



UNiversal solutions in TElemedicine Deployment for European HEALTH care

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Abstract

The Final Report is the United4Health project's closing report. It is intended for an external audience to gain an overview of the project objectives, activities and results. The report summarises the key aspects of the project and directs readers to appropriate project material for more in-depth information.

Key Word List

Objectives, activities, results, lessons learned, impact, European added value, telehealth deployment, repository of material

Executive Summary

The Final Report of United4Health - *Universal solutions in telemedicine deployment for European health care* – marks the end of the 36-month journey which 32 organisations from across Europe embarked on together back in January 2013. The report summarises the key activities and work which were undertaken during the project period as well as the project's final results and output.

United4Health (U4H) has implemented a range of telehealth solutions and developed new associated care delivery processes based on the belief that telehealth can play an important role in addressing the challenges that all European healthcare systems are facing. The overall ambition of U4H was:

Transforming the patient experience through telehealth in Europe

The deployment sites in the project introduced telehealth services that enabled patients to manage their chronic conditions at home or in a home-like setting. U4H focused on Diabetes Mellitus, Chronic Obstructive Pulmonary Disease (COPD), Congestive Heart Failure (CHF) and Hypertension.

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

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

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

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

Using the Model of Assessment for Telemedicine (MAST), the evaluation of aggregated data from all deployment sites for each disease indicated some **improvements in patients' health and wellbeing**.

The evaluation did not, however, demonstrate such positive outcomes in relation to the cost-effectiveness of telehealth deployments **at project disease level** mainly because of significant variations between the deployment sites in:

- number of patients able to be supported as a result of telehealth investment;
- costs of telehealth solutions;
- existing support infrastructure, including technology and staff; and
- existing models of care for the management of chronic diseases.

The organisational assessment identified **large variations in the local services**, as well as **the importance of local context**. Patient satisfaction was generally high, although clinician satisfaction was more variable.

Based on these results, the majority of the regions have **continued deployment and made plans for further scaling of the services**, as well as applying their experiences from U4H to other planned telehealth services within their regions.

The U4H partnership has collated the experiences, lessons learned and expertise gained as a result of the project into public materials that are now available to other organisations across Europe. This report makes reference to these materials, according to themes (Evaluation, Deployment, Technology, Policy and Other), with signposting where they can be found on the project website:

www.united4health.eu

The overall U4H project achievements can be summarised as follows:

United4Health has enabled the redesign of care processes and the integration of telehealth into routine care delivery services. It has been a very complex and time-consuming process, but U4H deployment sites have shown that it is possible to deploy telehealth solutions at scale.

United4Health has demonstrated that telehealth is as safe as routine care, and has provided evidence of clinical benefits at project disease level. It has also demonstrated that patients accept telehealth and are satisfied with the services.

A total of 6,902 patients received a telehealth service, and data on 4,509 patients was evaluated, making it one of the largest studies of telehealth deployment in Europe. Using the MAST Framework, the project also assessed the economic and organisational aspects of telehealth.

United4Health has gathered its lessons learned and produced guidelines for the procurement and implementation of telehealth.

90% of United4Health services have continued running after the evaluation ended, and further scaling up is in process within most U4H regions.

Change History

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0.6	Final draft
1.0	Initial version for issue
1.1	Revised following final review
1.2	Revised following feedback from EC reviewers

Outstanding Issues

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1. Introduction

1.1 Purpose of this document

This deliverable serves as the final report of the United4health project. The report summarises the key activities that were undertaken during the project, as well as the project's final results and outputs.

1.2 Glossary

CHF	Congestive Heart Failure
CIP	Competitiveness and Innovation Programme
COPD	Chronic Obstructive Pulmonary Disease
DM	Diabetes Mellitus
GP	General Practitioner
ICT-PSP	Information & Communication Technologies Policy Support Programme
MAST	Model for Assessment of Telemedicine
RCT	Randomised Controlled Trial
RH	Renewing Health
TM	Telemonitoring
U4H	United4Health

2. United4Health

2.1 Overview

United4Health - *Universal solutions in telemedicine deployment for European health care* - is a Pilot A project under the ICT-PSP Competitiveness and Innovation Framework Programme, supported by the European Commission. The project ran from January 2013 - December 2015, a total of 36 months.

The project involved 32 organisations from across Europe. Some organisations represented regional healthcare institutions or authorities, while others were multi-national organisations or specialist organisations with a wider supporting role. See Chapter 6 for more information about the project partners.

2.2 Ambition

Healthcare services throughout Europe are witnessing a significant increase in demand due to the increased prevalence of chronic conditions and ageing populations. To assist healthcare providers in meeting these challenges, the United4Health (U4H) project implemented a range of telehealth solutions and developed new associated care delivery processes. Each deployment site's telehealth service enabled patients to manage their chronic conditions at home or in a homely setting. The ambition of United4Health was:

Transforming the patient experience through telehealth in Europe

U4H has generated significant learning from the implementation of telehealth solutions designed to support people living with diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) and Hypertension. An evaluation using the MAST model (Model for Assessment of Telemedicine) has provided evidence on the effectiveness of the technology solutions deployed in 14¹ regions across Europe.

2.3 Main achievements

United4Health has enabled the redesign of care processes and the integration of telehealth into routine care delivery services. It has been a very complex and time-consuming process, but U4H deployment sites have shown that it is possible to deploy telehealth solutions at scale.

United4Health has demonstrated that telehealth is as safe as routine care, and has provided evidence of clinical benefits at project disease level. It has also demonstrated that patients accept telehealth and are satisfied with the services.

¹ One region, Nord Pas de Calais, France deployed a Hypertension service; as they had already started their project before the start of U4H, the evaluation was not done according to MAST.

A total of 6,902 patients received a telehealth service, and data on 4,509 patients was evaluated, making it one of the largest studies of telehealth deployment in Europe. Using the MAST Framework, the project also assessed the economic and organisational aspects of telehealth.

United4Health has gathered its lessons learned and produced guidelines for the procurement and implementation of telehealth.

90% of United4Health services have continued running after the evaluation ended, and further scaling up is in process within most U4H regions.

2.4 Lessons learned

The complexity of embedding telehealth within routine care provision in health and social care systems, as United4Health deployment sites have achieved, has generated valuable lessons learned based on the real life experiences of all the healthcare professionals, patients, technicians and other stakeholders involved.

The lessons learned have been gathered, analysed and documented in order to support the further implementation of telehealth, for both U4H regions and others across Europe and beyond.

U4H has also produced guidelines for procuring and implementing telehealth. These are detailed in the report D3.8 Guidelines for procurement and implementation of telehealth. Section 5 of this document, entitled U4H Learning Resources, contains references to where this report can be found.

