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Abstract

This reports on visits to deployment sites undertaken to discuss the various aspects of decisions made on the choice of technology at the deployment sites. The report gives an overview of the current situation when it comes to the procurement process, the use of technology in the U4H deployment sites, as well as other aspects.

Key Word List

N/A

Executive Summary

Based on the first European Commission Review report, and after consultation with the members of the Industry Advisory Team, the Project Co-ordinator (NHS 24) and further discussions at the Project Assembly meeting in Norway in June 2014, it was decided that COCIR would coordinate 5-7 site visits with the support of the Continua Health Alliance with the objective to openly discuss the various aspects of decisions made on the choice of technology at the deployment sites. The purpose of this report is to give an overview of the current situation when it comes to the procurement process, the use of technology in the U4H deployment sites, as well as other aspects. There will be another report looking at interoperability issues.

The sites visited were: (1) Galicia in Spain, (2) Cosenza in Italy, (3) Slovenj Gradec in Slovenia and (4) Olomouc in the Czech Republic, (5) Wales and (6) Scotland in United Kingdom and (7) Lappeenranta in Finland. Kristiansand in Norway, was visited earlier and therefore the interview was conducted via a teleconference.

All visited sites were up and running, and on their way to attracting more patients in order to reach their goals. Just two out of eight deployment sites have real problems with meeting the targeted number of patients. One of the obstacles which held back the procurement process was that it took a year for the medical protocol to be agreed upon in the research group. As a result, there was a short time span for the technical procurement and finding the right equipment.

The procurement process was done very differently in each region. One region did not have a procurement, and another bought / leased a service function rather than purchasing technical products. In most of the cases, agreements were made with vendors that had a previous contract relationship and good experience with healthcare. Trust between the vendor and healthcare organisation was considered paramount for the successful deployment of a telehealth system/service. Only one deployment site had an EU wide tender; all others either had local tenders or used research and development procurement processes.

There are two countries (Norway and Finland) that are integrating the U4H telehealth service into their existing infrastructure. One of the objectives for U4H was to give more power to the patients. It was suggested that this could be done by collecting patient data in a Personal Health Record. This implementation and collecting of the data into a PHR has only happened in Finland. Although the initial intention was to share and learn from each other, the regional projects have worked mostly on their own, with limited sharing and cross-fertilization when it comes to procurement and use of medical devices.

Having collected all the data from the different deployment sites in this study, there are three areas that had key implications based on the answers to our questions. They are:

- Scalability and sustainability.

- Knowledge sharing:
  - Different levels of understanding telemedicine / telehealth.
  - Knowledge sharing within the deployment sites.
  - Knowledge sharing between the different sites.

- Governance:
  - Complex model to have all projects move toward a common goal.

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1. Background of United4Health

The project United4Health was established to see how telemedicine could be implemented on a large scale, having the patient in the central role for managing their disease. It also builds on the result of the Renewing Health project. At the same time, it has the ambition to do research on how telemedicine will work for different patient groups. The three pathologies that are studied in this telemedicine project are DM (Diabetes Mellitus, Lifelong Diabetes), COPD (Lung disease; Chronic Obstructive Pulmonary Disease) and CHF (Congestive Heart Failure).

It is hoped that the United4Health deployment sites will progressively converge toward common interoperable architectures.

First goals were set to target more than 10,000 patients with this project. It was also decided that there should be control groups to see how the use of telemedicine was affecting patients' health.

In summary[1], United4Health should demonstrate, once and for all, through the deployment of services at scale, the benefits of telehealth, and unlock the market for these services in the whole of the European Union. It is hoped it will promote collaboration between EU regions, and establish a network for exchanging successful experiences, best practices and benchmarking.

Industry involvement has been considered essential for the success of United4Health. An Industry Advisory Team (IAT) was established to provide advice to the Consortium from companies and people with profound knowledge of the technologies and the market trends. COCIR is part of this IAT, together with the Continua Health Alliance and GSMA.

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[1] Source: Rasmussen, 2013

2. New Assessment from the Industry

Based on the first European Commission Review report, and after consultation with the members of the Industry Advisory Team and the Project Co-ordinator (NHS 24) and further discussions at the Project Assembly meeting in Norway in June 2014, it was decided that COCIR would coordinate 5-7 site visits with the support of Continua Health Alliance, with the objective to openly discuss the various aspects of decisions made on the choice of technology at the deployment sites.

2.1 Sites visited

This report covers the visit of seven sites, and one site where the interview was performed by teleconference. The sites that have been visited are: (1) Galicia in Spain, (2) Cosenza in Italy, (3) Slovenj Gradec in Slovenia, (4) Olomouc in the Czech Republic, (5) Wales and (6) Scotland in United Kingdom and (7) Lappeenranta in Finland. Kristiansand in Norway was visited earlier, and therefore the interview was conducted via a teleconference.

2.2 Methodology

The interviews took place at the selected sites between the 29th September and the 19th December. They were conducted by Helene Richardsson (HR) representing COCIR and Bridget Moorman (BM) representing Continua Health Alliance. In all sites, the regional project team made a presentation of the project in their region; this brought about open discussion and answers to the questions provided to the team before the site visit. The questions sent beforehand are presented in Appendix A. BM did not attend the meetings in Spain; she did visit Norway in June 2014. Due to time restrictions, HR's interview with Norway was conducted through a teleconference.

The professionals participating in the interviews were chosen by the different sites. All names are listed under each site visit report. They were members of the clinical staff who knew the content and organisation of the telemedicine intervention, along with the site project leader and people involved in the procurement process. The site visit questions were sent in advance, and there was time to ask clarifying questions. The meetings were recorded, notes prepared for all of the meetings. A summary of each visit is presented in Appendix B.

