>St. Error</th>
<th>Std. Test Statistic</th>
<th>P-value</th>
<th>Adj. P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwest Moravia–Basque Country</td>
<td>-20.506</td>
<td>16.005</td>
<td>-1.281</td>
<td>0.200</td>
<td>1.000</td>
</tr>
<tr>
<td>Northwest Moravia–Scotland</td>
<td>70.286</td>
<td>16.942</td>
<td>4.149</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Northwest Moravia–Slovenia</td>
<td>-74.063</td>
<td>15.331</td>
<td>-4.831</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Basque Country-Scotland</td>
<td>49.781</td>
<td>12.995</td>
<td>3.843</td>
<td>0.000</td>
<td>0.001</td>
</tr>
<tr>
<td>Basque Country-Slovenia</td>
<td>53.557</td>
<td>10.762</td>
<td>4.976</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Scotland-Slovenia</td>
<td>-3.776</td>
<td>12.112</td>
<td>-0.312</td>
<td>0.755</td>
<td>1.000</td>
</tr>
</tbody>
</table>

a. Each row tests the null that the distributions between the two regions' samples are the same.
b. Asymptotic significance (two-tailed) p-values. Significance level is 0.05.

This shows that, in line with the figure above, the distribution of satisfaction scores is similar in Scotland and Slovenia. These regions have higher satisfaction median scores that the other two, as documented also by the pairwise comparisons. In addition, Northwest Moravia and the Basque Country have similar distributions of scores, which are in fact lower than those of the other two regions. The common finding is nevertheless that in all regions satisfaction seems to be high.
Figure 14: Medians of “Kit as substitute” across regions

In Figure 14 shows that median opinions might differ as to whether the kit can be a substitute for established care. Indeed, a median test and a Kruskal-Wallis test are both significant (p<0.01).

Table 14 Mann-Whitney tests with Bonferroni adjustments for multiple comparisons, shows that the opinions in Northwest Moravia and Slovenia are more favourable than the respective views of Scottish patients and Basques regarding the potential of substituting standard care with telemonitoring.

Table 14: Mann-Whitney pairwise tests with Bonferroni corrections for “Kit as Substitution” scale

<table>
<thead>
<tr>
<th>Sample 1 – Sample 2a</th>
<th>Test Statistic</th>
<th>St. Error</th>
<th>Std. Test Statistic</th>
<th>P-value</th>
<th>Adj. P-valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basque Country–Scotland</td>
<td>8.017</td>
<td>13.554</td>
<td>0.591</td>
<td>0.554</td>
<td>1.000</td>
</tr>
<tr>
<td>Basque Country–Northwest Moravia</td>
<td>58.581</td>
<td>16.646</td>
<td>3.519</td>
<td>0.000</td>
<td>0.003</td>
</tr>
<tr>
<td>Basque Country–Slovenia</td>
<td>58.898</td>
<td>11.216</td>
<td>5.251</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Scotland-Northwest Moravia</td>
<td>-50.564</td>
<td>17.682</td>
<td>-2.860</td>
<td>0.004</td>
<td>0.025</td>
</tr>
<tr>
<td>Scotland–Slovenia</td>
<td>-50.882</td>
<td>12.702</td>
<td>-4.006</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Northwest Moravia-Slovenia</td>
<td>-0.317</td>
<td>15.961</td>
<td>-0.020</td>
<td>0.984</td>
<td>1.000</td>
</tr>
</tbody>
</table>

a. Each row tests the null that the distributions between the two regions' samples are the same.
b. Asymptotic significance (two-tailed) p-values. Significance level is 0.05.

Table 15 presents the medians for all subscales across regions for the sake of completeness. These indicate that, regarding the “Kit as substitution” scale, Northwest Moravia and Slovenia CHF patients mildly-to-moderately agreed that the kit could substitute standard care. Scottish patients instead were indifferent and Basques had only a mild positive view. Perhaps another interesting finding was that in Slovenia there seemed to be distinctively lower strength of belief (i.e. they were
less convinced) that the kit did not raise issues about privacy and discomfort or problems with the staff undertaking the telemonitoring tasks.

Table 15: Median subscale scores across regions

<table>
<thead>
<tr>
<th>Region</th>
<th>Scale</th>
<th>Enhanced Care</th>
<th>Increased Accessibility</th>
<th>Privacy &amp; Discomfort</th>
<th>Care Personnel Concerns</th>
<th>Kit as Substitution</th>
<th>Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland</td>
<td></td>
<td>5.8</td>
<td>5.33</td>
<td>6.0</td>
<td>6.0</td>
<td>3.66</td>
<td>6.0</td>
</tr>
<tr>
<td>Northwest Moravia</td>
<td></td>
<td>5.8</td>
<td>5.25</td>
<td>5.5</td>
<td>5.0</td>
<td>4.66</td>
<td>5.33</td>
</tr>
<tr>
<td>Slovenia</td>
<td></td>
<td>6.0</td>
<td>6.0</td>
<td>4.37</td>
<td>4.5</td>
<td>4.5</td>
<td>6.0</td>
</tr>
<tr>
<td>Basque Country</td>
<td></td>
<td>5.0</td>
<td>5.0</td>
<td>5.75</td>
<td>5.66</td>
<td>3.83</td>
<td>5.33</td>
</tr>
</tbody>
</table>

4.5 Effects of demographic and other variables on patient acceptability

Our original aim was to include as regressors gender (dummy: 1=female, 0=male), age (categorical with three categories), education level (categorical with four categories), familiarity with a PC (familiar with PC or not), time from trial start to questionnaire administration (TIME in days), and severity of CHF (LVEF%). Age was entered into the model by means of two dummy (AGE65-75 and AGE75+) variables (reference category excluded: patients <65 years). Education was meant to be incorporated with three (EDUCprimary, EDUCsecondary, EDUCunicolleg) dummies (reference category: no formal schooling).

Eventually, however, we did not use the full list of independent variables since such an approach was unfeasible. This is because there were no available data on education level and familiarity with a PC. These two variables were thus de facto excluded, raising the possibility of omitted variable bias.

Figure 15: PP-Plot of residuals

There were some departures from normality but not so profound so as not to use OLS. Breusch-Pagan tests did not indicate heteroscedasticity for “Enhanced care”, “Privacy and discomfort” and “Kit as substitution” (p>0.05). These regressions were
estimated by OLS. However, heteroscedastic variances were found for “Increased Accessibility”, “Care personnel concerns” and “Satisfaction” (p<0.01). Therefore, heteroscedasticity consistent standard errors in STATA 13 were obtained. According to the results of Table 16, only patients older than 75 years seemed to have a milder agreement that the kit enhanced care or increased accessibility than patients younger than 65. As time evolved from the first time patients used the kit, they seemed to agree more that the kit could be a substitute for usual care.

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>Std. Error</th>
<th>t</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE75+</td>
<td>-0.257</td>
<td>0.132</td>
<td>-1.94</td>
<td>0.05</td>
</tr>
<tr>
<td>Increased Accessibility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE75+</td>
<td>-0.402</td>
<td>0.198</td>
<td>-2.03</td>
<td>0.045</td>
</tr>
<tr>
<td>Privacy and Discomfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care personnel concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kit as substitution</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIME</td>
<td>0.002</td>
<td>0.001</td>
<td>2.12</td>
<td>0.036</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Due to the shortcomings of the above analysis, we also examined bivariate relationships rather than base our conclusions solely on a dubious multivariate regression for CHF patients. Due to the non-normal distribution of SUTAQ scales, we employed non parametric Mann-Whitney and Kruskal-Wallis tests, as well as Spearman correlation coefficients to assess potential relationships. We also checked other variables in addition to those used in the regression analysis mentioned above.

Scale scores did not differ according to gender, or whether the patient had any informal assistance at home (p>0.05). The distribution of “Enhanced care” significantly differed across age groups (p=0.012). Mann-Whitney tests with Bonferroni corrections showed that there was a statistically significant difference in the distributions of patients older than 75 years (median 5.0) and those younger than 65 (median 5.6, Adj. p=0.009). Therefore, CHF patients older than 75 years only moderately believed that the kit enhanced their care, whereas those younger than 65 had stronger positive preferences. There were no statistically significant differences in other scales’ scores across age groups. Insignificant correlations were found between scale scores and time from trial initiation to survey administration (p>0.05). The same was true for LVEF%, that is, severity of CHF. Finally, an interesting finding was that the number of times healthcare professionals contacted the patients by telemonitoring was significantly negatively related to the score of “Enhanced care” (r=-0.232, p<0.01). This implies that more frequent contacts with the patients were associated with less positive views as to whether the service enhanced the healthcare they receive.
4.6 Reliability, validity and ceiling effects of the sub-scales

This supplementary analysis that follows is meant to assess the psychometric properties of the SUTAQ questionnaire in the sample of CHF patients that was used in the study. It will allow us to draw conclusions about the robustness of the results presented above.

Reliability refers to the consistency of the measurement. Internal consistency reliability was evaluated by computing Cronbach’s alpha coefficient for each sub-scale. In addition, for each scale the coefficients were recalculated with a particular item first being deleted. This showed us if the reliability of a scale could be improved if it was found to be less than satisfactory. If coefficients are found to be unacceptable, Cronbach’s alpha should be computed also for each region’s dataset, to see which dataset provides the more reliable results on which to place greater confidence.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Cronbach’s alpha</th>
<th>Cronbach’s alpha with item deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced care</td>
<td>0.718</td>
<td>-</td>
</tr>
<tr>
<td>Increased accessibility</td>
<td>0.739</td>
<td>-</td>
</tr>
<tr>
<td>Privacy and discomfort</td>
<td>0.741</td>
<td>-</td>
</tr>
<tr>
<td>Care personnel concerns</td>
<td>0.563</td>
<td>0.571 (Q20)</td>
</tr>
<tr>
<td>Kit as substitution</td>
<td>0.567</td>
<td>-</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>0.688</td>
<td>-</td>
</tr>
</tbody>
</table>

In parentheses we mention the item, which once deleted from the scale, increases its reliability.

On inspection of Table 17, we see that the reliability of the first three scales can be considered very satisfactory. In addition, the most informative scale of patient “Satisfaction” has marginally acceptable reliability. However, scales “Care personnel concerns” and “Kit as substitution” seem rather problematic. Their Cronbach’s alpha coefficients do not significantly improve if we exclude certain items, so that it could render them reliable. We would thus place a low confidence weight on their values.

It is hence worth considering some sensitivity analysis in the sense of looking whether the medians in the regions that might have higher internal reliability in the two underperforming scales differ in their medians compared to the overall median findings discussed so far. The first of the two underperforming scales took better values in Northwest Moravia (α=0.659) whereas the second is Scotland (α=0.582). The medians for “Care personnel concerns” in Northwest Moravia and for “Kit as substitution” in Scotland were 5.0 and 3.66. The respective median values for the overall sample were 5.0 and 4.33. This means that results are unaltered with respect to “Care personnel concerns”. However, it seems that the somehow more reliable finding regarding “Kit as substitution” turns an indifference to mild agreement that telemonitoring could replace usual care. In any case, generalisation of this finding from the single region to other regions cannot be made.