2.4.1 Implementation

While many lessons learned were identified, three major challenges stand out as having had the most profound impact on the majority of the deployment sites:

- **Clinician engagement**, specifically physician engagement, is critical to successful telehealth deployment, and presented a significant challenge in almost all of the sites. However, these challenges were successfully addressed in most cases through the implementation of ongoing, targeted awareness and engagement activities.
- The **procurement of technology** and the integration of technology into existing workflows and technology infrastructures was complex and more time consuming than originally anticipated.
- The **evaluation methodology** required for real life deployment is radically different from traditional pilot-based research methods. The appropriate methodology for a deployment project is a formative methodology that is iterative, with learning gathered at key stages to inform the necessary changes. The imposition of standard research approaches can, in fact, impede effective and scalable deployment.

The guidelines derived from U4H for implementing telehealth, especially at scale, are comprehensively detailed in the U4H Guidelines Report (D3.8). Overall, the guidelines cover:



2.4.2 Procurement

There were considerable differences in how the deployment sites obtained their telehealth systems and devices. Some regions did not go through a procurement process. Some bought or leased a service rather than purchasing technical products. In most cases, regions made agreements with vendors with whom they had a previous contractual relationship – clearly, they valued the trust relationship with their vendors. Only one deployment site issued an EU wide tender; all others either procured locally or used research and development procurement processes to obtain the needed telehealth solutions.

The procurement processes adopted by deployment sites were adequate for fulfilling the service requirements of the project objectives. However, project timescales did not allow enough time for sites to undertake a full review of “state of the art”, standards based solutions.

The experience of U4H holds a number of lessons for other regions or healthcare providers wishing to procure telehealth technologies. Technology is but one part of the telehealth ecosystem: it needs to support patients and healthcare professionals, ideally integrate with other ICT systems and devices, and be sustainable and future-proof.

WHERE CAN I LEARN MORE ABOUT THIS?

**U4H report D3.8 Guidelines for Procuring and implementing telehealth
U4H Procurement Checklist (Annex to D3.8)**

2.5 Policy messages

Telehealth is designed to offer more accessible, equitable and sustainable services for the benefit of people in Europe. It does this in the face of considerable challenges to the sustainability of Europe's healthcare systems. In recent years, we have witnessed convergence between telehealth, mHealth, health analytics and electronic record systems in many U4H deployment sites. This convergence will gather pace as healthcare systems are able to embrace “bring your own device” solutions, and respond to the increasing realisation that telehealth is a critical component in the transformation and sustainability of Europe's healthcare.

Through its User Policy Advisory Board (UPAB), U4H took responsibility for ensuring policy engagement and the development of policy messages for the upscaling of telehealth in Europe.

Policy makers at European, Member State, regional and local levels are in a position to enable, promote and support the upscaling of telehealth by:

Ensuring a policy environment that promotes and supports telehealth deployment

Seeking national consistency with local adaptation

Empowering patients, carers and healthcare professionals to take full advantage of telehealth

Based on their experiences during the U4H project, the deployment sites encourage policy makers to:

- Ensure that the regulatory environments necessary for telehealth deployment are jointly assessed by Member States in order to lower market barriers, and that regulation keeps pace with innovation in telehealth technologies.
- Initiate funding programmes for scalable telehealth deployment to enable the transformation of health and care delivery across Europe.
- Support those who deploy telehealth by enabling the collection and sharing of good practices and key learning at European, national and regional levels from large scale deployments.
- Promote the use of validated evaluation methodologies and tools that can be applied in an action research approach.
- Ensure that all those involved in funding decisions (including external evaluators) assess proposals and projects in accordance with programme priorities and calls, i.e. deployment and not just research.
- Include these policy messages on the agenda of the eHealth Network and other policy fora for European health and social care policies.

The policy messages were presented, shared and discussed with European policy makers at the Science and Technology Options Assessment (STOA) session in the European Parliament on 1st December 2016.

The project key policy messages and learning were also presented to the eHealth Network² on 7th June 2016, during eHealth Week in Amsterdam - http://ec.europa.eu/health/ehealth/events/ev_20160607_en.htm.

² http://ec.europa.eu/health/ehealth/policy/network/index_en.htm

WHERE CAN I LEARN MORE ABOUT THIS?**U4H Report Upscaling Telehealth – the need for policy engagement
(D4.3, Annex 1)**

2.6 Value for Europe

Across Europe, health and care systems are looking for ways to ensure sustainability of their systems in the light of the growing challenges. The European Commission has had this on its agenda for many years, and has supported innovation and research in health and care through various mechanisms. eHealth, telehealth / telemedicine and mHealth are some of the areas promoted under these innovation and research activities.

Simultaneously, local, regional, national and European initiatives from healthcare providers, authorities, industry, etc. have developed, tested, evaluated and at small scale implemented such solutions.

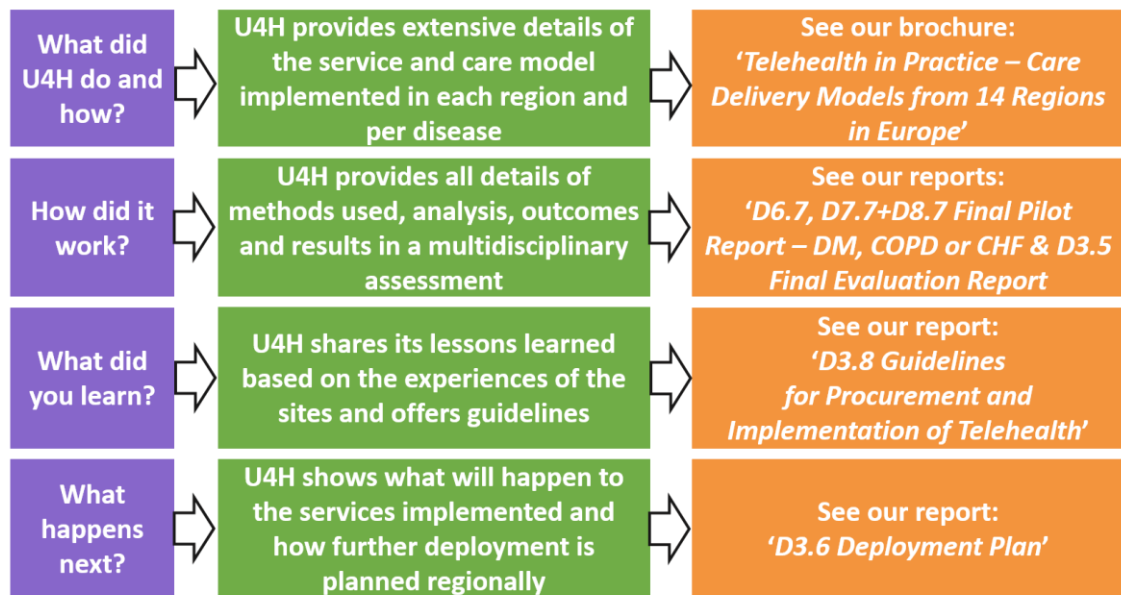
In U4H, 14 regions from 10 European countries have deployed 20 different telehealth services support four chronic conditions. . A total of 6,902 patients received a telehealth service, and data on 4,509 patients was evaluated, making it one of the largest studies of telehealth deployment in Europe. Using the MAST framework, the project also assessed the economic and organisational aspects of telehealth.

