The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability.
Key Word List

Blood-sugar, Type 1 Diabetes, Type 2 Diabetes, Primary care, Telemonitoring, Self Management, Self monitoring, Secondary care
Executive Summary

This intermediate trial report provides details on United4Health WP6 Multicentre real-life pilot in diabetes. This report covers the progress achieved up to end December 2014. Further information is provided on the progress within each of the pilot areas, update on recruitment including the sample size, participant flow and breakdown of recruitment progress.

Points to note within this interim report:

- **Current Management**
  Diabetes mellitus is a major cause of morbidity and mortality worldwide; the multi-vascular risk factors and wide-ranging complications mean that management of type 2 diabetes requires complex and time-consuming healthcare management. 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 for patient centred care. The aim of United4Health is to trial telemonitoring solutions and evaluate the effectiveness of these in relation to disease management.

- **Technical application for telemonitoring**
  The intervention aims to promote self-care and self-management by encouraging use of self-monitoring of glucose and lifestyle risk factors, and by providing ongoing health coaching. The patient will be aware that telemonitoring is not a replacement, but instead works in conjunction with routine healthcare for long term condition / disease management.

- **Technological capability within each region**
  The aim of United4Health is to implement integrated telemonitoring solutions at scale, to allow self care and self management with the use of telemonitoring applications to support routine care.

- **Training required and undertaken for patients and staff recruitment**
  Following the recruitment of patients as per the agreed protocols, patients are being monitored for up to 12 months following recruitment. Patients and staff are being trained; however this varies between regions with length of training dependant on the telemonitoring solution being trialled.

- **Recruitment, sample size, mitigating factors**
  Recruitment figures for patients with either Type 1 or Type 2 Diabetes vary across the participating regions with mitigating planning underway.

*This section will be completed in the Final Trial evaluation*
Change History

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0.1 25\(^{th}\) November 2014  Initial draft
0.2 14\(^{th}\) January 2-15
0.3 8\(^{th}\) February 2015
0.4 4\(^{th}\) March 2015
0.5 16\(^{th}\) March 2015
1.0 16\(^{th}\) March 2015

Version Changes
0.1  Initial Table of Contents
0.2  Country contributions for Scotland, Wales, Slovenia, Northwest Moravia, Cosenza (Calabria), South Karelia added
0.3  Minor updates
0.4  Country contributions for Greece and Campania added
0.5  Executive Summary added, minor updates
1.0  Version for issue

Outstanding Issues
Participant flow / recruitment figures from Berlin (section 3.2.9).
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1. Introduction

1.1 Purpose of this document

This document contains the initial collection of data for the MAST domains for the diabetes trials in the United4Health project. It has been prepared to document the data available following completion of recruitment.

1.2 Structure of the document

Section 2 contains information for MAST Domain 1: The health problem and the telemedicine 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

Note that many results from the pilots are not available for this Intermediate Pilot Evaluation, and will be described in the Final Pilot Evaluation. To preserve the structure of this document as a stepping stone towards the Final Pilot Evaluation, the section heading for the results has been included, with the text: “This section will be completed in the Final Trial evaluation”.

1.3 Glossary

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HbA1C</td>
<td>Glycated Haemoglobin</td>
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<tr>
<td>IDF</td>
<td>International Diabetes Federation</td>
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<td>MDMW</td>
<td>My Diabetes My Way</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>SMBG</td>
<td>Self Monitoring Blood Glucose</td>
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<tr>
<td>SMHIT</td>
<td>Self-Management Health Information Technology</td>
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<tr>
<td>SMS</td>
<td>Short Message Service</td>
</tr>
</tbody>
</table>
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**

Diabetes mellitus is a major cause of morbidity and mortality worldwide. In 2013, the International Diabetes Federation (IDF) estimated the worldwide prevalence to be 382 million (8.3% of the global population) and predicted that by 2035 the prevalence will have risen to 592 million[1]. It is predicted to become the seventh leading cause of death in the world by the year 2030. Total deaths from diabetes are projected to rise by more than 50% in the next 10 years. 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[1].

The multi-vascular risk factors and wide-ranging complications mean that the management of type 2 diabetes requires complex and time-consuming healthcare management[2]. 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[2,3].

2.2 **Burden of the disease**

Diabetes results in high healthcare costs, loss of labour productivity, and decreased rates of economic growth. Globally, healthcare expenditure for diabetes totalled USD 465 billion in 2011, equivalent to 11% of total health spending. Without an investment in making effective treatments for preventing diabetes complications widely available, this is predicted to rise to USD 595 billion by 2030[1].
2.3 Current management

2.3.1 Scotland

One in 20 people in Scotland have diabetes. There were 268,154 people diagnosed with diabetes in Scotland recorded on local diabetes registers at the end of 2013 [1]. This represents 5% of the population. Crude prevalence of diabetes ranges from 4.34% to 5.8% across NHS Boards [2]. The majority of people living with diabetes (88.2%) have Type 2 Diabetes, and nearly 11% have Type 1 Diabetes.

The provision of diabetes services in Scotland is complex; care is provided by a wide range of professionals including:

- General Practitioners (GPs).
- Consultants.
- Primary & secondary healthcare professionals.
- Specialist diabetes teams.

The achievement of good outcomes for people with diabetes in Scotland is dependent on the provision of well-organised and coordinated diabetes services that draw on the knowledge and skills of health and social care professionals working across both primary and secondary care.

Type 1 and Type 2 Diabetes services across are co-ordinated & delivered through both primary and secondary care services in Scotland. However, Type 2 patients are predominately managed in primary care diabetes clinics / centres, and include patients newly diagnosed with Type 2 and those stabilised on insulin therapies. The care of people within primary care is provided by a multidisciplinary team, including, as a minimum, the GP and practice nurse, supported by administrative staff. All patients with Type 1 Diabetes and secondary diabetes and complex Type 2 are managed by a Consultant Diabetologist and/ or Specialist Clinicians based within secondary care through attendance at outpatients appointment / clinics.

People with diabetes, irrespective of whether their care is managed within primary or secondary care, will at a minimum have an annual review with their Consultant or GP which typically includes:

- BMI measurement.
- Foot examination.
- Eye examination.
- Urinary albumin.
- Blood sample (HbA1c / lipids).
- Blood pressure assessment.
- Smoking habits.
- Lifestyle and physical activity levels.
- Review method of glucose monitoring.
- Review of perception, understanding of condition/self care.

The SIGN guideline includes recommendations on:

- lifestyle interventions for people with type 1 and type 2 diabetes;
- managing psychosocial issues in people with diabetes;
- managing type 1 diabetes;
- glucose lowering therapies in people with type 2 diabetes;
- self monitoring of glycaemia;
- managing cardiovascular, kidney and foot disease;
- preventing visual impairment in people with diabetes;
- Managing type 2 diabetes and gestational diabetes during pregnancy.

Further information on clinical standards and guidelines is available at www.sign.co.uk.

In Scotland, approximately 90% of people with diabetes self manage. (Diabetes, UK, 2013). Services promoting supported self-management and enabling people to have the confidence and skills to better deal with their diabetes increasingly form a key part of the wider policy context in Scotland to support people with long-term conditions. For diabetes services, this includes providing patients with structured education programmes, the provision of high quality information, enhanced use of technology to promote self care, care planning and peer support.

2.3.2 Wales

Type 2 Diabetes is mostly managed in primary care by GPs and practice nurses with a special interest in diabetes. Patients are called into their surgery by appointment to have, as a minimum, annual reviews including HbA1c, health style advice, renal function and lipid monitoring, blood pressure monitoring and microvascular / neuropathic assessment. Patients are also requested, again by appointment, to attend annual retinopathy screening at a local screening clinic.

2.3.3 Slovenia

Current management of DM at the General Hospital Slovenj Gradec (SB-SG) and the healthcare centre Ravne (RavKor) is based on self-management of diabetes supported by regular visits to specialist outpatient clinics at the SB-SG hospital and healthcare centres in the Koroška region. One of them is RavKor.

Current management aims to achieve the following goals:

- Achieve the target values of glycated haemoglobin Hb1A1c.
- Achieve and maintain an adequate body weight (over 80% of patients with DM type 2 are overweight).

1 http://www.sign.ac.uk/guidelines/fulltext/116/
• Achieve the target values of blood pressure.
• Achieve the target values of cholesterol.

Self-management of DM Type 2 within their home environment depends on the level of the disease and the treatment that patients receive:

• Patients on insulin:
  - Patients daily monitor their blood sugar by performing tests before and after their daily meals (6 points profile).

• Patients on tablets:
  - Patients check their blood sugar 1-2 times per month using 4-6 points daily profile. They have to buy test strips at their own expense.

• Patients on diets only:
  - Patients check their blood sugar once per month, using 4-6 points’ daily profile.

All the patients have to keep written records of measurements in a dedicated notebook. The records are checked by the diabetologist at regular scheduled visits, and serve as a basis for further treatment of the patients. All are advised to regularly monitor their blood pressure. In addition, they are advised to maintain an adequate diet. It is adjusted by the diabetologist in accordance with the recorded values of blood sugar.

All the DM patients are provided with regular periodic control visits to the diabetologist at the specialist department at SB-SG and RavKor. Regular period is six months if the patients meet their personalised target values of blood sugar. If not, the specialist shortens the period by increasing the frequency of visits to put a positive pressure on patients who do not stick with the suggested regimen.

Many patients have difficulties adhering to the prescribed diet and treatment regimen. Some of them also falsify the real results of self-management by recording data that have not been really measured.

We believe that with the telemedicine support to the DM patients we will:

• Collect results that reflect the real situation of diabetes for each patient.
• Raise motivation of the patients to cooperate with the therapy.
• Reduce, in the long-term, the number of DM patients’ visits to the specialist centre, in particular those patients who visit the diabetologist more frequently than every six months.

2.3.4 Northwest Moravia, Czech Republic

Current management of DM at University Hospital Olomouc (Northwest Moravia) is in accordance with Czech Diabetes Society Guidelines on diabetes mellitus type 2 treatments. Frequency of outpatient visits depends on patient’s status and diabetes progression, but it is usual to arrange outpatient visits at least every three months for most patients. The diabetologist normally checks older measurements in patient’s glucometer memory or patient’s diary, and levels of HbA1c by laboratory test.
2.3.5 ARSAN Campania, Italy

In 2013, the national prevalence of diabetes was 4.9%; in the Campania region, the prevalence was around 6%, reaching over 12% with increasing age. The male population has a higher prevalence than the female one, but after 75 years of age, this ratio is reversed. The mortality rate is the regional population is among the highest in Italy: 57.8 per 100,000 male inhabitants, second only to the Sicilians, and 51.2 per 100,000 female inhabitants, the highest in Italy.