3. General observations from industry

Having collected all the data from the different deployment sites in this study, there are three areas that had key implications based on the answers to our questions. They are:

- Scalability and sustainability.
- Knowledge sharing:
    - Different levels of understanding telemedicine / telehealth.
    - Knowledge sharing within the deployment sites.
    - Knowledge sharing between the different sites.
- Governance:
    - Complex model to have all projects move toward a common goal.

3.1 Scalability and sustainability

3.1.1 Short term perspective

Most sites had a short-term perspective when choosing a technical solution. They concentrated on reaching their goals rather than looking at a service that can be both scalable and sustained over a longer time. The Cosenza site was very open about the fact that this is the first time they were involved in a telemedicine / telehealth project as well as participating in an EU project. They were there to learn and are eager to understand telemedicine better.

Scotland, which has an established telehealth division, looked upon this as a chance to see what technical solutions would best fit their service requirements, and opted for three different solutions in three different regions, as all three had different levels of telehealth service implementation. This was surprising, as Scotland had the largest number of patients to recruit, and implementing one solution might have shown the benefits of scaling and sharing the same experience.

3.1.2 Buying from existing national procurement framework agreements

There are sites that have not done any formal procurement due to the fact that they have access to and are using existing framework agreements. If these agreements were tendered a few years ago, they might not have the interoperable functionality specifications within them, and therefore the sites might end up with devices / systems that cannot be used for an integrated solution in the future. This makes them less scalable as well as less sustainable for the future.

3.1.3 Manual handling of data

Another reason for having a short term perspective was to be able to use the free software and sensor devices that were provided by the vendor. Looking into the solution (Italy) we can see that there is a lot of manual handling of data. Will it be possible in the long run to have a doctor or nurse manually move data from one source to another when there are larger populations using the telehealth service?

The other interesting aspect of manual data handling was the sites which allowed patients to manually enter the sensor data into tablet / mobile phones / computers. This tended to introduce several data entry cycles into the workflow in order to ensure a high level of data quality and veracity. In one case, the deployment site modified the data entry notation to include a meta-tag which identified if the data entered had been done manually or automatically, to better communicate to the clinician the data provenance.

From a clinical perspective, there are two different opinions regarding allowing patients to enter their data manually. Some clinicians realise that the veracity of manually entered data can be suspect, and therefore may not give it as much value when they are reviewing the data and how they might affect the patient therapy, so would prefer automatic data transmission upon measurement. Other clinicians want the patients to be aware of their personal physiological measurements, hoping this will lead to promoting a more active role for the patient in the management of their chronic condition.

3.1.4 Scalability

If telehealth is going to be used on a large scale, there is a need to integrate existing EHRs and/or PHRs with the data collected from different devices. There are existing interoperable solutions that could be used, instead of using systems with a lower initial cost that demand more work be done by the professionals. That is time that could be better spent treating patients.

In addition, the issue of scalability becomes paramount as a telehealth system becomes part of standard care. With more patients, their families and clinicians using the system, it must be able to service a larger volume of users and be easily serviceable. Having the data be available in several systems can ease the volume burden on one system, so anticipating the requirement for data integration across the system along with proper data tagging is an exercise that should be part of the telehealth implementation for scale. This process was not clearly evident at the deployment sites; for future projects it should be a goal.

3.2 Knowledge sharing

3.2.1 Different levels of understanding telehealth

If we look at the different sites, we have some that have very little experience of working with telehealth, and others that have been in this area for many years.

For example, Finland has participated both in Renewing Health as well as the EU project SUSTAINS; through that experience, they have a much better understanding of what is needed for a successful telehealth service in the long run. As of next year, they will be using a Personal Health Record that can be accessed by the patients on-line, or via a smartphone; this is being integrated into the overall e-services platform. The hospital organisation is cooperating with the home-care organisation, which in Finland reports upward to the same organisation. In order to achieve their goals within their budget, they will rely upon patients using their own devices.

This is a good example of a system that is scalable and sustainable, and where the governance of the project works within the region. Having this knowledge exchange early on in the project between the deployment sites would have benefited all of the regions / deployment sites from a European perspective.

During our visits, all sites have expressed interest in learning what is going on in the different deployment sites. Until now, there has been limited time at the general meetings for an exchange of information regarding findings and lessons learned, and very few special meetings set up for this type of information exchange.

3.2.2 Knowledge sharing within the deployment sites

At many of the deployment site visits, our meeting was the first occasion during the project at the regional level in which all the participating staff of the deployment team sat down and talked to each other. Previously, there were usually separate meetings that were functionally based, and within one group of professionals. We understand that the reason for this approach is the fact that the healthcare organisation needs to treat patients; however, it was clear that our visit and the subsequent multi-disciplinary gathering was both appreciated and needed.

3.2.3 Knowledge sharing between the different sites

During our visits, all sites have been very keen to hear what has been going on in the other sites. Despite the Project Assemblies that usually take place every six months, there was a desire and urge to listen and to learn from other sites; "How are we doing? Do they have different solutions, etc?" When discussing this issue, it was clear that no one thought they had the time to do this knowledge sharing during the Project Assemblies, nor afterward. All of the sites are occupied with meeting their own recruitment and service goals. From a European perspective, a preliminary and ongoing knowledge sharing function to include all aspects of the project might have helped some sites avoid mistakes.

3.3 Governance

This is a very large, complex project with many partners that understandably brings about different perspectives regarding the overall aims and scope of the project. Each region had a different perception of what project participation meant to them. For example, in Wales and Scotland, it was inferred that the patient recruitment targets were perceived as *feasible patients to be recruited* rather than a set target for the deployment sites.

