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Towards Interoperability: Findings and Recommendations
Version 1.0

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Abstract
The European Project United4Health aims to demonstrate the ‘normalisation’ of the provision of remote monitoring in the continuum of care for the management of the chronic diseases of congestive heart failure, diabetes and chronic obstructive pulmonary disease. This document describes the general system architectures to support these conditions, and each deployment site’s specific implementation of these architectures, along with an analysis of their progress towards standards-based solutions. In closing, the report discusses the status of the telehealth industry and its interoperability in Europe generally, including the facilitators and barriers, before moving to a set of recommendations.

Key Word List
Chronic conditions, chronic diseases, CHF, COPD, diabetes, deployment, interoperability, standards, telehealth, telemedicine, telemonitoring

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Executive Summary

The United4Health project (www.united4health.eu) has been driving telemedicine deployment in Europe between 2013 and 2015. Fourteen regions all over Europe have introduced telemonitoring technologies into their normal delivery of healthcare to monitor and treat patients with four chronic conditions: diabetes, congestive heart failure, chronic obstructive pulmonary disease, and hypertension. They aligned their treatment protocols, but deployed technologies and systems according to their local circumstances.

This report provides a final technical summary and analysis of the United4Health deployment sites’ technical solutions. The key findings from this analysis include:

- **Preference for outsourcing**: Several regions outsourced the complete remote monitoring / telehealth solution; at times, this introduced a discontinuity in the clinical workflow which became evident when the decision was made to integrate the service into normal healthcare delivery.

- **Slow integration with electronic health records**: Only some regions integrated data from remote monitoring into their regional electronic health / medical records; this reflects technical limitations, but also a concern among healthcare professionals about the quality and veracity of data.

- **“Bring your own device (BYOD)”**: Four out of 14 deployment sites expected their patients to supply their own medical devices, computer gateways (mobile or home-based) and/or internet connections for the remote monitoring service. Many services also relied on patients’ home data networks and mobile phone contracts, thus asking them to share or bear the cost of communication.

- **Manual data entry prevails**: In ten out of 14 regions, patients entered data manually into the gateway (mobile / smartphone, tablet or laptop), especially for devices which are patient owned (usually glucometers and weight scales).

- **Standardised networks…**: Standardised electronic network protocols such as Bluetooth or GSMA were used in all regional implementations.

- **…but proprietary message formats**: In almost all sites, messaging and data formats were proprietary, reflecting the dearth of standards compliant products, as well as local preferences and conditions.

- **Mobile devices**: Smartphones and tablets were used as gateway devices in 11 out of 14 of the deployment site solutions.

- **Trend towards web portals**: Seven out of 14 sites asked patients to use web portals to input and send data to the remote healthcare provider. Web portals have a number of technical advantages including easier development, deployment and upgrade paths, flexible access from mobile phones, tablets and computers, and easier accommodation of patient owned devices.

- **ICT network quality affects telehealth**: The quality of the patient home and regional networking capability continues to limit remote monitoring or telehealth services. Some regions with poor ICT coverage require that vendors offer alternative options to mobile data transmission, including wired, landline telephone, and lower level wireless / mobile network protocols.
Patients require assistance and training: Most of the patients like the systems, however many have needed assistance to use them. Many sites in U4H had the luxury to choose the patient cohort, but as services become part of normal care, patients and their carers may require more technical and clinical assistance to ensure good service provision outcomes.

In addition to these general findings, the report also delivers an assessment of the technology used in the sites in terms of their compliance with interoperability requirements. The authors distinguish between four levels of interoperability:

- **Foundational** interoperability allows data exchange from one information technology system to be received by another.
- **Structural** interoperability defines the syntax of the data exchange.
- **Semantic** interoperability connotes the ability of two or more systems to use the information that has been exchanged.
- **Clinical workflow** interoperability denotes the compatibility of telehealth monitoring with the existing healthcare service.

The authors assessed all deployment sites on their performance. No site achieved the highest level, currently available interoperability. All sites have used “foundational” data exchanges, and most achieved structural interoperability, meaning the receiving machine “understood” the data it received. Only a few have made progress towards semantic interoperability, where a receiving system (such as an electronic health record system) was able to use and action the data it received. One reason was that not all sites sought to integrated telemedicine with electronic health record systems (some sites did not have such a system). The critical limitation is that almost none of the sites have relied on the available standards or profiles for information exchange. This goes against both the project’s professed intention to use technology that complies with interoperability requirements, and against recommendations from the Industry Advisory Team.

Why did the sites make the choices they did? They had to procure technologies that worked with their systems and processes, and often showed a preference for working with existing, local vendors. In many cases, sites chose to completely outsource the technology, while in at least one case technology was used that came for free, further limiting the sites’ choices. In those cases where sites issued tenders to procure best available technology, the markets failed to deliver, for various possible reasons: the market was too small, the tender volume too limited, the development timeline too ambitious, or the costs for interoperable solutions too high. There are signs that the market for telemedicine suffers from a “chicken and egg” problem: procurers do not demand interoperability compliant solutions because they are not available in sufficient numbers to make public tenders possible, therefore vendors do not bring such solutions to market.

There are encouraging signs that this market failure is being addressed. The European Commission situation has developed an eHealth Interoperability Framework that gives industry profiles such as Continua and IHE formal recognition. Some European health ministries have developed telemedicine action plans that provide guidance or mandates to pay attention to standards and interoperability in their technology procurements. And many procurers have started to send signals to their vendors that they will give preference to interoperability compliant solutions, if not today, then in the future. If the customer demands interoperability, the market will deliver.
## Change History

### Version history:

- **0.1** 19<sup>th</sup> July 2015
- **0.2** 2<sup>nd</sup> August 2015
- **0.3** 7<sup>th</sup> August 2015
- **0.4** 8<sup>th</sup> August 2015
- **0.5** 14<sup>th</sup> August 2015
- **0.6** 23<sup>rd</sup> September 2015
- **0.7** 26<sup>th</sup> October 2015
- **0.8** 30<sup>th</sup> October 2015
- **1.0** 5 November 2015

### Version changes

- **0.1** Initial draft
- **0.2** General edits, revised structure, changes to sections on U4H and IAT.
- **0.3** Further edits, glossary and references incorporated, consistency of region/site names
- **0.4** Further edits, consolidation of interoperability section, new appendix B with overview tables
- **0.5** Further edits, new executive summary, new findings section and perspectives section, for review of the Industry Advisory Team (IAT)
- **0.6** Incorporation of IAT feedback, version to be validated with sites
- **0.7** Validation with deployment sites in the Prague workshop and many additional comments and contributions
- **0.8** Inclusion of IAT comments and edits in final version for submission.
- **1.0** Final version with comments from project management integrated.

### Outstanding issues

None
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1. **Introduction**

1.1 **Purpose of this document**

The United4Health (U4H) project has been implementing telehealth solutions for the monitoring and treatment of chronic conditions since 2013. Fourteen regions in Europe aligned their medical protocols and service architectures for the four conditions of diabetes, lung disease, heart disease and hypertension. They adapted and deployed these models to their circumstances, using diverse and locally procured technologies, reaching in total more than 10,000 patients. The project has been co-financed by the European Union and will end in December 2015.

The Industry Advisory Team (IAT) in United4Health has supported the project with advice on technical issues and interoperability. Among other tasks, it was asked to analyse the various technological platforms, to provide advice for the evolution of current services and their integration and convergence towards standard platforms, and to monitor progress towards that objective. This document is the second and final report: D5.8 “Towards Interoperability: Findings and Recommendations”.

Before publication, this document was reviewed by the members of the U4H Industry Advisory Team (IAT) and the consortium, and discussed in a workshop with representatives from all deployment sites on 6th October 2015 (see the workshop report D5.7 Interoperability in practice: lessons learned).

1.2 **Structure of document**

- Section 1 details the purpose of this document.
- Section 2 gives a background of the U4H project and the IAT, and briefly defines the term interoperability and describes its role at different levels of system architectures and healthcare service delivery.
- Section 3 describes the U4H generic system functional architectures and clinical protocols that the deployment sites agreed upon to structure their telehealth systems.
- Section 4 is the heart of this report: it gives descriptions of final system implementations and technical architectures for each deployment site along with their follow-on plans for the telehealth services beyond the U4H project timeline. It also offers an assessment of their interoperability performance.
- Section 5 offers a summary of key findings from the U4H pilots.
- Section 6 provides an analysis of the state of interoperability in U4H, puts it in a wider context of market and industry trends, and offers recommendations for all relevant players on how to advance towards eHealth interoperability.

1.3 **Glossary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADSL</td>
<td>Asymmetric Digital Subscriber Line</td>
</tr>
<tr>
<td>APN</td>
<td>Adaptive Private Network</td>
</tr>
<tr>
<td><strong>Abbreviation</strong></td>
<td><strong>Definition</strong></td>
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<td>-----------------</td>
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<tr>
<td>BT</td>
<td>Bluetooth</td>
</tr>
<tr>
<td>BYOD</td>
<td>Bring Your Own Device</td>
</tr>
<tr>
<td>CHF</td>
<td>Congestive Heart Failure</td>
</tr>
<tr>
<td>COPD</td>
<td>Chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CUI</td>
<td>Clinical User Interface</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>ebXML</td>
<td>Electronic Business XML</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiography</td>
</tr>
<tr>
<td>EDGE</td>
<td>Enhanced Data Rates for Global Evolution – also known as enhanced GPRS, a digital mobile phone technology</td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
</tr>
<tr>
<td>Gateway</td>
<td>ICT device which acts as ‘ramp to network’ for data transmission</td>
</tr>
<tr>
<td>Glucometer</td>
<td>A medical device for determining the glucose level in the blood</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner (medical professional)</td>
</tr>
<tr>
<td>GPRS</td>
<td>General Packet Radio Service</td>
</tr>
<tr>
<td>GSM</td>
<td>Global System for Mobile Communications – digital mobile phone technology</td>
</tr>
<tr>
<td>HIS</td>
<td>Health Insight Solutions (a vendor)</td>
</tr>
<tr>
<td>HTN</td>
<td>Hypertension</td>
</tr>
<tr>
<td>IAT</td>
<td>Industry Advisory Team</td>
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<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
</tr>
<tr>
<td>Interface</td>
<td>Point where two computer systems connect and interact</td>
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<tr>
<td>MDMW</td>
<td>My Diabetes My Way (Scotland)</td>
</tr>
<tr>
<td>Pedometer</td>
<td>A device that counts steps and can calculate the distance travelled</td>
</tr>
<tr>
<td>PHR</td>
<td>Personal Health Record</td>
</tr>
<tr>
<td>PIN</td>
<td>Personal Identification Number</td>
</tr>
<tr>
<td>PUI</td>
<td>Patient User Interface</td>
</tr>
<tr>
<td>Pulse oximeter</td>
<td>A medical device that measures the pulse rate and oxygen level in the blood</td>
</tr>
<tr>
<td>SCI-DC</td>
<td>Scottish Care Information-Diabetes Care</td>
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<tr>
<td>SIM</td>
<td>Subscriber Identity Module</td>
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<tr>
<td>SMS</td>
<td>Short Message Service – text messaging on mobile phone</td>
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<tr>
<td>SOA</td>
<td>Service Oriented Architecture</td>
</tr>
<tr>
<td>Spirometer</td>
<td>A device for measuring the volume of air exhaled by the lungs</td>
</tr>
<tr>
<td>SQL</td>
<td>Structured Query Language</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>TPHR</td>
<td>Treatment Pathway Health Record</td>
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<tr>
<td>UMTS</td>
<td>Universal Mobile Telephone Service</td>
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<tr>
<td>USB</td>
<td>Universal Serial Bus</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>VPN</td>
<td>Virtual Private Network</td>
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<tr>
<td>WAN</td>
<td>Wide Area Network</td>
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<tr>
<td>WS</td>
<td>Web Service</td>
</tr>
<tr>
<td>WSS</td>
<td>Web Service Security</td>
</tr>
<tr>
<td>XML</td>
<td>eXtensible Mark-up Language</td>
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2. Background

2.1 About United4Health

U4H is a European project that seeks to deploy and assess the impact of innovative healthcare services for the remote monitoring of patients with chronic conditions. The project includes 19 deployment sites in 14 regions in 10 countries that:

- tested the deployment of innovative healthcare services;
- procured the necessary technology while addressing interoperability requirements; and
- analysed lessons learned and project results to inform health policy makers, regulatory authorities; and other providers seeking to deploy telehealth.

The sites deployed telemonitoring and treatment of patients suffering from diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) or hypertension (HTN). The countries and regions were:

<table>
<thead>
<tr>
<th>Czech Republic</th>
<th>Northwest Moravia</th>
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<tbody>
<tr>
<td>Finland</td>
<td>South Karelia (Etelä-Karjala)</td>
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<tr>
<td>France</td>
<td>Nord Pas de Calais</td>
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<tr>
<td>Germany</td>
<td>Berlin</td>
</tr>
<tr>
<td>Greece</td>
<td>Central Greece (Στερεά Ελλάδα)</td>
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<tr>
<td>Italy</td>
<td>Calabria</td>
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<tr>
<td></td>
<td>Campania</td>
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<td>Norway</td>
<td>Northern Norway</td>
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<td></td>
<td>Southern Norway</td>
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<tr>
<td>Slovenia</td>
<td>Slovenia</td>
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<tr>
<td>Spain</td>
<td>Basque Country</td>
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<td></td>
<td>Galicia</td>
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<tr>
<td>United Kingdom</td>
<td>Scotland</td>
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<tr>
<td></td>
<td>Wales</td>
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</tbody>
</table>

More information about the 14 regions in the consortium can be found on the project website at www.united4health.eu.

