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The Current State of Digital Healthcare towards Medical Application

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SUMMARY Infrastructures for the evaluation of the state of health of individuals using a standardized communication network consisting of advanced instruments and subsequent data analysis have been developed. Here we report that this developed infrastructure has been tested in the field in 100 houses and involving almost 300 users. The communication protocol part of this infrastructure has been standardized as IEEE 11073-20601. Continua Health Alliance, an international not-for-profit industry organization which has nearly 230 member companies, has adopted this IEEE 11073-20601 to establish an ecosystem of interoperable personal connected health systems that empower individuals and organizations to better manage their health and wellness. Currently nearly 100 Continua certified products are available in public including smartphone.

key words: *digital healthcare, Continua, m-health, personal healthcare*

1. Introduction

Japan benefits from one of the highest average life expectancies in the world. However this phenomenon has resulted in an increasing problem of rapid aging of its population with concomitant change in the health profile of the nation. The proportion of lifestyle diseases such as cancer, ischemic heart disease, cerebral vascular disorder and diabetes is increasing and are now the cause of around 60% of deaths. Treatment of lifestyle conditions now claims up to 30% of the national healthcare system spending [1]. Furthermore the proportion of people suffering from, or displaying early signs of conditions such as diabetes, hypertension and hypercholesterolemia which are recognized indicative factors for certain lifestyle diseases, in particular heart disease and cerebral vascular disorder are increasing. For example, diabetes affects approximately 8.2 million Japanese with another 18.7 million patients displaying preliminary signs of the disease [2].

Against this background, a reform of the system for healthcare provision in Japan commenced in 2006 led to the introduction in April 2008 of a program mandating the provision of health checks and medical advice focusing on early diagnosis of so-called "metabolic syndrome" amongst participants in the national health insurance and the health insurance association administered by the Ministry of Health, Labour and Welfare, aged 40 and over. However, although a range of initiatives aimed at the prevention of lifestyle diseases has been put in place, as these conditions in many cases develop with symptoms that go unnoticed by the patient it is often very difficult for sufferers to recognize the need for increased measures to improve their health lifestyle. Accordingly the success or failure of initiatives for the prevention of lifestyle diseases is closely bound up with increased recognition of the importance of healthy behavior and concrete, continuous and persistent changes in patterns of behavior on the part of individuals. As a result there is an unarguable need for the creation of systems that provide tools suited to the needs and preferences of patients that permit and encourage them to carry out ongoing and voluntary management and monitoring of their own health conditions.

However, current systems and instrumentation for this kind of monitoring require face-to-face consultation between the patient and relevant specialists such as healthcare professionals for the acquisition of data and its subsequent analysis and translation into healthcare advice. Accordingly it is very difficult for users to carry out self-monitoring as the system is focused on the specialist and medical agencies the location and time in which monitoring can be carried out are greatly restricted. Therefore there is a demonstrable need for the provision of devices and systems that impose minimum burden on the patient and which are allied to their needs and choices and which permit continuous self-monitoring of the health status of individual patients.

2. Proof of Concept and Standardization

2.1 Proof of Concept

Japan's infrastructural response to the prevailing situation was swifter than that of many other countries. For example in 2003 the New Energy and Industrial Technology Development Organization (NEDO) operating under the auspices of the Ministry of Economy, Trade and Industry (MITI) set up the "Enterprise model project of home healthcare" which brings together 12 leading technology companies (Mitsubishi Electric, Mitsubishi Electric Engineering Co., Hitachi, Fujitsu Software Technologies, SHARP, Matsushita Electric Industrial (later renamed Panasonic Corporation), Toshiba Consumer Marketing, TOTO, Matsushita Electric Works, Citizen Watch, Tanita and Omron Healthcare) under one umbrella (Fig. 1).

The project utilizes a system in which inputs from different devices are collected using a common wireless protocol and routed through a single terminal within the dwelling (known as the "gateway"). This data can then be transmitted over the internet and accumulated into a dedicated database

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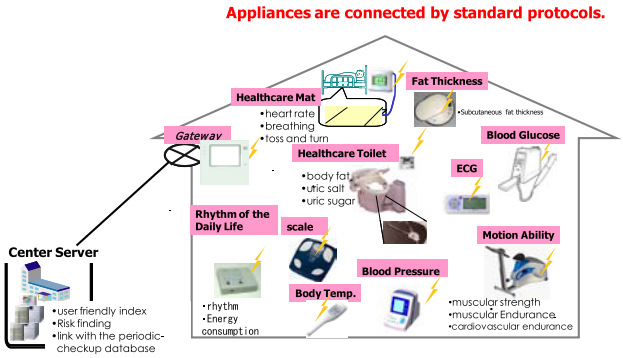

Fig. 1 Overall system view of "The Development of high performance equipment measuring vital data for home healthcare" subsidized project by NEDO.