The common goals of the project are as follows: *"United4Health should demonstrate, once and for all, through the deployment of services at scale, the benefits of telehealth, and unlock the market for these services in the whole of the European Union. It will promote collaboration between EU regions and establish a network for exchanging successful experiences, best practices and benchmarking."* In order to achieve this, there seems to be a need for an overall governance model that takes this into consideration. As it is now, all effort is going into to delivery according to the set plan, rather than reaching the overall goal of the joint project. Attaining these goals should be the goal of the U4H steering committee.

4. Findings from the questions

4.1 Overview

Project time issues

All sites have said that they had little time to get the deployment site up and running on time for the project. They had to implement a technical solution very quickly so as to not slow down the process of recruiting patients. The major reason for this was the late delivery of the medical protocols set by their scientific committee. It took almost one year to understand the complexity, and to negotiate it among all participating sites.

Use of interoperable solutions

The project could not require that deployment sites procure standards based solutions (for example Continua certified devices), although the Industry Advisory Board did deliver an educational workshop on the benefits of standards and interoperability in month six of the project, and equipped deployment sites with a check list to inform their discussions with vendors. Nevertheless, standards and interoperability were not a mandatory requirement in most of the sites. In those sites that did specify some standards based solutions, the vendors balked and stated the prices would be higher and that the devices were not available in the local marketplace. All sites do wish to use open-standard based products as much as possible, but they had to take into consideration the need for a solution that was up and running before the project would end.

Patients using telehealth services

During the site visits, we had the chance to see the systems up and running with patients using the system. As for patient empowerment, most of the patients stated they have a better picture of their health and they can have a direct conversation with the health professionals when needed. In one case, a patient stated that the telehealth system provided the external discipline for measuring key physiological parameters in a timely fashion. Use of the system became part of their daily routine. Most patients required informal caregivers to assist them in using the system; this informal caregiver dimension was significantly important at times when the clinicians recruited patients for the deployment.

At the sites where we had the chance to meet with patients (or to see a consultation done remotely); in Italy, Spain, Slovenia and Wales it was clear that the patients are very fond of the system and service. They all expressed that they feel much more secure since they know that they are looked after on a daily basis. One patient said that she used to go to her doctor once every second or third week; however, after using this system, she now she just needs to visit every third month.

Not only did the patients save time going to the hospital / clinic for their test, they brought the devices with them during the day to use *outside* their house as well. The systems designed with mobility allowed the patients to live their lives, while also allowing them to meet therapy guidelines.

The use of tablets and mobile phones differed across the sites. Two regions wanted patients to bring their own device. In other sites, patients could use the phones / tablets for their personal use if they paid for the incremental increase in telecommunications costs. However, in most places this was not possible due to restrictions from the healthcare organisation.

During the visits, it became clear that nurses that have direct contact with the patient in their home need to be a person who is a telehealth "evangelist" and comfortable in the use of ICT. We did interview a nurse who was not comfortable with mobile phones, and therefore was not keen to promote this system or service to her patients.

Education of the patients

Most patients are trained by an appointed nurse in charge of telemedicine in the area; however, there were cases where the doctors interacted directly with the patients and the telehealth service (Italy, Slovenia, and Czech Republic).

It is important that the patients have someone to call if there is issue with the devices or system. The most common failure was that the phone had not been recharged (battery management issues). If there was an issue, the patient would call the telehealth nurse. In most sites, this is done by the nurse that sees the patient in their home. In Galicia, Spain, this was outsourced to a telecom-company, taking care of all the functionality of the telecom and system, leaving care to the healthcare organisation. For the deployment sites, when they received a call from the patient regarding a system issue, they would resolve it by calling the pertinent service line of the vendor providing the service. This service tended to divide into two different types: telecommunications service and platform / devices service.

All sites have written explanations / tutorials for the patients on how to use the different devices in their own language, and also offer either clinic / hospital based or hands-on training in the home.

Targeted number of patients

During the site visits, the total number of enrolled patients were recorded against the targeted number of patients.

Table 1: Number of targeted patients

Pathology	Scotland	Wales (UK)	Southern Norway (N)	Slovenia (SL)	Calabria (IT)	Galicia (ES)	North Norway (N)	South Karelia (FI)
DM	1200/ 4400	400	0	400	250	0	0	150
COPD	838	200	200	0	0	500	200	0
CHF	1250	0	0	200	0	0	0	0

Table 2: Number of enrolled patients as at 6th October 2014

Pathology	Scotland	Wales (UK)	Southern Norway (N)	Slovenia (SL)	Calabria (IT)	Galicia (ES)	North Norway (N)	South Karelia (FI)
DM	0/1544	90	0	314	197	0	0	40
COPD	15	38	17	0	0	176	0	0
CHF	42	0	0	101	0	0	0	0

*Scotland has not included any of the SMBG DM patients (1200) at that time, but part (1544) of the My Diabetes My Way registrations (4400).

4.2   Patients' recruitments

Availability of medical protocols

One of the largest obstacles contributing to the procurement processes and technical systems fielded was the fact that the medical protocol for recruiting the patients was not agreed upon until one year in to the project.. This made it difficult for the sites to both recruit patients and at the same time find technical solutions that would work on a large scale. All sites who had procurements needed to include the medical protocol in their procurement specifications, so this delayed the procurement process.

Patient recruitment at hospital

It was also highlighted that for the COPD patients, there was the requirement that patients be recruited directly from the hospitals, which was difficult as the patients were quite sick when being hospitalised, and interest was lacking at that particular time for them. One way of overcoming this issue has been to present the telehealth service to them while they are at the hospital and then re-visit and recruit them once they are back home in a safer environment.