Additional partners of the consortium that serve in an advisory function include:
- Continua Health Alliance (CHA);
- European Coordination Committee of the Radiological, Electromedical and Medical IT Industries (COCIR);
- European Health Telematics Association (EHTEL);
- European Wound Management Association (EWMA);
CHA, COCIR and the GSMA formed the Industry Advisory Team, managed by CHA.

2.2 About the Industry Advisory Team

To facilitate input and advice from industry, the project invited three industry associations to join the consortium: CHA, COCIR, and GSMA.

- **CHA** is a non-profit, open industry coalition of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. CHA is dedicated to establishing a system of interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals, and provides the opportunity for truly personalised health and wellness management. CHA has more than 150 member companies including multinational companies and SMEs. Continua was founded in 2006 in the United States; its European office was incorporated in Belgium in 2008. In 2014, CHA joined the Personal Connected Health Alliance, PCHA. (See www.continuaalliance.org.)

- **COCIR**, founded in 1959 and headquartered in Brussels, counts today as its members more than 30 companies and 14 national member associations in the radiological, electromedical and healthcare IT industry in Europe. It supports its members on issues which affect the medical technology sector and works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems. (See www.cocir.org.)

- **GSMA** represents the interests of the mobile telephone industry, with a membership of nearly 800 of the world’s mobile operators from more than 200 countries, as well as nearly 250 other companies in the broader mobile ecosystem, including handset makers, software companies, equipment providers, and others. GSMA’s end goal is to drive the growth of the mobile communications industry. GSMA has offices in the Americas, Europe and Asia, with its headquarter in London, UK. (See www.gsma.com.)

Together the three associations formed the Industry Advisory Team (IAT) to manage the project's work package 5 (WP5), which was tasked:

"[…] to provide advice to the Consortium from companies and people with profound knowledge of the technologies available and of market trends. The [IAT] will bring together experts with competence in management of clinical data, standards, open sources, business trends in the Personal Health System sector, mobile communications, semantic integration, etc."

The main objectives of this WP5 include:

- Bring together a team of experts in several fields from industry leaders in the eHealth sector.
- Manage the communication and knowledge transfer between members of IAT and the Project Team in an efficient and effective manner to secure the success of the pilots and the further scaling up of the services.
- Analyse and advise pilot regions on standards for interoperability between platforms and devices.
- Analyse the regulatory environment to identify barriers to deployment of telemedicine and interoperable, multi-vendor device chains.
- Provide education both inside and outside the project on standards, interoperability and regulatory issues affecting deployment.

The IAT and the overall WP5 have been led and managed by Michael Strübin, Continua Programme Manager Europe. CHA’s principal writer and researcher for the reports has been Bridget Moorman, CHA’s Technical Manager. The main contacts at COCIR and GSMA have been Nicole Denjoy and Helene Richardsson (COCIR), and Rob Childs (GSMA).

2.3 About Interoperability

A principal objective of the project has been to support the participating regions in selecting and deploying technology that is interoperable so that data and information can travel from the patient to the healthcare provider, and (if applicable) to an electronic health record, and back. But what is interoperability?

In healthcare, the Health Information Management Systems Society (HIMSS), the biggest member organisations in this field with worldwide operations, offers the following definition of interoperability: “the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged."¹ HIMSS further distinguishes interoperability as having three successive levels, each of which relies upon the ‘lower’ level to ultimately achieve full interoperability: foundational, structural and semantic.

- **Foundational** interoperability allows data exchange from one information technology system to be received by another. An example of is the ability of a smartphone to connect to a mobile phone network.
- **Structural** interoperability defines the syntax of the data exchange, and ensures that data exchanges between information technology systems can be interpreted at the data field level. An example of structural interoperability is the ability of a remote monitoring system to send a message to an electronic medical record (EMR) system and have the EMR recognise it.
- **Semantic** interoperability is the ability of the EMR system to understand the type of data in the message and place it appropriately where it is best used in the healthcare system.

In addition to these levels of interoperability, there are interoperability domains which can define the type integration required for interoperability. These domains are local, enterprise and community:

- The “local” domain may denote a home or a doctor’s office.
- “Enterprise” can refer to a hospital or a hospital system. In an enterprise, the infrastructure is under central control.
- “Community” can mean a regional network of healthcare providers, or a region or country. The defining feature of a community is that there are disparate infrastructures (for example hospitals, GP offices) that need to interface.

Each domain requires different approaches to interoperability in order to succeed. Within the community domain, governance is typically established by following the principle of federation, which recognises the existence of independent domains governed by their own authorities, while providing agreed interaction standards between these domains. Most of the U4H deployment sites and regions represent a community, so a federated approach with regard to fostering interoperability would be the most appropriate approach. One way to bring about community interoperability is to adopt open standards published by a Standards Development Organisation (SDO).

One way to federate using standards is also to take advantage of a service-oriented architecture (SOA) which:

“is an architectural pattern in computer software design in which application components provide services to other components via a communications protocol, typically over a network. The principles of service-orientation are independent of any vendor, product or technology. SOA makes it easier for software components on computers connected over a network to cooperate. Every computer can run any number of services, and each service is built in a way that ensures that the service can exchange information with any other service in the network without human interaction and without the need to make changes to the underlying program itself. Services are unassociated, loosely coupled units of functionality that are self-contained.”

Use of web-based portals and protocols is one type of SOA. SOA techniques rely upon standards at the interfaces in order to operate.

But interoperability is not just about ICT systems. It also defines how technology is integrated with clinical workflows, and vice-versa. There is an iterative cycle with the adoption of technology systems in healthcare: to be truly interoperable, the technology should not disrupt the clinical workflow. If remote monitoring data is to be integrated into an EHR, then the process by which it is integrated should not be an added burden to the clinical workflow. Ideally, it will improve or enhance the workflow by moving data rather than people, or by replacing simple or routine human tasks with ICT. The underlying technical interoperability brings about better clinical interoperability. This can be seen with some implementations that promote integrated care: by enabling care givers to use a common ICT platform, care

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2 According to this definition, some European regions could be defined as an enterprise or a community, depending on their level of integration and central control.
becomes more integrated and patient-centred, as the data is shared amongst different care professionals.

In U4H, all of these aspects of interoperability were attempted at the deployment sites, although with varying results. As part of this report, we offer an assessment and grading of each deployment site on how they performed in terms of interoperability in each of the four areas (foundational, structural, semantic and workflow), along with notes regarding their levels of interoperability. This grading is done on a scale of 0, 1, or 2:

(0) no interoperability is demonstrated in that particular area;
(1) minimal interoperability is demonstrated in that area;
(2) the best interoperability currently available is demonstrated in that area.

For example, if a deployment site used:

- the latest available networking capability for their system they were given a score of 2 for foundational interoperability;
- HL7 messaging or some other type of messaging standard to send the clinical data to an EMR system, then they were given a score of 2 for structural interoperability;
- a data standard to structure that message (example: IEEE 11073, SNOMED or LOINC), then they were given a score of 2 for semantic interoperability.

For clinical workflow interoperability, a deployment site received a 2 if:

- it is going to use the system (clinical workflow and technical remote monitoring system) or an evolved variation of the system as part of their standard care following the project;
- it truly integrated the technology and affiliated workflow into their existing systems, for example by:
  - making the remote monitoring information available in their EMR;
  - de-centralising the service and making it available across a region or regions; and/or
  - training most clinicians who would be treating the chronic condition to use the service.

Most of the pilot sites got 2’s in the foundational interoperability, while none of them got 2’s in the semantic interoperability. More than half received a 2 on clinical workflow interoperability.
14 U4H regions trialled the remote monitoring and treatment of chronic patients living with diabetes, COPD or cardiovascular conditions. The services were designed to give patients a central role in the management of their own diseases, allowing clinicians to fine-tune the choice and dosage of medications by more closely tracking patient response using the remote monitoring data, promoting compliance with treatment, and helping healthcare professionals to detect early signs of worsening in the monitored chronic conditions. There are three main differences between the U4H project and its predecessor project, Renewing Health.

- The nature of the U4H trial was observational, while the Renewing Health project conducted a randomised controlled trial.
- The telemedicine service in U4H was to be integrated into the regular continuum of care, i.e. be offered to any patients who meet the entry criteria and the clinical protocol, versus a separate stand-alone research project.
- All regions had to work towards a common clinical protocol for each chronic condition. Measured data were the same across all of the pilot sites.

The main purpose of U4H was to ‘normalise’ the provision of telemedicine services into the healthcare delivery process, while secondarily furthering the clinical research regarding the efficacy of telehealth for chronic condition management.

All pilot projects in the U4H programme treated at least one, and sometimes two or three chronic conditions: Diabetes, Chronic Obstructive Pulmonary Disease (COPD), and Congestive Heart Failure (CHF). One site (France) focused only on Hypertension (HTN).

3.1 Diabetes Mellitus (DM)

Diabetes mellitus (DM), also referred to as diabetes, is a metabolic condition in which patients suffer from high blood sugar (or glucose) levels because their body has lost the ability to regulate it through insulin. Patients with type 1 diabetes develop the condition at a young age due to genetic defects; patients with type 2 diabetes acquire the condition as a result of lifestyle and diet. Patients with diabetes should monitor their glucose levels and take appropriate action if the level gets too high or low. Diabetes can be managed, and complications can be avoided, if patients maintain a healthy diet, engage in physical activity, and (if necessary and supported by their GP) regulate their blood sugar level through medication (including insulin). Almost one in ten adults has diabetes, with trends going up. Thus diabetes presents a compelling case for remote monitoring and telehealth.

Figure 1 below depicts the system architecture that all pilot sites participating in the diabetes pilot were asked to implement.
The goal and clinical protocol are as follows:

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

- The patient at home uses the device provided, a blood glucose meter or glucometer, to measure blood glucose levels. The device, used by the patient, collects the data and sends them to the gateway automatically.

- The gateway device transmits data collected by the patient to the server of a Regional eHealth Centre, where they are processed according to local policy, i.e. the data can be made available or forwarded to the appropriate person.

- The telemonitoring software allows healthcare professionals to monitor and manage the data as agreed locally, including the provision of a summary and access to the web based portal to monitor the patients’ health conditions at any time.

### 3.2 Congestive Heart Failure (CHF)

Congestive heart failure (CHF), also known as chronic heart failure, congestive cardiac failure (CCF), or heart disease, occurs when the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs. Symptoms include shortness of breath, excessive tiredness, and leg swelling. In developed countries, around 2% of adults have heart failure, a percentage that rises to 6-10% in those over the age of 65. In the year after initial diagnosis, more than one third of patients die; after the first year, the risk of death decreases to below 10% each year. Thus, remote monitoring of patients with heart disease seeks to prevent deterioration of the condition through monitoring heart rate, blood pressure, and body weight.

Figure 2 below depicts the system architecture that all pilot sites involved in the CHF pilot implemented.
Figure 2: CHF system architecture

The goal and clinical protocol are as described below:

- The patient at home uses the provided devices for the measurement of heart rate, blood pressure, pulse-oximetry and weight (in accordance with the treating physician’s prescription, but at least once per week). Reminders are sent if the centre did not receive measurements for longer than a week, including a specific question: “Do you feel worse than last week?”
- The telemonitoring devices used by the patient collect the data and send them to the gateway wirelessly. The gateway device then transmits the data collected by the patient to the system server.
- An operator checks the data sent by the patient, accessing them through the portal.
- In the case where clinical parameters are outside the normal range, as set by the treating physician for each patient, the system’s software detects the alert and the operator manages it, following the standard protocol set by the physician. He/she contacts the patient to verify the alert. If the alert is verified, depending on its severity the operator contacts the reference clinician for that patient or follows the alert procedure.
- After notification from the operator, the clinician accesses the relevant portal to check patient data and take the appropriate actions.
- Clinicians can monitor the patients' health conditions via the portal at any time they would like, and not only in the case of an alert.

3.3 Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD), also known as chronic lung disease, is a type of obstructive lung disease characterised by poor airflow. The most common cause is tobacco smoking, but environmental and genetic factors can also play a role. The condition typically worsens over time. Its main symptoms include shortness of breath, cough, and sputum production. Exacerbations of COPD
often leads to hospitalisation, but appropriate treatment, including regular measurements of pulse and blood oxygen at home, can prevent repeated hospitalisation and improve quality of life.

Figure 3 below depicts the system architecture that all of the pilot sites involved in the COPD chronic condition implemented.

The clinical protocol is:

- A patient admitted with a COPD exacerbation is discharged from hospital and provided with a telemonitoring package that includes video conferencing and a pulse oximeter.

- The telemonitoring intervention is conducted at three levels:
  1. High Level Telemonitoring with daily tele-consultation (preferably via video-consultation or telephone if not possible): pulse oximetry data and daily symptom questions are uploaded prior to the tele-consultation, and provide a partially standardised structure to the interview. The projected timeframe for this level of telemonitoring is 10 working days after discharge, but could range, depending on individual circumstances, from five days up to 30 days.
  2. Moderate Level Telemonitoring: following the high level telemonitoring stage, patients upload daily their pulse oximetry data and symptom questions for up to 12 weeks (a minimum of four weeks) after discharge. Tele-consultation with a health professional is no longer part of the routine.
  3. Low Level Telemonitoring: After the end of the moderate level telemonitoring phase, patients can receive behaviour prompts via text message or website links to a smartphone for up to 12 months after discharge. They also keep the option to submit their answers to symptom questions, but no longer send pulse oximetry or other data.
Data recorded during High and Moderate Telemonitoring includes: pulse, oxygen saturation, and patient answers to six pre-selected questions on symptoms.