The complications of diabetes which cause more hospitalisations are those related to peripheral circulatory disorders, as confirmed by the high number of amputations in people with diabetes, about 600 per year. These and other severe complications, such as the loss of kidney function, sight or limbs, are often due to the improper management of peaks and troughs of blood glucose suffered by diabetics.

In the Campania region in 2011, hospitalisations due to complication in the diabetic disease were about 8,000, with a diminishing trend in the last 10 years. Nevertheless, the number of inappropriate and avoidable hospitalisations is still high. Other open issues in the management of care for the diabetes by the Regional Healthcare System are related to the delays in the provision of diagnostic and therapeutic services, and to the regional mobility, mostly due to waiting times.

In order to cope with the epidemiological data and the high consumption of resources, the Regional Healthcare System is deploying a major reorganisation of the healthcare delivery system, based on the integration among the various levels of care through the adoption of integrated care pathways, which vary with the level of complexity in the patient’s needs. These include:

- the active involvement and empowerment of patients in the management of diabetes, especially for the self-monitoring of blood glucose, adherence to treatment, and the adoption of healthy lifestyles;
- a deeper involvement of GPs in the management of diabetic patients with no or stabilised complications;
- integration between secondary care and hospitals in the management of the more complex patients.

2.3.6 ASP Cosenza, Calabria, Italy

Regarding the presence of diabetes in Italy, data provided by ISTAT indicate that the figure is constantly increasing. In Italy, in 2010, patients suffering from diabetes were 4.9% of the population (5.2% of the female population, and 4.5% of the male population).

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2 Sources: “Piano sulla malattia diabetica” by the Ministry of Health, DG Health Planning, National Diabetes Committee; 6th December 2012
Diabetes is currently the second disease in terms of direct costs, representing 10-15% of healthcare costs in Italy in 2010. In the absence of complications, the costs would be about €800/year per person, whereas in the presence of complications, they may vary between €3,000 and €36,000/year per person.

**Diabetes care in Italy**

The Italian care system has been developed after the Law no. 115 of 16th March 1987 and the Memorandum of Understanding between the Ministry of Health and the Prime Minister of 30th July 1991. Nevertheless, the features are not completely cohesive.

In recent years, the Ministry of Health has played a significant role in making the specific rules on diabetes current and innovative; it has identified strategies whose operating procedures are based on a broad dialogue and collaboration between the main care actors, in a synergy between the regions, professional associations, volunteers, state and private institutions.

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3 Source: Istat. Multipurpose survey "Aspects of daily life"; 2010
Long-term complications of diabetes are the main cause for reduction of patients’ quality and duration of life; they severely increase the costs. As such, these complications were included in the areas of priority interventions in the 2005-2007 National Prevention Plan, as set out in the Memorandum of Understanding between the State and the local Regions of 23rd March 2005. This objective was being pursued through the adoption of disease management programmes that refer to a strategy for the management of chronic diseases.

**Young population suffering from diabetes**

The primary level of care in this area is mainly delegated to paediatricians, supported by the National Health System. Despite being widespread throughout the country, most paediatricians, in the presence of problems caused by Type 1 Diabetes, would decide that it is more appropriate to directly refer the patients to specialised centres. The second level of care is quite homogeneous, despite not always being well formalised. This level is almost exclusively located in hospitals, universities, or IRCCS.

**Adults suffering from diabetes**

General practitioners (GPs) of the National Health System represent the primary level of care. It has been estimated that every GP has between 60 and 80 diabetic patients for every 1,000 patients; the average annual contacts are 18 visits per year, rising to more than 20 when it comes to over 70 year-old patients (Health Search, 2005).

Diabetic patients have a decent compensation (53% of them have a level of HbA1c that is lower than 7%). They can be treated either with oral hypoglycaemic agents (61%) or only with insulin therapy; or with no drug treatments.

Diabetes centres represent the second level of support. There is an extensive network of centres, located within hospitals and universities, and in local contexts. In region Calabria, territorial diabetes care is widespread and extensive. However, the supply of resources varies between different regions of Italy.

Although a decent number of highly specialised and equipped centres are aimed to address complex issues, only 29% of them have adopted models of integration and communication with GPs. In addition, only less than half of them have activated a specific clinic for diagnosis and treatment of complications; and just a minority regularly deliver structured programmes of therapeutic education.

The current situation shows that regardless of the percentage of subjects that achieve adequate metabolic control and receive appropriate periodic inspections, there is room for further substantial improvement both in primary care and in diabetes centres.

Region Calabria has started a reorganisation of the public healthcare delivery network. This implies that GPs would play a vital role in the care of chronic illnesses with non complex needs, including diabetes. This elaborate reorganisation is still in its early stage, and the opportunities and risks of using the expected results in the design of the local study have been evaluated. It was then decided that the diabetologists would have a bigger role in the study, in close cooperation with their ambulatory nurses.
Conversely, we should consider the following elements as indispensable: the recall system of patients; organisational models integrated with other specialists for diagnosis and treatment of complications; regular follow-up starting at the same time as diagnosis of the disease; active involvement of the person with diabetes; and integrated management with GPs.

2.3.7 South Karelia, Finland

About 500,000 people suffer from diabetes in Finland, a number which is predicted to double within the next 10–15 years. At the moment, diabetes can be neither prevented nor cured. Diabetes is associated with macro vascular complications (coronary heart disease, stroke) and micro vascular disorders (kidney, eye and peripheral nerves). These complications affect the quality of life of patients and account for a substantial proportion of healthcare costs in Finland. The current guidelines offer recommendations for the diagnosis, screening, prevention and treatment of diabetes and its complications.

2.3.7.1 Diagnosis

Diagnosis criteria are: an increased plasma glucose concentration (at least 7 mmol/l), glucose tolerance test increased value (over 11mmol/l) or HbA1c more than 6.5% (48mmol/l) value.

2.3.7.2 Diabetes treatment and follow-up

The aim of diabetes management is to prevent the complications of diabetes and guarantee quality of life. Primary responsibility for disease management is the diabetic patient himself. Plasma glucose home measuring is an important and essential part of the diabetes. Diabetic patients' diet is similar to the general population, a little hard and moderately soft fat, high in fibre and low in salt.

Complications of diabetes screening are systematic. Under good control, diabetes patients should be monitored every 3-6 months. Before a good treatment balance is achieved, follow-ups are more frequent. Once a year, there is a more comprehensive inspection.

2.3.8 Central Greece

Participants in the control group receive usual care. Usual care consists of regular visits to the specialist or to a primary care facility at mean intervals of three months. During these visits, HbA1c and glucose measurements are taken, and if necessary the current oral or insulin therapy is modified. Patients also undergo basic education regarding the management of diabetes. More frequent visits are take place if clinically necessary.

2.3.9 Berlin, Germany

45% of the population in Berlin (about 170,000 diagnosed people) have diabetes recorded in the local Master Plan Berlin at the end of 2012. About 3% of the population in Berlin (3.4 million. people) are not yet recognised as diabetics. In particular, older and dependent patients have a high relevance in this respect.
The majority of people living with diabetes (about 80%) have type 2 diabetes.

The provision of diabetes services in Berlin are complex. Responsible for care are the diabetes centres of the hospitals, or integrated into the care management of the healthcare providers by a wide range of professionals, including GPs, consultants and other primary & secondary healthcare professionals and specialist diabetes teams.

In addition, since 2001 there have been special disease management programmes (DMP) for diabetes, and so-called integrated care contracts with health insurances.

The aim of diabetes mellitus type 2 (DM2) management is a near-norm adjustment by Pflegewerk regarding the current management of the blood sugar, to minimise the risk of long-term consequences associated with diabetes. They are suggested in clinical practice guidelines released by various national and international diabetes agencies. The targets were: HbA1c 6%-7%, or up to 8% for persons with life expectancy of less than 5 years.

Type 2 diabetes is treated first with weight reduction, a diabetic diet, and exercise. If these measures fail to control the elevated blood sugars, oral medications are used. If oral medications are still insufficient, treatment with insulin is considered. There are different forms of insulin (rapid-acting, short-acting, intermediate-acting, long-acting and pre-mixed) and application (with different kinds of pens and injectors or with an implanted insulin pump).

2.4 Use of the technical application

2.4.1 Scotland

The telehealth intervention being used in Scotland aims to promote self care and self management by encouraging use of self monitoring glucose and lifestyle risk factors including ongoing health coaching. For this to be successful, patients need to learn about their diabetes and how to safely care for it on a daily basis. They also need information about symptoms, lifestyle choices, and how to make changes in their behaviour. In addition, patients need to understand their role as a decision-maker and how to better assume responsibility for their care.

All three U4H pilot sites in Scotland (Lanarkshire, Ayrshire & Arran, and Greater Glasgow & Clyde) are introducing the same new software technology to promote the centralised integration of home blood glucose monitoring (HBGM) into two established systems: MyDiabetesMyWay (MDMW) and SCI-diabetes. Alongside promoting patient registration on MDMW self manage website, registered clinical staff and patients will be given access to software to upload and view blood glucose measurement via My Diabetes area of the website (closed area based on user) and staff via SCI-Diabetes through use of DIASEND.

Testing and implementing this one integrated solution at scale through U4H will identify whether the technology solution being used is suitable for scaling up nationally across the remaining geographical areas and Health Boards across Scotland.
The combination of a rich information resource and a strong and established brand identifies the MDMW website as the ideal platform upon which to build a system to support the digital integration of HBGM.

Through use of DIASEND, information is presented in clear and structured reports no matter what the blood glucose monitoring device is or how the data is stored. Patients will also be able to easily link their existing blood glucose monitor to their own computer to automatically upload readings to share them during their review with their healthcare professional or healthcare provider (Figure 2 & Figure 3).

In addition, the integrated web based intervention enables:

- Increased access to disease specific information to help patient to understand and self manage symptoms more effectively.
- More flexible options for care provision involving fewer face-to-face contacts and more remote clinical consultations.
- Easy, faster and more flexible access to accurate blood glucose readings enabling improved self management of their condition, and make changes to behaviour / lifestyle in order to improve health and well being.
- Opportunities for patients to be involved in new, innovative approaches to service delivery to promote self management and co-production.

![Figure 2: Patient reports viewed through MDMW website](image-url)
A wide range of different healthcare professionals and administration staff access SCI Diabetes portal, including consultants, GPs, district nurses, diabetes nurses and specialist clinicians. They will use this key information via DIASEND to support direct management of diabetes care. Only professionals and healthcare staff from the three Scottish pilot sites will be able to access Diasend integrated software, and hence view patient results through SCI Diabetes.

2.4.2 Wales

Potential participants will all have a diagnosis of T2DM who currently self monitor their blood glucose levels.