Patient family support

When talking to the patients, it has often been the case that another family member has helped with the equipment as well as transmitting the data. They are a team that are both involved in this project, and they want to contribute to research that can help others to have a better way of living. Moreover, this family or informal caregiver support has at times become a key criterion for ensuring recruited patients are able to participate in the project.

Other ways of build patients' interest

In Slovenia and Wales, the project coordinator has worked with patient organisations who are trying to recruit people with diabetes from places outside the healthcare organisations. These organisations have asked for demonstration kits and, for example, have demonstrated the devices and recruited patients at shopping malls and patient organisation meetings.

4.3 Regional vendors

In all instances, there has been communication with vendors in the regions to different degrees. The chosen vendor to work with has usually been a vendor that the healthcare organisation had experience with from the past, and that they trust. For example, based on national procurement legislation, the Czech Republic had as their chosen solution a system developed by an Israeli software developer in cooperation with a local telecom and medical device distribution company.

In Spain, they invited vendors to open meetings in order to get a better idea of what to use in this specific project. Ninety vendors attended the meetings and forty-one provided feed-back. All vendors needed information about the healthcare enterprise infrastructure which was made available for the vendors on the hospital web-site.

4.4 Procurement process

We observe a variety of procurement approaches:

- Procurement of a functionality solution rather than devices and a system.
- No procurement:
  - The vendors gave away the software and devices.
  - Bring your own devices: the project provided the portal / platform in which the patients used their own devices to enter the data.
  - Re-use of existing devices from the EU project Renewing Health/
  - Costs were under the EU procurement level, so use of research and development procurement processes.
  - Use of existing national framework agreements for acquiring needed devices / systems.
  - Construction of a consortium in order to be able to buy from one consultant / vendor who had the required experience and knowledge in implementing telehealth systems.
- Procurement on EU-level.

Reasons for choosing a functional solution

Spain chose their solution since they wanted to be able to concentrate on the patient rather than on technical issues. They had three open meetings with vendors, and all of the material could be accessed on their website. They had 41 vendors provide feed-back on the procurement. The solution they chose is a solution where a telecom company is in charge of everything. They install the system in the patients' home and manage any problems with the devices / system. This allows the clinical team to focus on providing the telehealth service. According to the project team, this is a key success factor for the project in their region.

Reason for no procurement

In Italy no procurement was done since they did not have the money to buy new equipment, and it was not covered by the project. They wanted to have a solution that was up and running as soon as possible; they therefore used an existing solutions that was available from their current EHR provider (Lifescan / EuroTouch /

One Touch, from Johnson and Johnson). Both the software and devices were given to the clinicians and patients by the vendor. The patients that are asked to participate in the study must have both their own broadband telecommunication connectivity and a personal computer, and must be able to install the necessary software from the web to provide the device data downloading and transmission functionality.

By using existing national framework agreements within the healthcare organisations, a few sites did not have to go through a formal procurement process.

Another reason for not conducting a formal procurement was that in some countries a project that is regarded as a research project and not a normal service within healthcare has other rules and options when it comes to system and equipment procurements.

EU rules for procurement

According to the legislation for public procurement within EU, all member states need to do a formal procurement if the estimated value of the tender will be above 207000€ for certain telecommunications services and R&D services. The Czech Republic went with this option and got a solution that was cheaper than expected and with the required functionality.

4.4.1 Procurement overview in different sites

The following table is an overview of the answers from question 5 and 6 in Appendix A.

Table 3: Summary of procurement

	Procurement?	Solution?	Own qualification?	Vendors' interaction?	Vendors?
Galicia, Spain	Yes	Outsourced	Yes, easy to write	Open meetings	Telefonica and Indra
Cozensa, Italy	No. Suggested solutions cost too much. No budget for it.	Lifescan and given devices	Yes, easy to write	Fancy solutions but could not be used	Lifescan (EuroTouch and OneTouch) (Johnson and Johnson)
Slovenia	One company to deliver all	Health Insight Solutions along with custom front-end for clinicians - New database	Informatic knowledge but no technical experiences.	Italy and Austria	Infonet, company that works in Slovenia and in other ex-Yugoslavian countries.
Czech Republic	Yes, according to EU and Czech national regulations.	Telecom and NESS	Yes, easy to write with the technical specification.	No one was able to deliver Continua devices.	NESS, Vodafone telecom, Westech integration

	Procurement?	Solution?	Own qualification?	Vendors' interaction?	Vendors?
Wales	No need, value under required value as well as defined as research project; they also used national framework agreement	Florence Whzan Docobo	Yes, easy to write with the technical specification, but lack of informatics skills. Connected to telephone line.	No	Simple Telehealth – Florence Link to Florence
Scotland	No need, value under required value; used national framework agreement	Four different solutions:	Yes, easy to write with the technical specification.	Yes	Simple Telehealth-Florence; Microtech-Medvivo Homepod; Patient Safe systems; Diasend
Finland	Yes, three vendors	Application for all smartphones	Building on Renewing Health	Yes	Mediconsult-Medinet
Southern Norway	No, software developed by student and industry partner.	Tablets and software	Yes	Yes, known vendor.	Devo, Norwegian Telecom; Hewlett-Packard tablet with Microsoft OS-locked down

Recommendations on procurement process in this project:

Not in order of importance:

1. Buyers like the vendors to be present in the country / region: If vendors want to succeed in selling telehealth systems and services, they should work through a local partner.

2. Vendors should listen to the needs before recommending a solution.

3. Vendors should build trust with the healthcare organisations and show that their solution has worked in other regions.

4. Buyers should emphasise the need for standards in the devices, as well as at the system interfaces; the vendors should do their best to comply.

5. Healthcare organisations should aim for solutions that can be integrated and interoperable within the healthcare enterprise systems, and not stand-alone solutions.