The respiratory nurse specialist contacts the patient for either video / telephone review or a home visit, or advises the patient to attend the hospital according to their discretion. Criteria for hospital treatment follow local protocols.

Figure 4 depicts the intervention timeline model.

![Figure 4: COPD intervention timeline](image)

### 3.4 Hypertension (HTN)

Patients with hypertension (HTN), also known as high blood pressure or arterial hypertension, suffer from a chronically elevated blood pressure in the arteries. Hypertension usually does not cause symptoms initially, but sustained hypertension over time is a major risk factor for heart disease, coronary artery disease, stroke and a number of other medical conditions. Dietary and lifestyle changes can improve blood pressure control and decrease the risk of health complications, although treatment with medication is still often necessary in people for whom lifestyle changes are not enough or not effective.

The figure below depicts the system architecture implemented by the pilot site (France) involved in the HTN chronic condition.
The goal and clinical protocol are described below:

- Each time the participant executes a measurement with these devices (sphygmomanometer, weight scale, etc.), the results are automatically sent to the information system which stores and analyses them.

- A web portal is available to the participants and medical staff to access the collected results and some additional information:
  - General information about the programme (available to everyone).
  - An e-learning module available to all the persons who have participated in the screening programme (but not necessarily entered the healthcare programme).
  - A complete view of the participant’s file, available only to the participant in the healthcare programme and authorised medical staff (the information available is restricted and limited depending on who accesses the file).

- Email and SMS notifications can be sent to the participant and to the authorised medical staff (if agreed to at registration).
4. Technical setup of all deployment sites

The following sections describe and analyse the technical setup in each deployment site. They are ordered alphabetically by country, analogous to the list of all regions in section 2.1. A summary of key findings across all deployment sites is provided in section 5.

4.1 Northwest Moravia, Czech Republic

Northwest Moravia participated in U4H with the chronic conditions of diabetes and CHF.

According to the study protocol, each enrolled diabetic patient received a mobile gateway (a smartphone or tablet), glucometer (with test strips), weight scale, blood pressure monitor and pulse oximeter based on their chronic condition. The patient was appropriately educated and obtained training materials. An Android application called Medimonitor with user friendly interfaces ran on the smartphone (or tablet) as the gateway. Data and other measured values from the devices were sent to the telehealth portal and stored in the database. The information was then accessible to medical staff and telemonitoring centre operators (clinicians, nurses and biomedical engineers) via web browser and secured login. The telehealth portal and Medimonitor were developed according to the requirements of the hospital.

The following devices were used in the CHF pilot: weight scale (A&D Medical UC-351PBT-Ci), upper arm blood pressure monitor (A&D Medical UA-767PBT-Ci), wrist pulse oximeter (Chiocemed), and Samsung Galaxy Tab 3 8.0 (the gateway device on which the Medimonitor app is installed). For diabetes, the devices were a glucometer (Fora Diamond Mini) and mobile gateway (4.5 inch Android Samsung Galaxy Express 2). Wireless data transmission was between medical devices and gateway (via Bluetooth) and between gateway and system servers with databases (via GPRS/EDGE/3G). The Medimonitor app was developed on request by Ness Solutions and Services. The patient portion of the application was contextual, i.e. the information shown to the patient at any one time is relevant to the user's current task, as against showing a hierarchical set of folders from which a patient would need to choose. Data and other measured values from the devices were sent to the telehealth portal and stored in a database. The information was then accessible for medical staff (clinicians, nurses and biomedical engineers) via web browser and secured login.

The authors' assessment of the Northwest Moravia pilot in terms of interoperability is as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundational</td>
<td>2</td>
<td>Uses networking standards and HL7 messages. Stand-alone system; does not use data standards. Telehealth program is not fully incorporated into standard of care; treated as research project.</td>
</tr>
<tr>
<td>Structural</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Semantic</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
4.2 South Karelia, Finland

The South Karelia Social and Health Care District (Eksote) participated in U4H with the chronic condition of diabetes. The technical architecture diagram for the South Karelia pilot is shown in Figure 6.

Figure 6: South Karelia’s telehealth technical architecture diagram

Eksote’s procurement documents specified a preference for the use of the Continua 1.0 guidelines at the first (left) interface in the diagram above. Due to the limited availability of Continua-compliant measurement devices, Eksote could not buy them, but had to procure solutions using proprietary interfaces. However, the specification of open database schemas for the PHR database to allow connectivity with other systems (Interface 6) was more successful. This ensured it was compatible with the service oriented architecture (SOA) and web based platform which provides a wide range of generic services, such as authentication, for various information systems in the Eksote area.

It was expected that patients used their own glucometers and blood pressure meters. Most of the patients used their own glucometers or blood pressure meters acquired from many vendors.

Gateway: Patient-owned mobile phones or home computers were used as the gateway device. The patient used the web portal Hyver.fi to navigate to their PHR and manually enter the pertinent clinical information which could then be viewed by the clinician.

Web PHR application: For U4H, the web PHR application was developed by Mediconsult Oy, and was integrated with the portal (ww.hyvis.fi) to provide functionality to view and manage personal health data stored in the PHR database, and to support the self-management process. The application provided user interfaces for patients, care personnel and administrators. All interfaces are browser-based. The core functionalities are:

- Storage and management of personal health data entered by the patient, providing the possibility to view data entered by patients and care personnel.
• Support for safe messaging (off-line) between patient and care personnel based on a secure https connection between the browser and the self-management server.

• Creating and maintaining personal self-management plans.

• Rule-based provision of alerts, reminders and feedback for patients and caregivers.

• Protection of information against unauthorised use.

• Applications receive data via web services or other standard integration protocols.

The Hyver.FI portal built for U4H diabetes will become part of Eksote’s overall personal health portal offerings available to all citizens in the region.

Our assessment of the South Karelia pilot in terms of interoperability is as follows:

| Foundational | 2 | Comments: Uses networking standards. The PHR as part of the EHR portal offered to all citizens; bring your own device assumed; manual data entry from patient into PHR; does not use messaging or data standards. Is a standard of care in the region. |
| Structural | 2 |
| Semantic | 0 |
| Clinical Workflow | 2 |

4.3 Nord Pas de Calais, France

Nord Pas de Calais was the only participant with the HTN chronic condition. Below is a diagram of their system architecture supporting U4H.

Figure 7: Nord Pas de Calais hypertension remote monitoring architecture

The region of Nord Pas de Calais contracted with Malakoff Médéric to technically integrate the HTN program which is officially called Vigisanté SAS. Malakoff Médéric
designed a system which used Parsys’ Telemedicine Box to measure blood pressure, weight, 12 lead ECG and medication adherence in the patient’s home. The Parsys Telemedicine Box communicates with the medical devices via Bluetooth, and then communicates with the data centre via GPRS. A clinician validated the ECG data via a web connection using a product from Inovelan which provides cardiology information management (verification and validation of ECG readings) via web access to health data. The Inovelan product also included a web application interface for patients, GPs and nurses to all of the patient data in this study. Orange Business solutions delivered the telecommunication connections, the data storage solution (which was branded by the French national health service) and the secure web access.

Our assessment of the Nord Pas de Calais pilot in terms of interoperability is as follows:

| Foundational | 2 | Comments: Used networking standards. Stand-alone system; does not use data standards. Was a research project, and is not part of the standard of care. |
| Structural   | 1 |
| Semantic     | 0 |
| Clinical Workflow | 1 |

4.4 Berlin, Germany

The Berlin pilot, run by Pflegewerk, participated in the project with the chronic conditions of diabetes and COPD. Pflegewerk has a mature remote telemonitoring architecture in its assisted living complex in which residents are remotely monitored both physiologically (physiological parameters for chronic disease management) and functionally with regard to their mobility around their apartment and the environment. The functional monitoring is done through 'smart-home' technology.

The technical architecture diagram below depicts the different monitoring devices and communication hubs used for remote telehealth monitoring. The monitoring devices are connected to a smartphone which collects the data and sends them to a centralised database. These data are compared with multi-valued threshold levels; statistics are collected and stored in an electronic PHR specific to the U4H project. A doctor, a family member, the patient or any other person explicitly authorised for this by the patient can access the PHR, look at the data, identify any values that raise concern, and act in a timely fashion.

Patients take their measurements themselves, but can rely on the assistance or coaching of a nurse if required. Optionally, alarms are sent to family members, caregivers and/or doctors. Otherwise, the assisting nurse can immediately provide the necessary care. Telephone contact with the patient is then made more often than before.
Figure 8: Berlin telehealth technical architecture diagram with mobile phone used as communication hub

The technology of the telemedicine application in Berlin has three elements that relate to: measuring devices, smartphone and a web-based database:

- **Measuring devices** equipped with Bluetooth interface to send data to a suitable receiving device. Such equipment has been on the market for a time, but is not yet widely used. The Bluetooth interface increases the cost of the equipment and makes it mainly suitable for telemedicine applications. As these applications increase in number in the near future, the devices should become more affordable.

- **Smartphones** used as a sensor / receiver and gateway for the measurement and transmission of data. These are becoming more and more widespread and therefore also affordable, and quality is improving very rapidly. This is important to ensure that the measurements are correct and get to the right place at the right time.

- **A web-based database** to store the data and an application to process them, and to make some calculations and presentation (e.g. in the form of charts). This technology is also not new, but it is being improved dramatically. One of the challenges of the application is keeping up with these technological improvements.

At the moment, the application used in Berlin is a fairly stand-alone and proprietary application, but steps are being taken to ensure this does not remain so. Integration with the electronic patient records of Pflegewerk is under discussion with the providers of the two software solutions. Other software solutions are being
investigated that will allow integration of the application both with the patient management software of Pflegewerk, and with a future German centralised patient health record.

Our assessment of the Berlin pilot in terms of interoperability is as follows:

| Foundational | 2 | Comments: Uses networking standards. Stand-alone system; does not use data standards. Is treated as a research project and not a part of standard care. Is limited to the Pflegewerk site and not Berlin-wide. |
| Structural | 1 |
| Semantic | 0 |
| Clinical Workflow | 1 |

4.5 Central Greece

The consortium of Central Greece that implemented U4H built upon a previous pilot and infrastructure, updated for the U4H deployment. The consortium participated with the chronic condition of diabetes. The technical architecture diagram of the Central Greece pilot is shown below.

![Technical Architecture Diagram](image)

**Figure 9: Greek telehealth technical architecture diagram**

Central Greece uses the CardGuard system which provides a web-based PHR called PMP4 for both patient and clinician access. The medical devices interface to the PMP4 system. Therefore, from an interoperability standpoint, this is a closed system provided by a single vendor.

Pictures of the glucometer (a proprietary glucometer provided by PMP4 which plugs into the mobile phone using the PMP4 system) interfacing to the mobile phone are shown below.
Our assessment of the Central Greece pilot in terms of interoperability is as follows:

| Structural    | 1 |
| Semantic      | 0 |
| Clinical Workflow | 2 |

### 4.6 Calabria, Italy

Azienda Sanitaria Provinciale (ASP) Cosenza is the healthcare authority that serves the population of the province of Cosenza in Calabria, Italy; it participated in U4H with the chronic condition of diabetes.

ASP Cosenza procured devices and a central diabetes management server system from Johnson & Johnson (Lifescan and Eurotouch 10). The patient used the device provided at home to collect blood glucose measurements according to the scheme indicated by the Consultant Diabetologist, and used the software provided by the device. The patient or their caregiver then transferred the glucose measurement data to the online computer daily through a cable with a USB port, and then transmitted the data collected to the server at a service centre through the gateway which is the network connection associated with the patient's home computer. A ‘cloud’ server which has the Eurotouch 10 diabetes management software interfacing with the Lifescan glucometers was networked to the computers of the diabetes centres participating in the study. The blood glucose data of all the patients enrolled in the project fed into a single Eurotouch 10 database, and was tracked for
each individual patient by the registered nurse and endocrinologist / diabetologist responsible for the surveillance and integration between the sites.

Eurotouch Home is an application for people with diabetes that allows collection and processing of self-monitored blood glucose data with modules that display the aggregated patient information with the aim to help patients and doctors analyse their diabetes management history. Data management functions transform the data into a graphical representation of self-monitoring that allows the interpretation of blood glucose data in the light of variables such as meals, nutrition, insulin therapy, and physical activity. There is also a therapy module devoted to the recording of drug therapy. Other examination information (labs, etc.) is recorded in the module titled “blood tests and other clinical parameters”, and a complications module is devoted to recording the users’ other clinical information.

![Figure 11: Self-monitoring blood glucose meter OneTouch® Verio®IQ - ASP Cosenza](image)

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

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

The two applications were installed on the patients’ personal computers, following the instructions provided in a user manual. Since they use email as a communication channel, they have to be configured with the email addresses of the diabetologist and the professional nurse coordinating the study.

On the healthcare professionals’ side, the received data were imported into an Electronic Medical Record (or data management application) routinely used in the Diabetology Centre. A screenshot of the graphical interface presenting subsequent measurements is shown below.

**Figure 12: ASP Cosenza technical infrastructure**
Using email as a communication mechanism also allowed for a way to troubleshoot issues and correct and improve the transmission of data between medical investigators, the registered nurse, the patients, and their informal caregivers.

Our assessment of the Calabrian pilot in terms of interoperability is as follows:

<table>
<thead>
<tr>
<th>Foundational</th>
<th>Structural</th>
<th>Semantic</th>
<th>Clinical Workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Comments: Used networking standards. Stand-alone system; does not use data standards. Not a part of standard care; is a research project.

4.7 Campania, Italy

Agenzia Regionale Sanitaria (ARSAN) is the Health Agency of the Campania region which surrounds the southern city of Naples, Italy. ARSAN participated with the chronic condition of diabetes.