We also applied the multi-trait / multi-method approach to assess the UK WSD model’s (questionnaire’s) convergent and divergent validity. Due to the skewness observed in the data, we computed Spearman correlation coefficients between each item (question score) and the subscales (SUTAQ subscale scores). Correlations of items with their own scales were corrected for overlap. Convergent validity is
present if correlations of items with their own scales are greater than 0.40. Divergent validity is documented if these same correlations are in fact higher than the correlations of items with unrelated scale scores. If tests for statistical significance are required, these will be performed with Steiger’s test for differences in dependent correlation coefficients.

Table 18: Multi-trait / multi-method analysis

<table>
<thead>
<tr>
<th>Subscale / Item</th>
<th>Enhanced Care</th>
<th>Increased Accessibility</th>
<th>Privacy and Discomfort</th>
<th>Care Personnel Concerns</th>
<th>Kit as Substitution</th>
<th>Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enhanced Care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 10</td>
<td>0.610 (^b)</td>
<td>0.617</td>
<td>-0.087</td>
<td>-0.004</td>
<td>0.542</td>
<td>0.505</td>
</tr>
<tr>
<td>Item 11</td>
<td>0.579 (^b)</td>
<td>0.495</td>
<td>-0.048</td>
<td>-0.011</td>
<td>0.353</td>
<td>0.460</td>
</tr>
<tr>
<td>Item 13</td>
<td>0.571 (^b)</td>
<td>0.449</td>
<td>0.023</td>
<td>0.083</td>
<td>0.213</td>
<td>0.470</td>
</tr>
<tr>
<td>Item 15</td>
<td>0.535 (^b)</td>
<td>0.454</td>
<td>0.016</td>
<td>-0.006</td>
<td>0.355</td>
<td>0.478</td>
</tr>
<tr>
<td>Item 17</td>
<td>0.524 (^b)</td>
<td>0.455</td>
<td>-0.012</td>
<td>0.030</td>
<td>0.280</td>
<td>0.441</td>
</tr>
<tr>
<td><strong>Increased Accessibility</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 1</td>
<td>0.534</td>
<td>0.552 (^b)</td>
<td>-0.025</td>
<td>-0.056</td>
<td>0.378</td>
<td>0.458</td>
</tr>
<tr>
<td>Item 3</td>
<td>0.540</td>
<td>0.621 (^b)</td>
<td>-0.058</td>
<td>0.038</td>
<td>0.388</td>
<td>0.468</td>
</tr>
<tr>
<td>Item 4</td>
<td>0.618</td>
<td>0.553 (^b)</td>
<td>-0.098</td>
<td>-0.031</td>
<td>0.389</td>
<td>0.540</td>
</tr>
<tr>
<td>Item 19</td>
<td>0.558</td>
<td>0.561 (^b)</td>
<td>0.072</td>
<td>0.177</td>
<td>0.453</td>
<td>0.463</td>
</tr>
<tr>
<td><strong>Privacy and Discomfort</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 2</td>
<td>0.001</td>
<td>-0.014</td>
<td>0.568 (^b)</td>
<td>0.488</td>
<td>0.031</td>
<td>0.103</td>
</tr>
<tr>
<td>Item 5</td>
<td>-0.141</td>
<td>-0.223</td>
<td>0.673 (^b)</td>
<td>0.548</td>
<td>-0.115</td>
<td>-0.019</td>
</tr>
<tr>
<td>Item 8</td>
<td>-0.041</td>
<td>-0.126</td>
<td>0.588 (^b)</td>
<td>0.510</td>
<td>-0.047</td>
<td>0.039</td>
</tr>
<tr>
<td>Item 12</td>
<td>-0.171</td>
<td>-0.191</td>
<td>0.545 (^b)</td>
<td>0.643</td>
<td>-0.038</td>
<td>-0.020</td>
</tr>
<tr>
<td><strong>Care Personnel Concerns</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 9</td>
<td>-0.142</td>
<td>-0.148</td>
<td>0.608</td>
<td>0.389 (^b)</td>
<td>-0.068</td>
<td>0.002</td>
</tr>
<tr>
<td>Item 20</td>
<td>0.410</td>
<td>0.221</td>
<td>0.274</td>
<td>0.221 (^b)</td>
<td>0.132</td>
<td>0.312</td>
</tr>
<tr>
<td>Item 21</td>
<td>-0.048</td>
<td>-0.033</td>
<td>0.597</td>
<td>0.350 (^b)</td>
<td>-0.069</td>
<td>0.075</td>
</tr>
<tr>
<td><strong>Kit as Substitution</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 16</td>
<td>0.378</td>
<td>0.314</td>
<td>0.064</td>
<td>-0.009</td>
<td>0.395 (^b)</td>
<td>0.065</td>
</tr>
<tr>
<td>Item 18</td>
<td>0.176</td>
<td>0.187</td>
<td>0.248</td>
<td>0.187</td>
<td>0.329 (^b)</td>
<td>0.152</td>
</tr>
<tr>
<td>Item 22</td>
<td>0.675</td>
<td>0.603</td>
<td>-0.098</td>
<td>-0.065</td>
<td>0.447 (^b)</td>
<td>0.456</td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 6</td>
<td>0.458</td>
<td>0.412</td>
<td>-0.005</td>
<td>0.064</td>
<td>0.206</td>
<td>0.466 (^b)</td>
</tr>
<tr>
<td>Item 7</td>
<td>0.489</td>
<td>0.492</td>
<td>0.108</td>
<td>0.126</td>
<td>0.306</td>
<td>0.479 (^b)</td>
</tr>
<tr>
<td>Item 14</td>
<td>0.572</td>
<td>0.507</td>
<td>0.186</td>
<td>0.194</td>
<td>0.328</td>
<td>0.482 (^b)</td>
</tr>
</tbody>
</table>

a. Spearman correlation coefficients.
b. Item-scale correlations corrected for overlap.

Table 18 presents the findings. Convergent validity requires correlations of items with their own scale to be higher than 0.40. Most subscales satisfy this condition, with the exceptions of “Care personnel concerns” and “Kit as substitution”.

The high correlation of “Satisfaction” and some other scales can be explained perhaps by the fact that it can alternatively be seen as an overall concept influenced
by some of the other dimensions of the questionnaire, such as enhanced care or increased accessibility (the perceptions of patients for these might in fact affect a patient's level of satisfaction). However, it is apparent that there is overlap and lack of discriminant validity between other scales, and not only regarding "Satisfaction". This is the case since some items seem to correlate more (or some correlate similarly) with unrelated scales than with the scale they supposedly belong to. There are therefore some problems with construct validity.

We examined construct validity further by means of Confirmatory Factor Analysis. This allowed us to assess whether the sub-scale structure, suggested by the initial UK study that developed SUTAQ, is in line with our data in the U4H setting. Note that a translated and culturally adapted questionnaire might not perform equally well as in the country of origin. We applied the statistical methodology to the overall sample of all regions. We allowed for possible correlation between the subscales. Since the sample was relatively small, Asymptotically Distribution Free estimation was not feasible in AMOS due to the limited sample size for this diagnosis, and hence we estimated the model with Maximum Likelihood despite the non-normal nature of the data (Figure 16).

![Figure 16: Path diagram of the Confirmatory Factor Analysis of the UK subscales](image)
The estimated standardised regression weights should be >0.45. Two such factors loadings, namely Q16 and Q18 equal 0.42 and 0.32, respectively, and thus fall short of the chosen cut-off. This implies some problems in the construct validity of the “Kit as substitution” scale.

The fit indices obtained were the following:

- **Bentler’s Comparative Fit Index (CFI) = 0.804.** It compares the fit of the UK model to the fit of an independent model, that is, a model in which the variables are assumed to be uncorrelated. In this context, fit refers to the difference between the observed and predicted covariance matrices, as represented by the chi-square index. CFI is not too sensitive to sample size and its values should exceed 0.93.

- **Root Mean Square Error of Approximation (RMSEA) = 0.083.** It is the square root of the average of the covariance residuals, that is, the differences between the corresponding elements of the observed and the predicted covariance matrix. Again, the index is not sensitive to sample size, and its value should be less than 0.08 for an adequate fit and ideally less than 0.05 for a good fit.

- **Chi square / df = 2.785.** The chi-square statistic indicates the difference between observed and expected covariance matrices, but is sensitive to sample size. Its value should be less than 2 for a good fit, but large samples sizes (>200) and non-normal data increase its value regardless of the appropriateness of the proposed model.

Floor effects are the % of observations that take the lowest value (i.e. 1) of a scale. They were very low and ranged from 0.4 to 1.9% in the various scales. Ceiling effects are the % of observations that take the highest value (i.e. 6) of a scale. These were low in the kit as substitution scale (3.5%) and higher for other scales, reaching 44% in the "satisfaction" scale.

Overall, the evidence on the psychometric properties of the SUTAQ questionnaire implies that there are some reliability and validity issues with some of the SUTAQ multi-item scales.

These data were collected for the first 100 patients in the intervention group in each region. Scotland also collected for the last 100 patients.

The number of patients who were screened but not included in the study and the underlying reasons were registered and analysed with a view to identifying patient subgroup populations who are currently excluded from the provided services.

Such classification of reasons for non-participation would be of help to identify existing barriers to provision of telemonitoring services to patients with chronic conditions, and to work further to overcome the ones which are not patient-related[33]. The following reasons for non-participation have been examined:

- **Patient refuses the use of devices**
  - Patient refused participation in the study in general (refused to be monitored, to participate in an “experiment”, etc).
  - Other reasons, please specify (open space).

- **Logistic / technical limitations**
  - No network coverage (broadband, 3G, 4G...).
  - Patient did not live in the area receiving healthcare coverage by the hospital, or was about to leave this area during the study period.
- Patient who transferred to a different health centre (including nursing home) where the intervention (telemonitoring) could not be carried on.
- Other technical reasons please specify (open space).

- Clinicians Assessment
  - Patient was unable to communicate (physical or cognitive condition).
  - Patient was not totally reliable for using the device (not meeting requirements for proper use and conservation of equipment and devices).
  - Other: please specify (open space).

4.7 Discussion of findings

Patients from Scotland, Northwest Moravia, Slovenia and the Basque Country that participated in the U4H CHF deployment have a high acceptability and satisfaction associated with the telemonitoring intervention.

Home health monitoring had a perceived positive impact on patients' lives. Patients said that telemonitoring did not cause privacy or discomfort issues and did not create problems related to the personnel that provided the new intervention. They felt knowledgeable about the kit, and agreed that telehealth increased the healthcare they received.

There was also mild agreement that the kit could act as a substitute to standard care, but in different degrees across different regions. Patients did have a positive view about substituting established care with the kit; however, they were not fully convinced regarding the potential of substituting standard care with telemonitoring - Northwest Moravia and Slovenia were more favourable than Scotland and Basque Country.

Sub-group analysis showed that older patients might have less positive views about telemonitoring, especially its dimensions “Enhanced care” and “Increased Accessibility”. An interesting finding was that more frequent contacts of healthcare professionals with patients were associated with less positive views as to whether the service enhanced the healthcare they received.