6. No matter how good the end-devices and systems are, if the broadband connectivity is poor, it is not going to work. Vendors should have tiered solutions available that can be effective in lower bandwidth areas.

7. "Bring your own device" is happening in healthcare; healthcare organisations and vendors should accommodate this.

8. The vendors should look upon the development of system software as a real opportunity to understand the processes in healthcare; many times it will be used and expanded beyond the original clinical workflow intent.

5. Lessons learned and conclusions

All doctors have said they can see the benefits for the patient and their practices, even before the end of the project and the evaluation. They agreed they now have a better way of treating patients, with accurate and timely and sometimes new types of data. They have also said it is easier to make more efficient and timely changes to the therapy and treatment of their patients.

All deployment sites expressed the desire to continue with the service even after the project has ended, and for some of them, even if they are not funded. In more than one place, this type of eHealth / treatment service will be in their strategic documents for their healthcare organisations. Their main concern is ensuring they have the financial and clinical resources to continue the services after the project ends.

Most sites realise that adoption of telehealth is an iterative process, and that as they incorporate telehealth into their standard care, their clinical workflows will change. Also, with the introduction of new technology capability, there will be further changes to the workflows. It is also true that change in clinical workflow expectations will drive technology and system changes. Most of these workflow changes will be due to changes in availability of resources, but also due to the demands of the patients and clinicians.

Overall, the deployment sites had happy patients, and successful systems up and running regardless of their chosen technology.

There are some issues (see those listed below), that need to be resolved before telemedicine / telehealth can take off.

5.1 Integration to existing solutions and care processes

In this project, it is said that telemedicine / telehealth should be integrated with existing solutions in healthcare. However, some routines at hospital level as well as municipality level (homecare) need to be changed in order to make this efficient. This has to deal with how information is shared when a patient is discharged from the hospital (secondary and tertiary care), and how the information is sent to the primary care doctor, etc. Until these issues are solved, we will not see the desired large scale implementation. This is one of the main obstacles that has been identified throughout the visits.

5.2 Focus of the project

After having done this observation into the reality of eight sites that are working with the management of chronic disease patients in their home, we observed the difficulty in mixing research projects with large scale implementation. The aim of United4Health was to prove that telehealth solutions could be adopted and deployed / implemented on a large scale. For all the sites visited, it was reported that it took a long time to agree on common medical protocols, which was a requirement of the EC call for proposals. Many sites feel that it might have been better to use existing ones that are there in the different countries and concentrate on the patients and

their use of telemedicine. We share the belief that this is the biggest reason for perhaps not reaching the first targeted goal of more than 10.000 patients, although we recognise the need for common medical protocols as a key condition for scalability and interoperability.

It seems the primary emphasis of the project and project meetings has focused on the clinical research aspect of the project, and not necessarily on the large-scale system deployment goal. In terms of the initial project agreement, the emphasis probably should have been reversed, with the large scale system deployment being a primary emphasis with the clinical research being a secondary goal. However, it is unknown if there would have been as much high-level clinical involvement in the project if the clinical research aspect of the project had not been emphasised. It is important to have the clinicians involved, as they end up championing the adoption of the telehealth systems as a standard of care; therefore, as a compromise, the research and deployment goals could have a more equal focus versus what is seen currently.

On another note, from a project management perspective, the process used to have all deployment sites agree upon clinical protocols with similar functional system architectures to support the protocols demonstrated that a project-wide (and could be inferred EU-wide) agreement upon 'interoperable' protocols and architectures is possible if there is a strong management focus on meeting this goal and enforcing it. If this type of goal could be extended to include the adoption of open standards based solutions in all of the deployment sites, then technically interoperable solutions could be implemented, which could then be adopted in other regions along with the protocols and architectures.

It is known there is a 'chicken and egg' problem to the adoption of technically interoperable and standards based solutions. The vendors state that the procurers do not require standards based solutions, whereas the procurers say they want standards based and interoperable solutions, but they are not available in their region or there are not enough standards based solutions available to have an effective competitive procurement process. The project and the project management has an opportunity to emphasise the procurement of the standards based solutions by requiring it; this can send a clear message to the market about what the expectations are.

5.3   Different projects, different goals

Another complicating factor, but at the same time enabler, is the fact that most sites are funded by money from different sources. Additionally, some deployment sites are participating in other research projects. This gives a situation where goals can conflict; this makes it harder for knowledge sharing. It also negates the underlying goal of having telehealth be a self-sustaining service which becomes part of the local standard of care. If the funding is ad-hoc and not sustained, then the service will not be sustainable over time and after the project ends.

5.4   Need for a governance model

There is a need for a project governance model that tackles regional and overall knowledge sharing to move toward a common project goal. There are over-arching

models and methodologies used in the project, but they are mostly used for evaluation and to run the separate site projects. It is therefore found challenging to achieve the common goal of United4Health system scaling and integrating into a standard of care.

As described above, the project management leadership influences what is finally implemented across the project. If the leadership focus is weighted towards some goals more than others, the result may not be totally in alignment with the EU expectations. As the project is 50% funded by the EU and 50% by the regions and project participants, the dynamic between trying to meet both the overall EU project goals and the local goals can sometimes be very difficult / challenging.

Having key people emphasise the need of having all the regions agree upon a standard for deployment beyond just the protocols and architectures would have possibly led to a more standardised technically interoperable solution being deployed across the project, and meeting the large scale deployment intent.

With an overall standardised technical interoperable solution agreement in place, procurements might have been more productive and uniform across the project. Additionally, this would have moved towards the goal of having the ability to possibly use a solution implemented in one region moved to another region. This is what can bring about true scaling of telehealth systems on the European level.