Patients were equipped with a standard glucometer; they sent the measurements to a web-based software platform called “Diabetel.net”. The devices and gateways used by the patients were provided by FORA Care Suisse AG; the software platform by Meter s.r.l. The following devices were used:

i. Fora Diamond GD50 glucometer;
ii. Fora Telehealth Gateway GW9014; and
iii. an ADSL router (provided by the patient himself).
Data transmissions between the glucometer and the gateway are wired, via RS232, with the connection between the gateway and the ADSL router wired via Ethernet.

The technical platform deployed in the Campania Region to support the telehealth service is depicted in Figure 14.

At the patient's home, the glucometer connected to the gateway via a cable, and the gateway to the modem/router ADSL via a standard Ethernet cable. Data were transferred to/from Diabtel.net over the Internet in an encrypted format.

Operationally, the glucose measurements are initially stored in the glucometer which, when connected to the hardware gateway, are automatically forwarded to Diabtel.net and stored in the server database. The data are transferred from the hardware gateway to the Diabtel.net over the Internet in a proprietary encrypted format.

The information stored in the Diabtel.net is accessible to medical staff via a web browser and secure login. The Diabtel.net portal supports role-based access control policies in order to regulate access to patients’ data to authorised users only, i.e. the patient him/herself, and his/her specific healthcare professionals. Credentials to access the Diabtel.net portal are based on user ID and password.
The Diabtel.net also supports viewing data with tables, charts and statistics, as well as the management of alerts to the clinicians about deviations from standard values, which can be notified via email or SMS as seen in the next Figure 16.

**Figure 16: A screenshot of the Diabtel.net**

Our assessment of the Campania pilot in terms of interoperability is as follows:

<table>
<thead>
<tr>
<th>Foundational</th>
<th>2</th>
<th><strong>Comments:</strong> Used networking standards. Stand-alone system; does not use data standards. Not a part of standard care; is a research project.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural</td>
<td>1</td>
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</tr>
<tr>
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<td>0</td>
<td></td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### 4.8 Northern Norway

The Northern Norway pilot participated with the chronic condition of COPD, and cooperated with the Southern Norway pilot in significant respects. Although Northern Norway (Tromsø) had a system to support diabetes, and was part of the Renewing Health project, for COPD they opted to use the same technical system setup as Southern Norway, using the same vendor (Sykehuspartner). One difference with the Southern Norway system was that Telemedicine Sentral (TMS) was installed in one of the Tromsø hospital departments, as opposed to in the municipalities in Southern Norway.

### 4.9 Southern Norway

Southern Norway participated with the chronic condition of COPD.

To support U4H, a medical team was established consisting of dedicated COPD nurses, local doctors and COPD specialists at the telemedical centre of Sørlandet Hospital. The technical solutions implemented gave access to the patient’s daily
measurements and reported questionnaires for all the healthcare partners, within a secured solution implemented in the Norwegian Health Network.

4.9.1 Legal and security requirements in Norway

The legal requirements for access to electronic health records in Norway are strict: only the employees within the actual organisation responsible for the patient's treatment can access the patient record. There are currently no methods for shared access across organisational borders. However, within the Norwegian healthcare services, all actors can send electronic messages based on a defined electronic business extensive mark-up language (ebXML) as the syntax for a national message standard. (“Electronic Business XML” is a project to use the Extensible Markup Language (XML) to standardise the secure exchange of business data.) Among other purposes, ebXML could replace the other business information exchange standard called Electronic Data Interchange (EDI). According to existing routines, a discharge message was sent from the hospital to both the patient's GP and the municipality healthcare services.

In the project, a dedicated server and database were established as a tailored Treatment Pathway Health Record for temporary storage of patient information. In the clinical protocol step of “After terminating the low level of telemonitoring”, the stored medical data for the patient will be exported to the traditional electronic health record (EHR) for permanent storage; anonymised data will be exported to the project report database.

For secure access to medical information, the servers used in the U4H project were implemented within the secure framework of the Norwegian Health Network. Sykehuspartner, which is a public company responsible for the ICT infrastructures for hospitals in Southern Norway, provided the required servers. Sykehuspartner set up a dedicated secured VPN tunnel that enabled a patient with a tablet-PC to upload daily vital signs measurements and responses to a questionnaire. This VPN setup complied with the requirements and specification of the Norwegian Health Network. In addition, there was a secure video communication solution implemented based upon the existing infrastructure established within the Norwegian Health Network. This video communication solution uses the Cisco product “Jabber Video Communication”; the corresponding address book is defined within the Norwegian Health Network supporting all video conference systems.

4.9.2 Technical telehealth set-up

In the Southern Norway setup, a Vital Sign server was installed with secure access controlled by AAA-server (Authentication, Authorisation and Accounting). From the patient’s tablet-PC, a dedicated VPN tunnel was established in order to have a secure upload of data to the server. The tablet-PC was equipped with a SIM-card and used mobile data communication on 3G or 4G.

Healthcare personnel needed to be within a secure zone in the Norwegian Health Network, and they needed a digital-ID on a smartcard for secure log-on to the server. Those principles are illustrated in the Figure 17 below.

In the Northern Norway trial, the system setup was identical; however, the personnel at University Hospital of North Norway took care of the daily patient follow-up.
The technical architecture diagram for the Southern Norway pilot is shown below.

Figure 17: Southern Norwegian COPD telehealth technical architecture diagram

4.9.3 Treatment Pathway Health Record (TPHR) and Information Integration Portal (IIP)

For the integration of medical devices and questionnaire information, University of Agder developed a dedicated Information Integration Portal (IIP). This portal is based upon open standards for publishing sensor information (RESTful web services), and a personal Electronic Health Record database linked to this portal that imports all data uploaded from the patient’s home. The Treatment Pathway Health Record (TPHR), developed by University of Agder and Devoteam Solutions, provided a dashboard that enabled collaboration between the involved healthcare personnel by documenting both the patient’s recordings and actions taken. This solution was based upon secure access by both healthcare personnel and the patient to upload new data to the centralised server database.

Figure 18: Southern Norway Service Oriented Architecture (SOA) diagram
4.9.4 Tablet-PC, devices and software

To meet high security requirements, the project did not allow patients to use their own device. Instead it provided each patient with a tablet-PC (Windows 8) with an encrypted hard disk (secured by user log-in and PIN-code) and with dedicated software developed by University of Agder. The software included an SQL database for storage of vital signs measurements and results from the daily questionnaires. No other Windows operating system functions or apps were available to the user, in order not to compromise security. The pulse oximetry device was a Nonin PureSat which used a serial Bluetooth communication to the tablet-PC. All software applications used in the Norwegian systems were declared as medical software.

Dedicated medical devices and a Windows 8 Tablet-PC with medical software

Figure 19: Southern Norway home telehealth devices

The end-to-end connectivity included a secured VPN tunnel from the patient’s tablet-PC, and a standard mobile data communication (3G/4G) to a dedicated VPN firewall at the Norwegian Health Network. Before implementing the system, the project analysed security and risks to guarantee compliance with specifications and legal requirements in Norway.

Figure 20: Southern Norway end-to-end COPD telehealth monitoring architecture
Following the U4H project, Southern Norway is extending their U4H ICT platform to all 30 municipalities in the Agder region with necessary upgrades and adaptation. Currently, they have three Telemedicine Sentral (TMS) systems installed in the municipalities of Kristiansand, Farsun and Risør, which support 30 municipalities with the telehealth service. The Norwegian national authorities are also supporting this with funding.

Our assessment of the Norwegian pilots in terms of interoperability is as follows:

<table>
<thead>
<tr>
<th>Foundational</th>
<th>2</th>
<th>Comments: Uses networking standards and security standards. Partially integrated system, and is working towards use of data standards; uses messaging standards. Is standard care that is being offered region-wide.</th>
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<tbody>
<tr>
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<td></td>
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<tr>
<td>Clinical Workflow</td>
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<td></td>
</tr>
</tbody>
</table>

### 4.10 Slovenia

The General Hospital Slovenj Gradec (SB-SG) in Slovenia participated in the remote monitoring of the chronic conditions of DM and CHF patients.

For the purposes of implementing U4H, SB-SG, together with subcontractors, set up a telehealth service centre called CEZAR. The centre's technological infrastructure is based on technology provided by Health Insight Solutions (HIS). This solution is similar to that used by Berlin detailed in section 4.4. Slovenia uses the wireless set-up, with the clinicians using an Internet portal to access the patient data. The server which hosts the HIS portal is a part of the SB-SG hospital, behind healthcare enterprise firewalls. It is hoped that later the portal will be fully integrated in the national healthnet infrastructure (zNET). The CEZAR centre provided the following medical devices for physiological monitoring: IEM Librograph weight scale, Cignus SeniorLine blood pressure monitoring system, Nonin Onyx II pulse oximeter, and Cignus ProfiLine glucometer. CEZAR uses Bluetooth 3.0 or higher versions for these devices. For the home gateway, HIS used an application for any Android version 2.3 operating system or higher device (tablet or mobile phone).

Each CHF patient using telehealth support received:

- Blood pressure meter (Cignus TD Senior Line).
- Pulse oximeter (Nonin Onyx II 9560).
- Weight scale (I.E.M Librograph).
- Smartphone with a HIS telemedicine app serving as a gateway.

Each DM patient using telehealth support had:

- Gluometer Cignus ProfiLine.
- Smartphone with a HIS telemedicine app serving as a gateway.

The gateway and the set of medical devices were matched and personalised before they were handed to the patient. As scheduled by their doctor, the CHF patients measured consecutively weight, blood pressure, heart rate and oxygen saturation; the DM patients measured their blood sugar. After the result of each measurement...
was displayed on the measuring device, the data were automatically sent to the hospital server. No other action was needed on the patient side.

Slovenia integrated the U4H system by having two virtual servers within the hospital IT centre infrastructure to run the telemedicine service: one for the HIS system, and the other for the medical portal. The servers on which the telemedicine service for telemetric support of DM and CHF patients was based were integrated into the SB-SG hospital information infrastructure. They ran in a safe environment where all information safety measures were guaranteed, and all measures were in place to safeguard privacy when handling sensitive personal data.

The architecture for the Slovenian implementation is below.

![Figure 21: Slovenian system architecture for diabetes and congestive heart failure using Health Insight Solutions products](image)

Following the U4H project, SP-SG wants to expand the use of the system to provide new services for obesity, hypertension, heart and kidney transplantation, haemophilia, and eventually provide remote monitoring services nationally.

Our assessment of the Slovenian pilot in terms of interoperability is as follows:

<table>
<thead>
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<th>Category</th>
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<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Used networking standards and security standards. Does use messaging standards. Stand-alone system; does not use data standards. Is standard care for the region.</td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
4.11 Basque Country, Spain

Osakidetza, the public healthcare system of the Basque Country, participated in the chronic condition associated with CHF. It integrated home monitoring via a web service (WS) that allowed a home health gateway device to send the biometric information to platforms implementing the communication of the service. The technological infrastructure of the web service contracted included the following: provision of devices, phone lines, management software (PNC6 call monitoring and management system from Tunstall), and hardware infrastructure (computer telephony integration and a database managed by Sybase).

The home telemonitoring platform was integrated with the alarm management platform and Osakidetza's EHR via WS and Web Application Firewall (WAF). Thus, the telemonitoring data collected by the gateway device are incorporated into the patient's EHR through Osakidetza's WS. The integration complies with Osakidetza's strategic criteria which determined that the clinical information coming from the patient's home or healthcare providers has to be managed through its own systems, reducing the number of interactions between professionals and distinct applications and interfaces. The communication between the telecare centre and Osakidetza's information systems is bidirectional.

The selected sensors used for remote monitoring in the home were:

- Nonin 9560 Onyx II pulse-oximeter.
- A&D UA-767PBT blood pressure monitor.

Figure 22: Basque Country CHF service architecture
- A&D UC-321 PBT digital scale
- Tunstall Lifeline Vi Telecare device

The Home Gateway device provided had two options:
- Mymedic II (Tunstall): non-mobile solution.
- CarelineH@me (Saludnova): mobile solution.

![Figure 23: Basque Country home medical devices](image)

The system integration was based on a Service Oriented Architecture (SOA) and on the implementation of the security policies of Osakidetza, which stipulate that all internal web service (WS) calls made through the integration bus (Oracle Service Bus - OSB), which is dedicated to Internet interface, have to be made by a secure protocol (HTTPS) and applying web services security (WSS) policies of signing and authorisation. This architecture required a certificate of application and implementation of security policies defined by Osakidetza and based, in turn, on Oracle Web Services Manager (using an x509 token mechanism). This process guarantees the integrity of the messages.
In terms of next steps after the project is ended, Osakidetza has built their U4H remote monitoring in such a way that it was already integrated into their EHR for review by clinicians, and can be widely deployed outside of the original U4H cohort. Remote monitoring services are viewed in a separate remote monitoring view within the EHR application.

Our assessment of the Basque Country pilot in terms of interoperability is as follows:

| Foundational | 2 | Comments: Uses networking standards. Integrated into EMR; does not use data standards, uses messaging standards. Is part of standard care in the region. |
| Structural | 2 |
| Semantic | 1 |
| Clinical Workflow | 2 |

4.12 Galicia, Spain

SERGAS, the public health authority in Galicia, participated in the COPD trial. The architecture of their system is shown below.
Figure 25: Galician COPD telehealth system diagram

The platform consisted of a central digital home care system that provided the added value modules for supporting clinical protocols and all patient communication functions.

The system was designed to seamlessly integrate all information flows with the patient into the EHR and clinical applications for the professionals.

