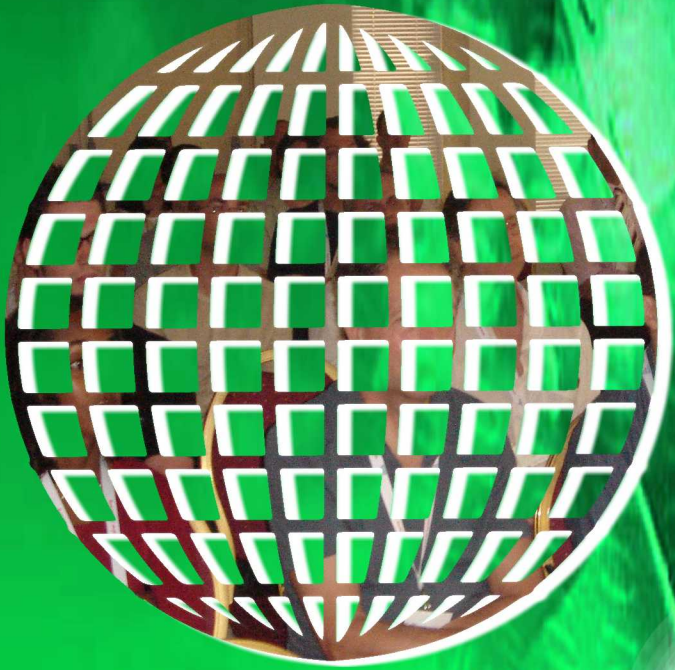


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Global System for Mobile communications (GSM) Electromagnetic Waves affect the Activity, Morphology, and Structure of Skeletal Muscles in Adult Male Rats

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Abstract—The use of cellular technology is overwhelming our lives these days. Global System for Mobile communications (GSM) waves -the basis of cellular technology - are high frequency, high energy electromagnetic waves that may pose as a threat to man. The current work studies the effect of such waves on two types of skeletal muscles, the slow and fast twitching muscles in adult male rats. The activity, morphology, and structure of the affected muscles are studied and analyzed against control. Experiments evaluate changes in body weight, muscle mass, water and protein content, total RNA concentration, testosterone level, and Myosin Heavy Chain (MHC) isoforms expression. Our results show that in both muscles, there are changes in the distribution of muscles proteins and in the percentage of MHC isoforms suggesting that the GSM antenna relay affects the plasticity of skeletal muscle fiber by transforming slow type to faster one.

Keywords-GSM electromagnetic waves; skeletal muscles; proteins content; testosterone level; MHC isoforms.

I. INTRODUCTION

The widespread use of mobile phones has been going sky-high over the past decade and the applications offered by mobile phone technology have become an essential part of personnel, business and social life. We have recently reported that the structure, the morphology and the activity of 2 types of striated muscles in rats have been altered by the exposition to electromagnetic waves emitted from mobile phones devices [1]. In fact, mammalian striated muscle myofibrils are composed of repeating units called sarcomeres that are arranged in series. Sarcomeres in turn are composed of contractile filaments termed myofilaments that are of two major types, actin (thin filament) and myosin (thick filament), which interact together to generate force

and contraction. These myofilaments are large polymers of noncovalently associated contractile proteins, actin and myosin, which comprise 70% of myofibrillar proteins in skeletal muscles [2]. The isomers of Myosin Heavy Chains (MHC) are often used to distinguish the types of skeletal muscle fibers: slow-twitch – or type I – muscle fibers, where MHC I isoform is abundantly expressed; and fast-twitch – or type II – muscle fibers (types IIa, IIb, and IIx/d), where MHC IIa, IIb, IIx/d predominate, respectively [3-5]. Slow-twitch fibers are adapted for continuous activity, and they are rich in myoglobin and oxidative enzymes. A typical example is the soleus muscle. Fast-twitch fibers are adapted for rapid activity, and they produce energy through glycolytic metabolism. A typical example is the *extensor digitorum longus (edl)* muscle [6].

A remarkable characteristic of striated muscles is plasticity. This term refers to the ability of these muscles to remodel and thus change their contractile and metabolic makeup, and – hence – their type from slow to fast, or vice versa, in response to specific environmental challenges, such as exercise, temperature, or gravitational loading, or internal challenges such as nutritional conditions as well as neuronal, mechanical, metabolic or hormonal stimuli [7]. This may be attributed to a reversible change in the muscle gene expression that leads to reversible structural and functional modifications [8].

One of the important challenges that have developed in the last decade and is thought to have an effect on health is the population exposure to electromagnetic waves, particularly the Global System of Mobile (GSM) communication signals. These signals are emitted from diverse sources particularly from cell phones and base station antennas. Also, they may come from industrial processes, where workers in broadcasting, transport, and

communication industries are highly exposed. They are also emitted from medical devices like electrosurgical devices and diagnosis equipment. Numerous studies have been conducted to measure, document, and archive the amount of Radio Frequency (RF) energy emitted from GSM sources in residential areas [9]. Thus, concerns from the risk of GSM signals on health arise from long term exposure, as well as from the cumulative effect of these waves. Researchers have been seeking options to minimize additional radiation exposures for the population and reduce the potential risk for harmful exposures.

Tyagi et al. studied the effect of mobile phone radiation on brain activity. They comparatively analyzed the effect of more than one type of radiations, and concluded that their effects on brain activity cannot be attributed to chance [10]. Tomruk et al. reported the substantial hepatic oxidative DNA and lipid damage on pregnant, non-pregnant, and newly-born rabbits [11]. Several studies reported the possibility that radio-frequency electromagnetic fields (EMF) used in cellular technology might influence DNA integrity of male germ cells as well as sperm motility. There was evidence that GSM radiation could induce, in vitro, the activation of stress conditions and response in human sperm cells [12]. The major mechanism by which such waves can induce an effect on biological systems is the thermal mechanism by which EMF at high intensities can increase the tissue or body temperatures above the normal value. Non-thermal mechanisms are under wide investigation in recent studies [13-16].

To understand the effects of EMF radiations, it would be beneficial to appreciate the nature and mode of action of this type of energy. EMF radiation is a form of potential energy exhibiting wavelike behavior as it travels in the space.

EMF radiation has both electric and magnetic field components that oscillate – in phase – perpendicular to each other and orthogonal to the direction of energy propagation [16]. Such radiations can be classified as ionizing and non-ionizing radiation, based on capability to ionize atoms and/or molecules, and to break chemical bonds. The non-ionizing type is associated with potential non-thermal hazards. The short high energy or the chronic low energy exposure of biological tissues to EMF radiations has been shown to change the functional activities of cells, resulting finally in some diseases [10].

Few studies have investigated the effect of electromagnetic waves on skeletal muscles. In fact, Radicheva *et al.* (in 2002) has shown that a 2.45 GHz microwave field could possess a stimulating effect on muscle fiber activity, which is in part due to its specific non-thermal properties [18]. Moreover, our previous study has shown that one hour of exposure to electromagnetic field at 900 MHz modulated by human voice could have an effect on the excitation-contraction coupling mechanism of mammalian fast-twitch skeletal muscles [19]. However, no

study to date has investigated the effect of electromagnetic waves emitted by GSM relay antenna on muscle composition. Consequently, this study is designed to investigate the effect of 25V/m of electromagnetic waves emitted by GSM relay antenna on animal body weight, muscle mass, proteins and water content, total RNA expression, serum testosterone level and myosin heavy chain isoforms expression in the two types of skeletal muscle fibers, slow and fast-twitches.

Kaasik et al. have shown that MHC I isoform relative content in human muscle was 2.6 times higher than in horse and 6.3 times higher than in rat muscle. This may be related to the differences in endurance capacity of human, horse, and rat muscle [20]. Indeed, these authors have shown that the main difference between the distribution of myosin light chain (MLC) isoforms in human, horse, and rat skeletal muscle is the relatively low level of regulatory MLC isoforms in human skeletal muscle. MLC isoforms distribution in skeletal muscle has been shown to be related to the physiological role and adaptational capacity of muscle to everyday motor activity [21]. Despite the relative proportions of each fiber type vary between homologous muscles of different species [22-23], and in the absence of human data, research with experimental animals is the most reliable means of detecting important toxic properties of chemical substances and for estimating risks to human and environmental health. Thus, we decided to use as animal model, the rat, in order to study the effects of GSM electromagnetic waves on skeletal muscles. The exposures received by animals can be compared to those received by humans in order to interpret test results and predict risk. This in turn helps regulatory agencies to prioritize funding for environmental cleanup.

This paper studies the effect of GSM waves on skeletal muscles in rats. A background of the study is given in Section I. The materials and methods used in the study are mentioned in Section II. The results are presented in Section III and discussed in Section IV.

II. MATERIALS AND METHODS

A. Experimental Design

All procedures in this study were performed in accordance with the stipulations of the Helsinki Declarations and with the current Lebanese laws for animal experimentation. Twenty adult Sprague-Dawley male rats with an average weight of 190 ± 5 g were divided equally into 2 groups. One group was subjected for 6 weeks to whole continuous (24 hours/day) body exposure to EMW (900 MHz, $E_{\text{eff}} = 25\text{V/m}$) (Fig. 1). The other group was considered as control and maintained in the same environmental conditions under the turned off antenna. Both exposed and control animals were housed in a temperature-controlled room (22°C) on a 12:12-h light-dark cycle. They were daily supplied with the same kind of food and water.

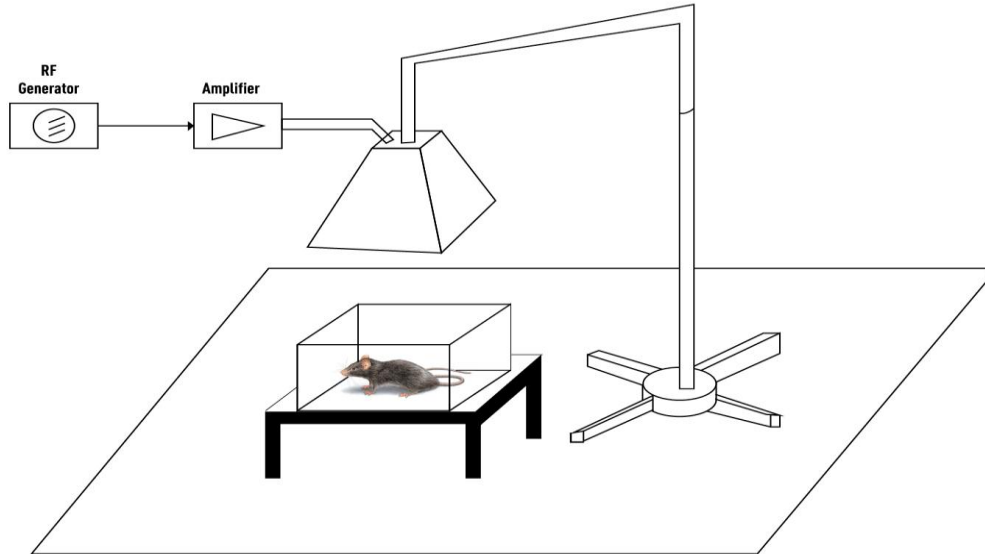


Fig. 1. GSM electromagnetic Waves exposure system

B. Dissection

After the exposure period, the rats were gently sacrificed and trunk blood was collected. Soleus and *edl* muscles were rapidly excised from the hind limbs of each rat. The muscles are weighted and preserved at -80°C for later analysis.

C. Total RNA extraction

Total RNA was extracted from muscle samples using **RiboZol™ RNA Extraction Reagent** from AMRESCO, according to the vendor's instructions (American Research Products, 30175 Solon Industrial Parkway, Solon, OH 44139-9827 USA).

D. Serum testosterone level determination

Collected blood was centrifuged at 3500 rpm for 5 minutes. Serum of each rat was preserved at -20°C . Serum testosterone, insulin and cortisol levels, in control and exposed groups, were measured by Enzyme-Linked ImmunoSorbent Assay (ELISA) technique based on the principle of competitive binding, according to instructions supplied by the vendor.

E. Proteins dosage

Protein dosage was performed according to Bradford Technique [24]. Pieces of frozen muscles were mechanically disrupted and spliced in 5 volumes of washing buffer containing 20 mM NaCl, 1 mM EGTA (pH 6.4), and 5 mM PO_4 . After 5 minutes of centrifugation at a high speed (12000 rpm), the supernatant is collected and the quantity of the protein is determined with the Bradford method (Bio-Rad, Hercules, CA), where the results were expressed as a ratio of milligrams of proteins to 100 milligrams of muscles. The pellet was then washed with 3 volumes of extraction buffer containing 5 mM EGTA, 1mM

dithiothreitol (pH 8.5), and 100 mM sodium pyrophosphate, and incubated in cold overnight. The next day, the mixture was centrifuged at 12000 rpm for 10 minutes and the supernatant – which contained the protein myosin – was collected and the amount of myofibrillar proteins was determined. Small volumes (50 μL) of the supernatant were diluted twice with glycerol and stored at -20°C for electrophoresis.

F. SDS-PAGE electrophoretic separation of Myosin Heavy Chain isoforms

To analyze the content of MHC I, MHC IIa, IIb, IIc/x isoforms in the extracts, we used simple vertical migration of SDS-PAGE electrophoretic separation. The separating gel was prepared from 99.5% glycerol, 30% acrylamide, 0.6% bis acrylamide, 1.5 M Tris (pH 8.8), 1 M glycine, 10% SDS, 10% ammonium persulfate, and TEMED. The stacking gel was prepared from 99.5% glycerol, 30% acrylamide, 0.6% bis acrylamide, 0.5 M Tris (pH 6.8), 10% SDS, 0.1 M EDTA (pH 7), 10% ammonium persulfate, and TEMED. For best quantification, 2-3 μg of myosin were loaded in each well. Electrophoresis was performed using a Cleavage, Scientific Ltd, system. Gels were run at constant voltage (70V) for 24 h and then stained with silver reagent that allowed the detection of the MHC bands corresponding to I, IIa, IIb, and IIc/x isoforms. The stained gels were scanned using a Canon digital imaging system and the density of bands was estimated using the UN-Scan-IT software [25].

G. Statistical analysis

All values are expressed as means \pm SE for n observations. Data were analyzed by One-Way ANOVA

(StatView; Alsyd, Meylan, France) statistical test. A level of $p < 0.05$ indicated statistical significance.

III. RESULTS

A. Effect of GSM waves exposure on Body mass

As shown in Fig. 2, all animals steadily gained weight and there was no difference observed between the control and exposed animals after 6 weeks of GSM waves exposure (Control: 283 ± 8 g; Exposed: 295 ± 7 g, $n=10$)

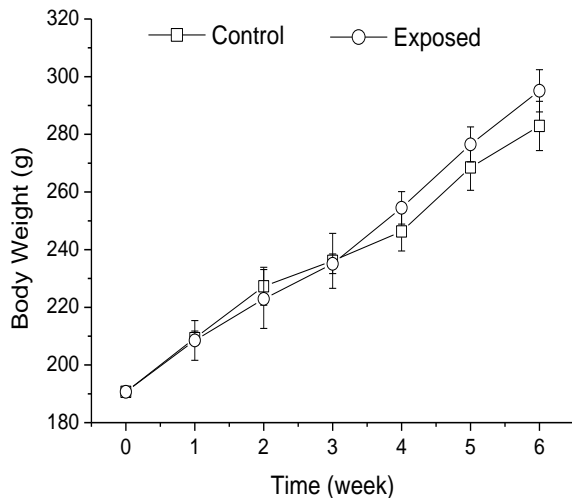


Fig. 2. Effect of GSM electromagnetic waves exposition on Body mass. Each value displays mean \pm SE.

B. Effect of GSM waves exposure on muscles mass

Although body weight was not affected by the exposure, six weeks of exposure resulted in a significant decrease in *edl* mass by 16% (Control; 133.56 ± 3.69 mg; Exposed: 112.19 ± 2.57 mg, $n=20$, $p < 0.05$). However, no significant effect was observed in soleus muscle mass (Control; 120.06 ± 2.89 mg; Exposed: 117.49 ± 3.11 mg, $n=20$) (Fig. 3).

Such a decrease in muscle mass observed in *edl* muscle could be related to modification in water content and/or in the proteins content. Consequently, the water content and the soluble and myofibrillar proteins content were estimated.

C. Effect of GSM waves exposure on muscles water content

In control group, water content expressed as percentage is estimated to $37.5 \pm 0.7\%$ in soleus muscles and $26.9 \pm 0.6\%$ in *edl* muscles. After 6 weeks of continuous electromagnetic waves exposure, and although no significant effect was observed in soleus muscle mass, an increase by 17% in percentage of water content was observed ($43.9 \pm 1.2\%$, $n=12$, $p < 0.05$). However, no significant effect was observed in *edl* muscles ($28.1 \pm 0.6\%$, $n=12$) (Fig. 4).