It is acknowledged that there were limitations and constraints to the studies conducted in U4H in relation to:

- smaller evaluation population cohorts than planned;
- the comparator groups included some of the same patients' prospective data before the telehealth service was introduced;
- the intervention and comparator groups were not well matched at baseline;
- heterogeneity and lack of normality of data;
- variable rates of missing data for some indicators and questionnaires.

The economic analysis shows that for the most part, telehealth interventions have a high cost per patient, often due to the technology solutions chosen by the deployment sites. However, the COPD study reported a mean reduction in costs, and some sites have also shown a reduction in healthcare costs per patient for their diabetes and/or CHF telehealth care models. Overall, the services have been considered a success locally; sites have continued to offer the service to appropriate patients in most of the deployment sites once enrolment to the evaluation was completed. In addition, most sites have also put actions in place to secure further deployment and upscaling.

This implies that other healthcare providers in Europe can also be successful in deploying telehealth. The experiences, outcomes and lessons learned from the U4H project can be helpful in this process, as highlighted below:



Information on where to find all the mentioned United4Health material is set out in Chapter 5 U4H Learning Resources .

3. Activities & Results

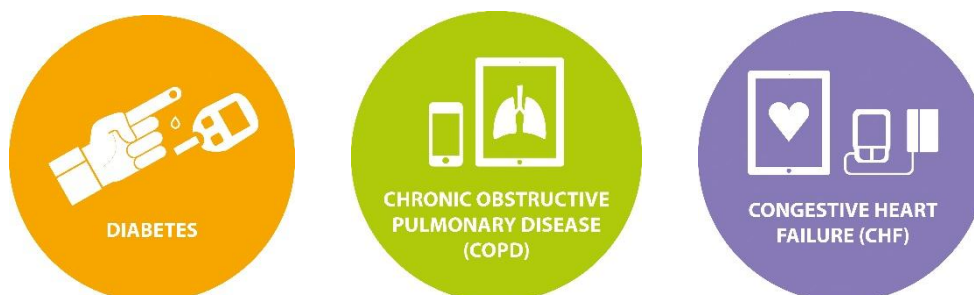
3.1 Background

U4H was preceded by another ICT-PSP CIP Pilot A project, Renewing Health (RH), that was a telehealth research project with a focus on measuring the efficacy of telehealth interventions for COPD, diabetes and CHF patients through randomised controlled trials (RCT). Inspired by the solutions evaluated in RH, U4H has deployed and assessed four telehealth interventions (Diabetes, COPD, CHF and Hypertension) in real-life healthcare environments and chronic management care pathways in fourteen European regions. The RH interventions were not directly transferred, but the telehealth interventions in U4H were the result of a common agreement among the sites on a generic service model and protocol, based on RH, in each disease. The protocol and telehealth services were then further customised locally for adaptation to the local healthcare environment.

A fourteenth region had implemented a Hypertension telehealth service, but this work had already begun before the project started, and therefore has no link to the telehealth interventions that U4H designed based on the lessons from RH.

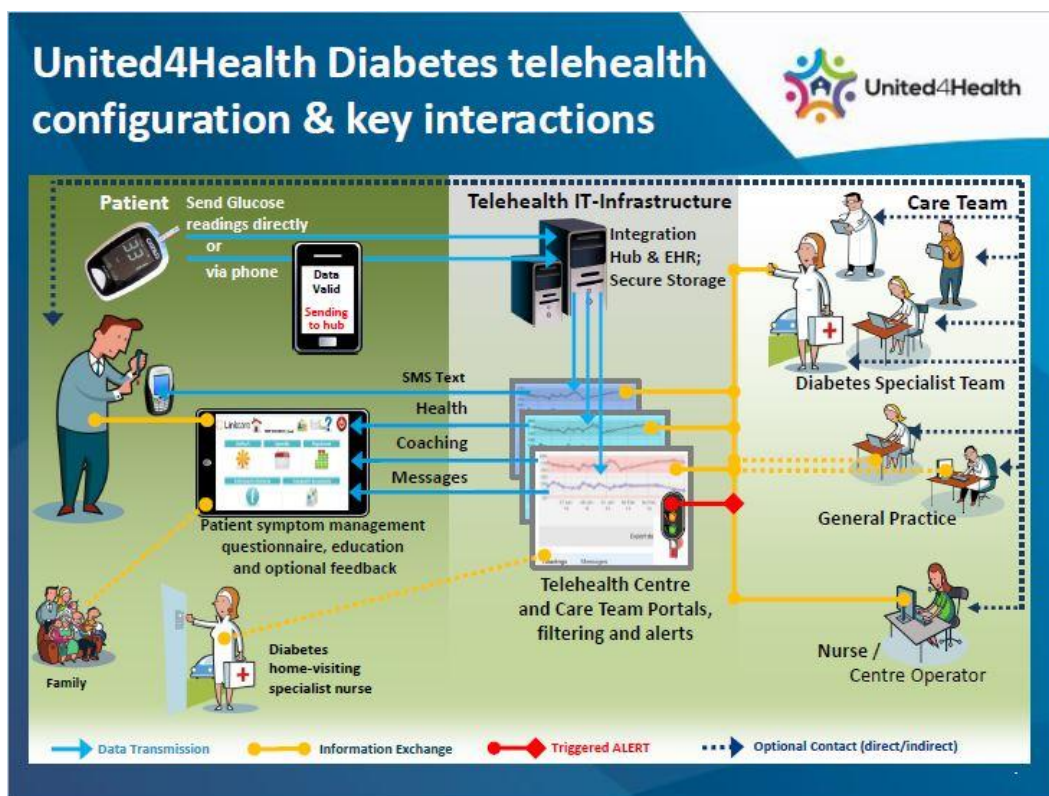
3.2 Telehealth services

U4H has deployed four overall telehealth service models for the management of chronic conditions across different regions in Europe. The overall aim has been to shift the care process and enable better and longer self-management and supported self-management, thus reducing the period of specialist supported management.



