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Abstract

This report describes the outcomes of the MAST evaluation of the services deployed for the management of Type 1 and Type 2 Diabetes in the United4Health. The report follows the MAST reporting structure, including all domains and transferability.

Key Word List

Analysis, MAST, Outcomes, TeleHealth, Telemonitoring, Type 1 Diabetes, Type 2 Diabetes, Self-management, Self-monitoring

Executive Summary

This deliverable *Final Pilot Evaluation – Diabetes* is the complete account of the evaluation of the diabetes telehealth intervention deployed and studied in real-life healthcare environments across nine regions in Europe; the evaluation follows the Model for Assessment of Telemedicine framework (MAST).

- Scotland, UK
- Wales, UK
- Slovenia
- Northwest Moravia, CZ
- Campania, IT
- Calabria, IT
- Thessaly, GR
- Berlin, DE

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 aimed "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 needed 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 was presented to the U4H 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 Diabetes Mellitus Scientific Committee, chaired by Sandeep Thekkepat (Diabetologist, Clinical Lead of NHS 24 and WP6 Leader). This plan was completely followed, but extended to include additional regression analyses because unexpected and significant differences were observed between intervention and comparator groups.

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.**

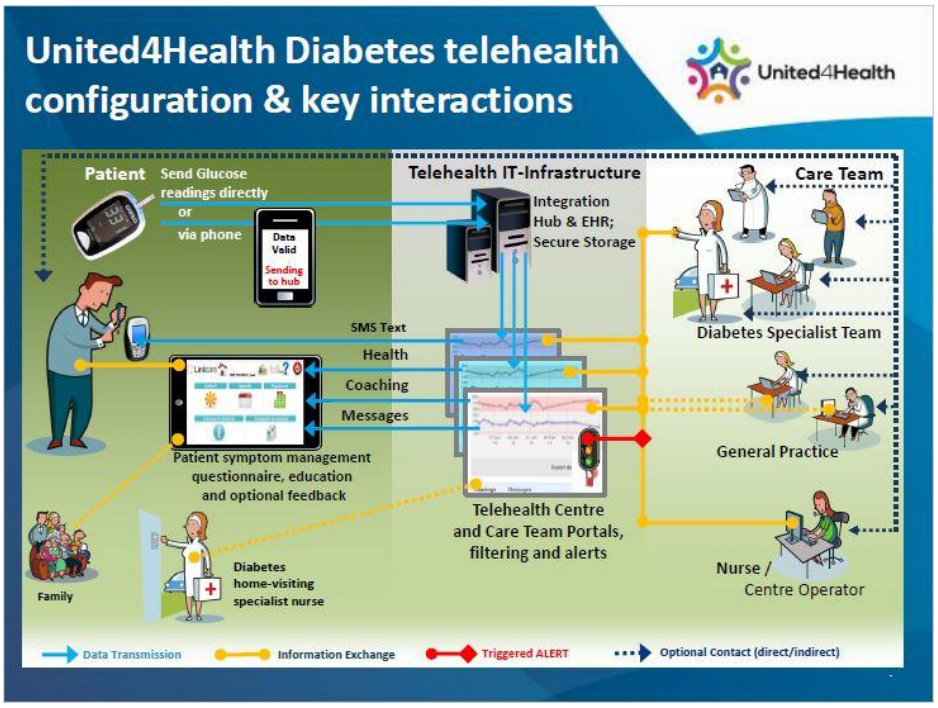
- **The intervention and comparator groups were significantly different and not matched at baseline, indicating a potential selection bias.**
- **Significant heterogeneity of healthcare resource use was found among the deployment sites.**
- **The data was incomplete in a non-random, but systematic way. 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

Diabetes is a major cause of morbidity and mortality worldwide. Globally, healthcare expenditure for diabetes is equivalent to >10% of total health spending. Without an investment in making effective treatments for preventing diabetes complications widely available, this is predicted to rise considerably.

Telehealth allows the opportunity for patients to play a new and more direct role in their treatment and care. Remote home monitoring of blood glucose levels via telehealth has been found to improve glycemic control. Technology also allows access to varied, structured, self-education programmes, offering access to health coaching programmes at any time of day. The telehealth intervention for diabetes in United4Health (U4H) aimed to promote self-care and self-management by encouraging the use of self-monitoring of glucose and lifestyle risk factors, and by providing ongoing health coaching.



Each deployment site implemented the model into their local healthcare systems, taking into account local variations and adjusted accordingly. Using telehealth, they 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 reduced the period of specialist supported self-management, which is the most costly part of the pathway.

Domain 2 and 3: Safety and Clinical Effectiveness

U4H has demonstrated that telehealth interventions can be deployed at scale for the management of diabetes. The evaluation cohort in the diabetes study was 2,541 (Type 1 and 2).

The primary end-point of the project was face-to-face contacts with GPs and diabetologists; U4H found a significant reduction on the number of face-to-face contacts. The secondary end-points showed that there was a statistically significant reduction in HbA1c and hospital admissions. The caveat remains that the interventions were different for different areas, and also that the care systems were not entirely comparable.

A key lesson learned from U4H is that healthcare systems should recognise from this evidence that there is a compelling need to redesign care pathways / services with telemonitoring / telehealth as a core part of routine care. With improvements in HbA1c, it can be argued that if the reduction is long-term, this will lead to reduction in diabetes complications and hopefully reduction in healthcare costs.

Domain 4: Patient perspectives

The analysis of patient perspectives through SUTAQ showed that the median patient with Diabetes Mellitus believed that telemonitoring enhanced the care he/she received from the healthcare system, and increased their accessibility to healthcare services, whilst at the same time it did not create problems with privacy, cause discomfort, nor cast doubt about the personnel delivering telemonitoring services. However, the patient was rather indifferent as to whether the telehealth equipment can be a substitute to usual care. Nevertheless, the patient was overall very satisfied with the telehealth equipment.

Domain 5: Economic aspects

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

- The telehealth intervention in the diabetes trial increased the average costs per patient by about 153€, mainly because of the costs of the telehealth intervention. However, in four of the nine regions, a reduction in the mean costs was found.
- Many sites reported that more time and effort than expected was needed to get the applications to run smoothly and to make sure that the patients felt ready and secure.
- There were large differences in the way the sites organised the provision of their telehealth service, and the types of ICT solutions involved for diabetes patients in the different regions.
- The length of training courses for staff varied widely, from a few hours to a 60-hour course. The training varied in content and duration due to the different levels of detail that was required for each professional group.

Domain 6: Organisational aspects

Due to wide variations in the organisation of the health sectors of the participating sites, it was difficult to compare and assess the organisation of the diabetes services in a meaningful manner; e.g. some sites involved the hospital sector in the telehealth service, whereas others delivered the service from a primary care setting. Nonetheless, the organisational assessment revealed some generic prerequisites or conditions for implementation of telehealth in respect to organisational aspects:

- National focus on telehealth (e.g. telehealth being an integral part of the national health strategy) makes a positive difference to the implementation and dissemination of a new telehealth solution.
- Positive staff attitudes are crucial for successful deployment. Also, roles and responsibilities for all participants (including sectors) must be clearly defined from the start, and realistic expectations for time and staff resources required are essential.
- ICT infrastructure must be in place and running smoothly from the beginning of the project or deployment process.
- Continuous adjustment and further development of the telehealth service is necessary. All U4H sites required a revision of the service from its present form in order to continue after the end of the project period.

Domain 7: Socio-cultural, ethical and legal aspects

The issues encountered by each site were, in some cases, very similar and were addressed in a similar way, e.g. consent. Appropriate measures were taken in relation to ethical committees if relevant, but in all cases following the local codes of practice. 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 domain are, in some cases, to be perceived as transferable, while in other cases they are very specific to the local context. For example, a statistically significant improvement in HbA1c and reduction in hospital admissions and GP/diabetologist visits were found. United4Health is the first at-scale deployment project to be able to demonstrate this, and it is a result that should impact how other regions across Europe view the role of telemonitoring / telehealth in their future service delivery models for the management of diabetes patients. However, the exact same outcome might not be fully replicated in another individual region, as the outcome is based on data from nine sites that were also different in their local implementation of the telehealth intervention.

Change History

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0.1 25th October 2015
0.2 3rd November 2015
0.3 8th December 2015
0.4 16th December 2015
0.5 17th December 2015
0.6 23rd December 2015
0.7 14th January 2016
0.8 26th January 2016
0.9 29th January 2016
1.0 31st January 2016
1.1 4th March 2016
1.2 7th March 2016
1.3 22nd July 2016
1.4 20th December 2016

Version Changes

0.1 Initial draft
0.2 Second draft
0.3 Third draft
0.4 Fourth draft
0.5 Fifth draft
0.6 Sixth draft
0.7 Seventh draft
0.8 Eight draft
0.9 Ninth draft
1.0 Initial version for issue
1.1 Economic aspects added to Executive Summary, and sections 5.3 & 5.4
1.2 Table 1 and Figure 29 corrected
1.3 Addition of limitations section to Executive Summary and section 3.12 following final review meeting, sections 3.11.1 & 3.11.2 added, text added to section 6.1, 6.3 & 6.4.2, table added to 6.4
1.4 Revised following feedback from EC reviewers

Outstanding Issues

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1. Introduction

1.1 Purpose of this document

This document contains the final outcomes and results of the diabetes evaluation in the United4Health (U4H) project, presented according to the MAST (Model for Assessment of Telemedicine) framework.

The MAST framework ensures a rigorous evaluation of telemedicine applications in the healthcare sector. The model was developed as part of the MethoTelemed project, which aimed to provide a structured framework to assess the effectiveness and contribution to quality of care of telemedicine applications.

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

ANOVA	Analysis of Variance test
BMI	Body Mass Index
DM	Diabetes Mellitus
DMZ	De-Militarised Zone (security related)
GP	General Practitioner
HbA1C	Glycated Haemoglobin
HBGM	Home Blood Glucose Monitoring
IDF	International Diabetes Federation
MAST	Model for Assessment of Telemedicine
MDMW	My Diabetes My Way
RH	Renewing Health
SIGN	Scottish Intercollegiate Guidelines Network

SMBG	Self-Monitoring Blood Glucose
SMHIT	Self-Management Health Information Technology
SMS	Short Message Service
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
Tmon	Telemonitoring
U4H	United4Health
WSD	Whole System Demonstrator (UK trial)

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

2.1 The health problem of the patients

As evidenced from the International Diabetes Federation's World Atlas 2015, Diabetes Mellitus is a major cause of morbidity and mortality worldwide.

The worldwide prevalence is estimated to be 415 million people between 20-79 (equivalent to 8.8% of the population group) and it is predicted that by 2040, the prevalence will have risen to 642 million (equivalent to 10.4% of the population group) [i]. Currently 1 in 11 adults has diabetes and by 2040, it will be 1 in 10. Every six seconds a person dies from diabetes.

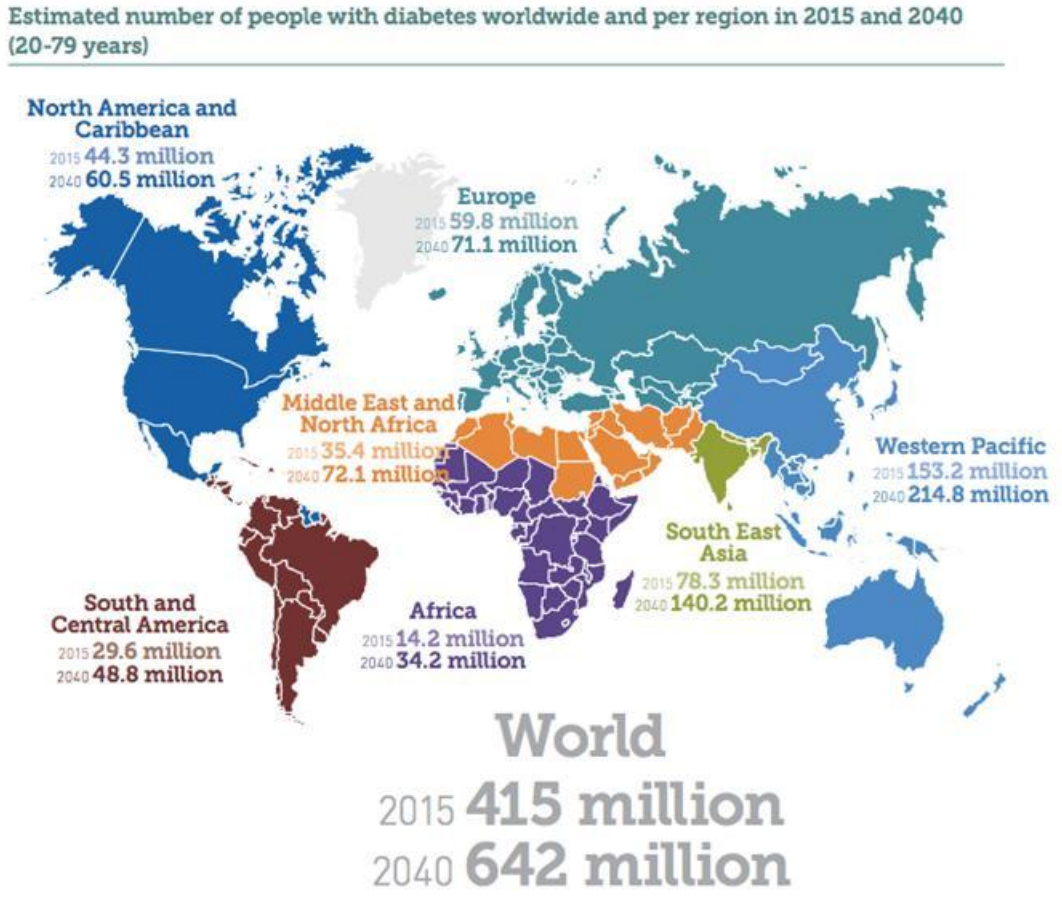


Figure 1: Global estimation of diabetes in 2015 and 2040

There are three major types of diabetes - Type 1 diabetes, Type 2 diabetes and Gestational diabetes. Type 1 diabetes, a result of autoimmune process, needs insulin therapy to survive. Type 2 diabetes (formerly called non-insulin-dependent or adult-onset diabetes), is a disease caused by the body's ineffective use of insulin - often resulting from excess body weight and physical inactivity. It is characterised by insulin resistance and relative insulin deficiency; either of these may be present at the time that diabetes is diagnosed.

The diagnosis of Type 2 diabetes usually occurs after the age of 40 years but can occur earlier, especially in populations with high diabetes prevalence. Type 2 diabetes can remain undetected, i.e. asymptomatic, for many years; the diagnosis is often made from associated complications, or incidentally through an abnormal blood or urine glucose test. It can lead to micro vascular complications, e.g. retinopathy, renal disease, peripheral neuropathy and macro vascular complications, i.e. arterial disease, leading to heart attack, stroke, dementia or amputation. Type 2 accounts for around 90% of all diabetes worldwide[i].

The multi-vascular risk factors and wide-ranging complications mean that the management of Type 2 diabetes requires complex and time-consuming healthcare management [ii]. The necessary lifestyle changes, complexities of management, and side effects of therapy, make self-monitoring and education a priority for patients who wish to self-manage. Ideally, patients with Type 2 diabetes should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If managed in collaboration with healthcare professionals, the preferences of people with diabetes are more likely to be realised and their personal goals attained. As the ratio between people being diagnosed with diabetes and healthcare professionals available to manage them grows wider on a daily basis, we must look at new ways of working – constantly striving to for patient centred care[ii,iii].

2.2 Burden of the disease

In addition to placing a large financial burden on individuals and their families due to the cost of insulin and other essential medicines, diabetes also has a substantial economic impact on countries and national health systems. This is because of an increased use of health services, loss of productivity, and the long term support needed to overcome diabetes related complications, such as kidney failure, blindness or cardiac problems. Globally, healthcare expenditure for diabetes totalled US $673 billion in 2015. The majority of countries spend between 5% and 20% of their total health expenditure on diabetes. With such a high cost, the disease is a significant challenge for healthcare systems [i].

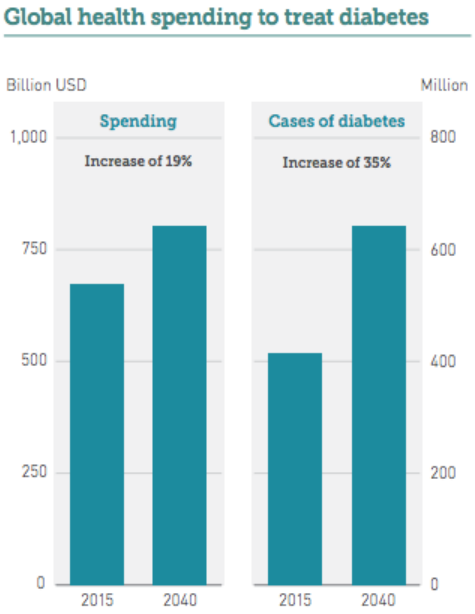


Figure 2: Global health expenditure for diabetes 2015 and 2040

2.3 Diabetes care and telehealth service

Telehealth (or the use of technology in accessing healthcare) allows the opportunity for patients to play a new and more direct role in their treatment and care[iv,v,vi]. Diabetics have undertaken self-monitoring of blood glucose for many years, but it is acknowledged that this is not always reliable[vii]. Structured self-monitoring of blood glucose improves glycemic control, and provides guidance in prescribing diabetes medications in patients with relatively well-controlled non-insulin treated type 2 diabetes[v]. Remote home monitoring of blood glucose via telehealth has been found to improve glycemic control[viii], and patients find this acceptable[ix], resulting in potential for adjustment in medication and access to relevant clinical advice sooner than may have been available with conventional monitoring. Technology also allows access to varied, structured, self-education programmes, offering access to health coaching programmes at any time of day. The use of self-management health information technology (SMHIT) has been found to significantly improve glycemic control and improve patient centred care[vi].

Telehealth is not designed to replace conventional models of care, but can provide further options for self-care at home, potentially both reducing the requirement for some face-to-face interactions with healthcare professionals, and reducing HbA1c[ii,iii,viii].

The telehealth intervention for diabetes in U4H aimed to promote self-care and self-management by encouraging the use of self-monitoring of glucose and lifestyle risk factors, and by providing ongoing health coaching.

The generic U4H diabetes model that was implemented across the nine sites is as follows:

- The patient at home uses the provided device for the measurement of blood glucose level. The device, used by the patient, collects the data and sends it to the gateway device automatically.
- The gateway device transmits the data collected by the patient to the server of a Regional eHealth Centre, managed according to local policy.
- The telemonitoring software will allow healthcare professionals to monitor and manage the data, as agreed locally, including provision of a summary and access to the web based portal to monitor the patient's health conditions at any time required.

Each deployment site within the diabetes study implemented the model into their local healthcare systems, taking into account local variations and adjusting the model accordingly. In the sections below, the ambition, routine care management and the U4H telehealth enabled care model are described; the diabetes telehealth solution configuration and key interactions are illustrated for each deployment site in the diabetes study.

2.3.1 Scotland

Ambition

The aim of the telehealth intervention being used in Scotland for patients living with Type 1 and Type 2 Diabetes is to improve self-management and support and enable positive changes to behaviour / lifestyle through digitalised self-monitoring of blood glucose to reduce the risk of developing disease related health complications. The centralised integration of home blood glucose monitoring (HBGM) into two national

established systems within Scotland will improve care coordination and facilitate more flexible treatment pathways.

Diabetes routine care management

Routinely, patients with Type 1 and Type 2 Diabetes monitor their own blood glucose levels and are supported to self-manage (*Green* in the figure below) through coordinated services delivered in primary, community and secondary care sectors. New patients diagnosed with Type 2 Diabetes, and those stabilised on insulin therapies, are managed by primary care and have an annual review as part of the Quality and Outcomes Framework (QOF) in their GP practice diabetic clinic (*Amber)*, whereas patients living with complex Type 2 and Type 1 Diabetes have their annual reviews during an outpatient consultation in secondary care, as these patients are predominantly managed by hospital-based diabetes specialists who also assist patients to self-manage (*Red)*. A range of healthcare practitioners including diabetologists, diabetic specialist nurses, and community / home-visiting nurses, GPs and online digital services and platforms (NHS Inform, MyDiabetesMyWay) currently provide information support and advice to patients and carers regarding self-management, symptom management and prevention of long term diabetes-related complications.

Figure 3: Scotland: Diabetes care model

U4H telehealth enabled care model

The telehealth care model deployed within U4H has enhanced the national NHS Scotland's MyDiabetesMyWay (MDMW) interactive website designed to support people who have Type 1 Diabetes and insulin dependent Type 2 Diabetes to better self-manage and control symptoms. MDMW allows patients access to their own diabetes electronic medical record; patients involved in U4H are now able to upload their blood glucose readings into their record *(Green)*. This functionality is achieved through the integration of software (Diasend) which links the MDMW website and an electronic diabetes medical record (SCI-Diabetes). The patient at home uses their NHS-provided home glucose monitoring device and downloads the Diasend software to their own Internet-enabled device (smartphone / tablet / computer). This software allows the transmission of the measurements to the patient's secure area

of the self-management website, MDMW[1]. The measurements are integrated into the patient's medical record within SCI-Diabetes, thus allowing both patients and clinicians a digitally captured, up-to-date picture of an individual's blood glucose measurements and trends, a summary of which can be produced anytime. This integrated use of MDMW and Diasend strengthens self-management and self-care provision, and enhances routine care services by enabling more flexible treatment and care options, including more remote clinical consultations which are provided either in the patient's GP practice or community and hospital specialists as required *(Amber/Red)*.

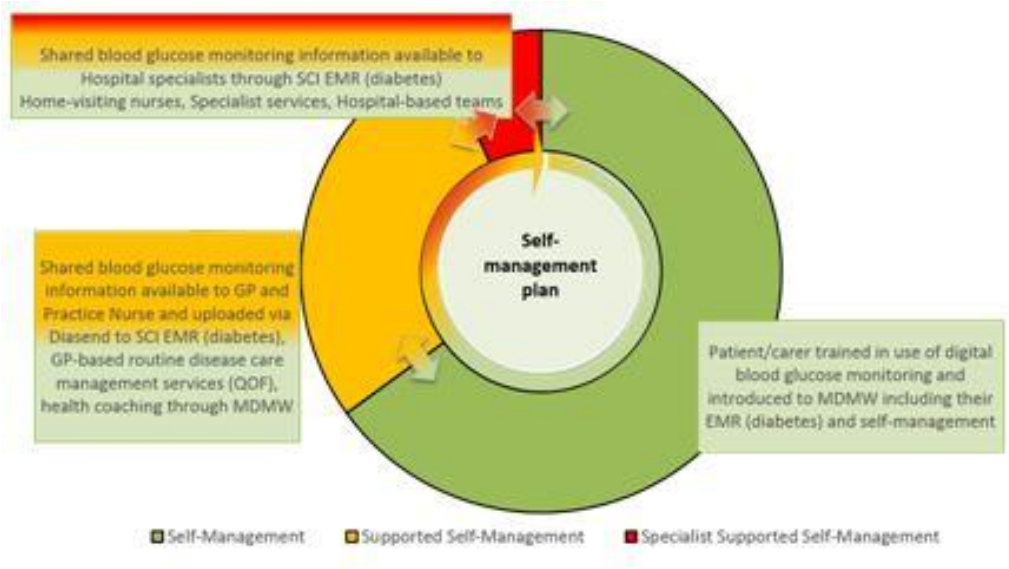


Figure 4: Scotland: Diabetes telehealth enabled care model

Figure 5 below illustrates the diabetes telehealth solution configuration and key interactions in Scotland.

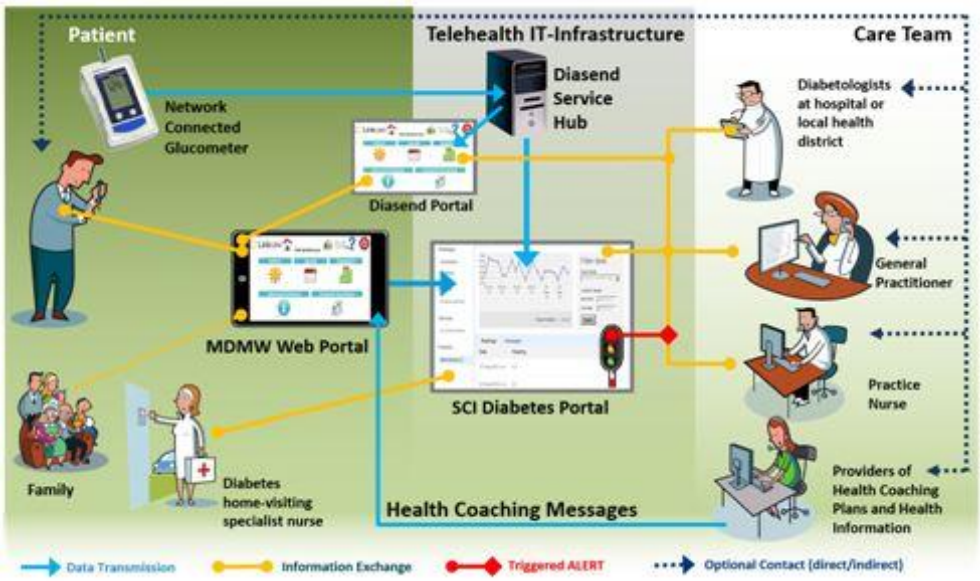


Figure 5: Scotland: Diabetes process workflow

[1] http://www.mydiabetesmyway.scot.nhs.uk/

2.3.2 Wales

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their blood glucose levels is to support the individual patient's endeavours to self-manage and lead a lifestyle to reduce their risk of developing diabetes-related complications.

Diabetes care management – 'usual care'

Usual care for patients with Type 2 Diabetes is undertaken by the patient themselves (*Green*) supported predominantly by their GP and GP practice nurse who has a special interest in diabetes in primary care (*Amber*). Patients are invited to have, as a minimum, annual reviews as part of the Quality and Outcomes Framework (QOF) which includes testing their HbA1c and renal function, measuring their blood pressure and lipids, undertaking a micro vascular / neuropathic assessment, and providing them with health and lifestyle advice. In addition, patients receive a retinopathy screening appointment annually. Patients are able to be referred to medical and nursing diabetes specialists in the hospital and/or community services if required (*Red*).

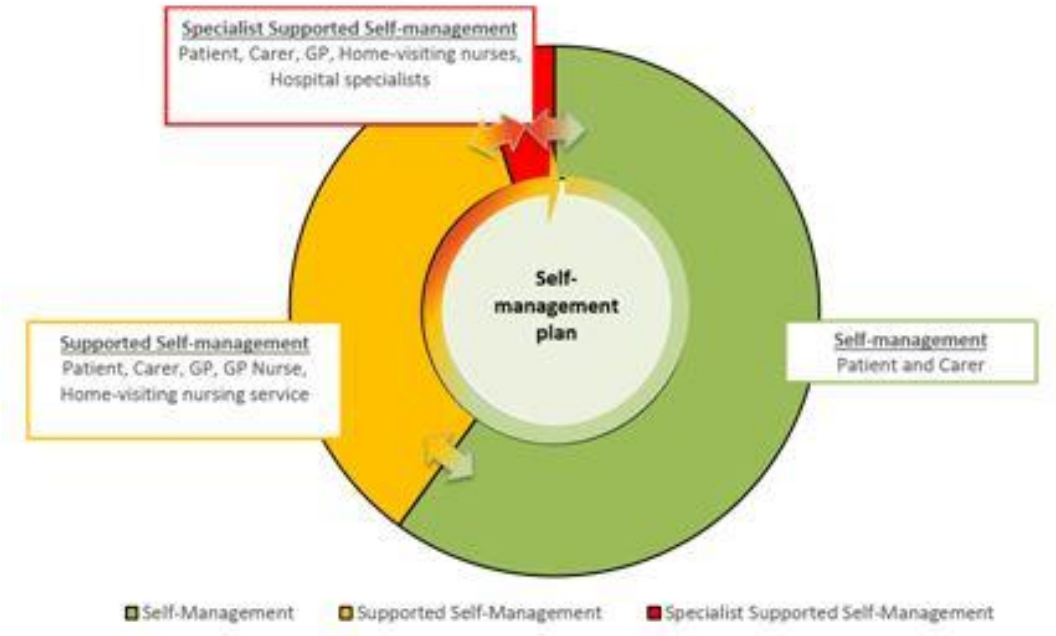


Figure 6: Wales: Diabetes care service model

U4H telehealth enabled diabetes care management

The telehealth service has been designed to help patients self-manage (*Green*) and enhance the routine diabetes care service model delivered by professionals working in primary and home care settings (*Amber*) by strengthening self-management with health coaching interventions and support.

Patients receive automated text message reminders from Florence© (Flo) to perform their blood glucose readings using their own glucometers according to the regime agreed between the patient and their GP practice. The Simple Telehealth program analyses the patient's readings according to their individualised parameters

agreed between patient and clinical team, and 'Flo' provides instant feedback to the patient via their mobile phone along with locally agreed advice and health coaching messages if required. Should a parameter be critically breached, the patient will be advised on what immediate action to take and who to contact. An alert message is also sent to their nominated diabetes care professional (either practice nurse, GP or home-visiting specialist nurse), and this can be reviewed immediately via a secure internet connection, or the next working day if the anomalous parameter occurred out of working hours. The patient continues on low-level telemonitoring, receiving on their mobile phone web links to be viewed via the Internet on a device of their choice, different text prompts via Flo, Simple Telehealth web-based monitoring system for up to 12 months following enrolment. Any worsening symptoms will be treated according to local standard protocols, e.g. GP appointments with the option of referral to the home-visiting diabetes specialist nurse, emergency room attendance or hospital admission (*Red*).

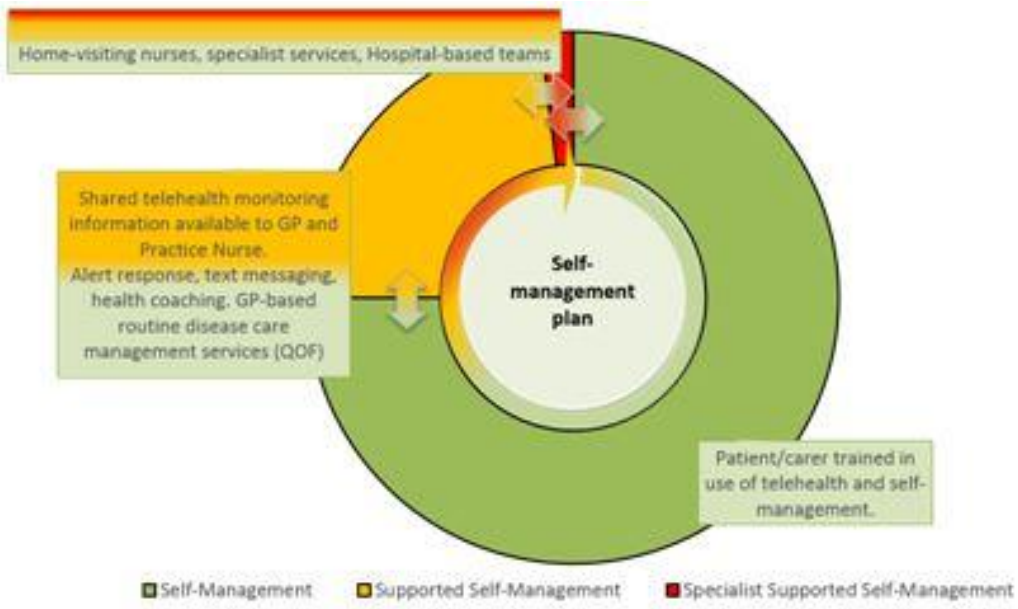


Figure 7: Wales: Diabetes telehealth enabled care model

Figure 8 below illustrates the diabetes telehealth solution configuration and key interactions in Wales:

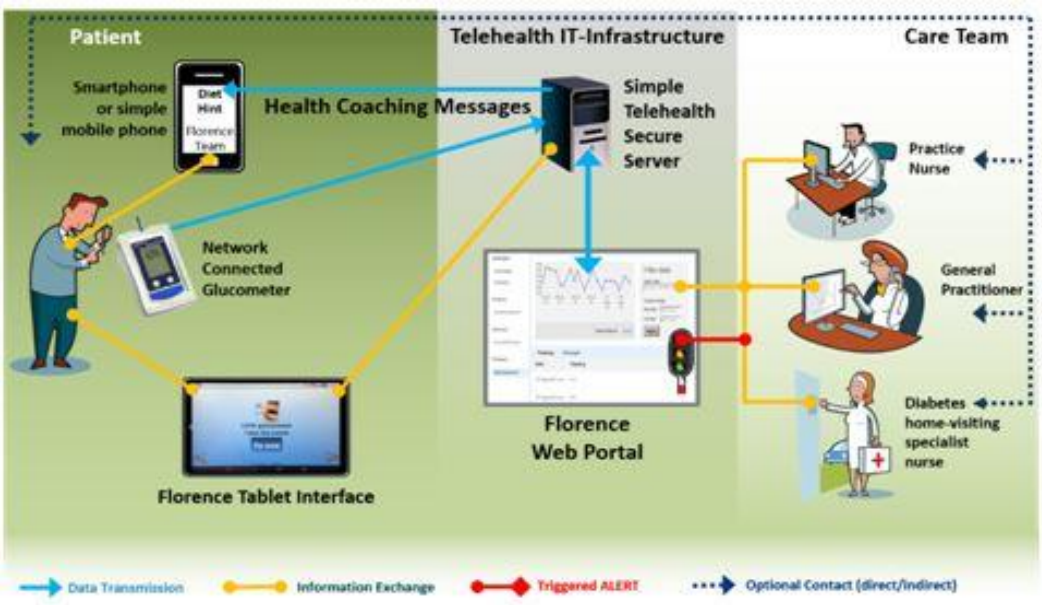


Figure 8: Wales: Diabetes process workflow

2.3.3 Slovenia

Ambition

The aim of the telehealth service for patients living with diabetes is to support and improve levels of self-management and achieve equally good clinical outcomes as routine care, particularly in relation to glycated haemoglobin HbA1c.