Appendix A: Questions to the sites

1. What were you assumptions of the Project to start with? Are you in sync with the goals?

2. If not, what are the obstacles? What is blocking you? How to get around the problem?

3. How are you going to plug it in to your regional/national Health system?
   1. Is there an existing framework on a national level for implementation of eHealth solutions?
   2. How has interoperability been used in this Project?
   3. How will the service be used after the Project has ended?
      1. Who will be responsible for the service later on?

4. Once the data has been produced, what is the strategy for the stakeholders so that they can use it for his/hers specific role?
   1. Who owns the collected data?
   2. Role of the patient?

5. What were the procurement assumptions for not doing it the right way?
   1. Legacy?
   2. Tender?
   3. Language?
   4. Awareness of Products?
   5. Time?
   6. Don't want to change existing Products?
   7. Costs?
   8. Public tender?
   9. What were you not aware of?

   Did you feel that you/the organisation had the qualifications to evaluate the response from the vendors?

6. Did you approach a vendor organization prior to your procurement or did you just send out the tech specification?

7. Is there some incentive for the patient to use telemedicine?

8. How does the patient get recruited, who is in charge of that process?

9. Do you know why your used Product is not Continua compliant?
   1. What have been the answers from the vendor about Continua compliance?

Appendix B: Detailed Country Summary

B.1   Galicia, Spain

	Project coordinator in Galicia, Spain Susana Fernández Nocelo
	Site visit on the 30th of September: Julio Garcia Comesaña, Deputy director of care management and organizational innovation Javier Quiles del Río, Head of TICs, head of products. Susana Fernández Nocelo, Coordinator U4H Blanca Cimadevila Alvarez, Primary care doctor Angelica Fraga Liste, Nurse, giving a demo of the solution.

B.1.1   Reason for visit

The only region which is integrating their United4Health services into their EHR application. They believe that all of their clinicians should have one user interface to review patient clinical information, so they insist that any clinical data be integrated into their EHR. Their experiences will be of value to those regions wanting to integrate remote monitoring / patient generated data into an EHR.

B.1.2   Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Leased tablets that are locked down so they can only be used for the telehealth function
Incentives for patients	Improved care
Comments so far by patients	Want to continue with the service

B.1.3   Present situation

In sync with the goals	Yes
Responsible for recruitment of patients	Doctors and nurses
Integration to other systems	Manually done by nurse into EHR
Main obstacles for implementation	Clinical protocols and patient recruitments, short time to find technical solution. Implementing to existing care process.

Integration to regional or national system	Patient summary
Will you continue with the service even when the project as ended?	Yes, it is now within our hospital strategy document.

B.1.4 Procurement

Did you do a procurement?	Yes
Interaction with vendors	Invitation to open meetings and then feedback from vendors before the call for tender.
Vendors	Telefonica and IT- company Indra
Solutions	Bought technical functionality, including installation as well as problem handling by the telecom company.
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.

B.2 Slovenj Gradec, Slovenia

	Project coordinator in Slovenj Gradec, Slovenia Dr Drago Rudel
	Site visit on the 20th of October: Janez Lavre Director General Marius Kosi, Medical Doctor Cirila Slemenik Pusnik, Cardiologist Metka Epsek-Lenart, MD,CHF lead Apolon Marolt, MD Maja Rakusa, nurse Majda Klanik, nurse Stanislav Pusnik, Lead U4H Slovenia, MD Dr Drago Rudel, U4H Coordinator Dr Zdrav Balorda, project leader, U4H data manager, custom SW developer Dare Oberzan, Eng, patient's support

B.2.1 Reason for visit

Slovenia had no remote monitoring services available until they joined United4Health. They are a good example of a region building a remote monitoring service with no requirements for including legacy systems.

B.2.2   Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Vital monitoring devices/sensors and smart phones
Incentives for patients	Improved care
Comments so far by patients	Want to continue with the service, biggest problem is battery management for the phone and management of telecommunication charges

B.2.3   Present situation

In sync with the goals	Yes
Responsible for recruitment of patients	Doctors
Integration to other systems	Can look at patients' data via a separate front-end application that meets the clinical requirements better.
Main obstacles for implementation	Protocols and the cost for each patient, some mobile connectivity issues.
Integration to regional or national system	No
Will you continue with the service even when the project as ended?	We hope so, but we need money for the devices.

B.2.4   Procurement

Did you do a procurement?	No, they wanted supplier of the system.
Interaction with vendors	Yes with vendors from Austria and Italy; also used vendor fair put on by IAT in Ljubljana.
Vendors	Health Insight Solutions
Solutions	Measuring set-up, connectivity and a simple data and patient system provided by HIS. New database and a custom front end for clinicians.
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.

B.3 Cosenza, Italy

	Project coordinator in Cosenza, Italy Dr Alfonso Longobucco
	Site visit on the 10th of October Dr Francesca Faggiano (diabetician) Dr Alfonso Longobucco (diabetician) Mr Longobucco, translator during the meeting Mrs. Enza Tenzi (nurse) Mr. Francesco Perri (Lifescan - Technology provider) an enrolled patient of Dr Alfonso Longobucco Mariaangela Contenti, consultant for the PA in Cosenza

B.3.1 Reason for visit

We had no input from Italy for the first deliverable, so a visit was required to determine what exactly they are doing.

B.3.2 Patient empowerment

Owner of data	Patient
Patients role	Better understanding of their treatment
Devices used	Patients' own devices, personal computers and internet connections.
Incentives for patients	Improved care
Comments so far by patients	Want to continue with the service.

B.3.3 Present situation

In sync with the goals	Yes
Responsible for recruitment of patients	Doctors (and nurses)
Integration to other systems	Data moved from one system to another manually by doctor, data from patients are sent via gmail.
Main obstacles for implementation	Clinical protocols and the cost for each patient, some broadband issues. No previous knowledge of telemedicine.
Integration to regional or national system	No, no regional EHR.
Will you continue with the service even when the project as ended?	We hope so, but we need money to continue. Not affordable by public healthcare.