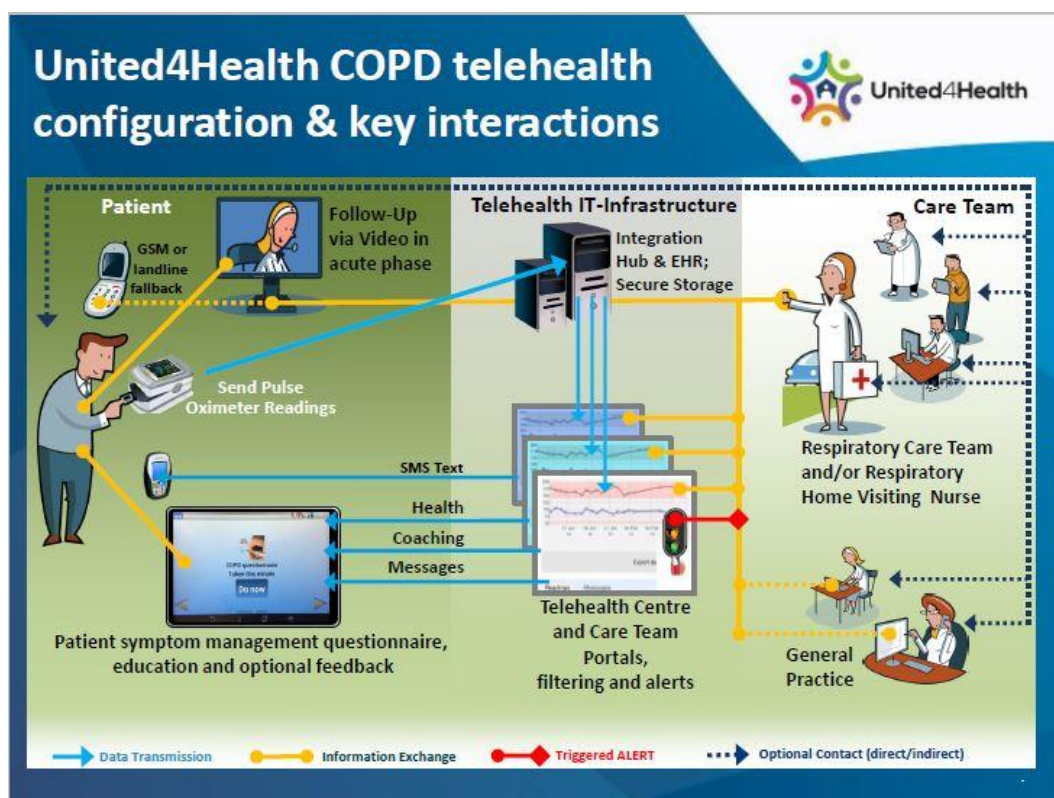
3.2.1 Diabetes

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



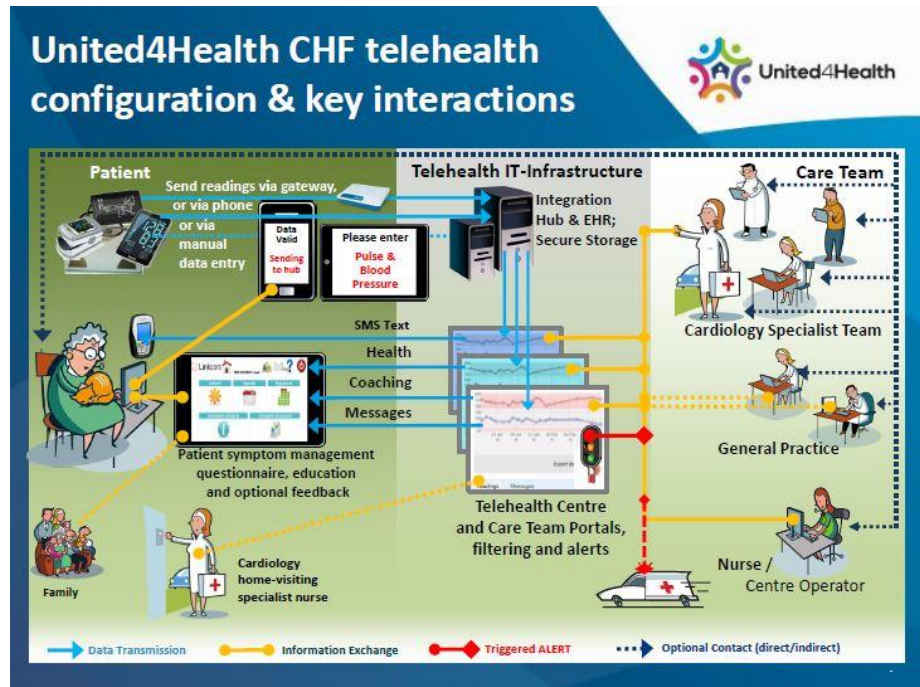
3.2.2 Chronic Obstructive Pulmonary Disease (COPD)

The ambition of the COPD intervention was to support at home, patients discharged from a hospital admission due to an exacerbation, through telemonitoring and consultation in a step-down approach (high level, moderate and low).



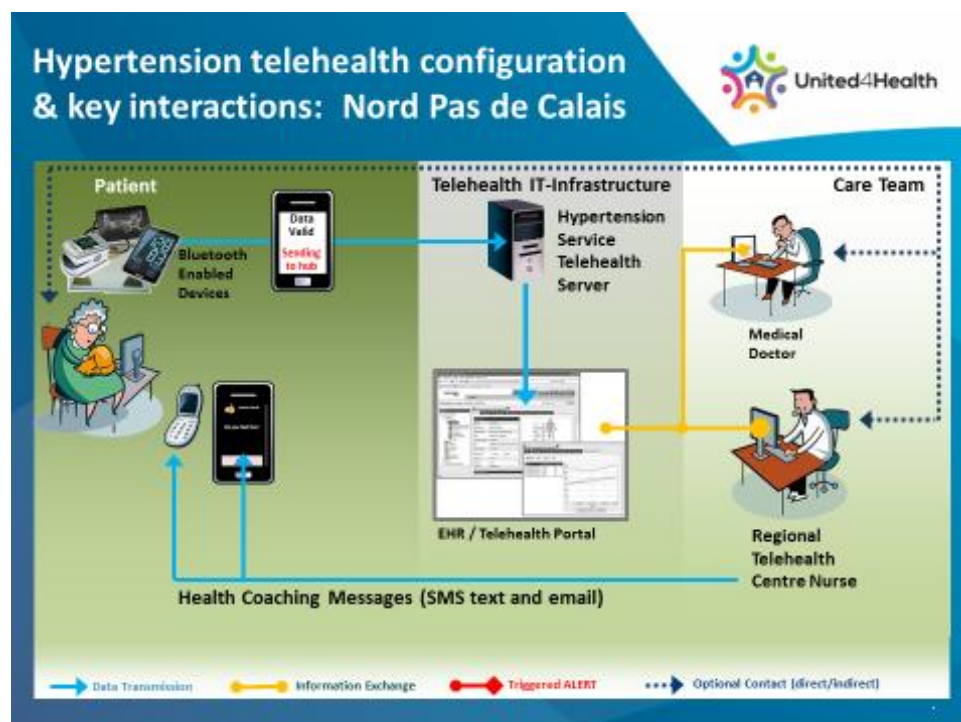
3.2.3 Congestive Heart Failure (CHF)

The ambition of the telehealth service for CHF was to improve the chronic care management by prompting timely intervention when necessary, and promoting self-management through regular uploading of physiological measurements.