Diabetes care management – routine care

Patients with diabetes implement their self-management plan (*Green*) and have regular (six monthly if stable) specialist consultations in hospital outpatient clinics and health centres in the Koroska region (*Amber/Red*). Routine care management aims to achieve personalised goals in relation to HbA1c. Patient self-management plans vary according to their disease level, with the frequency of blood glucose monitoring varying for those on insulin, oral medication or diet only. Patients enter their blood glucose measurements in a dedicated diabetes booklet, the information in which is reviewed by the diabetologist at regular scheduled consultations. All patients are given personalised advice in relation to their diet according to the blood glucose levels. If their blood glucose levels are not well controlled (*Amber/Red*) they are reviewed in the hospital outpatient clinic or regional health centre more regularly than every six months.

Figure 9: Slovenia: Diabetes care service model

U4H telehealth enabled diabetes care management

The telehealth service is provided by specialists from the Slovenj Gradec regional hospital. Using physiological measurement devices (glucometers), patients take their blood glucose measurements once a week 3-6 times during the day (whole daily profile). The readings are transmitted over Bluetooth to a smartphone provided by U4H, and subsequently uploaded to the Telemedicine Service Centre at the hospital (*Green*). An alert is generated when the system detects that the blood glucose readings are outside the patient's set parameters. In such cases, an eHealth coordinator from the Telemedicine Service Centre contacts the patient by phone to check the data upload (*Red*). If the data is correct, the coordinator contacts a hospital diabetes specialist seeking advice on further action, e.g. change of therapy, or unscheduled hospital consultation. Any changes are communicated to the patient by phone, and followed up by a paper report sent by post. 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 (*Amber*). In addition, diabetologists 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.

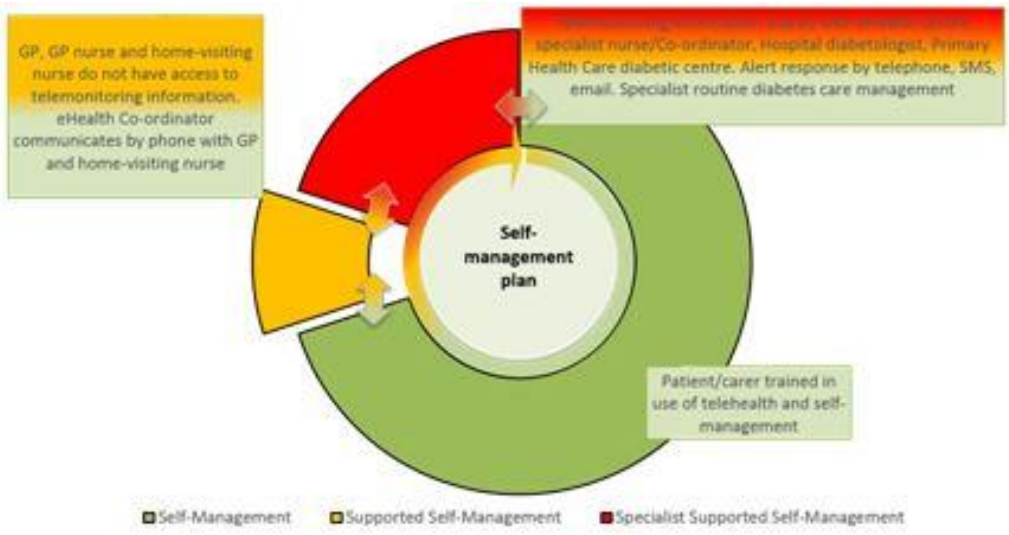


Figure 10: Slovenia: Diabetes telehealth enabled care model

Figure 11 below illustrates the diabetes telehealth solution configuration and key interactions in Slovenia:

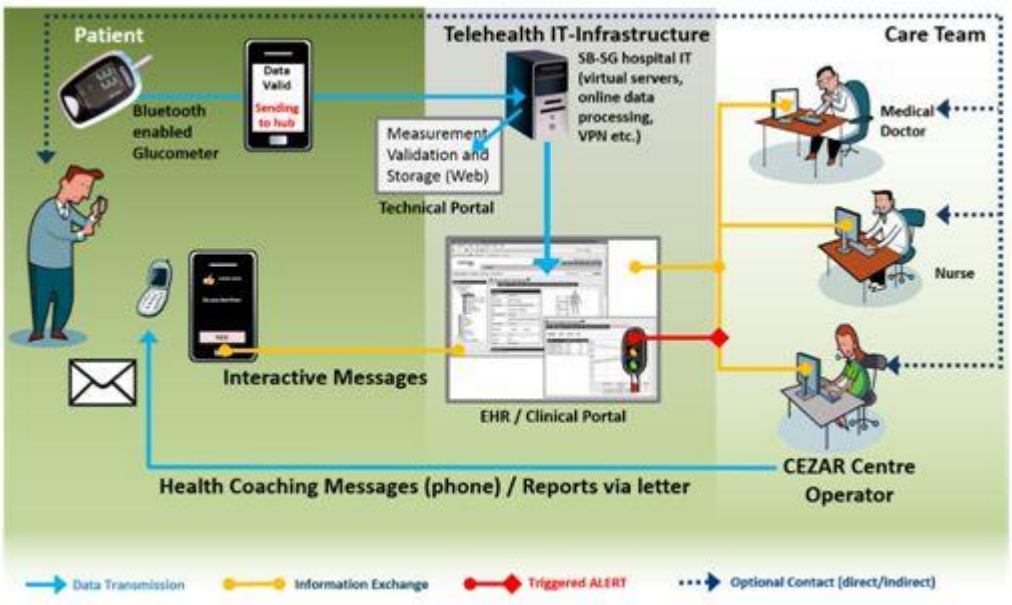


Figure 11: Slovenia: Diabetes process workflow

2.3.4 Northwest Moravia, Czech Republic

Ambition:

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their blood glucose levels is to support and improve the individual patient's endeavours to self-manage and lead a lifestyle to reduce their risk of developing diabetes-related complications through new treatment pathways.

Diabetes care management – routine care

The routine care for patients living with Type 2 Diabetes takes place at the University Hospital Olomouc and follows the Czech Diabetes Society guidelines on diabetes mellitus type 2 treatments. 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 blood glucose measurements that can be provided via their diary, patient's glucometer memory, and any HbA1c laboratory tests. GPs are not funded to provide diabetes care management (*Amber)*.

Figure 12: Northwest Moravia: Diabetes care service model

U4H technology enabled diabetes care management

Patients are provided with a smartphone or tablet, glucometer and test strips, and are given training to use the Medimonitor app on the smartphone (*Green*). The smartphone or tablet acts as a gateway to upload vital signs, including blood glucose readings, according to their individualised self-management plan, to the telemonitoring centre located in the hospital's Cardiac Clinic. Doctors, specialist nurses and biomedical engineers are able to access the telehealth portal database via a web browser and secure login (*Red*). The Medimonitor system generates alerts in response to:

- A patient's vital signs readings are outside their threshold parameters. Patient 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 diabetologist 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 uploads, either 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.

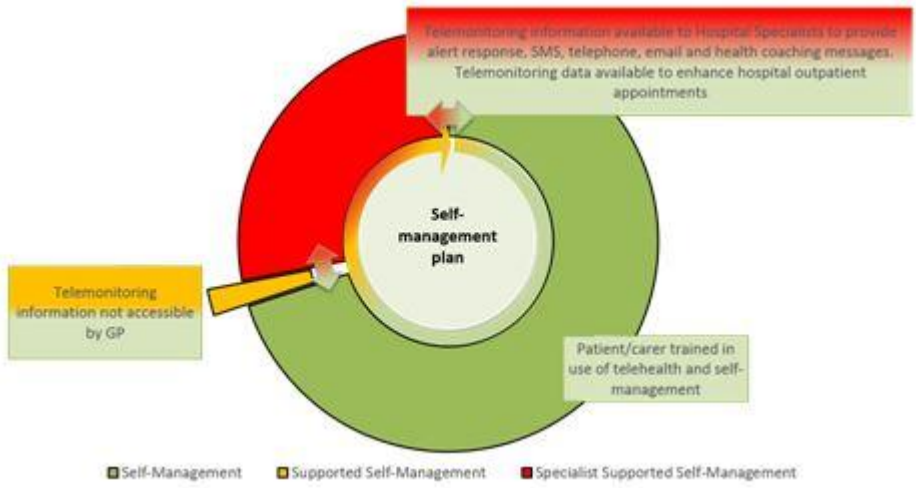


Figure 13: Northwest Moravia: Diabetes telehealth enabled care model

Figure 14 below illustrates the diabetes telehealth solution configuration and key interactions in Northwest Moravia.

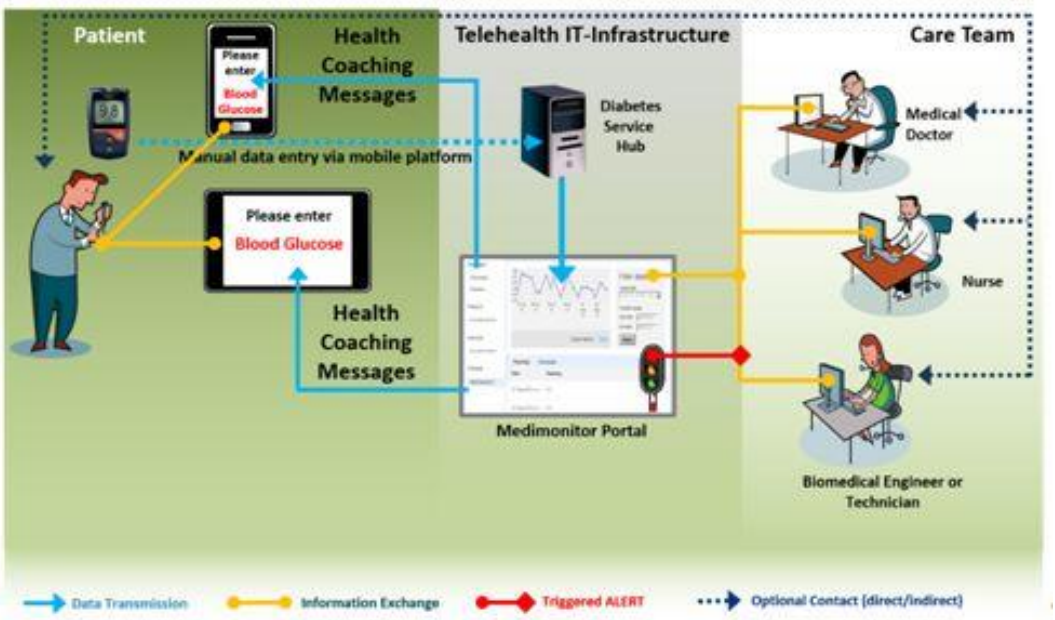


Figure 14: Northwest Moravia: Diabetes process workflow

2.3.5 ARSAN Campania, Italy

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their blood glucose levels is to support and improve the individual patient's endeavours to self-manage and lead a lifestyle to reduce their risk of developing diabetes-related complications.

Diabetes care management – routine care

Routine care for patient with Type 2 Diabetes varies according to the severity of their disease and the level of patient self-management (*Green*), and is part of an integrated care model.

Patients with no complications or with complications that are under control are managed by GPs, who receive the patient's individual care plan from the diabetologist which includes their blood glucose levels. The patient's GP is contracted to monitor their anthropometric indices (height, weight, waist circumference), provides educational reinforcement at least every three months, and HbA1c values at least every six months. In addition, the GP ensures the patient is referred annually for relevant specialist assessments, including the screening for any complications (*Amber*).

Patients living with unstable diabetes and related complications are managed by the diabetologists in community based Diabetes Centres. Their follow up (including the assessment and screening for complications) is in accordance with their individual care plan and review (*Red*).

Patients can be referred to medical specialists in the hospital and/or community services if required.

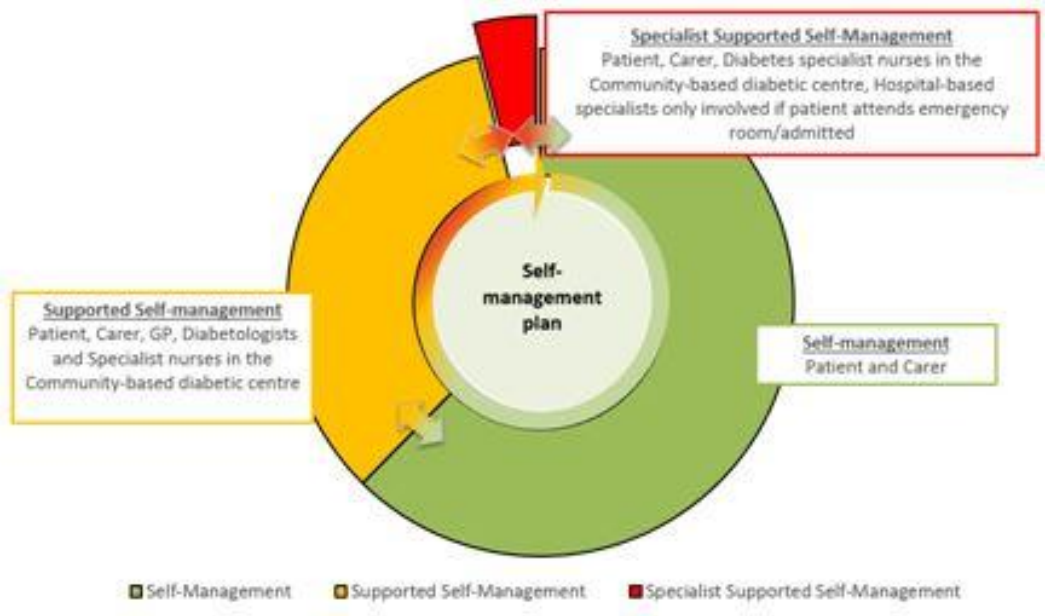


Figure 15: Campania: Diabetes care service model

U4H telehealth enabled diabetes care management

The telehealth service is only offered to patients living with unstable diabetes and related complications, and has been designed to improve the routine care service model delivered by specialists working in the community-based Diabetes Centres by strengthening interventions and support to help patients self-manage (*Green/Amber*).

Patients take and upload their blood glucose readings using the glucometer and telehealth device gateway provided by the Diabetes Centres according to the regime agreed between the patient and the diabetologists (*Red*).

On a weekly basis, a member of the patient's care team reviews the patient data uploads received, and contacts the patient by phone, SMS or email if data is missing; they will offer the patient additional telehealth training and support if it is considered necessary. If the data upload review shows that a patient's blood glucose readings are outside their agreed parameters, the care team member will seek advice from the diabetologist on how to proceed. The diabetologist would contact the patient to elicit additional information to assess the severity of the situation, and take one or more of the following actions:

- health coaching to reinforce their diabetes self-management education, psychosocial support and/or motivational guidance, in order to improve their adherence to their self-management plan and to facilitate lifestyle changes;
- self-management plan changes, e.g. diet or activity level;
- an unscheduled outpatient consultation for further investigations or if a change in their blood glucose monitoring regime is required.

Remote contacts with the patients are by e-mail, text or telephone according to the preferences, capabilities, and individual needs of the patient.

GPs and home nurses, if relevant, are notified when a patient has the telehealth service added to their care plan.

Figure 16: Campania: Diabetes telehealth enabled care model

Figure 17 below illustrates the diabetes telehealth solution configuration and key interactions in Campania:

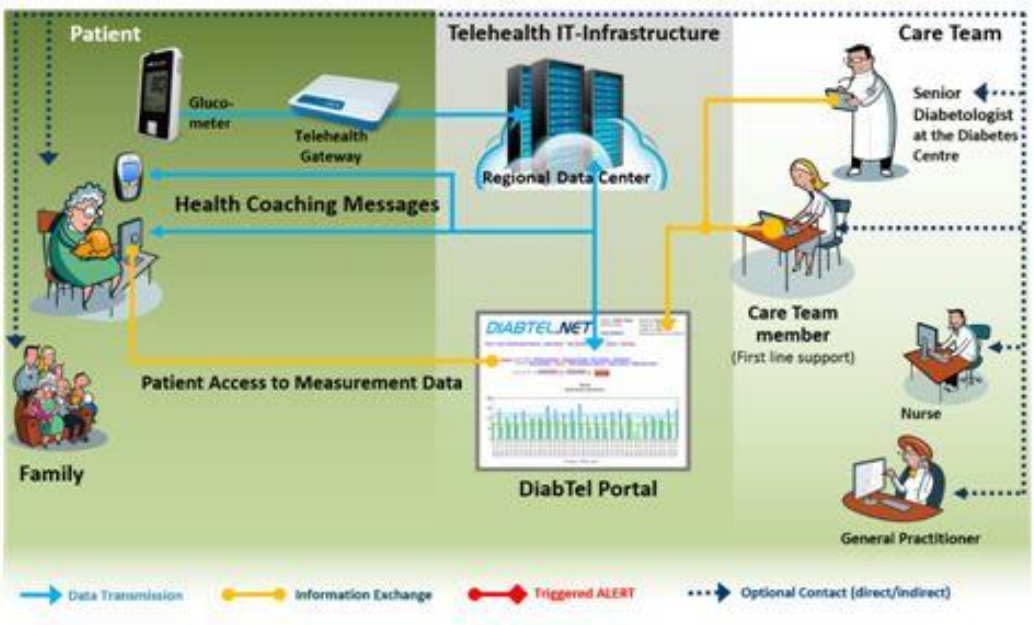


Figure 17: Campania: Diabetes process workflow

2.3.6 ASP Cosenza, Calabria, Italy

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their blood glucose levels is to support and improve the individual patient's endeavours to self-manage and lead a lifestyle to reduce their risk of developing diabetes-related complications.

Diabetes care management – routine care

On a daily basis, patients with Type 2 Diabetes monitor their blood glucose levels (*Green*), with any routine care predominantly undertaken in the community based Diabetes Centres by diabetologists and diabetes specialist nurses (*Amber/Red*). Patients have follow-up appointments according to their individual care plan, and as a minimum are offered an annual review which includes testing their HbAc1, renal function, lipids; measuring their blood pressure, and follow-up / secondary prevention of complications with specialist consultation (cardiology, neurology, nephrology, oculist). Patients can be referred to medical specialists in the hospital if required.

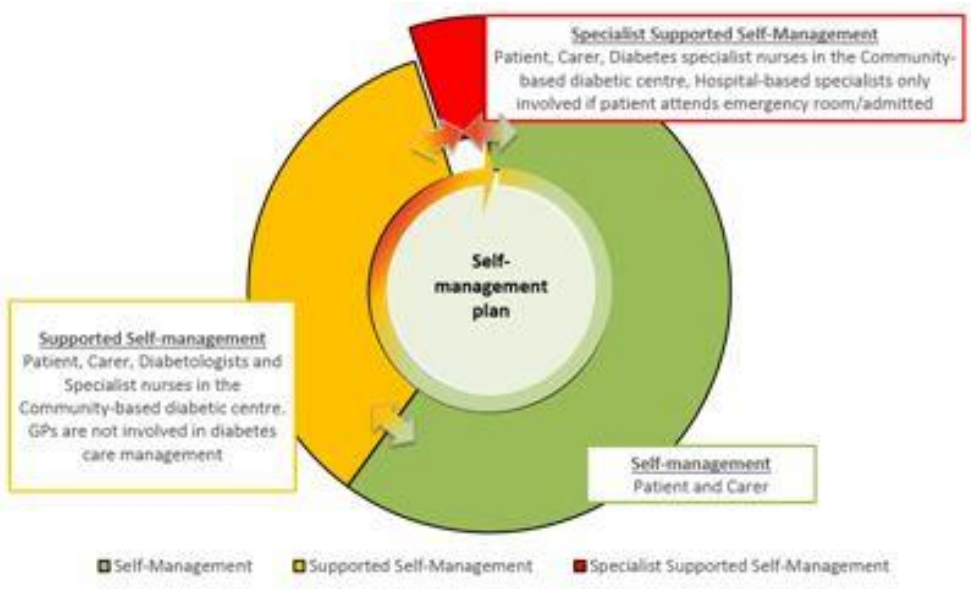


Figure 18: Calabria: Diabetes care service model

U4H technology enabled diabetes care management

The telehealth service has been designed to enhance the routine diabetes care service model by strengthening interventions and support to help patients self-manage (*Green*).

Patients send their blood glucose readings using the glucometer and the Eurotouch Home® PHR according to the regime agreed between the patient and the diabetologists (*Amber/Red*).

Bi-weekly, diabetologists review the patient data uploads received, and contact the patients if data is missing or readings are outside the parameters set for the patient. Patients can be offered:

- additional telehealth training and support if required;
- health coaching to reinforce their diabetes self-management education, psychosocial support and/or motivational guidance, in order to improve their adherence to their self-management plan and to facilitate lifestyle changes;
- self-management plan changes, e.g. diet or activity level;
- an unscheduled outpatient consultation for further investigations or if a change in their blood glucose monitoring regime is required.

Remote contacts with patients are by email, SMS or telephone according to the preferences, capabilities, and individual needs of the patient.

GPs and home nurses, if relevant, are notified when a patient has the telehealth service added to their care plan.

Figure 19: Calabria: Diabetes telehealth enabled care model

Figure 20 below illustrates the diabetes telehealth solution configuration and key interactions in Calabria:

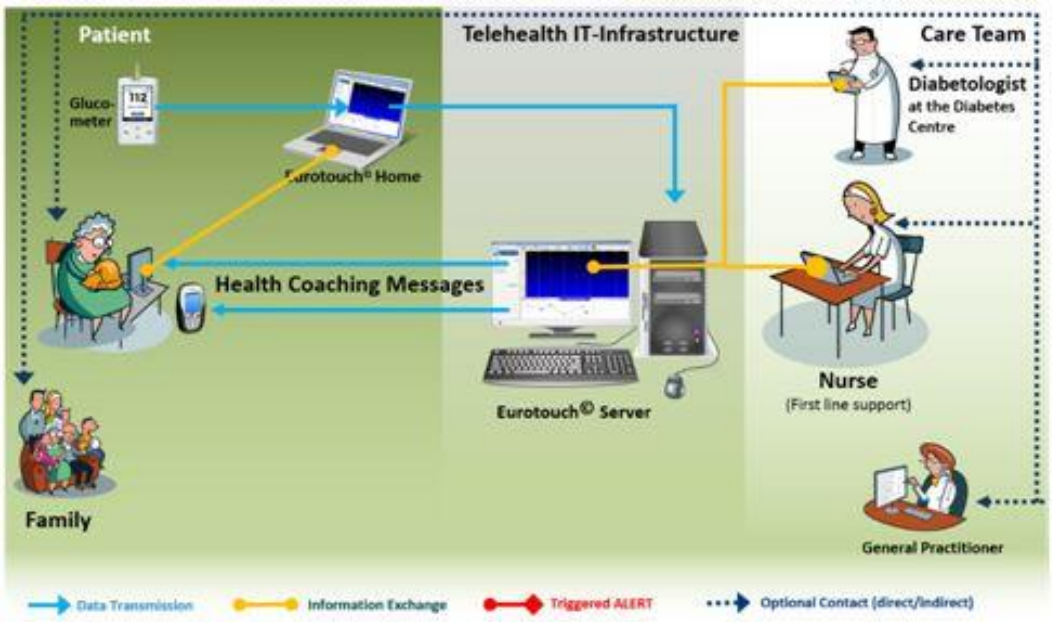


Figure 20: Calabria: Diabetes process workflow

2.3.7 Thessaly, Central Greece

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their blood glucose levels is via the support of a single entry point to existing health and social services. Medical intervention and social support is combined based on the telehealth service, which becomes a catalyst to break the silos between the two different organisations (Regional Health Authorities and Municipal Social Services), aiming to provide an integrated ICT based health and care service for patients with Type 2 Diabetes.

Diabetes care management – 'routine care'

Routine care for patients with Type 2 Diabetes is undertaken by the patient themselves (*Green*), supported every three months by their diabetologist / endocrinologist at the outpatient department of the Regional University Hospital (*Red*). In addition, on a monthly or up to three months basis, their family doctor (GP) prescribes their medication and give advice when needed (*Amber*). Patients are invited to have, as a minimum, reviews include testing their HbA1c and blood pressure every three months, and an annual assessment of renal function and lipids, and undertaking a micro vascular / neuropathic assessment, and providing them with health and lifestyle advice as part of each consultation. In addition, patients receive a retinopathy screening appointment annually. Patients can be referred by their family doctor (GP) to other medical specialists in a hospital.

In case of an emergency, the patient has to refer themselves to the EMS (emergency medical services).

Any patients with comorbidities, disabilities or lack support from informal caregivers, are eligible to receive home care nursing services provided by the Municipalities.

Figure 21: Central Greece: Diabetes care service model

U4H telehealth enabled diabetes care management

In addition to routine care, individual patients were equipped with light-weight handheld physiological measurement devices as well as a suitable mobile phone to undertake regular telemonitoring as part of their self-management (*Green*). They received training on the telehealth equipment from nurses within the municipal homecare service (*Amber*). Patients record their vital signs at home; these are then uploaded (via the telehealth centre) to the Regional University Hospital of Larisa (endocrinology clinics), over internet and GPRS. The diabetologist reviews the telemonitoring data and provides feedback to the patient by phone or via a request for a physical consultation in the outpatient department (*Red*).

The telehealth service has been designed to help patients self-manage and enhance the routine diabetes care service model delivered by health professionals working in home care settings by strengthening self-management with health

coaching interventions and support. The homecare service has been expanded to include patients who have health problems, as well as those to those with social needs and disabilities. Access by patients to their diabetologist/ endocrinologist is also more frequent than the routine care model.

In case of an emergency, the patient has to refer themselves to the EMS (emergency medical services). The telemonitoring does not provide an emergency service.

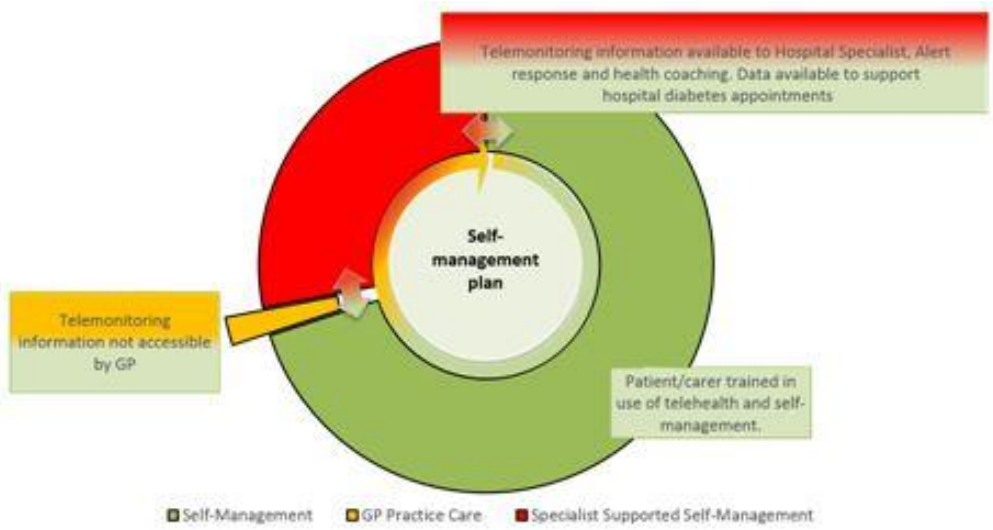


Figure 22: Central Greece: Diabetes telehealth enabled care model

Figure 23 below illustrates the diabetes telehealth solution configuration and key interactions in Central Greece:

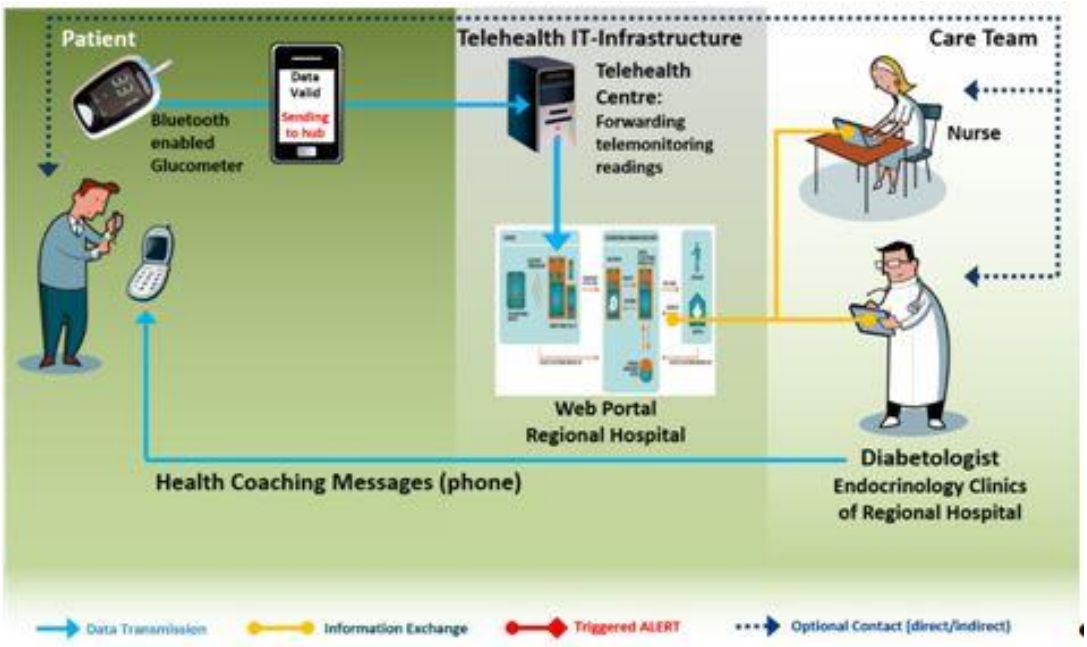


Figure 23: Thessaly: Diabetes process workflow

2.3.8 Berlin, Germany

Ambition

The overall aim of implementing telehealth into the care management programme for patients living with Type 2 Diabetes who monitor their own blood glucose levels, or have help to do so, in the Berlin deployment site is to reduce their risk of developing diabetes-related complications and improve self-management where appropriate.

Diabetes care management – routine care

The provision of diabetes services in Berlin is complex. U4H has included the Pflegewerk healthcare provider which delivers the diabetes disease management programme (DMP) as part of its integrated care contract with health insurance companies. Some patients live in their own home or flat fully independently, take their measurements on their own, and are visited by the nurse as needed (*Green*). Others live in their own home and are visited regularly, but still take their measurements independently (*Green*). Some patients involved in U4H live in assisted living units that belong to Pflegewerk, where they are assisted to take measurements regularly (*Amber*), but they still conduct a fairly independent lifestyle, with community rooms where they eat, chat, play cards, watch TV and conduct social life all together. Those patients in most need live in nursing homes, where they are supervised 24/7; nurses take the measurements and provide the necessary care (*Amber*).

The DMP, following clinical practice guidelines published by various national and international diabetes agencies, is delivered by a wide range of professionals including GPs, consultants, specialist diabetes teams, as well as other primary and secondary care professionals.

Pflegewerk are contracted to provide regular face-to-face visits to the patient's home by GPs or specialist doctors and nurses. During these visits, the patient's health and wellbeing is reviewed, and their care plan and self-management plan adjusted accordingly.

Patients receive specialist diabetes care when they attend the emergency department or have an emergency admission to hospital (*Red*).

Figure 24: Berlin: Diabetes care service model

Telehealth enabled diabetes care management

Berlin provides life-long monitoring services for patients living with diabetes. Patients either take their own weight, blood pressure and pulse and blood glucose measurements with a frequency prescribed by the specialist on first contact (in the project the frequency was once a week at least, unless prescribed differently by the doctor), or they are assisted in using their telehealth or have their measurements taken for them by a nurse. The system uses Bluetooth technology to transmit the readings to a smartphone which then uploads the data to a central database as well as into the electronic Patient Health Record (PHR). The telehealth system generates alerts if measurements are outside the patient's personalised parameters and according to the service protocol. The alerts are sent to one or more people, such as doctor, care home nurse, family member, patient themselves, or other person explicitly authorised by the patient in order for appropriate action and/or response to be taken. These authorised members of the patient's care team can access the PHR to gain further information on the health status of the patient. Remote contacts with the patients are by telephone.

Pflegewerk have plans to integrate the telehealth data into the patient management software and the central electronic patient health record in Germany.

Figure 25: Berlin: Diabetes telehealth enabled care model

Figure 26 below illustrates the diabetes telehealth solution configuration and key interactions in Pflegewerk, Berlin.

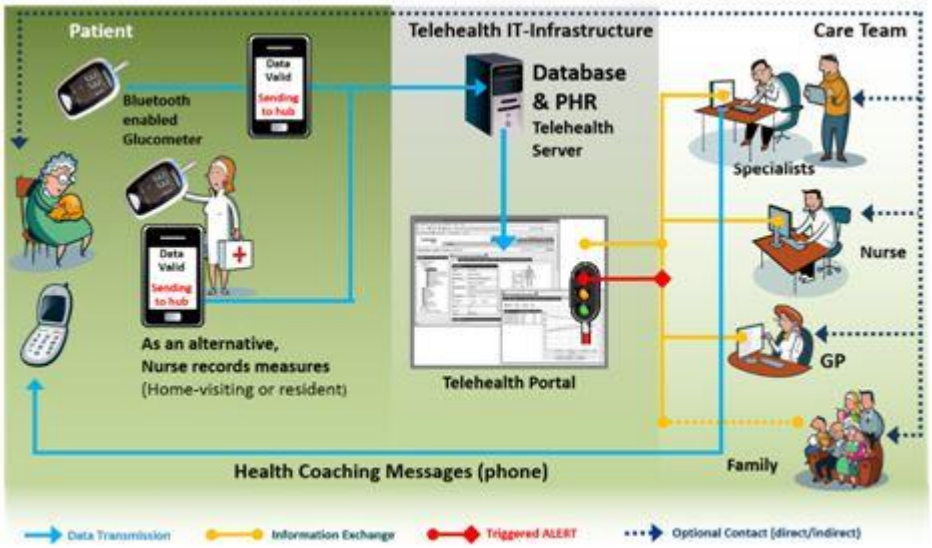


Figure 26: Berlin: Diabetes process workflow

2.4 Requirements

2.4.1 Scotland

Equipment

No new hardware has been installed for this project.