Enrolment will be carried out by a team experienced in T2DM and telemonitoring. Close collaboration with primary care staff is essential. Prior to the primary care diabetic annual review consultation, a candidate’s medical notes will be screened for inclusion and exclusion criteria, and the patient will be sent an information sheet informing them about the nature and objectives of the intervention. Additionally, patients may self refer themselves to the study, but acceptance into the study will be in accordance with the inclusion / exclusion criteria, and will adhere to the governance surrounding appropriate informed consent (e.g. having at least 24 hours to consider the study before consenting).

Study subjects will be connected to the backend monitoring via a usual primary care visit, and set up through Florence©, Simple Telehealth, Web based monitoring system (Stoke on Trent, NHS England) (www.florence.co.net). The patient will be trained in the use of the telemonitoring equipment, and will need to demonstrate satisfactory understanding of text messaging before the patient consents to use.
The study subject will use a provided blood glucose monitoring device to measure blood glucose levels, and will be sent reminders to perform their blood glucose readings by an automated program. The device feeds back the blood glucose level to the patient, who then uses a gateway device manually or automatically to transmit the data to an automated program. This program analyses the data according to an individualised set of parameters, and provides instant feedback to the patient via their gateway device along with locally agreed advice messages if required. Should a parameter be critically breached, the patient will be advised on immediate action and who to contact. An alert message will also be sent to their primary healthcare provider which can be reviewed immediately, or the next working day if the anomalous parameter occurs out of working hours. During the study, the subject will also receive standardised, weekly, health coaching messages; study subjects will be reminded upon entering the study and through the Patient Information Sheet that if they require the attention of a healthcare professional in relation to their diabetes and the message that they have received, it is their responsibility to make the contact.

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. Transmission of the results is provided via a free-number, and so there are no cost implications for patients. 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.

### 2.4.3 Slovenia

The telemedicine service aims to achieve the same goals as current management, namely:

- Achieve the target values of glycated haemoglobin Hb1A1c.
- Achieve and maintain an adequate body weight (over 80% of patients with DM type 2 are overweight).
- Achieve the target values of blood pressure.
- Achieve the target values of cholesterol.

Diabetic patients measure their blood sugar by a glucometer once per week, providing a whole day profile with 4-7 measurements. Each patient has a smart mobile phone that serves as a mobile gateway. Data are transferred from the glucometer to the gateway via Bluetooth, and then over a mobile network to a telemedicine service centre at SB-SG. The received data are stored on the telemedicine service server that is a part of the hospital network infrastructure, and are processed by the server application as described below.

Telemetrically collected data are accessible through the LAN or remotely by VPN access. The received data values are assessed by the server telemedicine application against set thresholds and trends. If the received data exceeds the individually set threshold limit (set by the medical specialist), a telemedicine centre coordinator (a nurse) receives a warning email. Optionally, if the coordinator does
not confirm receipt of the email, it is forwarded to the medical specialist on duty. The
cordinator calls the patient by phone to get more information on the background of
the exceeding data values. The measurements are repeated if there is any doubt
about data reliability. If the measurements confirm deteriorated conditions, or they
are indicated by the patient him/herself, the coordinator consults the specialist on
duty and informs him/her of the findings. The specialist decides on the action to be
taken by the patient. This could be: advice, change in medication / treatment, a visit
to his/her GP, a visit to the hospital clinic during regular working hours, or an
emergency visit to the hospital. The information is conveyed to the patient by the
coordinator over the phone, and later as a written report by a normal mail. Every
phone call, advice, change in therapy, home visit or other action is registered in the
patient's electronic record.

A mobile team of field nurses is planned to visit those patients who are willing to
cooperate, but who do not feel capable of managing the telemedicine devices by
themselves.

2.4.4 Northwest Moravia, Czech Republic

Main target of telemedicine intervention in DM is to reduce the information gap
about patient’s status development between two outpatient department visits, and
also to improve compliance of the patients. Telemonitoring enables collection of
HbA1c values, but diabetologists also have better insight into patient's regime and
adherence to treatment.

According to the study protocol, each enrolled diabetic patient receives a mobile
gateway (based on smartphone) and glucometer (with test strips). He is
appropriately educated and obtains training materials. Android app called
Medimonitor with user friendly interface runs on the smartphone (or tablet) as
gateway. Data and other measured values from the devices are sent to telehealth
portal and stored in database. The information is then accessible to medical staff
and telemonitoring centre operators (clinicians, nurses and biomedical engineers)
via web browser and secured login. Telehealth portal and Medimonitor were
developed according to the requirements of the hospital.

There are two types of software alert detection: a) if patient’s clinical parameters
exceed threshold values or b) if there are uncompleted measurements. Application
is administered by team of two biomedical engineers and three doctors of internal
medicine (diabetologists). They provide regular telephone support to patients, and
solve immediate situations directly according to alerts and clinical parameters of
patients. Frequency of measurements of glycaemia depends on patient status, and
is strictly individualised by diabetologist. There is also continuous telephone
technical support for patients from two biomedical engineers, who are based in the
telemonitoring centre, which itself is located in the cardiology clinic of the hospital.

2.4.5 ARSAN Campania, Italy

From a clinical point of view, the study intends to observe the impact of the
telehealth service in enhancing the self-monitoring of blood glucose in patients at
high risk of complications, in order to achieve a more stringent control of the
glycaemic trend, by detecting and preventing, as much as possible, the peaks and
troughs suffered by diabetics.
From the perspective of healthcare provision, the study intends to evaluate the effects of the telehealth service on the consumption of resources of the Regional Healthcare System (e.g. remote contacts, outpatient visits, hospitalisation, etc.).

Operationally, the measurements of blood glucose level are collected by the enrolled patients using their glucometer, and sent via a domestic gateway to the web based software platform “Diabtel.net”. The devices and gateways for the patients are provided by FORA Care Suisse AG. The Diabtel.net software platform is developed by Meter s.r.l.

By accessing the Diabtel.net web based portal, healthcare professionals periodically monitor and manage patients' health conditions. The platform is also able to send to the healthcare professional, via e-mail and SMS, appropriate notifications about individual patients, e.g. in case of exceeding the thresholds defined for the measured parameters. The monitoring of patients' health conditions via the telehealth service is not in real time, thus it is not intended to provide assistance in case of emergency.

Healthcare professionals assess patients' health conditions; at any time, health coaching and/or small adjustments to the care plan are performed, if required. They will contact the individual patient by phone, email or SMS. In case of complex situations, individual patients could be called back for an outpatient visit.

All the healthcare professionals involved in the observational study in the Campania Region are diabetologists. This is because of:

- the need to start the activities of the pilot sites in a very short time;
- the level of complexity of the patients enrolled in the study;
- the specific constraints in the Campania Regional Healthcare System (hiring freeze in the public sector, shortage of professional nurses, national stringent regulations on the processing of health data).

In more detail:

- The management / review of the care plan for an individual patient is provided by senior permanent diabetologists. They are also in charge of the supervision of the activities in the pilot sites.
- The remote monitoring of blood glucose and the management of the patient-doctor relationship by phone and SMS are performed by young temporary diabetologists. They are also in charge of carrying out the operational coordination among the pilot sites.

The functioning of the telehealth service delivered in the observational study is depicted in the figure below (caption in Italian).
2.4.6 **ASP Cosenza, Calabria, Italy**

ASP Cosenza is one of the pilot sites conducting the long-term multicentre study on monitoring of diabetes aiming to reduce the burden of the disease and promote patient engagement. Technically, this would mean to improve the adherence to care plans, encourage healthy lifestyles, and reduce the waiting list for outpatient care appointments.

ASP Cosenza participates in the United4Health project to gain experience about the outcomes and the operational issues related to the activation and maintenance of home-based telehealth services. This would also give continuity to local telemedicine initiatives, started with the two regional services recently launched in telecardiology and teleradiology.

In ASP Cosenza, four diabetologists participate in the United4Health pilot diabetes study. They operate from six outpatient clinics of the ASP, mainly located in the District of Cosenza: in Cosenza (the main city) and the towns of Castrovillari, Castrolibero, Acri, Mendicino and Casole Bruzio.

The implementation of the telehealth service is based on both pre-existing and brand new components with free licence to use, donated to ASP Cosenza by Lifescan Italy, a branch of Johnson & Johnson Medical S.p.a.:

- 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 the Eurotouch® Home, a standalone patient health record for the self-monitoring of blood glucose.
- An *ad-hoc* connector enables the online exchange of the encrypted data from the patients’ homes to the physicians and the nurse.

After evaluating several solutions and their different complexities, and recognising time and budget limitations, this configuration was the most effective, viable and affordable solution for the implementation of the study at ASP Cosenza.
Contacts with patients take place via email or phone. When necessary, they are invited to come to the clinic for an outpatient visit. Early results show a significant acceptance and satisfaction by patients, but also an extra workload for the diabetologists; further improvements are under evaluation.

2.4.7 South Karelia, Finland

In the trial, we want to improve the patients’ self-management skills. Based on the reported data, patients will receive notifications generated by the self-management server (PHR in the Eksote’s e-health services). Feedback is generated based on the reported health parameters and their compliance with the self-management plan. When they need to contact health professionals, patients can send a safe message via the web PHR application.

2.4.8 Central Greece

Telem medicine use for diabetes care has been proposed as a means to improve the treatment of patients with DMT2.

The following meta-analysis indicates that telemonitoring of patients with DMT2 is feasible and acceptable. Its effectiveness, though, on improving HbA1c, reducing costs while maintaining HbA1c levels, and improving other aspects of diabetes management, still needs to be proven through larger trials (Figure 5).