The results of the present research should nevertheless be seen with some caution. Some reliability and validity problems exist for SUTAQ, implying that the questionnaire developed in the UK may not perform ideally in terms of measuring telemonitoring settings in other countries. Besides that, missing data for demographic and other variables did not allow us to derive clear evidence on the possible associations these might have with patient acceptability of telemonitoring.
5 Domain 5: Economic aspects

5.1 Purpose

In order to assess the economic consequences of the telehealth intervention in the United4health project for patients with diabetes, a study of the costs of the intervention has been carried out as described in the protocol.

The study of the economic consequences of the telehealth intervention is based on the same observational study and the same collection of data as described in the presentation of the clinical outcomes.

The aim of the economic evaluation is to estimate impact on the mean costs per patient of using the telehealth intervention, including both the costs of the telehealth intervention and the change in the costs of use of healthcare services in general by comparing with patients in the comparator group.

These data will be used to carry out a cost-analysis in accordance with Drummond et al. (2005).

5.2 Method

The perspective of the economic analysis is on the costs of the healthcare sector, including costs in both primary and secondary care.

To assess the economic consequences of the telehealth intervention, two types of data are collected:

- Data on the costs of the telehealth intervention.
- Data on the impact of the telehealth intervention on the patients’ use of healthcare.

5.2.1 Patient population

Described in domain 1 and 3.

5.2.2 Comparators

Sites deploying telehealth services for patients with CHF have included distinct types of comparator groups in the study:

- **Same patients before**: each intervention group patient serves as his own control, by including information on a 12-month period prior to receiving the telehealth service (Slovenia).
- **Other patients’ retrospective**: different individuals compared to the intervention group, but the follow-up period is the 12-month time span prior to receiving the telehealth service (Northwest Moravia, Slovenia and Basque Country).
- **Parallel group**: concurrent group with different individuals followed during the same period as the intervention group. This parallel group has been recruited from the same organisations and from the same geographical locations as the intervention cohorts (Northwest Moravia and Scotland).
This different framework of telehealth deployment in each site implies that a different set of costs could be imputed in each site. Consequently, a direct impact on a high variability of costs can be expected.

5.2.3 Data on costs of the telehealth intervention

The costs of the telehealth intervention are estimated based on data from each of the participating regions. Each region was asked to submit information in September 2015 on:

- **Fixed costs (investments):**
  - Investments made in technical infrastructure, e.g. servers, WiFi, computers, phones, software, web based portal, system integration.
  - Use of time by healthcare professionals on management, education and training in order to establish the telehealth service.
  - The total number of patients per year expected to be able use the telehealth service by these investments.

- **Variable costs (cost that vary with the number of patients):**
  - Costs per patient for use of the telehealth devices, e.g. gateway, video conference equipment, devices for home measurement of blood glucose, pulse oximeter, blood pressure, heart rate and weight.
  - Average use of healthcare professionals per patient in the production and delivery of the telehealth service, e.g. staff used at call centres and staff monitoring patients’ data from telehealth devices.
  - Other costs that should be included.

The information on investment and running costs was collected from each of the participating regions by use of a template, see Appendix C. After collection of the data contact was made by use of videoconferencing with representatives from each region in order to ensure that the information was correct. This was necessary because a number of misunderstandings were found in the first information that was collected:

- Some regions included costs related to administrative tasks that were carried out as part of the United4Health project, but were not a necessary part of the intervention.
- Other regions reported costs as a one-off payment, but the costs were actually recurring annually.
- Some regions did not include the costs of use of telehealth devices that were paid for by other projects or by medical device suppliers.
- Finally, some regions did not understand the question about the potential number of patients, and reported the actual number of patients included in the project.

Based on information about the fixed costs and the investments made in each region, the mean costs per patient were estimated by assuming that all investments would last for three years and replaced thereafter. Estimates of the equivalent annual costs per patient were made using an assumed discount rate of 2%, thereby taking account of the societal time preferences in accordance with Drummond et al. (2005).

To estimate the costs per patient, the total annual costs were divided by the number of patients using the resources. For investment in servers, electronic health record systems, etc., the number of users is not just the patients included in the evaluation in this project, but also other patient groups using the system. Therefore regions
were asked to provide information about the total number of patients that are expected to use these resources within the next 2-3 years. This number is used to estimate the fixed costs per patient. With regard to investment in the staff, e.g. training of nurses and medical doctors, regions has been asked to provide information about the number of patients using these human resources at the moment. This number is used to estimate the fixed cost per patient with regard to the costs of staff. Therefore two different numbers of patients have been used in the estimates; these are presented in the tables below.

5.2.4 Data on patients’ use of health

With regard to data on the patients’ use of healthcare resources, the following types of healthcare are included in the estimates of the economic consequences of the use of telehealth:

- Number of admissions to hospital.
- Number of ED visits.
- Number of GP visits.
- Number of outpatient clinic visits.

Based on the data from the clinical study, the difference in the use of these services by the intervention and the comparator groups has been estimated and adjusted for potential differences and confounders in the two groups by use of multiple regression analysis in accordance with guidelines for reporting of observational studies by von Elm et al. (2007). Details of data collection are described in the scientific protocol for the multicentre studies, deliverable D3.1.

Information about the prices for these healthcare services has been collected from the deployment teams in each region based on a common template in the autumn of 2015.

Based on the data described above, the net costs per patient using telehealth is estimated as the costs of the telehealth service minus the saved costs of usual care:

\[
\text{Net costs per patient} = (FC_{TM} + VC_{TM}) - (PA \times RA) - (PED \times RED) - (PGP \times RGP) - (POV \times ROV)
\]

where:

- \( FC_{TM} \) = the fixed costs of the telehealth service per patient
- \( VC_{TM} \) = the variable costs of the telehealth service per patient
- \( PA \) = Price per admission
- \( RA \) = Reduction in the number of admissions by use of telehealth per patient
- \( PED \) = Price per emergency department visit
- \( RED \) = Reduction in the number of visits to emergency department by use of telehealth per patient
- \( PGP \) = Price per visit to general practitioner
- \( RGP \) = Reduction in the number of visits to general practitioner by use of telehealth per patient
- \( POV \) = Price per outpatient visit
- \( ROV \) = Reduction in the number of outpatient visits by use of telehealth per patient

Note that all reductions in use of healthcare (denoted \( R \) above) are estimated for each multicentre study by use of all data from all patients in all regions included in the study. For CHF this is four regions. Therefore these estimates are an average of the impact of the intervention in all regions included in each multicentre study. This
estimate is made in order to have the largest possible sample size as the basis for the estimate of the effectiveness of the interventions.

Thus, the change in the mean cost per patient by use of telehealth is estimated including both the total costs of the telehealth intervention itself and the impact on the costs of patients’ use of healthcare in general.

Estimate of the mean costs per patient was made at both a European level based on data from all countries in each of the multicentre studies, and at the level of the specific region. Thus, differences in the economic impact of the telehealth interventions between countries can be identified.

5.3 Results

5.3.1 Estimates of costs of the telehealth service

Table 19 describes the estimated prices of the telehealth intervention per patient in each of the participating regions in the CHF multicentre trials.

It was planned to split the costs of investment into three: devices, infrastructure and management, education and training. However, for some regions it was not possible to separate the costs of devices and the costs of infrastructure (e.g. costs of servers, software, WiFi); therefore for some countries these costs are combined in the tables.

For the regions in the CHF trial, the weighted mean (the number of patients in each region is used as weight) costs per patient of the telehealth service are €277 as shown in Table 19. The variation from region to region is less than in the other two multicentre trials: from €168 to €731. The variation reflect mainly the very low costs in Scotland, where patients are using their own devices, and the variation in the number of patients.

In each case where the cost per patient is significantly higher than other sites for the same disease, the cost is due to the level of investment required to design, develop and implement a telehealth service in deployment sites that had little or no previous experience of telehealth. Noted that the costs associated with the physiological measurement devices have come down significantly during the three-year period of the project.

More details about the explanatory factors are presented in the section below.

The table describes large differences with regard to the distribution of the costs by type of costs. For some regions the telehealth devices are the most costly (e.g. Basque Country and Slovenia), but in Scotland and Moravia the mean costs of the use of staff in the telehealth service is the most costly. These differences reflect large differences in the organisation of the telehealth service and type of devices used. Some regions have invested in buying the telehealth devices, while other regions are renting equipment and paying an annual rental or using the patients’ own devices.
Table 19: Average costs of the telehealth intervention per patient in the CHF trial

<table>
<thead>
<tr>
<th>Type of costs</th>
<th>Scotland</th>
<th>Basque country</th>
<th>Moravia</th>
<th>Slovenia</th>
<th>Weighted average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment in telehealth application</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Devices, technical infrastructure</td>
<td>16</td>
<td>113</td>
<td>186</td>
<td>364</td>
<td>71</td>
</tr>
<tr>
<td>- Management, education, training</td>
<td>1</td>
<td>14</td>
<td>5</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Total investment costs</td>
<td>17</td>
<td>127</td>
<td>191</td>
<td>365</td>
<td>74</td>
</tr>
<tr>
<td>Variable costs:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Telehealth devices</td>
<td>0</td>
<td>396</td>
<td>108</td>
<td>220</td>
<td>85</td>
</tr>
<tr>
<td>- Staff</td>
<td>151</td>
<td>35</td>
<td>140</td>
<td>146</td>
<td>118</td>
</tr>
<tr>
<td>- Other costs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total variable costs</td>
<td>151</td>
<td>431</td>
<td>248</td>
<td>366</td>
<td>203</td>
</tr>
<tr>
<td>Total costs</td>
<td>168</td>
<td>558</td>
<td>439</td>
<td>731</td>
<td>277</td>
</tr>
<tr>
<td>Expected number of patient per year</td>
<td>2500/1250</td>
<td>1600/300</td>
<td>100</td>
<td>200</td>
<td></td>
</tr>
</tbody>
</table>

5.3.2 Narrative description of the estimated costs in each site

Below is a short description of the main characteristics of the telehealth services. The differences in these characteristics may go some way to explain the variations in the costs.

Scotland – CHF

The figures represent the average costs for the three sites included in U4H from Scotland. Two of the sites in Scotland procured end-to-end technology solutions, with patients receiving education and training for device use by a member of their care team. One of these two sites had a Telehealth Hub established as an integral component of their Virtual Ward model; the Hub provided first line response and triage for technical support and clinical triage of alerts. The third site used a simple text messaging telehealth system called Florence which used patients’ own mobile phones wherever possible. This site required additional investments to provide the community / home-visiting staff with mobile technologies such as tablets and smartphones. Therefore the device and infrastructure costs are relatively low.

The Basque Country – CHF

In the Basque Country, U4H funding was used to invest in the ICT and EHR infrastructure to provide a region-wide capability to provide telemonitoring to eligible patients and for the data to be integrated within the EHR. The reach of the investment has been based on the number of patients with CHF and COPD who could be offered the service in the near future. Therefore the estimate is based on an assumption of 500 patients using the system annually. The day-to-day telemonitoring service is provided by the region’s Telecare Centre as a complete end-to-end service per patient per day. This includes the equipment, installation, de-installation, decontamination, patient training and technical support, together with first level triage of alerts.