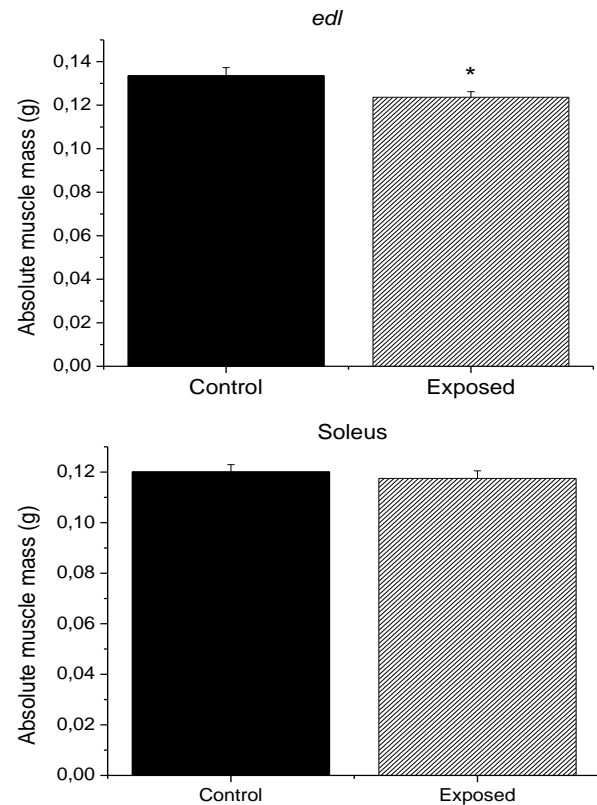


Fig. 3. Effect of GSM waves exposure on muscles mass of the *edl* and soleus muscles. Each histogram displays mean \pm SE. * $p < 0.05$

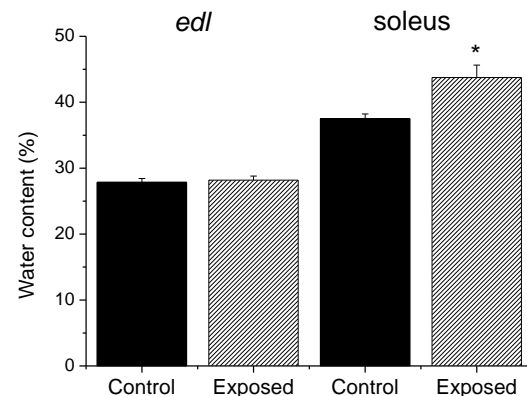


Fig. 4. Effect of GSM electromagnetic waves exposition on muscles water content of the *edl* and soleus muscles. Each histogram displays mean \pm SE. * $p < 0.05$

D. Effect of GSM waves exposure on proteins content

In soleus control muscles, soluble and myofibrillar proteins content were 2.71 ± 0.13 and 3.42 ± 0.26 mg/g of muscle, respectively. The six weeks of continuous electromagnetic waves exposure induced an increase by 23% of soluble proteins (3.34 ± 0.16 mg/g, $n=24$, $p < 0.05$); however, a decrease by 32% of myofibrillar proteins was observed (2.33 ± 0.29 mg/g, $n=24$, $p < 0.05$) (Fig. 5).

In *edl* control muscles, soluble and myofibrillar proteins content were 3.56 ± 0.18 and 3.83 ± 0.11 mg/g of muscle, respectively. Six weeks of continuous GSM waves exposure induced a decrease by 28% and 24% of soluble and myofibrillar proteins, respectively (Soluble proteins content: 2.78 ± 0.19 mg/g; Myofibrillar proteins content: 2.91 ± 0.22 mg/g of muscle, $n=24$, $p < 0.05$) (see Fig. 5).

These modifications in proteins content in both soleus and *edl* muscles should be correlated to total RNA level expression.

E. Effect of GSM waves exposure on total RNA

In control condition, the total RNA values were 755.21 ± 16.72 $\mu\text{g}/\mu\text{l}$ and 548.32 ± 14.98 $\mu\text{g}/\mu\text{l}$ in *edl* and soleus muscles, respectively. After 6 weeks of GSM exposure, a decrease by 29% and 25% were shown in both *edl* and soleus muscles, respectively ($n=10$; $p < 0.05$) (Fig. 6).

This decrease in the amount of total RNA expression could be related to the modification in the serum testosterone level.

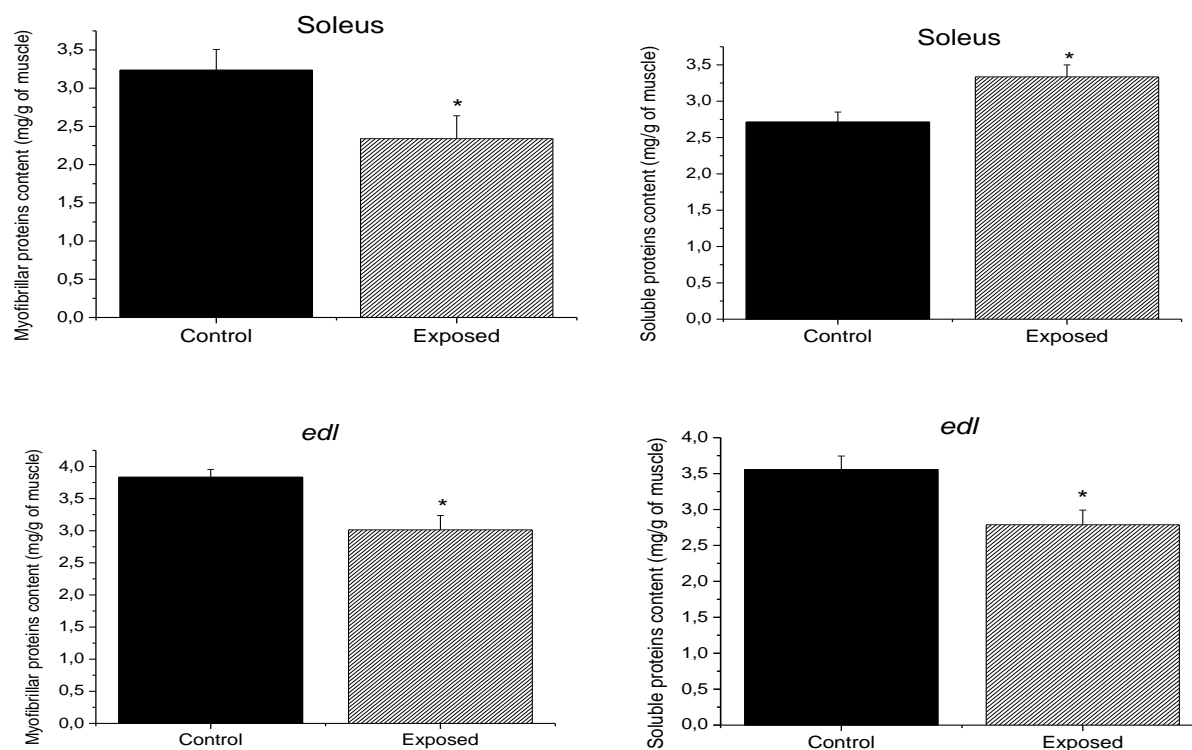


Fig. 5. Effect of GSM waves exposure on Myofibrillar proteins content and soluble proteins content on both soleus and *edl* muscles. Each histogram displays mean \pm SE. * $p < 0.05$

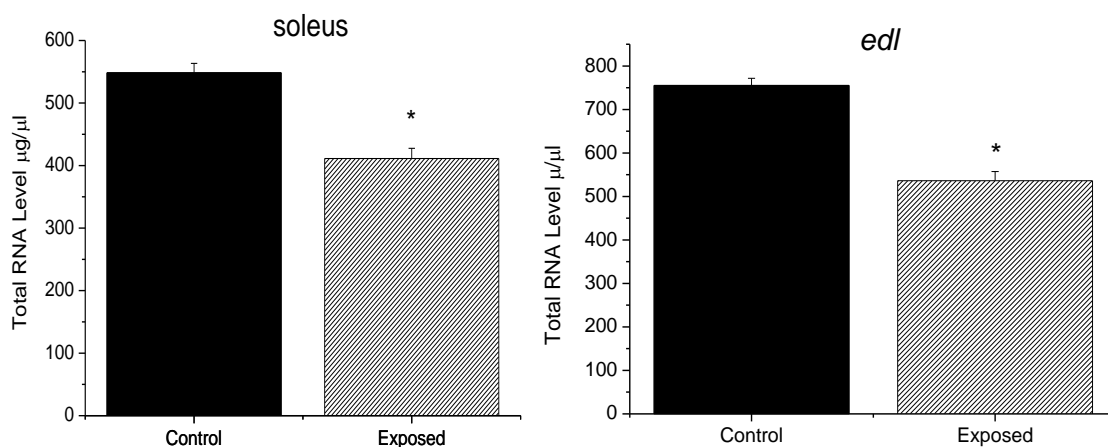


Fig. 6. Effect of GSM waves exposure on total RNA in both soleus and *edl* muscles. Each histogram displays mean \pm SE. * $p < 0.05$

F. Effect of GSM waves exposure on serum testosterone, insulin and cortisol level

In control condition, the Enzyme-Linked ImmunoSorbent Assay showed that serum testosterone level was 82.12 ± 4.39 ng/ml. Six weeks of GSM waves exposure induced a decrease by 50% in serum testosterone level (40.91 ± 5.71 ng/ml, $n=10$, $p<0.05$) (Fig. 7).

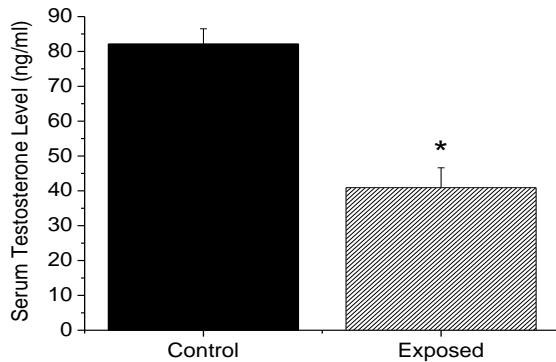


Fig. 7. Effect of GSM waves exposure on testosterone levels in both control and exposed rats. Each histogram displays mean \pm SE. * $p < 0.05$

The serum insulin level shows a significant increase by 30% in rats exposed to the GSM (Fig. 8).

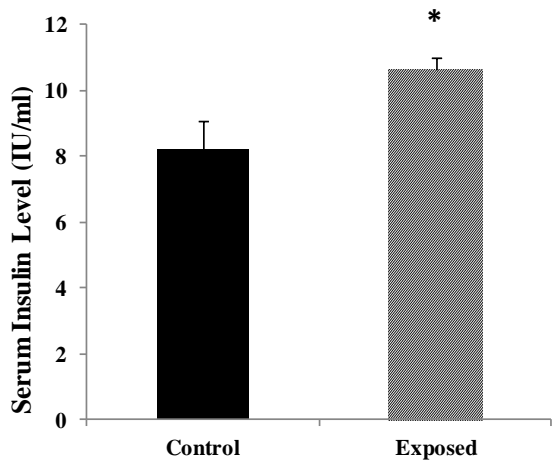


Fig. 8. Effect of GSM waves exposure on insulin levels in both control and exposed rats. Each histogram displays mean \pm SE. * $p < 0.05$

On the other hand, no significant difference was observed in the serum cortisol level after 6 weeks of GSM exposition (Fig. 9).

G. Effect of GSM waves exposure on Myosin Heavy Chain Isoforms expression

Separation and analysis of MHC isoforms by SDS-PAGE allowed the estimation of the density of the bands corresponding to each of the MHC isoforms (MHC I, II_a, II_b, and II_x) using the UN-Scan-IT software. These isoforms are differentially expressed in the different muscle fiber types.

In control conditions, the *edl* muscle expresses 34.6 ± 0.2 % of MHC II_x and 66.4 ± 2.8 % of MHC II_b, while the soleus muscle expresses 5.1 ± 1.7 % of MHC II_a and 94.6 ± 1.5 % of MHC I.

The 6 weeks of GSM waves exposure induced, in *edl* muscle, a significant increase by 63% in the expression of MHC II_x isoforms (56.3 ± 4.2 %) and a significant decrease by 33% in MHC II_b isoforms expression (44.9 ± 3.4 %, $n=24$, $p<0.05$).

Moreover, in soleus muscle, the exposure induced a significant increase in the expression of MHC II_a isoforms (16.1 ± 1.7 %) with a significant decrease in the expression of MHC I isoforms (84.3 ± 1.5 %, $n=24$, $p<0.05$) (Fig. 10).

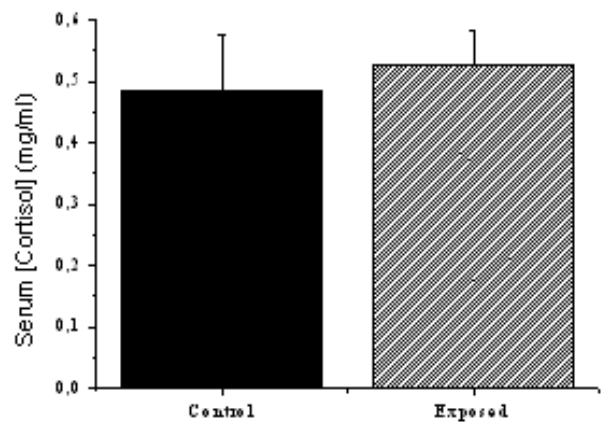


Fig. 9. Effect of GSM waves exposure on cortisol levels in both control and exposed rats. Each histogram displays mean \pm SE.

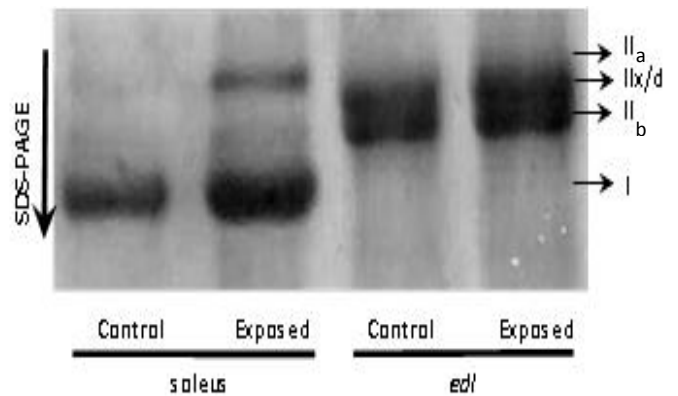


Fig. 10. Separation and analysis of MHC isoforms by SDS-PAGE in soleus and *edl* muscles in control rats and in rats exposed to 6 weeks of GSM waves. This figure show the bands corresponding to each of the MHC isoforms (MHC I, II_a, II_b, and II_{x/d})

IV. DISCUSSION

Many questions were raised about the possibility that exposure to electromagnetic fields emitted by mobile

phones or their base stations could affect the health of users. If there is a health impact, there will be a global impact because the number of active cell phones is estimated to reach 7.3 billion by 2014. For this, the World Health Organization (WHO) established the International EMF Project in 1996 to assess the science, and recommends research to fill gaps in the knowledge of risks arising from exposure to electromagnetic fields on health [8]. Safety is a valid concern for the users of wireless equipment, especially in regard to possible hazards caused by electromagnetic fields (EMFs). There has been increasing concern about the possible adverse health effects resulting from exposure to radiofrequency radiations (RFR), such as those from mobile communication devices, in general, and cellular phones, in particular. Mobile communication technology is achieved when signal is transferred via electromagnetic wave through radio frequency and microwave signals. This signal produces electromagnetic radiation in the form of thermal radiation that consists of harmful ionizing radiation and harmless non-ionizing radiation. When using mobile phone, electromagnetic wave is transferred to the body, potentially causing health problems, especially – for example – at the place near the ear skull region, where they are known to affect the neurons. Neurophysiological studies identified that radiations interfere with the electrical impulses that two neurons connect each other with. This can lead to adverse effects, from headache to blurred vision, to deafness and migraines. People using cell phones are susceptible to high blood pressure and other symptoms such as headaches and fatigue [26, 27]. There have been various studies into the connection between mobile phones and memory and the results were confusing and sometime contradictory [28-30].

Other studies have explored the possibility that radio-frequency electromagnetic fields (RF-EMF) employed by mobile phone technology could influence the genetic makeup and physiology of some specific cells, i.e., male germ cells, and sperm mobility [12]. It was shown that upon prolonged exposure to RF-EMF, sperm surface area and acrosomal region were significantly reduced. It was also shown that the primary function of sperm cells – binding to human oocytes – was significantly compromised.

Furthermore, the effect of RF-EMF radiations was studied vis-à-vis their induction of cellular stress response. This was evaluated by quantifying the expression and activity of heat shock proteins (Hsp), namely Hsp27 and Hsp70, but was shown not to have measurable differences from normal [12].