Access to all the components of the diabetes technical solution is via the internet:

- MyDiabetesMyWay (MDMW) is an established website.

- SCI-Diabetes is a real time, web-based clinical information system available to all clinicians in Scotland supporting the care of all people with diabetes.
- Diasend offers web access for both clinicians and patients. However, access will be encouraged via MDMW, which will give users the full services / support / information available via this nationally supported website.

Web access will be via existing computers with internet access.

Patients will continue to use their current home blood glucose monitoring device. Diasend supports the upload of information from most (but not all) of the devices used in the Scottish diabetes service. A USB cable will be required; this usually comes with the device. Note: Roche Accu-Chek® meters require an Actisys IR wireless download cable (ACT-IR224UN-Li). All other devices require their corresponding USB cable.

The patient will download software onto their home computer to facilitate the upload of data from their blood glucose monitoring device.

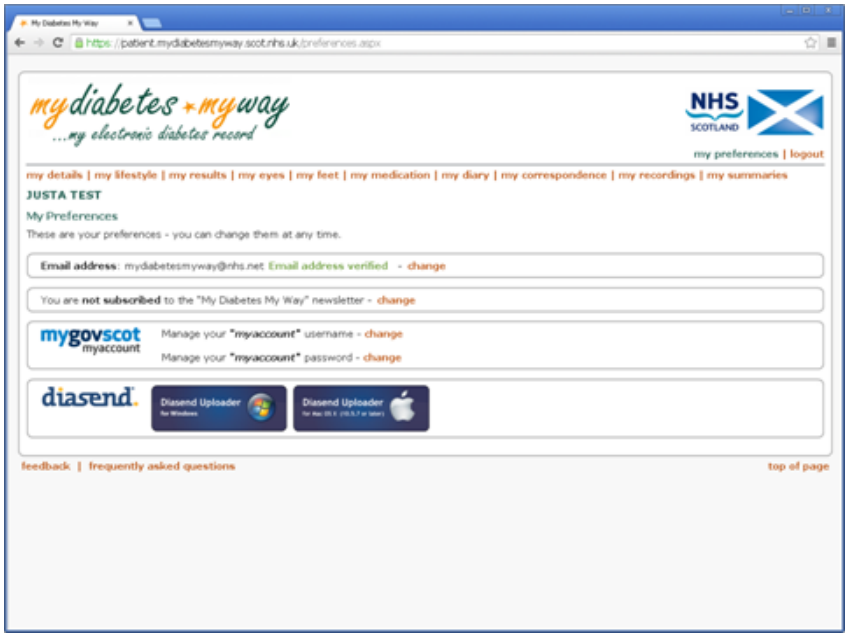


Figure 27: Scotland: MyDiabetesMyWay

Patients will receive a personal account which will be registered with Diasend; the process is yet to be defined as part of integration work being undertaken at present. After the registration process, they will be able to install Diasend® Uploader onto their PC or Mac (Windows XP, Windows Vista, Windows 7, **Mac: OS X 10.5.7 or later). The instructions for installation pop up on the computer screen to download and run the installation file.

Following installation of Diasend® Uploader, the USB cable will be connected to the computer and the device drivers will be installed. The user will then connect their device. The first time users transmit from a device, they will be asked to validate their user account, by typing in username and password.

Training needs - patients

MyDiabetesMyWay

The MyDiabetesMyWay website is constructed principally for the users, i.e. people who have diabetes, and their family and friends; it is very user-friendly in navigation, usability and language. Using the website to find information, coaching and patient access to own test results, clinic letters and treatment plan does not require exact training; patients and their relatives involved in the project can use the guidelines and user advice available on the website.

A video was developed to support patients with registration and enrolment on the website: www.youtube.com/watch?v=yRwZ_Xgv7cE.

Diasend

Patients receive instructions both orally and in booklet form at the diabetes clinic from a member of the Diabetes Team on downloading Diasend software via MDMW website. Patients are also shown at the clinic to how to connect their meter to PC / laptop to download their blood glucose readings. Patients are advised to contact the Centre if they experience any problems or require any additional support to use the software.

A website link offering patients additional support and information about Diasend has been developed on the MDMW website:
www.mydiabetesmyway.scot.nhs.uk/diasend/

Training needs - healthcare professionals (HCPs)

MyDiabetesMyWay

MDMW is not directed at healthcare professionals, but the same information in the system is accessible to them as to patients and their relatives. Staff who are involved in recruitment and registration of patients have been provided with refresher training, and opportunities to test the new resources on the website, with the intention that this promotes further patient registration.

Diasend

Some of the health boards currently use Diasend within their outpatient clinic environments, so additional training in this web interface is not anticipated. However, training in the new software registration process was required.

A series of training sessions have been designed and delivered to all clinical staff across all three pilot sites in Scotland (60+) from the MDMW development team, U4H project team, and Diasend representative. In addition, to support use of the new Diasend software, a user guide for Diasend registration has been developed for staff alongside a quick reference guide to support HCPs, consultants and GPs to register patients and view results.

Training programme consists of:

- New patient registration process on the Diasend website.
- MDMW registration using SCI-Diabetes.
- USB cable compatibility & testing.

- Accessing Diasend data on MDMW.
- Supporting patients and carers in the use of Diasend.
- Support for clinics using a Diasend transmitter.
- Trouble shooting solutions.
- Where to access further Information and support.

2.4.2 Wales

Equipment

The devices used for telemonitoring will be the patient's own, unless they do not already have one, in which case one will be supplied by their GP surgery as part of their routine care. The mobile phone used to transmit the glucose readings will once again be the patient's own; if they do not possess one, they will be provided with one by the lead Research Nurse. Patients who are provided with a phone will only be able to use it to send and receive telemonitoring messages; it will not have the capability to send or receive telephone calls, additional text messages, etc., and the participant must return it at the end of the study period. Transmission of the results is provided via a free number, and so there are no cost implications for patients. The software is the Florence system.

Training - patients

Patients within the Welsh trial are primarily those who already self-monitor their blood glucose levels, and so little or no training is expected to be given regarding the taking of blood glucose measurements.

Where training is given, on an individual basis, as provided by their healthcare professional, it is with respect to the interaction with the Florence software system. This is the system that they use to upload their results via a mobile telephone (texting function), and via which feedback messages and lifestyle coaching messages are also relayed back to the patient by use of a mobile telephone.

2.4.3 RavKor, Slovenia

Equipment and supplies

Each diabetes patient using telehealth support has:

- Glucometer (Cignus Profiline TM-TD4279 BT) with a built-in Bluetooth interface.
- Adequate test stripes.
- Lancets.
- Smart phone with a HIS telemedicine app serving as a gateway.

The gateway and the glucometer are matched and personalised prior being provided to the patient. As scheduled by his/her doctor, the patient performs glucose measurement as with an ordinary glucometer. After the result is displayed on their glucometer, the patient removes the test stripe and activates a button to send data to the hospital server. No other action is needed on the patient side.

Training of patients

A group of experts in the treatment of diabetes and providing telehealth service gives trainings to diabetes patients who are candidates for using the telehealth service. Training is organised for groups of up to 20 patients together with their relatives at the premises of SB-SG or RavKor.

Patients meeting U4H project diabetes inclusion criteria and who are mentally, cognitively and socially well, are personally addressed and invited to participate in the study at their regular visits to the specialist at the SB-SG Hospital or RavKor healthcare centre. Those who agree are invited for scheduled training in the use of the telehealth service; the purpose and methods of telemonitoring are explained. They are shown how the service functions. If they decide to participate, they obtain instructions for telemetric measurements, and are provided with user manuals for the equipment. Individualised telemonitoring equipment with a smartphone for connectivity is provided to the patient with instructions for use, contact for potential emergency situations, and service termination. They do the first few test measurements with their personalised equipment under supervision of the demonstrators. At the end of the training session, each patient has an initial interview where he/she confirms the decision to use the telemonitoring service.

In 2014, over 15 training courses that lasted about two hours each have been organised at which 220 diabetes patients participated. Experiences that have been gathered confirm that a group of 20 patients (some older patients were accompanied by a relative) is manageable if a group of four demonstrators is available, and everything is already in place (patient registrations in the database) and the equipment is personalised (matched measurement equipment and the smartphones, equipment linked to the patient's electronic record). It has also been noticed that patients rely on the information given at the training, and do not read the written instructions provided. Consequently, the training courses have become more exhaustive and last longer. This may influence a reduction of the training group size.

Training of medical staff (DM & CHF)

The medical staffs at the SB-SG Hospital and the RavKor healthcare centre have received dedicated training on the telehealth service, highlighting the provider's as well the patient's point of view. It was conducted by the subcontractor's technical staff (MKS Ltd. Ljubljana). The training was attended by health specialists / doctors (5), nurses (3), coordination staff (2) as well as administration staff (2) involved in the U4H project. First they were shown how the equipment is used by a remotely monitored patient. Then, each of the trainees tested at least one measuring device, providing several measurements. Data were monitored over two dedicated portals. Later they split into two groups: the first acted as monitored patients, the second as a telemedicine service centre coordinator.

Two nurses that serve as educators, patient data managers and telemedicine centre operators received additional training on the use of both portals. They are provided with permanent technical support from the subcontractor's technical staff.

In addition to the training, a temporary group was established (two physicians, two nurses, two engineers) to determine a process of patients' inclusion and to prepare and confirm relevant documentation for the patients: invitation, consent, user manuals, instructions for emergency, leased equipment list, etc.

2.4.4 Northwest Moravia, Czech Republic

Using the telehealth application requires medical devices (glucometers) and mobile gateways. The main supplies needed are test strips for glucometers. We found out that it is very important to provide quality technical telephone support for patients, as they have some difficulties handling Android smartphone.

Our biomedical engineers prepared sets of devices for each patient; this means creating patient's accounts on telehealth portal, installing android app, preparing sets (Bluetooth pairing, etc.). It is very important to educate each patient properly about using glucometers and smartphones with application. The length of training depends on if patient uses smartphone in ordinary life, and usually takes 30 to 60 minutes. Training for staff was really quick, as application is accessible via web browser with secure login; it is very intuitive for doctors and operators.

2.4.5 ARSAN Campania, Italy

In the observational study in the Campania Region, the enrolled patients:

- Must have the availability of:
  - a domestic ADSL connection, in order to allow the transmission of the measurements taken with the glucometer;
  - a telephone line to receive urgent communication from the healthcare professionals in case of need, or to contact the technical help desk.
- Should have the availability of:
  - a personal computer or a similar device with a browser in order to access to the Diabtel.net web-based platform;
  - contact details for receiving short message via email and/or SMS from the healthcare professionals.

In the enrolment phase, patients are equipped with a standard glucometer and gateway, bound together for licence and data management.

In addition to the standard training and coaching about the disease and its care, training is provided to use the telehealth service:

- the use of the glucometer, also provided regularly in standard care;
- the procedure to transmit the collected measurements, which is user-friendly;
- how to install the gateway at home; this activity is also supported by a technical help-desk which can be contacted by phone, and, if needed, on-site visits.

Equipment and supplies in use for the healthcare professionals include:

- a personal computer or a similar device with a browser and an internet connection to access the web-based Diabtel.net platform;
- a telephone line to call patients needing remote care, and the services to send short message via email or SMS to patients.

Healthcare professional involved in the observational study are trained on:

- the care pathway supporting the telehealth service;
- the functioning of the Diabtel.net web based platform;

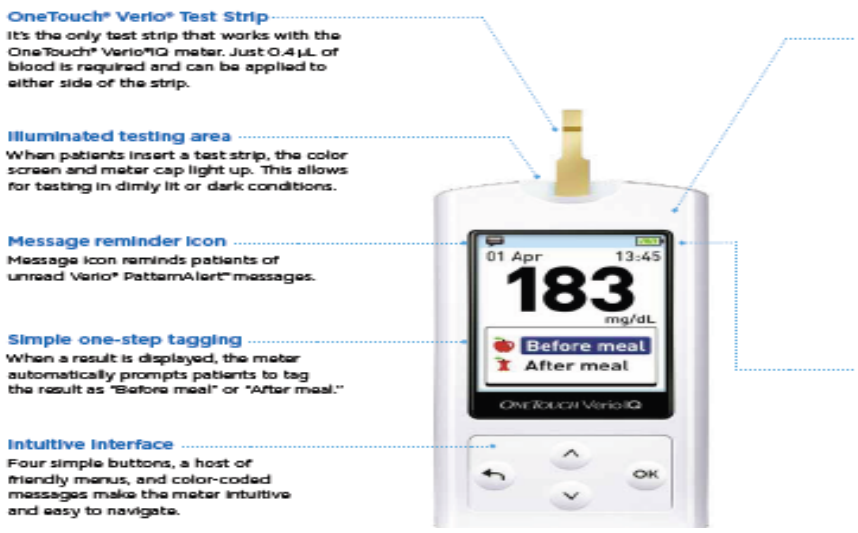
- the overall objectives of the U4H project, and the required data management.

2.4.6 ASP Cosenza, Calabria, Italy

Equipment and Supplies

Self Monitoring Blood Glucose (SMBG) Meter OneTouch® Verio®IQ

- No-code convenience.
- Automatically detects control solution.
- Test time: 5 seconds.
- Glucose range: 20 mg/dL – 600 mg/dL.
- Haematocrit range: 20% – 60%.
- Temperature range: 6-44°C - Humidity: 10% – 90% (non-condensing).
- Download of glycaemic data by plug and play connection to Software EUROTouch HOME (see above).



Software

Home patient software: EuroTouch HOME, downloadable from www.lifescan.it after registering and logging in.

Hospital / Diabetes Centre software: EuroTouch is a management software program with clinical experience of more than 20 years. EuroTouch incorporates: 1) analysis of glucose results, insulin intake and activity exercise on a model day; 2) analysis of paired glucose testing; 3) charting of patient laboratory tests and complications; 4) comparison from visit to visit lab testing and charting; as well as other functions.

The main clinical advantages of EuroTouch: it allows monitoring and following up of all aspects of a diabetic patient from the initial diagnosis; it helps professionals optimise time and resources since all data can be found on the same device. This has positive results for the self-evaluation of the daily clinical practice and the reduction of long-term complications.

Main administrator / doctor privileges and instruments: administering passwords and guaranteeing privacy; controlling the list of supported devices in the system per user; patient clinic management (anamnestic records, diagnosis, complication / co morbidities monitoring, therapeutic decision); and printing out medical exams.

Training - patients

It should be noted that the pre-selection of patients, carried out during periodic medical controls, includes a brief explanation by the diabetologist on the objectives and operating procedures of the study. During the pre-selection, the diabetologist asks the patient if they have a computer with Internet access, and if they know how to use it. Alternatively, the patient is asked if their caregiver (often a family member) can manage transmitting the blood glucose data via a computer. The preselected patients would have been measuring the values of blood glucose for some time. They monitor the values at home via a glucometer, according to the schedule agreed with the diabetologist.

The following materials have been provided to the patients by the diabetologists and the cooperating nurses of ASP Cosenza:

- Information for the patient form.
- Information for the GP form.
- Informed consent form.
- User manual OneTouch Verio IQ Lifescan glucometer with profile detector.
- Lifescan Italy explanatory demo; a file illustrating the procedure for the acquisition and transmission of the home measured blood sugar levels.
- Web address to use to download the app for exporting data.

The patients previously preselected are contacted by phone by the nurses of the site for special training sessions, at a rate of 10-12 patients per session and for a total of three hours.

The groups have been provided with full explanations on the objectives of the project by the diabetologists during the training sessions. In addition, the registered nurses and a technical representative of Lifescan Italy have explained how to use the meter, and the procedures for the transmission of blood glucose data via the Internet. There are opportunities for discussion and practical demonstrations, as well as the help of demos. If necessary for the purpose of transmission via computer, the patients will be accompanied by their formal and informal caregivers, who are already sufficiently experienced in data transmission. During the training sessions, the nurses and the representative of Lifescan have provided the *Information for the Patient* forms and OneTouch ®Verio® IQ glucometer with profile detector, with its user manual. Finally, the patients can either sign the informed consent or fill in the Reasons for rejection form.

Training - HCPs

During the first meeting of training at the end of February 2014, the following topics were covered:

- Explanation in outline of the European project.
- In-depth analysis of the operating protocol of ASP Cosenza.

- Dissemination and explanation of the information models and informed consent.
- Work organisation: changes and additions to the current ordinary work.

Another two meetings took place at the end of March and the beginning of May, involving all the HCPs of the U4H project in ASP Cosenza. During these meetings, technical and operational procedures were addressed. These two meetings were conducted with the assistance of the technical representative of Lifescan Italy.

The first meeting to review and develop the pilot project on diabetes of ASP Cosenza took place at the beginning of July 2014.

2.4.7 South Karelia, Finland

The web PHR application is a web-based application providing the functionalities to view and manage personal health data stored in the PHR database, and to support the self-management process. The application provides user interfaces for patients, care personnel and administrators. All interfaces shall be browser-based. The core functionalities are:

- Storage and management of personal health data entered by the patient, providing the possibility to view data entered by patients and care personnel.
- Support of safe messaging (off-line) between patient and care personnel based on secure https connection between the browser and the self-management server.
- Creating and maintaining personal self-management plans.
- Rule-based provision of alerts, reminders and feedback for patients and caregivers.
- Protection of information against unauthorised use.

All patients, who are included in the trial, will get training to use PHR via Eksote´s e-Health services. Training will be group training, or the patient will get information in the baseline visits with nurse / project worker.

2.4.8 Thessaly, Central Greece

2.4.8.1 Training of patients

Patients in this cluster are equipped with a mobile phone and a personal wireless blood glucose / blood pressure meter. They are able to systematically measure their blood glucose with this device from their home. The only thing required is to connect the specialised device with a mobile phone through a Bluetooth connection, and transmit the measurement data to a central server via the existing mobile telephone network. Medical staff are able to check the data, and provide updates and advice to patients regarding the treatment of their disease.

Approach to training

The training was carried out by the study nurses of the Renewing Health trial, and took place in groups within the hospital. Training was completed in one day. It varied in content and duration, depending on the disease and the process to be followed for each device. It was interactive, in the sense that every question was followed by an immediate response with simple examples, skipping if necessary the normal flow

of the course. For every cluster, the appropriate set of devices was displayed. The main idea was to demonstrate a number of realistic everyday life scenarios, introducing patients to the potentials of the equipment and the ease it provides. Firstly, the main part of the equipment was demonstrated, the specialised device. Its basic functions were briefly explained, and compared with the conventional ways of measuring biomedical signals. The second part demonstrated was the mobile phone. This device receives the measurements from the specialised device and transmits the biomedical data to the proper target (e.g. PC, mail, other mobile phone, etc). At the end of the training session, each patient was asked to perform a complete measurement in the presence of the study nurse. Patients were visited by the study nurse after one week, and were asked to perform a complete measurement, in order to ensure the proper use of the equipment.

Preparation of training material

Training material was divided into two sections: the proper use of the specialised equipment, and the performance of medical measurements, and transmission of data through the mobile phone device.

During the training process, patients were given educational material, such as an introduction to the eHealth applications and user manuals, included in the bag-pack of each device. More specifically, they were given:

- eHealth educational material.
- User manual for the devices to be used (cardiograph, spirometer, glucose meter, blood pressure).
- User manuals for the software of biological telemetry.
- User manuals for the software for receiving/transmitting medical data.

2.4.8.2 Training of staff

The following three categories of healthcare professionals required training: nurses, doctors and technicians. The training of each professional category was completed in one day (three days in total for all three categories), and varied in content and duration, due to different levels of detail necessary for each one. Training was interactive, in a sense that every question was followed by an immediate response with simple examples, skipping if necessary the normal flow of the course.

Approach to training

The training was carried out by experts of the technical provider (subcontractor). Depending on the healthcare professionals' category, a different level of detail was needed regarding the functionality of the equipment. In addition, different training regarding the functionality of the specialised devices was required for doctors.

The flow of the training had many similarities for all healthcare professionals' categories. Firstly, a general introduction to eHealth and applications was given, followed by a presentation of the conventional methods of measuring bio-medical data, and an explanation of the way these measurements can be taken by the specialised devices. The primary goal was to emphasise the ease that the project can provide to both sets of end users, the user / patient, and the doctor or nurse. An additional goal was the demonstration of a number of everyday life realistic scenarios, aiming to introduce the 'medical professionals' (doctors, nurses) to the potential of the equipment and the convenience it provides. This demo started with the presentation of specialised devices. Depending on the professional category, different levels of detail were explained about the functionality and abilities of the

devices. The simplest level of detail was shown to nurses; doctors had to learn all the capabilities of the devices regarding the medical measurements; while the technicians were trained in the total technical capabilities of the devices; the technicians, were trained so they could substitute the role of the expert performing any kind of troubleshooting, providing at any time advice and additional training to all other categories, from patients to doctors. The use of the mobile phone was also explained to the technicians.

Preparation of training material

Depending on the professional category, different training material was used.

Study Nurses

The study nurses were trained in the use of the specialised devices and the management of the online electronic medical folder (software for displaying bio-medical signals). The following training material was provided:

- eHealth educational material.
- User manual for the devices to be used (cardiograph, spirometer, glucose meter, blood pressure).
- User manuals for the software for bio-medical telemetry.
- User manuals for the software for receiving / transmitting medical data.

Doctors

Training courses for doctors (endocrinologists) focused on the use of the specialised devices and the management of the online electronic medical folder (software for displaying bio-medical signals).

During doctors' training, the following training material was provided:

- eHealth educational material.
- User manuals for the software for biological telemetry.

Technicians

Training courses for technicians focused on the use of the specialised devices and the management of the online electronic medical folder (software for displaying bio-medical signals), to a high level of detail.

During technicians' training, the following training material was provided:

- eHealth educational material.
- Technical manual for the devices to be used (cardiograph, spirometer, glucose meter, blood pressure).
- Technical manual of the system.

2.4.9 Berlin, Germany

For the application in Berlin, the following equipment and supplies were needed:

- Weight scale.
- Pulse-oxymeter.
- Blood sugar meter with the test stripes.
- Smart phone with the android operating system.

All these devices have to be capable of transmitting data via Bluetooth, and the smart phone must have an active internet connection (either via WiFi, or via UMTS or similar). In addition to that, they have to be equipped with appropriate software to ensure the safe transmission of the data.

At the other end, a computer with internet connection was needed to be able to access the database and display the data. The people who are expected to receive alarms must have an e-mail address, a fax machine or a mobile phone to receive texts (SMS).

The training needed for users is mainly on the application for the smart phone. It is assumed, and is indeed normally so, that both patients and staff are able to use the measuring devices, because they do not differ from the kind they are used to in their normal life. The only new part was this application, which is however very simple and can be learned very quickly. Although the application runs on any Android-based smart phone, it was advisable that one be chosen with a fairly large display in order to be able to read the names and the messages on the screen. This was especially true for older people with difficulties in seeing or understanding small text.

We estimated the time needed for a nurse to learn the application is two hours, and for a patient one week.

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)[x] in a study of the implementation of the WSD, the randomised design may result in a number of practical problems for the organisations who 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, United4Health 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 of efficacy demonstrated in several efficacy trials[xi], and are based on:

- Long follow-up period which allows for registering and monitoring long-term clinical effects and safety data [xii].
- 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 [xiii].
- 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 [xiv].

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 has assessed the real-life effectiveness of the trialled services with a high degree of external validity and generalisability of the results.

The observational study has used as a comparator group the total population of the patients fulfilling the eligibility criteria who have been treated and followed for at least one year before the implementation of the telehealth service, and 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 (Domains 4, 5 and 6).

The sites have sent all the collected data to the central database managed by Arsenal IT in a pre-agreed format. These files have been merged, so that the relevant pilot-level files have been produced in csv formats. These latter files have been sent to the evaluation team. The evaluation team, using statistical programming in IBM SPSS statistics software, analysed these data, produced new indicators and variables, and delivered the results of the analyses, in accordance

with the agreed analysis plan, to the WP leaders, the management team and the sites.

In the case of diabetes, the following files have been used for the statistical analyses (created on 16th October 2015, available to the evaluation team on 19th October 2015, start of analysis on 20th October 2015):

For DM:
1. DM_ENR
2. DM_12M_CD
3. DM_12M_ECON
4. DM_12M_ECON_TELEMED
5. DM_18M_CD*
6. DM_18M_ECON*
7. DM_18M_ECON_TELEMED*
8. DM_END_WSD

** Because of the delay in the recruitment, it was agreed that all the collected data (even if longer than 12 or 18 months) would be submitted in the 12-months excel spreadsheets.*

Additional files have been provided by the Scottish site directly to the evaluation team, in accordance with the protocol and the agreed codebooks, e.g. the sub-population of the Scottish diabetics using the MDMW services, and data for the deployment group (users of the U4H services who were not part of the evaluation group).

The primary and secondary outcomes will be presented as raw data, but they will also be presented adjusted for the length of follow-up for each individual patient.

Because of the different approach of the Berlin pilot, the diabetes Scientific Committee decided at the Project Assembly in Prague (September 2015) that the primary and secondary outcomes will not include Berlin, and that regression analyses would have to be performed excluding Berlin.

Significant efforts have been made in order to allow better stratification of the study population. The primary and secondary outcomes of the project have been estimated and compared for different subpopulations of the project population, based on the different stratification criteria presented during the second annual review. The scope of this additional analysis is to identify possible sub-populations who could benefit more from the U4H services.

The analysis of the clinical data followed the Guideline for reporting of observational studies by Elm et al. (2007). Thus, the tables were divided into:

1. Participants.
2. Descriptive data.
3. Outcome data.
4. Main results (unadjusted and adjusted).
5. Regression analyses.
6. Other analyses.
7. Telehealth resources.
8. Limitations of Study.

3.2 Methods: Participants

The eligibility criteria were a diagnosis of Type 2 Diabetes, and already in home monitoring of blood glucose. Optionally, patients with Type 1 Diabetes were eligible to participate in order to ensure recruitment of the total sample size.

Potential participants were selected by screening electronic healthcare records and/or hospital / national databases and/or during long-term condition annual reviews in the community setting. Candidates in the intervention group were informed about the nature and the objectives of the intervention. Once candidates had signed the informed consent form, they participated in the study, or, in the case of Scotland, if patients were happy to participate (which required no consent form).

3.2.1 Scotland

Eligibility is defined in the Clinical Protocol (D3.1 v1.5 Scientific Study Protocol). In Scotland, patients with a diagnosis of Type 1 and Type 2 Diabetes were eligible for recruitment. All eligible Type 2 patients undertook HBGM as part of their diabetes management plan. The comparator group was retrospective in nature, consisting of the same patients one year prior to inclusion in the intervention group.

As the diabetes intervention in Scotland was internet based, participants' only requirement was that they have regular access to a computer / laptop, and have suitable hardware.

All patients with a diagnosis of Diabetes are eligible to register for MDMW following appropriate authentication by a HCP.

3.2.2 Wales

Patients in Wales can self-refer, but were subject to the same consent process in order to participate.

3.2.3 Slovenia

Patients with a diagnosis of Type 2 Diabetes (DM Type 2) that already performed home monitoring of blood glucose were enrolled into the telemonitoring service. Patients with Type 1 Diabetes were also eligible to participate.

Participants were selected by screening their electronic or paper-based healthcare records or/and the hospital databases. Candidates in the intervention group were informed about the nature and objectives of the intervention. Once candidates had signed the informed consent form, they participated in the study.

The comparator group of patients in Slovenia was the intervention group itself, but for the period of one year prior to inclusion into the intervention group. Additional members of the comparator group were the patients who for any reason rejected their participation in telemonitoring.

3.2.4 Northwest Moravia, Czech Republic

Strictly followed the U4H study protocol, including eligibility criteria and the setting of study.

3.2.5 ARSAN Campania, Italy

In the observational study in the Campania Region, the eligibility criteria were as follows:

- Patients have a diagnosis of type 2 diabetes.
- They are regularly treated (for at least one year) in one of the outpatient services of the healthcare districts of the Local Health Trust ASL Napoli 1, involved in the observational study.
- They are all at high risk of complications.
- They include patients treated with intensive (or flexible) insulin therapy, as well as non-insulin treated patients.
- Patients should have a telephone line and a domestic ADSL connection, in order to allow the transmission of the measurements taken with the glucometer.

Patient candidates for enrolment in the observational study were selected by screening electronic healthcare records or/and during outpatient visits or annual reviews.

3.2.6 ASP Cosenza, Calabria, Italy

Diagnosis of Type 2 Diabetes and already in home monitoring of blood glucose. Also, patients with Type 1 Diabetes were eligible to participate in order to ensure the recruitment of the total sample size.

Participants were selected during long-term condition annual reviews in the community setting. Candidates in the intervention group were informed about the nature and the objectives of the intervention. Once candidates had signed the informed consent form, they participated in the study.

3.2.7 South Karelia, Finland

The study population consisted of patients diagnosed with Type 2 Diabetes, and who already monitored blood glucose at home. Nurses from the healthcare centres recruited their own patients when the patients came in for their control appointment. Nurses gave information sheets and more information if needed. The intention was that nurses assessed who would benefit from using PHR. They offered the opportunity to participate in research if they felt it to be of benefit to the patient.

3.2.8 Central Greece

Patients fulfilling the inclusion criteria and willing to participate in the telehealth service received the information material about the project and the telehealth service, and were requested to provide written informed consent for trial participation. This was followed by an educational visit to set up the system and explain how it works. After setting up and demonstration, patients are requested to download their measurements from their glucose meter to their mobile phone, and transfer the data to the regional database on a regular basis. The care team (a nurse specially trained and the allocated physician) regularly access the patient's home diary, and will provide the appropriate counselling and medication changes as frequently as necessary. In addition to blood glucose measurements, routine questions about symptoms and eventual difficulties related to diabetes, as well as

diabetic management, will be regularly captured and reported. Patients are offered the option to call the study nurse in case they encounter health problems, or have questions that are not covered by the routine assessment.

3.2.9 Berlin, Germany

The study population consisted of patients diagnosed with Type 2 Diabetes and who already monitored their blood glucose at home. The participants were suggested for participation by doctors or nurses. The nurses provided information sheets and further information if it was needed. The comparator group of patients in Berlin was the intervention group itself, but for the period of one year prior to inclusion into the intervention group.

3.3 Methods: Interventions

Refer to Domain 1 of the report.

3.4 Methods: Outcomes

Primary outcome: Reduction of the number of face-to-face contacts with GP or diabetologist, depending on local pathway.

Secondary outcomes:

- Reduction in HbA1c.
- Number of primary care professional contacts, including GPs, diabetologists, specialised or not nurses, community nurses etc.
- Number of visits to emergency department.
- Duration of use of the telemedicine device.
- Number of outpatient visits (consultant or specialist nurse).
- Number of outpatients visits to a diabetologist.
- Number of outpatients visits to other specialists in charge of the management of diabetes related complications (optional).
- Number of admissions (any admission during 12 months).
- Number of bed days (days of hospitalisation).

The following common, mandatory, data were collected for all patients in the intervention and comparator groups:

- Year of birth.
- Gender.
- Smoking.
- Assessment of comorbidity – ICD-10 (uses specific codes and define accordingly, YES/NO format).
- Insulin (yes/no).
- Date of diagnosis with Type 2 DM.
- Self-monitoring blood sugar (times/week).

In addition, partners could collect the following optional data:

- Has the patient a formal or informal care giver?
- PC user.
- Mobile phone user.
- Education: seven levels.

Patients were evaluated at recruitment and at the end of the study. They were followed and the data was collected for all patients, during a period of 12 months. For the sub-population with extended monitoring, there was an assessment at study start, at 12 months and 18 months.

The outcome measures included are described in detail in the protocol, D3.1 v1.5 Scientific Study Protocol, dated 31st March 2014.

3.5 Methods: Sample size

The following intervention group was identified in the U4H study protocol:

- Scotland: 5,600 (1,200 will receive a telemonitoring device allowing self-monitored blood glucose results to be uploaded to My Diabetes My Way web site (MDMW); 4,400 will be registered on MDMW, which is the NHS Scotland interactive diabetes website to help support people who have diabetes and their family and friends).
- Wales: 400 patients.
- Northwest Moravia: 40 patients.
- Slovenia: 400 patients.
- Campania: 200 patients.
- Calabria: 250 patients.
- South Karelia: 150 patients.
- Central Greece: 70 patients.
- Berlin: 300 patients.

The comparator group will consist of 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 (or MDMW in Scotland), and in the same health units as the intervention group, and whose data are available through EMR or other databases.

The population at the end of project inclusion period was as follows:

Table 1: United4Health project population – Diabetes trial

	Region									
	SC	**WA**	**CAL**	**SK**	**GR**	**GE**	**CZ**	**SL**	**CAM**	**Total**
Evaluation	**270**	**394**	**414**	**42**	**56**	**586**	**3**	**658**	**118**	**2,541**
Intervention group	81	76	189	42	30	293	3	280	22	**1,016**
Comparator group	189	318	225	0	26	293	0	378	96	**1,525**
Same patients before	189	0	225	0	0	293	0	373	96	1176
Other, retrospective	0	318	0	0	22	0	0	5	0	345
Parallel group	0	0	0	0	4	0	0	0	0	4
Deployment	**3,086**	**114**	**48**	**48**	**67**	**2**	**98**	**380**	**113**	**3,956**
Shorter Follow-Up	107	31	18	1	63	0	44	41	2	**307**
No Follow-Up	2,979	83	30	47	4	2	54	339	111	**3,649**
Total	**3,356**	**508**	**462**	**90**	**123**	**588**	**101**	**1,038**	**231**	**6,497**

The table above shows the whole U4H project population for the Diabetes study including evaluation and deployment patient groups. The deployment cohort consists of patients with either a shorter follow up period who were not included in the evaluation, or users of U4H services who were not part of the evaluation group. For Scotland, this category also included the patients from the MDMW deployment sub-group population, a total of 2,644.