Northwest Moravia – CHF

There were substantial costs associated with the use of staff for both education and training delivered to the team, and for assistance to the patients in this site, due to low level of computer literacy and experience with telehealth. In addition, the investment costs were higher than some other sites as a public procurement
process resulted in the chosen software requiring additional local configuration and adaptation.

**Slovenia – CHF**

Slovenia developed a telemonitoring system to support both diabetes and CHF. The costs reflect a procurement process which involved a local technology innovation company working with stakeholders to design, implement and support the telemonitoring service. They appointed a full time dedicated nurse who was trained to provide the first line clinical response to the data uploaded by the patients of both diseases.

### 5.3.3 Prices of healthcare services in the regions

Table 20 present prices of the different types of healthcare in each of the participating regions. The information was collected from the regions in September 2015, so the prices are 2015 price level. The prices are used in the calculation of the potential reduction in the costs of usual care for each region.

The tables generally show that the price per GP visit is the lowest and that the price per admission is the highest. The price per ED visit and per outpatient visit is often quite similar.

The prices are supposed to reflect the costs of producing the different types of usual care, as described in Drummond et al. (2015), and therefore be independent of who is paying for the service (a public health insurance, a private insurance of the patient). The prices are also supposed to reflect the general differences in the price level between the countries, thus high income countries are expected to have higher prices than low income countries.

However, it may be that the different regions have used different types of information and estimates to find the prices. Therefore there is a risk that the prices also reflect the local financing system in each country.

**Table 20: Prices for use of healthcare in the CHF trial (in €, 2015)**

<table>
<thead>
<tr>
<th>Type of health care</th>
<th>Region</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scotland</td>
</tr>
<tr>
<td>Price per visit to GP</td>
<td>63</td>
</tr>
<tr>
<td>Price per visit to emergency department</td>
<td>207</td>
</tr>
<tr>
<td>Price per outpatient visit at hospital</td>
<td>151</td>
</tr>
<tr>
<td>Price per admission to hospital</td>
<td>5,239</td>
</tr>
</tbody>
</table>

### 5.3.4 Estimated changes in the patient use of healthcare

As described in the analysis of the clinical results from United4Health, statistically significant differences were found between the telehealth group and the comparator group at baseline in each of the three clinical trials. Therefore adjustment for possible confounders was needed before assessment could be made of the effects of the telehealth intervention on the primary and secondary outcomes. In practice, this has been done by regression analysis as described in the presentation of the clinical results.
Table 21 below presents the results from the regression analysis. In the regressions, the patients' use of different types of healthcare is explained as a function of a number of different explanatory variables, including whether the patients are in the telehealth or comparator group. Thus, the table presents the estimated coefficients of the dummy variable representing whether the patients are in the telehealth group or not. A similar approach for presentation of results from regression analysis has been used in other observational studies, e.g. Park et al. (2014).

The estimated regression models are based on the full sample of patients, but excluding the data from Berlin because of the significant differences between the patients from Berlin and the other regions, as described in the section about the clinical results. Adjustment is also made for the duration of the collection of data for each patient, also as described in the section about the clinical results. The explanatory variables included in the regression models are described in the section about the clinical results.

For continuous variables (such as number of GP visits, ED visits and outpatient visits) linear multiple regression analysis was performed. The dummy variable describing whether the patient was in the telehealth group was equal to one for patients using telehealth and zero for patients in the comparator group. Thus, a negative estimated coefficient represents a reduction in the use of healthcare; a coefficient of e.g. -0.18 means that the number of visits is 0.18 lower per patient in the telehealth group.

For some types of use of healthcare (e.g. admission to hospital) a large proportion of patients did not have any use. Thus, the variable measuring the use is equal to zero for a large proportion of the patients. In this case, linear multiple regression analysis is not possible because the estimated model does not comply with the condition that the residuals should be normally distributed. Therefore logistic regression was used instead for these variables (use of admission to hospital, use of emergency department). This is indicated in the tables below. Since the estimated coefficient is difficult to interpret in logistic regression, the exponential value of the coefficient, which is equal to the odds ratio, is also presented in the table.

In the logistic regressions, the dummy variable describing whether the patient was in the telehealth group or not is reversed. This variable is equal to 1 for patients in the comparator group and zero for patients in the telehealth group. Thus, an odds ratio higher than one represents a reduction in the specific type of healthcare for patients in the telehealth group; an odds ratio of e.g. 5.2 means that proportion of patients in the comparator group using this type of healthcare 5.2 times as much as the patients in the telehealth group.

Table 21 presents the results from the CHF trial. The table shows that the proportion of patients with admission to hospital and the proportion of patient with a visit to the emergency department during 12 month is statistically significant lower for patients using telehealth than for patient in the comparator group. However, with regard to the number of GP visits and the number of outpatient visits, the telehealth patients have a higher number of visits; these differences are also statistically significant.
Table 21: Estimated coefficients for the impact of telehealth in the CHF trial (Adjusted for gender, CCI, smoking, age, number of COPD-exacerbations, number of admissions last 12 months, LFUc)

<table>
<thead>
<tr>
<th></th>
<th>Estimated coefficient (B)</th>
<th>Standard error</th>
<th>Statistical significance (p value)</th>
<th>Odds ratio - Exp (B)</th>
<th>Confidence interval for odds ratio (Exp(B))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of visits to GPs and primary healthcare</td>
<td>6.173</td>
<td>1.137</td>
<td>0.000</td>
<td>1.602</td>
<td>1.059 -- 2.424</td>
</tr>
<tr>
<td>Number of total ED visits for any reason (logistic)</td>
<td>0.472</td>
<td>0.211</td>
<td>0.026</td>
<td>1.602</td>
<td>2.699 -- 7.916</td>
</tr>
<tr>
<td>Number of outpatient clinic visits re</td>
<td>2.670</td>
<td>0.376</td>
<td>0.000</td>
<td>4.622</td>
<td>2.699 -- 7.916</td>
</tr>
<tr>
<td>Admissions to hospital (logistic)</td>
<td>1.531</td>
<td>0.274</td>
<td>0.000</td>
<td>4.622</td>
<td>2.699 -- 7.916</td>
</tr>
</tbody>
</table>

5.3.5 Estimated changes in total costs per patient

Based on the estimated costs of the telehealth intervention (see section 5.3.1), the estimated change in the patients’ use of healthcare (see section 5.3.4), and the local prices of healthcare in each region (see section 5.3.3), it is now possible to estimate the changes in the total costs of healthcare per patient in each of the three multicentre trials. In practice this is done by use of the equation presented in the methodology section.

Table 22 presents the estimated total costs per patient. The tables include both information about the costs of the telehealth interventions (from Table 19) and the change in the costs of using GP, ED, outpatient treatment and admissions. The results are presented for each of the regions in the three multicentre trials, based on the prices of healthcare from each specific region, and for each of the multicentre trials in total (the last column).

Note that to estimate the reduction in the costs of admissions it was necessary to use the number of admissions in the comparator group as the point of departure, because the logistic regression only shows the relative odds ratio and not the absolute reduction in the number of admission. Therefore, the estimated proportion of patients admitted in the comparator group adjusted for length of follow-up (annual rates) and excluding Berlin was used as a basis for the estimate.

The following estimate regarding the comparator group (from the section about the clinical results) was used as the point of departure in estimating the reduction in the number of admissions for the patients in the telehealth group: for CHF trial, proportion of patients with CHF related admissions per year was 39.6%.

Based on these estimates and the estimated odd ratio in Table 21, the reduction in the number of admission from the use of telehealth was estimated to be 0.31 admissions.

Table 22 shows the economics of the CHF trial. Overall, the four regions have found that the telehealth intervention reduces the mean costs per patient by 329€, but this is only due to the estimated cost reduction in Scotland, and the fact that the large number of patients in the Scottish estimates represents 68% of the total number of patients in the CHF multicentre trial. The low cost per patient in all regions is explained mainly by the high value of the reduction in the costs of admissions in the regions, while the costs of the telehealth intervention in all countries are fairly low.
Table 22: Estimated total costs per patient in the CHF trial

<table>
<thead>
<tr>
<th>Type of health care costs</th>
<th>Scotland</th>
<th>Basque Country</th>
<th>Northwest Moravia</th>
<th>Slovenia</th>
<th>Weighted average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs of telehealth</td>
<td>168</td>
<td>558</td>
<td>439</td>
<td>731</td>
<td>277</td>
</tr>
<tr>
<td>Change in costs of GP visits</td>
<td>386</td>
<td>333</td>
<td>43</td>
<td>99</td>
<td>296</td>
</tr>
<tr>
<td>Change in costs of ED visits</td>
<td>-35</td>
<td>-21</td>
<td>-3</td>
<td>-6</td>
<td>-25</td>
</tr>
<tr>
<td>Change in costs of outpatient visits</td>
<td>403</td>
<td>382</td>
<td>83</td>
<td>171</td>
<td>322</td>
</tr>
<tr>
<td>Change in costs of admissions</td>
<td>-1.624</td>
<td>-787</td>
<td>-192</td>
<td>-858</td>
<td>-1.198</td>
</tr>
<tr>
<td><strong>Total net costs per patient</strong></td>
<td><strong>-702</strong></td>
<td><strong>465</strong></td>
<td><strong>370</strong></td>
<td><strong>137</strong></td>
<td><strong>-329</strong></td>
</tr>
</tbody>
</table>

5.4 Discussion of findings

Based on the observational multicentre study and additional collection of data on costs of the telehealth intervention, the economic analysis shows that:

- The telehealth intervention in the CHF trial reduced the average costs per patient by 329€, mainly because the study in Scotland was able to demonstrate a reduction in costs. In the other three regions, the costs per patient are increasing.

- In some cases, this equipment was purchased for the project, in other cases it was already in place from other interventions before the start of the project, and finally some sites have used the patients' own devices.

- No site experienced that they saved time using the telehealth solutions instead of offering traditional care to CHF patients.

The strength of the economic assessment of the project is that it follows guidelines for health economic evaluation and studies of telehealth as described by Drummond et al. (2005) and Bergmo (2015). This study also includes the costs of supporting the healthcare providers in using the telehealth service such as training of staff, hardware investment, and help desks. This is important in order ensure that the complete costs of telehealth services have been estimated as underlined by Bergmo (2015). Thus, information about perspective, data sources, data collection, prices and methodology is presented. Similarly, a large number of different types of costs are included, and not just the savings in the costs of admissions of patients. Thus compared to the typical standard of economic studies of telehealth as described by Mistry (2011), this is an economic study of high quality.

On the other hand, a number of weaknesses of the assessment of the costs in the United4Health project should be addressed:

- The estimated effects on the patients use of healthcare is not based on a randomised controlled trial but on an observation study with a lower degree of internal validity. Thus, there is a principal risk of factors other than the telehealth intervention having an impact of the estimated clinical effectiveness.

- The observational study has collected data on groups of patients using telehealth and comparator groups that are not similar at baseline. As the clinical results describe, large and statistically significant differences were found between the two groups in all three multicentre trials. For example, in the CHF trials, the age of the patients was higher in the comparator group.
than in the telehealth group. This could suggest that selection bias is present e.g. because the oldest patients refuse to use the telehealth devices.