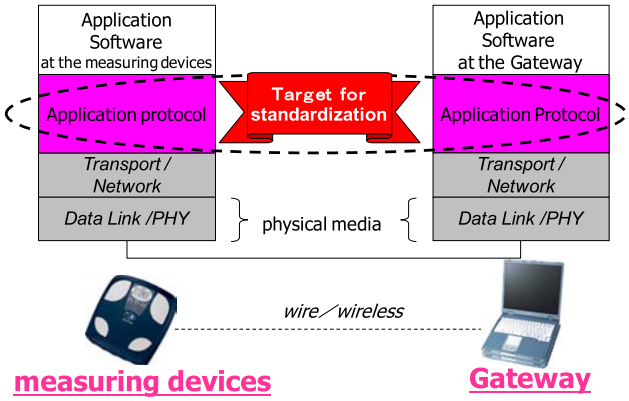

Fig. 2 Protocol stack.

at a health monitoring center and fed in real-time to users and healthcare professionals carrying out health status monitoring. The efficacy of this system has been tested practically under actual usage conditions in over 100 households located in three Japanese cities: Sapporo (71 households), Osaka (20) and Kobe (10) in a field trial of hitherto unprecedented scale which has drawn attention from all over the world [3].

2.2 Standardization

The unified wireless protocol developed for the aforementioned project is situated above the transport layer of the OSI model and defines the data exchange protocol and data format of the physiological data being exchanged between the health status monitoring equipment and the gateway (Fig. 2).

In view of the multifunctional nature of healthcare monitoring devices, the transmission protocol layer of the protocol stack has not been specified. This allows users to choose from a range of monitoring devices having the standardized protocol installed, and incorporating the functionality required by the user, and still gain access to the system in a straightforward manner. Furthermore, this arrangement allows device makers to concentrate on developing products with original features and functionality offering benefits to makers and users alike. This is expected to have the effect of stimulating the healthcare and preventative medicine market and has prompted the investigation of the possibility of creating a publically promulgated standardized technical specification based on Japanese Industrial Standards (JIS) laws.

In recent times there has been a similarly rapid move towards standardization in countries other than Japan. For example, in 2006 IEEE and Bluetooth SIG began work on the creation of transmission protocol specifications for medical systems and medical devices leading to the proposing of the aforementioned unified wireless transmission protocol as IEEE11073PHWG (Personal Health Data Working Group). This proposal formed the basis for further standardization exploratory work incorporating regulations for a variety of overseas medical devices and systems, leading in December 2008 to the release of datasheet IEEE11073-20601.

3. Towards a Framework for Growth

The move towards standardization has been accompanied by the creation by global corporations of industry-wide groups such as Continua Health Alliance, which was set up in 2006 as an NPO with the purpose advancing digitalization of healthcare and medical devices and unification of transmission standards with the aims improving the quality of personal healthcare solutions. The organization is now composed of close to 240 participating global corporations that between them are involved in a wide range of electronics industry sectors including healthcare and medical devices, electrical component manufacture, consumer electronics, software, systems and services. A region division was set up in Japan in 2006 with six companies and by July 2011 the chapter included 40 active member companies.

The types of activities covered by Continua can be broadly summarized into three areas below:

(1) Preventative healthcare management

- Health data monitoring
- Attainment of personal [healthcare] goals
- Acquisition and use of personal healthcare data

(2) Management of chronic conditions

- Efficient integration of patients, healthcare professionals and family members
- Effective management of conditions
- Regularization of medical expenses
- Quality of Life (QOL) improvement

(3) Independent living of senior citizens

- Interactions with family members
- Remote care
- Integrated management
- Early detection

- Regularization of medical expenses

Taking such use cases as a base Continua Health Alliance are pursuing the following initiatives:

(1) Setting of design guidelines
(2) Development and implementation of certification programs and awarding of certification logo.
(3) Liaison with government bodies such as the US Food and Drug Administration (FDA).

Although specifications for data content and transmission protocols have already been standardized under the aforementioned IEEE 11073, it is still not possible to actually connect up the system. However, new "design guidelines" are being produced based on existing specifications that permit the maintenance data interoperability. Accordingly, the data format of upper layers of the protocol stack are stipulated under the standardized specifications as shown in Figure 2 but the transmission protocols located in the lower layer are also defined by these design guidelines (Fig. 3).

In the case of the lower layer transmission protocols, in addition to the Bluetooth and USB devices shown in Figure 3, systems for others such as Zigbee and Bluetooth Low Energy are being planned and the investigation of other protocols is being progressed and as shown in Figure 4 protocols linking transmission terminals and service providers and protocols between service providers themselves are being established. Furthermore, liaison activities with healthcare bodies and government agencies, in particular accreditation bodies such as the FDA are ongoing with the aim of expanding the reach of devices, systems and services based on the design guidelines. In order to promote this expansion, approaches are being made to industry leaders. Healthcare Device Profile (HDP), or rather the HDP application interface, is now routinely incorporated into Google's Android 4.0 OS used in mobile information terminals and it is anticipated that this will have a profound effect on the sector going forward.