B.3.4   Procurement

Did you do a procurement?	No, no money for that in the project.
Interaction with vendors	Yes, but they offered solutions that were too expensive. Needed glucometer strips not available in Italy.
Vendors	Lifescan , EuroTouch and OneTouch (Johnson and Johnson)
Solutions	Lifescan and donated devices. (Business model is the glucometer strips that are provided by the healthcare system in Italy are free to the patients).
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.

B.4   Olomouc, Czech Republic

	Project coordinator in Olomouc, Czech Republic Zdenek Gutter
	Site visit to Olomouc (University Hospital Olomouc) on the 23rd of October. Lukaas Roubik, study coordinator Tereza Pridalova, project assistant Sabina Prochazkova, hospital lawyer Zdenek Gutter, project coordinator David Kula, project manager of Nat. eHealth cent.* Marie Lazarova, Medical Doctor Eva Strakova, project assistant *) National eHealth Centre is located on Cardiology clinic of the hospital.

B.4.1   Reason for visit

Initially, the Czech Republic had a tender which complied with all of the technical specifications as suggested by the IAT. However, due to vendor sourcing limitations and budget constraints, they had to waive the technical specifications and buy the components separately and integrate a system themselves.

We asked them for more details on their procurement process as well as how the integrated the system meets the clinical workflow requirements.

B.4.2 Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Tablets, meters (blood pressure, glucometer and scale) and smart phones
Incentives for patients	Improved care and the possibility to use the tablets to surf the internet
Comments so far by patients	Did not meet any patients in Olomouc.

B.4.3 Present situation

In sync with the goals	Yes
Responsible for recruitment of patients	Doctors
Integration to other systems	No, standalone application.
Main obstacles for implementation	Clinical protocols (selection criteria) and the cost for each patient, patients' capability to operate the devices.
Integration to regional or national system	VPN for communication. No integration with hospital information system. Nationwide EHR does not exist in the CR.
Will you continue with the service even when the project as ended?	We plan to continue with the service as we also own the system, extend number of interventions and flexibly add other capabilities to the system. All plans depend on available resources. Telemonitoring is still is still not reimbursed by health insurance.

B.4.4 Procurement

Did you do a procurement?	Yes, and it had to be the lowest price concept. Two vendors must be able to answer the tender. First call was overruled and an EU procurement was done.
Interaction with vendors	Just a few comments after the call for tender was sent. Had to relax the Continua compliant system requirement in technical specification.
Vendors	Vodaphone Telecom and Westech as integrators, used platform built by NESS; Westech supplied medical devices, Vodaphone supplied the tablets / phone and telecommunications service.

Solutions	Back end and mobile / tablet applications built by NESS. The only application that has the possibility for interaction from the doctor to the patients' devices directly, for example, to order an extra measurement or medication.
Own qualifications to write tender	Good knowledge in informatics but not the technical part.

B.5   Llanelli, Wales

	Project coordinator in Wales, Daniel Warm
	Site visit in Hywel Dda on the 5th of November Daniel Warm, Service Transformation Programme Manager Laura Smith, Project Support Officer Keir Lewis, MD COPD Lead Sarah Hicks, Clinical Lead for Telehealth Claire Hurlin, Head of Chronic Conditions Management Sam Rice, MD Diabetes Lead Anthony Tracey, Assistant Director for Informatics Chris Cottrell, Diabetes Nurse Specialist Jenny Willey, Community COPD Nurse Specialist Helen Rees, Community COPD Nurse Specialist Mark Harries, Community COPD Nurse Specialist

B.5.1   Reason for visit

Wales was from the beginning very knowledgeable on what technologies they needed and how they would procure their system using national framework agreements. They still experienced various technological difficulties and problems with connectivity and product functionalities and capabilities, and had to replace certain products and supplier causing delay in deployment and recruitment.

B.5.2   Patient empowerment

Owner of data	NHS Wales
Patients role	Better understanding of their treatment
Devices used	COPD includes easy to use phones with text functionality, smartphones, tablets, home monitoring devices thermometers and pulse oximeters. Diabetes includes easy to use phones with text functionality (if patient does not already have their own); glucometers (patients' own – the project does not provide one as patients included in the study are already self-monitoring their glucose levels)
Incentives for patients	Improved care and self empowerment

Comments so far by patients	Feels secure and looked after, no need to see the doctor as often as before.

B.5.3   Present situation

In sync with the goals	No (feasible patients rather than goal)
Responsible for recruitment of patients	Nurses, some not embracing telemedicine.
Integration to other systems	Not at present but will form part of future solution where applicable and appropriate.
Main obstacles for implementation	Clinical protocols and recruitments, big problem with connectivity issues. Research and development approach.
Integration to regional or national system	No, need to prove the service before implementing it.
Will you continue with the service even when the project as ended?	The service will be integrated in our next strategy document for the region.

B.5.4 Procurement

Did you do a procurement?	No, the expected value was under the required value for procurement. Different rules for R&D.
Interaction with vendors	Looked around in the market before choosing Florence.
Vendors	Simple Telehealth - Florence, developed by NHS Hardware: Solcom and Docobo
Solutions	Simple Telehealth - Florence, developed by NHS Hardware: Solcom and Docobo
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.