- In an attempt to adjust for the systematic differences between the telehealth and the comparator groups, regression analyses have been made. However, because of problems with missing data and a lower sample size than expected, it has not been possible to include all possible confounders. Therefore, there is a high risk that the estimated effect on the patients' use of healthcare services is biased, and more studies of the sensitivity of the results must be carried out.

- In the economic analysis of the costs per patient, all results from the regressions have been included, even though not all coefficients were statistically significant.

- The costs of the telehealth interventions are not based on data collection at patient level (e.g. of the number of minutes that clinical staff use the telehealth devices per patient) but on information provided by the project management in each region. The uncertainty in this information is unknown, but a common template and a number of meetings with the local management have been arranged to increase the validity of the information.

Even though the telehealth interventions in United4Health have been planned by the participating regions based on a detailed clinical protocol, large variation have been found in the implementation of the telehealth service in the local healthcare organisation. An example of this can be found in the diabetes trial in which Scotland and Wales are using 30€ and 1€ of staff time per patient, whereas Moravia and Berlin use their staff for more than 1,000€ per patient in the telehealth service. This is one of the reasons for the large variation in the costs of the telehealth interventions in the different countries, which is described in the organisational analysis from the United4Health project.
6 Domain 6: Organisational aspects

6.1 Methods

This deliverable has been produced based on the questionnaire in ID3.3, where the sections concerning organisational analysis have been selected for the report.

24 answers to questions concerning organisational assessment have been summarised in order to create an overview of the large body of responses.

A number of issues concerning organisational structure and process were described by means of document reviews: policy papers, benchmark reports, clinical guidelines, protocols and pathways, etc.

The methods applied by the sites to gain information on the organisational aspects of U4H services for CHF involved qualitative methods such as focus groups and individual interviews with key participants. The number of participants interviewed from each site varied widely. The extent of the answers to the questionnaire differed very much. Some sites provided elaborate answers, including examples and a number of appendices. Others gave short answers summing up the key messages. Some sites have focused extensively on the process, whereas others concentrate mainly on results.

6.2 Organisational structure

There were different organisational and staffing structures in the deployment sites reflecting differences between the structures of national or local health sectors. In some cases, the service was truly multi-sectorial and cross-disciplinary, whereas in others the service was concentrated in one sector (e.g. hospital department or local GP practices) or run by one professional group. In all six sites (three Scottish sites, Basque Country, Moravia and Slovenia) hospital departments were involved. In some cases, physicians played a major role, in other cases the service was run entirely by nurses. Some sites reported on the role of their technical and managerial staff, others focused on the healthcare professionals involved. The variety of hospital department involved appears to reflect differences in the organisational structures of hospitals. Some hospitals have very specialised individual departments, whereas others appear to have a kind of umbrella structure, in which for instance a department of internal medicine is hosting a number of specialised subsections. They also had different frameworks and reimbursement structures for the service.

The starting point for introducing telehealth services in the sites varied greatly. Some sites had already piloted telehealth solutions before the project started, and had gained some experience in advance, whereas others were completely new to the field. Some had acquired all the necessary equipment already, whereas others had to undertake major investments prior to project start. The involvement of different sectors and cooperation between them varied widely, partly based on differences in the structure of the healthcare sectors in the U4H sites.

Effort should be put into choosing the optimal point in a patient’s care pathway and disease trajectory for the service to be introduced. Depending on the complexity and/or severity of the patient, this could be either a highly specialised hospital setting, or in primary care. In the Basque Country, the new service has been
embedded within the “care as usual” organisational structure which includes hospital, home-visiting and primary care services, whereas in other settings it has been organised as a separate, stand-alone service. Five sites involved primary care; GPs and GP nurses are typically involved. Some sites’ models also included administrative staff and telehealth centre operators and administrators. One site placed emphasis on the need for management and strategic leadership, and one site included biomedical engineers to resolve any technical difficulties experienced by the patients and staff with the telehealth technologies.

6.3 Communication and stakeholder engagement

For Scotland, the description of the communication activities is collated from all three sites. Across Scotland, a number of different activities & approaches have been applied to support engagement with the stakeholders involved in the COPD pilots. Each area developed a communication strategy and engagement plan, which was tailored to local requirements. There were also a number of shared events, meetings and publications across Scotland to allow engagement of all COPD sites across Scotland.

In the Basque Country the project was presented to the management team of each integrated care organisation which was invited to participate in U4H. Once the managers were convinced of the benefits of the telemonitoring intervention, the head of the Cardiology Department was approached to explain the service and analyse its feasibility. If the relevant actors believed in the project and accepted to be involved, each integrated care organisation created a core working group which was in contact with the other organisations. In order to maintain the engagement of the professionals during the project, periodic meetings were organised to share problems, solutions and lessons learned. Additionally, on a monthly basis, a report was circulated among all stakeholders where information on recruitment rates, results, incidents, solutions and pending issues was summarised. The coordinator of the field study was in regular contact with all stakeholders to monitor the progress of the project and receive feedback from the actors involved.

In Moravia, the focus was on improving internal communication between nurses and physicians in order to solve different types of alerts (e.g. simple uncompleted tasks, or threshold values exceeded dangerously). It took a significant amount of time to set up the telemonitoring processes, communication, and software application correctly in order to meet physicians’ and patients’ needs with external contractor (Vodafone).

The U4H Slovenia team ran several promotional activities at different levels, different occasions and different places to promote the telemedicine service for DM and CHF patients that is currently available only regionally, but has the capacity to be extended to the national level in Slovenia. The team organised around 20 presentations (about 2-hour duration) with demonstrations for different stakeholders. Among the stakeholders were the Minister of Health, Municipality of Slovenj Gradec, the management of health insurance companies, patient organisations, the Slovenian Medical Informatics Association, healthcare professionals within the SB-SG hospital, and several medical professionals in person. The Slovenian U4H team also approached all four national telecom operators (Telekom Slovenija, T-2, SiMobil and TušMobil) to get them on board to take on the mobile operator’s role in the service.

The start of the project required a lot of learning, especially on the sites that had no prior experience with telehealth.
6.3.1 Managers

The role of managers and strategic leadership is underestimated. Only two sites (Scotland and Basque Country) mentioned management and strategic leadership as key components. Northwest Moravia reported the involvement of biomedical engineers who were already part of the cardiology department in the hospital. As Northwest Moravia procured all their medical and ICT equipment and services (including creation of mobile application, telehealth web portal, servers and ICT technical support) from an external provider, there was a high level of involvement of management staff.

6.3.2 Clinicians

The specialties involved differed widely, probably partly due to the way medical specialties are organised in various countries and regions. The following specialties are mentioned: cardiology, internal medicine (which in some cases may be an umbrella covering a host of medical specialties, including cardiology), medical receiving, and respiratory medicine. Coronary care unit and heart failure are mentioned as well. Typically, the hospital staff involved includes consultant physicians and cardiac specialist nurses. All sites except Northwest Moravia reported the inclusion of primary care in their telehealth care models. The professionals involved from primary care were typically GPs and GP nurses who may also visit patients in their own homes.

No site reported a reduction in working time for any profession. Three sites reported no changes in workload. Three sites reported increases in working hours for some staff groups. In one site, nurses' working hours increased, and in another site working hours for all professionals involved increased; in one site, the nurse responsible for cardiac care coordination was released from her previous position in the hospital, whereas the specialist physicians had to offer the telehealth service alongside their regular daily practice in other sites.

6.3.3 Patients / family carers

Three sites reported increased empowerment and confidence among patients. Some staff, however, reported an increased risk of dependency.

Statements describing the role of the patient's informal carer ranged from "not relevant" to "very important". Two sites reported that the informal carer played no role. Three sites reported that the involvement of the informal carer seems to be welcomed, but not formalised in the programme.

One site reported that the support of the informal carer appears to be crucial for the telehealth process. It should be noted that the routine care model also relies on the support of the informal carer, so this seems related to tradition rather than the telehealth process itself.

6.4 Workforce

In the new services, there are new professional profiles, mainly technicians, related to telehealth services. Nurses play a key role all cases, both in hospital and primary care, but also taking care of call centres that monitor health parameters. In fact, it seems that telehealth services are mostly managed by nurses. The responsibilities
of physicians have not undergone any significant change compared to routine care, being ultimately responsible for clinical decision making.

Some of the responsibilities of staff are attributed to the research element in U4H. Maybe in an established telehealth service some responsibilities of staff would change.

<table>
<thead>
<tr>
<th>Site</th>
<th>Sectors/ levels of care are involved</th>
<th>Professionals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland 1 Ayrshire &amp; Arran</td>
<td>Hospital departments (Medical reception, Heart Failure, Coronary Care Unit) Primary care</td>
<td>1 Nurse consultant, lead consultant for specialist nursing team and heart failure telehealth</td>
</tr>
<tr>
<td></td>
<td>Specialist heart failure nursing team (Community based) Telehealth administrator Outpatient clinics</td>
<td>5 Specialist heart failure nurses 1 telehealth administrator</td>
</tr>
<tr>
<td></td>
<td>Hospital departments (Cardiology Department) Primary care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Community care (district nurses) Administrative staff</td>
<td></td>
</tr>
<tr>
<td>Scotland 2 Greater Glasgow &amp; Clyde</td>
<td>Hospital departments (Cardiology Department) Primary care Community care (district nurses) Administrative staff</td>
<td>2 consultant cardiologists 1 prescribing heart failure nurse 2 specialist heart failure nurses Various GP practices 1 primary care support nurse Service Delivery manager IT services SPS representative Clinical director</td>
</tr>
<tr>
<td>Scotland 3 Lanarkshire</td>
<td>Hospital department, (Respiratory Medicine) Primary Care Management/Strategic leadership Clerical and administration</td>
<td>2 hospital MDs (Consultant Cardiologists) 5 Hospital nurses (specialist heart failure nurses with additional qualifications to their role to recruit and monitor patients) 108 GP practices 10+ practice nurses per GP practice Management and strategic leadership</td>
</tr>
<tr>
<td></td>
<td>Hospital department (Cardiology) Primary care eHealth centre Telecare centre</td>
<td></td>
</tr>
<tr>
<td>Basque Country</td>
<td>Hospital department (Cardiology) Primary care eHealth centre Telecare centre</td>
<td></td>
</tr>
</tbody>
</table>

### Site involvement

<table>
<thead>
<tr>
<th>Site</th>
<th>Sectors/ levels of care are involved</th>
<th>Professionals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwest Moravia</td>
<td>Hospital department: Department of Internal medicine</td>
<td>4 hospital MDs (internal medicine)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 Hospital nurses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 biomedical engineers</td>
</tr>
<tr>
<td>Slovenia (Diabetes and CHF answered together)</td>
<td>Hospital departments Primary care Community care</td>
<td>2 Hospital MDs (cardiologist and diabetologist)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 hospital nurses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 municipality GPs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 municipality nurse</td>
</tr>
</tbody>
</table>

### 6.4.1 Roles and responsibilities

Role shifts and changes have to do with the work flow and task distribution. Three sites reported no or minimal changes in the distribution of work. Telemonitoring has been embedded into the routine activities of the care team, although personalisation of thresholds for vital signs and daily review of the telehealth data uploads during an unstable phase are required.