The main functions that the digital home system provided were:

- Protocol and guidelines definitions available to the professional from EHR system. The system gave support to the defined processes for the follow up of chronic patients.
- All parameters were received from the patient’s home, and as of September 2015 were acquired by medical devices with Continua and IHE standards to guarantee that third party devices and applications can be integrated at different layers.

The system was completed by providing several functionalities that are available not only for COPD patients, but for any other chronic conditions that could be monitored in the future:

- Alarm threshold and messaging from patient to professionals.
- Telecare management programme.
- Analysis and parameters register.
- Control medication administration and adherence.
- Deployment of multimedia contents.
- Telecare (asynchronous) control.
- Tele-consultation (synchronous).
- Questionnaires for patients, made available to patient via computer tablet. (EQ5D questionnaire is used for COPD).
- Contents in multimedia format for instruction and training on how to use devices.

During the COPD service, a patient had a video consultation with a nurse who was located at the emergency dispatch centre for Galicia. The nurse used two separate systems: the Telefonica system which gathered the remote monitoring data and provided the video teleconferencing services, and the Galician EMR system. During the patient session, the nurse manually entered the patient data from the Telefonica system into the Galician EMR system. This workflow was designed to ensure data validation and a clinical level of data quality for the remote monitoring service.

Integration of service is shown in the following figure.

Figure 26: Galician clinical applications diagram with digital home remote monitoring integration

Clinical workflow regarding the clinical decision for the inclusion of a patient into the remote monitoring / telehealth service as well as integration of service provision is shown below.
SERGAS is modifying its platform for COPD management service to be migrated into the GPs' offices (versus centralised at the emergency service dispatch centre). SERGAS will be using the same clinical protocol developed by U4H for COPD management. Moreover, it will be adding a 'prescription' choice for the clinician to click on in their EMR patient hospital discharge task list which will include telehealth as an available service for COPD patients. This prescription will send an automated message to the telehealth service provider to implement the service, including installation of the equipment in the patient's home and activation of the patient in the telehealth vendor application database.

Our assessment of the Galician pilot in terms of interoperability is as follows:

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</tr>
<tr>
<td>Structural</td>
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<tr>
<td>Semantic</td>
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<td></td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
4.13 Scotland, United Kingdom

Scotland participated in the monitoring of three chronic conditions CHF, COPD and DM. In the case of the chronic conditions of CHF and COPD, Scotland implemented three separate solutions amongst their participating regions. In the case of diabetes, all three participating regions within Scotland implemented the same solution.

4.13.1 Ayrshire and Arran deployment site (CHF and COPD)

The solution used by Ayrshire & Arran for heart failure is Medvivo’s HomePod\(^5\). The Medvivo web and data servers (patient data) are hosted by Piksel (formerly loko).

The HomePod itself, which consists of tablet hardware with either Windows or Android, is the central hub. It communicates via broadband or 2G/3G/4G to the clinical triaging system, and by Bluetooth or USB to the patient’s medical devices. The medical devices used for the heart failure work stream are A&D Bluetooth blood pressure monitor, and A&D Bluetooth weight scales. The HomePod software which interacts with the patient is called the patient user interface (PUI). It supports the patient protocols and interacts with the medical devices.

![Image of HomePod system for CHF and COPD](https://www.medvivo.com/product/homepod)

**Figure 28: NHS Scotland Ayrshire and Arran: HomePod system for CHF and COPD**

The clinical user interface (CUI) resides on a clinician’s PC or tablet, or on a terminal in the triage / call centre within the pilot site. The CUI is the management console that interacts with the patient and HomePod in allowing the patient record to be set

up, protocols to be configured, readings to be monitored, and triage to be managed. There are two versions of the CUI: a version for Windows, which has extensive functionality and configurability, and a web version which is lighter and manages all the day-to-day activities of a clinician and a triaging centre.

Typical connection between the HomePod and the server is securely over GPRS. In areas of poor / no signal, POTS (dial up modems) are used. Connection via home-based ADSL / Internet is readily available, but generally it is policy not to use public networks for security / data compliance reasons.

The HomePod is used to collect patient vital signs data from the patient’s home, and then feed that data to a central server. All data transfers between the HomePod and central server (behind the N3 firewall) are transported over a secure 256 bit encrypted adaptive private network (APN). The APN connection used depends upon the communication method employed (GPRS / ADSL / POTS). The APN exclusively binds the HomePod to the server.

The data is uploaded immediately after the patient ends the session. In the event that a connection is not available, the HomePod will persist at pre-set time intervals until it is successful. This is the only point in time that results data are stored (encrypted) on the HomePod. After a successful transmission, the data registers are emptied.

**Figure 29: NHS Scotland Ayrshire and Arran network architecture for CHF and COPD**

Data downloads to the HomePod fall into two scenarios. Firstly, remote system updates or patient protocol changes, and secondly, a patient's request to retrieve results. The first scenario can be automatically initiated by the HomePod once the patient has entered their PIN. The second scenario is on a demand basis each time.
the patient requests some history. The update process is very scalable and sensitive to bandwidth / load balancing constraints.

Data is transported to and from a clustered SQL server database through a set of web services within a secure environment. This method of operation is used for both the HomePod and the CUI. It is also used for reporting and interfacing to third party systems. HL7 interfaces are also supported in this way. There are no direct connections to the database.

In relation to third party integration with the HomePod database, the CUI is able to support multiple coding schemas. The coding schemas depend on the type of system requiring integration. Scotland pursues integration with EMIS LV (Egton Medical Information Systems, UK vendor and product of GP-based electronic clinical documentation system) and INPNS VISION (UK-based electronic clinical documentation system), using READ2 (the standard clinical terminology system used in GP practices in the UK).

For CHF, medical devices used for the heart failure work stream are A&D Bluetooth blood pressure monitor, and A&D Bluetooth weight scales.

4.13.2 Greater Glasgow & Clyde deployment site (CHF and COPD)

This deployment site (located in Renfrewshire and East Renfrewshire) deployed a software platform called Safe Mobile Care (SMC)⁶. SMC is an end-to-end web based healthcare solution that uses clinically validated questionnaire sets, appropriate vital sign data capture, and medication reminders through the use of a specially configured smartphone or tablet device (the patient can choose). The gateway, along with the use of (wireless) peripherals, allows easy capture of vital signs, in particular pulse oximetry and body temperature. An overview of the set-up of Safe Mobile Care and technical characteristics is outlined below.

⁶ www.safepatientsystems.com
The responsible physician selects a suitable clinical questionnaire or develops his/her own content, sets vital sign parameters, and creates an individual care plan on the web based triage management software. This includes scheduling and alert protocols which generate a unique personalised PIN code for authentication. Once uploaded onto the device, the personal care plan will prompt the patient to supply data from the peripheral devices. The tablet has pre-loaded questions for the patient to answer, which have been agreed by the medical and specialist nursing staff, with patients prompted to answer yes or no to the questions, as per the specific clinical protocol. Immediate feedback is sent to the patients based on their responses, as well as an alert sent to the appropriate monitoring physician, or community team within GGC.

The monitoring clinician will access the patient’s information through the web platform, where they can review the cause of the alert and any relevant patient monitoring history. The system also allows the clinician to agree to actions or comment or agree on a health goal, which can then be linked and tracked directly to patient outcomes.

This solution has the built-in functionality to offer video consultation, which will be introduced as part of the pilot once the infrastructure within NHS Scotland is able to support it.

Greater Glasgow & Clyde also have a contract with Safe Mobile Care for the supply of telehealth equipment for heart failure. All patients are issued with a Nexus tablet and peripherals such as weight scales, pulse oximeter, and blood pressure cuff, which are attached to the tablet device via Bluetooth. The outcomes are monitored by specialist nurses five days a week, and nurses take action on the alerts which are raised. The devices / peripherals used by the patients are shown in Figure 31 below.
4.13.3 Lanarkshire deployment site (CHF and COPD)

The software solution installed in NHS Lanarkshire is Simple Telehealth, also known as Florence (FLO), developed by NHS England\(^7\). FLO is a text message service that sends information, collects data, and links directly to a clinician’s computer software. The software displays the data, and creates graphs and tables, so that clinicians can easily see the vital statistics on their patients’ health. Using the data collected, the system can also automatically advise a patient and/or clinician if pre-agreed action needs to be taken.

This system supports SMS texts from the patient’s own mobile device without the need to download software or an “app”. Patients or carers supply blood oximetry and temperature readings, and reply to questions about symptoms via SMS through a standard mobile telephone connection. Clinical parameters can be set for each individual patient by a specialist nurse, with alerts sent to the clinician’s mobile device, and shared with the wider clinical team as required. These alerts or “critical breaches” are based on a heart failure clinical algorithm and decision tree developed by clinical staff: they provide an alert to staff that a patient’s condition needs to be reviewed.

The FLO system is shown below (Figure 32). It requires minimal set up once the initial software has been installed on the main receiving unit. The clinician can view the results uploaded to FLO, alongside graphs, trends, alerts and messages on a secure internet connection, at any time. Additional benefits include the ability to send automated and specific texts to the patient to give instructions, reassurance or reminders of appointment time, or additional health coaching messages.

\(^7\) [www.getflorence.co.uk](http://www.getflorence.co.uk)
4.13.4 Scottish diabetes deployment sites

Diabetes is a chronic condition treated via telehealth at all three of the Scottish sites.

All three U4H pilot sites in Scotland (Lanarkshire, Ayrshire & Arran, and Greater Glasgow & Clyde) use the same new software technology to promote the centralised integration of home blood glucose monitoring into two established systems: My Diabetes My Way (MDMW) and SCI-diabetes (Scottish Care Information). Along with promoting patient registration on the MDMW self-managed website, registered clinical staff and patients were given access to software to upload and view blood glucose measurements via the My Diabetes area of the website (access is restricted based on user authorisations) and to staff only via SCI-diabetes through the use of Diasend.

Through Diasend, information is presented in structured reports no matter what the blood glucose monitoring device is or how the data is stored. Patients were also able to link their existing blood glucose monitor to their own computer to automatically upload readings to share them during their review with their healthcare professional or healthcare provider.

In addition, the integrated web based intervention enables:

- Options for care provision involving fewer face-to-face contacts and more remote clinical consultations.
- Access to accurate blood glucose readings enabling patients to better manage their condition, and make changes to their behaviour / lifestyle to improve health and well-being.
Figure 33 below shows what a patient would see through the MDMW portal: the daily measurements and a graphical view of those measurements. Figure 34 shows what a clinician would see in the SCI-Diabetes application through the Diasend interface. Essentially, Scotland has integrated a telehealth vendor’s data into their backend system for viewing in the healthcare enterprise systems, while allowing the patient to use the telehealth vendor’s portal to input and view their telehealth data. Additionally, there is no manual entry between the telehealth system and the Scottish healthcare enterprise system.

![Figure 33: NHS Scotland; diabetes patient reports viewed through My Diabetes My Way (MDMW) website](image1)

![Figure 34: NHS Scotland: Clinical staff and professionals view of Diasend through SCI-Diabetes](image2)

Only professionals and healthcare staff from the three Scottish pilot sites are able to access Diasend integrated software, and hence view patient results through SCI-Diabetes.
From a workflow perspective, the clinician initiates the workflow by obtaining the patient’s consent to receive blood glucose measurement results from their monitoring device. Once the patient is enrolled, the clinician’s user credentials are entered into the patient’s record to establish the link. This process generates an internal identifier (Diasend ID) which is then matched to the master patient index (CHI) in SCI-Diabetes. A batch processing job then collects new results from Diasend, stores them against the patient record in SCI-Diabetes, and transfers it to MDMW.

- **Remote login to Diasend**: One-off linkage process from Diasend ID to SCI-Diabetes mapped to CHI number; ability to store Diasend login credentials for a patient in MDMW; development of web services to authenticate user; launch window into Diasend; supporting documentation & analysis.

- **Diasend data import**: REST API / raw data import for Diasend.

- **Record Transfer from Diasend to SCI-DC to MDMW**: Web services to receive data from Diasend; ability to store Diasend patient identification credentials for a patient in SCI-Diabetes; ability to store Diasend patient identification credentials for a patient in MDMW; data linkage processes (Diasend ID matched to CHI, for example); data transfer mechanism; data presentation in MDMW; data presentation in SCI-Diabetes; supporting documentation & analysis.

![Figure 35: Scottish system architecture for diabetes](image)

The MDMW website also provides health coaching, and the 1,200 patients provided with the Diasend interface were encouraged to take advantage of this. In addition, 4,400 other patients will be registered onto MDMW and encouraged to take part in the health coaching aspects of the site and continue with self-monitoring of blood glucose as they have been previously.

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

Diasend is a standalone web based system for uploading information from most glucose meters, insulin pumps, continuous glucose monitoring devices and mobile apps. The Diasend system consolidates and presents information in structured reports independent of the device type or how the data are stored. SCI-Diabetes is at the core of the systems architecture, facilitating asynchronous communications between multiple systems. Home blood glucose monitoring results will be received from Diasend via a regular scheduled interface for those patients who have consented for their data to flow in this way.

The patient can then either view their results directly in MDMW, or click directly into Diasend to view a copy there. This process allows the patient and all members of the healthcare team have access to these results for discussion during physical or virtual consultations.

![Figure 36: Diasend interface and MDMW process flow in Scotland](image)

4.13.5 Follow-on plans to U4H project

Scotland has built its diabetes remote monitoring service into an already scaled-up national Diasend backend to the MDMW portal. Additionally, the Scottish Government is financially supporting the wider roll out of the U4H services through its £30M Technology Enabled Care Programme, whose funds are matched by local health and care partnerships.