3.5.1 Reasons for non-participation

Figure 28 below outlines the broad groupings for the main reported patient barriers experienced by the deployment sites during the project implementing the Diabetes TM solutions.

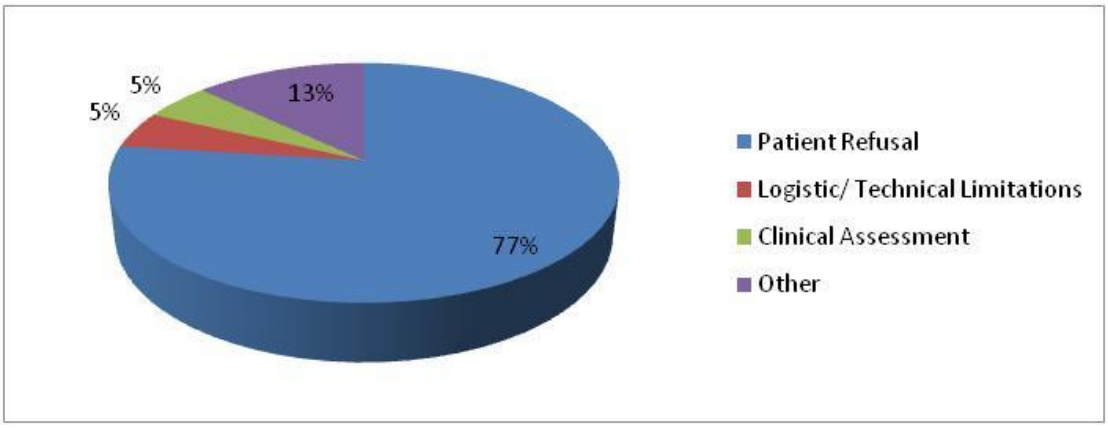


Figure 28: Reasons for non-participation Diabetes

Patient refusal was reported by all sites as the main barrier to recruitment. Consent and permissions procedures within regions was voluntary, and patients were not required to formally provide a reason for this refusal.

3.6 Methods: Statistical methods

The U4H Evaluation dataset (U4H-E) consists of all intervention and comparator group patients followed for a minimum follow-up of six months. For the official evaluation, patients with more than 179 follow-up days (*evalgoup=1*) were selected. Following the intent-to-treat principle, patients are analysed according to the treatment to which they were assigned at randomisation. The analysis of these data has produced the following tables and the main results of this project.

The U4H Deployment dataset (U4H-D) consists of the total number of patients receiving the U4H services and the total number of patients used as comparator group, who cannot be included in the U4H-E dataset either because of a shorter follow-up than accepted in the protocol (*evalgroup=2*), or because this population was not planned in any case to be part of the official evaluation, and so there are missing data (*evalgroup=3*). In addition, additional data for relevant subpopulations receiving the U4H services, or services complementary to U4H services, have been collected, e.g. MDMW (*evalgroup=4*).

The main biochemical indicator for monitoring diabetes is HbA1c. Officially, there is worldwide consensus that HbA1c should be reported in both NGSP (%) and IFCC (mmol/mol) units. However, the decision on what to report is actually being made country by country. The ADA, IDF, EASD, and ISPAD as well as other member associations in different countries, currently provide patient care guidelines that relate directly to NGSP (%) (DCCT/UKPDS) numbers. Diabetic patients with HbA1c less than 7.50% are considered **controlled patients**[2].

New variables were created / calculated to further increase the value of the collected data and the produced evidence, e.g. age, Body Mass Index (BMI), Charlson Comorbidity Index (CCI), Age-adjusted CCI (AACCI), etc., and existing variables were recoded to fulfil the purpose of the analysis, e.g. age, CCI, controlled, etc. Incidence rates of outcomes were calculated as the number of patients with events divided by the time at risk.

For example, the **age** was calculated by subtracting patients' year of birth from the current year. The **length of follow-up (days) (*LFU*)** was calculated for each patient who had not left the study, and for each patient who left the study or deceased separately: by subtracting *ADMISSION_DATE* (DM_ENR, 2.4) from the *ASSESS_DATE* (DM_12M_CD, 1.4) for each patient who had not left the study, or by subtracting *ADMISSION_DATE* (DM_ENR, 2.4) from the *LEAVE_DATE* (DM_12M_CD, 1.6) for each patient who left the study or deceased. The **eGFR (MDRD) (ml/min/1.73 m^2)** was calculated for men and women separately using the following formulas:

- 186x(Pcr)**(-1.154)x(age)**(-0.203)x0.742 if female, or
- 186x(Pcr)**(-1.154)x(age)**(-0.203)x1 if male,

  where Pcr denotes plasma or serum creatinine level, after conversion to mg/dl (1 mg/dl= 88.4 µmol/L). It was assumed that no African Americans have been included (lack of this data), so the above formulas were not multiplied by 1.210 {x(1.210 if African American)}.

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 significant delay of the project,

[2] Reference: http://www.idf.org/sites/default/files/IDF-Guideline-for-older-people-T2D.pdf, page 30)

the low recruitment rate, and the difference in the length of follow-up between the two groups. All outcomes were estimated for both the total population, and excluding Berlin's data, after deleting double entries.

Data on participants who did not have a primary outcome event were censored at the date of last available follow-up information for clinical events. The same approach was used for other time-to-event outcomes. For death from any cause, data were censored on the last date that the participant was known to be alive, which may have been later than the last clinical follow-up. Incidence rates per 100 person-years were also calculated.

All qualitative variables are presented as numbers of patients having this characteristic and percentages (n, %). All quantitative variables are presented as mean (SD), except for healthcare resources used for the telehealth service at 12 months, which are presented as numbers of patients, mean (SD), median, minimum, and maximum. Predefined primary and secondary outcomes and other clinical outcomes are also expressed as absolute and relative (delta, %) differences between intervention and comparator group.

Normality plots and tests assessed 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, and the statistical significance was assessed by Pearson's correlation coefficient (NA denotes not available).

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.

Regression analyses were conducted for (a) the number of face-to-face contacts with GP or diabetologist (adjusted) (*a_ftf_no*) and (b) the difference in Hba1c (%) (*dif_hba1c_percent*). The Durbin-Watson statistic was used to test for the presence of correlation among the residuals. Multicollinearity was detected by examining the tolerance for each independent variable, where tolerance values less than 0.10 indicated collinearity. Variables with insufficient cases were excluded from the analyses.

Logistic regression analysis was conducted for the number of hospital admissions (adjusted) (*a_admit_no*), since a high percentage of cases (90.53%) had zero values. The Omnibus tests of model coefficients showed that the overall model was significant, while the Hosmer & Lemeshow test was used to determine the goodness of fit of the logistic regression model. Multicollinearity was resolved by excluding the collinear variables *HBA1C_CODE* and *SELF_MONITORING*.

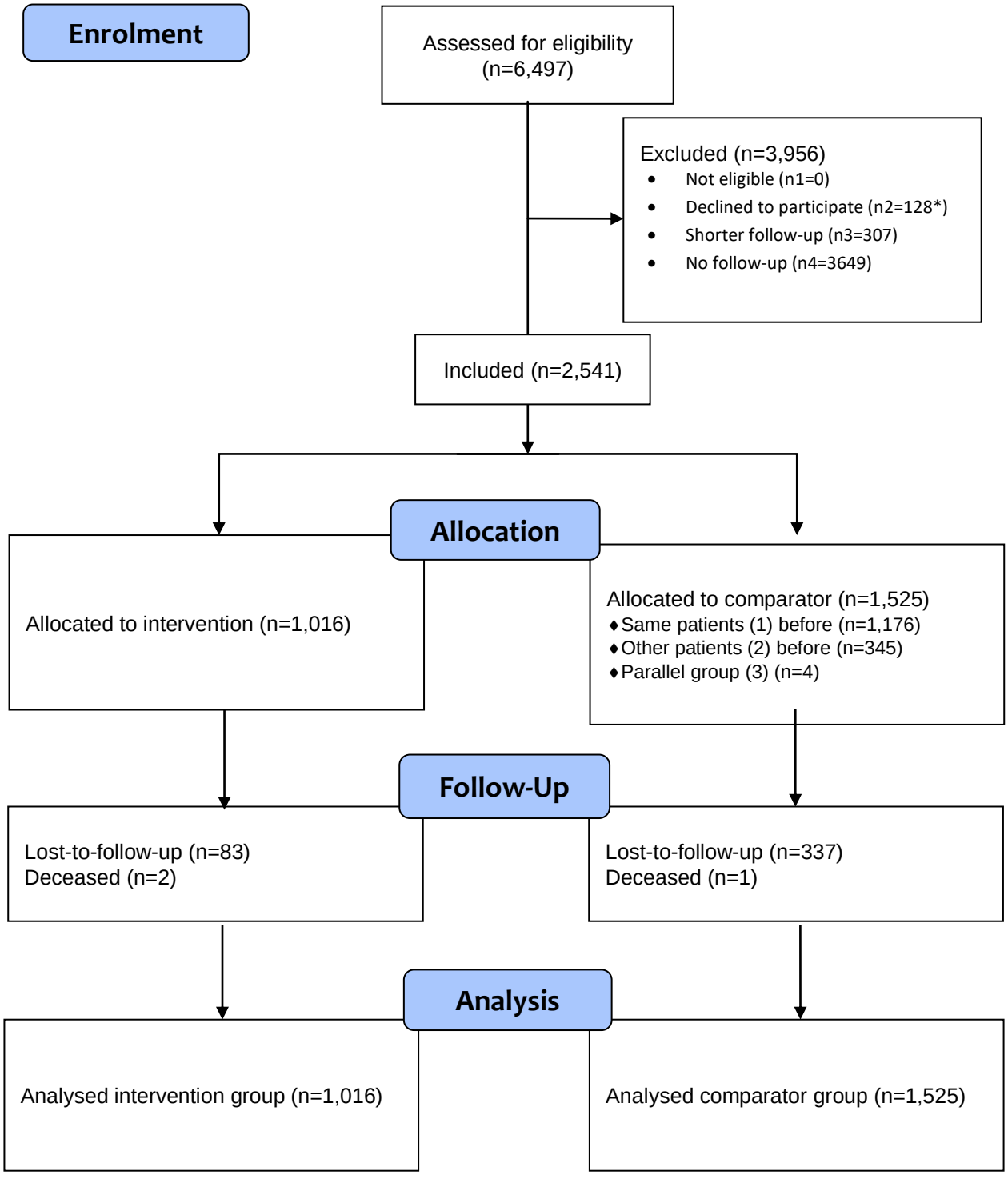
Non-parametric two-way ANOVA tests were conducted between quantitative dependent variables (number of hospital admissions (adjusted) (*a_admit_no*), difference in Hba1c (*dif_hba1c*) and number of face-to-face contacts with GP or

diabetologist (adjusted) (*a_ftf_no*)) and qualitative independent variables (patient group, age, gender, type of diabetes, CCI, educational level, PC use, etc).

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: Participant flow

In total, 2,541 people with diabetes formed the evaluation cohort, whilst a larger group of 3,649 people with diabetes had the telehealth intervention deployed, but did not form part of the evaluation cohort. Of the 2,541 eligible people, 1,016 were in the intervention arm of the project and rest in the comparator arm.



** Patients who declined to participate in the evaluation group received the U4H services as deployment group.*

Figure 29: Patient flow in diabetes pilot

3.8 Results: Baseline data

The United4Health project is real life deployment of telemedicine solutions at scale. The methods section describes the intervention and comparator arm. There were statistically significant differences in the groups at baseline, including age, smoking status, and if they were assisted at home. Baseline demographic characteristics

were statistically different in terms of age range for Scotland, as that region also recruited Type 1 diabetes patients.

Table 2: Baseline demographic characteristics

	Group		P-value
	Intervention	Comparator	
Age (years)	67.56 (16.01)	65.51 (16.76)	0.006
Age groups (n, %)	1016	1525	0.046
<65 years old	398 (39.2%)	670 (43.9%)	
65-75 years old	300 (29.5%)	431 (28.3%)	
>75 years old	318 (31.3%)	424 (27.8%)	
Male (n, %)	480 (47.2%)	770 (50.5%)	0.109
Smoking (n, %)	965	1472	0.000
Yes	116 (12.0%)	225 (15.3%)	
No	789 (81.8%)	1068 (72.6%)	
Ex-smoker	60 (6.2%)	179 (12.2%)	
Assisted at home (n, %)	387 (72.5%)	404 (63.2%)	0.001
Patients familiar with the use of technology			
PC use (n, %)	187 (32.5%)	204 (31.9%)	0.826
Mobile phone use (n, %)	384 (66.1%)	421 (65.1%)	0.706
Educational level	398	462	0.326
No formal schooling	28 (7.0%)	31 (6.7%)	
Primary school	43 (10.8%)	64 (13.9%)	
Secondary school	275 (69.1%)	295 (63.9%)	
College/University	52 (13.1%)	72 (15.6%)	

The majority of the patients assessed had Type 2 diabetes (Table 3). There was a statistically significant difference in relation to duration of diabetes, percentage self-monitoring, and also frequency of self-monitoring. More patients in the intervention arm were on insulin therapy (59.4% for Intervention group versus 53.8% for comparator group). This group of patients are typically more engaged in self-monitoring.

Table 3: Baseline clinical characteristics

	Group		P-value*
	Intervention	Comparator	
Type of diabetes (n, %)	1016	1525	0.028
Type 1	86 (8.5%)	177 (11.6%)	
Type 2	930 (91.5%)	1347 (88.3%)	
Other	0 (0.0%)	1 (0.1%)	
Number of years with diabetes	13.39 (8.42)	12.7 (8.7)	0.040
Family history of diabetes	14 (56.0%)	45 (68.2%)	0.277

	Group		P-value*
	Intervention	Comparator	
Self-monitoring (n, %)	979 (99.7%)	1188 (79.9%)	0.000
Frequency of self-monitoring (times/week)	5.16 (4.82)	6.78 (7.33)	0.000
Body weight (kg)	75.35 (19.43)	73.33 (17.93)	0.145
Height (cm)	166.19 (9.94)	165.13 (8.99)	0.143
BMI (kg/m^2)	27.29 (6.68)	26.91 (6.33)	0.450
Waist circumference (cm)	99.38 (8)	95.71 (14.84)	0.275
Systolic blood pressure (mmHg)	131.1 (13.9)	129.78 (8.4)	0.640
Diastolic blood pressure (mmHg)	76.15 (6.68)	79.22 (5.76)	0.004
Charlson Comorbidity Index (CCI)	1.90 (1.31)	1.91 (1.30)	0.974
Age-adjusted CCI	4.87 (1.87)	4.74 (2.01)	0.112

At baseline, the groups were not matched when laboratory parameters are considered. Statistically significant differences were noted in HbA1c measurements and glucose values. Other values including lipids, renal function and number of patients with optimal glycemia were matched.

Table 4: Laboratory examination at enrolment

	Group		P-value
	Intervention	Comparator	
HbA1c	57.56 (14.01)	58.84 (14.4)	0.026
HbA1c (%), mean (SD)	7.42 (1.28)	7.54 (1.34)	0.017
Glucose (mg/dl)	178.61 (80.68)	188.3 (81.47)	0.006
Total cholesterol (mg/dl)	169.24 (45.97)	173.41 (43.75)	0.225
LDL-cholesterol (mg/dl)	85.88 (34.06)	90.07 (33.94)	0.222
HDL-cholesterol (mg/dl)	47.80 (12.88)	46.94 (11.67)	0.499
Triglycerides (mg/dl)	183.74 (95.88)	179.39 (77.62)	0.746
Creatinine (mg/dl)	1.03 (0.49)	1.01 (0.33)	0.629
eGFR (MDRD) ml/min/1.73m^2	79.08 (25.48)	76.98 (24.26)	0.398
Controlled patients (%)*	589 (58.0%)	837 (55.4%)	0.184

* Diabetic patients with HbA1c less than 7.50% are considered controlled patients (Reference: http://www.idf.org/sites/default/files/IDF-Guideline-for-older-people-T2D.pdf).

The groups are well matched for co-morbidities, and 41.4% of the intervention group and 37.4% in the comparator group were reported to have a diagnosis of Diabetes Mellitus with complications.

Table 5: Assessment of comorbidity at enrolment

	Group		P-value
	Intervention	Comparator	
Charlson Comorbidity Index (CCI)	1.90 (1.31)	1.91 (1.30)	0.974
CCI group	1016	1525	0.422
1-2	815 (80.2%)	1207 (79.1%)	
3-4	161 (15.8%)	241 (15.8%)	
>4	40 (3.9%)	77 (5.0%)	
Age-adjusted CCI (AACCI)	4.87 (1.87)	4.74 (2.01)	0.112
Number of comorbidities (tot_com)	2.09 (1.07)	2.17 (1.15)	0.224

3.9 Results: Estimation of outcomes

At the end of 12 months there was a statistically significant difference in the measure of diabetes control, i.e. HbA1c, and the number of patients attaining good diabetes control.

Table 6: Clinical data at 12 months

	Group		P-value
	Intervention	Comparator	
Mean length of follow up (days)	334.14 (77.1)	369.1 (58.5)	0.000
Lost-to-follow-up	83 (8.2%)	337 (22.1%)	0.000
Deceased	2	1	NA
Reasons of deceased			NA
Related to diabetes	0 (0.0%)	0 (0.0%)	
Not related to diabetes	1 (50.0%)	1 (100.0%)	
Unknown	1 (50.0%)	0 (0.0%)	
HbA1c (mmol/mol)	54.09 (11.43)	58.55 (14.14)	0.000
HbA1c (%)	7.1 (1.05)	7.51 (1.29)	0.000
Controlled diabetics (%)*	715 (72.7%)	885 (58.2%)	0.000
Glucose (mg/dl)	155.53 (49.49)	167.05 (50.33)	0.002
Frequency of self-monitoring of glucose (times/week)	4.96 (4.65)	4.84 (4.95)	0.004
Insulin (n, %)	517 (55.7%)	616 (60.8%)	0.021

***** *Controlled patients (controlled) are defined the patients with HbA1c < 7.5%*[3]

[3] Reference: http://www.idf.org/sites/default/files/IDF-Guideline-for-older-people-T2D.pdf

3.9.1 Main results

The primary end point of the project was to assess any reduction in the number of face-to-face contacts with a GP or diabetologist, depending on local pathway. As there were variations in the various healthcare models in relation to who was the primary contact for diabetes care, the presented results may be influenced by this (Table 7 and Table 8).

The primary and secondary outcomes are adjusted for the length of follow-up (per patient year) for each individual patient. This is particularly important taking into consideration the significant delay of the project, the low recruitment rate, and the difference in the length of follow-up between the two groups.

The patients from the Berlin cohort were excluded from the analysis, as this group of patients were partially living in supported housing, where the medical presence was higher than when the patient lived alone.

Overall, whilst there was an increase in face-to-face GP and diabetologist visits, there was reduction in HbA1c, and a significant reduction in emergency department visits in the intervention group (see Table 7 and Table 8 below). Further regression analysis was carried out.

Table 7: Healthcare resources used per year of follow-up (excluding Berlin)

	Group		Absolute Difference	Relative Difference (Delta, %)	P-value
	Intervention	Comparator			
Patients admitted to hospital per year	42 (6.5%)	91 (14.1%)	-7.58%	-53.85%	0.196
Number of hospital admissions per year	0.15 (0.66)	0.18 (0.89)	-0.03	-16.67%	0.237
Number of days hospitalised per year	0.39 (1.99)	0.6 (4.11)	-0.21%	-35.00%	0.365
Patients gone to the ED per year	39 (6.0%)	107 (16.6%)	-10.52%	-63.55%	0.008
Patient visits to the ED per year	0.15 (0.68)	0.21 (0.89)	-0.06%	-28.57%	0.012
Outpatient visits at the hospital per year	390 (60.3%)	537 (83.1%)	-22.74%	-27.37%	0.000
Patient visits to the outpatient clinic per year	2.74 (3.35)	3.57 (3.5)	-0.83%	-23.25%	0.000
GP visits per year	392 (60.6%)	694 (107.4%)	-46.72%	-43.52%	0.000
Number of patient visits to GP per year	9.8 (6.86)	7.45 (7.29)	2.35	31.54%	0.000
Other primary care contacts per year	339 (52.4%)	660 (102.1%)	-49.66%	-48.64%	0.059
Patients who visited diabetologist per year	219 (33.9%)	316 (48.9%)	-15.01%	-30.70%	0.000
Number of patient visits to the diabetologist	1.07 (1)	1.25 (1.55)	-0.18	-14.40%	0.783
Patients who visited specialised nurse per year	57 (8.8%)	305 (47.2%)	-38.37%	-81.31%	0.000
Number of visits to specialised nurse	0 (0.06)	0.01 (0.19)	-0.01	-100.00%	0.696
Patients visited Community nurse per year	72 (11.1%)	18 (2.8%)	8.35%	300.00%	0.000
Number of patient visits to the community nurse per year	0.62 (1.69)	0.21 (2.2)	0.41	195.24%	0.000
Patients visited other type of primary care professional per year	142 (22.0%)	139 (21.5%)	0.46%	2.16%	0.000
Number of patient visits to other type of primary care professional per year	0.89 (1.52)	0.41 (1.34)	0.48	117.07%	0.000

Table 8: Predefined primary and secondary outcomes per year of follow-up (excluding Berlin)

	Group		Absolute Difference	Relative Difference (Delta, %)	P-value
	Intervention	Comparator			
Primary outcomes					
Number of face-to-face contacts with GP or diabetologist per year	11.72 (7.6)	8.51 (8.41)	3.21	37.72%	0.000
Secondary outcomes					
Reduction in HbA1c (unadjusted)	-0.28 (1.1)	-0.06 (1.09)	-0.22%		0.000
All primary care contacts per year	12.05 (6.22)	11.99 (7.45)	0.10	0.84%	0.219
Number of visits to the emergency department per year	0.15 (0.68)	0.21 (0.89)	-0.06	-28.57%	0.012
Number of outpatient visits per year	2.74 (3.35)	3.57 (3.5)	-0.83	-23.25%	0.000
Number of outpatients visits to a diabetologist per year	1.07 (1)	1.25 (1.55)	-0.18	-14.40%	0.783
Patients admitted to hospital per year	42 (8.1%)	91 (10.2%)	-2.1%	-20.48%	0.196
Number of hospital admissions per year	0.15 (0.66)	0.18 (0.89)	-0.03	-16.67%	0.237
Number of days hospitalised per year	0.39 (1.99)	0.6 (4.11)	-0.21	-35.00%	0.365
Other outcomes (unadjusted)					
Reduction in insulin units	-12.62 (53.62)	3.83 (6.47)	-15.83	-413.32%	0.001
Difference in controlled patients	11.70%	3.51%	8.19%	233.38%	0.003

3.9.2 Regression analyses

3.9.2.1 Annual face-to-face contacts with GPs or diabetologists (AFTFC)

The annual face-to-face contacts with GP or diabetologist after adjustments for all possible confounders have been reduced in the intervention group but not statistically significantly (-0.182, $p = 0.445$).

As was expected, an increased number of AFTFC have been measured in patients with higher values of HbA1c (>7 mmol/mol) (0.681, $p= 0.011$) and higher Charlson Comorbidity Index (more comorbidities) (1.493, $p < 0.001$).

Among the different sites, a higher number of AFTFC have been seen in Moravia (23.055, $p < 0.001$), Calabria (13.722, $p < 0.001$), Greece (10.734, $p < 0.001$) and Wales (0.828, $p = 0.011$), and reduced in Slovenia (-2.669, $p < 0.001$).

Table 9: Regression Coefficients Table

	Unstandardised Coefficients		Standardised Coefficients	t	Sig.	Collinearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
(Constant)	5.153	0.285		18.085	0.000		
GROUP	-0.182	0.238	-0.011	-0.764	0.445	0.927	1.079
REGION_Calabria	13.722	0.315	0.783	43.524	0.000	0.579	1.727
REGION_Greece	10.734	0.595	0.260	18.051	0.000	0.903	1.107
REGION_Slovenia	-2.669	0.313	-0.148	-8.516	0.000	0.623	1.606
REGION_NWMoravia	23.055	4.122	0.077	5.594	0.000	0.996	1.004
CCI_code2	1.493	0.427	0.048	3.498	0.000	0.978	1.023
HBA1C_CODE	0.681	0.233	0.044	2.924	0.004	0.838	1.194
REGION_Wales	0.828	0.326	0.041	2.542	0.011	0.713	1.403

The tolerance values for all of the independent variables are larger than 0.10. Multicollinearity is not a problem in this regression analysis.

The above analysis was conducted after adjusting for and recoding the variables as follows:

Variable	New values
GROUP	0→ Comparator 1→ Intervention
GENDER	0 → Female 1 → Male
COM_10	0 → No 1 → Yes
TYPE_DM	0 → Type 2 1 → Type 1
HBA1C_CODE	0 → Low Level (≤7) 1→ High Level
CCI_code2	0 → 1 or 2 1 → 3 or 4
PC_USE	0 → No 1 → Yes
SMOKE_YES	0 → No 1 → Yes
SMOKE_EX	0 → No 1 → Yes
ASSISTED_HOME	0 → No 1 → Yes
SELF_MONITORING	0 → No 1 → Yes
INSULIN	0 → No 1 → Yes
EDUCATION_PRIMARY	0 → No 1 → Yes
EDUCATION_SECONDARY	0 → No 1 → Yes
EDUCATION_COLLEGE	0 → No 1 → Yes

Variable	New values
REGION_Wales	0 → No 1 → Yes
REGION_Calabria	0 → No 1 → Yes
REGION_SouthKarelia	0→ No 1 → Yes
REGION_Greece	0 → No 1 → Yes
REGION_NorthwestMoravia	0 → No 1 → Yes
REGION_Slovenia	0 → No 1 → Yes
REGION_Campania	0 → No 1 → Yes
AGE	Numeric
DM_YEARS	Numeric
SELF_MON_TIMES	Numeric

The variables "PC_USE", "ASSISTED_HOME", "EDUCATION_PRIMARY", "EDUCATION_SECONDARY", "EDUCATION_COLLEGE" and "SELF_MON_TIMES" were not included in the analysis, since there were not enough cases.

3.9.2.2 HbA1c difference

- HbA1c has been reduced significantly more in the intervention group than in the comparator group (-0.224, $p < 0.001$).
- The reduction was higher in patients with increased baseline HbA1c values (-0.791, $p < 0.001$), but not for patients under insulin treatment (0.246, $p < 0.001$).
- We have seen a reduction in HbA1c in all of the participating regions, but this reduction was significantly bigger in Campania (-0.576, $p < 0.001$), Slovenia (-0.388, $p < 0.001$), Calabria (-0.323, $p < 0.001$) and Greece (-0.292, $p = 0.013$).

Table 10: Regression Coefficients Table

	Unstandardised Coefficients		Standardised Coefficients	t	Sig.	Collinearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
(Constant)	0.459	0.052		8.755	0.000		
GROUP	-0.224	0.042	-0.121	-5.389	0.000	0.966	1.036
HBA1C_CODE	-0.791	0.044	-0.441	-17.826	0.000	0.800	1.250
REGION_Campania	-0.576	0.085	-0.161	-6.759	0.000	0.860	1.163
REGION_Calabria	-0.323	0.059	-0.155	-5.499	0.000	0.619	1.616
REGION_Slovenia	-0.388	0.059	-0.205	-6.568	0.000	0.502	1.992
INSULIN	0.246	0.055	0.136	4.453	0.000	0.529	1.890
REGION_Greece	-0.292	0.118	-0.057	-2.481	0.013	0.929	1.076

The tolerance values for all of the independent variables are larger than 0.10. Multicollinearity is not a problem in this regression analysis.

The above analysis was conducted after adjusting for and recoding the variables as follows:

Variable	New values
GROUP	0 → Comparator 1 → Intervention
GENDER	0 → Female 1 → Male
COM_10	0 → No 1 → Yes
TYPE_DM	0 → Type 2 1 → Type 1
HBA1C_CODE	0 → Low Level (≤7) 1 → High Level
CCI_code2	0 → 1 or 2 1 → 3 or 4
PC_USE	0 → No 1 → Yes
SMOKE_YES	0 → No 1 → Yes
SMOKE_EX	0 → No 1 → Yes
ASSISTED_HOME	0 → No 1 → Yes
SELF_MONITORING	0 → No 1 → Yes
INSULIN	0 → No 1 → Yes
EDUCATION_PRIMARY	0 → No 1 → Yes
EDUCATION_SECONDARY	0 → No 1 → Yes
EDUCATION_COLLEGE	0 → No 1 → Yes
REGION_Wales	0 → No 1 → Yes
REGION_Calabria	0 → No 1 → Yes
REGION_SouthKarelia	0 → No 1 → Yes
REGION_Greece	0 → No 1 → Yes
REGION_NorthwestMoravia	0 → No 1 → Yes
REGION_Slovenia	0 → No 1 → Yes
REGION_Campania	0 → No 1 → Yes
AGE	Numeric
DM_YEARS	Numeric
SELF_MON_TIMES	Numeric

The variables "PC_USE", "ASSISTED_HOME", "EDUCATION_PRIMARY", "EDUCATION_SECONDARY", "EDUCATION_COLLEGE" and

"SELF_MON_TIMES" were not included in the analysis, since there were not enough cases.

3.9.2.3 Number of hospital admissions (any reason) adjusted for length of follow-up

For this data analysis, we used logistic regression analysis, since a high percentage of cases (90.53%) have zero values. In this analysis, the reference group is the intervention (group = 0) in contrast with the previous regression analyses in which the reference group was the comparator.

- The R^2 values tell us approximately how much variation in the outcome is explained by the model. We prefer to use the Nagelkerke's R^2 which suggests that the model explains roughly 35.4% of the variation in the outcome. Note that these R^2 values are approximations, and should not be overly emphasised. However, the number of hospital admissions (any reason) per year after adjustments for all possible confounders has been significantly reduced in the intervention group, by more than 5 times in comparison with the comparator group (5.249, 95% CI 1.728 – 15.946, p = 0.003)
- Female patients were 2.922 times more likely to be hospitalised than males (2.922, 95% CI 1.728 – 15.946),

Patients without diabetic complications were less likely to be hospitalised than patients with complications (0.097, 95% CI 0.030 – 0.317,

Table 11: Coefficients Table

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
GROUP	1.658	0.567	8.555	1	0.003	5.249	1.728	15.946
GENDER	1.072	0.399	7.216	1	0.007	2.922	1.336	6.390
COM_10	0.209	0.535	0.152	1	0.696	1.232	0.432	3.518
TYPE_DM	-1.119	0.715	2.446	1	0.118	0.327	0.080	1.327
CCI_code2	-2.336	0.606	14.858	1	0.000	0.097	0.030	0.317
SMOKE			46.355	2	0.000			
SMOKE(1)	-1.345	0.515	6.833	1	0.009	0.261	0.095	0.714
SMOKE(2)	-3.222	0.478	45.472	1	0.000	0.040	0.016	0.102
AGE	-0.037	0.020	3.479	1	0.062	0.964	0.928	1.002
DM_YEARS	0.012	0.023	0.292	1	0.589	1.012	0.968	1.058
Constant	1.365	1.148	1.414	1	0.234	3.915		

The above analysis was conducted after adjusting for and recoding the variables as follows:

Variable	New values
GROUP	1 → Comparator 0 → Intervention
GENDER	1 → Female 0→ Male
COM_10	1 → No 0 → Yes

Variable	New values
TYPE_DM	1 → Type 2 0 → Type 1
HBA1C_CODE	1 → Low Level (≤7) 0 → High Level
CCI_code	1 → 1 or 2 0 → 3 or 4
PC_USE	1→ No 0 → Yes
SMOKE(1)	1→ Smoke="No" 0 → Others
SMOKE(2)	1→ Smoke="Yes" 0 → Others
ASSISTED_HOME	1→No 0 →Yes
SELF_MONITORING	1 →No 0 →Yes
INSULIN	1 → No 0 → Yes
EDUCATION(1)	1 → No Formal Schooling 0 →Others
EDUCATION(2)	1 → Primary 0 → Others
EDUCATION(3)	1 → Secondary 0 → Others
REGION(1)	1 → Region="Scotland" 0 → Others
REGION(2)	1 → Region="Wales" 0 → Others
REGION(3)	1 → Region="Calabria" 0 →Others
REGION(4)	1 → Region="South Karelia" 0 →Others
REGION(5)	1 → Region="Greece" 0 → Others
REGION(6)	1→ Region="Nortwest Moravia" 0→ Others
REGION(7)	1→ Region="Slovenia" 0→ Others
AGE	Numeric
DM_YEARS	Numeric
SELF_MON_TIMES	Numeric

The variables "HBA1C_CODE", and "SELF_MONITORING" were not included in the analysis, since multicollinearity was a problem.

The variables "PC_USE", "ASSISTED_HOME", "EDUCATION(1)" and "EDUCATION(2)", and "EDUCATION(3)" were not included in the analysis since there were not enough cases.

3.9.3 Other analyses

The primary and the main secondary outcomes of the project have also been estimated and compared for different subpopulations of the project based on the different stratification criteria, presented during the second annual review.

The following stratification criteria and subpopulations have been analysed, in two-way ANOVA:

- Age group (<65, 65 – 75, >75).
- Gender.
- Type of diabetes.
- Duration of diabetes.
- Severity of diabetes.
- Presence of complications or not.
- HbA1c level at recruitment.
- Comorbidity group (CCI 1-2 vs ≥3).
- Educational level.
- PC use.