Three sites reported task shifting. In order to introduce these new tasks into healthcare professionals’ daily schedule, some other bureaucratic and administrative activities have been removed, shifted or facilitated thanks to technological advances. Others reported that extra tasks have been given to the nurses involved in the telehealth project. One site, the Basque Country, points out that the telehealth service might indirectly influence healthcare professionals’ diaries since face-to-face consultations with CHF patients have decreased. Thus, professionals invest their time in new tasks but, at the same time, spend less time in consultations. One of the recommendations made is that uploaded data has to be accessible to all relevant healthcare professionals involved in a patient’s care.

### 6.4.2 Training

All sites spent time and effort on training, although the form and extent differs widely. In many cases the training sessions were led by external suppliers of the equipment; some used in-house experts. Typically, the level and extent of the training received by each U4H participant depended on his or her specific task in the project. Some were given a general introduction lasting as little as 30 minutes, whereas others spent days learning to use the systems involved in great detail.

### 6.4.3 Experiences and perception

The perceptions of the telehealth service varied widely, but may be divided into two groups. Some stakeholders found the experience very positive, and saw fewer complications than expected. Some also cited increased reassurance concerning the patients’ condition and greater patient involvement. One site mentioned positive clinical results.

Other stakeholders, who had a less positive experience, tended to focus on the extra time they spent on the telehealth service. One site found the service hard, difficult and chaotic to start with. Some sites had more technical difficulties than expected in the beginning. One site also mentioned lack of clear reimbursement for telehealth as part of their experience.
Overall, all sites reported that generally the healthcare professionals were satisfied with the service, although they pointed out a number of possible future improvements.

6.5 Clinical work flow

Overall, the telehealth intervention was quite similar among local sites, regions and countries. The differences were mainly in the level of integration with overall healthcare provided or having it as a parallel, stand-alone service, and the degree of involvement of cardiologists and primary care practitioners. The first step of the telehealth intervention at home included a short period with intensive monitoring. Later, and up to 12 months, patients transferred data of their physiological measurements on a daily or weekly basis to the telehealth centre. They were contacted if their measurements were outside of individual established parameters.

Access to the telemonitoring data enabled better monitoring of an individual patient's status, and consequently more effective conduct of the CHF long term care management. Additionally, the data enabled timely intervention with change in medication to keep heart rate, blood pressure, and weight, at the desired levels. As a result, negative trends have been turned into positive ones in many patients. Interestingly, some sites reported that the collected telemonitoring data are used also by CHF specialist in the hospital not strongly linked to the TM service.

The organisational model of the telemonitoring service has to be well adapted to routine practice; integration of the new telehealth functions into clinicians' daily schedule is essential.

Some of the telehealth interventions of local sites, such as NHS Scotland, were managed by Heart Failure specialist nurses who make decisions about patient care according their severity. In the case of Slovenia or Basque country, the cardiologist and primary care physicians are also involved in the follow-up.

Sufficient working hours must be scheduled for staff involved in delivering the telehealth service. Although telemonitoring services are expected to save time, few sites reported actual time savings during the project. One site reported that initial fears of increased workload for specialist nurses was eased by a change in administrative processes. Another reported an increase in the number of contacts with patients, that the service would not help with non-compliant patients or levels of admissions, and that the workload increased.

Most sites also saw better access and accuracy of data as an added value; there is general satisfaction with the way the telehealth service influenced the relationship with the patients.

6.6 Views on technologies deployed

Basic equipment included servers, desktop computers, telephones, printers and iPads. In some cases, this equipment was purchased for the project, in other cases it was already in place from other telehealth pilots before the start of the project, and finally some sites used the patients' own devices (smartphones). A clinical interface for safe transfer of information was also part of the basic solution. In one case, integration with the electronic health record and its interface was one of the main challenges, requiring time and resources. It was considered an indispensable step for future sustainability of the service. In some cases, new smartphones and tablets
were provided for staff to facilitate their access to the telemonitoring data websites. Of the more specialised equipment, most frequently mentioned were telemonitoring devices: pulse-oximeter, blood pressure monitor and digital weight scales.

There were several technical difficulties reported. Although two sites reported no or few technical issues, four others reported a number: reading data, compatibility issues, freezing applications, data transfer. However, most reported that these issues were resolved quickly, mainly by suppliers / developers of the applications used. Technical support must be readily available. The technical solution should be ready and tested before the start of the deployment. If too much time is spent struggling with equipment, healthcare staff will become discouraged and stressed, and the patients will not feel secure. A telehealth solution will only become a success if it is easy to use for healthcare professionals and patients.

6.6.1 Clinicians

The overall feeling was that the U4H technology has been well received by those using it, and it has helped the nurses provide more efficient and better patient care. However, some sites have experienced technical problems, especially with compatibility of the equipment, primarily at the beginning of the project. The user interface presented challenges for some. As an example, in the Basque Country several health professionals dealing with the service agreed that they found it hard and difficult to start with. They all acknowledged a gradual but significant progress in the computer system which helped to improve the service, but there is still a need for further improvement in order for the service to be fully reliable and for health professionals to feel confident when using it. The telemonitoring application and telehealth web portal were created based on doctors' needs, and continuously improved based on doctors' and patients' comments. Usability is now very good, but there were a lot of technical issues in the beginning.

Staff had expected more people to report issues with the technology, but this has not been the case. Some sites reported that expectations of access to more precise information about the patients' condition and degree of compliance were met. One site reported time savings in relation to travelling fewer miles to see patients due to remote monitoring. Staff expected that the introduction of telehealth would increase dependency levels. This has not been the experience of the team, however.

6.6.2 Patients / family carers

The overall impression is that patients were very tolerant of the technical issues experienced within the service, and demonstrated a willingness to learn and self-manage. Three sites found that the service was user-friendly for patients. However, one site found the telehealth service difficult, costly, non-intuitive and complicated to learn, and another site reported that the patients needed more technical support than expected.

Training of patients and informal caregivers in the use of the devices also had to be taken into account. All sites offered training to patients prior to participating in the project. The training typically focused on the use of the telehealth solution in order for the patients to feel competent and confident. Individual sessions typically ranged from 45 minutes to two hours. Some sites offered individualised training sessions adapted to each patient's needs and abilities, whereas others had a more formalised training programme. One site offered training in small groups.
6.7 Main conclusions

- All sites reported that there was general overall satisfaction with the telehealth service, although a number of issues still needed to be addressed. Access to collected telemonitoring data enables better monitoring of individual patients' status, being able to detect early signs of decompensation, and consequently more effective conduct of the CHF long term care management.

- The overall feeling was that the U4H technology has been well received by those using it, and has helped nurses provide more efficient and better patient care.

- Sufficient working hours must be scheduled for staff. No site reported a reduction in working time for any profession. There is a need for existing resource reorganisation and definition of new roles; prioritise task shifting over the introduction of new staff. Reimbursement issues have to be addressed.

- A complete telehealth service has to be provided (device installation, technical support, maintenance and user training). A clinical interface for safe transfer of information was also part of the basic solution.

- There is a need for both administrative management and guarantee of good quality of telemonitored data received from patients (alert filtering and validation) to ensure that healthcare professionals only attend to health related alerts.

- Patients felt more empowered and secure. The benefits are mainly seen as patients being able to better self-manage their long term condition, with the technology helping to support and build patient confidence. Patient training (related to both health status and device handling) led by nurses and technicians is critical.

- Most stakeholders wanted to continue providing the telehealth service, although changes would be required in relation to the care model, duration of telemonitoring and targeting of the service.
7 Domain 7: Socio-cultural, ethical and legal aspects

7.1 Methods

The domain includes topics that identify the ethical, legal and socio-cultural aspects of the CHF telehealth service in United4Health.

The information has been collected and reported by key project members for each deployment site, e.g. clinical leads, project managers, service managers. They in turn have collected the information within their local project and specialist teams.

The issues are categorised as follows:

- Ethical issues:
  - Access and equity.
  - Patient self-esteem.
  - Patient autonomy.
  - Assessment of risk and benefit.
  - Risk of discontinuation of the telehealth support.
  - Normative Codes.

- Legal issues:
  - Information Governance.
  - Device certification.
  - Clinician accreditation.
  - Professional liability.
  - Telehealth service legally not yet recognised.

- Socio-cultural issues:
  - Changes for patient’s carers.
  - Shift of responsibility from patients to healthcare professionals.
  - Changes in patient’s roles.
  - Patient’s relatives and others.
  - Societal, political and context changes.
  - Changes in responsibilities.
  - Gender issues - equity.
  - Lifestyle changes.
  - Patient empowerment.
  - Technology access.