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment n</th>
<th>Mean (SD)</th>
<th>Control n</th>
<th>Mean (SD)</th>
<th>WMD (95% CI fixed)</th>
<th>Weight %</th>
<th>WMD (95% CI fixed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marrero (1995)</td>
<td>52</td>
<td>0.60 (2.08)</td>
<td>54</td>
<td>0.40 (1.82)</td>
<td>16.9</td>
<td>10.0</td>
<td>0.10 (-0.28, 0.48)</td>
</tr>
<tr>
<td>Chase (2003)</td>
<td>30</td>
<td>-0.40 (1.33)</td>
<td>33</td>
<td>-0.30 (1.36)</td>
<td>10.0</td>
<td>6.7</td>
<td>0.16 (-0.76, 0.45)</td>
</tr>
<tr>
<td>Welch (2003)</td>
<td>26</td>
<td>-0.43 (0.59)</td>
<td>26</td>
<td>-0.13 (0.86)</td>
<td>8.1</td>
<td>6.7</td>
<td>0.16 (-0.76, 0.45)</td>
</tr>
<tr>
<td>Ahring (1992)</td>
<td>22</td>
<td>-1.40 (2.93)</td>
<td>20</td>
<td>-1.00 (1.96)</td>
<td>6.7</td>
<td>6.7</td>
<td>0.16 (-0.76, 0.45)</td>
</tr>
<tr>
<td>Monori (2004)</td>
<td>14</td>
<td>-1.46 (1.28)</td>
<td>14</td>
<td>-0.65 (0.47)</td>
<td>4.1</td>
<td>4.1</td>
<td>0.16 (-0.76, 0.45)</td>
</tr>
<tr>
<td>Piette (2000)</td>
<td>124</td>
<td>-0.60 (1.96)</td>
<td>124</td>
<td>-0.30 (1.96)</td>
<td>30.4</td>
<td>39.4</td>
<td>0.15 (-0.40, 0.10)</td>
</tr>
<tr>
<td>Biermann (2000)</td>
<td>30</td>
<td>-1.20 (2.34)</td>
<td>18</td>
<td>-1.20 (2.24)</td>
<td>7.2</td>
<td>7.2</td>
<td>0.15 (-0.58, 0.58)</td>
</tr>
<tr>
<td>Wojszicki (2001)</td>
<td>17</td>
<td>-1.16 (1.20)</td>
<td>15</td>
<td>-1.40 (1.80)</td>
<td>5.1</td>
<td>5.1</td>
<td>0.15 (-0.54, 0.85)</td>
</tr>
<tr>
<td>Fallucca (1996)</td>
<td>7</td>
<td>-0.90 (2.60)</td>
<td>10</td>
<td>-1.30 (1.40)</td>
<td>2.6</td>
<td>2.6</td>
<td>0.19 (-0.78, 1.16)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>322</td>
<td>314</td>
<td>100.0</td>
<td>-0.31 (-0.27, 0.04)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity $\chi^2 = 6.66, df = 8, P = 0.57$
Test for overall effect $z = 1.42, P = 0.16$

Figure 5: Comparison of changes in HbA1c control vs. intervention

More specifically, the current data suggest that blood glucose home telem monitoring technologies confer a statistically significant reduction in HbA1c in comparison to usual care. Evidence, though, for their effectiveness in reducing costs and improving other aspects of diabetes management is missing (Figure 6).

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A systematic review and meta-analysis for diabetes management revealed that home telehealth interventions were effective in improving glycaemic control (HbA1c) for patients with diabetes in comparison to usual care\(^5\). Results also indicated that home telehealth interventions reduced the number of patients hospitalised and the number of bed days of care. In addition, the same study indicated that home telehealth interventions were similar or better than usual care in terms of quality of life, patient satisfaction, and adherence to treatment. However, research of higher methodological quality is required to give a more precise assessment of telemedicine applications.

In Renewing Health, in the Region of Thessaly a RCT evaluated whether the introduction of telemedicine applications for patients with Type 2 diabetes produces benefits in terms of clinical outcomes, such as HbA1c and health-related quality of life (HRQoL)\(^7\). In addition, it evaluated the economic\(^8\) and organisational impact\(^9\) of the new services, and examined their acceptability by patients and health professionals. The positive results led to the decision of the Region of Thessaly to participate in United4Health evaluation in order to further exploit the results of Renewing Health and contribute to the large scale deployment in everyday clinical settings.


\(^{\text{6}}\) Polisena et al, Home telehealth for diabetes management: a systematic review and meta-analysis, Diabetes Obes Metab 2009, 91


2.4.9 Berlin, Germany

Berlin provides life-long monitoring services for diabetes. The trial is based on a set of measurement devices connected to a client software application implemented on mobile telephones via Bluetooth, and on a web-based database where the collected data is stored.

The following diagram shows the flow of information for the technical application in Berlin:

![Image](image_url)

**Figure 7: Integration Platform for telemonitoring (Diabetes)**

In particular, the devices and the measurements taken are as follows:
- A weight scale.
- A sphygmomanometer to measure blood pressure and pulse.
- A blood sugar measuring device.

These devices are connected to a mobile device, namely a smart phone, which collects the data and sends them to a centralised database. These data are compared with multi-valued threshold levels; statistics are collected and stored in electronic Patient Health Records. There a doctor, a family member, the patient or any other person explicitly authorised for this by the patient himself, can look at the situation, and notice any values that may give rise to doubts in a timely fashion, and act accordingly.
Figure 8: The architecture of the technical application in Berlin.

Figure 9: The architecture of the nurse-assisted implementation of the technical application in Berlin

The patient's health records and some graphical representation of the measured data are shown in the following figures.
Measurements are taken directly by the patient himself, where possible. Where appropriate, however, the assistance / coaching of a nurse is provided. If necessary, alarms are sent to family members, caregivers and/or doctors. Otherwise, the assisting nurse could provide the necessary care immediately. Telephone contact with the patient is made more frequently than before.
If needed, doctors, specialists and nurses could receive a periodic report on the situation of the patient via email or fax. This report would look like this:

Figure 13: An example of report care givers can receive on demand

The ways in which this intervention is expected to improve the condition of patients were many:

- On the one hand, the smart phone includes a reminder function which helps to make sure that the patient does not skip a measurement. This has been a common problem in the past, both with measurements and with drugs. This improvement in compliance is expected to have a benefit for the life and health of patients.

- On the other hand, the automatic sending of alarms guarantees that these are sent quicker than before, and that appropriate measures are also taken faster.

Another improvement is in the psychological situation of the patient, who feels in touch with the world a lot more often than before, and feels that he/she is being taken good care of.
2.5 Technical characteristics

Telemedicine (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[4,5,6]. Diabetics have undertaken self-monitoring of blood glucose for many years, but it is acknowledged that this is not always reliable[7]. Structured self-monitoring of blood glucose improves glycaemic control, and provides guidance in prescribing diabetes medications in patients with relatively well-controlled non-insulin treated type 2 diabetes[5]. Remote home monitoring of blood glucose via telemedicine has been found to improve glycaemic control[8], and patients find this acceptable[9], 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 glycaemic control and improve patient centred care[6].

Telemedicine 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[2,3,8].

The intervention aims to promote self-care and self-management by encouraging use of self-monitoring of glucose and lifestyle risk factors, and by providing ongoing health coaching.

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 them to the gateway device automatically.

The gateway device transmits 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 patients’ health conditions at any time required.
Below is a description of the technical solutions in each region.

### 2.5.1 Scotland

In Scotland, the patient at home uses their currently provided home glucose monitoring device and a DiaSend device at home. This device allows the transmission of the measurement to the patient's self management website, MDMW (http://www.mydiabetesmyway.scot.nhs.uk/). This will then populate SCI Diabetes (Diabetes database in Scotland), thus allowing both patients and clinicians a digitally captured, up-to-date picture of the individuals blood glucose measurements and trends, a summary of which can be produced anytime, at either the patient or the clinician's end and managed as locally agreed.

The MDMW website also provides health coaching, the 1,200 patients provided with the DiaSend interface, will be encouraged to use this. 4,400 other patients will be registered onto MDMW and encouraged to take part in the health coaching aspects of the site and continue with SMBG as they have been previously.

SCI-Diabetes is a real time, web-based clinical information system to support the care of all people with diabetes in Scotland (Figure 15). Since the programme was launched in 2002, the SCI-DC team have demonstrated sustained development and implementation of clinically useful tools for the care of people with diabetes, using data captured from ~1,000 GPs, 40 hospital clinics, screening services and laboratories across Scotland.

My Diabetes My Way (MDMW – www.mydiabetesmyway.scot.nhs.uk) was launched in October 2008 as an online information hub containing static and interactive educational resources for people with diabetes and/or their carers. The resource is co-ordinated by a multidisciplinary project board consisting of patients, healthcare
professionals and information technology specialists from across Scotland. The information held on the website is based on nationally agreed and verified educational advice in a variety of multimedia formats.

An ICT system now links MDMW to SCI-DC data to allow patients to access their clinical information. This Personal Health Record is available to every individual with diabetes in Scotland aged 14 or older, regardless of their geographical location or demography. The ability to enter home-recorded results was implemented in January 2013. This allows users to manually enter home blood glucose results, blood pressure, cholesterol, weight, smoking status and allergies.

Diasend is a standalone web based system for easy uploading of information from most glucose meters, insulin pumps, CGMs and mobile apps. The Diasend system consolidates and presents information in clear and structured reports, no matter what the device or how the data is stored. This means patients and healthcare providers are easily able to share access and understand information by using Diasend.

SCI-Diabetes is at the core of the systems architecture, facilitating asynchronous communications between multiple systems. Home blood glucose monitoring results will be received from Diasend via a regular scheduled interface for those patients who have consented for their data to flow in this way.

![Figure 15: Architecture of integrated services / systems being used in Scotland](image)

The clinician initiates the workflow by obtaining the patient’s consent to receive HBG results from their monitoring device. Once enrolled into Diasend, the user credentials are entered into the patient’s record to initiate a one-off record linkage process. This process generates an internal identifier (Diasend ID) which is then matched to the patient’s master patient index (CHI) in SCI-Diabetes. A batch processing job then collects new results from Diasend, stores them against the patient record in SCI-Diabetes, and transfers it to MDMW.
The patient can then either view their results directly in MDMW, or click directly into Diasend to view a copy there. This process allows the patient and all members of the healthcare team access to these results for discussion during physical or virtual consultations.

![Process flow in Scotland](image)

**Figure 16: Process flow in Scotland**

### 2.5.2 Wales

The overarching schematic diagram of how the system operates is shown in Figure 17 below. An alert email / text is sent to the specialist diabetes nurse if blood glucose levels are either <4.0 or >15.0 mmols. The message that the patient receives is governed by the T2DM treatment plan.

The patient will continue on low level telemonitoring for up to 12 months after enrolment, receiving different text prompts and web links, sent through Florence©, Simple Telehealth, web based monitoring system (Stoke on Trent, NHS England) (www.florence.co.net). Any worsening of symptoms will be treated according to local standard protocols, e.g. GP appointments or emergency room / accident and emergency attendance.

Data can be accessed ‘live’ by the primary care health professionals via a secure Internet connection at any time, or if the patient phones with worsening symptoms. The final number of individual data points completed on the central server will be divided by the total number of data points possible to estimate telemonitoring usage. If there are 24 hours without data upload to the central server, a member of the CDMT will be alerted via email and text message.

It will be emphasised to the patient that telemonitoring is not a replacement for, but works in conjunction with, standard support.

All patients will be treated according to the clinical discretion of their primary care doctors, specialist nurses and hospital specialists.
Both Slovenian U4H partners (SB-SG and RavKor) use the common telemedicine service for CHF and DM patients offered by the SB-SG. The service was designed by strictly following the U4H proposed system architecture for the diabetes telemonitoring service as presented in Figure 14 in this document. The solution is completely wireless for the monitored DM patients.