Skeletal muscle is the most abundant tissue in animals representing up to 50% of body mass in some athletic species such as dogs and horses. Muscle fibers are composed of myofibrils arranged in parallel, which constitute the major compartment in muscle cells, comprising from 73.2% of muscle fiber volume in horses to 83.3% of muscle fiber volume in goats. Also, total myofibrillar volume is directly proportional to muscle mass with a scaling factor of 0.98 [31].

Mammalian skeletal muscle is a highly heterogeneous tissue, able to adapt to environmental challenges to which it is subjected. In rats and mice, this process is governed by a set of mechanical, hormonal and nutritional signals [32-34]. Phenotypic plasticity of muscle tissue allows it to be modified in order to meet the specific demands faced by an animal during its life [18]. This critical property leads to a conversion of muscle fibers from slow to fast or vice versa [3, 35]. A wide range of contractile properties are mainly attributed to the diversity of the isoforms of MHC, which can exist in different muscle fibers. Four MHC isoforms (I, IIa, IIx and IIb), each encoded by a separate gene can be expressed in adult skeletal muscle. The intrinsic differences in the properties of the ATPase of MJHC isoforms led to the classification of fiber muscle as slow or fast fibers [33, 36]. Generally, the fast-type genes appear to be expressed at birth, while the slow-type genes are expressed in response to changes in activity during development [32].

This study aims to examine the effect of electromagnetic waves emitted from GSM antenna relay, at 900 MHz frequency, on body weight, muscle mass, protein content and the expression of the isoforms of the myosin heavy chain (MHC) in 2 types of muscle fiber types. One is slow oxidative fiber and the other is fast glycolytic fiber.

Actually, very few studies have examined the effect of electromagnetic waves on the skeletal muscle. In one of them, the study was conducted in vivo and showed that the field of microwave of 2.45 GHz has a stimulating effect on the activity of the muscle fibers, which is in part due to its non-thermal specific properties [18]. In another, the study was conducted in vitro, and showed that one hour of exposure to 900 MHz of electromagnetic field modulated by the human voice could have an effect on the mechanism of excitation-contraction coupling of skeletal muscle fast-twitch [19].

The results of our present work show that electromagnetic waves do not affect the body weight of rat males. In addition, the exposure period results in a decrease in absolute edl muscle mass, while that of soleus is kept unchanged. The myofibrillar protein content is directly proportional to muscle mass. A decrease in the mass of the edl was translated by decrease of both myofibrillar protein content and soluble protein. The increase in soluble protein content in soleus muscle was compensated by the decrease of myofibrillar proteins content resulting in the maintenance of muscle mass of soleus. This can be explained by the compensatory mechanisms at the translational and post-translational levels as suggested by Nikolova et al. [37]. In addition, synthetic modification in myofibrillar and soluble proteins in edl and soleus may be the consequence of the changes of level of transcription of genes encoding these proteins or due to perturbation in the stability of their corresponding mRNAs [35]. Therefore, the quantification of the mRNA encoding the soluble and myofibrillar and measurement of protein half-life is necessary to detect the level at which the change has led to modify the level of

myofibrillar proteins and other proteins expressed in these two types of skeletal muscles. Our results provide new information by showing a decrease in the total RNA values in both edl and soleus muscles after 6 weeks of exposure to GSM in rats. These results are very propitious and may explain some of disorders observed in humans exposed to electromagnetic waves. However, further studies on human are needed in order to confirm these possible effects.

On the other hand, the effect of electromagnetic waves is specific and can be attributed to a modification in the activity of different hormones. In 2010, Meo et al. [38] showed that exposure to radiation emitted by mobile phone for 60 minutes / day for a period of 3 months significantly decreased the level of serum testosterone in albino rats Wistar. In 2008, Al-Akhras showed that exposure for 6 weeks in a sinusoidal electromagnetic field of 50 Hz resulted in a significant reduction in levels of gonadotropins (FSH and LH) in female rats [39]. These results are similar to our results, where we showed a decrease in the level of testosterone after 6 weeks of exposure to GSM waves. This decrease can explain the decrease in total RNA values in both muscles since it is known that testosterone binds with androgen receptors inside the nucleus of different target cells and turn on the synthesis of mRNA, which are then translated into specified proteins. Thus, the decrease of the level of testosterone may explain the decrease of the RNA levels. On the other hand, there was no change in the level of cortisol in the rats exposed to GSM electromagnetic waves. This result suggests that the exposition to these radiations will not affect the hypothalamus-pituitary-adrenal axis that regulates the stress behavior. Thus, it is possible to propose that the radiations emitted from GSM will not induce stress in rats exposed to them. However, our results show an increase in the level of insulin in rats exposed to electromagnetic waves. This finding is similar to those shown by Meo and Rubeann [40] who have demonstrated that exposure to mobile phones causes hyperglycemia with a simultaneous and significant increase in serum insulin levels. Eventually, a compensatory rise in insulin level helps to control the hyperglycemia. Considering this result and its connection with mobile phone radiation, it is important to find out whether it is associated with B-cell dysfunction or insulin resistance.

If insulin resistance was developed, this can be linked to the change in the percentage of MHC isoforms observed in the present study. In fact, our results show an increase of the MHC IIa isoform, but a decrease in the MHC I isoform in the soleus muscle. In the edl muscle, a significant increase in MHC IIx and a significant decrease of MHC IIb isoforms were observed. These results suggest that the GSM antenna relay affects the plasticity of skeletal muscle fiber by transforming slow type to faster one. Thus, insulin resistance decreases the entry of glucose in muscle cells. These cells will switch from the slow aerobic type to the fast glycolytic one in order to accommodate the decrease in glucose uptake. These suggestions need to be established by

confirming the development of the insulin resistance and by studying the glucose uptake by muscles cells in rats exposed to mobile phone radiation.

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Improving African Healthcare through Open Source Biomedical Engineering

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Abstract—The lack of accessible quality healthcare is one of the biggest problems in Africa and other developing countries. This is not only due to the unavailability of resources, but also to the absence of a structured formative process for the design and management of healthcare facilities. Crucial to the effective and efficient exploitation of healthcare facilities and biomedical technology is the support of Biomedical engineers, who form the link between technology and medical practice. Indeed Biomedical engineers, together with nurses and doctors, form the pillars of healthcare systems in the developed world. In this paper, the Open Source for BioMedical Engineering (OS4BME) project and its kick off summer school are presented. The OS4BME project aims at developing a new generation of biomedical engineers, able to exploit emerging technologies generated by the recent “Makers” revolution. During the one week summer school, students from various sub-Saharan countries were introduced to these new design, development and sharing paradigms. Students worked together to identify new simple biomedical devices, which could help in daily clinical practice in their countries. A cheap and easy-to-use neonatal monitoring device was chosen as a Crowd design project. The OS4BME Baby Monitor was designed and assembled by the students during the one week summer school, demonstrating the creative potential of the new generation of biomedical engineers empowered with the paradigms of crowdsourcing and rapid prototyping.

Keywords-Biomedical Engineering; Open Source; Open Hardware; Crowdsourcing; Africa.

I. INTRODUCTION

While the givers of healthcare are certainly doctors, clinicians and nurses, at least in the developed world, biomedical engineers are widely recognised as being the cornerstone of any medical facility with high technology diagnostic and therapeutic equipment and devices. In the less developed or emerging countries, the role of engineers in the hospital context is less well consolidated, as pointed out in our short paper presented at the VIII International Conference on Digital Society in 2014 [1].

Indeed, the scarcity of accessible quality healthcare in Africa is inextricably linked not only with the lack of resources, but also with the lack of adequately trained biomedical engineers [2]. Excluding South Africa, apart from few singular initiatives (in Nigeria and Ghana), no university in sub-Saharan Africa offers a fully-fledged Biomedical Engineering graduate and post-graduate programme [3].

Several reasons for this can be identified, but one of the most important is the absence of a clear common understanding of BioMedical Engineering (BME) as a field of study both in higher education as well as in the medical sector. Although there are a number of technical level clinical and biomedical engineering courses scattered through sub-Saharan Africa, their quality and content are often questionable [4]. Moreover, medical equipment does not have common standards or operating protocols; indeed in most developed countries, hospitals and clinics have very expensive maintenance contracts with manufacturers who train their own specialized technicians [3]. As a result, the medical device industry in Africa is largely absent and there is an over reliance on foreign companies to repair and design biomedical instrumentation, and resolve technical problems. Very often developed countries donate machines to African hospitals and clinics. While this is an honourable act, the machines usually end up being abandoned when they stop working due to lack of adequate maintenance [5] [6].

The experience of one of the authors in the *ASIALINK* project, “Development of Core Competencies in the areas of Biomedical and Clinical Engineering in the Philippines and Indonesia 2005-2008” [7] [8] has shown us that long term and sustainable improvements can only come through i) recognition on the part of policy makers, of the importance of in loco trained experts capable of managing and repairing biomedical equipment and ii) development of expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. These are the two keys to a sustainable and efficient health care system.

However, the world has completely changed with respect to 2006, when the *ASIALINK* project was considered a landmark in South East Asia. The continuous connectivity with tablets, mobile phones, the rapid dissemination of social networks, and the access to free e-learning [9], makes teaching easier and harder at the same time, because of the huge amount of available information.

The world of BME is also changing, here again thanks to various virtual communities that live, exchange and discuss on the web. While, a couple of years ago, the development of biomedical devices was essentially linked to companies and universities, now the first examples of open source biomedical devices, such as the Gammasoft Open electrocardiogram and

the Smartpulse oximeter are beginning to appear [10] [11]. Although these instruments are not accurate or safe enough to be inserted in the clinical routine, their use can probably save a life more than a damaged, unused (e.g., for high cost) or useless (e.g., because no one knows how to operate) Magnetic Resonance Imaging machine.

Indeed, as *The Economist* [12] points out in an insightful laymans overview of this burgeoning field, software-reliant devices have also brought on new types of potential risks for patients. The article underlines the difficulty of exposing specific problems with these products, given that medical software (and hardware) is proprietary and patent-protected, thus veiled in secrecy [13]. The open-source approach could, in theory, make it easier to fix, or even avoid, dangerous flaws before they hurt or kill hundreds or thousands of patients. Despite this virtual revolution the mainstream academic community in most countries, developed or not, remains largely ignorant of the potential of open source software, hardware and prototyping. This is particularly evident in Africa - we refer in this paper to sub-Saharan Africa excluding South Africa - where tradition and hierarchy play a strong role at all levels, more so in academia. The authors are of the opinion that academia, and specifically biomedical engineers in higher education, must embrace these new tools, and pass on the message that an Open Source product, developed by a community, without a multinational brand is not equal to un-reliable.

Indeed, today, thanks to crowdthinking and crowdsourcing, the design of several products has an intrinsic revision process, driven by the community, which has become an active player, and no longer a passive element. The community is the best analyst in terms of quality, reliability and feasibility. While this philosophy is now well accepted in the "software" world, there is still an unjustified unbelief in open "hardware", because many people are anchored to the consolidated production processes, in which product development is affected by high costs due to the inflexibility of high throughput fabrication technologies (e.g., injection molding). As described in the seminal work of Chris Anderson "*In the next industrial revolution, atoms are the new bits*" [14] [15] 3D printing (later described in the text) is giving everyone, companies, makers, and inventors, the tools that were the exclusive prerogative of a few companies less than ten years ago.

A note of caution however; the freedom given by the Web, and by the possibility to share, fork and re-implement projects, which characterises the Open Source Software, Electronic, and Hardware world, has one major drawback: organizing information (schematics, blueprints) and quality control are the boring parts that are not always pursued in a passion-driven and self assembled community. In the context of BME however, this latter aspect is critical for ensuring safety and efficacy of biomedical devices, and must go hand in hand with the adoption of open resources for medical applications.

We present here a **position paper** on the benefits and use of Open Source tools and platforms in BME specifically in Africa - a continent that needs to jump on the fastest, cheapest and greenest wagon to growth and self-sufficiency in healthcare or face being left behind. The adoption of these new methods of creating and thinking needs to be coupled with open standards and regulations for medical device safety. We thus argue that the new virtual sharing mentality should be

wholeheartedly embraced, valorised and overseen by African universities through a common Open Source for Biomedical Engineering platform (OS4BME) rendering the development, and maintenance of medical equipment accessible to the African continent.

After a discussion on the potential of Crowdthinking (Section II) and BME in an African context (Section III), we describe the OS4BME project (Section IV) and its kick-start initiative in Nairobi in 2013 (Section V).

II. CROWDSOURCING AND CROWDTHINKING PLATFORMS

Currently, there are several resource sharing platforms available on the internet. Their use is spreading throughout the developed World, starting from Europe and the US. The growing accessibility of these platforms, like any shared common resource, has resulted in the generation of huge amounts of garbage. Sifting the useless from the useful is a monumental task and requires experience in design and engineering as well as some skills in negotiating the now cluttered internet of things. More importantly, at present, there are no specific engines or platforms focused on the sharing of biomedical instrumentation and devices. This is because, by their very nature, biomedical devices possess stringent performance requirements to comply with regulatory standards to ensure patient safety.

In the past few years, various studies on social epistemology and group judgment aggregation have been published [16] [17] demonstrating both theoretically and practically the superior heuristic value of collective, non expert, knowledge compared to individual or small group assessment, based on consolidated rules and expectations. In 2006, Jeff Howe coined the Crowdsourcing Neologism in a futuristic article in *Wired* magazine [18]. Publishing of a neologism related to society cooperation in a magazine instead of in a traditional journal paper is a clear indication of how this new field is driven by a sort of creative talent of the community leading to tangible products for business and non-profit purposes [19].

Crowdthinking platforms are becoming important tools for design and development of new products. Platforms like Wikipedia [20], Thingiverse [21], YouMagine [22], Instructables [9] allow the generation of information that spans from text documents to complex designs and blueprints. Recently, the National Institute of Health of United States has proposed the 3D printing exchange portal [23], that collects 3D-printable files related to biomedical field from molecular and anatomical models to designs of prosthetic hands. Two more targeted initiatives are represented by Appropedia [24] and Open Source Ecology [25]. The first is focused on collaborative solutions in sustainability and poverty reduction, collecting projects on construction, energy saving, food, agriculture and also medical devices. The underlying theme is represented by the concept of Appropriate Technology, a term which indicates those technologies that are easily and economically used from readily available resources by local communities to fulfil their needs, complying with environmental, cultural, economic, and educational resource constraints of the local community [26]. The Open Source Ecology represents a network of people, farmers, engineers, architects and supporters, whose objective is to create an open technological platform that allows for the

easy fabrication of the 50 different Industrial Machines that it takes to build a small civilization with modern comforts. Thus, several web based communities [27] have an active role in crowd-development and crowdthinking and also various FabLabs (Fabrication Laboratories) [28] are being born with the aim of bring technology to the people, empowering the creative process with the possibility of building real, physical objects. Using this approach healthcare issues such as prosthetics are also being addressed. For example, *Not Impossible's Project Daniel*, uses 3D printers to make prosthetic arms for children in worn-torn Southern Sudan [29].

Leaving aside large diagnostic and imaging equipment and prosthetic implants, the vast majority of biomedical devices have a large turnover and no one company monopolizes the market. They are also extremely diverse: examples are plasters, thermometers, hospital beds, sphygmomanometers, etc. In this arena, there is huge scope for Crowd driven improvements and innovation.

In the context of BME, we still need a high level of supervision, to control the quality and to guarantee the respect of safety standards. By virtue of their access to the brains of the future, universities are the right (and perhaps the only) institutions to properly teach instruments for exploiting cloud and crowd based technology and "doing", while giving due importance to concepts, such as ethics, standards and regulations. However, the former is often unknown to even the most brilliant professors. More worrying is that fact that in very few universities do BME core competencies include knowledge on regulatory pathway development for medical devices. In addition, there are very few e-learning courses in BME and few universities make use of the newer technology platforms for teaching this discipline.

We define the Crowd, with a capital "C", as groups of individuals trained and assisted by institutions of technical and higher education, to design, innovate and build together through sharing. As such, the Crowd can and should consist of healthcare providers as well as engineers and technicians. If properly guided by standards and regulations, guaranteed by universities as the organ for control, certification, knowledge and learning, the Crowd is an enabling system for the design and development of medical devices. In addition, the Crowd philosophy can be extended to production processes so fostering local economic growth. In fact, the new methods of production now accessible to all do not require the delocalization of manufacture.