3.9.3.1 Two-ways ANOVA

In terms of HbA1c reduction, the subpopulations which benefit more are:

a. Older than 75 years old (but a significant reduction has been seen in all age groups).
b. Higher baseline values of HbA1c (>7%).
c. Current treatment with insulin.
d. Higher level of education (>12 years).

The two-way ANOVA showed that the subpopulations which benefit more from the U4H services in terms of reduction of hospital admissions are:

e. Patients younger than 65 years old.
f. Type 1 diabetics.

In terms of number of face-to-face contacts with GP or diabetologist per year, the results were better for the following subpopulations:

g. Patients younger than 65 years old.
h. Type 1 diabetics.
i. Without diabetic complications.
j. Higher baseline values of HbA1c (>7%).
k. Not familiar with the use of PC.

All two-way ANOVA tables are located in Appendix A for reference.

3.9.4 Healthcare resources

Table 12: Healthcare resources used for the telehealth service (at 12 months)

	Telehealth patients				
	Mean (SD)	**Median**	**Min**	**Max**	**Total**
Duration of telehealth service (days)	110.83 (151.45)	2.00	0.00	515.00	1848
Contacts between healthcare professionals and patients (e.g. video conference) (n, %)	428 (29.7%)				
Number of contacts	32.50 (24.12)	52.00	0.00	52.00	483

	Telehealth patients				
	Mean (SD)	**Median**	**Min**	**Max**	**Total**
Educational level of healthcare professionals (in contact with the patients)					
Community Nurse (n, %)	320 (30.5%)				
Hospital nurse (n, %)	676 (64.4%)				
Medical doctor (n, %)	34 (3.2%)				
Other education (n, %)	20 (1.9%)				
Time duration per contact					
Community Nurse	7.46 (5.76)	8.00	1.00	30.00	320
Hospital nurse					676
Medical doctor					34
Other education	9.10 (3.54)	10.00	5.00	15.00	20
All contacts	8.17 (4.94)	8.00	1.00	30.00	1050
Patients' health monitored by use of the telehealth application (without having contact with the healthcare professionals) (n, %)	577 (31.3%)				
Number of patients' health monitoring (using TM app without having contact with the healthcare professionals)	17.71 (20.52)	5.00	0.00	88.00	632
Educational level of healthcare professionals (using TM app)					
Community Nurse (n, %)	467 (58.6%)				
Hospital nurse (n, %)	6 (0.8%)				
Medical doctor (n, %)	304 (38.1%)				
Other education (n, %)	20 (2.5%)				
Time duration per telemonitoring					
Community Nurse	15.64 (1.88)	16.00	7.00	20.00	467
Hospital nurse					6
Medical doctor	14.57 (1.51)	15.00	5.00	15.00	304
Other education	9.75 (1.12)	10.00	5.00	10.00	20
All contacts	15.04 (2.00)	15.00	5.00	20.00	797

3.10 Results: Adverse events

There was no systematic method of recording data of suspected adverse events. However, no site reported any adverse events, i.e. deaths or increased risk due to their use of the TM service. Regions reported having in place appropriate clinical governance frameworks underpinning TM services.

3.11 Discussion of clinical findings

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

3.11.1 Diabetes routine care management

Patients living with Type 2 and Type 1 diabetes are offered planned care, treatment, support and education services as part of their diabetes disease management, monitoring and review in accordance with their disease severity and any associated health complications, capacity and capability to self-manage. As a minimum, all regions offer patients an annual review during which a range of physiological measurements are taken and recorded, often including BMI, waist circumference, as well as HbA1c, cholesterol, plasma creatinine, urinary albumin, eye screening, foot examination, smoking review, and blood pressure. In addition, the oral or insulin therapy is reviewed and modified if necessary, and individualised diabetes-related education is provided. These diabetes disease management consultations can be carried out in primary care by a GP nurse under the supervision of a GP, or in a hospital outpatient department, or community ambulatory diabetes care clinic, by doctors and nurses working together. Patients are also offered annual influenza and pneumococcal vaccinations by their GP practice. A patient may also receive diabetes care in unplanned consultations if their health status deteriorates.

3.11.2 Diabetes telehealth care

The remote monitoring service implemented in each region centred on the taking and uploading of blood glucose measurements and health coaching messaging. 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 diabetes disease management consultations and access to this trend data facilitates a patient-centred review and drawing up an optimal plan of ongoing care, treatment and support. The remote monitoring service was not designed as a substitute for the annual review consultations, but to optimise decision-making during both planned and unplanned consultations. In deployment sites where a patient's care plan included more frequent review consultations, e.g. every 3 or 6 months, some regions' ambition was that these consultations could be reduced through the introduction of remote monitoring. In addition, the telehealth also offered patients alternatives to face-to-face consultations in either their local hospital, GP practice or diabetes ambulatory care centre.

3.11.3 Discussion – scalability and clinical system architecture

The U4H project in diabetes demonstrated that telehealth interventions can be deployed at scale. The primary end-point of the project was face-to-face contacts with GP and diabetologist. Looking at the regression analysis and correcting for confounders, there was a significant reduction in the number of face-to-face contacts.

In relation to the secondary end-points, there was a statistically significant reduction in HbA1c and hospital admissions. The caveat remains that the interventions were different for different areas; also care systems are not entirely comparable.

The above results demonstrate that in the long run, decreased face-to-face contacts and hospital admissions, and an improvement in HbA1c, will lead to reduced healthcare costs. It is also heartening to know that in six months of follow-up, a decrease in HbA1c has been shown; there is clear evidence in published literature that reductions in HbA1c lead to reduced rates of complications and improved quality of life.

There is plenty of evidence in the literature suggesting improvements in diabetes care parameters with telehealth. But these are small RCTs / meta analyses. For the first time we now show an improvement in HbA1c and reduction in hospital admission and face-to-face contacts with GP / diabetologist at scale. Hopefully, healthcare systems will recognise with this evidence that there is a compelling need to redesign care pathways / services with telemonitoring / telehealth as a core part of routine care. With improvement in HbA1c, it can be argued that if the reduction is long-term, this will lead to a reduction in diabetes complications, and hopefully a reduction in healthcare costs. We need to continue the work of evaluating the different care models used in the sites.

The ultimate aim is to empower patients to look after their health. The health coaching and telemonitoring aspects of the care models go a long way to engage patients with their diabetes, educating them, and ultimately empowering them.

There were considerable technology, infrastructure and people challenges that teams implementing the telehealth model encountered. This is clearly seen in the original intervention numbers in the protocol (3,010) and the final evaluation cohort numbers (2,541, including comparator group). Integrating the technical solution to existing or redesigned clinical models of care was more time consuming than anticipated. Procurement of the technology was complex and long drawn out in certain sites, while others, especially centres who participated in the Renewing Heath trials, were able to start recruitment earlier. For some sites, the technology could not be bought off the shelf, but needed further development to integrate into the existing infrastructure and systems to support at-scale deployment.

Some centres continued to recruit patients to the telehealth intervention; this is borne out by the high deployment numbers reported earlier (Table 1). This reflects the number of patients receiving the TM services delivered through U4H.

In spite of the challenges, the delays in recruitment, and smaller numbers than anticipated, there is a large data set available from which we now have interesting results.

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 aimed “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 needed 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 U4H 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 Diabetes Mellitus Scientific Committee, chaired by Sandeep Thekkepat (Diabetologist, Clinical Lead of NHS 24 and WP6 leader). This plan was completely followed, but extended to include additional regression analyses because unexpected and significant differences were observed between intervention and comparator groups.

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.

These limitations constituted the biggest challenge for the evaluation, as it was unclear if the differences observed in the outcomes were as a result of the U4H services, or because the differences in the 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 [xv].

Since Cohen's 1968 seminal article [xvi], 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 [xvii].

The assumptions of multiple regression are:

- **Linearity:** Residual plots showing the standardised residuals vs. the predicted values are very useful in detecting violations in linearity [xviii]. 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 [xviii].
- **Independence of errors:** In order to diagnose violations of this assumption, the researcher has to study the boxplots of the residuals [xix].
- **Homoscedasticity:** This assumption can be checked by examining the plot of the standardised residuals by the regression standardised predicted value [xx].
- **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 in U4H:

i. Multiple regression analysis for the variable "Annual face-to-face contacts with GPs or diabetologists (A_FTF_NO)". For this variable, the assumptions of linearity, independence of errors, normality, homoscedasticity and multicollinearity are 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.

ii. Multiple regression analysis for the variable "Difference in Hba1c (%) (end–enrolment) (DIF_HBA1C_percent)". For this variable, the assumptions of linearity, independence of errors, normality, homoscedasticity and multicollinearity are 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.

iii. Multiple regression analysis for the variable "Outpatients visits at the hospital (A_OUT_NO)". For this variable, the assumptions of linearity, independence of errors, normality, homoscedasticity and multicollinearity are 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.

iv. Logistic regression for the variable "Number of hospital admissions (any reason) adjusted for length of follow-up (A_ADMIT_NO)". Note that for this variable, a high percentage of cases (90.53%) had zero values. This is the reason why we did not apply multiple regression analysis, but logistic regression. We also removed the outliers, that is, cases with absolute values in studentised residuals bigger than 2.

v. Logistic regression for the variable "Days of hospital admissions (any reason) adjusted for length of follow-up (A_ADM_DAYS_RECODE)". Note that for this variable, a high percentage of cases (87.60%) had zero values. This is the

reason why we did not apply multiple regression analysis, but logistic regression. We have also removed the outliers, that is, cases with absolute values in studentised residuals bigger than 2.

vi. Logistic regression for the variable “Patients visits to the emergency department adjusted for length of follow-up (A_ED_NO_RECODE)”. Note that for this variable, a high percentage of cases (87.60%) had zero values. This is the reason why we did not apply multiple regression analysis, but logistic regression. We have also removed the outliers, that is, cases with absolute values in studentised residuals bigger than 2.

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 diabetes 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, see the questionnaire in Appendix B. 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 pilots 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 is based on a literature review and testing in qualitative studies. The questionnaire was 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; 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 table below describes the number of patient included in the different regions.

Table 13: Data collection across regions

Region	Mode of Administration	Sampling Method	Study Period	Response Rate[a]
Scotland	Telephone at patient's home	Registered patients with contact info available	9.9.15	13.6%
Wales	Self-completed by mail at patient's home	All patients in the intervention arm	27.5.15-25.8.15	64.3%
Calabria	Self-completed by mail at patient's home	Mostly patients that had > 6 months telemonitoring	9.5.15-26.9.15	94.5%
South Karelia	Telephone at patient's home	All patients in Eksote pilot called	1.6.15-30.9.15	79%
Central Greece	Self-completed at home or outpatient dept.	All patients in the intervention arm	1.1.14-31.8.15	67%
Berlin	Self-completed or by interview at home	All patients in the intervention arm	1.4.15-18.9.15	100%
NW Moravia	Self-completed in hospital or by mail at home	All patients in the intervention arm	1.7.15-30.9.15	53.8%
Slovenia	Self-completed in hospital or by mail at home	Patients were given the questionnaires in regular visits to doctors	1.6.15-3.11.15	100%
Campania	Self-completed at diabetes centres	All patients that had > 6 months telemonitoring	23.9.15-30.9.15	94.5%

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

The measurement was carried out on a 6-point Likert scale. As is typical in the literature, this symmetrical scale was treated as a ratio, rather than ordinal, and therefore values from 1 to 6 were assigned to responses. The wording of these items (statements) in the questionnaire are 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 13. Regions have adopted various methods of questionnaire administration. All modes have their strengths and weaknesses, and hence a combination of methods might be seen as preferable. In most regions, the survey took place in 2015. The response rates varied, with most regions achieving satisfactory and even very high response rates.

In the overall diabetes sample, observations from the following regions participating in the telemonitoring intervention were combined: 24 respondents from Scotland, 78 from Wales, 185 from Calabria, 33 from South Karelia, 65 from Central Greece, 294 from Berlin, 15 from Northwest Moravia, 232 from Slovenia and 23 from Campania. A total sample of 949 patients was thus employed. However, in some parts of the analysis that follows, we excluded the observations from the Berlin region, since the population and intervention seemed to differ from other regions and, in addition, there were more issues related to the reliability of the survey conducted there.

4.3 Sub-scales

Data was 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 in order to check whether the same coding indicated by the DM 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. Therefore, 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; that is, it signifies a positive view of 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 DM 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 that country, 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. summated 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, multitrait 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 converting the 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.

4.3.1 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 DM sample, the highest percentage of missing values was 3%, and the values were in fact much lower for most items. Two exceptions were Q16 and Q20, but this was solely due to fact that Slovenia excluded these items as not being relevant in their setting and did not collect any data.

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. It is evident from Table 14 that the distributions are non-normal.

We therefore employed appropriate measures such as medians, interquartile ranges, Spearman correlation coefficients, Kruskal Wallis, Mann-Whitney tests and appropriate estimation techniques (e.g. asymptotically distribution free estimation of the Confirmatory Factor Analysis model) that are suitable for such data, throughout the analyses that follow.

Table 14: Tests of normality

	Kolmogorov-Smirnof[a]		Shapiro–Wilk	
Sub-scale	***Statistic[b]***	***p-value***	***Statistic[b]***	***p-value***
Enhanced care	0.089	0.000	0.954	0.000
Increased accessibility	0.077	0.000	0.962	0.000
Privacy and discomfort	0.088	0.000	0.963	0.000
Care personnel concerns	0.127	0.000	0.956	0.000
Kit as substitution	0.085	0.000	0.986	0.000
Satisfaction	0.131	0.000	0.912	0.000

a. Lilliefors significance correction.
b. df = 906.

Next we present, for each subscale, the median, 95% confidence interval for the median, interquartile range 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 potentially conservative measurement of the positive views of DM patients.

It is apparent from Table 15 that overall more than seven out of ten patients had a mild, moderate or strong positive view about the various aspects of telehealth and believed (each with varying strength of preferences) that the intervention enhanced their care, increased accessibility without adversely affecting their privacy or making them feel discomfort or distrust towards staff and the continuity of care. They were thus satisfied with the telemonitoring experience. However, only a minority of four out of ten patients believed that the kit could in fact substitute their standard care.

Table 15: Subscale descriptive statistics and confidence intervals

Subscale	Mdn	CI (95%)	IQR	% Positive Views[a]
Enhanced care	4.75	4.60 – 4.80	1.60	74.5
Increased accessibility	4.50	4.33 – 4.50	1.25	72.8
Privacy and discomfort	4.50	4.50 - 4.75	1.25	74.9
Care personnel concerns	4.66	4.33 – 4.66	1.00	78.2
Kit as substitution	3.66	3.50 – 3.66	1.33	40.1
Satisfaction	5.00	4.66 – 5.00	2.00	74.0

a. % of patients with subscale scores ≥ 4.

The median values give a similar picture. There was moderate agreement between DM patients that telemonitoring enhanced the care they received from the health care 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. It should be noted that 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.

Moreover, there was mild to moderate 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 mild to moderate agreement that the kit did not create problems with the privacy of the study participants, or caused any discomfort to them. Therefore, it seems that the median diabetic patient believes that the kit has not interfered with his everyday routine, nor it has invaded his privacy. It has not made him feel uncomfortable, nor worried about the confidentiality of the private information exchanged through it.

Similarly, diabetic 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 inadequate level of expertise.

Unsurprisingly, given the above positive views on specific characteristics and dimensions of the telemonitoring experience, results indicated an overall satisfaction with it. In fact, DM patients moderately 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 convinced that the kit could act as a substitute to usual care. Specifically, they were indifferent as to whether it could substitute their regular face-to-face consultations with healthcare professionals. According to patient preferences, telemonitoring is not as suitable as face-to-face consultations, and the kit did not make them less concerned about their health status.

Summing up, results indicated a high acceptability and satisfaction among diabetic patients associated with the telemonitoring intervention. Patients nevertheless do not believe that this type of care can in fact serve as a substitute to their established face-to-face care.

In passing, it might be the case that opinions differ to some extent across different regions. Regions that participated in the U4H DM overall sample of patients are Scotland, Wales, Calabria, South Karelia, Greece, Berlin, Northwest Moravia, Slovenia and Campania. Median tests indeed suggested that the median levels of each and every subscale differ across regions ($p<0.01$). Kruskal-Wallis tests of whether the distribution of the subscales were the same across regions corroborate the previous findings ($p<0.01$). It is therefore interesting to see at least for the "Satisfaction" and "Kit as substitution" scales, which specific region(s) depart from the others.

Figure 30 suggests that the median patient in Berlin and South Karelia might have different levels of satisfaction compare to other regions.

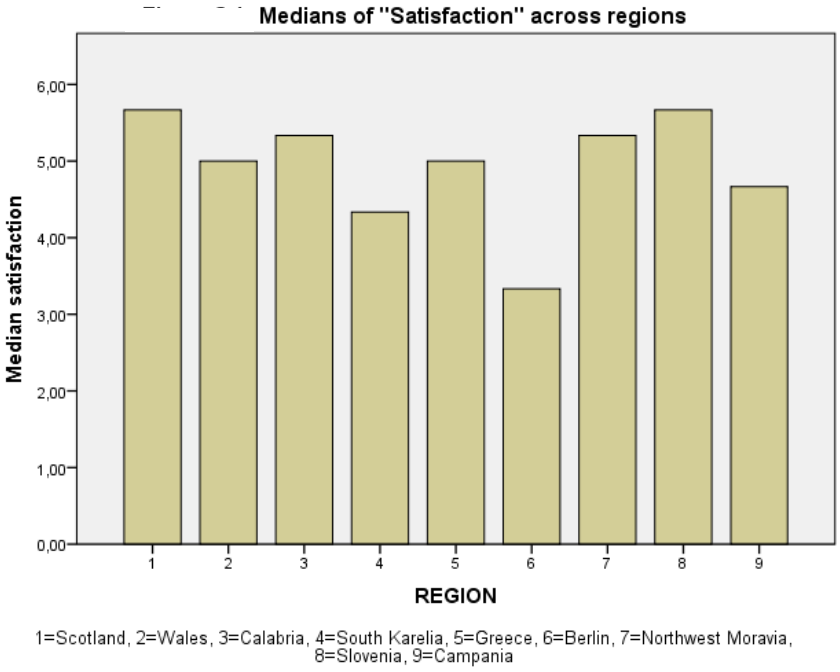


Figure 30: Medians of satisfaction across regions

Mann-Whitney tests with Bonferroni corrections for multiple comparisons are shown in Table 16. Only significant tests are reported, since a total of 36 pairwise comparisons had to be examined.

Table 16: Mann-Whitney significant pairwise tests with Bonferroni corrections for "Satisfaction"[a]

Sample 1 – Sample 2	Test Statistic	St. Error	Std. Test Statistic	P-value	Adj. P-value[b]
Berlin – South Karelia	180.964	49.766	3.636	0.000	0.010
Berlin – Campania	-258.335	59.916	-4.312	0.000	0.001
Berlin – Wales	326.657	34.525	9.461	0.000	0.000
Berlin - Northwest Moravia	-362.131	71.754	-5.047	0.000	0.000
Berlin – Greece	366.269	37.154	9.858	0.000	0.000
Berlin – Calabria	368.819	25.524	14.450	0.000	0.000
Berlin – Slovenia	-448.340	23.805	-18.834	0.000	0.000
Berlin – Scotland	459.964	57.547	7.993	0.000	0.000
South Karelia – Greece	-185.305	57.941	-3.198	0.001	0.050
South Karelia – Calabria	187.855	51.266	3.664	0.000	0.009
South Karelia – Slovenia	-267.376	50.432	-5.302	0.000	0.000
South Karelia – Scotland	279.000	72.721	3.837	0.000	0.004
Wales – Slovenia	-121.683	35.479	-3.430	0.001	0.022

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

The tests suggest that the distribution of satisfaction scores differed mainly in Berlin compared to all other regions. In Berlin, DM patients were at best indifferent (median 3.33), that is neither agreed nor disagreed with a statement posed to them that they were overall satisfied with telemonitoring. Other regions had a positive view of the experience. South Karelia distribution of scores also differed, having significantly lower median satisfaction scores (4.33) compared to Scotland, Calabria, Central Greece and Slovenia. In other regions, higher levels of satisfaction were evident. These differences could be due to differences in the interventions between regions, and even the characteristics of the DM patients that could also in principle affect their expectations and therefore the level of their satisfaction.

As far as the "Kit as substitution" scale is concerned we already mentioned that a median and a Kruskal–Wallis test indicated that differences exist between at least some regions. Figure 31 also suggests that it might in fact be the case that, once again, Berlin as well as Scotland and Wales might have lower medians than other regions.

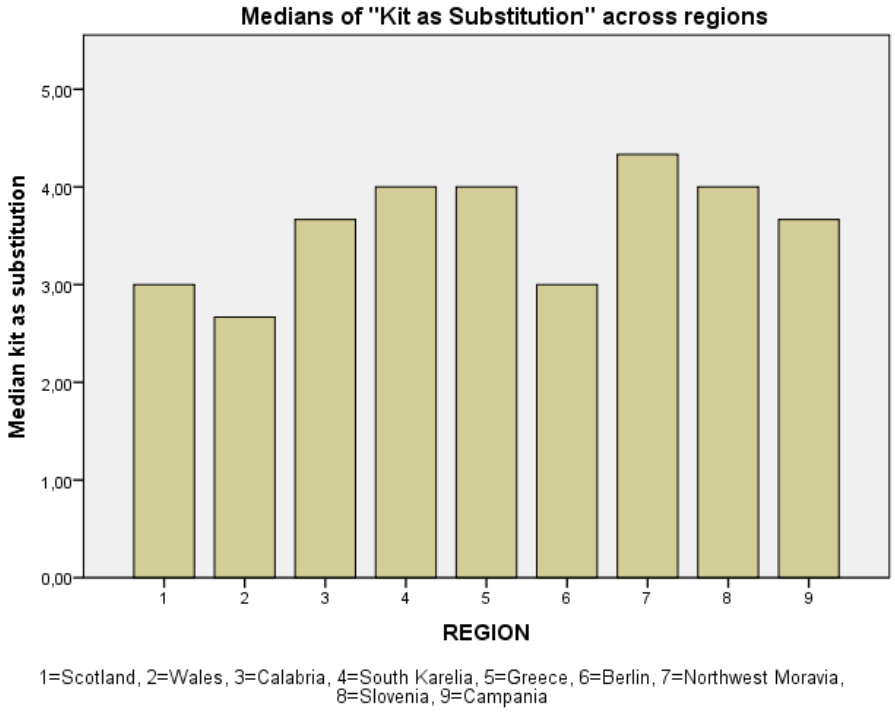


Figure 31: Medians of "Kit as substitution" across regions

Table 17: Mann-Whitney significant pairwise tests with Bonferroni corrections for "Kit as substitution" scale[a]

Sample 1 – Sample 2	Test Statistic	St. Error	Std. Test Statistic	P-value	Adj. P-value[b]
Berlin – South Karelia	189.005	49.291	3.834	0.000	0.005
Berlin Northwest Moravia	-303.036	71.070	-4.264	0.000	0.000
Berlin – Greece	245.897	36.800	6.682	0.000	0.000
Berlin – Calabria	152.455	25.155	6.061	0.000	0.000
Berlin – Slovenia	-247.798	23.966	-10.340	0.000	0.000
Wales – Calabria	-212.636	36.552	-5.817	0.000	0.000
Wales – South Karelia	-249.187	55.973	-4.452	0.000	0.000
Wales – Greece	-306.079	45.360	-6.748	0.000	0.000
Wales – Slovenia	-307.980	35.745	-8.616	0.000	0.000
Wales - Northwest Moravia	-363.217	75.857	-4.788	0.000	0.000
Calabria – Slovenia	-95.343	26.772	-3.561	0.000	0.013

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.

In Table 17 it can be seen that this is not the case for Scotland; that is, the views of Scottish DM patients do not seem to be significantly different than those in other regions. In contrast, the Mann-Whitney pairwise comparisons reveal that Berlin and Wales depart in their views. Berlin again had a lower median (Table 18) and its patients mildly disagreed that the kit could become a substitute to standard care. The same might hold *a fortiori* for Welsh patients, since they had an even lower median. In any case, the common denominator in all regions is that no patient seems to moderately or strongly believe that his standard care can be substituted by the kit.

Table 18: Median subscale scores across regions

Region/Scale	Enhanced Care	Increased Accessibility	Privacy & Discomfort	Care Personnel Concerns	Kit as Substitution	Satisfaction
Scotland	5.2	4.5	6.0	6.0	3.0	5.66
Wales	4.8	3.5	5.2	4.33	2.66	5.0
Calabria	5.2	5.0	5.0	5.0	3.66	5.33
South Karelia	4.5	3.5	5.25	5.0	4.0	4.33
Greece	5.0	4.75	5.25	5.33	4.0	5.0
Berlin	3.8	4.0	4.0	4.0	3.0	3.33
Northwest Moravia	5.8	5.75	5.5	4.33	4.33	5.33
Slovenia	5.4	5.0	4.5	4.5	4.0	5.66
Campania	4.8	4.41	4.0	4.33	3.66	4.66

Finally, it has been also suggested that the setting in Berlin might be different than that of other regions. Specifically, the intervention might be such that the patients do not directly benefit from telemonitoring, since the nurses still continue to provide care and measurements in a home-based setting without significant changes in their everyday care. Therefore one would not expect SUTAQ to reveal enhanced care, increased accessibility, satisfaction or even problems with the kit.

Table 19: Subscale descriptive statistics without the Berlin data

Subscale	Mdn	CI (95%)	IQR	% Positive Views[a]
Enhanced care	5.2	5.00-5.2	1.20	91.8
Increased accessibility	4.75	4.5-4.75	1.25	78.7
Privacy and discomfort	5.0	4.75-5.0	1.25	84.2
Care personnel concerns	5.0	5.0-5.0	1.33	84.2
Kit as substitution	3.66	3.66-4.0	1.50	48.8
Satisfaction	5.33	5.33-5.33	1.33	93.1

a. % of patients with subscale scores ≥ 4.

Also presented here are the descriptive statistics for the overall sample, excluding observations from the Berlin region (Table 19). It is apparent that the values of the scales are higher compared to those in Table 15 which contains the overall sample results. In most scales, a moderate positive view towards telemonitoring is observed. An exception is the “kit as substitution” scale where the median remains the same as in the overall sample, although the percentage of those patients reporting an agreement that the kit can be a substitute to standard care (even a mild one) has increased.

Finally, we compared the distribution of the “Satisfaction” scale across Diabetes Mellitus (DM), Chronic Obstructive Pulmonary Disease (COPD) and Congestive Heart Failure (CHF) patients; that is, the samples in the three observational studies of United4Health. In this comparison, Berlin data were not taken into account. A Kruskal-Wallis test showed that the distributions of satisfaction scores differed across the interventions for the three conditions (p=0.000). Mann-Whitney tests with Bonferroni corrections were thus performed (Table 20).

Table 20: Mann-Whitney pairwise tests with Bonferroni corrections for "Satisfaction" across regions

Sample 1 – Sample 2	Test Statistic	St. Error	Std. Test Statistic	P-value	Adj. P-value
DM-COPD	-195.855	23.810	-8.226	0.000	**0.000**
DM-CHF	-130.797	23.973	-5.456	0.000	**0.000**
CHF-COPD	65.058	28.545	2.279	0.023	0.068

The medians for "Satisfaction" in DM, COPD and CHF samples were 5.33, 6.00 and 5.66, respectively. It thus seems that in the DM intervention, satisfaction was lower than in the COPD and CHF patients. Nevertheless, this difference should not be overemphasised since in all three cases a moderate or strong agreement of patients that they were satisfied was documented.

4.3.2 Effects of demographic and other variables on patient acceptability

Initially, we excluded from regression analysis observations from the Berlin region. The reason was twofold: a) the intervention in that region differed considerably from all other regions, in that patients continued to receive care as before in their homes with no changes in their daily living, and b) our analyses showed that the reliability of the scales in this region was very low. We also excluded observations with improbable values (for instance, negative values for the time from trial initiation to SUTAQ administration).

One problem that might exist due to the non normal nature of SUTAQ subscale scores is potential departure from normality of the regression error terms. Substantial departures from normality might distort relationships and significance tests. Therefore, although we estimated the regression with Ordinary Least Squares, we examined the PP-plots on the standardised residuals to check any significant problems with the distribution of the error terms that would force us to try various transformations of the dependent variable or even employ alternative more advanced methods of estimation. We ran six regressions, one for each SUTAQ subscale score that was used as the dependent variable.

Regressors were gender (dummy), age (categorical with 3 categories), education level (categorical with 4 categories), familiarity with a PC (PC USE dummy), time from trial start to questionnaire administration (TIME continuous variable, in days), and the existence of chronic complications (COMPL dummy). Type of diabetes was entered only with one dummy (=0 for type 1 and =1 for type 2) since there were few cases for type 3 DM. Age was entered into the model by means of two dummy ($AGE_{65\text{-}75}$ and AGE_{75+}) variables (reference category excluded: patients <65 years old.). Education was incorporated with three ($EDUC_{primary}$, $EDUC_{secondary}$, $EDUC_{unicollleg}$ dummies (reference category: no formal schooling).

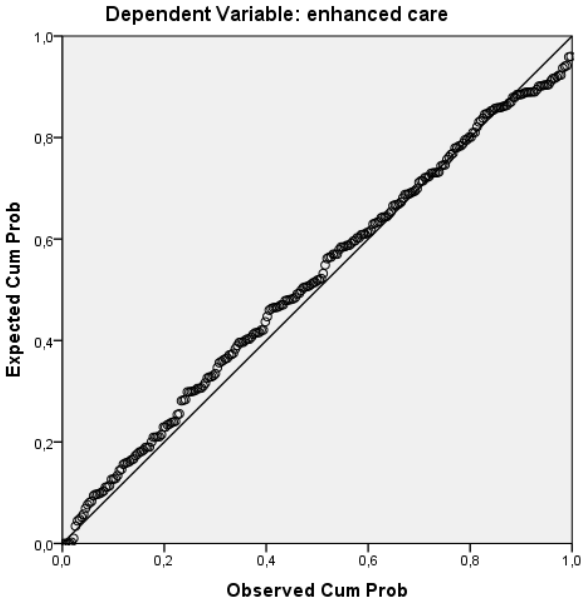


Figure 32: Normal P-P plot of standardised regression residuals.

The regression PP-plot for "Enhanced Care" did not show worrying departures from normality. The same was true for other subscales (other P-P plots not presented here). Another potential violation of the classical linear regression assumptions that might harm our results is heteroscedasticity. The Breusch-Pagan test rejected the null of homoscedastic variances in the subscales "Privacy and discomfort" (p=0.043) and "Care personnel concerns" (p=0.009) and therefore heteroscedasticity consistent estimators were used instead of OLS. The six regressions employed between 254 and 257 observations.

Regressions results are presented in Table 21. Only significant coefficients are reported. The familiarity of some of the patients with a PC was associated with lower scores in the "Enhanced Care", "Increased Accessibility" and "Satisfaction" scales. It might be that these patients were less readily impressed by new technologies or that they had higher expectations regarding technological advances. In contrast, the opposite finding one could equally expect that those with PC familiarity would find the kit friendlier and easy to use does not seem to hold. If we take into account the magnitude of the coefficients and the medians for these scales, it seems, nevertheless, that patients with familiarity with a PC might still have positive views about the kit. The same holds for Satisfaction with the kit, in that although patients familiar with a PC report lower satisfaction, they do nevertheless moderately agree that they were indeed satisfied with telemonitoring.

Table 21: Significant regression results without Berlin data

Variable	B	Std. Error	t	p-value
Enhanced Care				
PC USE	-0.237	0.117	-2.020	0.045
Increased Accessibility				
PC USE	-0.285	0.144	-1.98	0.049
Privacy and Discomfort				
$EDUC_{primary}$	1.140	0.567	2.01	0.046
TIME	-0.002	0.000	-2.55	0.011

Variable	B	Std. Error	t	p-value
Care personnel concerns				
		NS		
Kit as substitution				
TIME	-0.002	0.000	-2.36	0.019
Satisfaction				
AGE_{75+}	-0.419	0.204	-2.05	0.041
$EDUC_{primary}$	0.901	0.395	2.28	0.023
$EDUC_{secondary}$	0.799	0.392	2.04	0.043
$EDUC_{unicolleg}$	1.089	0.410	2.65	0.009
PC USE	-0.361	0.126	-2.85	0.005

Education seems to affect patients' views about whether the kit raised privacy issues or made them feel discomfort. Patients without formal schooling reported less agreement that the kit did not create such problems, than did DM patients that went to elementary school. It is also the case that they were less satisfied overall by the kit compared to all other patients that had elementary, secondary and college/university education. This could be due to the fact that people with no formal education might have faced greater problems understanding the telemonitoring process and coping with the new service.

Patients older than 75 years were less satisfied (still, satisfied) than patients younger than 65 years. This could be due to the difficulties faced by older patients to cope with the telemonitoring process, or a greater reluctance towards the new service. Finally, the time from trial start to questionnaire administration seems to have a similar effect regarding patient views on the privacy and discomfort and kit as substitution. Given the estimated coefficients, we can say that as time evolves patients seem to adjust downwards their beliefs about the kit and report a more positive agreement that the kit did not create privacy and discomfort issues or even a negative mild view regarding the possibility of the kit substituting usual care.

4.3.3 Reliability, validity and ceiling effects of the sub-scales

The supplementary analysis that follows is meant to assess the psychometric properties of the SUTAQ questionnaire in the sample of DM 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 coefficient was recalculated with a particular item first being deleted. This showed us if the reliability of a scale could be improved if in fact it was found to be less than satisfactory. In case coefficients are lower than expected, the Cronbach should be computed also for each region's dataset alone, to see which dataset provides the more reliable results on which to place greater confidence.