A patient (1) uses a glucometer with stripes as a telemonitoring device to take measurements of the blood sugar. The measured values are sent over a Bluetooth (2) link to a gateway that is a smart phone. Data are forwarded to the regional telemedicine centre over a mobile network (3). There, data are passed onto a broadband Local Area Network (LAN) and stored in the telemedicine service server. Regional centre operator monitors flow of patients’ data (5). In case of missing measurements, he/she calls the patient (primary level interventions) and asks him/her to take an additional measurement. Diabetologist or his/her co-worker (other healthcare professionals) is alerted by the operator (5, 4) when an intervention on the second level is required, e.g. when two consecutive daily profiles show substantial deviation from the estimated values. The diabetologist, the other healthcare professionals and family members are informed by the regional centre operator (7) when their assistance is needed, e.g. to take their relative to see a diabetologist. All the involved parties send their feedback to the regional centre operator (7) using standard communication means (phone, email, SMS, written reports). GPs are not a part of the response system, as the diabetologists at SB-SG cover the secondary and the primary healthcare level needs. The patient has an optional communication channel (6) to contact the regional centre operator by phone. The same channel (6) is used by the regional centre operator when the patient is contacted.

Data are monitored over two dedicated portals, having in the background two databases. The first portal (https:his.u4h.sb-sg.si) serves as a technical tool that supports telemetry, and the second (http://mks.u4h.sb-sg.si) is to maintain
telemedicine personal health records, data presentation and the telemedicine service support tools. Telemetrically collected data are accessible through the LAN or remotely by VPN access.

2.5.4 NorthWest Moravia, Czech Republic

Telemonitoring of DM is strictly in line with U4H study protocol in Northwest Moravia. Each patient is properly educated and equipped with glucometers and test strips (Fora Diamond Mini) and mobile gateway (4,5 inch Android Samsung Galaxy Express 2) with wireless data transmission between medical devices and gateway (via Bluetooth) and between gateway and system servers with databases (via GPRS/EDGE/3G). Patient’s application Medimonitor is tasks-based.

2.5.5 ARSAN Campania, Italy

The technical platform deployed in the Campania Region to support the telehealth service is depicted in the figure below.

Patients are equipped with a standard glucometer with which to collect the blood glucose measurements and send them to the web based software platform “Diabtel.net”. The devices and gateways used by the patients are provided by FORA Care Suisse AG; the software platform by Meter s.r.l.

At the patient's home, communication between the glucometer and the gateway, and communication between the gateway and the modem/router ADSL are based on wired connection; the latter with a standard Ethernet cable.

Data are transferred to/from the Diabtel.net over the Internet in an encrypted format.

The Diabtel.net portal supports role-based access control policies in order to regulate access to patients’ data to authorised users only, i.e. the patient him/herself, and his/her specific caring healthcare professionals. Credentials to access the Diabtel.net portal are based on userid/password.

Figure 18: ARSAN Campania communication schema
2.5.6 ASP Cosenza, Calabria, Italy

The technical infrastructure supporting the pilot in ASP Cosenza is based on the software components provided by Lifescan Italia, with a licence free of charge for use for the U4H study. The software solution is fully distributed, with the client on the patient side communicating with the specific database of his/her caring diabetologist, as depicted in the figure below.

![ASP Cosenza technical infrastructure](image)

**Figure 19: ASP Cosenza technical infrastructure**

The client on the patient side is composed of two modules:

- a stand-alone Patient Health Record, the so-called Home EuroTouch, downloadable from the Lifescan website;
- an add-on for the export and remote transmission of data, downloadable from a special link provided to the patients during the enrolling phase.

The two applications are installed and set-up by the patients themselves on their personal computers, following the instructions provided in a user manual. Since the add-on uses as communication channel the email service, it has to be configured with the email addresses of the caring diabetologist and the professional nurse coordinating the study.

On the healthcare professionals side, the received data are imported into an Electronic Medical Record (or data management) routinely used in the Diabetology Centre. Screenshots of the graphic interface presenting subsequent measurements is shown below.
The connection via email addresses also allows useful information to correct and improve the correct transmission of data between medical investigators, the registered nurse, who is responsible for coordinating and planning the ASP sites for diabetes care, and the diabetic patients, and possibly their caregivers if there are any.

2.5.7 South Karelia, Finland

The pilot is exploiting existing Eksote's e-Health services (hyvis.fi). The purpose is to start using PHR in the chronic disease patient’s care processes. PHR is one of the e-Health services.

![South Karelia system architecture](image.png)

**Figure 20: South Karelia system architecture**
2.5.8 Central Greece

The EHR system of Municipal Telehealth Centre generates and manages electronic medical files for each patient, accessible from any handheld or PC browser. Experts receive a secure patient database to host the patient's medical files and test results.

![System Architecture Diagram]

**Figure 21: System Architecture**

The Municipality provides monitoring equipment to individual citizens of central Greece with type 2 diabetes.

Individual citizens were equipped with light-weight handheld medical devices as well as a suitable mobile phone. They record their vital signs at home, which are then transferred (via the Telehealth Centre) to the Regional University Hospital of Larisa (pulmonary, cardiology, endocrinology clinics), over internet and GPRS, for review and feedback by the experts.

To use the service, the patient has the following list of vital signs monitoring devices: a blood glucose monitor and a mobile phone device. The Telehealth Centre provides the equipment to the patient, ready for use.
Blood Glucose Telemonitoring Devices

These monitor blood glucose, using Bluetooth and GPRS to transmit the data to the Telehealth Web Centre where they are stored in the patient’s personal medical file for review by the experts.

Software

The EHR, installed in the Telehealth Centre of Trikala, is a wireless healthcare system. It provides the tools required for screening, monitoring, diagnosis and disease management, especially targeting chronic patients. Each handheld monitor measures and transmits test results to a cellular phone. The data is uploaded to the Telehealth Centre of Trikala for analysis, follow-up and storing in the form of an electronic medical record. Experts and physicians can access this web centre using a PC based browser.

The new software installed in Trikala web centre consists of:

1. Send / receive software, installed on the mobile phones.
2. Telemetry software (EHR), which is used to manage the electronic health information about individual patients.
3. Health telematics database, connected by telemetry software to EHR.
Send / receive software

The send / receive software is intended to perform tests using monitoring devices, save the test results, and synchronise data and tests results with the Telehealth Web Centre.

This is a new component, as a software application for mobile phones has not been used before in the Telehealth Centre of Trikala.

The telemetry software (EHR) and database

The telemetry software to be installed in the Telehealth Web Centre offers the capabilities of a complete EHR (identification & demographic data, medical evidence etc.), as well as accessibility capabilities for the regional hospitals. Sorting of data by patient, test, treating physician, etc. is also supported. All tests and examinations along with their diagnostic commentaries will be stored and archived.

The telemetry software supports different access levels in order to accommodate the various types of users (physicians, nurses, administrative staff, etc). Access to new or older archived items is permitted from different work stations.

2.5.9 Berlin, Germany

The technology of the telemedicine application in Berlin mainly uses three sorts of devices:

- Measuring devices equipped with Bluetooth interface to send the data to a suitable receiving device. Such equipment has been on the market for a time, but is not yet widely used. The Bluetooth interface increases the cost of the equipment and makes it suitable only for a telemedicine application. However, it is expected that these applications will increase in the near future, and this will make the devices more affordable.

- Smart phones as a receiver of the measurement data. These are becoming more and more available, and therefore also affordable, and the quality is improving very rapidly. This is important to ensure that the measurements are correct, and get to the right place at the right time.

- A web-based database to store the data and an application to manipulate them, and to do some calculations and presentation (e.g. in the form of charts). This is also a technology that is not new, but it is being improved dramatically on a daily basis; one of the challenges of the application is keeping up with these technological improvements.

The application used in Berlin is a fairly stand-alone and proprietary application, but steps had been taken to ensure this does not remain so. Integration with the electronic patient records of Pflegewerk was under discussion with the providers of the two software solutions, and it was possible to find an integrated solution for the trial. This software solution will allow integration of the application both with the patient management software of Pflegewerk, and with the German central patient health records.
2.6 Requirements

2.6.1 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:

- 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 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.

![My Diabetes My Way](image)

Figure 24: Scotland - My Diabetes My Way

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 then 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

My Diabetes My Way

The MyDiabetesMyWay website is constructed principally for the users, i.e. people who have diabetes and their family and friends; it is thus 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 verbally 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)

My Diabetes My Way

MDMW is not directed at healthcare professionals, but the same information in the system is accessible to them as to the 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,
United4Health 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 step guide to registration 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 & carers in use of Diasend.
- Support for clinics using a Diasend transmitter.
- Trouble shooting solutions.
- Where to access further Information & support.

### 2.6.2 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. Transmission of the results is provided via a free number, and so there are no cost implications for patients. 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. The software is the Flo system as described in section 2.4.2.

**Training - Patients**

The 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.

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 by use of a mobile telephone back to the patient.

### 2.6.3 RavKor, Slovenia

**Equipment and supplies**

Each DM patient using telemedical 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 DM and providing telemedicine service gives trainings to DM patients who are candidates for using telemedicine 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 DM 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. They receive a formal invitation document explaining their role and the potential benefits they and other patients may gain. Those who agree are invited for scheduled training in use of the telemedicine service, the purpose and methods of telemonitoring are explained. They are shown how the service functions. If they decide to participate, they give a written consent, obtain instructions for telemetric measurements, and are provided with user manuals for the equipment. Individualised telemonitoring equipment with a smart phone for connectivity is provided to the patient with instructions for use, contact in potentially emergency situations, and regarding 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 last about 2 hours each have been organised at which 220 DM 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 all evidence is already in place (patient registrations in the database) and the equipment is personalised (matched measuring equipment and the smart phones, equipment linked to the patient’s electronic record). It has also been noticed that the 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 telemedicine 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), the coordination staff (2) as well as administration staff (2) involved in U4H project. Firstly they were shown how the equipment is used by a remotely monitored patient. Later, 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 MD, 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.

2.6.4 **Northwest Moravia, Czech Republic**

Using the telemedicine application requires medical devices (glucometers) and mobile gateways listed previously. The main supplies needed are test strips for glucometers. We found out that there is great importance to provide quality technical telephone support for patients, as they have some difficulties to handle android Smartphone.

Our biomedical engineers prepared sets of devices for each patient; this means creation of patient’s accounts on telehealth portal, installing android app, preparing sets (Bluetooth pairing etc.). It is very important to educate each patient very properly about using glucometers and Smartphone’s with application. Length of education depends on using 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 secured login; it is very intuitive for doctors and operators.