III. CONTEXTUALIZATION

A. Biomedical Engineering for Africa Today

As Nkuma-Udah et al. point out [3], there are few African universities which offer BME courses. Those that do are based on curricula which were designed for Western universities over 20 years ago and which place undue emphasis on niche subjects like MicroElectroMechanical Systems (MEMs), nano medicine and cell engineering and less on the learning of new, hard technology and equipment management, maintenance and repair [30]. Evidence from the *ASIALINK* project has demonstrated the value of developing expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. While we are

not advocating a complete revolution in BME teaching here, we are strongly in favour of the upgrading of curricula based on solid engineering principles (as outlined by Linsenmeier [31]) with new courses, new technology and new ways of thinking and problem solving, specifically adapted to the needs of countries with few resources. This approach is similar to that proposed by Tzavaras et al. [32] on computer enhanced education laboratories. Fusing the crowd design philosophy with the Biomedical Engineer's objective of improving human healthcare requires that patient safety and efficacy be the paramount concern and also the motivating force behind Crowd driven innovative biomedical device design. Biomedical devices must be designed with safety and efficacy in mind, and they should adhere to regulatory standards (albeit most of the countries in the region of interest have no regulatory authority for biomedical devices). Thus, the Crowd not only needs to be empowered with the technological know-how, but also be given the means to intelligently scan and filter the internet for useful open source materials without being overwhelmed by the choice available. To do so requires fundamental knowledge on biomedical devices, ergonomics, engineering and human physiology: this multidisciplinary cries out for Crowd, but with a controlled accredited infrastructure capable of design-ranking and accreditation, as we discuss in Section V.

B. Social Context

Today, Africa's healthcare systems are at a turning point. A growing urban middle class is willing to pay for better treatment. Donors and governments are now beginning to provide better healthcare facilities and increased access to medicine, at least in urban areas. There is no question that technology has played a key role in improving the quality and cost effectiveness of health services as well as access to health care facilities. Technology is at the heart of effective healthcare services helping medical and paramedical personnel in all stages of their work: from prevention to diagnosis, treatment and monitoring. Yet, technology entails huge investments in economic, physical and human resources; it comes with a price tag that can bear heavily on the limited resources of many African countries. To be able to function properly and safely, it requires an appropriate physical environment, proper care and maintenance, and skilled operators. However, Africa lacks the human resources needed to install, maintain, manage, upgrade, design and produce medical devices, leaving it ever more reliant on foreign technical expertise. Honourable initiatives, such as the Engineering World Health (EWH) [33] or the Amalthea Trust [34], which work in partnership with local hospitals, educational institutions and governments, providing training courses for improving local capacity, have a limited impact because they are not Africa-driven programmes. Thus, once the volunteer goes home, there is no-one left to take over.

We are fully aware that although professors, students and technicians maybe very enthusiastic with the idea of open source and Crowd driven biomedical device design, some Ministries of Health, or some powerful economic and other interest groups in developing countries could to be linked to major device manufacturers and therefore can block or hinder our initiative because their interests are threatened. For this reason, part of our project is also focused on creating awareness-raising activities and workshops targeting policy-makers, e.g., representatives of the Ministries of Health and

Education. Through the help of our funders we will develop advocacy campaigns for the recognition of the importance and relevance of biomedical and clinical engineering in the health care system. Policy makers will be made aware that local and locally trained Biomedical Engineers equipped with the means to create, design, innovate *and* fabricate are crucial for generating and managing a sustainable high technology health care system, which does not rely on foreign economic aid or volunteers. Indeed, our aim is to give the universities the tools, guide them through the platform and then let them research the best social conditions (at state level, society level, and so on) to turn the implementation of the project into a success. We are extremely sensitive about the issue of not imposing our ideas and cultural values on the People of Africa. Unfortunately, as recently observed by many African NGOs and local leaders, the passion for helping Africa is, more often than not, driven by the need to feel good about ourselves and seldom truly serves Africans or Africa to move forward. This push has to come from within Africa and should not be propelled by our need for self fulfilment or create publicity. The Daniel Project is a good example of this type of high profile, unsustainable aid.

IV. OS4BME PROJECT: THE CROWD PHILOSOPHY IN THE BME CONTEXT

What we advocate therefore is giving biomedical engineers in sub-Saharan Africa, through their universities, the tools and know-how they need to design, develop and maintain their own equipment based on the new open hardware and open source revolution, which is happening before our eyes. To achieve this ambitious goal, we outline three main objectives:

- the development of human resources in higher education in Biomedical Engineering in Africa,
- the creation of the expert-based OS4BME infrastructure, a sharing, making and repository platform (based on the customization and integration of already available web tools) for vetting, searching and ranking designs to propel continuous improvement and innovation;
- the making of a new genre of Biomedical Engineer (in Africa but also in the western countries) equipped with the capacity to exploit and develop innovative designs on the OS4BME platform and of discriminate use of web based and open source resources.

OS4BME capacity building efforts in design, entrepreneurship and regulation will ensure that Africa can timely exploit the open revolution. Setting up the OS4BME platform requires the creation of a professional BME working group, versed in the regulatory aspects of biomedical safety and standards, which is able to assess, vet and categorize projects, designs or blueprints and then make them available through the platform open repository. The philosophy is summarised in Figure 1.

Device development will be underpinned by quality and performance benchmarks to ensure safe human-device interaction, as the first step towards harmonisation of technology and biomedical device regulations across the African continent. At the same time, worldwide institutions involved in Biomedical Engineering, rapid prototyping, healthcare technology, higher

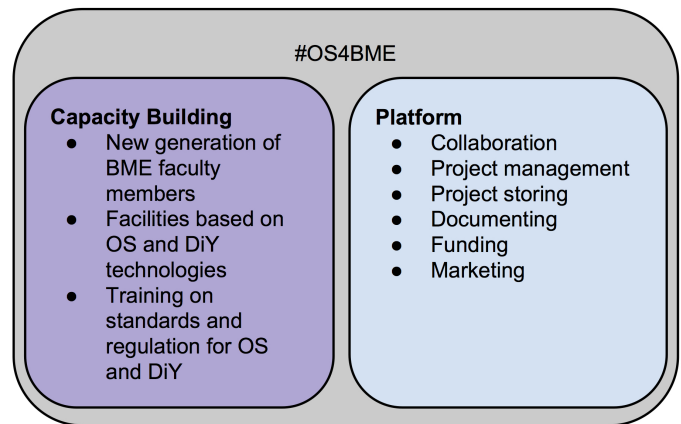


Figure 1. Scheme of the OS4BME project: integrating capacity building with a web platform for the creation of safe open source biomedical devices

education, medical device and prosthesis development can use the design, data and technology sharing platform as a reliable repository of innovative projects, ideas and networks for cooperative and excellent research and growth.

A. Capacity building: A New Genre of BMEs Empowered with Crowd Thinking and Design Tools

The Open revolution is creating a deluge of information where only some “pearls” are contained. Building a new genre of BME professionals means making them able to find these cores of quality information. To do this, they have to be trained not with a new set of disciplines but rather with a new “formamentis” giving them the proper tool-set. Maths and Physics remain cornerstones but their use in design and prototypes dramatically changed in the last 10 years: nowadays, the designing phase can be interwoven with prototyping steps creating the new concept of prototyping [35]. Having the possibility to do “tangible design” means optimizing the entire design process, but also enhancing new ideas and solutions.

The identification of the most suitable instruments and classroom management and organization is the first step to demonstrate the potential of open source in the BME context. We targeted three main areas of teaching, necessary to give a shape, a brain and to share the ideas:

1) *Rapid prototyping*: The term Rapid Prototyping (RP) indicates a group of technologies that allows the automatic fabrication of physical models based on design data using a computer. RP processes belong to the generative (or additive) production processes. In contrast to abrasive (or subtractive) processes, such as lathing, milling, drilling, grinding, eroding, and so forth in which the form is shaped by removing material, in rapid prototyping the component is formed by joining volume elements. In general, RP techniques follow a Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) approach. The object is designed using a computer (CAD), which then sends the instructions to the machine to obtain the desired shape (CAM), fabricated layer by layer. For the implementation of the RP principle several fundamentally different physical processes are suitable, such as photopolymerisation, conglutination of granules or powders by additional binders,

extrusion of incipiently or completely melted solid materials [36] [37]. RP was originally conceived as a way to make one-off prototypes, but as the technology spreads more things are being printed as finished goods [38]. Although 3D printing is not competitive for mass production (millions of parts), it is perfect in fields where the customization of products is important: because the expense of making tools no longer figures in the equation, the economics of mass production will give way to mass customisation. Parts will then be made in production runs not of a million or even of a few thousand, but of one. Thus, 3D-printed products will continue to creep into the medical, dental and aerospace industries where clients are willing to pay a premium for custom products. In industries that are not built on “markets of one”, 3D printing will help product designers accelerate the design process. 3D printers would also be invaluable in remote areas [39].

Thanks to the various Do-It-Yourself (DIY) communities, several models of Open 3D printers are now available on the Web. One of the most famous is the RepRap community [40] built around the ideas of Adrian Bowyer. He imagined a printer that can print its own parts, and hence through a process of self replication is able to spread this technology throughout the population [41]. The Fused Deposition Modelling (FDM) approach was chosen for its simplicity: a filament of plastic material is extruded through a hot nozzle following a predefined tool-path to build the various slices of a layered object [36]. All the parts of this 3D printer (there are several versions) are open source. The electronics is based on Arduino (see the next section), the software is open source and produces standard G-code files. Designs can be shared and any unprinted parts of the machine are easy to find in any DIY shop. Although, the quality of 3D printed parts made by a RepRap is not high, we believe it is the right starting point to teach the potential of 3D printing to newcomers. The design and printing process is completely transparent so that each step of the complex procedure is easy to follow and replicate. Furthermore, recently the open 3D printing has been indicated, for the African scenario, as an Appropriate Technology [26]. As a confirmation of this statement, the supply of printing filament material, even in remote areas, can be based on plastic recycling, whose energy cost is lower than the price of commercial filament [42]. Open source devices which can produce useable filament from recycled post-consumer plastic are current available on the web [43].

2) *Electronic Prototyping Systems*: Until about ten years ago, electronic system design and development was a field accessible only to skilled users, such as engineers, technicians, physicists, etc. Each time an electronic control system was required in a project, the design process had to necessarily include the choice of microcontroller, of a communication system, of a power source, etc. This choice was then binding for the selection of further components, interfaces and programming software. In 2005, a team of designers led by Massimo Banzi created Arduino [44], a tiny board onto which a microcontroller was mounted together with all the necessary circuits and peripherals required for powering, communication and expansion. A revolution had begun: electronic control systems were not the bottleneck of prototyping anymore. With Arduino, even users without electronics and programming skills could integrate and electronic control system in their own project pushing the limits of complex system design and

prototyping. The key factor of the Arduino platform is not only the board but also the easy-to-use programming environment, which allows unskilled users to program through a very intuitive C like programming language. These two factors allowed the birth of a huge user community, which empowered the home and even industrial and academic electronics world through the sharing of code, libraries and projects with open source license. The availability of a pre-made piece of code allowed people to focus their designs on the development of functional and challenging parts using other projects and codes as inputs for their own designs.

3) *Content Management and Sharing platforms*: As highlighted previously, the fast growing DIY community leaves several interesting projects to languish without documentation or with missing parts because a new, more interesting idea was released. Indeed, one of the most challenging aspects of cooperation in design and development is the organization and sharing of information and content. However, thanks to the revolution introduced by the blogging phenomenon, there are various free and open source Content Management Systems (CMS) available nowadays, which allow an easy and intuitive co-production of documents. These systems have been demonstrated to be useful even for the documentation of engineering and technical projects. MediaWiki [45] in particular is the core engine of the most famous web based encyclopedia Wikipedia. With MediaWiki or similar engines it is possible to create hypertexts made of a huge number of cross-linked pages allowing the creation of very detailed documentations and designs. MediaWiki is designed for the creation of text based documents with embedded pictures and table. Graphics and templates are very minimal allowing users to focus on the real content, which is a core feature of a concurrent design.

B. OS4BME platform design and implementation

The OS4BME platform is a virtual research infrastructure conceived as a facility for creating open excellence in Biomedical Engineering, comprising an array of design resources, including blueprints and performance data.

The platform will be composed of four sections, to fulfill specific tasks of the project lifecycle:

- a **needs identification** section, open to everyone (general public, healthcare providers), aimed at identifying problems using forums and surveys, and also at generating disruptive new ideas;
- a **project management** part, open to accredited Crowd and coordinated by the new BMEs, using specific project management tools (e.g., Redmine [46]);
- a **repository**, for free download of projects blueprints which passed the development phase and have been certified as compliant with standards;
- a **funding** section, for supporting selected OS4BME initiatives.

The development of a generic project is described in the following subsections; here it is important to highlight the differences with respect to the most popular web repositories [21] [22] [23]: the OS4BME platform will allow a coordinated development of a each single project and it will be

downloadable only after vetting by a team of BME experts, which will assess and score designs; only those considered safe will be accessible for download. Moreover, full performance and safety documentation and instructions on calibration and maintenance have to be available. The OS4BME project goes beyond the mission of EWH or Amalthea Trust [33] [34], coupling capacity building to Africa-driven concurrent design, achieved through the OS4BME platform.

1) Platform management and maintenance: As already stated above, organizing information (schematics, blueprints) and quality control are usually the weak point of the self assembled communities for the “classic” open development. Furthermore, in the context of BME, devices demands in terms of safety and efficacy require a more structured design. For this reason, the OS4BME platform will foresee a Managing Group (MG), composed of the new genre of BMEs, with the aim at formalizing the problems and the needs that have to be solved and fulfilled, and series of Project Leaders (PLs) that will organize the specific project into horizontal or vertical tasks. While the MG have to be considered as a sort of “resident” group, any user can be the PL. The developers, above defined as Crowd, can participate to carry out the various tasks, according to their specific skills. From the formal point of view, there are no limits, in terms of academic title, to be part of the network as a user, as it happens with other developer communities; and it seems also reasonable that an academic group can be logged as a single unit with the same flag as a single user.

The maintenance of the OS4BME organization/platform (servers, people, meeting, summer schools and workshop organizations) will have of course a certain cost. We identified possible sources for the upkeep:

- fee payment from non-African Universities and Research Institutes. The participation in a program as OS4BME is to be considered prestigious, offering students the possibility to design useful biomedical devices, with a collaborative approach;
- financing from government. Considering the potential impacts on education on economy that the OS4BME project can develop, it seems reasonable that national and international governative organizations can fund this initiative;
- crowdfunding: specific projects, under the initiative of the project leader, can opt to access to Crowdfunding, publishing the campaign in the “funding section” of the OS4BME platform, or accessing other services such as Kickstarter [47];
- economic contribution from companies (see ensuing paragraphs): companies that want to commercialize the products developed thanks to the OS4BME platform can contribute as an investment to this “distributed” R&D sector;
- private donations.

2) Needs identification and project development: That the devices developed be useful in the African healthcare context is central to the OS4BME philosophy. Quite often biomedical equipment is left in the hands of healthcare workers through

donations, whether they are needed or not. Local conditions such as availability of water, electricity and dust are quite different in rural hospitals, and these must also be taken into account. Thus, the most important criteria for identifying devices for the platform is that they respond to specific needs and provide specific solutions to daily problems that healthcare workers face. This requires close contacts with medical and nursing staff and local knowledge, thus the establish of formal relationships with hospitals is an important component in the implementation of the project. After the identification of the needs and the constraints, the project is formalized by the MG in terms of objectives, norms and standards. At this point, any user can propose himself as PL, organizing the work packages of the project, receiving feedback from other users who can participate in the various tasks according to their skills. At this stage of development, the decision on the validity of the project proposal is made in an indirect way by the Crowd itself, supporting or not a project. The PL has in any case the possibility to revoke a task and assign it different users if a deadline or a project specification is not respected. When a project is completed, the MG has the role to verify the quality of the specific products and its conformity to standards. A sustainable approach can be the assignment to three different Universities (not involved in the project) the task to built and test the product, according to the documentation provided by the developers. If this internal quality check is passed, the MG will ask three Hospitals, which are part of the OS4BME network, to test the product. After that, it will be available for downloading.

As depicted in Figure 2, the lifecycle of a project also comprises other two sections, the fund raising, and industrial upscale. While the latter is not strictly part of the OS4BME platform, a section of the platform is dedicated to support from the economic point of view. In particular, crowdfunding can be considered as a showcase for involving more partners; furthermore, the MG can help the PL to write a winning proposal to the various calls of funding agencies. Investor and business angels can also see a fertile ground to sponsor challenging ideas in OS4BME.

3) Project ranking: Starting from the consideration that more than one design can be proposed to fulfill a specific task/need, a classification is required in order to facilitate the users in the choice of the best solution for the specific case, on the basis of local conditions. Starting from the necessary requirement that the downloadable projects respect safety standards, we identified three different criteria for ranking:

Feasibility The feasibility criterion is related on the building phase of the device, and thus the following entries have to be taken into account: cost (raw material and time), components and material availability, construction simplicity (equipment, and thus skills needed), procedures for quality check.