7.2 Ethical issues

Table 23: Ethical issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>How issue was addressed</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access and equity</td>
<td>Personal interviews with patients.</td>
<td>All patients passing the inclusion criteria were offered the telehealth service support regardless age, sex and social status if they met inclusion criteria set by U4H project. The patients have also been allowed to cease participation for whatever reasons at any stage.</td>
</tr>
<tr>
<td>Issue</td>
<td>How issue was addressed</td>
<td>Evidence</td>
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<tr>
<td>Access for patients with cognitive or visual impairment.</td>
<td>Specialist nurses spoke with carers and relatives of patients with cognitive impairment. They agreed to assist in uploading results and, when appropriate, speak with specialist nurses when alerts were raised. Where relevant, family / carers were invited to assist the patient with input of clinical measurements / symptom questions. Voice controls were available if required. All information can be made available in different format / language in accordance with NHSL Equality and Diversity policy.</td>
<td></td>
</tr>
<tr>
<td>Strategy adherence.</td>
<td>In relation to access and equity, the Consent Policy on Healthcare Assessment Care and Treatment, which was produced by NHS Scotland Inequalities and Planning directorate, was impact assessed by the NHS Greater Glasgow &amp; Clyde Corporate Inequalities team. To meet the needs of equality legislation, Glasgow has developed a strategy “A fairer NHS Greater Glasgow &amp; Clyde” which covers all aspects of inequality and access to services; this strategy was followed as part of the programme.</td>
<td></td>
</tr>
<tr>
<td>Patient self-esteem</td>
<td>Presentation of data to the telemonitored patients at regular visits to the cardiologist. At regular visits to a cardiologist, medical staff review with each patient his/her telemetrically collected and processed data on body weight, blood pressure, heart rate and oxygenation. They are presented in numeric and graphical form. Confronted with their data, patients may see a direct influence of their lifestyle on the data. Some patients have been additionally encouraged to continue their endeavours to stick with the cardiologist’s individual treatment plan. In many such cases, specialists have noticed improvements of the patients’ self-esteem.</td>
<td></td>
</tr>
<tr>
<td>Patient autonomy</td>
<td>Training of healthcare professionals and patients. Nurses, physicians and technical support team were trained on how to approach patients and how to educate them. They also received training about the intervention concept, technology for data collection, and patient equipment, as well as access to the data. All the patients were individually educated in the intervention, and received written information, with a message that contained general information about the intervention, about voluntariness of participation, advantage of participation for the patients, and a statement that non-participation does not influence quality of current care provided to the patients. Participating patients signed an informed consent form approved by the corresponding Ethical Committee.</td>
<td></td>
</tr>
<tr>
<td>Issue</td>
<td>How issue was addressed</td>
<td>Evidence</td>
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</tr>
<tr>
<td>Consent to treatment.</td>
<td>All patients and, where appropriate, relatives and carers, were fully informed of participation in the programme before giving informed consent in writing. Those patients who signed consent were offered training and education on the devices and peripherals. Specialist nurses went through participation in the programme with patients. Once patients had been given all appropriate information, informed consent was obtained in writing. Patients were given a Patient information pack, which contained clear, concise instructions. Devices were installed within a few days, and patients, or their relative / carer, received full training on the devices and peripherals to upload their readings. Patients were advised they could withdraw from the programme at any time. Patients who discontinued the programme were followed up by usual services and existing care pathways.</td>
<td></td>
</tr>
<tr>
<td>Assessment of risk and benefit</td>
<td>Potential risks and benefits were analysed before the interventions started; they influenced technical specification of the system procured, concept of data collection, and additional features prepared for electronic communication with the patient (such as handling of manually entered data in specific cases); they were also reflected in the content of information for patients and in education content. The expected benefits were estimated by medical staff, and served to adjust the interventions for CHF patients.</td>
<td></td>
</tr>
<tr>
<td>Benefits to patients.</td>
<td>Patient’s acceptance was sought using two validated questionnaires – WSD and QUEST2. No adverse incidents were reported.</td>
<td>Any adverse incidents are reported via NHSL Datix risk management process – not recorded for this study. Patient questionnaires, evaluation of data including pre and post intervention cohort. Economic benefits are being analysed as part of U4H evaluation process. Outcome yet to be received. Staff focus groups on qualitative experience have been carried out.</td>
</tr>
<tr>
<td>Patient Privacy</td>
<td>Patients’ privacy was ensured by a Data Protection Agreement which was drawn up between NHS Ayrshire &amp; Arran and Microtech. Any patient identifiable data was shared within one dedicated secure website. All patient information transferred to NHS24 and EC was non identifiable.</td>
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</tr>
<tr>
<td>Issue</td>
<td>How issue was addressed</td>
<td>Evidence</td>
</tr>
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</tr>
<tr>
<td>Infrastructure</td>
<td>There were some infrastructure issues, although the devices provided did not require access to broadband; the main problem was signal, as there are many rural areas in NHS A&amp;A.</td>
<td>There were no infrastructure issues as the devices provided did not require access to broadband. The devices did offer the facility for other languages, and for those with eyesight issues, the device offered audio facility.</td>
</tr>
<tr>
<td></td>
<td>There were a few infrastructure issues in some geographical areas with limited mobile signal access. Participants required access to personal mobile phones, which could be a basic model, and have minimum credit if not on contract – the system was free to the user.</td>
<td></td>
</tr>
<tr>
<td>Risk of discontinuation of the telehealth support</td>
<td>Permanent endeavours at institutional level to get the work paid and to attract further investments.</td>
<td>A real threat of discontinuation of the telehealth support to CHF patients. Decision based on collected data and feedback information from the specialists. Stopping delivering the service after U4H project conclusion would be the largest breach of ethics.</td>
</tr>
<tr>
<td></td>
<td>Professional and organisational Codes of Practice.</td>
<td>Clinical staff adhere to their specific professional and organisational codes of practice with regard to all aspects of their practice including equality and diversity, data protection, privacy and confidentiality.</td>
</tr>
</tbody>
</table>
### 7.3 Legal issues

#### Table 24: Legal issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>How issue was addressed</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telehealth service not yet legally recognised</td>
<td>Suggestions for changes in laws on healthcare services.</td>
<td>The Slovenian legislation does not recognise telehealth as an official healthcare service. Providing telehealth is tolerated, but the service is not coded in a “green book” of healthcare services, and consequently it cannot be reimbursed by the health insurance system. The Slovenian partners in U4H (SB-SG, RavKor) and their subcontractor (MKS Ltd, Ljubljana) have invested a lot of their time and efforts addressing the Ministry of health and the compulsory Health Insurance Institute to include TM services into the regulatory documents. Changes proposed to relevant laws in their preparatory phase have been without any positive effect. Personal contacts with health ministers have not helped to change the situation.</td>
</tr>
<tr>
<td>Device certification</td>
<td>Declaration on use of the devices for research purposes.</td>
<td>Health inspection visit to the General Hospital of Slovenj Gradec revealed a problem of certification of measuring devices used by patients at home. All medical devices should have so called “M label” which confirms that the devices are suitable for medical use. As the devices are used to collect data on which a medical professional will act to adjust the patient’s treatment, the home used personal device change their status from “home used device” to “medical device”. The adequate interpretation of this legal uncertainty is an open issue.</td>
</tr>
<tr>
<td>CE Declaration of Conformity – all devices (weight scale, BP meter, oximeter, glucometer and gateways - Bluetooth-GSM/3G).</td>
<td>All devices CE marked. Other documents are filled by the respective authorised representatives of the devices manufacturers, or metrology specialists.</td>
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<tr>
<td>Issue</td>
<td>How issue was addressed</td>
<td>Evidence</td>
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<tr>
<td>Review quality control and certification for devices.</td>
<td>Identified that relevant documentation for safety and quality was in place by provider of devices and peripherals before commencement of the programme. Microtech telehealth devices are approved to ISO 9001 (inc. BS EN ISO 13485) ISO 45001, OHSAS 18001. Additional compliance / conformance: MDD 93/42/EEE – Conformance; IGSOC – Compliant, TG Accredited (Australian Therapeutic Goods Regulations), SFDA Registered, Member of the TSA. Quality control: Project Quality Gates are defined and audited by the internal Project Management Office. The Release Readiness Review Process is engaged for all product releases.</td>
<td></td>
</tr>
<tr>
<td>National standards.</td>
<td>Patients’ own mobile phone and peripherals supplied all meet national standards. Patients used their mobile phones: no device accreditation / certification was required. All peripherals (pulse oximeters, BP monitors and scales) meet UK standards. The Florence system is provided by Mediaburst and a signed DPA with NHSL is in place. Registration to national standards is verified annually by NHSL information governance office.</td>
<td></td>
</tr>
<tr>
<td>Clinician accreditation</td>
<td>All medical staff (nurses, physicians) maintain capability to treat patients as required by national law. No need for changes or upgrade of accreditations / attestations was found. All medical staff subject to continuous lifelong training and education. Healthcare organisations and their management systems are accredited and certified according to the corresponding law or standard.</td>
<td>Existing professional accreditations cover the requirements of the service, and all staff suitably qualified under their current professional accreditation.</td>
</tr>
<tr>
<td>Professional liability</td>
<td>Healthcare professionals follow appropriate general procedures reflected in laws, rules or guidelines of the corresponding policy body. Professional liability is covered by the healthcare organisation insurance.</td>
<td>Liability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Existing liability sufficient.</td>
</tr>
<tr>
<td>Issue</td>
<td>How issue was addressed</td>
<td>Evidence</td>
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<tr>
<td>Information Governance</td>
<td>The central telehealth system was professionally developed by certified IT company with appropriate access control to the data, and also to the patients’ devices by hospital authorised staff. Patients’ gateways (system enabled smartphones / tablets with dedicated software) are password protected.</td>
<td>Password management system has been maintained. Database with data received from patients (both measurements and inputs made by the patients) are located in secure data centre of the technology supplier; security and data protection aspects are subject of agreement with the hospital and also subject to rules enforced by relevant legislation. Data collection tool is a software application that runs in the course of the interventions in the telemonitoring centre; it produces output csv files that were regularly sent by our site data collection manager to U4H project central data collection facility.</td>
</tr>
</tbody>
</table>
| Review of procedures.        |                                                                                                                                                                                                                                                                                                                                                         | A Privacy Impact Assessment was completed and forwarded to NHS A&A Information Governance. As all patient data which was forwarded to NHS24 and EC was non identifiable, a Caldicott guardian was put in place both at local and national level. For evaluation purposes, patient identifiable data was transferred between employees in NHS A&A through a secure site. Discussions took place between IT Information Department of NHS A&A and Microtech for any possible adjustments required. NHS A&A strategies and policies were followed when transferring personal data:  
• NHS Information Governance Strategy.  
• Confidentiality & Data Protection Policy.  
• Data Breach Policy.                                                                                                                                                                                                                     |
| Patients’ Rights             | Rights.                                                                                                                                                                                                                                                                                       | Patient’s rights are addressed under the Patient Rights (Scotland) Act 2012 and Consent Policy.                                                                                                                                                                                                                                          |
### 7.4 Socio-cultural issues

