

## Continua: The Impact of a Personal Telehealth Ecosystem

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### Abstract

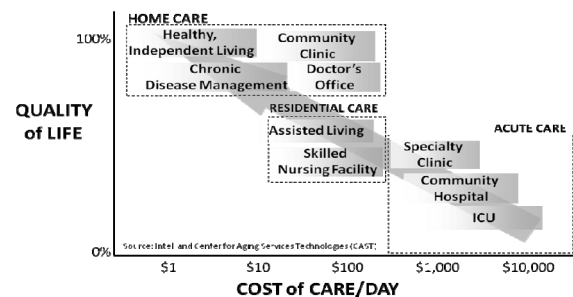
The Continua Health Alliance is nearing the first release of its Design Guidelines, an important milestone towards the establishment of a personal telehealth ecosystem. These guidelines address the technical barrier for a personal telehealth ecosystem: interoperability amongst multivendor systems. This paper describes why it is essential to address interoperability, regulatory aspects of multi-vendor systems and reimbursement for establishment of a personal telehealth ecosystem. In addition we elaborate on the impact that Continua has on the development of the personal telehealth domain. First we motivate why the establishment of such an ecosystem is an essential part in addressing the healthcare challenges in society.

### 1. Introduction

In 2006 the cost for healthcare in the United States rose to \$2.1 trillion or 16 percent of the gross domestic product (GDP) [1]. This correlates with the fact of an aging population and an increase of chronic diseases, which account for more than 75% of the total US healthcare costs [2]. Considering diabetes as an example, it is expected that the prevalence of diabetes in the US increases by more than 70% until the year 2030 compared to 2000 [3], which is alarming. This effect is to a large extent due to the aging society and a more sedentary lifestyle as the population growth rate in the US is estimated to be clearly lower [3]. However, this development is not restricted to the US but is a worldwide problem that both developed and developing countries are facing [3]. Hence, a major challenge in healthcare is to more efficiently provide high-quality care for an increasing number of patients using limited financial and human resources.

Personal telehealth systems, including remote patient monitoring and management, are increasingly recognized as having the potential to help addressing that resource challenge. In personal telehealth systems

the caregiver is geographically separated from the care consumer with the care plan being individually tailored to the patient's needs. This patient-centered concept of bringing the care from the hospital to the patient at home is expected to result in cost-reduction and improved quality of life as is depicted in Figure 1. Through daily automated, but personalized, patient intervention, the care providers can optimize the patient's medication and treatment and more efficiently manage a larger group of chronic disease patients.



**Figure 1: Reducing costs and improving quality of life**

However, while personal telehealth systems offer many potential benefits, there are a number of challenges that have to be overcome to support larger scale growth. These include technical issues (e.g. interoperability, reliability, privacy, security, etc.) as well as legal and regulatory issues (e.g. liability), and financial issues (e.g. reimbursement, who pays).

Many sophisticated, but isolated and proprietary solutions exist today. These proprietary solutions lack interoperability, and hence prevent that the mentioned issues are solved in a unified, standardized and cost-effective way. Without interoperability it is not possible to combine the health data that a person gathers with various telehealth devices and services. Thus part of the opportunity to fully use this data for improving the health of the person is lost.

## 2. The Need for Interoperability in Personal Telehealth

The personal telehealth domain is broad and complex. It can be categorized in three sections; disease management for patients with chronic conditions, health & fitness for consumers that want to stay fit and aging independently to support elderly in living comfortably in their own home. In order to provide solutions for each of these categories, but also to support interaction between systems in different categories, companies in this space have been working together. This allows each company to focus on its core competencies while relying on the expertise of others for complementary competencies.

A good example of cooperation can be found in the measurement devices used in telehealth systems. In order to support a wide range of diseases it is necessary for such a system to work with a large variety of measurement devices, such as blood pressure monitors, weighing scales, glucose meters, pulse oximeters, ECG monitors, peak flow meters, etc. For each of these measurement device types there are a number of companies making them, but none of the companies makes all of these devices. So a telehealth system vendor will need to work with different suppliers to provide a complete set of measurement devices to its customers.

Today, each of these devices from each of these vendors communicates in a different way. Even if some devices use the same transport mechanism, such as Bluetooth, USB, Infrared or a serial cable, each of them will still use a different way of transmitting the data over that transport mechanism. It becomes clear very quickly that it is a daunting task for a telehealth system vendor to make its system work with all of these different devices from different vendors.

Another example of need for cooperation is the integration of personal telehealth data into electronic and personal health records (EHR/PHR). Often the supplier of a telehealth system is not the supplier of the EHR or PHR system that is used to store health data about the patient. Since there were no proper standards in place yet to transfer health data from a telehealth system into an EHR or PHR system, the telehealth vendor had to work with all major EHR/PHR providers to develop custom interfaces for transferring this data. Again a huge amount of work that created a significant barrier for proper integration of telehealth data into EHR/PHR systems and thus limiting the potential health benefits and efficiency improvements that personal telehealth could offer.