Our assessment of the Scottish pilot in terms of interoperability is as follows:
Towards Interoperability: Findings and Recommendations

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<td>0</td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Comments: Uses networking standards. System integrated into national web portal for diabetes; does not use data standards. Stand-alone systems for other chronic conditions (CHF/COPD) management; does not use data standards. For diabetes it is part of standard care; for CHF/COPD it is still in the research phase and not yet standard care.

4.14 Wales, United Kingdom

Hywel Dda University Health Board in Wales is participating in the monitoring of two chronic conditions: COPD and Type 2 Diabetes Mellitus (T2DM).

4.14.1 Type 2 Diabetes Mellitus

The system used for T2DM is Florence (FLO), provided by Simple Telehealth. This is an NHS hosted non-commercial product supported by Simple Telehealth, similar to that used by NHS Scotland-Lanarkshire (see section 4.13.3).

For T2DM, the overarching schematic diagram of how the system operates is shown in Figure 37. An alert email / text is sent to the specialist diabetes nurse if blood glucose levels are either below 4.0 mmols or above 15.0 mmols. The message that the patient receives is governed by an individualised T2DM self-management plan.

Data is accessed ‘live’ by the primary care health professionals via a secure Internet connection at any time, or if the patient phones with worsening symptoms. If more than 24 hours pass without a data upload to the central server, a member of the clinical team is alerted via email and text message.

The devices used for diabetes participants are glucometers (several brands, as patients already have their own glucometers) and mobile phones. The mobile phones were generally the patients’ own; however, if the patient did not have one, they received one as part of the project. The glucometer devices were not connected directly to the gateway communication hub: patients manually entered the information into their mobile phone. All data is transmitted via the mobile phone network to the FLO interactive program following a pre-approved standardised or individualised protocol. Disease specific advice and health coaching messages are returned to the patient automatically via FLO, or manually by the clinician in case of an alert or a breach of parameters. Transmission of the results is provided via a free number (the remote monitoring service paid for the transmission costs for the system), so the only cost to the patient was the electric charge of the equipment. Patients who were provided with a mobile phone could use it for personal usage provided they paid for it themselves. These mobile phones were returned at the end of the intervention.

FLO analyses the data according to an individualised set of parameters, and provides instant feedback to the patient via their mobile phone along with locally
agreed advice messages as required. If the readings submitted are outside of the individually agreed parameters, an alert is sent to the patient in the first instance. A message is then sent back to the patient via FLO, advising the patient to act according to a self-management plan agreed by the patient and the practitioner. An alert message is also sent to the primary healthcare provider, classified as a ‘critical breach’ (known colloquially as a red flag) according to parameters set around the alert, advising the healthcare provider to review the patient, e.g. if the patient’s readings were outside set parameters on all occasions. The review happens either immediately, or on the next working day, if the anomalous parameter occurred outside of normal working hours.

Incorporated into the T2DM telehealth program is a system to provide a health e-coaching message every three days that advises the patient on both T2DM specific and general health and wellbeing issues. All messages are reviewed by a health psychologist and a readers panel (a group of people comprised of participants from the Health Board communication team, and patients) that ensures that the language used in any patient document / message is suitable for most patients.

Figure 37: Wales DM and COPD telehealth service architecture

4.14.2 COPD

There were two systems used for COPD patients. Initially, patients were to access FLO (provided by Simple Telehealth) via a third-party equipment provider – WHZAN. This was on the expectation of the system being able to communicate via GPRS and a patient’s own wifi or landline. Patients were provided with a ‘briefcase’ containing a pulse oximeter, thermometer, and computer tablet that uses Bluetooth technology to transmit that data. They were then given the opportunity to videoconference with their clinician. The medical devices and gateway used were TaiDoc VTrust handheld pulse oximeter, TaiDoc Lever TD ear thermometer, TaiDoc blood pressure monitoring system, and Nexus computer tablet.
A second system was introduced because of infrastructure limitations: a landline-based health hub provided by Docobo®. Peripherals were provided; however, the pulse oximeter was wired to the Docobo health hub rather than using Bluetooth.

Irrespective of the device used, for the next stage of COPD monitoring, a patient or their carer performed the blood oximetry, temperature and symptom questions daily. However, once results were uploaded, there were significant differences between the two systems.

For FLO, the oximetry and temperature recordings were sent to the computer tablet via Bluetooth. The patient (if required with the help of a carer) responded to symptom questions manually, using a multiple answer set on the computer tablet. All readings were then transferred to an individualised decision tree in FLO.

FLO analysed the data according to an individualised set of parameters, and provided instant feedback to the patient via their computer tablet along with locally agreed advice messages as required. If the readings submitted were outside of the individually agreed parameters, an alert message was sent to the patient in the first instance advising them to act according to a self-management plan agreed by the patient and the practitioner. The alert message was also sent to the primary healthcare provider, classified as a ‘critical breach’ according to parameters set around the alert, advising them to review the patient, e.g. if the patient’s readings were outside a set parameters on four occasions over a 48 hour period. This could be reviewed immediately, or on the next working day if the anomalous parameter occurred outside of normal working hours.

For the Docobo system, the patient entered their readings and completed the multiple answer set (i.e. the symptom questions) onto the health hub on a daily basis. On uploading data to the Docobo system, an alert was communicated to the clinician if two or more parameters were considered anomalous.

### 4.14.3 Both pathologies

Beyond the U4H project, Hywel Dda University Health Board is using their platform to support health and wellbeing in other long term conditions, for example nutritional support. In addition they are looking to incorporate this system into their standard of care by having telehealth services included in the health board future plan.

Our assessment of the Welsh pilot in terms of interoperability is as follows:

<table>
<thead>
<tr>
<th>Interoperability Type</th>
<th>Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundational</td>
<td>2</td>
<td>Uses networking standards. Stand-alone system; combination of automatic and manual data entry; does not use data or messaging standards. Is going to be part of standard care for diabetes and COPD.</td>
</tr>
<tr>
<td>Structural</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Semantic</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
5. Key findings from the deployment sites

The U4H project ends in December 2015, and the observation and evaluation period was completed in the summer of 2015. Section 4 contains the technical analysis of the deployment sites. Aggregate tables with overviews of the parameters and data types collected across all pilots, as well as summaries of devices, interfaces, and telehealth software capabilities, are included in Appendix B. Below are ten findings of relevance to the project related to standards, industry offers, and the overall state of the telehealth field:

- **Preference for outsourcing**: Several regions outsourced the complete remote monitoring / telehealth solution and merely defined the interface to their own ICT systems; this at times introduced a discontinuity in the clinical workflow which became evident when the decision was made to integrate the service into normal healthcare delivery.

- **Slow integration with electronic health records**: There is some integration of data from remote monitoring into the healthcare and regional electronic health / medical record systems (EHR or EMR), however, it is being done carefully to ensure the data integrated is of a similar quality to that collected in controlled healthcare environments (clinics and hospitals). Where patient-generated data is integrated, it is either displayed in a separate ‘view or window’, or a clinician enters it manually into the EMR. This reflects the medical profession’s scepticism vis-à-vis patient generated data; the debate about whether this data ‘validation’ step can be eliminated is ongoing.

- **“Bring your own device (BYOD)”**: Finland, Italy, Wales and Scotland pilot sites had an expectation that patients would supply their own medical devices, and sometimes computer gateways (mobile or home-based) and internet connections for the provision of the remote monitoring service. This reflects an increasing trend that healthcare providers rely on patients to supply their own technology, not only just for consumer devices (mobile phone / home computers), but also for medical devices such as glucometers. Healthcare providers also take advantage of the widespread patient population’s use of internet (i.e. WLAN) and mobile communications networks, allowing the cost of the telecommunications to be borne by the patients.

- **Manual data entry prevails**: The trend towards patient-supplied hardware limits technical interoperability between sensors and gateways. As a result, in ten out of 14 regions, patients entered data manually into the gateway (mobile / smartphone, tablet or laptop), especially for devices which are patient owned (usually glucometers and weight scales).

- **Standardised networks...**: Standardised electronic network protocols such as Bluetooth or GSMA were used in all regional implementations. For example, 80% of the pilot sites used solutions that relied on Bluetooth for a wireless connection between the physiological monitoring devices and the gateway (mobile / smartphone or tablet), usually for pulse oximetry and blood pressure measurement.

- **...but proprietary message formats**: In almost all pilots, messaging and data formats were proprietary, reflecting the dearth of available standards or standards compliant products, as well as the preferences of the deployment
sites and the conditions in their local markets. (See section 6 for a more detailed discussion.)

- **Mobile devices:** Smartphones and tablets were used as gateway devices in 11 out of 14 of the pilot site solutions. This appears to reflect less a desire for patient mobility, but rather the convenience and ease of use of mobile devices, compared, for example, to home computers.

- **Trend towards web portals:** Seven out of 14 sites used web portals and secure data transmission via web protocols. All other sites implemented specific configured applications which required implementation on a provided gateway device (mobile phone, tablet or computer) and used either land-line phone service, mobile telecommunications service, or another patient provided network protocol (home Wi-Fi for example). This trend towards the use of web-based portal solutions to support the remote monitoring applications at the patient interface has the following advantages:
  - Web portals allow for easier deployment and upgrade paths.
  - They allow a modular approach towards development of the services and architecture.
  - They also lend themselves to data and service provisioning within most web browser applications, which scale from mobile phones to tablets and other computing platforms.
  - They lend themselves to the adoption of a ‘bring your own device’ (medical and gateway) policies for healthcare providers in their implementation of remote monitoring services.

- **ICT network quality affects telehealth:** The quality of the patient home and geographical region networking capability remains an important limiting factor as to what type of remote monitoring or telehealth service can be implemented. Some regions have poor ICT coverage, so wired, plain old telephone service (POTS), and lower level wireless / mobile network protocols need to be included as networking options in vendor product solutions.

- **Patients require assistance and training:** Most patients like the telehealth systems; however, many have needed assistance to use them. As the services become part of normal care, there may need to be more technical and clinical assistance provided to patients (and/or more informal carer assistance to patients) to ensure good outcomes.

Almost all pilot regions realise that the ICT platforms that they have procured for U4H can be used to provide clinical services outside of those defined in U4H. They have expanded and/or are planning the expansion of the use of their system beyond the project timeline into other healthcare and/or geographical areas. Moreover, many of the pilot regions have and/or are procuring local funding to support this, and are closely integrating the service into their standard care and enterprise technology infrastructure.
6. Perspectives on interoperability and adoption

6.1 Summary

U4H sought to promote the use of international standards and the progressive convergence towards common interoperable architectures. In section 2.3, we discussed the meaning and the elements of eHealth interoperability and proposed a grading system; in section 4, all sites are rated according to this system. Below is a summary table of the interoperability ratings for all U4H deployment sites.

Table 1: Scoring of deployment sites across four levels of interoperability

<table>
<thead>
<tr>
<th>Interoperability Category</th>
<th>Foundational</th>
<th>Structural</th>
<th>Semantic</th>
<th>Clinical Workflow</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northwest Moravia, Czech Republic</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>Uses networking standards and HL7 messages. Stand-alone system – does not use data standards. Telehealth program is not fully incorporated into standard care; treated as research project.</td>
</tr>
<tr>
<td>South Karelia, Finland</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>Uses networking standards. PHR as part of overall EHR offerings – bring your own device assumed – manual data entry from patient into PHR - does not use messaging or data standards. Is standard care in the region.</td>
</tr>
<tr>
<td>Nord Pas de Calais, France</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>Used networking standards. Stand-alone system – does not use data standards. Was a research project and is not part of standard care.</td>
</tr>
<tr>
<td>Berlin, Germany</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>Uses networking standards. Stand-alone system – does not use data standards. Is treated as a research project and not part of standard care. Is limited to the Pflegewerk site and not Berlin-wide.</td>
</tr>
<tr>
<td>Central Greece</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>Uses networking standards. Not integrated into EHR. Does not use data standards. Part of clinical workflow and standard care.</td>
</tr>
</tbody>
</table>

As discussed in section 2.3, the three successive levels of full interoperability are:
- foundational: e.g. the ability of a smartphone to connect to a GSMA network;
- structural: e.g. the ability of a remote monitoring system to send a message to an electronic medical record (EMR) system and have the EMR recognise it;
- semantic: e.g. the ability of the EMR system to understand the type of data in the message and appropriately place it where it is best used within the application.