3.2.4 Hypertension

Vigisanté combined screening for hypertension in companies, supported by a medicalised platform, in connection with general practitioners (GPs) and telemonitoring of hypertensive patients at home.



3.3 Evaluation and results

From a review of the existing publications of telemonitoring (TM), it has been concluded that: TM is safe; TM is at least as effective as usual care; favourable clinical effects have been demonstrated in selected populations and services; there is unclear or controversial economic outcomes; there is no evidence about real life effectiveness if deployed at large-scale; and no evidence of transferability of best practices and sustainability.

The evaluation objectives in United4Health were therefore to:

- Increase the current evidence base on the benefits that telehealth services can provide in routine care for chronic disease management.
- Validate and strengthen the evidence for these telehealth solutions, especially on economic and organisational outcomes.

Using MAST (Model for Assessment of Telemedicine) as the evaluation framework, and through an observational study design, U4H has assessed the impact of deploying innovative healthcare services for the remote monitoring of patients with chronic conditions at scale, and has put emphasis on the economic and organisation aspects (Domain 5 & 6 in MAST). U4H thereby helps to pave the way for the adoption of telehealth in routine care and real life healthcare provision.

In U4H, a total of 6,902 patients received a telehealth service, and data on 4,509 patients was evaluated, with 1,776 allocated to the intervention group, while 2,743 were allocated to the comparator group.

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

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

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

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

Below is a brief account of the results in relation to safety and clinical effectiveness, organisational aspects, economic aspects, and patient perception for each intervention.

3.3.1 Diabetes Mellitus

Deployment Sites:

- Scotland, UK
- Wales, UK
- Northwest Moravia, CZ
- Slovenia, SL
- Campania, IT
- Calabria, IT
- South Karelia, FI
- Central Greece, GR
- Berlin, DE



The study of the deployment of the telehealth intervention for diabetes included a total population of 3,251. **2,541 patients were enrolled in the evaluation cohort**, from where 1,016 were allocated to intervention and 1,525 to comparator group. This makes it the largest diabetes population evaluated in regards to TM. In addition to the total population, Scotland also included a deployment sub-group of DM patients (2,644) who in United4Health have registered with the national self-support tool with health coaching functionality, but were not telemonitoring their blood glucose levels.

3.3.1.1 Clinical

The primary outcome of the study was a reduction in the number of face-to-face contacts with GP or diabetologist. **The results show that the number of face-to-face GP and diabetologist contacts is lower in the telemonitoring group than in the comparator group, although it is not statistically significant.**

The secondary outcomes were a reduction in number of admissions to hospital, and a reduction in HbA1c levels. **The results show that the number of admissions to hospital is lower in the telemonitoring group, and that the reduction in HbA1c is bigger in the telemonitoring group; both are statistically significant.**

3.3.1.2 Organisational

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

- **National focus on telehealth** (e.g. telehealth being an integral part of the national health strategy) makes a positive difference for implementation and dissemination of a new telehealth solution.
- **Positive staff attitudes are crucial for successful deployment.** Also, roles and responsibilities for all participants (including sectors) must be clearly defined from the start, and realistic expectations for the time and staff resources required are essential.
- **ICT infrastructure** must be in place and running smoothly from the beginning of the project or deployment process.

- **Continuous adjustment and further development** of the telehealth service is necessary. All sites require a revision of the service from its present form in order to continue after the end of the project period.

3.3.1.3 Economic

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

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

3.3.1.4 Constraints

The pragmatic approach of the evaluation, focused on the assessment of deployment and not of clinical effectiveness, as well as the significant delays in the procurement of the necessary infrastructure and in the organisational changes, resulted in significant delays in recruitment of the study population, resulting in the following limitations of the evaluation:

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

3.3.1.5 Patient perception / acceptability

The median patient with Diabetes Mellitus believes that telemonitoring enhances the care the patient receives from the healthcare system, and increases accessibility to healthcare services, whilst at the same time it does not create problems with his/her privacy, cause discomfort, nor cast doubts about the personnel delivering the telemonitoring service. However, the patient is rather indifferent as to whether the kit can be a substitute to usual care. Nevertheless, the patient is overall very satisfied with the kit (93.1%).

The analysis also indicates which demographic and other variables appear to affect satisfaction levels:

<u>AGE</u>	Patients older than 75 years reported lower satisfaction (still, they were satisfied).
<u>EDUCATION</u>	Patients with no formal schooling stated lower satisfaction (still, they were satisfied).

FAMILIARITY WITH PC

Patients familiar with a PC reported lower satisfaction (still, they were satisfied).

TIME

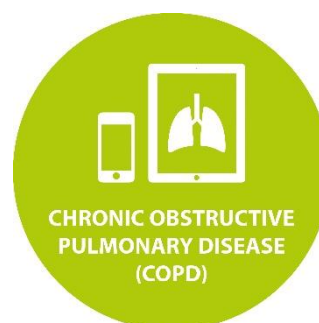
Patients for whom the time from telemonitoring initiation to survey administration was longer, stated less positive views as to whether telemonitoring could substitute standard care, and whether they faced privacy or discomfort issues with it.

WHERE CAN I LEARN MORE ABOUT THIS?
U4H report: D6.7 Final Pilot Evaluation - Diabetes

3.3.2 Chronic Obstructive Pulmonary Disease (COPD)

Deployment Sites:

- Scotland, United Kingdom
- Wales, United Kingdom
- Galicia, Spain
- Southern Norway, Norway
- Northern Norway, Norway
- Berlin, Germany



The study of the deployment of the telehealth intervention for COPD included a total population of 2,460. **1,357 were enrolled in the evaluation cohort**; 483 were allocated to the intervention group, and 884 to the comparator group.

3.3.2.1 Clinical

Despite lower recruitment than anticipated, and variability within regional systems and services, the project included nearly 1,200 people hospitalised with COPD (483 receiving TM) and is the largest study researching this particular cohort to date. The COPD cohort overall is perceived to be typical and generalisable to similar studies and current clinical services looking at acute admissions.