## 3. The Continua Health Alliance

In 2006 Philips was one of the founding members of the Continua Health Alliance; an organization comprised of technology, medical device and health care industry leaders dedicated to making personal telehealth a reality [4]. Currently the Alliance consists of over 150 member companies all working together towards the same goal of improving healthcare worldwide by establishing a system of interoperable personal telehealth solutions that fosters independence and empowers people and organizations to better manage health and wellness.

The examples described in section 2 focused on the technical barriers. However it is important to understand that taking down the technical barriers is only the first step towards unlocking the true potential for growth of the personal telehealth market, as there are also other barriers. The main barriers that restrain the growth of the personal telehealth market identified by Continua are:

1. Technical; the lack of interoperable telehealth standards and equipment.
2. Regulatory; current safety regulations hamper the creation of multi-vendor solutions.
3. Financial; economic value (Return on Investment) of personal telehealth has proven difficult to demonstrate in a scientifically sound way, which restrains the adjustment of reimbursement models that support personal telehealth.

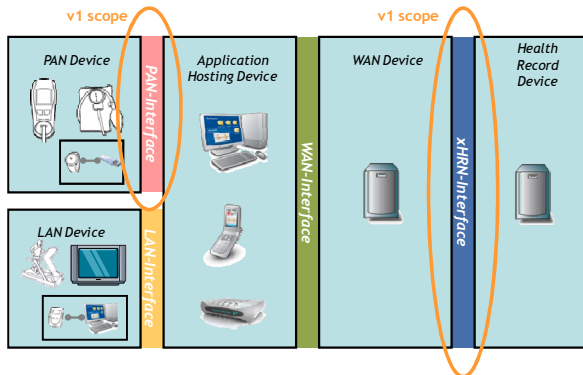
If the regulatory and financial barriers are left in place, the personal telehealth market will keep facing large restraints. Therefore the Continua Health Alliance is actively pursuing solutions to all three barriers:

1. Technical solution; design guidelines to support interoperable sensors, platforms and services and a logo & certification program to signify the promise of interoperability to the customer.
2. Regulatory solution; work with regulatory agencies to safely and effectively manage diverse vendor solutions.
3. Financial solution; work with leaders in the healthcare industries to develop new ways of addressing the costs of providing personal telehealth systems, such as new reimbursement models and co-pay solutions.

## 4. Design Guidelines

For the past two years the Continua Health Alliance has been working towards the development of the Version One Design Guidelines. At the basis of these guidelines lie the use cases that were submitted by the Continua members. The use cases describe the functionality that a personal telehealth system should deliver and what different components a personal telehealth system consists of.

These use cases were then analyzed to identify the interoperability needs. Since Continua only focuses on the interoperability aspect and not prescribes specific functionality, the interest for Continua lies in the connections between the different components of a personal telehealth system. Figure 2 shows the Continua Reference Architecture [5] that contains the type of components of a personal telehealth system and how they are connected.



**Figure 2: Continua Reference Architecture**

For the first version of the design guidelines Continua focuses on the Personal Area Network (PAN) interface and the Electronic/Personal Health Record Network (xHRN) interface. This first selection was made to demonstrate workable results in a limited amount of time and to focus the effort of the organization on the highest priority interfaces first.

### 4.1. PAN Interface

The PAN interface describes the connection between PAN devices, such as sensors and actuators, and Application Hosting Devices (AHD), such as mobile phones, PDAs, computers and set-top boxes.

Continua has selected standards for two different levels of the PAN interface; the transport level and the data level. For the transport level Continua has selected Bluetooth Health Device Profile [6] for wireless communication and USB Personal Healthcare Devices [7] for wired communication. Above the transport level

is the data level. Continua has selected the ISO/IEEE 11073 Personal Health Device family of standards [8] to enable data format interoperability.

To ensure interoperability Continua has created guidelines that reference these standards and remove optionality. In the first version of the guidelines Continua supports the following list of personal health devices: weighing scale, blood pressure monitor, glucose meter, pulse oximeter, thermometer, strength fitness, cardiovascular fitness and the aging independently activity hub.

The first version of the Continua guidelines enables technical interoperability between PAN devices and Application Hosting Devices of different vendors. Many of these devices need to work within the existing regulated scenarios, meaning that depending on the intended use of a particular set of devices there needs to be evidence that this particular set is a safe and effective way to work within the intended use. Regulatory aspects are not covered by the design guidelines and are left for the system integrator at this point. The Continua regulatory working group is working with regulatory agencies such as the FDA on how to address regulatory aspects in an ecosystem as envisioned by Continua.