Usability The usability of the specific design solution refers to those features related to the operating performance and operating condition of the device: accuracy, adaptability to various working conditions (e.g., salability of water, stable power supply), level of competences needed, easy of use, reusable/disposable.

Maintenance The maintenance criterion will provide a classification on the basis of the procedure needed to upkeep the device in optimal working condition: number and costs of maintenance interventions, necessity of specialized techni-

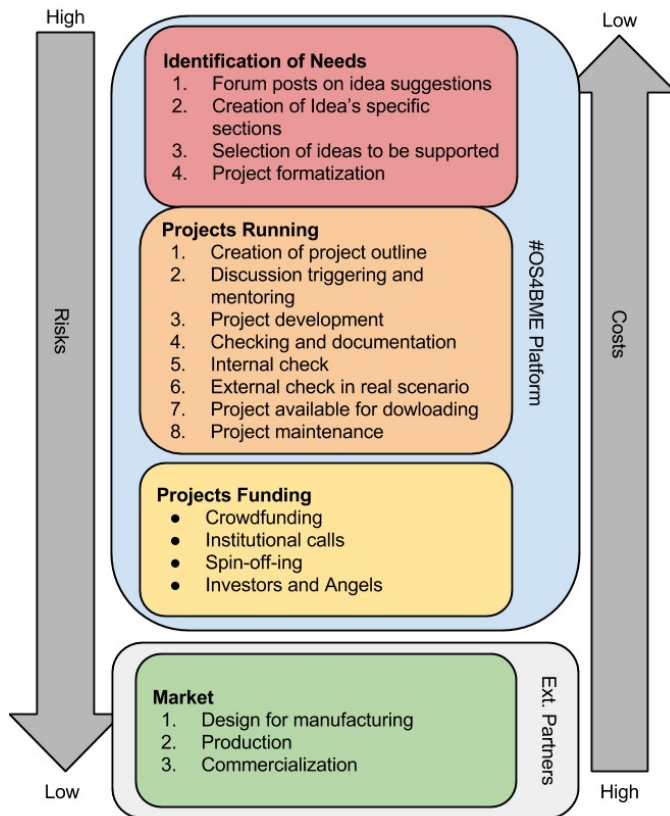


Figure 2. Project lifecycle, from the identification of needs to the design of a product, up to a possible commercial exploitation, under open license, by an external partner

cians.

After an initial score given by the developers and platform board members, the ranking will be updated on the basis of the users' feedback.

4) *OS4BME as a flywheel for local economies*: The authors are aware of the differences that exist between the design for prototyping and the design for manufacturing. The projects available for downloading are safe and compliant to standards, but are far from being defined as a "product" in the industrial sense (e.g., optimization of the production procedure, supply chain). Design for manufacturing, the business model, the business plan, the marketing campaign are beyond the limits of the OS4BME platform, which however encourages the entrepreneurial spirit. The biomedical devices are in general high added-value products, and authors believe that the platform can be a flywheel for local economies. In order to to guarantee a sustainable development of these "spin-offs", and ensure that the open-source aspect will remain intact, the following three requisites have to be satisfied:

- the products and their documentation have to continue to be open-source;
- the companies have to be located in Africa;
- the companies will economically sustain the OS4BME project.



Figure 3. Group photo from OS4BME class, hosted by the innovator Summer School, in the Kenyatta University Conference Center.

The MG will be in charge of signing agreements with these companies. It is also expected that some of the products will be copied by other entities in other countries (as it happens sometimes also with patented products), but they will be not branded as "OS4BME compliant".

V. OS4BME CLASS

To kick start the initiative and to demonstrate the potential of a regulated open source design and prototyping platform to academics and regulators/decision makers, we proposed a short term intensive course. The course was implemented in August 2013 in Nairobi, Kenya. Our aim was to introduce the OS4BME concept to the African Engineering community and thus create a small working group who will be involved in the set-up of the new platform. To fulfil this objective, the course was focused on the design of a biomedical device from first principles, its assembly and testing and discussion of regulatory issues in device development.

The OS4BME course was hosted by the Innovators Summer School held at the Kenyatta University Conference Center, Kenya and took place from the 12th – 16th of August 2013. The Innovators Summer School is an initiative of United Nations Economic Commission for Africa (UNECA [48]), and is aimed at fostering the economic development of Africa by powering the higher education of the African students. The key player in the initiative is the African Biomedical Engineering Consortium (ABEC [49]), a consortium of African universities with the common mission of bringing excellence to BME in Africa. Over 48 students, technicians and lecturers from the ABEC universities: Kenyatta University (Kenya), University of Nairobi (Kenya), University of Eldoret (Kenya), Addis Ababa University (Ethiopia), Makerere University (Uganda), Kyambogo University (Uganda), Mbarara University (Uganda), University of Malawi (Malawi), Muhimbili University of Health and Allied Sciences (Tanzania), University of Zambia (Zambia) and University of Pisa (Italy) attended the course (Figure 3).

After introductory lessons to explain the aim of the course, and some preliminary basics on RP Hardware, software, electronics, and safety regulations, hands-on sessions were provided, giving the students the opportunity to learn by doing. Following the spirit of the course, the free and open CAD/CAM software programs (FreeCAD [50], Slic3r [51], and Pronteface [52]) were adopted to introduce the design

approach for 3D printing. For the electronics part, the Arduino platform was selected, for both price, ease of use and flexibility. All documentation was reported using Mediawiki. The keystone of the course was represented by the brainstorming coordinated by the authors with the help of Dr. Molyneux, a pediatrician from the University of Malawi, to understand the problems of a pediatric department in an African hospital context.

The discussion was centred on the respiratory problems of new born premature babies and the monitoring of breathing and body temperature. Together the class established the aim of designing and building a low cost device, for monitoring respiratory movements and temperature, able to shake the cot to resuscitate the normal breathing of the baby when it stops, and equipped with a sound and light alarm to call a nurse to the cot. The implementation of these features was defined together with students, after the brainstorming session. The discussion was focused not only on the functional aspects of the devices, but also on their cost, feasibility safety and reliability, giving the right direction to the project from its start.

After the definition of design specifications, students and attendees were divided into four thematic groups, on the basis of their previously indicated preferences: 1) mechanical design; 2) electronic design; 3) software design; 4) standard and regulation identification, and documentation. The subdivision in groups was fundamental in order to keep everyone involved in something they enjoyed: creativity is fed by passion and enthusiasm, boredom kills innovation.

The proposed approach led to the design and fabrication of an open source and low cost baby monitor (Figure 4) in the space of 3 days. The monitor was composed of three modules:

- an elastic band, to monitor the temperature and the respiration of the baby;
- a vibrating box, activated when the baby stops breathing for more than 15 seconds;
- a control unit, with a LCD display, 3 LEDs, sound alarms and all the control boards.

Students were encouraged to refer to ISO standards, such as IEC ISO 80601-2-56, with the aim of using these documents to help their work rather than a constraint.

At the end of the course an evaluation survey was conducted by the funders. Over 81% of participants expressed extreme satisfaction in the course, although a good proportion (46%) of them could have benefited from more time and previous knowledge on electronics, CAD and programming. In fact, only one participant had previously been exposed to open source technology. There was also interest in the regulatory aspects and standards in medical devices. As the participants were from different backgrounds, many had very little idea what medical devices are and the critical importance of safety issues in such devices. The action thus served to bring home the importance of this aspect during the design of instruments for BME.

VI. CONCLUSION AND FUTURE WORK

The objective of the OSBME project was to develop and nurture resource sharing and technological self-competency

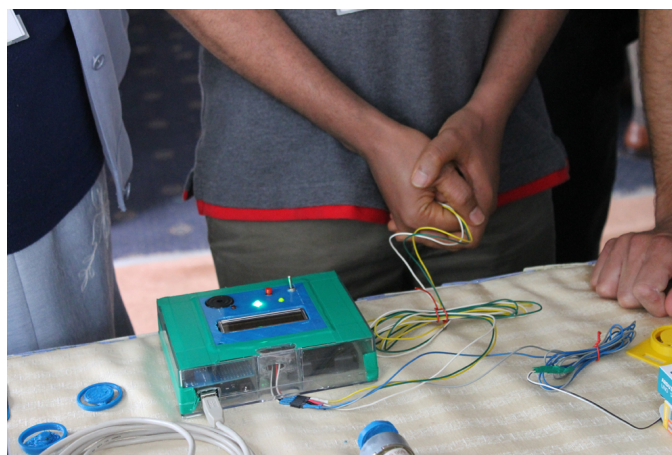


Figure 4. Some moments during the OS4BME class: preliminary test of the device.

through the establishment of a virtual platform containing ideas, blueprints, ranking criteria, FAQs and safety regulations for creating new, competitively priced and innovative biomedical devices. We envisage an OS4BME platform managed, regulated and monitored through an academic led pan-African organization, assigned with the task of collecting, classifying, vetting and disseminating information and know-how on the design and development of biomedical devices and instrumentation. In the long term, the sharing of ideas and designs should become the norm, allowing continuous user-driven improvements in healthcare.

A summer school was organized to kick off these ideas, with the aim to create a cohesive working group to initiate the construction of the the platform. The response from students, professors and technicians involved in the school was enthusiastic. It was crucial for participants to play an active role in the identification of the problem, selection of components, design, assembling and testing of the device and in the discussion of regulatory issues in the development of the device. Participants were able to gain a hands-on introduction to electronic system design and programming. All teaching materials, including course documentation, the baby monitor design blueprints are available online for the community to take on and develop further. The 3D printer and all components are now hosted at Kenyatta University's Faculty of Engineering (Figure 5) and being put to good use.

According to the funders' survey the course was an undoubted success. Most students and staff were unaware of the existence of tools, such as Arduino, FreeCad, Slic3r, Media Wiki, etc., let alone the power and implications of open source design and prototyping. The experience was instrumental in bringing this knowledge to the participants, and their keen interest throughout, particularly on 3D printing was apparent.

The blueprints of the devices developed in OS4BME, which comprise not only the designs, but also the proper guidelines and data for needs, quality and safety assessment will be shared by and through the OS4BME community. In the long term, the community will embrace not only African and European universities and research centers, but also hospitals, giving the possibility, through Creative Commons-like licenses, to fabricate medical devices that will greatly enhance the qual-



Figure 5. Final ceremony of the OS4BME summer school. The 3D printer, printing materials, Arduino electronic boards and the baby monitor were donated to Kenyatta University.

ity of healthcare in developing countries. As a consequence, the project will also foster economic growth both by creating a substrate of highly-skilled personnel and by transforming ideas generated by OS4BME open and crowd approach into commercial products. In addition, national legislation on medical devices amongst the ABEC countries is highly fragmented and/or non-existent. The infrastructure will provide a common substrate through which local biomedical device regulations can be harmonised with the specific contribution of local regulatory authorities.

Although there are several resource sharing platforms available as well as several courses on RP, digital design and embedded electronics, none of these is dedicated to biomedical devices. This is because biomedical devices must be designed first and foremost with patient safety and efficacy in mind. The OS4BME infrastructure, managed by the new genre of biomedical engineers, can be the tool to address this challenge, and its implementation is our objective in the next few years. The initial cornerstone of this project was an intensive course, the first of its kind, addressing safety, ergonomics, biomedical device design, and RP in an integrated manner. Further courses of a similar nature are planned at all participating universities. This open education and crowd-based design model could be exported to universities in developed countries. Let us not forget that the true beneficiaries are the students, who are exposed to the web world at an early age. Educators should keep pace with the open revolution and their pupils' modes of learning, adopting and integrating the approaches proposed here in the teaching curricula. When embraced, the presented Open Source tools and sharing mentality will give BME a new impetus, open to novel teaching, learning, and design paradigms.

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of guidance throughout the summer school. The authors would like to thank also the University of Pisa and the FabLab Pisa for supporting the preparation and organization of the summer school. Part of the electronic material used for the course and for the development of the Baby Monitor was donated by Arduino [44] and the OS4BME experience was reported on their official blog [53]. Finally the authors would like to thank Eng. Giorgio Mattei, Eng. Serena Giusti and Alejandro Callara for their excellent work in supporting and tutoring the OS4BME summer school student groups during the course.

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An Economic Model of Remote Specialist Consultations using Videoconferencing

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Abstract - Remote specialist consultations using videoconferencing have the potential to reduce costs and improve access to health care services. The University Hospital of North Norway now plans to replace some outpatient consultations with videoconferencing. As part of this initiative, a project assessing the use of models to analyse the economic impact of videoconferencing has been initiated. In this project, existing evidence found in the peer-reviewed literature and local cost data were used to build a model that illustrates the decision problem associated with investing in videoconferencing. This paper proposes a generic model that can be used as a template for more specific videoconferencing models. This work also presents a specific model illustrating the expected outcomes in the field of urology. Both of these models can be used to clarify the options under consideration, to assess potential costs and benefits, and to determine whether further analysis is needed to enable informed decision making in the field. This paper also presents a threshold analysis and shows values for when a conclusion changes in favour of one of the options.

Keywords – remote care; telemedicine; videoconferencing; randomised trial; literature review; economic modelling; cost-effectiveness analysis.

I. INTRODUCTION

The current paper provides an extended version of the work presented at The Sixth International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED) in 2014 [1].

Telemedicine has been around for almost two decades, but it is still viewed as outside of the mainstream of most health care services [2]. Implementing telemedicine technologies as part of routine health care delivery requires evidence of its technical feasibility, practicality in a clinical setting, and its being worthwhile (i.e., the additional costs are met with savings or improvements in health outcomes) [3, 4]. The main arguments for introducing telemedicine services have been to decrease costs, improve efficiency, and increase access to health care services. These cost savings and efficiency potentials make economic evaluation of central importance to telemedicine evaluations. To be able to make well-informed resource decisions, information on costs and consequences associated with these decisions must be available. Information on costs and consequences can be

collected in two ways: alongside trials and observational studies (primary data), and from the existing literature (secondary data) [5].

A. Economic data

New primary economic data can be collected alongside randomised controlled trials, non-randomised interventions, and observational studies (issues in economic evaluations are common to all of these) [5].

Randomised trials are designed to investigate the relative effectiveness of different medical interventions [6]. The most important advantage of randomisation is that it minimises allocation bias and balances other factors that might affect the result, both known and unknown. Strictly controlled trials are not very common in telemedicine research for practical reasons, nor are they well suited for economic evaluations. The more controlled a trial is, the less that can be concluded about how much the intervention costs and how well it works for normal caseloads in everyday practice. The trial context is often very different from real-world decisions, and conditions that will improve internal validity in randomised controlled trials will undermine the economic evaluation [7]. Clinical trials in the real-world setting are in many telemedicine situations time consuming, difficult to conduct (too few participants), and expensive to run. These obstacles leave decision makers without information about the clinical and economic consequences of different telemedicine interventions.

Another way to inform decision makers is to use the best available evidence from existing sources and decision models. Secondary data can come from clinical trials, observational studies, meta-analysis, and case reports found in the literature. Data can also be found in databases and administrative records. Decision models provide a means of collating this evidence in a systematic way.

B. When to model

A well-designed model is essentially a tool that can simulate or mimic a clinical trial [8]. Models can simulate different scenarios by making explicit assumptions about the incidence, prognosis, duration, benefits, quality of life and costs. A model allows one to investigate how cost and benefits might change if the values of key parameters in the model change. The purpose of modelling is not to

make unconditional claims about the consequences of an intervention, but rather to reveal the relationship between assumptions and outcomes [9].

The decision of whether to use new trial-based data or existing data and decision models in an economic evaluation of telemedicine should be considered in relation to the study's objective and role and the perspective of those who are expected to use the results [7]. A randomised trial focuses on particular measurements for specific patients in a given setting. These trials are essential as a first stage in developing telemedicine applications by establishing safety and clinical effectiveness. The evidence base for decision making should be based on the best available measurements of clinical and economic outcomes and these come from trials. Decision models are useful in situations where more evidence is required than can be obtained in a single trial. When a decision has to be made without evidence from trials, modelling can help structure the problem, assess potential pathways, and identify the level of uncertainty. Such models are valued for their simplicity and transparency and can be an excellent way to clarify the options of interest [10].

In this paper, a combination of existing evidence found in the peer-reviewed literature and local cost data are used to build a model for the provision of specialist consultations through videoconferencing. The main aim is to build a general model that structures the decision problem and forms the basis for assessing economic consequences in more specific models. This paper is structured as follows: Section II describes the background including an overview of the local context, the use of clinical videoconferencing, and the rationale and aim of this project. Section III outlines the materials and methods including an overview of the modelling study, the literature review, and the model parameters. Section IV reports the results and proposes two models. Section V discusses implications and limitations. Conclusions and future work are discussed in Section VI.