The study concluded that: TM is **safe and popular with users; confers some clinical benefit, probably in the longer term; and should not be offered to patients immediately following acute admission for COPD**, but rather recruit patients post-discharge to improve take-up.

3.3.2.2 Organisational

All deployment sites involved hospital departments, most of which are specialised in lung disease, although the titles and apparent organisation within the hospitals differed. All sites except one also involved primary care, and **community / home-visiting nurses played a key role to the delivery of the telehealth service** in most cases. Other organisational conclusions are:

- The start of the project **required a lot of learning**, especially for sites with no prior experience with telehealth.
- Some sites reported no task shifting at all due to the project, while other sites reported major changes in the distribution of work and a shift in responsibility for the telehealth patient group between sectors.

- **Realistic expectations for the time and staff resources** required are crucial, as many sites reported that more time and effort than expected was needed to get the telehealth applications and service to run smoothly, and to make sure that patients felt ready and secure.
- **ICT infrastructure** must be in place and running smoothly from the beginning of the project or deployment process.
- The staff reported **patient recruitment problems and overtreatment of some patients at the beginning of the service**, erring on the side of caution rather than trusting their professional judgement.
- Four sites reported that **their experience was mainly positive**. Patients felt empowered and use of the service was less complicated than expected. Access to data saved time, and led to reassurance for the healthcare professionals knowing the health status of their patients; this reassurance was expressed by the patients as well.

3.3.2.3 Economic

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

- The telehealth intervention in the COPD trial reduces the average costs per patient by about 2,377€, mainly because a reduction is found in the number of admissions. Some variations are found between the six regions involved, but all regions were able to demonstrate a reduction in the costs per patient.
- For the COPD trials, there is great variety in the setup of the COPD service, although all sites involve at least one hospital department.
- In some cases, the equipment was already in place from previous projects, in some cases it was bought for U4H, and in other cases patients used their own cell phones, with some additional equipment provided by the project.

3.3.2.4 Constraints

The results need to be taken with caution for four main reasons:

- **The groups were not matched at baseline**; those receiving TM had significantly worse disease than Comparators, as evidenced by significantly more COPD admissions in the preceding year and by a number of other markers of worse prognosis, e.g. longer duration of COPD diagnosis, more likely to have been intubated in the current admission, worse lung function (FEV1), etc. (all $p < 0.05$).
- The intervention group being adapted with telehealth is compared with a group where TM adaption has not been tested. Several centres experienced an adaption rate of 30-40% (most probably underestimated in the figures given), and is then compared with an unselected COPD population from the year before telehealth was introduced. This **selection bias** cannot be adjusted for in the analyses.
- Comparing with a **historical cohort has some inherent design faults**, and the differences between Groups regarding important clinical confounders may be due to **selection bias**: patients with a more severe disease are more willing to try anything to avoid yet more admissions, and staff are more willing to approach patients they know well from recurrent admissions.
- The **data was incomplete in a non-random but systematic way**. In general, the data was less complete for people with worse clinical outcomes (i.e. death or more admissions). This data availability makes any definitive conclusions difficult;

e.g. for our first regression model, complete data on the variables we were most interested in was only available for 400 out of 1,400 patients.

3.3.2.5 Patient perception / acceptability

The median patient with COPD moderately agreed that telemonitoring enhanced the care the patient received from the healthcare system, and increased accessibility to healthcare services, whilst at the same time it did not cast doubt on the personnel delivering the telemonitoring services. Patients strongly agreed that the process did not create problems with their privacy, nor caused any discomfort; the patient was thus satisfied with the telemonitoring experience (96.2%). However, the patient was rather indifferent as to whether the kit could be a substitute to usual care (44.3%).

The analysis also indicates which demographic and other variables appear to affect satisfaction levels³:

AGE

Patients on the 65-75 age group reported lower ratings on increased accessibility and privacy and discomfort than did patients younger than 65 years

WHERE CAN I LEARN MORE ABOUT THIS?
U4H report: D7.7 Final Pilot Evaluation - COPD

3.3.3 Congestive Heart Failure

Deployment Sites:

- Scotland, UK
- Basque Country, ES
- Northwest Moravia, CZ
- Slovenia, SL



The study of the deployment of the telehealth intervention for CHF included a total population of 1,106. **611 were enrolled in the evaluation cohort**; 277 were allocated to the intervention group, and 334 to the comparator group. 495 have had a shorter or no follow-up at the time of the analysis. The non-participation rate was 29%.

3.3.3.1 Clinical

The study found that telehealth is a good tool to improve coordination, patient empowerment, treatment adherence, and anticipatory care for CHF patients.

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

Patients in intervention group:

³ Missing data on potentially important variables might obscure the picture though.

- were **4.62 times less likely** to have a heart failure related hospitalisation;
 - had **5.22 times fewer** hospitalisation days;
- than the patients included in the comparative group.

3.3.3.2 Organisational

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

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

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

3.3.3.3 Economic

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

- The telehealth intervention in the CHF trial reduced the average costs per patient by 329€, mainly because the study in Scotland was able to demonstrate a reduction in costs. In the other three regions, the costs per patient are increasing.
- In some cases, equipment was purchased for the project, in other cases it was already in place from other interventions before the start of the project; finally, some sites have used the patients' own devices.
- No site found that they saved time using the telehealth solutions instead of offering traditional care to CHF patients.

3.3.3.4 Constraints

The same constraints observed in the other two diseases have also been observed in the CHF study. In summary:

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

3.3.3.5 Patient perception / acceptability

Patients in the United4Health CHF study have a high acceptability and satisfaction associated with the telemonitoring intervention. Satisfaction rate was 96.5%, which is the highest of the three diseases. Home health monitoring had a perceived positive impact on patients' lives. Patients reported that telemonitoring did not cause privacy or discomfort issues, and did not create problems related to the personnel

that provided the new intervention. They felt knowledgeable about the kit, and agreed that telemedicine increased the healthcare they received. There was also mild agreement that the kit could act as a substitute to standard care, but in different degree across different regions. 64.2% of the patients had a positive view of telehealth as a substitute for standard care. This is also the highest of the three diseases.

The analysis also indicates which demographic and other variables appear to affect satisfaction levels:

AGE

Patients older than 75 years reported lower ratings on enhanced care and increased accessibility (still, they had a positive perception).

TIME

As time passed, patients revised upwards their perception on whether the kit could substitute their standard care.

WHERE CAN I LEARN MORE ABOUT THIS?

U4H report: D8.7 Final Pilot Evaluation - CHF

3.3.4 Hypertension

The hypertension study concluded that self-measurements and coaching lead to better control of blood pressure, patient participation, and health professionals' management. However, the Vigisanté programme was shown to be more expensive and less effective in terms of reduction in blood pressure than the traditional follow-up by GPs. The cost differences were due to the technology costs rather than increased care utilisation by the intervention group. In addition, the study suggested that clinical benefits may require a longer follow-up to provide more robust evidence.