2.6.5 **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 for receiving 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 Diabetel.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 a 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, regularly provided in standard care also;
• 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 have access to 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 United4Health project and the required data management.

2.6.6 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 programme 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.

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 sources thanks to the fact that all data could be found on the same device. This has positive results on the self-evaluation of the daily clinical practice and the reduction of long-term complications.

Main administrator / doctor privileges and instruments: administrating 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 Un4Health project of 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.

2.6.7 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.

2.6.8 Central Greece

2.6.8.1 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.
2.6.8.2 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.

2.6.9 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)[10] 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 will study the effectiveness of the interventions in an observational design by comparing a control group treated before the implementation of the telemedicine interventions with an intervention group treated after the implementation of telemedicine. The strengths of this study design are complementary to the evidence of efficacy demonstrated in several efficacy trials[11], and are based on:

1. Long follow-up period which allows for registering and monitoring long-term clinical effects and safety data [12].
2. Big sample size representative of the general population, which allows for stratification analysis and identification of patient subgroups that benefit the most from the intervention [13].
3. Real-life data about impact on costs and organisation (structure and processes) which allows the identification of barriers and facilitators for a wider service implementation [14].

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 will assess the real-life effectiveness of the trialled services with a high degree of external validity and generalisability of the results. Due to inclusion of patients from many European countries, this study will be able to provide to other regions in Europe a very valid estimate of the expected impact of the interventions.

The observational study is using 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 telemedicine 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 telemedicine service, patient perception and organisational aspects will be collected for the intervention group.
3.2 Methods: Participants

**Eligibility criteria:** Diagnosis of type 2 diabetes, and already in home monitoring of blood glucose. Optionally, patients with type 1 diabetes will be eligible to participate in order to ensure the recruitment of the total sample size.

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

3.2.1 Scotland

Eligibility is defined in the Clinical Protocol. In Scotland, patients with a diagnosis of Type 1 and Type 2 Diabetes are eligible for recruitment with a 50% split across to diagnostic groups. All eligible Type 2 patients will currently be undertaking HBGM as part of their diabetes management plan.

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

3.2.2 Wales

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

3.2.3 Slovenia

**Eligibility criteria**

So far 270 patients with a diagnosis of Type 2 Diabetes (DM Type 2) that already perform home monitoring of blood glucose have been enrolled into the telemonitoring service. In the future patients, with Type 1 Diabetes will be eligible to participate in order to ensure the recruitment of the total sample size of 400 DM patients.

**Patient selection**

Potential participants are selected by screening their electronic or paper-based healthcare records or/and the hospital databases. Candidates in the intervention group are informed about the nature and objectives of the intervention. Once candidates have signed the informed consent form, they participate in the study.

The Slovenian partners SB-SG and RavKor are regional healthcare institutions providing healthcare to around 100,000 people. The partners have some difficulties in reaching the target number of 400 DM telemonitored patients within that population due to exclusion criteria set within U4H, their rejection, or because of their death. Consequently they have started activities to encourage neighbouring hospitals to participate in U4H by including their patients.
Comparator group

The comparator group of patients in Slovenia will be the observed group itself, but for the period of one year prior to inclusion into the observed group. Additional members of the comparator group will be the patients who for any reason rejected their participation in telemedicine monitoring. The total population of patients in the control group will be over 400 for DM group.

SB-SG and RavKor plan to gradually retrieve all the necessary data for the patients in the comparator group until the end of the observation period.

3.2.4 Northwest Moravia, Czech Republic

We strictly follow 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 are 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 are 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 will be eligible to participate in order to ensure the recruitment of the total sample size.

Potential participants are selected during long term condition annual reviews in the community setting. Candidates in the intervention group are informed about the nature and the objectives of the intervention. Once candidates have signed the informed consent form, they participate in the study.
3.2.7 South Karelia, Finland

The study population consisted of patients diagnosed with Type 2 Diabetes, and who already monitor blood glucose at home. Nurses from the healthcare centres will recruit their own patients when patient are in the control appointment. Nurses give information sheets and give more information if it is needed. The intention is that nurses assess who would benefit from using PHR. They offer the opportunity to participate in research if they feel 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

3.3 Methods: Interventions

Refer to domain 1.

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 are collected for all patients in the intervention and control 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 can collect the following optional data:
• Has the patient a formal or informal care giver?
• PC user.
• Mobile phone user.
• Education: seven levels.

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

The outcome measures included are described in detail in the protocol, D3.1 dated 31st March 2014.

3.5 **Methods: Sample size**

Intervention group:
• Scotland: 5600 (1200 will receive a telemonitoring device allowing self monitored blood glucose results to be uploaded to My Diabetes My Way website (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.
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 telemedicine 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 final size of this population will be defined before the implementation of the new service.

3.6 Methods: Statistical methods

Analysis of the results will be done in accordance with the STROBE guideline for reporting of observational studies.

Firstly, the patient characteristics of the intervention and comparison group will be compared and tested for statistically significant differences by use of t-test and chi-square test (or non-parametric tests). Thereafter unadjusted differences in primary and secondary outcomes in the two groups will be compared by use of the same statistical tests. Finally, adjustment for differences between the patient groups with regard to age and severity of illness of the patients will be made by multiple regression analysis.

The statistical analysis will be done by use of STATA13.

3.7 Results: Participant flow

3.7.1 Scotland

As of December 2014, NHS24 has recruited the following number of patients for United4health:

- Diasend registration: goes live in December 2014.
- MDMW: 1,744 registrations across all three pilot sites, representing 39% of the recruitment target for Scotland.

Figure 25 below gives a breakdown of recruitment numbers per pilot site
Recruiting patients to the Diasend Intervention in Scotland commenced in December 2014. These delays have been due to the delayed launch of the Diasend / MDMW technology integration work which was original due for completion in May 2014. This was not completed until September 2014.

3.7.2 NHS Wales

As of 18th December 2014, Wales has:

- Recruited 106 participants;
- 82 are currently actively using the system;
- Sent out approximately 1,000 letters to potential patients meeting the inclusion criteria;
- Begun comparator note collection.

Recruitment has been compromised through poor engagement by a number of GP practices. However, significant effort has been made to meet with individual practices to discuss the research and to encourage participation. The research has been highlighted in regular newsletters that are sent to all GP practices within the intervention area; it has been presented at GP Forum meetings and through engagement with our U4H Diabetes Clinical Lead for the research. Further practices are coming on-board as a result of these actions.

To further mitigate against recruitment issues with GP practices, Wales has undertaken research amendments to potentially increase participation, this includes the production of patient recruitment posters; individual letters of invitation to potential patients meeting the inclusion criteria, as identified through GP systems; and recruitment stands at high profile local events.

Figure 25: Recruitment in Scotland
3.7.3 Slovenia

The number of DM patients that will be observed in Slovenia for 12 months period is 400.

At the end of December 2014, over 120 CHF and 270 DM patients have been supported in Slovenia by the telemedicine service provided by SB-SG. The first patients were enrolled at the beginning of April 2014. Since then the number has been increasing as presented in the Figure 26 below.

![Figure 26: Inclusion of DM and CHF patients into the telemedicine service in Slovenia](image)

3.7.4 Czech Republic

UPOL, Northwest Moravia region, Olomouc, has recruited 21 diabetic monitored patients in U4H at 25th February 2015.

3.7.5 Campania

Because of the large delay in the start of the local study in the Campania Region, the start of the recruitment has been rescheduled to start in January 2015.

3.7.6 ASP Cosenza, Calabria, Italy

210 patients recruited

3.7.7 South Karelia, Finland

End of year 2014 50 has recruited on the pilot.

This section will be completed in the Final Trial evaluation.

![Figure 27: Flow diagram](image)
3.8 Results: Baseline data

Describe the baseline data by referring to a table similar to Table 3 in the guideline, and comment on the results. What characterises the patients in the study? Are the groups similar and does randomisation seem to have worked well?

This section will be completed in the Final Trial evaluation.

### Table 1: Baseline demographic characteristics

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size (n)</td>
<td>Number</td>
<td>Number</td>
</tr>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Men (gender)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal schooling</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Less than primary school</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Primary school</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>High school</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>College/University</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Post graduate degree</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Currently married</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Separated</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Divorces</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Cohabitating</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td><strong>Work status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government employee</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Non-government employee</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Non-paid</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Student</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Homemaker</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Retired</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Unemployed (but able to work)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Unemployed (unable to work)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td><strong>Smoker - yes/total (%)</strong></td>
<td>Yes/total (%)</td>
<td>Yes/total (%)</td>
</tr>
<tr>
<td><strong>Alcohol</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>5-6 days/week</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>1-4 days/week</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>1-3 days/month</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Less than once/month</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td><strong>Height in cm</strong></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td><strong>Weight in kg</strong></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td><strong>Comorbidity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart diseases</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Cerebrovascular diseases</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Dementia</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Chronic pulmonary disease, incl. COPD</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Connective tissue disease/rheumatic disease</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Ulcer disease</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Liver disease</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Hemiplegia</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
</tbody>
</table>
3.9 Results: Estimation of outcomes

Describe the results and the estimated improvements in primary and secondary outcomes. Are the effects statistically significant? Produce a table similar to Table 4 and Box 7 in the guideline

This section will be completed in the Final Trial evaluation.

Table 2: Results of analyses

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>Mean difference after 6 month between groups (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>After 6 month</td>
<td>Baseline</td>
</tr>
<tr>
<td>Primary</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Secondary</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Secondary</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Physical function (PF)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Role-physical (RP)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Bodily pain (BP)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>General health (GH)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Vitality (VT)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Social functioning (SF)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Role-emotional (RE)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Mental health (MH)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
</tbody>
</table>

Textbox 7 from Guidelines. Example of Description of primary and secondary outcomes

Primary outcome measure
A total of 85.6% of patients in the telemonitoring group made at least one call; among these patients, adherence to the intervention was highest, 90.2%, during the first week of the study period and decreased to 55.1% by week 26. A total of 29,163 variances were generated during the study period, with a median of 21 (interquartile range, 5 to 54) per patient. No significant difference was seen between the two groups in the rate of the primary end point, which occurred in 432 patients (52.3%) in the telemonitoring group and in 426 patients (51.5%) in the usual-care group (difference, 0.8 percentage points; 95% confidence interval [CI], −4.0 to 5.6; P = 0.75 by the chi-square test) (Table 2). The hazard ratio for the primary end point with telemonitoring versus usual care was 1.04 (95% CI, 0.91 to 1.19).