II. BACKGROUND

The University Hospital of North Norway (UNN) plans to replace some of its outpatient consultations with real-time telemedicine consultations. The UNN is the leading healthcare provider and health trust in the northernmost region in Norway. The UNN also serves as the local hospital for residents of Troms County and parts of Nordland, providing the full range of hospital functions (see Fig. 1). Troms County includes many isolated areas with long distances to the hospital. The county has a scattered population of 162,050 in an area of 26,000 square meters and consists of 24 municipalities.

In May 2011, the management at UNN decided to invest in videoconferencing equipment at scale to provide specialist services to patients at local health centres and general practice clinics in the region.



Figure 1. Troms County and the northern part of Nordland County (inserted).

A committee report from 2011 estimated that 7,000 patient consultations annually could be handled by video consultations, saving both hospital visits and travel costs (unpublished but available from the author on request). The implementation has been postponed, awaiting further investigation into conditions for and potential consequences of a large-scale videoconferencing network.

The reason for the videoconferencing initiative is twofold: First, it has been recognised that high-quality services for patients cannot be provided by one health care discipline alone or by a single sector [11]. Using videoconferencing can contribute to more personalised and integrated care pathways: it will give patients the opportunity to obtain treatment locally, they might avoid burdensome travel, and this could improve the quality of care through better coordinated and integrated health service delivery. Second, the management at UNN wants to lower costs by reducing hospitalisation and outpatient visits and to save on travel costs (the health authorities cover travel costs in Norway).

A. Clinical videoconferencing

The use of videoconferencing to examine and treat patients from a distance can be used in most medical specialties and settings [3, 12]. In a remote specialist consultation, the patient, usually accompanied by a health care worker, meets the specialist in real time via videoconferencing. This type of telemedicine consultation has been used in psychiatry [13-15], dermatology [16, 17], oncology [18], cardiology [19], in diabetes, asthma, epilepsy [20, 21], to support renal dialysis [22], and for group counselling [23]. There is now a range of evidence demonstrating that videoconferencing for a variety of conditions produces similar health outcomes to treatment delivered in person [12, 24, 25]. However, there is no robust evidence that remote video consultations are cost effective compared to conventional health care delivery. Wade (2010) reviewed the literature on real-time video communication and found it to be cost effective for home care and access to on-call hospital specialists; whereas, for rural service delivery, video communication showed mixed results, and it was not cost effective for local

delivery of services between hospitals and primary care [26]. It is not realistic to make one general recommendation for cost effectiveness across services and settings. The local context will determine important cost parameters, such as travel costs, the need for investment in infrastructure and technologies, and the opportunity costs of health professionals, all of which make it difficult to compare results across evaluations. Most reviewers, however, report that the evidence of cost effectiveness is scarce and more research on resource allocation and costs is still needed [27, 28].

B. Aim

In this project, a combination of existing evidence found in the peer-reviewed literature and local cost data are used to build a model of specialist consultation provided via videoconferencing. The model is used to structure and simulate patient pathways with and without videoconferencing, to identify the expected outcomes of different strategies, and to explore the costs and benefits of various scenarios under different assumptions. The main aim is to develop a general model that can be used as a template to assess the potential economic consequences of investing in videoconferencing in more specific models. This work consists of three related phases:

1. To develop the structure of the model and identify key parameters relevant to the decision problem;
2. To identify local setting parameters such as the medical field, investment and technical support costs, and personnel and travel costs;
3. To populate the model and analyse the economic impact of remote specialist consultations using videoconferencing in the hospital's catchment area.

This paper describes the economic modelling study, presents results, and discusses the rationale for using economic models to support health care managers in deciding whether to invest in videoconferencing or not.

III. METHODS

The following section provides a description of the materials and methods used in this project. This section outlines the model framework, the design of and processes used in the literature review, the model probabilities found, and the local cost parameters used in the models. For more details on the systematic review see [1].

A. Model overview

This paper constructs an economic model to analyse the economic consequences of providing specialist consultations through videoconferencing. In the model, remote specialist consultation refers to situations in which the patient, usually accompanied by a health care worker

at one location, consults with the specialist at the hospital using videoconferencing. Usual care refers to situations in which the patient sees the specialist in a face-to-face consultation at the hospital.

The primary outcomes in the economic model are costs and effectiveness measured as episodes of care or number of patients managed. The measure of quality-adjusted life-years (QALYs) was initially planned as an outcome measure, but no existing studies have collected QALYs in randomised trials of videoconferencing. Therefore, a net cost (or net benefit) per episode of care (patient consultation) was used as a pathway outcome. The model assesses short-term alternative branches or events defined as consultations. One-way sensitivity analyses were conducted to assess the robustness of the results. Parameters have been varied one at the time to assess the effect of the model and to determine threshold values.

The model was populated with parameters collected from the peer-reviewed literature in combination with local cost data. The evaluation takes a health provider perspective, that is, only costs within the health care budget have been included; travel costs are included since these are covered in the health care budget in Norway.

The data was collected in two steps. The first step was to conduct a systematic literature search to identify existing studies analysing the effectiveness and cost-effectiveness of videoconferencing alongside randomised trials. The literature provided information on structural assumptions, parameter inputs, and areas of uncertainty. The second step was to collect local cost parameters including equipment costs, technical support costs, personnel costs, travel costs, and other health care costs from the health clinics involved.

The models were built and analysed using the software program TreeAge Pro 2015.

B. Overview of the literature review

A systematic literature search was conducted to collect information on a) previous cost-effectiveness analyses and decision modelling studies in real-time telemedicine studies; and, b) to collect data on structural assumptions, probabilities, and clinical effectiveness from randomised controlled trials on the use of videoconferencing.

The following databases were searched: PubMed, PsycINFO and ISI Web of Knowledge, CINAHL, Cost-Effectiveness Analysis Registry, and the NHS Economic Evaluation Database (NHS-EED). Reference lists in the retrieved articles and existing reviews were also screened. The Cost-Effectiveness Analysis Registry and the NHS Economic Evaluation Database (NHS-EED) were searched using videoconferencing, video-consultation, or video-link as search words. Only articles published in peer-reviewed journals were included. The search was limited to English language texts and a publication date in the range of 1990 to 2013. A subsequent search was conducted to include papers from 2014. No additional studies were found.

The articles included in the review covered remote specialist consultations using real-time audio and visual telemedicine technologies (videoconferencing) and only included aspects in which the patients were directly involved and present at the general practice office, local health centre, or rural hospitals. Studies analysing video contact from home, store-and-forward transmissions of data, e-mail consultations, or structured telephone support were excluded. To ensure the quality of the data on clinical process or patient flow through the health system and the clinical effectiveness of videoconferencing, only randomised trials were included.

The search strategy included two main search terms:

1. Real-time telemedicine or videoconferencing or video-link or video-communication or videophones or video-consultation or hub and spoke or remote teleconsultation or real-time consultation and
2. a) Economic modelling or economic model or decision model or decision analytic model or decision modelling or cost-effectiveness or cost-utility or
b) Randomised or randomised

Selection of relevant publications was based on information found in the abstracts. Full-text articles were retrieved when the abstract indicated that the article would include a cost-effectiveness analysis and an assessment of effectiveness and patient flow through the health system. The full text was retrieved for closer inspection if the abstract did not provide clear indication of the content.

The literature search identified 1265 records. These were found by searching PubMed (n = 618), ISI Web of Knowledge (n = 532), CHINAL (n = 81) PsycINFO (n = 21) and NHS Economic Evaluation Database (NHS-EED) (n = 13). No articles were found by searching the Cost-Effectiveness Analysis Registry. From these records, 46 full-text articles were retrieved for further inspection. Two more articles were identified by screening reference lists. See Bergmo (2014) for details [1].

The literature search found ten articles that met the inclusion criteria. These were randomised trials and included information on the structural assumptions, probabilities, and clinical effectiveness of using videoconferencing [29-38]. Six non-randomised studies were included. These analysed clinical effectiveness or cost-effectiveness and included information on the clinical process. These studies used case-crossover design [39-41] and retrospective pre-post design [42], and two of the studies presented models based on data from the literature [43, 44]. Reliable parameter data from these studies have also been used to support parameter values from the randomised trials. The studies included data on the following parameters:

- The proportion of patients for which videoconferencing is a suitable and reliable option compared to face-to-face consultations.

- The proportion of patients in need of a second consultation (follow-up).
- Time use for the different alternatives.

C. Model assumptions and probabilities

Data on patient management and patient flow found in the literature suggest that videoconferencing is acceptable for approximately 70% of patients [38, 40, 41]. This indicates that not all patients can be seen via video, suggesting that patients have been pre-selected or self-selected. Videoconferencing can be less suitable for patients with a hearing problem and patients with dementia or other communication barriers, for example. Some patients may need a physical examination, while others prefer to meet the specialist in person, which varies between medical specialities. Videoconferencing is more suitable in psychiatry than orthopaedics, for example [37, 40].

The studies reported a higher follow-up rate for patients utilizing telemedicine [29, 31, 32]. For example, one large telemedicine trial found that the follow-up visits for video consultations compared to usual care in general practice had an odds ratio of 1.52, 95% CI 1.27 to 1.82. [29]. The difference in the follow-up rate also differs between specialties [29, 31, 32, 39], with less difference in dermatology [36].

None of the studies used QALYs to measure the clinical effectiveness of videoconferencing. Most studies took a cost per patient approach. Therefore, a net cost (or net benefit) per episode of care (patient consultation) was used as a pathway outcome in the present study.

The time health professionals spend to complete a video consultation and an outpatient consultation was assessed in Jacklin et al. (2003) [30]. These time measurements included the total time spent by the specialist and the general practitioner, who were both present during one video session. These time estimates were based on observations of a small sample of consultations [30]. Details on the model inputs are shown in Table I.

D. The local cost parameters

Only provider costs have been included in this modelling study. These include health care costs and travel costs. Regional health authorities cover all travel costs except for a small user fee.

The cost of a video consultation includes investment costs, technical support, the costs of using the network (line rental), and the time costs for the health providers. Investment costs have been collected from suppliers and from the IT and accounting departments at the hospital and local health clinics

In the current project, a health professional accompanies the patient during the videoconferencing session, which assumes that the clinics have invested in a standard standalone videoconferencing unit placed in a dedicated office or studio.

TABLE I. MODEL INPUTS

Definition	Value	Source
Proportion of patients seen		[38, 40, 45]
Videoconferencing Outpatient	0.71 (0.64-0.75) 1*	
Proportion of follow-up		[29, 31, 32, 36]
Videoconferencing Outpatient	0.36 (0.26-0.52) 0.29 (0.22-0.41)	
Professional time per consultation		[30]
Videoconferencing Local Physician Specialist	26 min (158 NOK [§] , €18.9) 20 min (140 NOK [§] , €16.7)	SSB
Outpatient Specialist	11.8 min (83 NOK [§] , €9.9)	
Costs per episode of care		Local costs
Videoconferencing VC units#	311 NOK (€37.2)	
Network rental	43 NOK (€5.2)	
Time costs	298 NOK (€35.7)	
Outpatient Specialist costs	83 NOK (€9.9)	
Travel cost	823 NOK (€98.5)	[46]

€1 = 8.41 Norwegian Kroner (NOK) 15 May 2015

* Assuming that all patients receive treatment if referred by GP

§ SSB Statistics Norway 2014 <https://www.ssb.no>

Includes equipment, installation, and annual support costs.

Total annual cost 85 850 NOK (assuming 3% discount rate and 5-year equipment lifetime).

This is the most commonly used equipment for video consultations and meetings in the region. The cost calculation is based on investing in videoconferencing equipment from Cisco TelePresence MX300 G2.

The total investment costs including equipment and installation costs were annuitized into an equivalent annual cost assuming a 3% discount rate and a 5-year lifespan for the equipment. The unit costs (i.e., cost per patient consultation) were calculated assuming six consultations a week for 46 weeks (276 patient consultations annually). This annual workload was estimated by a medical expert and is based on a videoconferencing service in the orthopaedic unit at the hospital.

The cost of an outpatient consultation at the hospital includes time costs for the specialist and travel costs for the patients. The average travel cost estimate for the region was found in Augestad et al. 2013 [46]. This estimate was calculated by dividing the total travel costs for the region by the total number of trips. Time costs for the medical professionals were estimated based on the national average for the monthly wage of specialists working at the hospitals and for locally employed physicians at health centres (see Table I for cost details). Overhead costs are not included because these are assumed to be small and to not affect the results. All costs are in Norwegian Kroner (NOK).

E. Other assumptions

The model includes a second consultation after the initial video consultation to account for the higher follow-

up rate of videoconferencing. It has also been assumed that a small proportion of the second consultations in the videoconferencing option are outpatient consultations at the hospital.

IV. RESULTS

The data found in the literature suggest a model with two main options, one with videoconferencing and one without. This model assumes a screening process to select the patients suited for remote consultations beforehand. The studies also suggest that more patients will be scheduled for a follow-up consultation in the videoconferencing option compared to the outpatient option.

The model is shown in Fig. 2 and illustrates the different options that are present in the decision problem. The model calculations are based on the model specification, technical equipment, and local cost estimates described above (Section III, C and D). Whether or not to invest in videoconferencing based solely on cost effectiveness can be viewed as a decision problem with two options. The costs of the videoconferencing option will also include the costs of treating the patients when videoconferencing is not suitable (the branch labelled outpatient consultation in Fig. 2). The net costs will also depend on the different follow-up rates included in the model. This model shows that the 'invest in videoconferencing' option has the lowest net costs (see Fig. 2 for details).

This model includes average values, making it less useful for decision making in specific areas. However, a generic model can be used as a template for more specific models adapted to one defined clinical field in a particular local practice or health clinic. The model input can easily be altered to fit any setting in which the decision problem is whether to invest in videoconferencing or not.

Fig. 3 illustrates the use of the generic model adapted to the same decision problem in the clinical field of urology. In this model, the decision problem is whether to set up videoconferencing in the field of urology at a local health centre 67 km from the specialist hospital. In the literature, 46% of the urology patients in the telemedicine option were offered a follow-up consultation compared to 35% in the outpatient option [29]. In this context, the travel cost to the hospital was NOK 300, assuming that all patients travelled by bus.

Assuming similar patient workloads and costs as in the generic model, the least costly alternative in the field of urology is outpatient consultation at the hospital (see Fig. 3 for details).

The parameters most sensitive to the model results are the unit costs of the videoconferencing option, as either equipment prices or as the number of patient consultations (annual workload), and the distance from the local health centre to the specialist hospital.

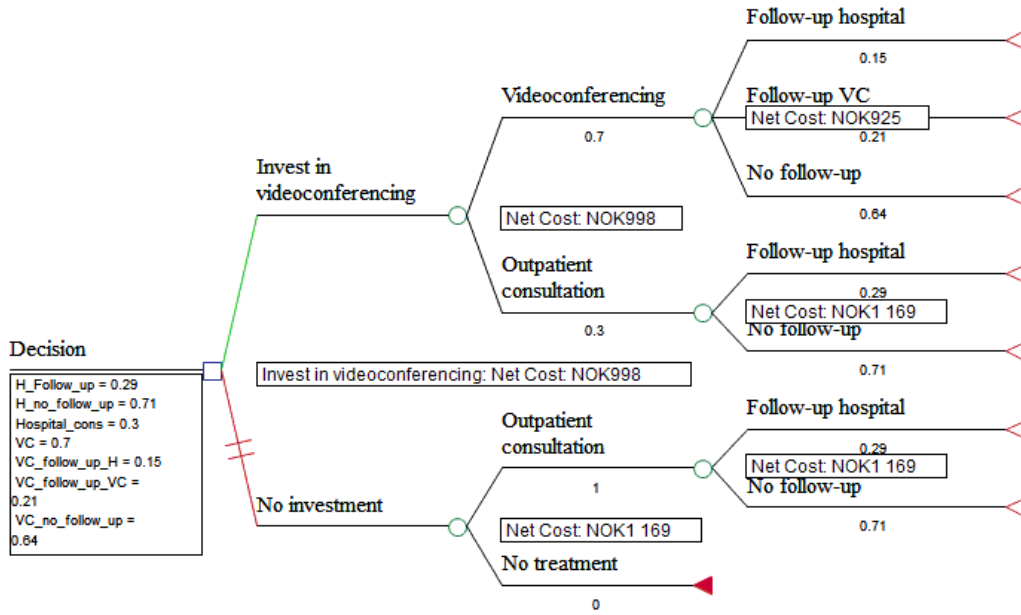


Figure 2. The videoconferencing model.