From the patients' point of view, the medical information present in eHealth programmes can **improve diagnosis and treatment**. 59% of patients involved in the Vigisanté programme experienced an improvement in their health, 80% were satisfied with the follow up of their hypertension monitoring and support, and more than 80% of attendees would recommend it to relatives.

From the physicians' point of view, the implementation of such a service **strengthens the role of the GP**. The study showed that for 69% of GPs, the integration of patients into Vigisanté allowed global health benefits, including blood pressure. The cutting edge of the study is the empowerment given by the Vigisanté programme, that is to say, giving patients the means to become responsible for their own health.

WHERE CAN I LEARN MORE ABOUT THIS?

U4H report: D9.2 Final Pilot Evaluation - Hypertension

3.4 Further deployment and scalable services

The experiences of the U4H deployment sites have been hugely valuable in setting the foundation for sustainability and scaling up of the services implemented locally.

The number of patients receiving the services continues to rise daily, because in most regions the services did not stop with the end of the evaluation, but have continued as part of mainstream service delivery; albeit that the scale of deployment varies from region to region.

In some cases, U4H services are still being deployed as part of a local continuing project, where funding has been secured to support the further enrolment of patients. In Scotland, for example, a national implementation and scaling programme for Technology Enabled Care (TEC) funds and manages the considerable scaling up of all three services to more patients. Only a few telehealth services will not continue to be provided following the end of U4H; however, it is anticipated that they will emerge again in a modified form in the near future.

For all U4H deployment sites, each site has been able to learn from and adapt the experiences they obtained from deploying telehealth services in real-life settings. Their adaptations range from: minor changes in patient population (inclusion or exclusion criteria); when the service is offered (time of enrolment); to the organisation of the provision of the service (workflow or care process). These adaptations will further ensure the scalability, generalisability and sustainability of the services in local health and care environments.

WHERE CAN I LEARN MORE ABOUT THIS?

U4H report: D3.6 Deployment Plan and D6.8, D7.8, D8.8 + D9.4 Guidelines for selection of patients for further deployment

4. Impact

4.1 Healthcare provision

Diabetes, COPD, CHF and Hypertension are conditions that affect millions of people across the world, and have a significant negative impact on quality of life, health and mortality. Both primary and secondary care provision are greatly affected by the continuous rise in chronic conditions and co-morbidities which, in turn, put pressure on available resources, both human and financial.

U4H has implemented telehealth services that can be part of the solution to these challenges, and help transform the patient experience. The telehealth services deployed in the U4H regions enable the patients to manage their chronic conditions at home or in a home-like setting. The healthcare providers have enhanced their delivery of care, utilising available ICT infrastructure, integrated with other local digital health and care initiatives.

While recognising there are limitations to the study, U4H has, nevertheless, demonstrated that health and wellbeing benefits to patients can be achieved. Patient satisfaction was high, and while patients were perhaps indifferent or negative towards technology as a substitution for standard care, U4H has never sought to replace standard care with telehealth, but to integrate telehealth into (redesigned) existing care processes.

The results of our project should be taken into consideration by healthcare providers in terms of telehealth's role as an enabler for redesign of services that are sustainable and more adapted to meeting existing and future challenges. Patients' and healthcare professionals' associations, societies and federations should also take note and respond appropriately.

4.2 Market and Industry

The experiences and results of U4H have resulted in both the U4H regions, as well as others, rethinking how technology should be deployed. From U4H, we have learned to better determine which patients may benefit from a service, and if the service is appropriate in relation to the patient's current health status, i.e. what type, intensity and frequency of monitoring is needed. This has an impact on choice of technologies and devices to purchase or lease, as well as infrastructure requirements.

U4H showed that cost-effectiveness was not evident in all services or sites, mainly as a result of both the initial purchase and ongoing running costs of the intervention. This should lead to consideration and reflection not just among health and care providers and authorities, but also the industry in respect of their business models and ways to boost the market.

As many U4H deployment sites are moving towards deploying telehealth at scale, there is now a more advanced understanding of the benefits of interoperability. If they follow the procurement guidelines, buyers will do their share to advance interoperability. The U4H partners also call on technology providers to play their part in addressing this critical issue. Technology providers should develop and bring

products to market that meet guidelines and protocols, where they exist, and support the development of new guidelines and protocols where they do not, especially for those use cases that lend themselves to remote monitoring. Suppliers should understand that procurers will increasingly demand messaging standards and eventually data standards, at least at the interface to the healthcare providers' systems.

It has been observed that the market for interoperable telehealth solutions reflects a chicken and egg situation. Ultimately, the market will follow the buyers: if they demand interoperability by following U4H guidelines, the market will deliver.

4.3 Society and Policy

Telehealth and other eHealth services are a critical component for the transformation of Europe's healthcare. They offer more accessible, equitable and sustainable services for the benefit of people in Europe. Therefore, policy-makers need to support and enable the deployment of telehealth. This has become obvious to the U4H consortium members and their networks, both through the work they have done, and their observations of developments over recent years.

The wider policy perspective of deploying telehealth at scale based on U4H was summarised in section 2.5, and will not be repeated here. However, an example of how U4H guidelines link to policy is provided below.

United4Health hopes to empower healthcare providers in the procurement of interoperable products by sharing information on existing best practice on standards and interoperability:

Consider including guidance on interoperability standards in telehealth strategies and action plans, with appropriate targets and timelines that give all stakeholders time to adjust. An interoperable eHealth ecosystem benefits everybody, but the market might need support from government and regulators to achieve this.