The grading is done on a scale of 0, 1 and 2, as follows:
- 0: no interoperability is demonstrated in that particular category;
- 1: minimal interoperability is demonstrated in that category; and
- 2: the best interoperability currently available is demonstrated in that category.
The overall picture of deployment sites’ achievements in terms of interoperability and standards is mixed. No deployment site achieved the highest level, that is interoperability that is currently available in the market. All sites score well on the “foundational” data exchanges, meaning they have followed telecommunication standards with regard to network protocols, including Bluetooth or GSMA. Most have achieved a good level of structural interoperability, meaning that the receiving machine “understood” the data it received. Only a few have made progress towards semantic interoperability, where a receiving system (such as an EHR system) was able to use and action the data it received. The critical limitation of the project overall

<table>
<thead>
<tr>
<th>Region</th>
<th>Foundational</th>
<th>Structural</th>
<th>Semantic</th>
<th>Clinical Workflow</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calabria, Italy</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>Used networking standards. Stand-alone system – does not use data standards. Not part of standard care; is a research project.</td>
</tr>
<tr>
<td>Campania, Italy</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>Used networking standards. Stand-alone system – does not use data standards. Not part of standard care; is a research project.</td>
</tr>
<tr>
<td>Northern Norway</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>See Southern Norway</td>
</tr>
<tr>
<td>Southern Norway</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>Uses networking standards and security standards. Partially integrated system and are working towards use of data standards – does use messaging standards. Is standard care and being offered region-wide.</td>
</tr>
<tr>
<td>Slovenia</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>Used networking standards and security standards. Does use messaging standards. Stand-alone system - does not use data standards. Is standard care for region.</td>
</tr>
<tr>
<td>Basque Country</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>Uses networking standards. Integrated into EMR – does not use data standards, does use messaging standards. Is part of standard care in region.</td>
</tr>
<tr>
<td>Galicia, Spain</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>Uses networking standards. Integrated system – use manual entry between telehealth system and EHR – does not use data standards; (however in September 2015, devices will be Continua and IHE compliant). Is part of standard care.</td>
</tr>
<tr>
<td>Scotland, United Kingdom - Diabetes</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>Uses networking standards. System integrated into national web portal for diabetes – does not use data standards. For diabetes is part of standard care.</td>
</tr>
<tr>
<td>Scotland, United Kingdom – CHF, COPD</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>Uses networking standards, stand-alone systems for other chronic conditions (CHF/COPD) management – does not use data standards. For CHF/COPD is still in research phase and not yet standard care.</td>
</tr>
<tr>
<td>Wales, United Kingdom</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>Uses networking standards. Stand-alone system – combination of automatic and manual data entry - does not use data or messaging standards. Is going to be part of standard care for diabetes and COPD.</td>
</tr>
</tbody>
</table>
is that deployment sites did not specify data and messaging standards for healthcare such as those recommended by Continua and IHE-PHD. This is despite the project’s professed intention to use technology that complies with interoperability requirements, as recommended by the IAT. Why?

### 6.2 Procurement: theory and practice

In looking to the market for medical devices that could interface with the mobile phones or use the data and network standards as recommended by Continua and IHE-PHD, many deployment sites had difficulties finding them. Because of rules governing public procurement, it was not enough that there was one device available: there had to be at least two or more vendors offering the devices that complied with these requirements. In the fragmented European markets and with the small volume of procurements, this threshold number was often not met, especially where the required use of local language in contractual and equipment information was a barrier for new international players. One site representative suggested that their national market did not seem large enough just yet for many competitors in the telehealth area.

But this is not just the market’s fault. Midway through the project, a separate report was prepared by COCIR (with assistance from Continua) in which eight deployment sites were visited to ascertain how they procured their systems and what the barriers were to procuring interoperable systems.\(^9\) Key findings regarding adoption and procurement of interoperable solutions from that report were:

- **There is a ‘chicken and egg’ problem** to the adoption of technically interoperable and standards based solutions. One the one hand, vendors observe that the procurers do not require standards based solutions and therefore do not bring them to market. On the other hand, 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 organise an effective competitive procurement process. This leads procurers to loosen or cut their demands for standards in their tenders, thus eliminating an incentive for vendors to bring these products to market.

- **The sites used a variety of procurement processes.** These included use of donated systems, use of national framework agreements, local procurements, and in one case an EU-wide procurement. However, in all cases, the deployment sites’ decision makers preferred to have a vendor with a local presence. Trust between the vendor and healthcare organisation was considered paramount for the successful deployment of a telehealth system / service.

- **Time constraints exerted further pressure.** Where there was open procurement, it occurred late in the project, and decision makers were under significant time pressure. This was attributed to project delays, including the extended time required to get agreement between the deployment sites regarding the clinical workflows, protocols, and system architectures (described in section 3).

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\(^9\) Richardsson, Helen and Bridget Moorman, United4Health D5.6 Annex 1, Pilot Site Assessment Report, v1.0, 17 February 2015.
Diversity of technology solutions across deployment sites: A mandate for standards or an agreement on common technology solutions across all deployment sites for each chronic condition would have been preferable, however this would have required the completion of other project initiation activities, and it would have been difficult to achieve due to the heterogeneity of clinical practices, infrastructures, and legacy systems in the deployment sites.

Perhaps in this regard the project missed an opportunity: the process used to have all sites agree on clinical protocols with similar functional system architectures could have been used to drive agreement upon ‘interoperable’ protocols and architectures. But project timescales made this difficult.

In addition, procurers do not seem to always send the appropriate signals that they prefer interoperable systems. A survey of the deployment sites’ wishes for standards-based products was conducted midway through the project. The table below depicts the results overall (5 is highly desired, 1 is minimally desired):

Table 2: United4Health standards desirability survey results

<table>
<thead>
<tr>
<th>Deployment Site</th>
<th>Require Standard Solution</th>
<th>Physical</th>
<th>Network</th>
<th>Data</th>
<th>Message</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Karelia, Finland</td>
<td>Yes</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>To reporting</td>
</tr>
<tr>
<td>Central Greece</td>
<td>Yes</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td>Yes</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>Web</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Basque Country, Spain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>XML, web, real-time subscription services</td>
</tr>
<tr>
<td>Scotland, UK</td>
<td>Yes</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>Use of consumer devices</td>
</tr>
</tbody>
</table>

In theory then, deployment sites want a high degree of interoperability in their solutions. What role did standards play in their actual implementations? The following table gives an overview:

Table 3: United4Health interface standards used

<table>
<thead>
<tr>
<th>Region</th>
<th>Condition</th>
<th>Means of Transmission from Medical Device</th>
<th>Means of Transmission from Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwest Moravia (CZ)</td>
<td>CHF, DM</td>
<td>Bluetooth 3.0</td>
<td>GSM, Internet (Web)</td>
</tr>
<tr>
<td>South Karelia (FI)</td>
<td>DM</td>
<td>Manual Entry</td>
<td>GSM, Internet (Web)</td>
</tr>
<tr>
<td>Nord Pas de Calais (FR)</td>
<td>HTN</td>
<td>Bluetooth</td>
<td>GPRS via Orange Business Services</td>
</tr>
<tr>
<td>Berlin (DE)</td>
<td>COPD, DM</td>
<td>USB, Bluetooth</td>
<td>Internet</td>
</tr>
</tbody>
</table>

In comparing the two tables above, one can observe a disconnect between what the deployment sites wish for and what they implement. They want solutions with data and messaging standards, and physical and networking standards, and yet they neither require nor implement solutions using these data and messaging standards.

The reasons for this vary. Some vendors could not provide cost-effective and competitive solutions using data and messaging standards. The restricted project time frame, compounded by delays in finalising some project initiation activities, resulted in solutions being implemented that were readily available, as opposed to those which may have required additional time or development to incorporate standards.

Overall it appears that the market is trapped in a “chicken and egg” situation: there is limited supply of interoperable solutions, so there is no demand, especially as long as interoperability remains largely theoretical. Policy makers, consumers, buyers and industry agree on the benefits of interoperability, but the tipping point at which interoperability could happen “naturally” has not yet been reached.

### 6.3 The push from policy

Resolving this “chicken and egg” situation in a timely fashion may go beyond the power of the market. Especially in European healthcare systems that are largely regulated and/or funded by governments and other public bodies, policymakers possess an arsenal of instruments to prod the market to deliver standards-based solutions. These instruments include direct procurement, setting guidelines for procurements, defining mandatory technical specifications for public or private EHR systems, and developing telehealth action plans that set out targets and timelines for healthcare actors to follow. There are encouraging signs that policymakers are realising that they have a role to play.

The European Commission has no power to intervene in national or regional healthcare systems, or to mandate that Member States adopt specific standards. Of
course, the Commission has funded large scale pilot initiatives (including U4H) to promote the testing and deployment of interoperable telemedicine solutions. However, these pilots do not appear to have substantially advanced agreements on specific standards.

At the policy level, the Commission in 2013 proposed the eHealth European Interoperability Framework with a summary of relevant standards and profiles, including those developed by Continua and IHE. More recently, in 2015 the Joint Action to support the eHealth Network (JAseHN), funded by the European Commission, has been developing a collaborative platform of SDOs and national eHealth competence centres to resolve gaps or overlaps between standards (again including Continua and IHE profiles). Ultimately it is the Member States that have to formally accept or adopt these initiatives.

Clearly, the appropriate level of decision making on standards, such as a formal endorsement, has to be made at Member State level (or, in those Member States where health policy is devolved, the regions). Some Member States have begun to act. The health ministries of Denmark (2012) and Norway (2014) have mandated that healthcare providers require Continua compliant devices and solutions. These endorsements are part of a formal push and investment programme in these countries to advance their national telemedicine infrastructures. These policies should act as powerful incentives to vendors to bring compliant products to market.

The Nordics' actions on standards may have wider implications, especially as there are efforts among Nordic countries to align their infrastructures and legal / regulatory requirements, thus creating a potential healthcare market that serves 26 million people with significant public investment in new telemedicine technologies. In combination with the Nordics’ reputation for innovation and social cohesion, spillover effects into other European markets are expected, especially when the benefits of telemedicine large scale deployments with interoperability become apparent.

6.4 Addressing other barriers

Interoperability of telemedicine solutions is the principal focus of this report, but there are other barriers that slow the adoption of telemedicine. Fortunately some are being addressed.

- Privacy and security of data: Users’ concern about the integrity and privacy of their data remains an important barrier to the adoption of personal health solutions. In a 2014 study by Mobiquity, 61% of participants cited privacy concerns as the primary reason stopping them from using apps even more

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12 As of August 2015, more Nordic countries are expected to follow. The Danish announcement is at [http://www.continuaalliance.org/sites/default/files/Denmark_Action_Plan_RELEASE_FINAL.pdf](http://www.continuaalliance.org/sites/default/files/Denmark_Action_Plan_RELEASE_FINAL.pdf). The Norwegian announcement is at [https://www.regjeringen.no/no/aktuelt/standardisering-av-velferdsteknologi-med-continua/id2356200/](https://www.regjeringen.no/no/aktuelt/standardisering-av-velferdsteknologi-med-continua/id2356200/).

13 A discussion and list of the growing number of devices that comply with Continua guidelines and IHE profiles is in Appendix A.
than they were.\textsuperscript{14} The 2014 public consultation of experts and stakeholders following the European Commission’s Green Paper on Mobile Health also yielded a strong majority in favour of strong privacy and security principles to build user trust.\textsuperscript{15} As a result, the Commission has assembled a working group to develop a voluntary code of conduct for mHealth developers that will clarify the legal environment and give app developers clear guidance on good practices. An initial draft of the code is expected in late 2015 or early 2016.

- **Regulatory uncertainty:** The concern of app developers to avoid the medical device regulatory regime has slowed innovation and the adoption of mHealth. Regulatory agencies are struggling to recalibrate the balance between promoting innovation and consumer safety. The U.S. Food and Drug Administration has issued and updated guidelines that distinguish between those mobile apps that are medical devices and those that are not. Included in the exempt category are those devices that merely display information, perform simple calculations, provide coaching, or smartphone cameras that take a picture of a wound sent to a doctor.\textsuperscript{16} In the European Union, a new Medical Device Regulation is currently under review and is projected to be finalised in 2016, with the European Parliament and the European Council (representing the Member States) currently discussing its final outcomes. A contested issue remains whether a device (i.e. a smartphone) displaying medical information is an accessory to a medical device and therefore subject to the Regulation, or whether it is not. The outcome of this discussion will impact whether private smartphones can be used in telehealth. If they cannot, it will add cost and inconvenience, and further slow the adoption of mHealth.\textsuperscript{17}

Other barriers remain. The field of medical practice is conservative and slow to change. In line with the prevailing professional ethos, many clinicians require evidence of the efficacy of telemedicine before embracing telemedicine. Similarly, healthcare managers continue to await proof that telemedicine is more cost effective than conventional healthcare delivery. Because evidence in the field is still emerging, there are few reimbursement models that deliver appropriate incentives for patients, healthcare providers and carers.

### 6.5 Assessment and recommendations

Achieving better interoperability and scalability of services were beyond the scope and time frame of the U4H project. However, the project has helped to push in the right direction. As many U4H deployment sites are moving towards further taking telehealth to scale, there is now a more advanced understanding of the benefits of interoperability.


\textsuperscript{16} The latest version from February 2015 is at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.

\textsuperscript{17} For a comprehensive discussion of the regulatory environment affecting telemedicine consider “Industry Report on Telemedicine Legal and Regulatory Framework” (U4H deliverable D5.5), available at http://bit.ly/1Noo2wB.
Further progress towards interoperability requires efforts among all players. We recommend:

- **For healthcare providers:** Support standards adoption by purchasing standards-compliant products, or by including a preference for them in procurement documents. This should include compliance with data and messaging standards, and interoperability with other existing systems. Where such products are not available, healthcare providers should contract with suppliers that commit to moving towards standards.  

- **For technology providers:** 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. Providers should understand that procurers will increasingly demand messaging standards and eventually data standards, at least at the interface to the healthcare providers' systems.

- **For healthcare policymakers:** 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 actors time to adjust. An interoperable eHealth ecosystem benefits everybody, but the market might need support from government and regulators to achieve this.

It has been observed that the market for interoperable telehealth solutions reflects a chicken and egg situation, but ultimately the onus is on the buyers: if they demand interoperability, the market will deliver.

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18 For procurers to demand what is needed, they may require information, assistance and help. The IAT prepared a checklist document to assist United4Health pilots in promoting the demand for standards. Owing to the limited availability in the market of products utilising these standards, the document listed preferences for the use of the standards, rather than a mandatory requirement. That interoperability checklist is available on the United4Health website at [http://bit.ly/1PHpnRD](http://bit.ly/1PHpnRD) (Annex B). All procurers are invited to review and adapt it to their circumstances.
7. References


United4Health D5.6 Annex 1, Pilot Site Assessment Report, v1.0, 17 February 2015, Helen Richardsson and Bridget Moorman

Appendix A: Interoperable products on the market

A.1 Continua Certified Products

Continua offers guidelines for vendors to produce standards based products at several interfaces along the data transmission path for medical devices that could be used in a personal or remote setting. Currently, these guidelines are augmented with constrained standards at the interfaces to foster plug-and-play interoperability. Additionally, testing labs around the world offer independent interface testing for product certification to guidelines adherence.