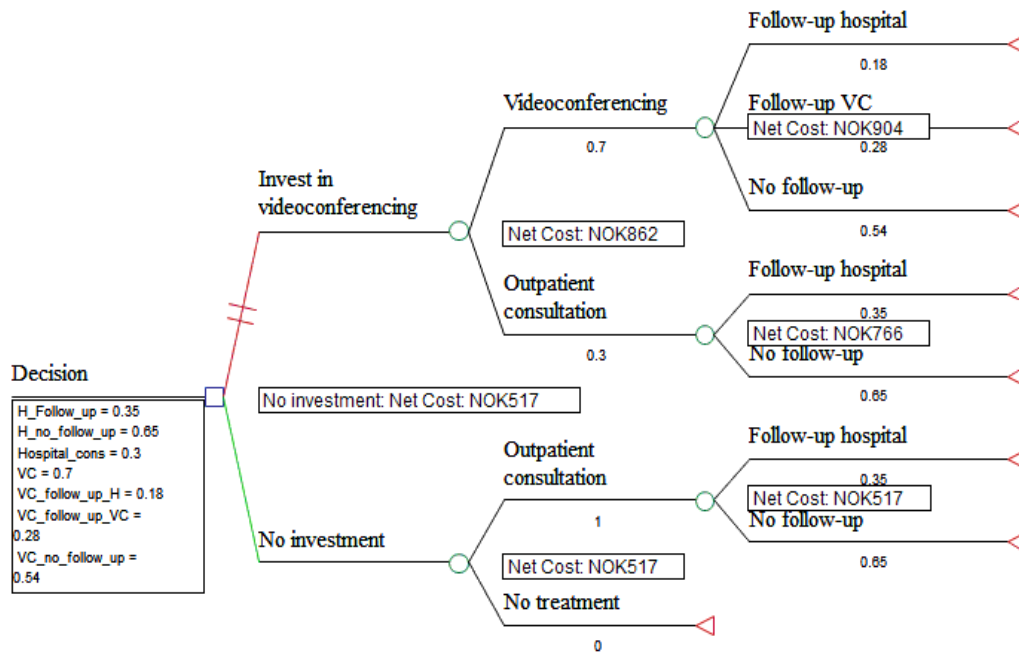


Figure 3. The model adapted to urology.

Halving the number of patient consultations in the videoconferencing option in the generic model (from six consultations each week to six consultations every two weeks), alters the results in favour of the ‘no investment’ option (model not shown). Another example is to analyse the use of video consultation in urology at a different location where the travel cost is twice the amount used in the urology model shown in Fig. 3. This changes the results and makes the ‘invest in videoconferencing’ the least costly option (model not shown).

One-way sensitivity analyses were conducted on the data in the generic model. The analyses show that for videoconferencing cost estimates above NOK 853 (e.g., a service with less than 167 video consultations per year or less than 4 per week), or for travel costs that equal less than 610 NOK per patient, the results change in favour of the ‘no investment’ alternative (see Figs. 4 and 5). The results are not sensitive to changes in the other model parameters.

V. DISCUSSION

This paper developed an economic model describing the decision problem associated with investing in videoconferencing to provide remote specialist consultations. The results show that the decision to invest in videoconferencing depends on more than the cost difference between the two modes of consultations. The total cost of investing in videoconferencing must also consider the costs of those patients who are not suited for videoconferencing and a higher follow-up rate for the patients who participated in videoconferencing.

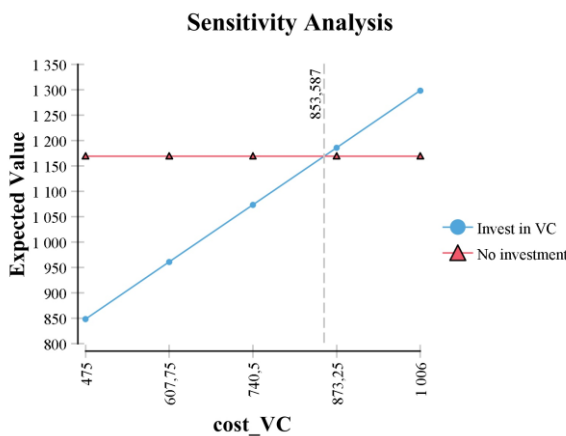


Figure 4. Sensitivity analysis showing the net costs (expected values) with different VC-cost estimates ranging from 475 NOK (3 patient consultations per week) to 1006 NOK (9 patient consultations per week) in total (from €56.9 to €120.4).

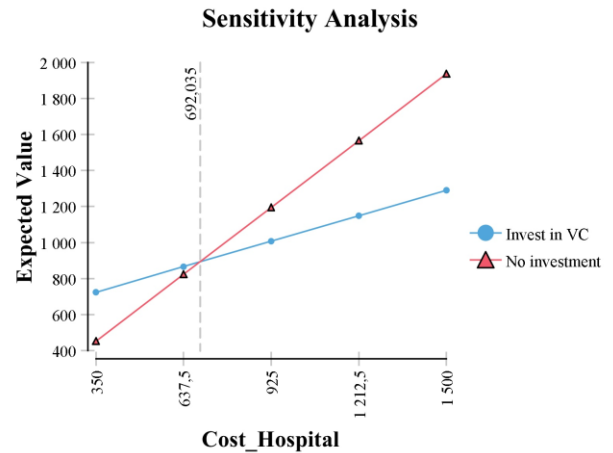


Figure 5. Sensitivity analysis showing the net unit costs (expected values) with different outpatient cost estimates ranging from 350 to 1500 NOK (€41.9 to €179.6).

This generic model is intended to be used as a template for more specific models that analyse the economic impact of providing specialist care to patients living in remote areas. The model can also be used as a framework for indicating whether a more detailed analysis is needed. Decision modelling is increasingly being used to assess the need for and value of additional research [10]. The generic model can also be further developed to include other technologies in a home-based setting, for example.

There are valid concerns about using models to assess the economic consequences of new interventions [47]. The most important concern is the quality of the data used. The quality and validity of the results from modelling studies are not any better than the data used in the models. Telemedicine research has in general been criticised for being full of demonstration projects, anecdotal evidence, and poor study design [48]. One way to ensure quality data in this study has been to limit the data sources to include only randomised trials.

The literature on telemedicine is extensive. A search in PubMed in March 2015 found over 18,000 papers on the topic. There are, however, a relatively small number of randomised trials in telemedicine research and even fewer analysing the effect of using videoconferencing. A review from 2012 identified 141 randomised controlled trials in telemedicine [49]. These studies analysed interventions in chronic disease management and the majority analysed home monitoring and telephone support. Few studies examined the use of videoconferencing. Recent telemedicine research seems to focus more on home-based services using monitoring and telephone contact with less focus on remote specialist consultations using videoconferencing.

None of the studies found in the literature used QALYs to measure clinical effectiveness. One reason for this may be that videoconferencing is used as a substitute for a face-to-face consultation, and therefore has little or no effect on

a patient's health. The benefit for the patients is most likely the avoidance of burdensome travel. However, QALYs have been used as outcome measures in monitoring and other home-based telehealth studies [50]. Because no QALYs were found, a net cost per episode of care was used as a pathway outcome (assuming similar health outcomes).

The main purpose of the literature search was to identify randomised trials that analysed the effect of remote specialist consultations. Consequently, the scope of the review study is narrow. Another limitation is that only articles written in English and published in peer-reviewed journals were included to provide some basic quality control. The search strategy used might have missed some evaluations, partly because the term remote specialist consultation is not easily defined. Some analysts might have used terms to describe the provision of specialist treatment from a distance that differed from the search terms used in this review.

The proposed model structure can be seen as a hypothetical trial with two arms. In some contexts, the model might include a third option in which the specialist travels to the remote health centres or clinics. None of the reviewed studies included this option, but the generic model can easily be adapted to include a third option.

Some of the model inputs were not available in the literature and have been estimated. A medical expert working with remote consultations in orthopaedics estimated the annual workload used to calculate the unit cost of videoconferencing. An expert also estimated the probability of additional follow-up after a video consultation as an outpatient referral. Using expert opinions to estimate model input is acknowledged as a limitation.

The costs included in the real-time telemedicine option were based on the purchase of standard standalone videoconferencing equipment. Leasing can be more suitable in some settings. Any change in equipment types and prices will influence the investment cost. For example, a desktop computer could be sufficient in some settings where only two persons (specialist and patient) are present in the consultation. The type of equipment that the clinics choose to purchase is one of the main cost drivers in the model. The choice of equipment will depend on what the specialist deems appropriate for the patients involved in the video sessions.

The assumed number of patient consultations per year used to calculate the annual costs is another uncertain parameter. A change in annual workload will alter the result, and if the equipment is used for multiple purposes, then the cost must be shared between all users. Sensitivity analysis can be used to illustrate different threshold values when a conclusion changes in favour of one of the options. This allows decision makers to determine whether videoconferencing is a potential cost effective solution in their designated area or whether a more detailed analysis of cost and benefits is needed.

The cost of outpatient consultations has been simplified to include only the costs of the health

professionals involved and travel costs for the patients. Only costs assumed to differ between the alternatives and costs that have the potential to affect the outcomes have been included. More detailed cost estimates will increase the precision of the model and allow the calculation of more accurate potential cost savings.

Another limitation is the perspective chosen for this study. A health provider perspective only includes costs borne by the health provider and excludes private costs and costs to employers in the form of production losses. A societal perspective that considers all costs regardless of who incurs them is recommended in the literature [5]. However, there is no consensus on whether productivity costs should be included in cost-effectiveness analyses. Nor is there any consensus on how such costs should be valued if they are included [51, 52]. The reason for choosing a provider perspective in this study was that the provider covers most of the costs including travel costs. Another argument is that shorter health visits might not represent production losses at all. Some types of work can be postponed until the patient returns or the work can be handled by a colleague, for example [5].

To use episode of care as an effectiveness measure assumes that there is no difference in health outcomes for the patients, which seems to be a reasonable assumption. A range of evidence has demonstrated that videoconferencing for a variety of conditions produces similar health outcomes to treatment delivered in person [12, 24, 25]. However, using episode of care as an effectiveness measure when analysing the cost effectiveness of an intervention can miss important benefits such as easier access to medical care, avoidance of burdensome travel, and a feeling of improved continuity of care.

Another challenge of economic analyses in the telemedicine field is generalisability. High diversity in terms of specialty, technology, applications, objectives, context, and stakeholders can be a major challenge for economic evaluations [12, 53]. The local setting will decide the most important cost parameters in an evaluation such as travel costs, the need for investment in infrastructure and technologies, prices, and the opportunity costs of health professionals. The evaluation result of a particular telemedicine and e-health service is of most value in the setting where the evaluation was conducted. In this modelling study, data from the literature were used to establish the structure of the decision problem, making the result more transferable to similar clinical settings. The model is designed to be transparent and includes relatively few assumptions that can be easily tested. This modelling study is also transparent in terms of the model inputs, making it easy to change the medical specialty and the local cost parameters.

This modelling study lacks a probabilistic sensitivity analysis because the data inputs were only available as point estimates. Future models of other telemedicine applications might benefit from a formal test of the uncertainties in a full probabilistic sensitivity analysis.

VI. CONCLUSION AND FUTURE WORK

This paper proposes a generic economic model describing the decision problem associated with investing in videoconferencing as part of providing specialist consultations. The generic model can be useful as a template for more specific models assessing real-time telemedicine in designated areas in the Helse Nord region. This work presents one such specific model illustrating the expected outcomes in the field of urology. The models presented can be used to clarify the options of interest, to assess potential costs and benefits, and to determine whether further analysis is needed to enable informed decision making in the field. Future work should develop a broader model that includes the use of telehealth and e-health services in a home care setting.

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COMPETING INTEREST

The author declares no competing interest.

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A Cloud Based Patient-Centered eHealth Record

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Abstract - This research focuses on the Patient-Centered e-Health (PCEH) concept by introducing its importance and demonstrating a multidisciplinary project that combines advanced technologies. The project links several aspects of PCEH functionality, such as: (a) homecare telemedicine technologies, (b) e-prescribing, e-referral, e-learning and (c) state-of-the-art technologies like cloud computing and Service Oriented Architecture (SOA), will lead to an innovative integrated e-health platform that delivers many benefits to the society, the economy, the industry and the research community. This paper provides insights of the PCEH concept and the current stages of the project. In doing so, we aim to increase the awareness of this significant work and disseminate the knowledge gained so far through our work.

Keywords-Personal Healthcare Record; Cloud Computing; Healthcare Information Systems Integration.

I. INTRODUCTION

Healthcare Information Systems (HIS) integration has been associated with various aspects, amongst others: strategic, social, and/or organisational [1, 2]. In this respect, there is a common trend to address HIS integration by an overall approach, seen as integrated patient centered care [3]. Integrated patient centered care reflects on integrated HIS (with elements as e-health services) requiring coordination across professionals, facilities, support systems that is continuous over time and between patient visits [4]. This approach is observed on national healthcare strategies that encourage patient involvement in their healthcare treatment. Moreover, in the USA and Europe, online personal health records that allow patients to manage their health data have emerged [5]. For example, in Finland, this integration trend can be observed in a legislation that allows citizens to access and interact with their own Electronic Healthcare Records (EHRs), ePrescriptions and audit-logs via the Internet [6].

Following similar legislative opportunities worldwide, patients increase their involvement with HIS. This is a growing involvement, seen in parallel with mechanisms for the collection of information (obtained by mobile and other sources) in order to develop an enhanced, complete and

integrated view of citizens health status. The latter is reflected in EHRs and Personal Health Records (PHRs), which are being enriched and exploited by different actors and stakeholders (i.e., health and care professionals, citizens, nutrition experts, hospitals, etc.) in the health ecosystem. Three general PHR models have been proposed [7]: a) the stand-alone model, b) Electronic Health Record (EHR) system, and c) the integrated one, which is an interoperable system providing linkage with a variety of patient information sources, such as EHRs, home diagnostics, insurance claims etc. The main types of health information supported by PHRs are problem lists, procedures, major illnesses, provider lists, allergy data, home-monitored data, family history, social history and lifestyle, immunizations, medications and laboratory tests [8, 9]. Widely known PHR platforms in terms of centralized web-based portals include Dossia [10] and Microsoft Health Vault [11] platforms. Many systems presented in literature offer integration with already established PHRs platforms [12, 13]. Early experiences from the adoption of PHR-based systems have been found to be positive, showing that such systems can be feasible, secure, and well accepted by patients [14]. Nonetheless, today's EHRs and PHRs are far from being what the citizens consider as of value to their health, since for the public view, health means more than being disease-free.

Following this trend for patients' empowerment, academics, practitioners and patients advocate in favor of the patient centered healthcare systems. Still the aforementioned advocates have not yet reached a concise definition of Patient-Centered e-Health (PCEH) that is shared across the research disciplines that focus on health and Information Technology (IT) [15]. The lack of consensus can be attributed, amongst other, (a) on the number of challenges that are involved in transitioning healthcare delivery to a more patient-centered system and (b) the lack of proof-of-concept through well-documented and effective PCEH projects.

Healthcare is unique and complex ecosystem that poses several challenges on developing PCEH [16]. The healthcare ecosystem consists of several networking organisations that constantly interact with each other, but also differentiate amongst them. The differentiation can be noted in issues, such as: (a) medical specialisations, (b) socio-technical and IT capacities, (c) organisational cultures, (d) structures, (e) actors

and (f) business process [2]. More precisely, healthcare tasks are distributed between several actors (physicians, nurses, residents, and other clinical support staff) and artefacts (information technology, healthcare specific machines, paper notes) [17].

Thus, the challenge to integrate and redesign existing healthcare systems towards a more patient-centered exists [3]. This challenge is emphasized when integration efforts as the PCEH projects try to leverage the different actors and their sub-sequential attributes. Apparently, the professional healthcare actors with their many years of training, qualifications and expertise have much more medical knowledge than their patients. As a result, a paternalistic system has evolved where physicians expect, and patients expect them, to make the decisions about, or at least recommend, an appropriate course of treatment [18]. Therefore, an integrated system of personal healthcare information that is governed by the patient him/herself contradicts the established norms and highlights new challenges (e.g., validity and royalty of medical data, decision making culture etc.). For example, following a more shared decision making or interpretation of the enclosed data, as the PCEH entails, requires (a) a plethora of the necessary medical data integrated in an easily accessible and comprehensible platform adequate for decision-making and (b) the physicians' arbitration to support or contradict those decisions. This requires well-developed sophisticated systems with clear boundaries on decision-making, responsibilities and availability of data.

Regardless the challenges, moving toward patient-centeredness is important [15]. To this end, this paper aims to introduce: (a) the main concepts surrounding the PCEH and (b) a PCEH project utilizing cloud computing.

With this section introducing the reader to the research the rest of the paper is structured as follows; Section II presents the Patient Centered E-health (PCEH) theory, Section III lists relevant PHR and cloud computing projects, Section IV depicts the PINCLOUD project, Section V addresses the main ideas behind the PINCLOUD project, Section VI analyses the E-referral business process, Section VII highlights the expected benefits and Section VIII presents the conclusions and future research agenda.