5. U4H Learning Resources

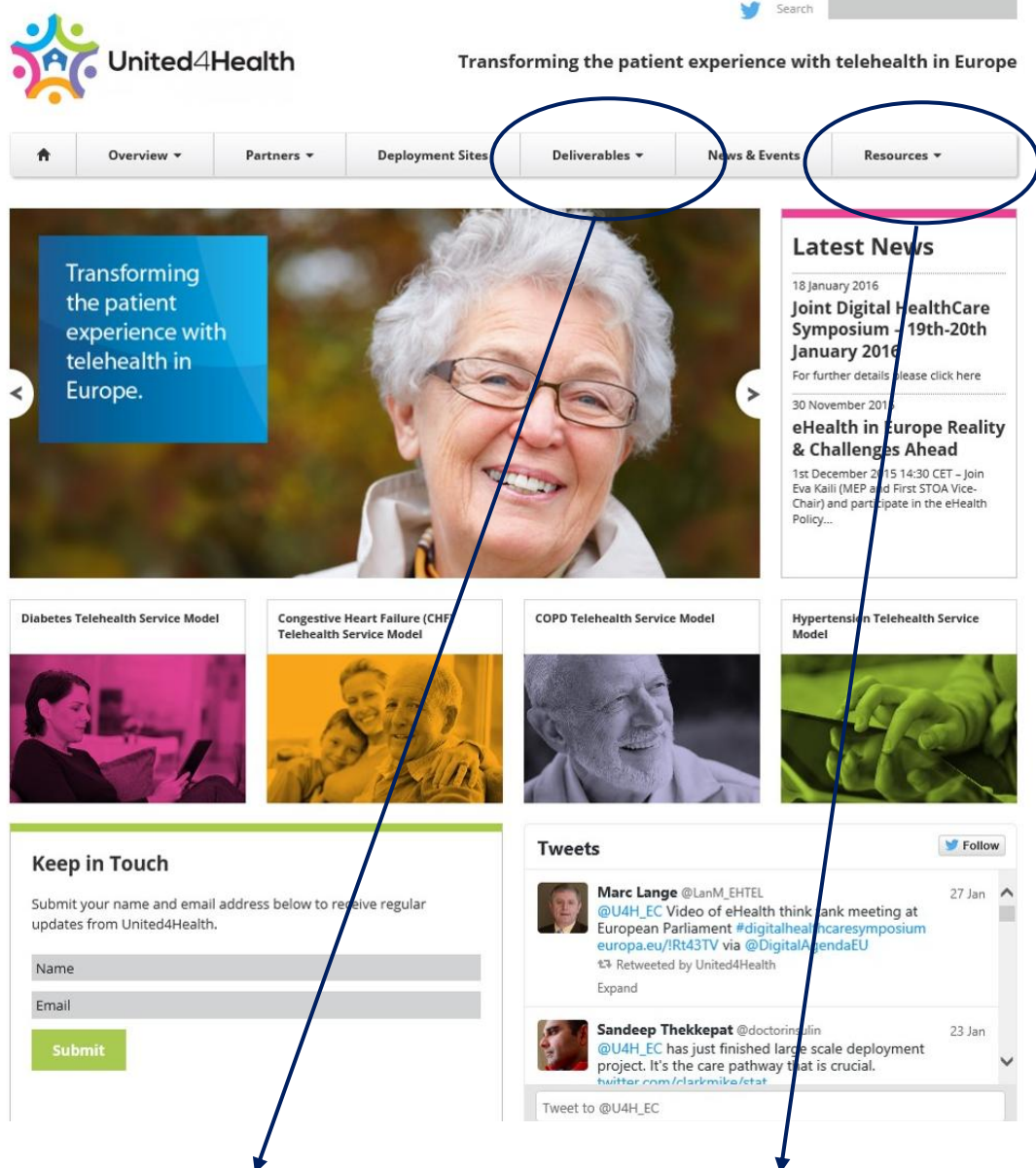
Over the last three years, U4H has produced a range of reports and materials that are publicly available on the project website: www.united4health.eu.

The matrix below shows the overall learning themes, and the reports and materials that are relevant under each theme (all are available on the U4H website):

Evaluation	Scientific Trial Protocols for each of the Multicentre Trials
	Final Evaluation Report
	Comparison of results between United4Health and Renewing Health
	Final Pilot Evaluation - Diabetes
	Final Pilot Evaluation - COPD
	Final Pilot Evaluation - CHF
	Final Pilot Evaluation - Hypertension
Deployment	Guidelines on Procuring and Implementing Telehealth
	Deployment Plan
	Guidelines for selection of patients for further deployment - Diabetes
	Guidelines for selection of patients for further deployment - COPD
	Guidelines for selection of patients for further deployment - CHF
	Guidelines for selection of patients for further deployment - Hypertension
Policy	User Advisory Board Final Feedback
	Policy Messages Briefing
Other	Leaflet – Transforming the patient experience through telehealth in Europe
	Telehealth in Practice – Care Delivery Models from 14 Regions in Europe
	United4Health Youtube Channel
	Partner Showcases
Technology	Workshop for Regions: Procuring interoperable solutions
	Technical Document and Recommendations
	Workshop: Interoperability in practice and assessment
	Regulatory environment and good practice
	Regulatory practices and telemedicine
	Workshops “Talkshops”
	Workshop: Interoperability in practice lessons learned

All public material and reports from U4H can be found at the project website:

www.united4health.eu



This area contains all deliverables that are public from the project work packages:

- WP1 – Project management
- WP2 – Dissemination
- WP3 – Evaluation
- WP4 – User Policy Advisory Board
- WP5 – Industry Advisory Team
- WP6 – Diabetes pilot
- WP7 – COPD pilot
- WP8 – CHF pilot
- WP9 – Hypertension pilot
- WP10 – Liaison activities

This area contains project material of various kinds:

- Banner, flyer and posters
- Leaflets
- Partner showcases
- Reports
- Service model brochure
- Videos

**@U4H_EC**

The website includes a twitter feed to track communication on the project.

Keep in Touch allows visitors to the website to leave their email address. This will allow the project to further disseminate project outcomes and information wider than the consortium.

Also note that United4Health has a YouTube channel:

**www.youtube.com/user/United4Health**

The website will continue to be updated to ensure that post project, deliverables and further dissemination is available!

6. Partnership

6.1 Consortium members

Scotland (UK):	NHS 24 (Project Coordinator)
Czech Republic:	UPOL, Northwest Moravia
Denmark:	Region of Southern Denmark
France:	Vigisanté Telecom Bretagne – Institut Mines Telecom French Ministry of Health
Germany:	Phlegewerk Managementgesellschaft
Greece:	5 th Regional Health Authority of Thessaly and Sterea e-trikala Digital Cities of Central Greece SA Hellenic Ministry of Administrative Reform and E-Governance
Italy:	Campania regional healthcare Agency – ARSAN Local healthcare Authority ASP Cosenza, Calabria Veneto Region – Arsenal IT
Norway:	Sörlandet Sykehus, SSHF University of Agder Norwegian Centre for Integrated Care and Telemedicine
Poland:	The John Paul II Hospital in Krakow
Slovenia:	General Hospital Slovenj Gradec, SBSG Ravne healthcare Centre
Spain:	Osakidetza, Basque Country Kronikgune, Basque Country Public Health Authority in Galicia (SERGAS) Agencia de Qualitat I Avaluacio Sanitaries de Catalunya (AQuAS)
Wales (UK):	Hywel Dda University Health Board
Finland:	South Karelia Social and health Care District (Eksote)
Multinational organisations:	AIM COCIR Continua Health Alliance EHTEL European Wound Management Association GSM Association Health Information Management SA (HIM SA)

For more information on each organisation, please visit:

<http://united4health.eu/partners/>