Table 22: Internal consistency reliability of subscales

Subscale	Cronbach's alpha	Cronbach with item deleted
Enhanced care	0.770	-
Increased accessibility	0.730	-
Privacy and discomfort	0.677	-
Care personnel concerns	0.514	-
Kit as substitution	0.429	0.444 (Q18)
Satisfaction	0.717	-

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

On inspection of Table 22 we see that the reliability of the first three scales as well as that of "Satisfaction" can be considered satisfactory. However, subscales "Care personnel concerns" and "Kit as substitution" seem rather problematic, and their Cronbach does not significantly improve if we exclude certain items. Since this casts doubts on the values derived from these two latter scales, we examine also whether in some regions they performed better in order to place a higher quality weight on them during our conclusions.

It is indeed 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 from the overall median findings. The first of the two scales took better Cronbach values in Wales (α=0.613), Calabria (α=0.601) and Central Greece (α=0.714). The other regions had reliabilities lower than 0.50. Re-calculating (in the sense of performing sensitivity analysis) the median of the "Care personnel concerns" with the sub-samples of only these three countries yielded a value of 5. This is somewhat higher than the median for the overall sample of all regions obtained earlier (see Table 15) which equals 4.66. In any case, the conclusion still remains the same: there is moderate agreement among DM patients that there were no problems related to the personnel involved in the telemonitoring process.

Table 23: Multi-trait / multi-method analysis[a]

Subscale / Item	Enhanced Care	Increased Accessibility	Privacy & Discomfort	Care Personnel Concerns	Kit as Substitution	Satisfaction
Enhanced Care						
Item 10	0.462[b]	0.452	0.162	0.177	0.413	0.346
Item 11	0.612[b]	0.504	0.280	0.255	0.385	0.532
Item 13	0.619[b]	0.464	0.271	0.271	0.359	0.567
Item 15	0.678[b]	0.478	0.433	0.344	0.393	0.719
Item 17	0.604[b]	0.431	0.294	0.265	0.363	0.577
Increased Accessibility						
Item 1	0.604	0.509b	0.221	0.202	0.470	0.515
Item 3	0.393	0.558b	0.156	0.187	0.328	0.306
Item 4	0.562	0.428b	0.192	0.167	0.386	0.493
Item 19	0.366	0.481b	0.145	0.142	0.311	0.246

Subscale / Item	Enhanced Care	Increased Accessibility	Privacy & Discomfort	Care Personnel Concerns	Kit as Substitution	Satisfaction
Privacy and Discomfort						
Item 2	0.240	0.177	0.457b	0.329	0.109	0.256
Item 5	0.275	0.155	0.507b	0.399	0.160	0.287
Item 8	0.242	0.129	0.511b	0.409	0.157	0.289
Item 12	0.309	0.191	0.491b	0.441	0.181	0.336
Care Personnel Concerns						
Item 9	0.340	0.207	0.495	0.351b	0.222	0.389
Item 20	0.342	0.210	0.379	0.385b	0.132	0.356
Item 21	0.254	0.177	0.385	0.408b	0.226	0.248
Kit as Substitution						
Item 16	0.276	0.327	0.168	0.179	0.275b	0.268
Item 18	0.223	0.233	0.159	0.204	0.165b	0.177
Item 22	0.523	0.457	0.212	0.222	0.250b	0.383
Satisfaction						
Item 6	0.533	0.361	0.279	0.261	0.280	0.546b
Item 7	0.535	0.411	0.348	0.324	0.373	0.545b
Item 14	0.723	0.514	0.390	0.363	0.416	0.683b

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

Regarding the “Kit as substitution” subscale, for the sample of South Karelia alone, the reliability coefficient did take an acceptable (in fact, a very high 0.868) value. The median of this scale in South Karelia was 4.0. Two other regions had by far lower Cronbach’s alpha coefficients that were close to zero or even negative. We hence re-calculated the median value of the overall sample with the exclusion of the observations in these two regions to see if the value is different from the median of 3.66 we reported earlier in our main analysis in Table 15. Yet, the re-computed median turns out to be exactly the same, that is, 3.66, corroborating the initial finding.

We also applied the multi-trait / multi-method approach to assess the UK WSD model’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 23 presents the findings. Convergent validity requires correlations of items with their own scale to be higher than 0.40. Four subscales satisfy this condition, with the exception of “Care personnel concerns” and “Kit as substitution”. These are indeed the scales that also had low Cronbach’s alpha coefficients.

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, like 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 as well. This is the case since many items seem to correlate more with unrelated scales than with the scale they supposedly belong to. Even without formal statistical testing of the differences in correlations, it is evident that there are some problems with construct validity.

We examined construct validity further by means of Confirmatory Factor Analysis. This allows 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. One should keep in mind 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 and performed an Asymptotically Distribution Free (ADF) estimation given the large sample size and the lack of normality in the data, as indicated by skewness and kurtosis statistics for SUTAQ items and a multivariate normality test (Figure 33).

The estimated standardised regression weights should be >0.45. One such factor loading, namely Q18, equals 0.27 and thus falls short of the chosen cutoff. This implies some problems in the construct validity of the "Kit as substitution" scale.

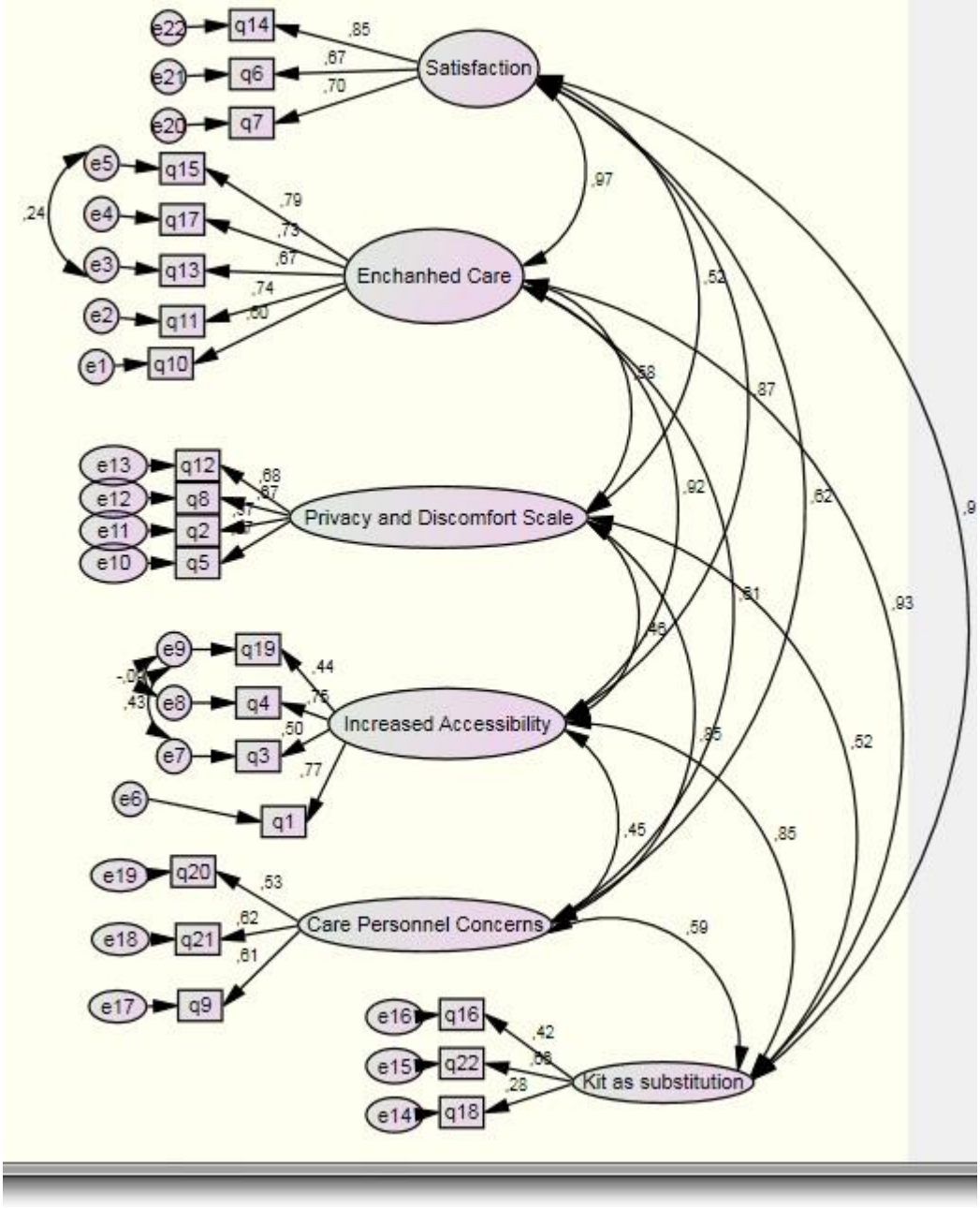


Figure 33: Path diagram of the Confirmatory Factor Analysis of the UK subscales.

The fit indices obtained were the following:

- Bentler's Comparative Fit Index (CFI) = 0.797. 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.
- Goodness of fit index (GFI) = 0.917. It is a measure of fit between the hypothesised model and the observed covariance matrix. Adjusted GFI (AGFI) = 0.890. It adjusts CFI for the number of indicators of each latent variable. The value of this index should exceed 0.90 for an acceptable model fit.

- Root Mean Square Error of Approximation (RMSEA) = 0.044. 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 = 2.811. 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 0.5 to 2.1% 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 (2.6%) and higher for other scales, reaching 31.9% in the “Satisfaction” scale.

Overall, the evidence on the psychometric properties of the SUTAQ questionnaire implies that there are some issues with the reliability of some scales in some regions, but this does not seem to affect considerably the main conclusions. There are also some validity concerns acting as study limitations.

4.4 Discussion of findings

Summing up, it seems that the median patient with Diabetes Mellitus believes that telemonitoring enhances the care the patient receives from the healthcare system and increases the accessibility to healthcare services, whilst at the same time does not create problems with his privacy, cause discomfort nor cast doubts about the personnel delivering telemonitoring services. However, the patient is rather indifferent as to whether the kit can be a substitute to usual care. Nevertheless, the patient is overall very satisfied with the kit.

In the telemonitoring for the life-long management of diabetes patient satisfaction was lower than in the respective interventions for the short-term follow up after hospital discharge of COPD patients and remote monitoring of congestive heart failure. Nevertheless, this difference should not be overemphasised, since in all three trials a moderate or strong agreement of patients that they were satisfied was documented.

Sub-group analysis showed that beliefs might differ between regions. In fact, patients in Berlin were rather indifferent rather than satisfied with the kit, which can be explained by the different population and service / intervention compared to other regions in U4H. It is also the case, however, that the patients in South Karelia also had lower satisfaction ratings than other regions. In fact, a mild satisfaction rather than moderate preference is documented. This could be due to different expectations, differences in the experience, or a combination of the two. There were also differences regarding the views in different regions about the possibility of substituting standard care with the kit. Patients in Berlin, but also Wales, had significantly lower ratings, indicating that they mildly disagreed that the kit could be seen as a substitute, whereas in other regions an indifference or mild positive view was evident.

It was also shown that DM patients who were familiar with the use of a personal computer had less positive views about telemonitoring (still positive though) and its ability to enhance care and increase accessibility to healthcare services. Furthermore, patients with no formal schooling had more concerns about privacy and felt more discomfort than patients with primary education. Moreover, they were less satisfied with the kit compared to patients at all other education levels. Patients older than 75 years were less satisfied than patients younger than 65 years, a finding that could be due to a reluctance of older persons to adopt the kit, or even an inability to cope with the demands of the new service. Finally, it seems that in the longer period of implementation of telemonitoring, patients have more concerns about privacy and feel more discomfort about the kit, thus adjusting their moderate positive ratings to milder ones regarding this dimension of the telemonitoring experience. Similarly, they tend to believe even less than in the beginning of the trial that the kit can substitute their usual care.

The results of the present study should be considered with some caution. Although reliability issues did not significantly alter the main findings, some validity problems did exist for SUTAQ, implying that the questionnaire developed in the UK may not perform ideally in terms of psychometric properties in other telemonitoring settings.

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 Domains 1 and 3.

5.2.2 Comparators

Described in Domain 1.

5.2.3 Data on costs of the telehealth intervention

The costs of the telehealth intervention were 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 was 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 was used to estimate the fixed costs per patient. With regard to investment in the staff, e.g. training of nurses and medical doctors, regions were asked to provide information about the number of patients using these human resources at the moment. This number was 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 were 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 at the project disease level rather than individual deployment site level, 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 was estimated as the costs of the telehealth service minus the saved costs of usual care:

Net costs per patient = $(FC_{TM}+VC_{TM}) - (P_A*R_A) - (P_{ED}*R_{ED}) - (P_{GP}*R_{GP}) - (P_{OV}*R_{OV})$

where:

FC_{TM} = the fixed costs of the telehealth service per patient
VC_{TM} = the variable costs of the telehealth service per patient
P_A = Price per admission
R_A = Reduction in the number of admissions by use of telehealth per patient
P_{ED} = Price per emergency department visit
R_{ED} = Reduction in the number of visits to emergency department by use of telehealth per patient
P_{GP} = Price per visit to general practitioner
R_{GP} = Reduction in the number of visits to general practitioner by use of telehealth per patient
P_{OV} = Price per outpatient visit
R_{OV} = Reduction in the number of outpatient visits by use of telehealth per patient

Note that all reductions in use of healthcare (denoted R above) were estimated for each multicentre study by use of all data from all patients in all regions included in the study. For diabetes this is nine regions. Therefore, these estimates are an average of the impact of the intervention in all regions included in each multicentre study. This estimate was 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 was 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 were identified.

5.3 Results

5.3.1 Estimates of costs of the telehealth service

Table 24 describes the estimated prices of the telehealth intervention per patient in each of the participating regions in the diabetes 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 have been combined in the tables.

For the regions in the diabetes trial (see Table 24) the weighted mean (the number of patients in each region is used as weight) cost per patient of the telehealth service is €334, but with wide variations from region to region (from €33 to €1.365). This reflects both, that the technical solutions vary, that the number of patients varies (from 100 to 8000) and that the characteristics of the patients vary as described in the section on clinical results. More details about the explanatory factors are presented in the section below.

The table also presents the number of patients using the telehealth service in each region.

For some regions (Scotland, Wales, South Karelia) information was provided on both the potential number of users and the actual number of patients with diabetes using the service. When estimating the cost per patient on investment in devices and technical infrastructure, the total cost of investments was divided by the potential number of patients. When estimating the cost per patient of investment in the staff, the actual and smaller number of patients was used.

In each case where the cost per patient was significantly higher than other sites for the same disease, the cost was 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. This finding also impacted on the running costs, as the telehealth technologies in some of these sites did not include alert algorithms, so that all patients' uploaded data was required to be reviewed daily. Note also that the costs associated with the physiological measurement devices came down significantly during the three-year period of the project.

The costs did not include any costs associated with project management, development and procurement, asset management, documentation production and publicity / communication activities.

The table below also shows a large difference with regard to the distribution of the costs across the types of costs. For some regions, the telehealth devices were the most costly (e.g. Wales and Slovenia), but in other regions the mean cost of the use of staff in the telehealth service was the most costly (e.g. Moravia and Berlin). Again this reflects large differences in the organisation of the telehealth service and type of devices used. Some regions invested in buying the telehealth devices, while other regions rented equipment and paid an annual rental.

Table 24: Average costs of telehealth intervention per patient in the diabetes trial

Type of healthcare	Region				
	Scotland	Wales	Northwest Moravia	Slovenia	South Karelia
Investment in telehealth application					
- Devices, technical infrastructure	1	9	165	143	15
- Management, education, training	2	3	24	1	0
Total investment costs	3	12	189	144	15
Variable costs:					
- Telehealth devices	0	54	0	340	0
- Staff	30	1	1.036	146	28
- Other costs	0	0	140	0	0
Total variable costs	30	55	1.176	486	28
Total costs	**33**	**67**	**1.365**	**630**	**43**
Expected number of patient per year	8000/ 1200	400/126	200	400	8500/ 150

Type of healthcare	Region				Weighted average
	Central Greece	Berlin	Campania	Calabria	
Investment in telehealth application					
- Devices, technical infrastructure	62	6	23	5	33
- Management, education, training	2	9	6	5	4
Total investment costs	64	15	**29**	**10**	**37**
Variable costs:					
- Telehealth devices	0	0	0	0	44
- Staff	274	1.113	374	127	238
- Other costs	14	60	0	0	15
Total variable costs	288	1.173	**374**	**127**	**297**
Total costs	**352**	**1.188**	**403**	**137**	**334**
Expected number of patient per year	100	300	200	250	

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 – Diabetes

The NHS in Scotland has a national approach to diabetes care management. Through the U4H project, they have further invested in their My Diabetes My Way (MDMW) online information portal, together with the SCI diabetes medical record system to integrate patient level blood glucose measurements into the patient's PHR within the MDMW portal as well as their diabetes EMR. Blood glucose measurements are not monitored in real time by the patient's clinical team, and no alerts are generated. The data is reviewed as part of routine care consultations in either primary or secondary care settings. Any future investments in enhancing both MDMW and the SCI diabetes record will be taken at a national level. In addition, investment costs are divided between the 8,000 patients expected to use the system in the coming years. Therefore, the costs per patient of the intervention in Scotland are lower than in other regions.

Wales – Diabetes

The low investment and running costs for the service in Wales are as a result of their care delivery model being based on routine primary care and providing patients living with Type 2 diabetes with the Florence telehealth system. This enables patients to text their regular blood glucose measurements and receive automated diabetes care management health coaching text messages to support self-management. Thus, the system is an automated health coaching system that automatically submits information to patients. This is done without any involvement of the clinical staff; the staff costs are therefore very low.

Campania – Diabetes

Inability to secure structural funds for telehealth technologies led to Campania requiring all patients recruited to have access to the Internet either through their own device or that of a relative or friend. Therefore, the cost of devices and infrastructure is low. The diabetes telemonitoring service was provided by dedicated temporary newly qualified diabetologists under the supervision of a consultant. The telemonitoring system did not include any alert functionality, so the diabetologists reviewed each patient's readings daily.

Calabria - Diabetes

Calabria's costs reflect a telemonitoring delivery model provided by a commercial vendor at no cost to ARSAN. The region is expecting to use a similar solution in the future.

Berlin – Diabetes

Pflegewerk is a managed care organisation in Berlin which provides care and support to 900 people living in a range of supported living accommodation. Therefore, the telemonitoring service will not be expanded to reach more people, but may be extended to cover additional chronic diseases in the future, e.g. CHF. Note that the investment costs included additional physiological measurement devices which were not required by the protocol. The managed care contract requires the doctors and nurses to monitor their patients either through virtual or face-to-face visits; therefore, some of the healthcare usage figures, i.e. number of visits, will not reduce under the current contract model.

South Karelia – Diabetes

The investment costs included in the South Karelia figures are based on taking a percentage of the region's annual whole population Personal Health Record (PHR) investment costs. This system enables patients living with diabetes to enter their daily blood glucose measurements into their PHR. The system is expected to be used by 8,500 patients in the coming years, and the costs of investment are therefore divided by this large number of patients. In addition, patients are using their own devices, and there is therefore no cost for devices. The patients' care team did not monitor their readings, and no alerts were generated; responsibility is given to the patient to message their care team if their readings were outside their parameters. Therefore, the costs of staff are very low.

Greece - Diabetes

The diabetes care service in Greece is provided by hospital-based diabetologists; the cost of their involvement is reflected in both the staff training and running costs.

The telehealth system did not include alerts, and the diabetologists were required to review patients' blood glucose readings according to their uploading regime. In addition, the telemonitoring market is very small in Greece, and limited to only two vendors; the price point is therefore unlikely to be lowered significantly in the future.

Northwest Moravia – Diabetes

There were high costs associated with the education and training delivered to the team in this site due to their low level of computer literacy and experience with telehealth. Even though the hourly costs of doctors and nurses are low in Moravia, a large number of hours of assistance from medical doctors, nurses and technical staff results in high costs of staff per patient in this region. In addition, the investment costs were higher than many other sites as a public procurement process resulted in the chosen software requiring additional local configuration and adaptation.

Slovenia

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 the 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 for both diseases.

5.3.3 Prices of healthcare services in the regions

Table 25 presents 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 were 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 was the lowest and that the price per admission was the highest. The price per ED visit and per outpatient visit was often quite similar.

The prices for Scotland and Wales were similar because the two regions are both part of the UK's National Health Service.

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 25: Prices for use of healthcare in the diabetes trial (in €, 2015)

Type of healthcare	Region				
	Scotland	Wales	Northwest Moravia	Slovenia	South Karelia
Price per visit to GP	63	63	7	16	232
Price per visit to emergency department	207	207	15	33	184
Price per outpatient visit at hospital	151	151	12	64	126
Price per admission to hospital	5.239	5.239	412	2.769	3.192

Type of healthcare	Region			
	Central Greece	Berlin	Campania	Calabria
Price per visit to GP	10	22	12	12
Price per visit to emergency department	5	85	241	241
Price per outpatient visit at hospital	5	160	13	13
Price per admission to hospital	1.735	3.580	4.552	4.552

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 26 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 26 presents the results from the diabetes trial. The table shows the proportion of patients with admission to hospital and the proportion of patient with a visit to the emergency department during 12 months was statistically significant lower for patients using telehealth than for patients in the comparator group. A similar reduction was found in the number of GP visits and the number of outpatient visits. But these differences are not statistically significant.

Table 26: Estimated coefficients for the impact of telehealth in the diabetes trial (Adjusted for gender, type of diabetes, smoking, age, years of diabetes, CCI, COM10)

	Estimated coefficient (B)	Standard error	Statistical significance (p value)	Odds ratio - Exp (B)	Confidence interval for odds ratio (Exp(B))
Number of visits to GP or diabetologist	-0.182	0.238	0.445		
Use of emergency department (logistic)	2.660	0.568	0.000	14.291	4.698 – 43.469
Number of outpatient visits at the hospital	-0.063	0.127	0.620		
Use of admission to hospital (logistic)	1.658	0.567	0.003	5.249	1.728 – 15.946

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 was possible to estimate the changes in the total costs of healthcare per patient. In practice this was done by use of the equation presented in the methodology section.

Table 27 presents the estimated total costs per patient. The table includes both information about the costs of the telehealth interventions (from Table 24) 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 diabetes trial, proportion of patients admitted per year was 10.2%.

Based on these estimates and the estimated odd ratio in Table 26, the reduction in the number of admission from the use of telehealth was estimated to be 0.04 admissions.

Table 27 shows that on average the use of telehealth in the diabetes trial increased the mean costs per patient by 153€. The main reason for this result was the cost of the telehealth service; these costs were higher than the savings in the cost of admissions. Note that the difference in the change in the costs of the different types of visits reflected the difference in the prices of these services between countries, because the change in the number of visits was the same, based on the results from the regressions including data from all sites.

However, the table also shows large differences between the different regions. Thus, in Scotland, Wales, South Karelia and Calabria, a reduction in the mean costs per patient was found, whereas in Berlin and Moravia the mean costs per patient increased by more than 1,000€ per patient by the use of telehealth. The main reason for this variation was the large variation in the costs of the telehealth intervention as described in section 5.3.3.

Table 27: Estimated total costs per patient in the diabetes trial

Type of health care costs	Region				
	Scotland	Wales	Northwest Moravia	Slovenia	South Karelia
Costs of telehealth	33	67	1.365	630	43
Change in costs of GP visits	-11	-11	-1	-3	-42
Change in costs of ED visits	-32	-32	-2	-5	-28
Change in costs of outpatient visits	-10	-10	-1	-4	-8
Change in costs of admissions	-210	-210	-16	-111	-128
Total net costs per patient	**-230**	**-196**	**1.345**	**507**	**-163**

Type of health care costs	Region				Weighted average
	Central Greece	Berlin	Campania	Calabria	
Costs of telehealth	352	1.188	403	137	334
Change in costs of GP visits	-2	-4	-2	-2	-8
Change in costs of ED visits	-1	-13	-36	-36	-21
Change in costs of outpatient visits	0	-10	-1	-1	-6
Change in costs of admissions	-69	-143	-181	-181	-147
Total net costs per patient	**280**	**1.018**	**183**	**-83**	**153**

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 showed that:

- The telehealth intervention in the diabetes trial increased the average costs per patient by about 153€, mainly because of the costs of the telehealth intervention. However, in four of the nine regions a reduction in the mean costs was found.
- Many sites reported that more time and effort than expected was needed to get the applications to run smoothly and to make sure that the patients felt ready and secure.
- There are large differences in the way the sites organised the provision of the telehealth service, and the types if ICT solutions involved for diabetes patients in the different regions.
- The length of training courses for staff varied widely, from a few hours to a 60-hour course. The training varied in content and duration due to the different levels of detail that was required for each professional group.
- No sites reported decreases in working hours.

In addition, the clinical results from the diabetes trial indicated that the patients have improved clinical outcomes because the long term blood sugar level (HbA1c) is reduced for patients using telehealth. If this effect is maintained in the long run, this will result in clinical benefits in the form of a reduction in the number of complications related to diabetes, and thereby in reduced costs of treatment of these patients. Therefore, the long term economic impact of the telehealth intervention for patient with diabetes may be a reduction in the costs per patient and not an increase as identified here.

The strength of the economic assessment of the project is that it followed guidelines for health economic evaluation and studies of telehealth as described by Drummond et al. (2005) and Bergmo (2015). This study also included 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 were 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 was 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 considered:

- The estimated effects on the patients use of healthcare was 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 collected data on groups of patients using telehealth and comparator groups that were not similar at baseline. As the clinical results described, large and statistically significant differences were found between the two groups in all three multicenter trials. This could suggest that selection bias was present e.g. because the oldest patients refused to use the telehealth devices.
- In an attempt to adjust for the systematic differences between the telehealth and the comparator groups, regression analyses were made. However, because of problems with missing data and a lower sample size than expected, it was not possible to include all possible confounders. Therefore, there is a high risk that the estimated effect on the patients' use of healthcare services was biased, and more studies of the sensitivity of the results should be carried out.
- In the economic analysis of the costs per patient, all results from the regressions were included, even though not all coefficients were statistically significant.
- The costs of the telehealth interventions were 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 U4H were planned by the participating regions based on a detailed clinical protocol, large variations were 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 culture for the diabetes study involved qualitative methods such as focus groups and individual interviews with key participants. Some sites interviewed everyone involved, whereas others chose a few participants. One site made two individual online interviews only. Another site commissioned University researchers to undertake a qualitative assessment of stakeholder perceptions and acceptance of U4H.

6.2 Organisational Structure

There are large differences in the way the sites organise the provision of the telehealth service to patients living with diabetes and these differences are also reflected in the routine diabetes care pathways.

The setup ranges from patients attending scheduled consultations in municipality / community-based diabetes centres, sites were the diabetes care service is delivered by teams of professionals from primary, community and hospitals working together, to a service involving a single hospital department with no involvement of primary care.

The introduction of the telehealth service does not appear to have increased the level of integration between the different health care sectors. However, the patient's access to diabetes specialist support was improved in those sites where the telehealth technology included alerts. It was interesting to note that the municipality / community-based diabetes centres in some sites provided the function of outpatient consultations as well as unscheduled / emergency care for patients.

Most sites' established their telehealth service through enhancing the roles and responsibilities of the existing healthcare professionals who deliver on-going diabetes care management. In Wales, Scotland, Finland and Slovenia, the service was provided by nurses with GPs and / or diabetologists being available for advice if necessary. The diabetes care models, and therefore the telehealth service in the Czech Republic and Pflegewerk in Germany involved nurses and doctors working closely together unlike ASP Cosenza and ARSAN in Italy where the service was provided by diabetologists working in the community diabetes centres and Central Greece whose service was also delivered by diabetologists but working in the hospital.

The table below describes the technical aspects of the IT infrastructures and telehealth devices available in each of the deployment sites. It is important to note that one of the eligibility criteria for enrolling patients into the study in Scotland, South Karelia and Campania was that they had access to an internet-enabled device, ie either a smartphone, tablet or computer.

Deployment Site	Model
Scotland (all sites)	Access to all the components of the diabetes technical solution is via the internet: My Diabetes My Way (MDMW) is an established website. SCI Diabetes is a real time, web-based clinical information system available to all clinicians in Scotland supporting the care of all people with diabetes. Diasend offers web access for both clinicians and patients. However, access will be encouraged via MDMW, which gives users the full services / support / information available via this nationally supported website. Web access was via existing computers with internet access. Patients continued to use their current home blood glucose monitoring device. Diasend supports the upload of information from most (but not all) of the devices used in the Scottish diabetes service. The patient downloads software onto their home computer to facilitate the upload of data from their blood glucose monitoring device. Physical structures are already in place within the hospitals and clinics. IT equipment such as PC and telephones are all already in place. New equipment required was the Diasend transmitters (patients already self-monitoring have blood glucose monitors). Additionally, Meter USB cradles have been required to ensure that the patients can access their readings on the MDMW website with their computer. There has also been a requirement to change certain BGMs as some were compatible with Diasend.
Wales	The Welsh solution is based on mobile phones. Patients with their own phones continued to use their own mobile network operator, there was no charge to receive or send text messages relating to their participation in the project – the cost was incurred by the Health Board. Patients without a mobile phone were provided one by the Health Board; this was a pay-as-you-go contract meaning that if patients wished to use it outside of the project they would have to incur the cost.
Northwest Moravia	Glucometers, test strips, mobile gateways (smartphones and tablets), application software, telehealth web portal, servers, databases, equipment for medical staff (larger tablets), SIM cards. Gateway is used to transfer measured data to the back-end part of the solution and to provide patients with new tasks and data. Mobile application represents the user interface through which patients realise measurements of selected vital parameters. The measurements are taken by vital sign monitors that communicate automatically with the mobile app via Bluetooth.
Slovenia	Private supplier of patient´s equipment. A national mobile service provider, Telecom Slovenia provides cell phones in bundles of 100.
South Karelia	Remote monitoring software was procured during the SUSTAINS project. Procurement materials were prepared with Eksote's in-house company Medi-IT.

Deployment Site	Model
Central Greece	Tele-monitoring services of the Municipalities are provided to individual citizens with chronic heart failure, chronic asthma, diabetes, arrhythmias, dementia and hypertension. However at large scale everyday clinical level, the telemonitoring of patients with diabetes type 2 is running. The equipment includes: • smart medical devices combined with internet access medium; • web-based software for telemonitoring of medical parameters. In particular, the telehealth centre provided telemonitoring services to chronic patients and the elderly as well as social services to the patients participating in the project. Telemedicine with CE /DOC certification as medical devices were used, for the wireless transmission of vital signs to a web-based platform.
Berlin.	The company Insight Health Solution GmbH from Munich provides the database, the device and the software. For this Pflegewerk paid a quarterly fee. Technical support for the integration of systems and the further procurement via the IT department of PW.

6.3 Communication and stakeholder engagement

All sites undertook a range of stakeholder awareness and engagement activities. Some sites developed promotional materials for different audiences (presentations, posters, leaflets, FAQs) and patient-specific information sheets; these were shared with other sites when requested. Communication and project progress was also reported through the various project organisational and governance structures that were put in place in each site.

Northwest Moravia and Berlin focused on internal communication. Northwest Moravia appeared to focus on improving internal communication between nurses and doctors in order to solve different types of alerts, thus improving patient safety. Berlin focused on better communication and cooperation within the project based on a better technical development and the optimisation of information management.

For the others, who communicated on a broader level, an important goal was to reach out to potential stakeholders in order to encourage more partners to consider joining the project or transforming some of their services to telemedicine.

This is true for the U4H Slovenia team, who have been running several promotional activities at different levels, to promote the telemedicine service for DM and CHF patients; this is currently available only regionally, but has capacity to be extended to the national level in Slovenia. The team organised around 20 presentations with demonstrations to different stakeholders.

The same happened in Wales, albeit at a more local level. Phone calls, emails and visits to GP practices to see Practice Managers, practice nurses and GPs were undertaken, to invite them to participate in the telemedicine activities.

The Scottish sites worked with communication in a systematic way, each site developing a defined communication strategy and engagement plan, which was tailored to specific local needs and perceived challenges and opportunities.

In Cosenza, engagement of the other physicians and nurses was carried out by one of the two diabetologists, mainly in an informal way. Other internal stakeholders such as the IT department, the purchasing department and the human resources department were involved only temporarily and marginally. No initiatives were undertaken for the involvement of external stakeholders (e.g. patients' associations).