### 4.2. xHRN Interface

The xHRN interface describes the connection between back-end services (Wide Area Network (WAN) Devices), such as weight loss services and disease management services, and electronic/personal health records (Health Record Devices). These back-end services are often under control of different companies and focus on a specific part of the personal healthcare needs of an individual. Electronic health records hold the promise of offering a broad overview of a person's health status in a central location.

Traditionally electronic health records come from the hospital domain where doctors have an electronic repository of the health data of their patients. The patients didn't necessarily get access, let alone control over the data that was gathered and stored about them. A current trend is to allow patients access to their data stored in electronic health records through so called patient portals. At the same time there is significant attention for initiatives like Microsoft HealthVault, Google Health and many others that allow patients to gather and store their own health data and have full control over their data. These systems are often referred to as personal health records (PHR) or PHR platforms.

Continua believes there is merit in both electronic health records and personal health records and deems it

important to be able to share health data available in personal telehealth back-end services with EHR and PHR systems. The xHRN interface enables exactly that.

Continua has selected the Integrating the Healthcare Enterprise (IHE) Cross-Enterprise Document Reliable Interchange (XDR) profile [9] as means to establish the communication between WAN devices and xHR systems. On top of this profile the Health Level 7 (HL7) Personal Health Monitoring (PHM) Report document format [10] was chosen to ensure consistent data encoding.

The guidelines for the xHRN interface now enable people using various personal telehealth systems to share that data with their own personal health record or the electronic health record under control of their doctor and get a broader and hopefully better overview of their health status, with the goal of supporting improvements in the medical care for these people.

## 5. Impact

A significant result of the work of Continua is the impact it will have on individuals, organizations and society as a whole. The full impact depends on the successful adoption by the market and possible changes in regulation and reimbursement, but there are a number of ways Continua can be expected to impact the world.

### 5.1. Cost Reduction

The market for personal telehealth systems is still relatively small and very scattered. The number of devices that individual companies produce in this area are limited. Based on these small volumes companies are not able to benefit from significant economies of scale. This holds for the devices itself as well as the components used to manufacture the devices.

Almost each company will develop a considerable amount of communication functionality for those devices in-house. This includes defining the data protocol, selecting or developing the physical connectivity means and integrating it into their various devices.

This results in many companies doing the same work in-house without the benefit of learning from others and economies of scale. Through the design guidelines of Continua and the standards that have been selected a lot of the connectivity design work has been done already. This means that individual companies can implement the guidelines in their device once and then work with different devices from various

companies without the need to adjust their device for every company that it needs to work with.

Already 3<sup>rd</sup> party companies are building components that incorporate all needed functionality to communicate according to the Continua guidelines [11]. This basically enables telehealth companies to take their existing devices, integrate such a component and have a Continua certified device with the appropriate communication means. This allows all companies to benefit from the economies of scale that the 3<sup>rd</sup> party company can achieve and thus reduce their costs.

The usage of Continua guidelines can reduce the development cost specifically when multiple devices need to be supported. Assume a mobile phone needs to support four different sensors in order to offer a health service. Development of the mobile phone would be simplified significantly when all four sensors use the same communication transport and data protocol.

### 5.2. Increased Competition

In the proprietary model each system integrator had to work with all of their suppliers and customers individually to create a proper telehealth system. This created a significant entry barrier for small and medium enterprises to jump into the personal telehealth domain. With the Continua design guidelines it will become easier for new entrants to play in this market, use existing products that are Continua compliant and focus on their own specific area of expertise. The reduction of the entry barrier and the entry of new players will result in increased competition. This means it will become increasingly important for each company to highlight their distinguishing features compared to their competitors.

The Continua guidelines will not only increase competition by the entry of new players, but also by more competition of existing players. In the current model a telehealth integrator selects a number of companies to work with, e.g. to buy sensors from a specific company. The integrator then implements his telehealth system to be able to communicate with these specific devices. Once the implementation is complete there will be significant switching costs if an integrator decides to work with a different sensor manufacturer as the software and possibly the hardware of his system needs to be adjusted. The current regulations enforce this even further as the whole systems needs to go through another round of regulatory approval if one of the sensors is changed for another brand or model.

When an integrator now implements the Continua guidelines he will be able, without significant adjustments in the hardware or software, to switch

from one sensor supplier to another, if these sensor suppliers also implement the guidelines. Current regulations still form a switching barrier, but once these regulations are adjusted to more easily allow the use of different sensors, the switching costs will be significantly reduced. Thus creating more competition between the different suppliers of a telehealth system.