Continua currently has 70 products which are certified with a projected ten more in the pipeline for the next year. Moreover, the work within Continua is working towards better enablement of web-based and mobile standards products. For a list of devices on the market that are Continua certified see http://www.continuaalliance.org/products/product-showcase.

In Europe, the Nordic countries of Denmark and Norway have specified the use of Continua guidelines in their procurement process for the purchase and integration of personally generated healthcare data into their national and/or regional EMRs. Other Nordic countries including Sweden and Finland are expected to follow.

A.2 Device Enterprise Communication (DEC)

Table 4 shows Device Enterprise Communication (DEC) IHE-PCD-01 products available as of European Connectathons 2010, 2011, 2013, 2014 and 2015. DEC is the profile in the Patient Care Device Domain of IHE and is used in the Continua guidelines at the wide area network (WAN) interfaces. DEC is one of the IHE profiles that can be used to guide vendors building standard based products and is specifically concerned with the integration or connection of medical device data to healthcare ICT systems.

Table 4: Device enterprise communication

<table>
<thead>
<tr>
<th>Device Observation</th>
<th>Consumer</th>
<th>Filter</th>
<th>Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Braun Medical</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CapsuleTech Inc.</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cardinal Health</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CareFusion</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cerner Corporation</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Draeger Medical Systems, Inc.</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ENOVACOM</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresenius Kabi</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
This list demonstrates that there are quite a few products and product classes (ranging from single sensor devices to EMRS) on the European market that specify standards at the WAN interface.
Appendix B: U4H deployment sites overview tables

B.1 Parameters and data types collected

Based on the breakdown of deployment sites for the chronic conditions of diabetes, COPD, CHF and HTN, the following table gives a summary of the parameters, data types and specific technical capability that was collected / required in the U4H Project’s pilots.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Chronic condition</th>
<th>Diabetes Mellitus (DM)</th>
<th>Chronic Obstructive Pulmonary Disease (COPD)</th>
<th>Congestive Heart Failure (CHF)</th>
<th>Hypertension (HTN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td>Nord Pas de Calais</td>
</tr>
<tr>
<td>Pulse oximetry (SPO2), pulse rate</td>
<td></td>
<td>Galicia, Northern and Southern Norway, Scotland, Wales</td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight scale</td>
<td></td>
<td></td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td>Nord Pas de Calais</td>
</tr>
<tr>
<td>Blood glucose</td>
<td></td>
<td>Berlin, Campania, Central Greece, Galicia, Scotland, Sicilia, Slovenia, South Karelia, Wales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video teleconference</td>
<td></td>
<td>Galicia, Northern and Southern Norway, Scotland, Wales</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B.2 Devices, interfaces, and telehealth software capabilities

Below is a summary table of the devices and interfaces used by each site, listed separately for each condition where they differ. The monitoring device may be a glucometer, blood pressure cuff, weight scale, spirometer, pulse oximeter, or an ECG.

Table 6: Devices and interfaces

<table>
<thead>
<tr>
<th>Region</th>
<th>Device-Interface</th>
<th>Condition</th>
<th>Monitoring device</th>
<th>Means of Transmission</th>
<th>Aggregation Gateway in Home (Application Hosting Device)</th>
<th>Means of Transmission</th>
<th>Personal Health Record</th>
<th>Electronic Health Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwest Moravia</td>
<td></td>
<td>CHF, DM</td>
<td>(A&amp;D Medical UC-351PBT-Ci weight scale, A&amp;D Medical UA-767PBT-Ci blood pressure monitor, Choicemed wrist pulse oximeter, Fora Diamond Mini)</td>
<td>Bluetooth</td>
<td>Samsung Galaxy Tab 3 8.0 and 4.5 inch Android Samsung Galaxy Express 2 (Medimonitor Android Gateway Application provided by Ness Solutions)</td>
<td>GPRS/EDGE/3G</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Karelia</td>
<td></td>
<td>DM</td>
<td>Glucometers- are patient owned so patients use different brands.</td>
<td>Manual entry</td>
<td>Patient owned mobile phone or home computer through web application (Hyvis.fi)</td>
<td>GSM, Internet (Web)</td>
<td>Mediconsult Oy</td>
<td>Effica (Regional EHR)</td>
</tr>
<tr>
<td>Nord Pas de Calais</td>
<td></td>
<td>HTN</td>
<td>Parsys non-invasive blood pressure machine, EKG, weight scale and pill box (medication adherence)</td>
<td>Bluetooth</td>
<td>Parsys Telemedicine Box and Inovelan Web client for EKG management and web access to patient data</td>
<td>GPRS via Orange Business Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device-Interface Region</td>
<td>Condition</td>
<td>Monitoring device</td>
<td>Means of Transmission</td>
<td>Aggregation Gateway in Home (Application Hosting Device)</td>
<td>Means of Transmission</td>
<td>Personal Health Record</td>
<td>Electronic Health Record</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Berlin</td>
<td>COPD, DM</td>
<td>SPO2-Nonin 9560 Onyx II Jaeger -Viasys AM1+BT Asthma Monitor (Spirometer); Glucometer – Cignus Diagnostics ProfiLine, IEM Libr-O-Graph mobile</td>
<td>USB, Bluetooth</td>
<td>Arbor Technology Medical Tablet PC M1255/N270 or Mobile phone (HTC Cha-Cha)</td>
<td>Internet</td>
<td>DM- LifeSensor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Greece</td>
<td>DM</td>
<td>Glucometer – Card-Guard PMP Self-Check Gluco module</td>
<td>Bluetooth</td>
<td>PDA QTEC 2020i and Vodafone ETEN</td>
<td>GSM (GPRS)</td>
<td>PMP4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calabria</td>
<td>DM</td>
<td>Glucometer – Lifescan, Johnson&amp; Johnson</td>
<td>USB and Manual entry</td>
<td>Home computer and cloud server with Eurotouch 10 (Johnson &amp; Johnson) Diabetic Management Database</td>
<td>Internet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Campania</td>
<td>DM</td>
<td>Glucometer – FORA Diamond GD50 by Care Suisse AG</td>
<td>RS232 wired and manual entry</td>
<td>Home computer and Web-based portal by Diabetel.net and Meter s.r.l</td>
<td>ADSL; Internet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northern and Southern Norway</td>
<td>COPD</td>
<td>Nonin PureSat pulse oximeter, Vitalograph 400 asma-1 spirometer</td>
<td>Bluetooth</td>
<td>Windows 8 Tablet ‘locked’ down; software will be classified as medical software; Cisco Jabber Video teleconferencing software</td>
<td>TeleNorway VPN tunnel</td>
<td>ePHR</td>
<td>Use of Transitional Personal Health Record (TPHR) to meet legal and security concerns; PDF import and export functions to exchange data with existing EHR systems</td>
<td></td>
</tr>
<tr>
<td>Device-Interface Region</td>
<td>Condition</td>
<td>Monitoring device</td>
<td>Means of Transmission</td>
<td>Aggregation Gateway in Home (Application Hosting Device)</td>
<td>Means of Transmission</td>
<td>Personal Health Record</td>
<td>Electronic Health Record</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>COPD, DM</td>
<td>IEM Librograph weight scale, Card Guard ECG, Nonin Onyx II pulse oximeter, Cignus ProfiLine glucometer, TaiDoc TD Ear thermometer, Vitalograph asma-1 spirometer</td>
<td>Bluetooth 3.0 or higher</td>
<td>Health Insight Solutions Santigo application on a tablet or other Android 2.3 or higher device</td>
<td>GSM, Internet</td>
<td>Portal access to monitoring information (HIS Santigo portal) via web-based browser. HIS portal is currently located at SB-SG hospital. Hope to have HIS Portal available to zNet (Slovenian national health information infrastructure) in future.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basque Country</td>
<td>CHF</td>
<td>Nonin 9560 Onyx II pulse-oximeter, A&amp;D UA-767PBT blood pressure monitor, A&amp;D UC-321 PBT digital weight scale; Tunstall Lifeline Vi Telecare device</td>
<td>Bluetooth and manual entry (weight)</td>
<td>Mymedic II (Tunstall); non-mobile solution, CarelineH@me (Saludnova): mobile solution</td>
<td>Landline (Internet-Web services), GPRS/3G</td>
<td>Osakidetza</td>
<td>Osakidetza</td>
<td></td>
</tr>
<tr>
<td>Galicia</td>
<td>COPD</td>
<td>Tablet Net-Pc Samsung ATIV Tab 5 XE500T1C – 29,5 cm (11,6&quot;) 64 GB-3G, Intel Atom Z2760 1,8 GHz-2GB RAM-Windows 8 Pro 32-bit-HSPA+-Hibrido-1336x768(LED Backlight)-Bluetooth and Pulsoximetre, Onix II</td>
<td>Bluetooth (to patient tablet) and Manual entry to EMR</td>
<td>Locked down tablet with Videoconferencing ability; pulse oximeter – all information is gathered and then manually entered into EHR application</td>
<td>Telefonica and Indra</td>
<td>Telefonica application – with manual entry to Galician EMR application</td>
<td>IANUS, Galicia Electronic Health Record</td>
<td></td>
</tr>
<tr>
<td>Region</td>
<td>Condition</td>
<td>Monitoring device</td>
<td>Means of Transmission</td>
<td>Aggregation Gateway in Home (Application Hosting Device)</td>
<td>Means of Transmission</td>
<td>Personal Health Record</td>
<td>Electronic Health Record</td>
<td></td>
</tr>
<tr>
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<td>------------------------</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>Scotland</td>
<td>CHF, COPD, DM</td>
<td>A&amp;D Bluetooth Blood Pressure Monitor, Weight Scale, ChoiceMed Bluetooth pulse oximeter, patient owned glucometers, so many brands</td>
<td>Bluetooth and USB and manual entry (glucometer)</td>
<td>Medvivo HomePod; Safe Medical Care Application- Portal- Nexus Tablet; home computer with Diasend software combined with SCI-DC and My Diabetes My Way (MDMW) portals</td>
<td>GPRS, GSM, Internet; 2G, 3G, 4G; VPN/APN (MedVivo)</td>
<td>Simple Telehealth Service (FLO); MedVivo web and data servers; Safe Medical Care web application; My Diabetes My Way (MDMW)(diabetes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wales</td>
<td>COPD, DM</td>
<td>TaiDoc VTrust Handheld Pulse Oximeter, TaiDoc Lever TD Ear Thermometer, TaiDoc Blood Pressure Monitoring System, patient owned glucometers, so many brands</td>
<td>Bluetooth, manual entry</td>
<td>Archos Computer Tablet, mobile phone (video-teleconferencing capability as well)</td>
<td>GPRS</td>
<td>Simple Telehealth Service (FLO)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The table below lists the U4H deployment site telehealth software capabilities or functionalities available for patients and clinicians.
Table 7: Deployment telehealth software capabilities for patients

<table>
<thead>
<tr>
<th>Region</th>
<th>Software Capability</th>
<th>Data Visualisation of Vital Signs</th>
<th>Alerting of Deviation / Normal Values</th>
<th>Input of Manual Measurements</th>
<th>Symptoms and Quality of Life Questionnaires Input</th>
<th>Satisfaction Questionnaires Input</th>
<th>Technical Questionnaires Input</th>
<th>Video/Voice or Text Communication with Clinician</th>
<th>Calendar Functions, Appointment Review and/or Petition</th>
<th>Reproduction of Educational Material</th>
<th>Medication Reminders</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Karelia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes (text, safety messaging)</td>
<td>Yes, part of eHealth servicing in Eksote</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Berlin</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>No</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Calabria</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Northern &amp; Southern Norway</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes, is an option with system, however</td>
<td>Yes</td>
<td>Yes, on separate portal</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes, is an option with system, however</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Basque Country</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td>Yes, as of Sep 2015</td>
<td>No</td>
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</tr>
<tr>
<td>Galicia</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes, is an option with system, however</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Scotland</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Wales</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No, but can if wanted</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
## Table 8: Deployment site telehealth software capabilities for clinical professional

<table>
<thead>
<tr>
<th>Software Capability</th>
<th>Data Visualization</th>
<th>Alerting of Deviation / Normal Values</th>
<th>Prioritisation of Patients According to their Risk Levels</th>
<th>Task Management</th>
<th>Structured Telephone Support (to get data from patients)</th>
<th>Video/Voice or Text Communication with Patients</th>
<th>Video/Voice or Text Communication/Reporting with/to Other Clinicians</th>
<th>Calendar Function: Appointment Review and/or Petition</th>
<th>Careplan Creation, edition and changing</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Karelia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, part of eHealth service in Eksote</td>
<td>Yes</td>
<td>No</td>
<td>Yes, text safety messaging</td>
<td>Yes, text safety messaging; data is available to other clinicians</td>
<td>Yes, part of eHealth service in Eksote</td>
<td>Yes</td>
</tr>
<tr>
<td>Berlin</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No, available on another portal</td>
<td>Yes, comment blog with text; automatic generation of clinician report</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Calabria</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Northern and Southern Norway</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No;</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>No</td>
<td>No, is an option with system, however</td>
<td>No</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes, on separate portal</td>
<td></td>
</tr>
<tr>
<td>Basque Country</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Galicia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Scotland</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Wales</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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</tbody>
</table>