6.4 Workforce

Table 28: Workforce in each region

Site	Levels of care / sectors involved	Professionals involved
Scotland 1 Ayrshire & Arran	Hospital departments Primary care Community care Management & leadership eHealth & National SCI Diabetes Team	2 Hospital nurses (diabetes specialists) 4 GP practices, 1 GP each site 4 practices, 2 GP practice nurses each site
Scotland 2 Greater Glasgow & Clyde	Hospital departments (2 acute hospital Diabetes Centres) Primary care Community care Management & Strategic Leadership Clerical and administration	2 Consultant diabetologists based within Diabetic Centres 3 Specialist diabetic nurses 1 Nursing assistant 1 GP All practices: 1 Primary care support nurse
Scotland 3 Lanarkshire	Hospital departments (2 hospitals) Primary care Community care Management & Strategic Leadership Clerical and administration	Hospital MDs (5 consultant diabetologists, 1 specialty doctor in diabetes) 9 Hospital nurses (7 specialist nurses, 2 clinical support workers) 1 Specialty GP in diabetes 1 GP practice nurses (community practice nurse) Service manager (diabetic specialist nurse manager)
Wales	Primary care Self-care (by patients) Technical support	43 GP practice nurses 1 Clinical Lead for telehealth
Northwest Moravia	1 Hospital department: Internal medicine. There was no integration between different levels of care. Telemedicine services were organised under the Department of Internal medicine of the University Hospital Olomouc.	3 Hospital MDs, all diabetologists 1 Hospital nurse 2 biomedical engineers

Site	Levels of care / sectors involved	Professionals involved
Slovenia (Diabetes and CHF answered together)	Hospital departments Primary care Community care	2 Hospital MDs, 1 cardiologist and 1 diabetologist 2 hospital nurses, telemedicine centre coordinator and operators 1 Municipality MD 2 Municipality nurses
South Karelia	Primary care Community care	11 GP practise nurses (17 were invited to join project)
Central Greece	Hospital departments: Diabetes Outpatient Department Municipality health / social care workers: nurses IT specialists	Hospital MDs: Resident in Endocrinology – Diabetology Consultant Physician Director 1 Hospital nurse 2 Municipality nurses IT personnel in the Municipal telehealth service
Berlin	Hospital departments (Internal Medicine and Geriatrics Section) Primary care Private medical centre Private health care with nurses and social services social care workers	4 Hospital MDs 8 Hospital nurses 15 Municipality MDs 12 GPs 28 Nurses and nursing assistants (employed by Pflegewerk (PW))
Cosenza Region	Municipality	3 Municipality MDs: Diabetologists resident in Diabetes Centres 3 Municipality nurses, specialist nurses resident in Diabetes Centre

6.4.1 Roles, responsibilities and collaboration

As most sites integrated the telehealth service into existing care pathways and care workflow processes, there was little or no task shifting amongst the care team. Of those sites that did report a shift, the nurses in the hospital providing the service in Northwest Moravia had an increased role and responsibilities in relation to the telehealth service compared to routine diabetes care; the telehealth model also included the biomedical engineers providing technical and telehealth-use triage support. In Central Greece, the municipality home care services had an increased role in assisting any of their patients being telemonitored to use their telehealth device.

Berlin reported a general shift on a national level towards integrated care provided by teams from hospital and non-hospital sectors and consisting of multidisciplinary teams which has been embraced by Pflegewerk, the private health care partner in the project.

Cosenza Region reported that although they saw no actual task shift, the workload for the diabetologists involved was increased.

One site reported that a new role of Clinical Lead for Telehealth was introduced (split across COPD and diabetes arms of United4Health) to take forward the stakeholder and operational engagement aspects of the project.

The responses were mixed, ranging from a lack of cooperation between professional groups to improvements in communication and cooperation to disappointment over the lack of commitment on the part of other groups. One site suggested that many of these problems could be solved with a clearer definition of roles and an overall better management of the human resources.

No sites reported that collaboration with other institutions in relation to the service deteriorated as a consequence of the service. Four sites saw no difference regarding collaboration with other institutions in relation to the service. For the remaining five sites the project has led to improved collaboration with other institutions. The institutions in question, however, vary greatly, from local nursing homes and GP practice staff to team members from different institutions and the Scottish Diabetes Forum as a whole.

6.4.2 Training

In all sites training was offered to participating professionals, the only exception being professionals who were already familiar with the technology and service from their involvement in previous telehealth projects. The duration of the training courses varied widely, from a few hours to a 60-hour course delivered in Slovenia where the nurses employed in the eHealth centre received disease-related education in addition to telehealth education and training. The training varied in content and duration due to the different levels of role and responsibilities given to the professional groups in each region.

In some cases the healthcare professionals were divided into groups according to profession and role.

In Central Greece, the professionals to be trained were distributed in three categories: nurses, doctors and technicians. The training for each profession took one day, and varied in content and duration due to the different levels of detail to be shown to each one. The training was interactive, and was carried out by staff of the technical provider in the first phase, and personnel of e-trikala SA in the later stages. Depending on the category, there was a different level of detail regarding the functionality of the equipment.

In Berlin, four groups of employees were functionally and qualitatively distinguished. The groups received the following training related to the project, respectively:

- Nurses: Orientation and training for technical handling.
- GPs and specialists: Orientation and training for technical handling, documentation on the electronic portal.
- Technicians: Installation, administration, data backup, data protection.
- Healthcare professionals and Case Managers: Patient coordination, route planning, billing.

One site also chose to train volunteer citizens to complement the healthcare professionals in providing training for patients. This was based on a belief that the citizens could teach and support patients from a different perspective than the healthcare professionals.

6.4.3 Experiences and perception

Overall, many expectations were fulfilled, although those sites which had previous experience with telehealth reported less favourably about their expectations being met compared to those sites that were new to deploying telehealth services. New sites seemed to have fewer problems with the WiFi and mobile phone signal strength and less complex diabetes care management organisational structures. Some clinicians felt that the study eligibility criteria reduced the level of clinical judgement that could be used to offer telehealth to patient patients that they felt could benefit.

Across all sites, those involved in delivering the telehealth service had a positive attitude towards the provision of the new service. One site emphasised how the telehealth service improved patients' ability to monitor their blood glucose and self-manage long term. However, concerns were expressed in relation to a number of issues with the technologies; especially at the beginning of the implementation stage; unresolved reimbursement for telehealth activity issues, human resource management and lack of commitment from some professionals, particularly GPs.

All sites expressed a willingness to continue the service after the end of the project period. Most sites, however, were of the view that for ongoing deployment, the service required changes to reflect the learning gained during the project.

Interestingly, although all the diabetes sites indicated that they wished to continue to deploy the service, albeit with minor or major modifications, the responses as to whether they were satisfied with the new service were mixed. The difficulties associated with the technologies, mobile phone signal and WiFi strength, recruiting patients despite huge effort being devoted to this activity, and the additional workload reported by some front-line clinicians seems to have contributed to the varied experiences of healthcare professionals.

No sites reported that the patient/healthcare professional relationship had deteriorated due to the project. Almost all sites' professionals reported improved relationships with their patients during the project period. Advantages such as better communication, commitment and feeling of security are listed. A few healthcare professionals reported that they feared that the telehealth service could make some patients feel distanced from the decision-making and care management. However, as the diabetes service was designed to improve a patient's ability to self-manage, perhaps there was a misunderstanding of the study's objectives by those with this view.

6.5 Clinical work flow

In general, ongoing Type 2 and Type 1 diabetes care management for those sites that included these patients in their study cohort was similar across the different regions involved in U4H. Patients were educated to record their blood glucose levels and make any necessary adjustments to their diet. The telehealth service provided patients with the opportunity to digitally record their blood glucose readings into either a telemonitoring device or an online web portal, and receive health coaching messages either via SMS, the telehealth device or through the educational content of the web portal. In the sites where a telehealth device was used, alerts were generated according to the local protocol if a patient's measurements were outside their individual parameters. These alerts would be sent to the patient's nominated diabetes care professional.

In Scotland and Wales, Type 2 diabetes care including the telehealth service is predominantly delivered by primary care with specialist input provided by home-visiting specialist nurses and hospital-based specialist nurses and doctors if necessary. Patients with Type 1 diabetes in Scotland receive their ongoing care from hospital specialists who collaborate with the patient's GP practice. Specialists working in Municipality diabetes centres in South Karelia, Campania and Cosenza provide ongoing diabetes care with diabetologists providing the telehealth services in Campania and Cosenza unlike South Karelia where nurses were mainly responsible. Slovenia established a Municipality-based eHealth centre where nurses provided the telehealth service and collaborated with the hospital-based specialists where necessary. Diabetes care in both Northwest Moravia and Central Greece is provided by specialists working in the hospital sector and in Greece both routine and telehealth care services are undertaken by diabetologists. Disease Management Programmes (DMP) as part of the insurance-based system in Berlin are provided by a range of healthcare professionals working in various settings; the telehealth service was integrated into the DMP contracts.

No sites reported decreases in working hours. A few sites reported increases in (official) working hours due to the introduction of the telehealth service, but some nurses and doctors reported that although no extra working hours had been allocated, their workload had increased, leading to overload.

6.6 Views on technologies deployed

6.6.1 Clinicians, Managers and Support Workforce

Most sites were quite satisfied with the usability of the telehealth technology they used, although some reported initial technical difficulties. One site was of the opinion that young people would perceive the usability of the applications more positively if adapted to mobile devices rather than the tablet or computer interface. Some sites stated that the quality of life could be improved for the patients via telehealth, and that telehealth could be integrated into the routine care pathway of services offered. However, the same site believed that telehealth cannot replace clinical examination in its current form as monitoring was not provided 24/7.

One region stated that the current platform supported very basic functionalities and significant improvements could be developed.

Three sites reported no or insignificant technical challenges.

The remaining sites encountered some difficulties. For most it was about data transmission and signal and mainly in the beginning. Most problems were solved or diminished by health professionals or technical staff in the early stages of the project. One site developed the integration component between the pre-existing diabetes EMR and the patient's person held record (PHR) accessed through an online portal as part of the telehealth service to ensure that the measurements taken by the patient at home were available within the EMR. This work was complex and had to overcome a number of challenges.

6.6.2 Patients / family carers

The views of patients were mainly obtained through the completion of the WSD questionnaire and reported under Domain 4. However, some sites organisational

assessment work included interviewing patients and below offers some insights into the training that patients were offered.

Some sites had problems engaging with the patients resulting in fewer patients agreeing to receive the service and some reported a reluctance by patients to use a mobile phone or tablet.

All sites offered patients training prior to their use of the telehealth service. For some, it was a formalised course, sometimes conducted in group sessions. In other sites, patients were given individually tailored training, in which the content and duration was personalised to the patient´s specific needs.

With one notable exception, a patient's family carers did not have a formal role in the project, but if needed they were able to participate in the education and training given to patients. The exception was Slovenia where many patients rely heavily on their family carers to assist them with their diabetes care management; they were, therefore, included as a participant in supporting the patient with the telehealth service.

6.7 Main conclusions

- National focus on telehealth (e.g. telehealth being an integral part of the national health strategy) makes a positive difference for implementation and dissemination of a new telehealth solution.
- A discussion is required concerning the most appropriate organisational setting for the telehealth service. Due to huge variation in the organisation of the health sectors of the participating sites, it is, however, difficult to compare the organisation of the service in a meaningful manner. As an example of the diversity, some sites involve the hospital sector in the telehealth service, whereas others deliver the service from a primary care setting. To complicate matters further, several sites have a specialised diabetes clinic in a municipal setting and two sites dedicated eHealth centres.
- In general, ongoing Type 2 - and Type 1 diabetes care management for those sites that included these patients in their study cohort, is similar across the different regions involved in U4H. Patients are educated to record their blood glucose levels and make any necessary adjustments to their diet. The telehealth service provided patients with the opportunity to digitally record their blood glucose readings into either a telemonitoring device or an online web portal, and receive health coaching messages either via SMS, the telehealth device or through the educational content of the web portal. In the sites where a telehealth device was used, alerts were generated according to the local protocol if a patient's measurements were outside their individual parameters. These alerts would be sent to the patient's nominated diabetes care professional.
- There is no overall pattern in the way the roles are distributed between sectors. In most sites, the telehealth role and responsibility resided with the same healthcare professionals who provided the routine diabetes care management. Roles and responsibilities for all participants must be clearly defined from the start.
- Positive staff attitudes are crucial for successful deployment. Some sites reported that one or more professional groups were sceptical and therefore did not act as champions of the service.

- All sites have offered training for staff involved in the diabetes project, except for health professionals who were already familiar with the technology from their involvement in previous projects. The length of the courses varied from a few hours to a 60 hours formalised course where nurses were also given education and training in diabetes care management.
- Resources must be allocated for continuous training of staff, which was also found in Rasmussen et al. (2015).
- Resources should be allocated for the continued training of patients and for technical support of the service after the project period ends.
- Realistic expectations for time and staff resources required are crucial: many sites reported that more time and effort than expected were needed to get the telehealth service to run smoothly and to make sure that the patients felt confident and secure.
- Most sites reported no or minimal task shifting. Three sites reported some task shifting:
  - Greater involvement of nurses and involvement of biomedical engineers (Northwest Moravia)
  - Task shifting from the health personnel working in the hospital to the home care services health personnel. (Greece)
  - A general shift on a national level towards integrated care provided by teams from hospital and non-hospital sectors and consisting of multidisciplinary teams (Berlin)
- No sites reported decreases in working hours for those delivering the telehealth service. A few sites reported increases in (official) working hours due to the project, whereas others reported that although no extra working hours had been allocated, the workload had increased for some staff, leading to overload. A number of sites reported changes in the tasks of one or more health professional groups, but not whether actual working hours were changed.
- IT infrastructure must be in place and running smoothly from the beginning of the project or deployment process.
- Diversity is the keyword when it comes to acquiring and using IT equipment. Some sites had all the equipment ready from earlier projects whereas others had to start from the beginning as they had no prior experience and had to buy everything at the start of the project.
- Younger patients require telehealth services which can be accessed on the go, i.e. from cell phones or tablets.
- Continuous adjustment and further development of the telehealth service is necessary. All sites require a revision of the service from its present form in order to continue after the end of the project period.
- Training of patients as well as all staff involved is recognised as a prerequisite for successful project implementation, and resources for continuous training programmes must be allocated.
- A strategy for reimbursement of the telehealth service must be in place prior to large scale deployment.
- One way to ensure the successful adoption of telehealth is to generate robust and reliable evidence that the systems are cost effective and effective for patients using formative rather than summative evaluation approaches applied at all stages of the project cycle.

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 diabetes 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:

1. Ethical issues:

- Overall questions: Does the application challenge religious, cultural or moral beliefs?
- Potential ethical problems, e.g. giving the responsibility to the patients.
- Autonomy: Is the patient's autonomy challenged or increased?
- Equity.

2. Legal issues:

- Clinical accreditation.
- Information governance.
- Professional liability.
- Patient control – consent, access.

3. Social issues:

- Changes in the patients' role in major life areas (e.g. social life, working life).
- Patients' relatives and others' understanding of the technology.
- Societal, political context and changes. Will the service influences the general model for the delivery of healthcare service if deployed.
- Changes in responsibility. Are the patients and/or relatives capable of handling there responsibility?
- Gender issues. Has the service any consequences on the position of gender?

7.2 Ethical issues

Table 29: Ethical issues

Issue	How issue was addressed	Dates	Evidence
Patient autonomy			
ASP Cosenza	Consent to treatment. Information sheet showing operational procedures and objectives of the project.	Month 1	A patient information pack was created, nurses were trained to deliver oral guidance with the written information, and patients' consent was recorded in writing.
ARSAN	Consent to treatment.		A patient information pack was created. The professional members of the care team were trained to deliver oral guidance with the written information during the meetings programmed for enrolment and training, or on demand. Patient consent was recorded in writing. The patient could withdraw from the service at any moment.
Slovenia	Patient self-esteem: Presentation of data to the patients in the intervention group at regular visits to a diabetologist.	Month 24	Medical staff communicated with each patient his/her telemetrically collected and processed data on blood sugar (numerical & graphical form). Confronted by their data, patients may see the direct influence of their lifestyle on the data. Some patients were further encouraged by getting confirmation of their endeavours to stick with the individual treatment plan. In many such patients, specialists have noticed improvements of the patients' self-esteem.

Issue	How issue was addressed	Dates	Evidence
UPOL	The interventions were approved by ethical committee in the regional hospital (University Hospital Olomouc) before the interventions started (in September 2014). Training of the hospital staff and patients education was organised before the interventions started. The education of the patients has been performed by nurses and technical staff of telemonitoring centre, which is an integral part of the hospital.	Month 3 - month 12	Nurses, physicians and technical support team for both the interventions 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 for the intervention and obtained written information for patients, with message that contained general information about the intervention, the voluntariness of participation, advantage of participation for the patients, and statement that non-participation does not influence quality of current care provided to the patients. Participating patients signed informed consent approved by the hospital.
EKSOTE	Consent to treatment and pilot.		A patient information pack was created, nurses were trained to deliver oral guidance with the written information, and patients' consent was recorded in writing.
Central Greece	Informed consent to the telehealth treatment. Informed consent to the participation to the survey.	Month 1 (of the service)	A patient information pack was created, nurses were trained to deliver oral guidance with the written information, and patients' consent was recorded in writing. Patients were allowed to withdraw after considering the written guidance provided by nurses, or at any time during the telehealth service and survey.
Berlin	Consent to treatment.	Month 1	Development of two-sided patient information sheet by the management and the legal department. The responsible employees are trained regarding the aspects of the project. All patients were informed of the terms and conditions both orally and in writing.
	To alter the engagement.	All the time	During the course of the project, all patients could end their participation at any time.
	Withdraw consent.		A written explanation from the patient, the members or the supervisor, was enough with the aim to secure a very low-threshold access to the project.

Issue	How issue was addressed	Dates	Evidence
	To ensure privacy.		The video conference was voluntary; the telemonitoring services were part of the care contract and part of the regulation performance of the doctor, and so terminable at any time. The visits were previously logged or agreed upon per schedule; family members or caregivers were included; for the current processes of nursing or doctors treatments, nothing has changed; the trusted caregivers or medical staff have been preserved; the freedom of choice of the patients remained secure; the data was encrypted and fully protected from unauthorised access by the ePortal; the access rights of employees were protected by the data protection officer.
Scotland /all	Consent to treatment.	Month 1	Patients gave consent through registering online at MyDiabetesMyWay site. Clinical staff, specialist nurses and participating GP practices received training on all aspects of MDMW/Diasend. A patient information pack was created containing clear information on registering on MDMW and Diasend. Nurses instructed patients on uploading their readings on to the site when they attended clinics. Patients could withdraw at any time from the programme.
Access and equity			
ASP Cosenza	Access to healthcare has improved.	Month 1-12	Questionnaires to patients, interviews with professionals, and questionnaires DM_12_CD, DM_12_ECON and DM12_ECON_TELEMED.
ARSAN	Involvement of Diabetes Centres.		The Diabetes Centres involved in the study are part of the Regional Health Service and are located in different geographical area of the region.
	Criteria for selection and enrolment of patients.		Candidates for the enrolment were screened by chance according to the schedule of the outpatient visits in the Diabetes Centres.
	The equipment for the telemonitoring service is provided free of charge.		The hardware gateway is provided free of charge as part of the project. The glucometer and the test strips are provided free of charge as well, as in standard care. The availability of a DSL-based connection is part of the enrolment criteria.

Issue	How issue was addressed	Dates	Evidence
Slovenia	Personal interviews with patients.	Month 12	All patients passing the inclusion criteria were offered the telehealth service support regardless age or sex.
Hywel Daa (Wales)	Patients own mobile phones used or mobile phones offered to patients to be able to take part.		None mobile phones were loaned to patients.
UPOL	Equal conditions for access to the intervention were observed.		The interventions have been offered to all patients regardless of their sex, age, social status, provided they fulfil inclusion criteria set by U4H project. The patients have also been allowed to end participation in intervention for whatever reason at any stage.
EKSOTE	Information of pilot were on Eksote´s web and eHealth services page; information was given to the nurses.		All patients with T2DM had the opportunity to get involved if they were over 18 years and they already used home monitoring.
Central Greece	Access of the patient to his/her data stored in the telehealth service.	All period of service	The patients receive a personal access code from the telehealth service, and they are able to access their data online.
Berlin	Equity assured.	Month 1	All patients were invited in individual interviews or shared information sessions to participate in the study; In addition, the members of the family, doctors and carers were included in the study.
	Cognitively impaired patient.		Patients, e.g. with dementia etc., could also participate as it was always possible that a nurse could take the measurements (needed adapted treatment). If the patients could not participate from the outset of their illness or for age-related reasons, then this was coordinated with the doctor giving the treatment.
	Exclusion.		Due to technical and financial aspects, or organisational conditions, no exclusion criteria existed; only the named in the trial.
Scotland /all	Uploading glucometer results to Diasend.		As patients are required to have laptop/PC to upload glucometer results to Diasend, in order to address access and equity, patients could attend the Diabetes Centres where kit was available to upload results.

Issue	How issue was addressed	Dates	Evidence
Scotland / NHS Lanarkshire			All information can be made available in different format / language in accordance with NHSL Equality and Diversity policy.
Normative Codes			
ASP Cosenza	Healthcare pathway provided by the Italian National Health Service as well as ASP Cosenza.	Month 1-12	Telehealth service has not replaced the standard healthcare procedures. More specifically, the telehealth service: is an additional service to the usual care; does not implies changes / reductions in the annual programme of outpatient visits for the control of diabetes and prevention of complications.
ARSAN	HBGM regimen and patients.		HBGM regimen are prescribed as in usual care according to the Regional Assessor's Decree n. 832/02 and the Italian Law 115/87
	Enrolment criteria and care pathway.		The Diabetes Centres only enrolled patients with unstable diabetes and related complications according to the Integrated Care Model adopted with the Commissioner Decree 87/13, art. 9 on Integrated Care for Diabetes.
Hywel Daa (Wales)	NHS Research Ethics Committee approval sought.		National Research and Ethical approval obtained.
	Enrolling HCP attended GCP training.		Good Clinical Practice (GCP) certification achieved for research staff.
	Nurses training programme developed and delivered with ongoing support.		Nursing and Midwifery Council Code of Conduct adhered to by nurses involved.
UPOL	National legislation applies.		Act. No. 372/2011 Coll. About healthcare services. Act. No 89/2012 Coll. Civil code.
Central Greece	GCP certification of the physicians involved in the U4H study.	Prior to deploy-ment of service	Good Clinical Practice certification.

Issue	How issue was addressed	Dates	Evidence
Berlin	Professional codes guide staff.	Month 1	Basis are the supply contracts acc. § 132 a SGB V and section 72 SGB XI, the professional rules and guidelines of the doctors, the guiding principle of the Company, the written carers contract, the medical guidelines of the medical societies and the standards of care, as set out in the Company. In the quality manual of the company, detailed ethical questions are addressed and regularly checked by the medical services of the health insurance companies. All rules and regulations are public and therefore transparent.
	Adequate involved.		The guidelines were taken into account in the telemonitoring pathways, all project-related documents for patients or staff have been adjusted accordingly.
Scotland / all	n/a		NHS Scotland 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.
Assessment of risk and benefit			
ASP Cosenza	Benefits for patients are increased thanks to the service.	Month 6-12	Questionnaires to patients, interviews with professionals, and questionnaire DM_12_CD and DM_12_ECON.
ARSAN	Telehealth service characteristics.		The telehealth service is mostly intended for prevention; it is an additional service, not replacing or reducing the offer in usual care. Patients and informal care giver are widely informed (also in writing) to rely on the usual care in case of significant needs' onset. Benefits are expected from the reduction of needs and, as a consequence, from the reduction of use of services of usual care.

Issue	How issue was addressed	Dates	Evidence
Slovenia	Risk of discontinuation of the telehealth support. Permanent endeavours at institutional level to get the work paid and to attract further investments.	Month 36	The largest ethical issue in the U4H Slovenia is a threat of discontinuation of the telehealth support to over 300 diabetic patients using the TM service. They rely on feedback information based on their TM collected data and the specialist's comments. Additionally, they expect that their therapy is immediately adjusted to their needs without going for an extra visit to the specialist's office. Stopping delivery of the service after the end of U4H project would be a major breach of ethics.
Hywel Daa (Wales)	Research methodology adopted.		Research and Ethics Committee approval obtained.
	Offered to all primary healthcare centres providing Type 2 Diabetes care, and at public events.		Respected rights of patient not to take part – documented in research master file.
	Patients only using telemonitoring occasionally were offered service for full 12 month term.		No service was stopped due to researchers' request during whole time of study.
	Patients assessed for telehealth suitability by trained HCP.		Good Clinical Practice certificates for the two enrollers. Written information sheets at least 24 hours prior to enrolment.
UPOL	Risk and benefit analysis made by the preparatory team in the hospital. The team designed the telehealth system and data collection tool.		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 (e.g. handling manually entered data in specific cases); they were also reflected in the content of information for patients and educational content. The expected benefits were estimated by medical staff of the hospital; they served to adjust the interventions for DM patients.
Central Greece	Informed consent of the patient. Clinical evaluation on whether a patient is able to participate in the telehealth service prior to approaching him/her.	Whole period of recruit-ment	

Issue	How issue was addressed	Dates	Evidence
Berlin	Benefit.	Month 1	Experiences from other telehealth projects, cooperation with the professional societies, cooperation with the technology centre of the Federal State of Berlin; collaboration with the Medical Council, the nursing associations and health insurance; addressing the topics in team meetings, consultation with the treating doctors, documenting status improvements in the carers' documentation, AIS; evaluations SF 3, HADS and WSD SUTAQ.
	Adverse incidents.		Within the standards of care and within the framework of the quality manual, there are standardised regulations for adverse incidents, also risk management.
	Feedback patient.		For years, there has been a structured complaint management and patient advocates in the company. A help desk was introduced, which identified and logged technical problems or documentation errors.
	Discontinuation / non-implementation.		Modifications have been made in response to implementation problems, for example, the guidelines of telehealth. With technical problems, HIS replacement solutions and alternatives were explored. E.g. Smartphone's were all completely replaced after six months, and changes made in the ePortal. All these errors were discussed and logged in the ongoing project meetings.
Scotland / NHS Lanarkshire	Benefit Assessment		Any adverse incidents are reported via NHSL Datix risk management process – non-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. Staff focus groups on qualitative experience have been carried out.
Scotland /all	Benefit Assessment.		Feedback on benefits was sought from participants using two patient acceptance questionnaires: WSD and QUEST2.

7.3 Legal issues

Table 30: Legal issues

Issue	How issue was addressed	Dates	Evidence
Clinician accreditation			
ASP Cosenza	Diabetologists and professional nurses are employed by ASP Cosenza.	Month 1	The diabetologists and the professional nurses involved as employees were hired after public competition based on qualifications and examinations, and receive a complete evaluation periodically.
ARSAN	Technology adopted.		FORA® Diamond blood glucose monitoring systems comply with specific EU directives IVDD (98/79 / EC): CE0344. The system met the accuracy standard ISO 15197:2003. It also exceeded the minimum acceptable accuracy standard required in the newer 2013 guideline (ISO 15197:2013).
UPOL	All medical staff (nurses, physicians) maintain capability to treat patients as required by national law.	Month 1	No need for changes or upgrade of accreditations / attestations was found. All medical staff subject to continuous lifelong training and education. The hospital has been accredited in line with Public Notice no. 102/2012 Coll. following Act no. 372/2011 Coll.; its management system has been certified according to standard EN ISO 9001:2008. The hospital also possesses HPH membership certificate from 2011. Internal hospital management rules.
Eksote	Professionals use their Smartcard.		Professionals use their Smartcard always when they log-in to Eksote's computers (programs).
Central Greece	Only professionally qualified nurses were employed in the telehealth service.	Month 1 of service	Professional certificates of accreditation
	The review of measurements collected from the personal health systems of the patients stored on the server was done by the physicians of the telehealth service.	During the whole period of telehealth service	

Issue	How issue was addressed	Dates	Evidence
Berlin	Review of all accreditations for nurses.	Month 1	Telemonitoring care is part of the treatment care, and therefore part of the training of nurses. Professional training is prescribed for certain diseases, such as ventilation in the context of diabetes. The implementation of telemonitoring is subject to the regulations of doctors according to § 37 SGB V.
	Existing accreditations.		Measurements may only be performed by qualified nursing staff. Nursing assistants may not perform these care treatments, and therefore no telemonitoring treatments. This is ensured through the operational planning of the employees and the responsibility of Care Management.
	Professional liability.		Establishments is carried out via the respective supply contracts with the health insurance companies, the quality manual and the responsibility of Care Management. System responsibility in the IT field has been established within the framework of the establishment plan and the job descriptions.
	Patient liability.		The patient may refuse a service, such as measuring vital signs, prescribed by the doctor. This is then documented, communicated to the doctor, and if necessary reported to the health insurance company. In doing so, all those concerned for the responsibilities of patients are protected. Also, upon termination of participation in the study, measurements of the patient, by the doctor's arrangement, are continued. But is done, in the conventional framework of primary care, i.e. outside the guidelines for telemonitoring.
Scotland /all			All staff suitable qualified.
Device certification			
ASP Cosenza	Lifescan devices' user manuals.	Month 1-12	Lifescan devices for monitoring blood glucose comply with specific EU directives IVDD (98/79 / EC): CE0344.

Issue	How issue was addressed	Dates	Evidence
Slovenia	Declaration on use of the devices for research purposes.	Month 34	Health inspection visit the General Hospital of Slovenj Gradec identified 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 device is 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 changes it status, becoming a “medical device”. The challenge of adequate interpretation of this legal gap has not yet been solved.
Hywel Daa (Wales)	Clinical Lead ensured that CE mark was on all equipment procured.	Month 1	Only CE marked equipment was procured; then all equipment was reviewed by NHS Electrical BioMechanical Engineering Department.
UPOL	CE Declaration of Conformity: all devices used in DM intervention (glucometer and gateways - Bluetooth-GSM/3G).		All devices CE marked. Other documents are filed by the respective authorised representatives of the devices manufacturers. In addition, glucometers' accuracy was verified by comparison with laboratory tests in the hospital.
Eksote	PHR is part of the eHealth services; it has certificate for all.		
Central Greece	Requirement of DOC/CE certificate at the procurement.	Procurement phase	DOC/CE certificates.
Berlin	Application certified.	Month 1	All systems or devices are certified according the Medical Device Directive CE. An approval exists on the part of HIS company's data protection officer for the ePortal.
Scotland / all			All devices suitably accredited.

Issue	How issue was addressed	Dates	Evidence
Information Governance			
ASP Cosenza	Home Patient Software: EuroTouch Home, downloadable from www.lifescan.it after registering and logging in. Hospital / Diabetes Centre software: EuroTouch is a management software programme with clinical experience of more than 20 years	Month 1	The electronic medical record that monitors measurements and conditions of patients is Eurotouch® v.10, a standalone software application, officially adopted by diabetologists from ASP Cosenza in 2009; the glucometer is One Touch® Verio®, which, via an USB connection, interfaces with Eurotouch Home, a standalone patient health record for self-monitoring blood glucose; an ad-hoc connector enables the online exchange of the encrypted data from the patients' homes to physicians and nurses. Eurotouch v.10 is a management software programme for main administrator / doctor privileges and instruments: administrating passwords and guaranteeing privacy.
ARSAN	Web-based platform deployment and features.		The Diabtel.net web-based platform is hosted in the DMZ of the ARSAN data centre, and its access is secured by a firewall. Diabtel.net also enforces role based access control policy, as well as encrypted communication over Internet.
	Declaration of consent for personal data management.		Patient consent recorded in writing, also includes a declaration of consent for the processing of personal data in order to deliver the service.
Hywel Daa (Wales)	Review of protocol & procedures by local Information Governance Department and Research Centre.	Month 1	Paperwork changed in accordance with IG advice.
		Month 6	Audit of research undertaken by NISCHR.
	All patient paperwork was translated into Welsh.	Month 1	All patients were offered the information sheets in both English and Welsh.

Issue	How issue was addressed	Dates	Evidence
UPOL	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.	Month 1	Password management system has been maintained. Database with data received from the 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 to agreement with the hospital, and also subject to rules enforced by relevant legislation). Data collection tool is a software application that runs during the interventions in the telemonitoring centre and produces output csv files that were sent regularly by our site data collection manager to U4H project central data collection facility.
Eksote	Patient use their bank authentications.		
Central Greece	A security plan was subcontracted to the Alexandrion Technical University of Thessaloniki. Licence from the Data Protection Authority of Greece.	Prior to deploy-ment of the service (within Renewing Health service)	Firewalls required adjustment; access protocols revised; patient access ensured (reference to new protocols).
Berlin	Data collection.	Month 1	All patients had to sign a declaration of consent.
	Information to the patient.		All patients were informed about the data collection, evaluation and archiving in detail, both orally and in writing.
	Data access.		In principle the patient also had the possibility for direct access to their personal area in the ePortal; there is also the option to provide a complete printout to the patient. (The ePortal is usually only accessed by the doctor or responsible caregiver.) During a hospital stay, the patient was asked whether their data could be shared.
	Correct or delete data.		All patients can have their data deleted after leaving the trial. Changes to the data can be made by the patient, if in doing so this ensures the carrying out the study. Otherwise, exclusion from the study must be decided on. Alternatively, the patient can participate in telemonitoring outside of the study.

Issue	How issue was addressed	Dates	Evidence
	Access to the data.		After obtaining the consent of the patient for: - prescribing doctor (diagnostic, vital signs, and if necessary, alarm management); - caregiver (vital signs, Alarm management); - system administrator (base data).
	Data controlled.		Password and ID.
	Data sharing.		In some cases with the hospital.
	Data stored.		Encrypted data transfer; secured ePortal, certification through the Data Protection Officer.
	Ensure integrity.		Patient has at any time access to, and the right of use, of the data even after approval of data processing in the trial. The system application is approved by the Data Protection Officer. All complementary systems (doctors' software, nursing documentation, etc.) are subject to the same conditions.
Scotland / NHS Lanarkshire	Sharing patient data.	Month 1	A Privacy Impact Assessment was completed. All patient data which was forwarded to NHS24 was non identifiable. A local and national Caldicott Guardianship was in place. Patient identifiable data was transferred between nhs.net secure site for evaluation purposes. All NHSL information governance policies and procedures were adhered to.
Scotland / NHS Ayrshire & Arran	Sharing Patient Data	Month 1	A Privacy Impact Assessment was completed and forwarded to NHSA&A Information Governance. All patient data which was forwarded to NHS24 was non identifiable. A local and national Caldicott Guardianship was in place. Patient identifiable data was transferred between nhs.net secure sites for evaluation purposes.