B.6   NHS, Scotland

	Project coordinator Michelle Brogan
	Site visit in Glasgow on the 7th of November **NHS 24 / SCTT, Scotland** Janne Rasmussen, European Engagement Manager Michelle Brogan, Service Development Manager Victoria Hunter, European Project Coordinator Thomas Buchendorfer, Technical Architect **NHS Ayrshire and Arran** Kathleen McGuire, Long term conditions and Community Ward Manager Sharon Callaghan, Service Improvement Facilitator Jim McNeil, Finance Manager Andrew Elliot, Head of procurement Derek Gemmell, Head of eHealth Service Delivery Natalie Berry, Project manager **NHS Greater Glasgow and Clyde** Janice Kinnaird, Project manager Dr Iain Findlay, Clinical Lead CHF Douglas Allan, Service Delivery Manager **NHS Lanarkshire** Morag Hearty, Project Manager Elizabeth Anderson, Respiratory Team Lead Lena Collins, Head of Planning and performance Jill O'Boyle, Senior Office

B.6.1   Reason for visit

In Scotland, the ambition is through United4Health to use technology to support redesign of service delivery across the whole system. Therefore Scotland will deploy the services at real large scale (over 60% of the entire United4Health patient group) and across three different Health Boards and seven local health and social care partnership areas with each their own management structure, budget etc.

B.6.2   Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Easy to use phones with txt functionality, smartphones, tablets, blood pressure machines, glucometers, scales, and pulse oximeters.
Incentives for patients	Improved care
Comments so far by patients	We did not meet any patients

B.6.3   Present situation

In sync with the goals	No (feasible patients rather than goals)
Responsible for recruitment of patients	Nurses

Integration to other systems	No
Main obstacles for implementation	Clinical protocol was not clear from the start, short time to find technical solution, Research and development approach. Clinical criteria not fitting with ours.
Integration to regional or national system	No for CHF and COPD, yes for Diabetes (through Diasend portal).
Will you continue with the service even when the project as ended?	We will see when this project has been evaluated.

B.6.4 Procurement

Did you do a procurement?	No, the expected value was under the required value for procurement. Yes in Lanarkshire.
Interaction with vendors	Some. Hard to get sustainable contracts when you have not got the funding. Lanarkshire did have more contact with the industry.
Vendors(Arran and Ayrshire; Lanarkshire; Renfrewshire)	Microtech was integrator and backend application provider – Samsung tablets and MedVivo Homepod end devices); Simple Telehealth - Florence application; Patient Safe System.
Solutions	They are working with three different systems in order to see what system will fit the best.
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.

B.7 Lappeenranta, Finland

	Project coordinator South Karelia Mira Pakanen
	Site visit in Lappeenranta 12th of November Mira Pakanen, project coordinator Eksote Mikko Rautio Medi-IT purchasing Katja Rääpysjärvi, Eksote Nora Jaatinen, Medikonsult Oy Tuula Karhula , MD,PhD, Director of the Health and Elderly Services Eksote Riitta Lehtonen, Eksote

B.7.1 Reason for visit

Finland was involved in Renewing Health and continued into United4Health. They are unique in their decision to scale up the remote monitoring services to their

region's population in general. They have built a region-wide Personal Health Record system, so their lessons learned in scaling will be of benefit to regions interested in serving larger populations with remote monitoring services

B.7.2 Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Patients' own smart phones and glucometers, pedometers and scales
Incentives for patients	Improved care
Comments so far by patients	We did not meet any patients

B.7.3 Present situation

In sync with the goals	Yes
Responsible for recruitment of patients	Nurses
Integration to other systems	Yes, the collected data is uploaded to a Personal Health Record which is part of their e-Service platform (Hyvis.fi).
Main obstacles for implementation	Recruitments of patients, not so much time allocated to work in the project (they were the only previous Renewing Health participant that was involved in U4H).
Integration to regional or national system	Yes, public platform accessible via internet for patients.
Will you continue with the service even when the project as ended?	Yes, it will be used for the population.

B.7.4 Procurement

Did you do a procurement?	Yes, three vendors
Interaction with vendors	Yes with vendors from Austria and Italy
Vendors	Mawell, Fujitsu and Mediconsult (the PHR and mobile phone software application vendor and integrator) build product called Medinet
Solutions	Application that will be available on all smartphones.
Own qualifications to write tender	Good experience from both Renewing Health as well as SUSTAINS, both EU projects.

B.8 Kristiansand, Norway

	Project coordinator Kristiansand, Norway Wenche Tangene
	Site interview 27th of November Professor Rune Fensli Professor Frode Gallefoss 19th of Dec

B.8.1 Reason for interview

In their tender for a system, they specified Continua compliance, however, they discovered some stability issues with the Android platform that would not meet their regulatory / privacy and security requirements. They have built a Personal Health Record network, which is unique within United4Health, and may be a solution for security and privacy concerns regarding inclusion of patient generated data into EHRs.

B.8.2 Patient empowerment

Owner of data	Healthcare organisation
Patients role	Better understanding of their treatment
Devices used	Pulse oximeters and locked tablets
Incentives for patients	Improved care
Comments so far by patients	Want to continue with the service, but need more money in order to do so.

B.8.3 Present situation

In sync with the goals	Yes, slowly growing numbers
Responsible for recruitment of patients	Doctors and nurses

Integration to other systems	No. Separate patient record, will integrate after deployment manually; Norwegian laws require clinician to enter information; use hospital based EHRs.
Main obstacles for implementation	Clinical protocols and recruitments. Delays by the IT-department.
Integration to regional or national system	Yes, are using a secured VPN connection.
Will you continue with the service even when the project as ended?	Yes, we hope so, but we need some more money. It is not part of our regular budget.

B.8.4 Procurement

Did you do a procurement?	No, software developed by students
Interaction with vendors	Yes, known vendor
Vendors	Devo, Nortel (VPN)
Solutions	Used locked down Microsoft tablets and software developed by students
Own qualifications to write tender	Yes, easy to write the specification due to recommendations from the project.