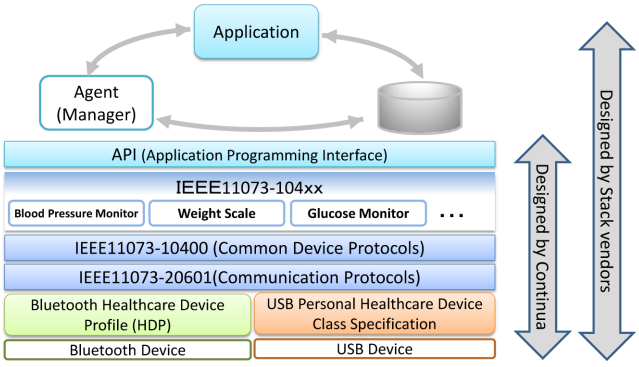

Fig. 3 Protocol stack designed by Continua Health Alliance.

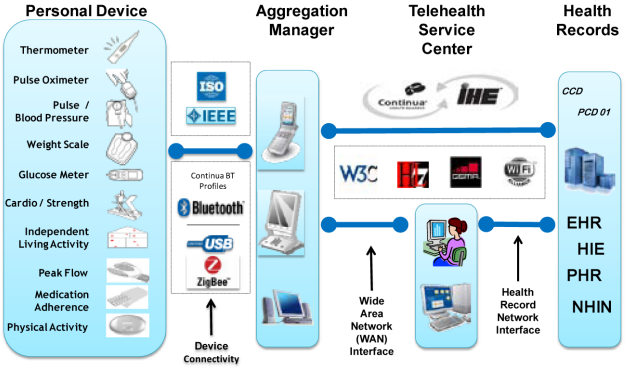

Fig. 4 Interfaces and standards designed by Continua Health Alliance.

4. Current Status of the Field and Future Issues

As described above, development initiatives at the country level, standardization activities and promotion by industry groups are ongoing, along with product development initiatives from across a range of industrial sectors. One example of this was the commercial launch in 2008 of the SH706iw "Wellness mobile" from NTT Docomo which can automatically display data obtained by Omron Healthcare's body composition monitors using a standardized transmission protocol developed by Sharp (Fig. 5).

This development has been followed since 2009 by a the bringing to market of a steady stream of Continua-accredited products such as body weight and blood pressure monitors made by A&D Co. and Omron Healthcare, PCs from Panasonic and Toshiba, mobile phones from Fujitsu and Sharp and gateway servers from Alive Inc. These have been supported by a range of services conforming to Continua specification. An example of this is the introduction in 2012 by NTT Resonant Inc. of "goo Body Log", a cloud-based health management service targeted at the general public that links Continua-compliant blood pressure and body composition monitors produced by A&D Co. to a range of 15 Continua approved Sharp smartphones (as of March 29th 2013) that have been launched over the period of the service.

A number of services aimed at general users that do not comply with Continua regulations have also been introduced and have been taken up by over one million users of mobile phone carriers such as NTT Docomo and KDDI.

Initiatives such as these introduced to confront the problems of metabolic syndrome have had a profound effect on the way general users are beginning to view health

Fig. 5 Cell phones introduced standardized protocol technology.

issues. According to a recent survey [4] around 70% of men and 80% of women are now paying more attention to controlling their weight.

Furthermore, the issue of increasing medical costs in due to an aging population is of international concern and must be addressed through a global framework of the kind represented by Continua Healthcare Alliance. The introduction of such a framework it is to be expected would lead to further development of digital healthcare platforms and the creation a more diverse health management infrastructure that allows the monitoring not only of body weight but also other parameters such as blood pressure and blood sugar. Whilst it may be said that digital healthcare devices, systems and services serve a useful purpose by alerting people to changes in the state of their health and providing an impetus towards a healthier lifestyle, it has so far not achieved changes in behavior such that users carry out daily monitoring and maintain a continuous healthy lifestyle. A typical example may be found in the case of the "Wii Fit" game produced by Nintendo which makes use of a balance board with a function that can measure the user's body weight. Over 35 million of these balance boards have been sold world-wide and have captured data from a multitude of users. In addition, a number of Wii Fit-related services have also been introduced. However, once the initial flush of enthusiasm has past, the valuable data that has been accumulated often lies dormant. It is reported that despite the existence of this simple framework for health data acquisition, less than a third of people in actually use the data to make changes to their diet and exercise regimes [4].

5. Conclusion

Digital healthcare has finally the start line of practicability. Demonstration experiments by national projects have been held and their standardization activities have been accepted internationally. Going forward there will doubtless be increased demand for the creation of structures and the development of devices, systems and services and that allow individuals to change patterns and maintain improved lifestyles.

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