Secondary outcome measures
No significant differences were seen between the two groups with respect to the secondary end points (Table 2). Readmission for any cause occurred in 407 patients (49.3%) in the telemonitoring group and 392 patients (47.4%) in the usual care group (difference, 1.9 percentage points; 95% CI, −3.0 to 6.7; \( P = 0.45 \) by the chi-square test). The hazard ratio for readmission for any cause with telemonitoring was 1.06 (95% CI, 0.93 to 1.22). A total of 92 patients (11.1%) in the telemonitoring group and 94 patients (11.4%) in the usual-care group died during the 180-day study period (difference, −0.2 percentage points; 95% CI, −3.3 to 2.8; \( P = 0.88 \) by the chi-square test). The hazard ratio for death was 0.97 (95% CI, 0.73 to 1.30). Readmissions for heart failure, the number of days in the hospital, and the number of readmissions were also similar in the two groups (Table 2). Kaplan–Meier time-to-event curves for the composite end point of readmission or death from any cause, as well as for each component separately, did not reveal a significant difference between the two groups (Fig. 2).

### 3.10 Results: Ancillary analyses

Describe the additional, ancillary analysis made in the project. Describe results of statistical analysis in relation to Table 4 (see above). Describe results of inclusion of covariates. Describe results from subgroup analysis.

This section will be completed in the Final Trial evaluation.

### 3.11 Results: Adverse events

Describe adverse events in the two groups, as in Table 6.

This section will be completed in the Final Trial evaluation.

<table>
<thead>
<tr>
<th>Table 3: Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interv</td>
</tr>
<tr>
<td>Morbidity, No (%)</td>
</tr>
<tr>
<td>Overall</td>
</tr>
<tr>
<td>Major</td>
</tr>
<tr>
<td>Minor</td>
</tr>
<tr>
<td>Mortality, No (%)</td>
</tr>
</tbody>
</table>

### 3.12 Discussion of findings

#### 3.12.1 NHS Scotland

**Technology readiness**

Ensure that the technological solutions being introduced have the functionality and flexibility to deliver at scale and within an agreed implementation timeline. For Scotland, delays in technology developments, particularly for Diasend, has impacted on project delivery timescale and delayed the start of recruitment. Any slippage
from technology roll out needs to be actively managed within the project, as there is a high risk of losing momentum and clinical engagement and confidence in project.

**Resolving issues & service mapping**

It is critical to bring technology development teams together with clinicians to explore benefits realisation, impacts, and agreed solutions to implementation and deployment challenges at local level rather than project level. This requires time and an agreed process, for projects of this size and complexity. Process mapping of service pathway has taken longer to complete than anticipated, and has deployed recruitment start date.

**Planning & change management**

The scale of change required to implement the technologies within U4H is significant, and required significant consultation and engagement with a wide range of stakeholders to reach consensus and development of new methods for collaboration. This has been vital to ensure implementation, but has been more time consuming than anticipated, and required a longer project lead-in time in preparation for “go live”.

**Workforce**

New ways of working and new equipment need to be accompanied by training for those who will be involved both within the professional workforce and for users and carers. An earlier review of the human and technological capabilities would have speeded up this process, and careful consideration given to the best methods of releasing clinical staff to attend and participate in training and workshops. Clinical staff can be sceptical of new technology, and only became more engaged once technology has been tested and was ready for go live.

**Organisational change**

Securing sustainable culture change and ongoing senior financial commitment to a deployment project of this nature and magnitude in a changing financial, operational and strategic business environment and conflicting demands like the NHS remains a challenge. Project plans have had to be continuously evaluated in real time and adapted as circumstances and local context alter. Financial pressures remain within the project and mitigation planning is underway.

**3.12.2 Campania**

Because of the delay in the start of the local study in the Campania Region, ARSAN has no significant observations to report so far.
4. Domain 4: Patient perspectives

4.1 Aim of study and the instrument used

The WSD questionnaire[15,16] on patient acceptability is used in the study to assess the perception of the telemedicine service by patients in the intervention group. This instrument was also used in the Renewing Health project; however the questionnaire has not been published yet, and the validity and reliability of this is still under consideration. The decision to use this questionnaire was based on the lack of a more appropriate and validated questionnaire, comparability reasons (comparison with WSD and RH projects), and the fact that the authors of the questionnaire have declared that it will be published by the end of 2013.

The questionnaire includes 22 items regarding:

- Utility of the “kit”.
- Effect on health status.
- Effect on health care/social care.
- Privacy.
- Suitability of the kit.
- Satisfaction with the kit.

These data will be collected for the first 100 patients in the intervention group in each region. In Scotland this will also be collected for the last 100 patients.

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

Such classification of reasons for non-participation would be of help to identify existing barriers to provision of telemonitoring services to patients with chronic conditions, and to work further to overcome the ones which are not patient-related[17]. The following reasons for non-participation will be examined:

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

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

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

4.2 Data collection

Describe when the study was made.
Describe how patients were approached.
Present response rate.
Refer to the description of participants in domain 3.

This section will be completed in the Final Trial evaluation

4.3 Subscales

Describe the patients’ acceptability of the telemedicine application by referring to the estimated subscales.

This section will be completed in the Final Trial evaluation.

Table 4: Estimated subscales based on respondents answers to SUTAQ

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Intervention After 3 months</th>
<th>Intervention After 6 month</th>
<th>Mean difference after 6 months (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced care</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
<tr>
<td>Increased accessibility</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
<tr>
<td>Privacy and discomfort</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
<tr>
<td>Care personal concerns</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
<tr>
<td>Kit as substitution</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (CI to CI)</td>
</tr>
</tbody>
</table>

4.4 Results from CFA

May not be relevant

Present results from the confirmatory Factor Analysis (CFA).
(CFA can be produced by professor Vassilis Aletras).

This section will be completed in the Final Trial evaluation

4.5 Effects of explanatory variables

May not be relevant

Present results from multivariate regression analysis of the effects of different explanatory variables.

This section will be completed in the Final Trial evaluation
4.6 Discussion of findings

This section will be completed in the Final Trial evaluation
5. Domain 5: Economic aspects

5.1 Viewpoint

The economic analysis will be made with a societal perspective on costs, thus changes in the costs of the patient, and of primary and secondary care will be included.

In accordance with Drummond et al. (2005), the total costs per patient will be estimated in both the intervention and the control group. For the telemedicine patients, this will be estimated as the sum of the costs of producing the telemedicine intervention and the costs of the resources used in the healthcare sector in general (inpatient or outpatient care, ED, other healthcare contacts or medication). For the patients in the control group, the costs of the resources used in the healthcare sector in general will be estimated. Based on the estimated mean costs in the two groups, the difference will be identified and tested for statistical significance. If the telemedicine intervention reduces the patients’ use of healthcare in general during the period of 12 months, the hope is that these savings (S) will exceed the costs of the telemedicine interventions (C), and thereby result in a total reduction in the costs per patient.

5.2 Selection of economic analysis

A cost-effectiveness analysis will be carried out because the intervention can affect both patient health and costs in accordance with Drummond et al. (2005)

5.3 Patient population

Described in domain 1 and 3.

5.4 Comparators

Described in domain 1

5.5 Range of costs and measurement,

The following economic indicators will be collected for all patients:

- Number of admissions (including readmissions).
- Number of bed days (days of hospitalisation).
- Number of GP visits.
- Number of visits to emergency department.
- Number of primary care contacts.
In addition, the following information will be collected for the first 100 patients: (and for the last 100 patients in Scotland):

- Number of contacts with the patient by use of telemedicine devices.
- Number of times monitoring the patient’s health by use of telemedicine devices.
- Type of health professional.
- Average duration of contacts / monitoring with the patient.

Finally, the following information will be collected for each region:

- Price of the telemedicine applications.
- Investments in infrastructure or training.

5.6 Prices

*Produce a table similar to Table 10.*

*Describe also the sources of the price information, e.g. time prices based on average salary for nurses at the specific hospital or national DRG reimbursement rates.*

This section will be completed in the Final Trial evaluation

**Table 5: Prices used in the calculation of costs (€, 2011-prices)**

<table>
<thead>
<tr>
<th>Type of costs</th>
<th>Price per unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment and running costs:</td>
<td></td>
</tr>
<tr>
<td>- Physical change of buildings</td>
<td>€€ in total</td>
</tr>
<tr>
<td>- Technical infrastructure</td>
<td>€€ in total</td>
</tr>
<tr>
<td>- Time used by staff:</td>
<td></td>
</tr>
<tr>
<td>- Nurses</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Medical doctors</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Secretary</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Staff time used by home care nurse</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Rent of telemedicine device</td>
<td>€€ per Briefcase</td>
</tr>
<tr>
<td>- Time used by patients</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Time used by relatives</td>
<td>€€ per hour</td>
</tr>
<tr>
<td>- Transport</td>
<td>€€ per kilometre</td>
</tr>
<tr>
<td>Effects on patients use of health care:</td>
<td></td>
</tr>
<tr>
<td>- Readmissions</td>
<td>€€ per readmission</td>
</tr>
<tr>
<td>- Inpatient days</td>
<td>€€ per day</td>
</tr>
<tr>
<td>- Outpatient visits</td>
<td>€€ per visit</td>
</tr>
<tr>
<td>- GP visits</td>
<td>€€ per visit</td>
</tr>
<tr>
<td>- Emergency department visits</td>
<td>€€ per visit</td>
</tr>
</tbody>
</table>
5.7 Average use of resources
Describe the average use of resources for the two patient groups and comment on the main differences and statistically significant differences. Produce a table similar to Table 12.

This section will be reviewed and completed in the Final Trial evaluation

Table 6: Average use of resources per patient in the Intervention and Control Groups

<table>
<thead>
<tr>
<th>Type of costs</th>
<th>Mean use per patient in</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention Group</td>
<td>Control Group</td>
</tr>
<tr>
<td>Running costs of the telemedicine service and comparator:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Time used by staff on education of patients</td>
<td>## min. ci: ##-##</td>
<td></td>
</tr>
<tr>
<td>- Time used by staff at the call centre</td>
<td>## min. ci: ##-##</td>
<td></td>
</tr>
<tr>
<td>- Number of tele-consultations</td>
<td># ci: ###-###</td>
<td></td>
</tr>
<tr>
<td>- Number of inpatient days</td>
<td># days ci: ###-###</td>
<td># days ci: ###-###</td>
</tr>
<tr>
<td>.........</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Time used by patients</td>
<td>## min ci: ##-##</td>
<td>## min. ci: ##-##</td>
</tr>
<tr>
<td>- Time used by relatives</td>
<td>## min ci: ##-##</td>
<td></td>
</tr>
<tr>
<td>Effects on patients’ use of health care:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Number of readmissions</td>
<td>#.# readmis. ci: ###-###</td>
<td>#.# readmis. ci: ###-###</td>
</tr>
<tr>
<td>- Length of stay for each readmission</td>
<td>#.# days ci: ###-###</td>
<td>#.# days ci: ###-###</td>
</tr>
<tr>
<td>- Staff time used by home care nurse</td>
<td>### min. ci: ###-###</td>
<td>### min. ci: ###-###</td>
</tr>
<tr>
<td>- Number of contacts to GP</td>
<td>#.# contacts ci: ###-###</td>
<td>#.# contacts ci: ###-###</td>
</tr>
<tr>
<td>- Number of contacts to emergency doctor</td>
<td>#.# contacts ci: ###-###</td>
<td>#.# contacts ci: ###-###</td>
</tr>
</tbody>
</table>

5.8 Measured effects and benefits
Refer to domain 3 for effects on e.g. SF-36, readmission
Produce a table with effects on SF-6D for intervention and control groups. Test for statistical significance.