Issue	How issue was addressed	Dates	Evidence
Professional liability			
ASP Cosenza	Professional liability of the employed diabetologists is guaranteed by ASP Cosenza by insurance agreed with a broker.	Month 1-12	The study of telehealth on DM was not the system used for emergencies, and did not replace the normal services to refer to, i.e. call the emergency number in severe cases, or the emergency medical service (doctor on call), or the GP (aware of the project).
ARSAN	Insurance policy for civil liability towards third parties of the Diabetes Centres.		Healthcare professionals in the care team who are employees of the Diabetes Centres are covered by an insurance policy for civil liability towards third parties taken out by the superordinate Local Health Trust.
	Individual insurance for professional liability.		The other healthcare professionals in the care team are covered by a personal insurance for professional liability.
Hywel Daa (Wales)	Nursing Midwifery Council (NMC) accreditation for all community nurses involved in management post discharge.	Month 1	Each nurse has individual professional liability insurance and adheres to the NMC Code of Conduct.
UPOL	The team dealing with patients and their information follows appropriate general procedures in the hospital which are in line with appropriate law, Czech Ministry of Health rules, and guidelines and recommendations of respective national medical societies. Professional liability is covered by the hospital insurance that is specifically developed for healthcare providers.		Accreditations, certifications as listed above. Audits results and hospital internal management documents. Insurance protocol.
Eksote	Nurses in the health care centres are responsible with GPs for the patients care processes.		

Issue	How issue was addressed	Dates	Evidence
Central Greece	No additional professional liability insurance is required in Greece for health professional involvement in services where DOC/CE medical devices are used.		Legislation and regulations of the National Organisation of Greece on Medicines and Health Technology
Berlin	Liability insurance mechanisms.	Month 1	Professional indemnity insurance also covers telemonitoring applications as specified by the company supply framework.
	New insurance.		Only expansion of equipment insurance.
	Liability balanced between partners.		The partners were asked to check their specific insurance coverage and, if necessary, e.g. expand professional liability.
Scotland / all	Existing liability sufficient.		
Other			
Slovenia	Telehealth service legally not yet recognised. Suggestions for changes in laws on healthcare services.	Month 12-36	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; 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 in addressing the Ministry of Health and the compulsory Health Insurance Institute to include telehealth services in the regulatory documents. Changes have been proposed to relevant laws in their preparatory phase without any positive effect. Personal contacts with health ministers have not helped to change the situation.

7.4 Socio-cultural issues

Table 31: Social issues

Issue	Key findings	Evidence
Changes in patient's roles		
ASP Cosenza	Patients who were already attending specialist's appointments on a regular basis before using telehealth have had further improvements in terms of health and life quality. The experience of telehealth has been too short (one year maximum) for those patients who were not sending glucose data regularly.	Questionnaires to patients, interviews with professionals, and questionnaire DM12_ECON_TELEMED.
ARSAN	The telehealth service boosts the patient's activation, in particular the adoption of healthy behaviours and medication adherence.	The medical devices in use by the patients for HBGM are substantially the same as adopted in usual care. The adoption of healthy behaviours and adherence to medication are periodically monitored and, when needed, reinforced with professional coaching.
	There are no other significant changes in the social and working life of the care recipients.	The offer of the other healthcare service provided by the Regional Health System in usual care remained unchanged.
Slovenia	Responsibility for a decision if a visit to a specialist is needed is now shifted from a patient to healthcare professionals.	When health condition deteriorated for a chronically ill patient living at home, his/her carers were in doubts whether or not to visit a specialist in a clinic. Their decision was based e.g. on the specialist's working hours, availability of carers, level of health deterioration etc. Frequently they took inadequate 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 on 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 specialist's support is now taken by healthcare professionals.

Issue	Key findings	Evidence
Hywel Daa (Wales)	Patients undertaking telemonitoring also accepted a research participant role.	Patient information sheets and questionnaires.
	Patients have become better self-managers and are taking more control of their disease pathway.	Patients self-reported in qualitative research that they gained more control over their clinical care through the education that telemonitoring and the tele-coaching offered.
	Decision making by patients relating to their condition and abilities changed.	In qualitative results, patients with good saturation values for that day felt empowered with greater reassurance; this increased confidence to engage with more activities.
UPOL	Patients have been more involved in their disease treatment procedures, which, together with interactive features of the TM system, can be considered the nucleus of a patient empowerment concept. This was not yet translated into changes of national treatment protocols that would determine a reduction of the number of regular outpatient department visits. However, closer contacts with patients enabled optimisation of their visits that would normally occur if no information from remote patients is available. Some of the outpatient department visits could then be avoided. Lower re-hospitalisation rate was encountered.	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.
Eksote	Patients take the greatest role in their own care when it is under their control. If diabetes is out of control, professionals need to ensure the realisation of treatment and good care.	
Central Greece	Receiving their treatment at home to a regular timetable enabled patients to stay in the labour force, as they did not need to take time off to visit clinics.	Qualitative study, with a focus group of patients, reported that benefit.
	More active involvement of patient in their treatment.	Qualitative study, with a focus group of patients, reported the benefit of patient's empowerment.

Issue	Key findings	Evidence
Berlin	Social life. Security. Self-determined life.	Internal surveys in the residential group with relatives and in individual interviews with doctors and nurses show that most patients feel more secure and thus feel more quality of life. The fear of a stressful hospitalisation decreases. Patients who measured themselves have a higher degree of freedom and are more active socially. Patients are no longer in the labour market.
Scotland /all	As patients now upload their glucose readings, this has potentially reduced the number of face-to-face contacts and the need for recipients to attend clinic appointments.	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.
Patient's relatives and others		
ASP Cosenza	Patients such as women in their fifties and people with computer savvy caring children living at home have embraced telehealth well. Patients' caregivers have done a vital job in more than half of cases. The main cause for leaving the project has been the lack of support in transmitting data via PC from those caregivers who had initially committed themselves to the task.	Questionnaires to patients, interviews with professionals, and questionnaire DM12_ECON_TELEMED.
ARSAN	There is no significant difference between the telehealth service and usual care in respect of the role of patient's relatives and others in the management of the HBGM, as the technology adopted to send the measurement via the hardware gateway is very user friendly and almost completely automated (a simple plug and send).	The definition of the telehealth service implemented and the technological solution adopted.

Issue	Key findings	Evidence
Slovenia	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-for person's health.	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 is informed of an adjustment in therapy 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.
Hywel Daa (Wales)	Significant enablers to telehealth use were the presence of supportive family members when integrating telemonitoring into their care. This helped them gain more psychological and educational benefits than those who were left in isolation.	Qualitative research results.
UPOL	Patient's relatives / carers roles are in close correlation with two characteristics of the patients: ability to use the technology, and their overall condition caused by the disease and co morbidities / reduced cognitive functions. With worse condition of the patients, the family relatives' role increases.	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.
Central Greece	Receiving the treatment at home to a regular timetable enabled patients' relatives to stay in the labour force, as they did not need to take time off to visit clinics to accompany patients.	Qualitative study: a focus group of patients and their relatives reported the benefit of patient's empowerment.
Berlin	Understanding from others.	Relatives and carers support the treatments for the reasons listed above. They do not see the technology as being something foreign, but as an improvement of treatment quality and networking with the various healthcare providers.

Issue	Key findings	Evidence
Societal, political and context changes		
ASP Cosenza	The telehealth service has significantly improved patient's commitment to treatment.	It was necessary to suspend the blood sugar level data transmission for the recruited patients in order not to treat them differently as compared to those who did not participate in the project. The telehealth system for diabetes is still not structured in accordance with the current care system in ASP Cosenza.
ARSAN	The telehealth service is intended as an addition to and not as a modification to the usual care offered by the health services in the Regional Health System. When implemented at large scale, telehealth has to be included in the offer of the Regional Health System and be integrated with the other healthcare services of usual care	In the large scale deployment of the service, it will be necessary to define regional policies and tariffs for access to the telehealth service (i.e. intended target populations, rules for co-payments, etc.). Given the fact that in the Campania Region, at the moment, there are still long waiting lists for specialist outpatient visits, integrated care pathways have to be designed to ensure the timely access to traditional care services, if for instance severe but non-urgent needs are detected through the telehealth service.
Hywel Daa (Wales)	Patients felt that the cost of any telehealth service should be kept to a minimum to encourage patient engagement.	Qualitative research results.
UPOL	Societal change was observed as to growing ICT literacy over the period of the project, enabling wider acceptance of the new telehealth methods on both sides: patients and medical staff. Various regional or healthcare provider contexts play a 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 us to initiate targeted discussion with relevant stakeholders of care models involving patient empowerment.	New Czech national strategy Health 2020 includes patient / citizen empowerment concept as an important element.

Issue	Key findings	Evidence
Eksote	Patient use PHR and secure messaging via eHealth services, but that does not change normal access to the healthcare services if there are some acute problems / symptoms. Patient can still go to the face-to-face appointment if he/she wants, but they can also make contact via eHealth services.	Assessment of the care processes.
Berlin	Influence.	For the care associations and the interest groups of the doctors, the testing of this application represents an important experience process. This relates to the improved communication with patients, increasing compliance, and better supply of information. This represents a major competitive factor for the company. Because of the integration of the project into the health and socio-political discussion in Berlin, important transfer potentials can be identified and perpetuated. Decisive is a well-functioning technical solution that if necessary can be shared in an exchange of experience with EU partners.
Scotland / NHS Lanarkshire	Under review pending evaluation and longer evaluation period.	Scottish Government funding has allowed the expansion of self-monitoring for people with diabetes.
Scotland / NHS Ayrshire & Arran	Clinicians in other areas within NHSA&A have expressed interest in being involved in the programme.	This will be explored and put into action.
Changes in responsibilities		
ASP Cosenza	Despite being young, well-educated and computer savvy, some Type 1 Diabetes patients have accepted telehealth reluctantly or even not at all. This is maybe because they knew they would have been checked on the regular use of self-monitoring	Questionnaires to patients, interviews with professionals, and questionnaire DM12_ECON_TELEMED.

Issue	Key findings	Evidence
ARSAN	Patients, besides periodically sending their measurements, have the responsibility to adopt healthy behaviours and to improve medication adherence. To support them, healthcare professionals have responsibility for the monitoring and coaching patients and their informal care givers.	By definition of the implemented telehealth service.
Hywel Daa (Wales)	Patients do not feel that telemonitoring can be a substitute for standard care, but that there was a need for a seven day reactive service rather than the usual five day service.	Qualitative research results.
	Health care professionals expressed that telemonitoring could take up more of their time to monitor patients.	Qualitative research results.
UPOL	Medical staff extended their responsibilities with tasks related to telemonitoring and communication with the patients. Technical staff have assigned appropriate roles.	Internal hospital organisational measure.
Eksote	Responsibility for care processes lies with GPs and GP nurses, but patient always has responsibility for his/her own care.	
Central Greece	The telehealth service introduced a more nurse led service, compared with the traditional health service.	Qualitative study, with in depth interviews of clinicians and study nurses reported this change.
Berlin		The results of the project show that patients of the providers will be equally experienced. The exchange of information is better. In-so-far as patients have telemonitoring available as a resource to cope independently with illness, their demands will change. Behavioural roles between patient and caregiver are changed to "equal footing".
Scotland / NHS Lanarkshire		Staff report more effective consultations due to high quality of data now available.
Gender issues - equity		
ASP Cosenza	Both women and men have participated in the project.	Questionnaire DM_ENR.

Issue	Key findings	Evidence
ARSAN	No aspect of the telehealth service is related to gender issues.	Candidates for the enrolment were screened randomly according to the schedule of outpatient visits in the Diabetes Centres. As a consequence, in the patient enrolled population, the distribution by gender is about 60% male and 40% female, which is similar to the distribution of diabetes in the population 65-74 years of age.
Hywel Daa (Wales)	Males consenting to telemonitoring = 78. Females consenting to telemonitoring = 48	Telemonitoring was offered to all patients with Type 2 Diabetes
UPOL	Approach to men and women was equal. However, gender issue is slightly relevant, considering the age composition of patients (mostly of 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 so they could also participate in the interventions.	Standard approach to gender equity in the hospital.
Central Greece	No problem reported on this topic.	
Berlin		There are no gender-specific effects apparent. Men and women have equal access and options.
Scotland / all	No inequality reported.	Relevant to demographics.

8. Transferability assessment

The purpose of transferability assessment, which is the final component of MAST, is to provide considerations of whether the results obtained in the study can be generalised from one setting to another. Three factors are to be considered

- Cross-border: Is it possible to transfer the results of the study conducted in one country to another, or are there differences in e.g. legislation, reimbursement or organisation of the healthcare sector that makes transferring the results impossible?
- Scalability: Are there factors influencing the possibilities for scaling the intervention within a department, community, region or country?
- Generalisability: Are the results of the study based on specific circumstances, e.g. so special and controlled in a RCT that the same results cannot be expected in real life?

The diabetes telehealth intervention was deployed across nine regions in United4Health, and the results have been analysed at disease level, i.e. data from all nine sites have been aggregated. This has a bearing on the assessment of transferability of the results. At the same time, the following conditions should also be considered:

- Assessment of transferability or generalisability has no standardised methodology or way of reporting.
- The local adaptation of the United4health diabetes telehealth intervention is heterogeneous, and there are large differences from one site to another in how the protocol and service model was implemented.

The sections below on clinical, economic and organisational aspects in relation to transferability are in nature more a summary at overall level rather than specifically assessing how to reproduce the intervention. Deliverable D3.8 Guidelines on Procurement and Implementation provides detailed insight into the how the services were locally deployed and what lessons were learned from that, as well as overarching guidelines which are of benefit in reviewing transferability of the telehealth service.

8.1 Assess transferability of clinical effects

Table 32: Transferability of clinical effects

Cross-border	Outcomes	A significant reduction was found in: • Number of face-to-face contacts; • HbA1c • Hospital admissions The caveat remains that the interventions were different for different areas; also care systems are not entirely comparable, meaning transfer of results cross-border will depend on the local environment. Nevertheless, these results should have an impact on other healthcare systems and inspire other healthcare systems to redesign their services and include telemonitoring / telehealth in their care pathways as part of routine care.

Scalability	Deployment continuation	The vast majority of the DM sites have continued deploying the U4H service in their region.
	Size of evaluation cohort	Was smaller than originally planned but it is nevertheless the largest study of TM in the field of diabetes to date.
Generalisability	Inclusion criteria	Assess if inclusion criteria are appropriate based on the results of the study. For DM, they were not so restrictive and both Type 1 and Type 2 were included.
	Bias	There were differences in intervention and comparator group at baseline which might impact the results; regression analysis was not able to take account of all of them.

8.2 Assess transferability of economic effects

Table 33: Transferability of economic effects

Cross-border	Regional variation	Local adaptation and local decisions on ICT solutions and technologies means there are large variations in costs. Regions and healthcare providers outside United4Health should refer to the descriptions of the diabetes service deployed in each region.
Scalability	Regional scaling	
Generalisability	Variation in costs	
	Estimation of costs	The costs are based on assessments made by people in each region rather than data collected at patient level.
	Reduction of cost of DM complications	Cost-effectiveness implications based on reduction of HBA1C and its impact on long term healthcare costs for complications for DM. This will of course differ between regions.

8.3 Assess transferability of organisational effects

Table 34: Transferability of organisational effects

Cross-border	National policy and strategy	The significance of national focus on telehealth plays and important strategic role in succeeding with telehealth deployment, particularly at scale.
Scalability	Staff	Staff play a vital role, and their involvement and support must be a priority when scaling the service.

	IT infrastructure	IT infrastructure issues will be an impediment to deployment at scale.
Generalisability	Service sustainability	Based on experiences from U4H, services will be adjusted or further developed according to local context to ensure their generalisability and sustainability. The U4H protocol, although not restrictive as in a RCT, still had limitations.

Appendix A: Two-way ANOVA Tables (Domain 2+3)

A.1 Two-way ANOVA - Number of hospital admissions (any reason) adjusted for length of follow-up

By age

Age (INTERACTION OF TWO-WAY ANOVA p = 0.014)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
<65	Intervention group	300	0.13	0.72	-0.12	-0.24	0.00	0.041
	Comparator group	514	0.25	1.13				
	Total	814	0.21	1.00				
65-75	Intervention group	174	0.12	0.43	0.03	-0.13	0.18	0.734
	Comparator group	262	0.10	0.37				
	Total	436	0.11	0.39				
>75	Intervention group	42	0.37	0.92	0.32	0.03	0.61	0.028
	Comparator group	113	0.05	0.23				
	Total	155	0.14	0.53				
Total	Intervention group	516	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	889	0.18	0.89				
	Total	1405	0.17	0.81				

By gender

Gender (INTERACTION OF TWO-WAY ANOVA p = 0.180)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Male	Intervention group	295	0.16	0.56	0.022	-0.096	0.140	0.712
	Comparator group	485	0.14	0.62				
	Total	780	0.15	0.60				
Female	Intervention group	221	0.13	0.78	-0.099	-0.233	0.034	0.144
	Comparator group	404	0.23	1.13				
	Total	625	0.19	1.02				
Total	Intervention group	516	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	889	0.18	0.89				
	Total	1405	0.17	0.81				

By type of diabetes

Type of diabetes (INTERACTION OF TWO-WAY ANOVA p = 0.001)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Type 1	Intervention group	85	0.24	1.22	-0.345	-0.55	-0.14	**0.001**
	Comparator group	176	0.58	1.80				
	Total	261	0.47	1.64				
Type 2	Intervention group	431	0.13	0.48	0.05	-0.05	0.14	0.312
	Comparator group	712	0.08	0.37				
	Total	1143	0.10	0.42				
Total	Intervention group	516	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	889	0.18	0.89				
	Total	1405	0.17	0.81				

By diabetes complications

COM_10_A (INTERACTION OF TWO-WAY ANOVA p = 0.478)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
DM with complications	Intervention group	113	0.07	0.31	-0.01	-0.18	0.16	0.914
	Comparator group	367	0.08	0.33				
	Total	480	0.08	0.32				
DM without complications	Intervention group	403	0.17	0.73	-0.08	-0.19	0.02	0.127
	Comparator group	522	0.25	1.12				
	Total	925	0.22	0.97				
Total	Intervention group	516	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	889	0.18	0.89				
	Total	1405	0.17	0.81				

By HbA1c

HbA1c (INTERACTION OF TWO-WAY ANOVA p = 0.227)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Low Level under 7	Intervention group	265	0.07	0.32	0.03	-0.18	-0.09	0.612
	Comparator group	432	0.04	0.23				
	Total	697	0.06	0.27				
High Level	Intervention group	250	0.23	0.89	-0.08	-0.19	-0.20	0.231
	Comparator group	445	0.30	1.22				
	Total	695	0.28	1.11				
Total	Intervention group	515	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	877	0.18	0.89				
	Total	1392	0.17	0.81				

By CCI

CCI (INTERACTION OF TWO-WAY ANOVA p = 0.582)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
1 or 2	Intervention group	486	0.15	0.67	-0.03	-0.12	0.06	0.574
	Comparator group	838	0.17	0.90				
	Total	1324	0.16	0.83				
3 or 4	Intervention group	30	0.16	0.50	-0.13	-0.50	0.24	0.480
	Comparator group	51	0.29	0.57				
	Total	81	0.24	0.55				
Total	Intervention group	516	0.15	0.66	-0.03	-0.12	0.06	0.237
	Comparator group	889	0.18	0.89				
	Total	1405	0.17	0.81				

By Educational level

Educational level (INTERACTION OF TWO-WAY ANOVA p = 0.333)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No formal schooling	Intervention group	11	0.00	0.00	-0.09	-0.25	0.07	0.267
	Comparator group	30	0.09	0.35				
	Total	41	0.07	0.30				
Less or primary school (0-6 or 7 years)	Intervention group	43	0.02	0.15	-0.11	-0.20	-0.02	**0.018**
	Comparator group	61	0.13	0.39				
	Total	104	0.09	0.32				
Less or secondary school completed (7-12 or 13 years)	Intervention group	209	0.03	0.17	-0.02	-0.06	0.02	0.310
	Comparator group	278	0.05	0.25				
	Total	487	0.04	0.22				
College / University (>12 years)	Intervention group	40	0.00	0.00	-0.04	-0.13	0.05	0.348
	Comparator group	69	0.04	0.21				
	Total	109	0.03	0.16				
Total	Intervention group	303	0.02	0.15	-0.04	-0.12	0.06	0.237
	Comparator group	438	0.06	0.28				
	Total	741	0.05	0.23				

By PC use

PC use (INTERACTION OF TWO-WAY ANOVA p = 0.258)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No	Intervention group	140	0.04	0.20	-0.06	-0.13	0.01	0.100
	Comparator group	161	0.10	0.34				
	Total	301	0.07	0.28				
Yes	Intervention group	128	0.03	0.23	-0.121	-0.19	-0.05	**0.001**
	Comparator group	161	0.15	0.42				
	Total	289	0.10	0.36				
Total	Intervention group	268	0.03	0.22	-0.09	-0.17	0.08	0.237
	Comparator group	322	0.12	0.38				
	Total	590	0.08	0.32				

A.2 Two-way ANOVA - Difference in Hba1c

By age

Age (INTERACTION OF TWO-WAY ANOVA p = 0.024)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
<65	Intervention group	351	-0.22	1.07	-0.15	-0.29	0.00	0.047
	Comparator group	634	-0.08	1.22				
	Total	985	-0.13	1.17				
65-75	Intervention group	230	-0.23	0.92	-0.16	-0.34	0.02	0.077
	Comparator group	366	-0.07	0.98				
	Total	596	-0.13	0.96				
>75	Intervention group	109	-0.55	1.46	-0.54	-0.79	-0.28	0.000
	Comparator group	215	-0.01	0.80				
	Total	324	-0.19	1.10				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	0.000
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By gender

Gender (INTERACTION OF TWO-WAY ANOVA p = 0.707)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Male	Intervention group	373	-0.28	1.05	-0.23	-0.37	-0.09	0.001
	Comparator group	671	-0.05	1.06				
	Total	1044	-0.13	1.07				
Female	Intervention group	317	-0.27	1.16	-0.19	-0.34	-0.04	0.013
	Comparator group	544	-0.08	1.12				
	Total	861	-0.15	1.14				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	0.000
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By type of diabetes

Type of diabetes(INTERACTION OF TWO-WAY ANOVA p = 0.496)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Type 1	Intervention group	61	-0.36	1.33	-0.32	-0.64	0.00	**0.052**
	Comparator group	164	-0.04	1.17				
	Total	225	-0.13	1.22				
Type 2	Intervention group	629	-0.27	1.08	-0.20	-0.31	-0.09	**0.000**
	Comparator group	1050	-0.07	1.07				
	Total	1679	-0.14	1.08				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	**0.000**
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By diabetes complications

COM_10_A (INTERACTION OF TWO-WAY ANOVA p = 0.569)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
DM with complications	Intervention group	247	-0.38	1.22	-0.25	-0.42	-0.07	0.006
	Comparator group	372	-0.13	1.08				
	Total	619	-0.23	1.14				
DM without complications	Intervention group	443	-0.22	1.03	-0.19	-0.31	-0.06	0.004
	Comparator group	843	-0.03	1.09				
	Total	1286	-0.10	1.07				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	0.000
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By HbA1c

HbA1c (INTERACTION OF TWO-WAY ANOVA p = 0.059)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Lower Level (under 7%)	Intervention group	387	0.09	0.74	-0.19	-0.32	-0.06	0.005
	Comparator group	572	0.28	0.78				
	Total	959	0.21	0.77				
Higher Level (over 7%)	Intervention group	303	-0.75	1.30	-0.38	-0.52	-0.24	0.000
	Comparator group	643	-0.37	1.22				
	Total	946	-0.49	1.26				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	0.000
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By CCI

CCI (INTERACTION OF TWO-WAY ANOVA p = 0.700)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
1 or 2	Intervention group	653	-0.28	1.11	-0.22	-0.32	-0.11	0.000
	Comparator group	1140	-0.06	1.10				
	Total	1793	-0.14	1.11				
3 or 4	Intervention group	37	-0.30	0.92	-0.13	-0.56	0.30	0.549
	Comparator group	75	-0.17	0.85				
	Total	112	-0.21	0.87				
Total	Intervention group	690	-0.28	1.10	-0.21	-0.32	-0.11	0.000
	Comparator group	1215	-0.06	1.09				
	Total	1905	-0.14	1.10				

By educational level

Educational level (INTERACTION OF TWO-WAY ANOVA p = 0.170)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No formal schooling	Intervention group	28	-0.25	1.08	-0.28	-0.80	0.24	0.287
	Comparator group	31	0.03	1.05				
	Total	59	-0.10	1.06				
Less or primary school (0-6 or 7 years)	Intervention group	43	-0.12	0.81	-0.15	-0.24	0.54	0.455
	Comparator group	64	-0.27	0.81				
	Total	107	-0.21	0.81				
Less or secondary school completed (7-12 or 13 years)	Intervention group	274	-0.17	0.89	-0.15	-0.31	0.02	0.086
	Comparator group	294	-0.03	1.10				
	Total	568	-0.10	1.01				
College/University (>12 years)	Intervention group	52	-0.46	0.98	-0.45	-0.81	-0.08	**0.016**
	Comparator group	72	-0.01	1.32				
	Total	124	-0.20	1.20				
Total	Intervention group	397	-0.21	0.91	-0.25	-0.55	0.19	**0.000**
	Comparator group	461	-0.06	1.10				
	Total	858	-0.13	1.02				

By PC use

PC use (INTERACTION OF TWO-WAY ANOVA p = 0.258)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No	Intervention group	148	-0.11	0.81	0.01	-0.19	0.20	0.939
	Comparator group	171	-0.12	1.00				
	Total	319	-0.11	0.92				
Yes	Intervention group	134	-0.15	0.82	0.17	-0.03	0.37	0.098
	Comparator group	176	-0.31	0.85				
	Total	310	-0.24	0.84				
Total	Intervention group	282	-0.13	0.81	0.09	-0.21	0.28	0.237
	Comparator group	347	-0.22	0.93				
	Total	629	-0.18	0.88				

By insulin

Insulin (INTERACTION OF TWO-WAY ANOVA p = 0,000)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Yes	Intervention group	427	-0.37	1.20	-0.38	-0.51	-0.24	0.000
	Comparator group	662	0.01	1.20				
	Total	1089	-0.14	1.22				
No	Intervention group	260	-0.13	0.90	0.02	-0.18	0.14	0.815
	Comparator group	551	-0.15	0.93				
	Total	811	-0.14	0.92				
Total	Intervention group	1089	-0.28	1.10	-0.22	-0.32	-0.11	0.000
	Comparator group	811	-0.06	1.09				
	Total	1900	-0.14	1.10				

A.3 Two-way ANOVA - Number of face-to-face contacts with GP or diabetologist per year of follow-up (adjusted)

By age

Age(INTERACTION OF TWO-WAY ANOVA p = 0.011)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
<65	Intervention group	305	11.3024	7.55337	2.51	1.40	3.62	0.000
	Comparator group	650	8.7937	8.34201				
	Total	955	9.5949	8.17869				
65-75	Intervention group	178	11.9401	7.64196	2.928	1.467	4.389	0.000
	Comparator group	366	9.0121	8.65707				
	Total	544	9.9701	8.44419				
>75	Intervention group	45	13.6795	7.57979	6.878	6.878	-0.28	0.000
	Comparator group	213	6.8010	8.00211				
	Total	258	8.0007	8.33651				
Total	Intervention group	528	11.72	7.60	3.21	2.37222	4.04096	0.000
	Comparator group	1229	8.51	8.41				
	Total	1757	9.4770	8.30447				

By gender

Gender (INTERACTION OF TWO-WAY ANOVA p = 0.817)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Male	Intervention group	302	11.6737	7.51394	3.12	2.011	4.229	0.000
	Comparator group	683	8.5536	8.19171				
	Total	985	9.5102	8.11489				
Female	Intervention group	226	11.7819	7.73094	3.319	2.050	4.588	0.000
	Comparator group	546	8.4631	8.68327				
	Total	772	9.4347	8.54535				
Total	Intervention group	528	11.7200	7.60049	3.21	2.37222	4.04096	0.000
	Comparator group	1229	8.5134	8.41029				
	Total	1757	9.4770	8.30447				

By type of diabetes

Type of diabetes(INTERACTION OF TWO-WAY ANOVA p = 0.002)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Type 1	Intervention group	85	7.8648	6.61646	0.21	-1.894	2.311	0.846
	Comparator group	177	7.6564	7.73700				
	Total	262	7.7240	7.38004				
Type 2	Intervention group	443	12.4597	7.55979	3.80	2.897	4.702	0.000
	Comparator group	1051	8.6601	8.51697				
	Total	1494	9.7867	8.42306				
Total	Intervention group	528	11.7200	7.60049	3.21	2.37222	4.04096	0.000
	Comparator group	1229	8.5134	8.41029				
	Total	1757	9.4770	8.30447				

By diabetes complications

COM_10_A (INTERACTION OF TWO-WAY ANOVA p = 0.000)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
DM with complications	Intervention group	114	14.1216	6.95308	8.007	6.318	9.697	0.000
	Comparator group	371	6.1141	9.17154				
	Total	485	7.9963	9.33511				
DM without complications	Intervention group	414	11.0587	7.64558	1.508	0.564	2.452	0.002
	Comparator group	858	9.5508	7.84012				
	Total	1272	10.0416	7.80639				
Total	Intervention group	528	11.7200	7.60049	3.21	2.37222	4.04096	0.000
	Comparator group	1229	8.5134	8.41029				
	Total	1757	9.4770	8.30447				

By HbA1c

HbA1c (INTERACTION OF TWO-WAY ANOVA p = 0.001)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
Low Level under 7	Intervention group	274	14.1216	6.95308	4.43	3.254	5.597	0.000
	Comparator group	572	6.1141	9.17154				
	Total	846	7.9963	9.33511				
High Level	Intervention group	253	11.0587	7.64558	1.71	0.522	2.889	0.005
	Comparator group	644	9.5508	7.84012				
	Total	897	10.0416	7.80639				
Total	Intervention group	527	11.6924	7.48565	3.20	2.25145	4.03255	0.000
	Comparator group	1216	8.4925	8.52463				
	Total	1743	9.4770	8.42568				

By CCI

CCI (INTERACTION OF TWO-WAY ANOVA p = 0.869)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
1 or 2	Intervention group	497	11.4568	7.61879	3.192	2.338	4.046	0.000
	Comparator group	1156	8.2648	8.34838				
	Total	1653	9.2245	8.26434				
3 or 4	Intervention group	31	15.9389	5.96232	3.488	.075	6.901	0.045
	Comparator group	73	12.4506	8.46465				
	Total	104	13.4904	7.93792				
Total	Intervention group	528	11.7200	7.60049	3.21	2.37222	4.04096	0.000
	Comparator group	1229	8.5134	8.41029				
	Total	1757	9.4770	8.30447				

By educational level

Educational level (INTERACTION OF TWO-WAY ANOVA p = 0.086)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No formal schooling	Intervention group	11	13.3921	7.39488	8.002	2.529	13.474	0.004
	Comparator group	30	5.3905	8.79608				
	Total	41	7.5373	9.09110				
Less or primary school (0-6 or 7 years)	Intervention group	43	14.7708	7.32404	-0.168	-3.239	2.903	0.914
	Comparator group	63	14.9391	6.13122				
	Total	106	14.8708	6.60762				
Less or secondary school completed (7-12 or 13 years)	Intervention group	222	15.4573	6.18542	2.172	0.792	3.551	0.002
	Comparator group	295	13.2855	9.47277				
	Total	517	14.2180	8.28681				
College/University (>12 years)	Intervention group	40	14.6420	5.37906	2.391	-0.670	5.453	0.126
	Comparator group	72	12.2507	8.13527				
	Total	112	13.1047	7.33647				
Total	Intervention group	316	15.1888	6.28794	2.3536	1.320	4.878	0.001
	Comparator group	460	12.8351	9.06056				
	Total	776	13.7936	8.12588				

By PC use

PC use (INTERACTION OF TWO-WAY ANOVA p = 0.004)		N	Mean	Std. Deviation	Mean Difference	Lower	Upper	P-value
No	Intervention group	148	13.53	6.99	-1.67	-3.162	-0.178	0.028
	Comparator group	171	15.20	7.40				
	Total	319	14.42	7.25				
Yes	Intervention group	133	17.02	5.23	1.50	-0.036	3.029	0.056
	Comparator group	173	15.52	6.97				
	Total	306	16.18	6.30				
Total	Intervention group	281	15.18	6.45	-0.18	-1.156	0.983	0.873
	Comparator group	344	15.36	7.18				
	Total	625	15.28	6.85				

Appendix B: SUTAQ (Domain 4)

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
☐	☐	☐	☐	☐	☐

Appendix C: Template for collection of data on costs of telemedicine intervention (Domain 5)

In order to be able to estimate the costs of providing the telemedicine interventions to the patients we need you to give your best answers to the following questions. In some cases, you will not have specific data on this (e.g. hours spent on education of the clinical staff), and in that case we ask you to provide your best guess.

Basic information

1. Name of the region?

2. Clinical condition of the patients? (mark with one X)

Diabetes	
COPD	
Congestive heart failure	

Investments and fixed cost

3. What investments have been made in technical infrastructure (e.g. servers, WiFi, computers, phones, software, web based portal, system integration) and **what are the total costs or total costs per year?**

Name of investment:	Total costs in €?	Total costs per year in €?

Note: Please provide information on EITHER total costs OR total cost per year for the total number of patients, depending on which information you have access to.

4. How much time has the health care professionals been using for management, education and training in order to establish the telemedicine service?

Staff:	Number of persons:	Number of hours of work in total	Salary per hour in €:
Medical doctors			
Nurses			
Technical staff			
Others:			
Others			

5. **What is the total number of patients per year that you expect to provide this telemedicine service for with these investments?**

Running costs for each patient

6. **What are the costs per patient for use of the telemedicine devices?** E.g. gateway, video conference equipment, devices for home measurement of blood glucose, pulse oximeter, blood pressure, heart rate and weight.

Name of device:	Costs per patient in €:

7. **What is the average use of healthcare professionals per patient in the production and delivery of the telemedicine service?** E.g. staff used at call centres and staff monitoring patients' data from telemedicine devices.

Staff:	Number of hours of work in total per patient:	Salary per hour in €:
Medical doctors		
Nurses		
Technical staff		
Others:		
Others		

8. **Are there other costs or use of resources we should take into account?** Please describe in text:

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