**Table 25: Social issues**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Key findings</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes for patient’s carers (relatives and others from his/her social network)</td>
<td>Where carers involved in the care of a TM service user are released from additional support to the chronically ill person in case of deterioration of the cared person’s health.</td>
<td>In the TM service model implemented in Slovenia, a specialist may change and/or adjust a patient’s therapy through a dedicated (U4H) clinical portal. The decision for a change is based on TM collected data. The patient for whom an adjustment in therapy is made is informed of the change by an eHealth coordinator from the TM service centre. Consequently, carers do not need to bring the patient to the clinic, which is time consuming and often requires major efforts from the ill person. Carers, usually persons in employment, are released from additional support to the chronically ill person in case of deterioration of the cared person’s health.</td>
</tr>
<tr>
<td>Shift of responsibility from patients to healthcare professionals</td>
<td>Responsibility for a decision if a visit to a specialist is needed is now shifted from a patient to healthcare professionals.</td>
<td>When health condition deteriorated in a chronically ill patient living at home and/or his/her carers were in doubt whether or not to visit a specialist in a clinic, their decision was based on e.g. the specialist’s working hours, availability of carers, level of health deterioration, etc. Frequently they took incorrect decisions, e.g. not going although the situation was serious enough for an intervention. With the TM system, medical staff at the TM service centre are alerted to the deterioration of health condition of the particular patient. The TM collected data are reviewed by the specialist who decides on further actions – whether to change the patient’s therapy or invite the patient to come for an unscheduled hospital consultation. With TM in place, a decision whether or not to seek the specialist’s support is now taken by healthcare professionals.</td>
</tr>
<tr>
<td>Issue</td>
<td>Key findings</td>
<td>Evidence</td>
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</tr>
<tr>
<td>Changes in patient’s roles</td>
<td>Patients have been more involved in their disease treatment procedures, which, together with interactive features of the telehealth system, can be considered the nucleus of a patient empowerment concept. However, this has not yet translated into changes of national treatment protocols that would reduce the number of regular outpatient department visits. On the other hand, closer contacts with patients enabled optimisation of their visits in specific cases that would normally occur if no information from remote patients was available. Some of the outpatient department visits could then be avoided. Lower re-hospitalisation rate was encountered.</td>
<td>Questionnaires and bidirectional communication channel between patients and hospital staff, enabled by the technology, as well as medication ordering system for patients, is used for trusted information exchange. Because of both predefined schedule and an induced interest in using the communication tools (and measurement devices), patients are attracted closer to their condition and felt a degree of supervision by the hospital staff from distance. This contributed to better adherence to treatment in most cases.</td>
</tr>
<tr>
<td></td>
<td>Patients, with the assistance of specialist nurses, took control of their treatment in the home setting. Reviewing outcomes to a regular timetable and in the home setting enabled patients to stay in work; they did not need to take time off to visit clinics so often. Patients were also able to get out and about without worrying about their condition.</td>
<td>Questionnaires to patients, interviews with focus groups (professionals), and patients’ stories were captured. Patients reported feeling “assured” when involved in the programme and also taking note of their symptoms.</td>
</tr>
<tr>
<td></td>
<td>Patients were able to record clinical readings from home or work, secure in the knowledge of their specialist monitoring. The system provided automatic feedback and advice as determined by their clinician. An amendment reducing the number of prompts / return texts has been developed specifically in response to patient feedback.</td>
<td>Patient and carer case studies / stories. An increased awareness of their condition led to confidence in continuing their preferred lifestyle. Patients reported being able to get on with their life unrestricted by clinic appointments, and reduce their perception of illness. Questionnaires to patients, and interviews with professionals. Awaiting outcome of evaluation. Clinicians reported that a large number of patients could be contacted over the phone rather than face-to-face.</td>
</tr>
<tr>
<td>Issue</td>
<td>Key findings</td>
<td>Evidence</td>
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<tr>
<td>Patient's relatives and others</td>
<td>Patient's relatives’ / helpers’ roles are in close correlation with two characteristics of the patients: ability to use the technology, and their overall condition given the disease and co morbidities / reduced cognitive functions. With worse condition of the patients, the family / relatives’ role increases.</td>
<td>Call centre experience, number of calls originated by their patients or relatives. Oral information provided by patients. Appearance of persons accompanying patients coming to the hospital and their expressions.</td>
</tr>
<tr>
<td>Societal, political and context changes</td>
<td>Societal change was observed as to growing ICT literacy over the period of the project, enabling larger acceptance of the new telehealth methods on both sides: patients and medical staff. Various regional or healthcare provider contexts play marginal role if scaling up of the interventions is considered, and if we disregard investment and operational cost aspects. The intervention and experience shared with other monitoring sites in the project enabled a targeted discussion with relevant stakeholders in the Czech Republic of care models involving patient empowerment.</td>
<td>New Czech national strategy Health 2020 includes patient/citizen empowerment concept as an important element.</td>
</tr>
<tr>
<td>Expansion of telehealth monitoring</td>
<td></td>
<td>Scottish Government funding has allowed the expansion of telehealth monitoring. Documentation has been developed and agreed to ensure telehealth monitoring is opened out to more people with heart failure living in the community. Criteria have been expanded to include all patients within the specialist nurse caseload where monitoring would be of benefit. Suitable protocols have been developed for this.</td>
</tr>
<tr>
<td>Issue</td>
<td>Key findings</td>
<td>Evidence</td>
</tr>
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</tr>
<tr>
<td>Changes in responsibilities</td>
<td>Medical staff extended their responsibilities with task related to telemonitoring and communication with the patients. Technical staff have been assigned appropriate roles.</td>
<td>Internal hospital organisational measure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Staff report more effective consultations due to high quality of data now available.</td>
</tr>
<tr>
<td>Gender issues - equity</td>
<td>Approach to men and woman was equal. However, gender issue is slightly relevant, considering age composition of the patients (mostly in senior age) and historic unbalanced experience with ICT between some men and women. Technical support team devotes particular attention to those women with lower practice with ICT in order that they could also participate in the interventions.</td>
<td>Standard approach to gender equity in the hospital.</td>
</tr>
<tr>
<td>Lifestyle changes</td>
<td>Participation in the programme did not affect or impinge on recipients’ lifestyle in any way. Recipients were able to continue with normal life, i.e. get out and about, receive visitors, continue working etc.</td>
<td>One patient story advised that the patient knew from readings when they could get out and about.</td>
</tr>
<tr>
<td>Patient empowerment</td>
<td>Both recipients and health professionals are pleased with the programme.</td>
<td>Recipients have embraced taking responsibility for managing their heart failure.</td>
</tr>
<tr>
<td>Technology access</td>
<td>Access to own mobile phone did exclude patients, however option of loan of mobile phone was available if wished.</td>
<td></td>
</tr>
</tbody>
</table>
8 Transferability assessment

This domain includes topics that identify the scalability and generalizability of the CHF telehealth service in United4Health.

The issues are categorised as follows:

- Assess transferability of clinical effects
- Assess transferability of economic effects
- Assess transferability of organisational effects

8.1 Assess transferability of clinical effects

Table 26: Safety and clinical outcomes

<table>
<thead>
<tr>
<th>Scalability</th>
<th>Patient engagement, effective and secure clinical outcomes, and operating systems suggest that telemonitoring could be scaled up within the countries.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Telemonitoring service facilitates an early detection of deterioration of patients' status, reduction of unplanned visits to hospital, and basic patient empowerment thanks to the positive health related impact of the service. It can be implemented at scale across different healthcare settings. For patients with CHF, immediately following hospital admission or ED visit, the result was positive. Patients from all sites have a high acceptability and satisfaction about associated with the telemonitoring intervention. U4H CHF experience suggests that telehealth has had a positive impact on self-confidence for the majority of patients recruited, and has enabled patients to develop a better routine of self-management which has improved treatment compliance. Technology has had a positive impact on the interactions between patients and clinicians.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generalisability</th>
<th>A significantly difference in demographic and clinical terms between intervention and comparator group suggests that there are some difficulties generalising the results of this study.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Although the inclusion criteria for the intervention and comparator groups were well defined in the protocol, overall intervention and comparator groups are quite heterogeneous, both in demographic terms and clinical baseline data. Most probably this is due to the weight of the Slovenian control group in the total sample. The differences between the deployment sites and in the period observed may have also contributed.</td>
</tr>
</tbody>
</table>
8.2 Assess transferability of economic effects

Table 27: Economic outcomes

<table>
<thead>
<tr>
<th>Scalability</th>
<th>Costs of implementing changes depend on the ambition to integrate the new telehealth service into the corporate ICT systems. It should be considered that it is easily scalable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generalisability</td>
<td>To analyse the generalisability of telemonitoring for CHF patients from an economic point of view requires more time than the timeframe of the project. Further analysis may show advantages for certain types of patients in terms of cost per patient and QALYs. Business models that incorporate budgeting, funding and/or reimbursement models have to be carefully developed. Intangible benefits such as patient empowerment and quality of life have to be considered. Externalities and opportunity costs and benefits such as freed resources also have to be taken into account.</td>
</tr>
</tbody>
</table>

8.3 Assess transferability of organisational effects

Table 28: Organisational aspects

<table>
<thead>
<tr>
<th>Scalability</th>
<th>TM service can be multi-level and cross-disciplinary, or concentrated in one sector (e.g. hospital department or local GP practices). Scalability differs in both of them.</th>
<th>Telemonitoring service has had a positive health related impact, enabled by: additional training, bi-directional electronic communication tool with the hospital staff; everyday regular measurements; availability of the values to the patients for self-test; reminders; and remote phone support from the telehealth centre. To achieve this, we have learned that it is important to redesign the right parts of care processes, get the right staff on board, involve the patients’ carers, target the right patients, and choose the right technology which offers flexibility and is easy to use by clinicians and patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generalisability</td>
<td>Assess if organisational changes are necessary for broadening inclusion criteria</td>
<td>Multilevel (primary care and hospital) and cross disciplinary services are more difficult to start with than outsourced services. However, once included in “care as usual” organisation, it is easier to extend. It will be necessary to redesign the work flow and care pathways to involve all the patient and carer representatives.</td>
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## Appendix A: SUTAQ Questionnaire

Service User Technology Acceptability Questionnaire (SUTAQ) © 2010 City University, London, UK.

**Instructions:** Below is a list of statements referring to the kit (TeleHealth and/or TeleCare equipment) you have received to support your care. Please indicate the degree to which you agree with each statement by TICKING the corresponding box.

1. The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often.
   - [ ] STRONGLY AGREE
   - [ ] MODERATELY AGREE
   - [ ] MILDLY AGREE
   - [ ] MILDLY DISAGREE
   - [ ] MODERATELY DISAGREE
   - [ ] STRONGLY DISAGREE

2. The kit I received has interfered with my everyday routine.
   - [ ] STRONGLY AGREE
   - [ ] MODERATELY AGREE
   - [ ] MILDLY AGREE
   - [ ] MILDLY DISAGREE
   - [ ] MODERATELY DISAGREE
   - [ ] STRONGLY DISAGREE

3. The kit I received has increased my access to care (health and/or social care professionals).
   - [ ] STRONGLY AGREE
   - [ ] MODERATELY AGREE
   - [ ] MILDLY AGREE
   - [ ] MILDLY DISAGREE
   - [ ] MODERATELY DISAGREE
   - [ ] STRONGLY DISAGREE

4. The kit I received has helped me to improve my health.
   - [ ] STRONGLY AGREE
   - [ ] MODERATELY AGREE
   - [ ] MILDLY AGREE
   - [ ] MILDLY DISAGREE
   - [ ] MODERATELY DISAGREE
   - [ ] STRONGLY DISAGREE
5. The kit I received has invaded my privacy.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

6. The kit has been explained to me sufficiently.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

7. The kit can be trusted to work appropriately.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

8. The kit has made me feel uncomfortable, e.g. physically or emotionally.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

9. I am concerned about the level of expertise of the individuals who monitor my status via the kit.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE
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<td>10. The kit has allowed me to be less concerned about my health and/or social care.</td>
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<td>11. The kit has made me more actively involved in my health.</td>
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<td>12. The kit makes me worried about the confidentiality of the private information being exchanged through it.</td>
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<td>13. The kit allows the people looking after me, to better monitor me and my condition.</td>
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<td>14. I am satisfied with the kit I received.</td>
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<td>MILDLY DISAGREE</td>
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### Service User Technology Acceptability Questionnaire (SUTAQ)© 2010. City University, London, UK.

15. The kit can be/should be recommended to people in a similar condition to mine.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

16. The kit can be a replacement for my regular health or social care.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

17. The kit can certainly be a good addition to my regular health or social care.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

18. The kit is not as suitable as regular face to face consultations with the people looking after me.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE

19. The kit has made it easier to get in touch with health and social care professionals.

- [ ] STRONGLY AGREE
- [ ] MODERATELY AGREE
- [ ] MILDLY AGREE
- [ ] MILDLY DISAGREE
- [ ] MODERATELY DISAGREE
- [ ] STRONGLY DISAGREE
20. The kit interferes with the continuity of the care I receive (i.e. I do not see the same care professional each time).

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21. I am concerned that the person who monitors my status, through the kit, does not know my personal health/social care history.

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22. The kit has allowed me to be less concerned about my health status.

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Thank you for your responses to this questionnaire, please check that you have answered all items.

Your responses will be kept confidential.
Appendix B: References

1. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. *European heart journal*. Jul 2012;33(14):1787-1847.


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