This section will be completed in the Final Trial evaluation

5.9 Average costs
Describe the differences in the average costs per patient in the two groups. Comment on statistically significant differences. Produce a table similar to Table 15.
This section will be completed in the Final Trial evaluation

### Table 7: Average costs of the treatment per patient in the intervention and control group (€, 2011-prices)

<table>
<thead>
<tr>
<th>Type of costs</th>
<th>Mean cost per patient in Intervention Group</th>
<th>Confidence interval</th>
<th>Mean cost per patient in Control Group</th>
<th>Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment in the telemedicine application</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Physical change of buildings</td>
<td>€####</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Technical infrastructure</td>
<td>€####</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Education of the staff</td>
<td>€####</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total investment costs</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Running costs:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Staff</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>- Telemedicine devices</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Inpatient days</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>- Readmissions</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Emergency department visits</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>- Home care nurse</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>- GP visits</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Transport</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total running costs €</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>Time costs (lost productivity):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Time used by patients</td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
<tr>
<td>- Time used by relatives</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total time costs</td>
<td>€####</td>
<td>ci: ##-##</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total costs</strong></td>
<td>€####</td>
<td>ci: ##-##</td>
<td>€####</td>
<td>ci: ##-##</td>
</tr>
</tbody>
</table>

### Incremental cost-effectiveness

Estimate the incremental cost-effectiveness of the intervention, e.g. the incremental cost per gained QALY and describe the results. Produce a table similar to Table 16.

This section will be completed in the Final Trial evaluation

### Table 8: Incremental cost-effectiveness ratios (ICER) in €, 2011-prices

<table>
<thead>
<tr>
<th>Case</th>
<th>Number of patients</th>
<th>Mean ICER</th>
<th>Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base case</td>
<td>XXX</td>
<td>€####</td>
<td>ci: ## - ##</td>
</tr>
<tr>
<td>Men</td>
<td>XXX</td>
<td>€####</td>
<td>ci: ## - ##</td>
</tr>
</tbody>
</table>
5.11 Sensitivity analysis

*Present analysis of sensitivity of the results with regard to parameters that are uncertain.*

This section will be completed in the Final Trial evaluation

5.12 Results from the business case

*Describe the results from the business case. Does use of the intervention produce a net gain or a net expenditure for the relevant institution? Produce a table similar to Table 17.*

This section will be completed in the Final Trial evaluation

Table 9: Estimated expenditures and revenue for hospital x of implementation of telemedicine for xxx patients (€, 2011-prices)

<table>
<thead>
<tr>
<th>Type of costs</th>
<th>Total expenditures or revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expenditures:</td>
<td></td>
</tr>
<tr>
<td>- Education of the staff</td>
<td>€ #####</td>
</tr>
<tr>
<td>- Physical change of offices</td>
<td>€ #####</td>
</tr>
<tr>
<td>- Telemedicine devices</td>
<td>€ #####</td>
</tr>
<tr>
<td>- Inpatient days</td>
<td>€ #####</td>
</tr>
<tr>
<td>- Readmissions</td>
<td>€ #####</td>
</tr>
<tr>
<td>- Outpatient visits</td>
<td>€ #####</td>
</tr>
<tr>
<td>Total expenditures</td>
<td>€ #####</td>
</tr>
<tr>
<td>Reimbursement</td>
<td></td>
</tr>
<tr>
<td>- DRG value of inpatient activity</td>
<td>€ #####</td>
</tr>
<tr>
<td>- DRG-value of inpatient activity</td>
<td>€ #####</td>
</tr>
<tr>
<td>Total reimbursement</td>
<td>€ #####</td>
</tr>
</tbody>
</table>

5.13 Discussion of findings

This section will be completed in the Final Trial evaluation
6. **Domain 6: Organisational aspects**

### 6.1 Method

Data will be collected by interview with the health professionals involved in delivering the telemedicine interventions.

The following indicators will be collected[18]:

- **Effects on work processes:**
  - Workflow: Effects on number of patients treated, procedures performed, etc.
  - Staff: Changes in distribution of work (task shifting).
  - Resources: Changes in working hours for each profession.
  - Training: Time spent on training to learn to use the application.
  - Internal communication.
  - External communication.

- **Effects on structural outcomes:**
  - Description and number of units collaborating in the production of the service.
  - Changes in organisation of generalist and specialist tasks.
  - Changes in geographical spread.
  - Changes in time spent on travel.

- **Cultural outcomes:**
  - Staff attitudes towards the application.
  - Staff experiences with the use of the application.
  - The experiences of the clinical managers.
  - The clinical managers view of the barriers and facilitators to adoption of the telemedicine service.

### 6.2 Process: Work flow

*Describe changes in the work flow.*

*Produce a figure similar to Figure 4.*

*This section will be completed in the Final Trial evaluation.*
6.3 **Process: Staff**
*Describe the staff involved, their training and task shifting.*

This section will be completed in the Final Trial evaluation

6.4 **Process: Communication**
*Describe changes in internal and external communication.*

This section will be completed in the Final Trial evaluation

6.5 **Structure**
*Describe organisations involved and organisational changes.*

This section will be completed in the Final Trial evaluation

6.6 **Culture**
*Describe the experiences and perception of the staff.*

This section will be completed in the Final Trial evaluation

6.7 **Discussion of findings**

This section will be completed in the Final Trial evaluation

---

**Figure 28: Patient care pathways**

**Referral from:**
- List1
- List2 etc

**Event (Randomisation)**

**TELEMEDICINE**

- T T O T T O T → Treatment completed

**CONVENTIONAL**

- O O O O O O O O → Treatment completed

T = Telemedicine consultation
O = Outpatient visit
7. Domain 7: Socio-cultural, ethical and legal aspects

7.1 Methods
Describe methods used for data collection.

This section will be completed in the Final Trial evaluation

7.2 Ethical issues
Describe ethical issues related to the use of the telemedicine application and produce a table similar to Table 19

This section will be completed in the Final Trial evaluation.

Table 10: Table for reporting of ethical issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>How issue was addressed</th>
<th>Dates</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient autonomy</td>
<td>Eg Consent to treatment</td>
<td>Month 3</td>
<td>Eg A patient information pack was created, nurses were trained to deliver oral guidance with the written information, and patients’ consent was recorded in writing. A 2 week cool-off period was introduced to allow patients to withdraw after considering the written guidance provided by nurses.</td>
</tr>
<tr>
<td>Access and equity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normative Codes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment of risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and benefit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7.3 Legal issues
Describe legal issues related to the use of the telemedicine application and produce a table similar to Table 20

This section will be completed in the Final Trial evaluation.
Table 11: Table for reporting of legal issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>How issue was addressed</th>
<th>Dates</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician accreditation</td>
<td>Eg Review of all accreditations for nurses</td>
<td>Month 1</td>
<td>Eg Found that nurses needed to prescribe certain treatments – accreditations changed (link to relevant code)</td>
</tr>
<tr>
<td>Device certification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Governance</td>
<td>Eg Review of procedures</td>
<td>Month 1</td>
<td>Eg Firewalls required adjustment; access protocols revised; patient access ensured (reference to new protocols)</td>
</tr>
<tr>
<td>Professional liability</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7.4 Socio-cultural issues

Describe socio-cultural issues related to the use of the telemedicine application and produce a table similar to Table 21

This section will be completed in the Final Trial evaluation

Table 12: Table for reporting of social issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>Key findings</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in patient's roles</td>
<td>Eg 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.</td>
<td>Eg Questionnaires to patients, interviews with professionals, report from senior doctor. 70% of those in work reported this benefit.</td>
</tr>
<tr>
<td>Patient’s relatives and others</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Societal, political and context changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes in responsibilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender issues - equity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. Transferability assessment

8.1 Assess transferability of clinical effects
Assess and discuss the transferability with regard to scalability and generalisability

This section will be completed in the Final Trial evaluation

Table 13: Domain 2-3: Safety and clinical outcomes

<table>
<thead>
<tr>
<th>Scalability</th>
<th>Generalisability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compare demographic characteristics with national data</td>
<td>Determine differences and assess how that would influence results on a national basis</td>
</tr>
<tr>
<td>Widening of inclusion criteria</td>
<td>Assess if other types of patients (i.e. lower or higher severity of disease) will gain more or less compared to trial patients</td>
</tr>
</tbody>
</table>

8.2 Assess transferability of economic effects
Assess and discuss the transferability with regard to scalability and generalisability

This section will be completed in the Final Trial evaluation

Table 14: Domain 5: economic outcomes

<table>
<thead>
<tr>
<th>Scalability</th>
<th>Generalisability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess what would be necessary if intervention should be scaled up within the country. How many telemedicine centres, how many patients etc.</td>
<td>Calculate the consequences in terms of costs/patient</td>
</tr>
<tr>
<td>Assess what would happen if inclusion criteria were widened. How many patients would benefit, how many centres would be necessary etc.</td>
<td>Calculate the consequences in terms of cost/patient and QALYs</td>
</tr>
</tbody>
</table>

8.3 Assess transferability of organisational effects
Assess and discuss the transferability with regard to scalability and generalisability

This section will be completed in the Final Trial evaluation

Table 15: Domain 6: Organisational aspects

<table>
<thead>
<tr>
<th>Scalability</th>
<th>Generalisability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess whether organisational aspects are unique for pilot within country</td>
<td>Describe how it is unique and what would be necessary for other regions if they decided to implement the telemedicine solution</td>
</tr>
<tr>
<td>Assess if organisational changes is necessary for broadening inclusion criteria</td>
<td>Discuss what would be necessary for the organisation, if inclusion criteria were broadened – and thus more patients included</td>
</tr>
</tbody>
</table>
Appendix A - References

12. Campbell B, Stainthorpe AC, Longson CM. How can we get high quality routine data to monitor the safety of devices and procedures? Bmj. 2013;346:f2782


18 REgioNs of Europe WorkINg toGether for HEALTH. The Renewing Health project. 2013. Accessed 17/11/2013