More competition is likely to put the price of the various telehealth components under pressure and reduce the margins for all players. The sensor manufacturers and system integrators in this domain will have to reconsider their strengths carefully and focus their efforts around the areas where they add most value. This triggers questions like: “Are we a device or service company?”, “Should we make all components in-house or only a limited set?”, etc.

### 5.3. Market Growth

The previous two effects will cause the prices of telehealth equipment to go down. One of the restraints of telehealth is currently the high price of telehealth equipment, thus it can be expected that by the reduction of the price the adoption of telehealth will grow.

Next to the current high price of telehealth equipment, purchasers of telehealth equipment (such as home health agencies and disease management organizations) were also afraid of vendor lock-in, which is a significant issue in the proprietary model and creates high switching costs for telehealth purchasers. For some purchasers this has been a reason to postpone the purchase of telehealth equipment.

So interoperability will not only enable market growth through lowered price, but also by lowering the fear of vendor lock-in and thus support more investments in this technology.

Market growth was one of the key reasons to form the Continua Health Alliance. For vendors of telehealth equipment market growth will offset the loss of income by the reduction of the margin, changing the market from low volume/high margin to higher volume/lower margin.

### 5.4. More Choice

Consumers will benefit from interoperability by lower prices for out-of-pocket services and equipment and more choice. Although for the real benefit of more choice the changes in regulatory policy will first need to take place. Currently most personal telehealth systems only work with a rather limited set of measurement devices as described earlier. This means that in most cases a person that is prescribed a

telehealth system or goes out to acquire one out-of-pocket does not have much choice in the combination of the telehealth equipment; it is often a single version package deal.

It is likely that in the future a person will have much more say about which kind of devices will be used in a telehealth system. If this person prefers weighing scales from brand *A*, glucometers from brand *B* and mobile phones from brand *C*, than if all of these devices are Continua compliant and meet the necessary quality levels for the intended use of the system, it should be possible for this person to use these devices in his telehealth system. As said it will definitely take time for this change to happen, but it is clearly moving in that direction.

### 5.5. Better Healthcare

In the end all of the work in Continua would be pointless if it wouldn't result in better healthcare for individuals and society. Continua believes that by using technology, better care can be provided at lower costs. In many countries around the world the current healthcare model is organized around treatment, which is not optimal for a population's health status and is not the most effective way to spend money on healthcare. The future of healthcare has a much higher focus on prevention. Keeping people as healthy as possible, given their circumstances and preventing unnecessary episodes of treatment.

Personal telehealth is an important step towards keeping the healthcare system sustainable; as such personal telehealth is one of the pillars of the future of healthcare. The impact of the Continua Health Alliance lies in making personal telehealth available to a broader audience by lowering the price, growing the market and improving the choice for people around the world.

## 6. Implementation

The Continua version one design guidelines will be completed and released at the end of 2008. Together with these guidelines a test and certification program is being developed to certify products and services that adhere to the guidelines. These certified products and services are then allowed to use the Continua logo to show that they are truly interoperable.

Many companies are already building products and services that implement the guidelines. To facilitate their testing Continua organizes so called “plugfests”; at these occasions different companies connect their prototypes and test if they are interoperable.

Continua also started to host public demonstrations at the quarterly summits. These demonstrations show to the world which companies are actively implementing the Continua guidelines and help to promote the Continua work by making the results tangible. At the first public Continua demonstration in October 2008 pre-certified products and services were shown by A&D Medical, Cambridge Consultants, Cypak, FitLinxx, Google Health™, IBM, Intel, National Health Service (NHS), Nonin Medical, Oracle, Partners, Philips, Roche Diagnostics, and University Health Network. The first certified products and services are expected early 2009.

## 7. Conclusions and Discussion

The Continua Health alliance is a significant force in the development of the personal telehealth domain and the first version of the design guidelines is an important step to support the growth of this field. However this is only a first step of a long journey. Many technical and non-technical challenges still exist that need to be addressed.

On the technical side Continua has already solicited input for new use cases and the technical implementation of those use cases is now ramping up. This includes addressing interfaces that were out of scope of V1 (see Figure 2) and extending the set of measurement devices that were supported in V1. A key factor for Continua is backwards compatibility to ensure interoperability between devices that implement different versions of the guidelines. At the same time discussions about regulatory changes and new reimbursement models are still ongoing.

The world around Continua also keeps changing. Over the past year we have seen the rise of personal health record infrastructures with new initiatives in the form of Microsoft HealthVault and Google Health. Microsoft and Google are addressing another part of the technical challenge of personal healthcare by focusing on the storage of, access to and control over personal health data. This is complementary to the interoperability that the Continua Health Alliance is striving for. Integrating the Continua enabled interoperability in Microsoft HealthVault and Google Health will allow the easy integration of data from any Continua certified measurement device into these PHR platforms.

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