II. PATIENT-CENTERED E-HEALTH (PCEH)

Most developed countries are facing important overall problems regarding health care services, such as: (a) aging population with increased demand on specialized health care services (e.g., Chronic diseases), (b) need for increased efficiency with limited financial resources (e.g., Staff /bed reduction), (c) requirements for increased accessibility of care outside hospitals (e.g., home care) to name a few. To these problems, advances in information and communication

technologies have provided considerable assistance in the form of EHRs [6]. Yet, it seems that traditional EHRs, which are based on the 'fetch and show' model, provide limited functionality that does not cover the spectrum of the patients' needs. Therefore, new solutions as the PHRs appeared to narrow this gap. In more detail, PHRs' data can come from various sources like EHRs, health providers (e.g., e-Prescribing, e-Referral), and/or directly from the patient him/herself – including non-clinical information (e.g., exercise habits, food and dieting statistics, etc.) [19].

The PCEH concept is a new multidiscipline area of research, with crucial aspects as it deals with the wellbeing of patients.

However, due to the length limitations of this paper we briefly present up-to-date research on the field, with the intention to fully present and analyse our rigorous research in a future publication. In this paper, we focus mainly on [15, 20] views. In more detail, [15] depicts that the PCEH should integrate three themes:

- **Patient-focus** - In many cases, e-health developers have created systems designed for patients' use that is not patient-focused but rather focused on healthcare organizations' objectives. Patient-focus requires PCEH strategies to be centered first and foremost on the requirements and perspectives of patients. To this extent if the patient require e-health services tailored to their needs, developers need to accommodate these needs. For example, young web-savvy patients expect their e-health applications to be responsive to their medium of choice (mobile, tablet, etc.), while more unexperienced elderly patients require a more user friendly environment.
- **Patient-activity** - Patient-activity requires comprehensive, interactive input by patients in providing data about themselves and representing their own perspectives as well as consuming information of interest to them. Yet, achieving high patient-activity in other e-health services may require reconceptualization of healthcare processes and information flows in order to provide opportunity to patients to add information they perceive to be relevant. The PHR is an example of such an e-health application.
- **Patient-empowerment** - in a technological perspective the empowerment happens through information-sharing, offering the patients a visual overview of their course of treatment, letting the patients take their own measurements, and letting them provide verbal and written inputs. From the PCEH perspective, however, patient-empowerment centers on providing similar levels of control via e-health that exist for patients in other modes of interaction with their healthcare providers.

The value of the three introduced characteristics is to ascertain the generalizability and abstraction properties of

patient-focus, patient-activity, and patient-empowerment to the theoretical domain and to explore relationships among the PCEH characteristics [20]. Although at an early stage [20] arguments provide helpful guidance in the emerging issue of patient-centered e-health and can be of value in the development, design and evaluation of PHRs. These issues are included in our research agenda as well.

III. PHR/EHR CLOUD-COMPUTING PROJECTS

Literature includes various examples of PHR and EHR approaches with different themes, addressing various aspects and produced in diverse settings (e.g., industry, academia etc.). This composes a mosaic of different examples that individual researchers of the field and/or developers need to consider before embarking in the Cloud-Computing e-health journey. Studying past endeavors one may learn from the successes and diverge from the mistakes of others. Therefore, our intentions for presenting such examples extent from providing a helpful list of recent PHR/EHR projects to illustrate unique techniques to implement Cloud services, describe ways to resolve the integration challenges faced, provide recent advances from academia and industry and highlight lessons learned and recommendations. The authors acknowledge that this is not an exhaustive list of examples but a suitable one for the theme and audience of this Journal.

To provide a better illustration and help the reader understand this important integration issue, the authors researched the literature and depict herein a twofold categorization of the findings, such as: (a) PHR/EHR solutions and/or (b) PHR/EHR components. This provides a useful categorization in the current ongoing PHR issues discussion. Starting with the PHR/EHR below the identified projects are presented in an alphabetical list.

CareCloud offers several approaches ranging from SaaS, to data analytics and IaaS. It offers healthcare practices a way to manage their practice with a plethora of tools. CentralCloud allows the management of patient records, appointments, billing and reporting. Charts solution provides an easy to use EHR system. CareCloud also has solutions for doctor – patient virtual interaction [21].

ClearHealth Office is a solution for small practice (fewer than ten physicians or 20,000 encounters per year) that can be distributed in two forms. The one is on premise and the second is cloud based. The first one (on premise), requires hardware and detailed setup processes. The second one is a cloud solution that removes the need for hardware and the problems with detailed setup. It is called HealthCloud and promises to deliver ready-to-go installations of ClearHealth Office on fully managed and secured datacenters owned by Amazon. This service is suitable for US practitioners, interested in self-serving their installations [22].

EMC Electronic Health Record Infrastructure Solutions consist of integrated, validated solutions with industry-leading healthcare (Independent Software Vendor) ISV

partners [23], clinical applications, and best-in-class hardware, software, and services to help caregivers to move forward with their EHR deployment. EMC provides the supporting IT infrastructure aligned with clinical services needs for the highest levels of performance, availability, security, virtualization, and integration [24].

Healthcare Trustworthy Platform is a multilevel Personal Health Record (PHR) platform based on the Trustworthy Cloud Technology that allows people to share health data while guaranteeing security and privacy. It aims at the integration of third party applications and give them access to user's health data (e.g., view, add and update). It also provides a high security model, which allows the patients to decide how and with whom to share data [25].

The most popular solution in our list is the well-known HealthVault. It is being distributed through Windows Azure cloud server, which is already widely implemented in business environments and in some public administrations. Microsoft HealthVault provides one place to store and access of health information online. It supports interoperability with other healthcare providers. There is a growing list of devices such as pedometers, blood pressure monitors, blood glucose monitors, and even weight scales, which work with HealthVault. In that way, the users do not have to enter anything by hand, just upload their data directly to HealthVault from compatible devices [26].

Medscribler is a SaaS solution for recording patient data. It uses mobile technologies such as tablets and smartphones and handwriting recognition software to allow ease submission of patient data. It is an EMR solution that provides a quick and intuitive way to update medical records of patients. These records can be stored in a cloud. This solution provides an innovative approach to the problems of mobile practicing of medicine. The doctor is able to update patient records via a network connection and thus has no need for bulkier equipment than a tablet computer [27].

OpenEMR is a free and open source Electronic Health Records (EMR) and medical practice management application that can run on multiple platforms. OpenEMR is supported by a community of volunteers and professionals. This software can be implemented into a cloud as SaaS. It supports cloud structures, encryption, remote access and web browser access [28].

SOFTCARE is a multi-cloud-enabled platform, which has developed a prototype of a monitoring system for seniors that allow caregivers (formal and informal) and senior users to get real-time alarms in dangerous or potentially dangerous situations and warnings on long-term trends that could indicate a future problem. It is based on Artificial Intelligence techniques that allow the recognition of daily activities based on the data obtained from an accelerometer (bracelet device) and location information [29].

Another integration platform is X1.V1. It offers effective tools to generate reports about (a) the general healthcare status of the population, (b) the quality of healthcare performance and (c) the financial costs. In that way, it

facilitates the cooperation among the different caregivers in the provision of diagnosis and treatment. Another intuitive feature is that enhances epidemic diseases and cancer detection rate [30].

Zappa is an open source, extensible, scalable and customizable cloud platform for the development of e-Health/m-Health systems. It aims at delivering resources as services over Internet (Cloud-Computing). Moreover, the platform is intended to provide uninterrupted monitoring with the goal of obtaining some information that can be subsequently analyzed by physicians for diagnosing. Two e-Health applications have also been developed based on that platform: (a) Zappa App, (b) Cloud Rehab.

Having described the PHR/EHR solutions, the second part of list, the PHR/EHR components are depicted.

Cloud Rehab is a full m-Health system that is used to monitor the daily activities of patients with severe brain damage. It is a component to the Zappa cloud platform mentioned above. Cloud Rehab consists of two applications (a) web application and (b) Android application. Web application is being used by the medical staff to manage patients' medical information. Whereas, Android application is being used by the patient. The mobile application monitors heart rate and sends the data to the cloud [23].

DAPHNE is a Data as a Service (DaaS) platform for collecting, managing and analyzing wellness data in order to provide healthy lifestyle and preventive medicine [31]. DAPHNE platform is open to hardware and software developers, providing data for different personalized health services, both for the citizen and the service provider.

EMC Collaborative Healthcare Solutions provides a patient-centric infrastructure to "content-enable" Picture Archiving and Communication System, Hospital Information System, and Electronic Medical Record applications for accessing all relevant clinical, financial, and operational data. Based on open standards, the solution is in accordance with the Integrating the Healthcare Enterprise initiative that promotes the coordinated use of established standards. Their solution enhances operational agility through the abstraction of applications and infrastructure, improves financial performance by managing physical and virtual assets with highly automated tools, and secures access to and prevents loss of protected health information [21].

VIGOR++ is an international research project that aims to create a personalized gastrointestinal tract model, which facilitates accurate detection and grading of Crohn's disease.

VIGOR++ processes multi-scale information from patients, including laboratory, MRI, colonoscopy and microscopy (histopathology) data.

Its techniques are integrated in the 3DNetMedical.com medical imaging cloud service, to make them immediately available in a clinically usable environment [32].

Zappa App is an m-Health system used to monitor the heart rate, temperature and blood pressure of the patient. It is a component to the Zappa cloud platform, which is mentioned above. In addition, Zappa App is able to save the vital sign values, detect health problems and share information with a doctor or medical staff that are in the same place that the patient (Bluetooth) [23]. The aforementioned categorized list is presented in Table I. The first column is an arithmetic count of the projects, the second the name, the third the type based on our categorization, the fourth the description and the last column the reference for each.

The aforementioned PHR/EHR solutions utilize the Cloud-Computing advances to achieve common goals, therefore they hold similarities such as: (a) integration, (b) interoperability and (c) lower business expenses. All of the aforementioned approaches try to integrate different systems to manage medical information based on a centralized system hosted on cloud. Furthermore, they try to provide users with the ability to access the systems through different type of operating systems (e.g., Windows, Linux, and MAC OS) and devices (e.g., desktop, laptop, tablet, smartphones, and medical sensors). The solutions presented in Table I leverage Cloud-Computing benefits to lower expenses both on Operating Expenditure (OPEX) and Capital Expenditure (CAPEX) at the health section. For example, solution number 7 can run in different systems, while 1, 4, 9 support integration of different type of systems resulting to lower business expenses.

Apart from the similarities, the above mentioned solutions also have differences between them, such as: (a) different type of users, (b) different target territories and (c) different type of devices. For example, solution number 8 is designed for senior people, 2 for small practices and 11 for patient with severe brain damage, 2 targets USA practitioners and 11, 15 address mobile devices implementations.

The aforementioned Cloud-Computing solutions hold several merits and aim at the same goal, provide better e-health services. Yet, due to the critical nature of healthcare and the importance of successful implementation of such endeavors, there is still need for rigorous research that can carefully examine the development steps and provide "best-fit" technologies. To accommodate this need the authors' involvement in a multidiscipline e-health integration project that utilizes Cloud-Computing. This endeavor is analyzed in the following section.

Table I. PHR Projects

Name	Type	Description	Reference
1. CareCloud	EHR	An easy to use EHR system which provides solutions for doctor – patient virtual interaction.	(SUCRE, 2014)
2. ClearHealth Office	EHR	Provides an open source solution for running a small practice.	(ClearHealth, 2013)
3. EMC Electronic Health Record Infrastructure Solutions	PHR/ EHR	Provides clinical applications, hardware, software, and services.	(EMC, 2014)
4. Healthcare Trustworthy Platform	PHR	PHR platform for sharing securely health data and providing integration with 3rd party applications.	(Telcouds, 2014)
5. HealthVault	PHR	Provides one place to store and access all health information online.	(Microsoft, 2014)
6. Medscribler	EHR	SaaS solution providing intuitive way to solve the mobile's practicing issues of medicine.	(Medscribler, 2014)
7. OpenEMR	EHR	Free and open source Electronic Health Records (EHR) and medical practice management application that can on multiple platforms.	(OpenEMR, 2014)
8. SOFTCARE	PHR	Multi-cloud-enabled platform monitoring senior people.	(AAL, 2013)
9. X1.V1	PHR/ EHR	Integrated platform with intuitive features statistical reports about patients, caregivers and financial costs)	(Deadalus, 2014)
10. Zappa	PHR/ EHR	Extensible, scalable and customizable cloud platform for the development of e-Health/m-Health systems.	(Ruiz-Zafra et al., 2013)
11. Cloud Rehab	COM /NT	M-health system monitor daily activities of patients with severe brain damage	(Ruiz-Zafra et al., 2013)
12. DAPHNE	COM /NT	Data as a Service (DaaS) platform for collecting, managing and analyzing wellness data in order to provide healthy lifestyle and preventive medicine	(Daphne, 2013)
13. EMC Collaborative Healthcare Solutions	PHR/ EHR	Provides a patient-centric infrastructure to "content-enable" Picture Archiving and Communication System, Hospital Information System, and Electronic Medical Record applications.	(SUCRE, 2014)
14. VIGOR++	COM /NT	Personalised gastrointestinal tract model, which facilitates accurate detection and grading of Crohn's disease.	(Vodera, 2014)
15. Zappa App	COM /NT	M-health system for monitoring the heart rate, temperature, blood pressure of patient	(Ruiz-Zafra et al., 2013)

To this end, we introduce in this paper our own practical involvement with a PHR project and provide a brief introduction in the following section.

IV. PROVIDING INTEGRATED E-HEALTH SERVICES FOR PERSONALIZED MEDICINE UTILIZING CLOUD INFRASTRUCTURE (PINCLOUD)

PINCLOUD is a multidiscipline research project involving partners both from academia and industry that seeks to integrate different application components, leading to the provision of an end-to-end personalized disease

monitoring and medical data service “anytime, anywhere”, which ensures an independent living regardless of age [33].

The scenario, upon which PINCLOUD is based, is depicted in Figure 1 and involves a patient that governs his\her PHR, which is also remotely monitored by a physician located either at a hospital or medical office. Complementary to the PHR’s stored information the doctor monitors the patient using a home care platform that receives and analyses patient’s medical data. The proposed home care platform will include among others the following services: (a) Asthma or Chronic Obstructive Pulmonary Disease (COPD) disease management; (b) Hyper-tension disease management; (c) Diabetes monitoring; (d) Electrocardiogram (ECG) monitoring; (e) Video/ Audio Access to physicians for remote consultation; (e) Remote picture and text archiving and communication service (back-up/long term archiving complementary to infrastructure operated by hospitals) and (f) Fall Prevention and Detection Services. The doctor can access the patient’s PHR on-line through a cloud computing service. The latter can support the doctor in decision making and results in better quality of health service. In more detail, the doctor retrieves and updates the patient’s medical data and can also use the proposed on-line system to: (a) prescribe a new medicine; (b) fill in an e-referral for specific exams (e.g., blood test); (c) inform and advise his/her patient or (d) ask the patient to visit the hospital. Following the doctor’s advice, the patient visits a pharmacy, or a diagnostic centre or a hospital. At the final stage, the healthcare service providers (doctors, hospitals, diagnostic centres) and pharmacies interact with the health insurance organisation to compensate all outstanding orders and medical actions.

Currently, PINCLOUD [19] is in its implementation phase, upon which the various components, such as: (a) PHR platform, (b) e-prescribing and e-referral, and (c) homecare applications, are being developed and tested.

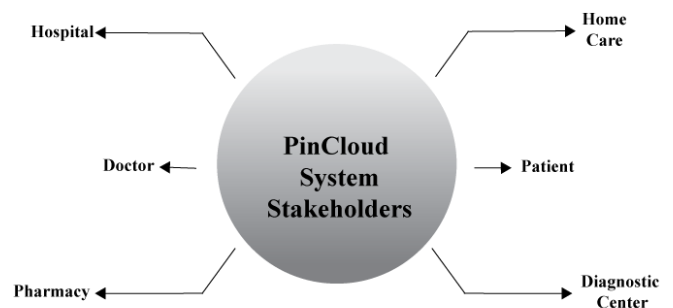


Figure 1. Providing Integrated e-Health Services for Personalized Medicine utilizing Cloud Infrastructure (PINCLOUD)

V. MAIN IDEAS

Service and data availability is crucial for healthcare providers who cannot effectively operate unless their

applications are functioning properly and patients' data is available in a consistent manner. This is also the case for PINCLOUD. PINCLOUD's services (e.g., E-Prescription, E-Referral, Home-Care and PHR) ought to be available continuously with no interruptions or performance degradation since they will be used for decision making regarding the patients wellbeing.

New research projects, as PINCLOUD need to reinsure service availability to the participating healthcare providers and other organizations. In addition, hardware and software installations, upgrades, and reconfigurations have to be managed and maintained without any service interruptions that may cause problems. In order to achieve the availability in a cost efficient way the use of Cloud-Computing seems to be the appropriate solution and thus the PINCLOUD was designed based on its features. These features as cost-saving, agility, efficiency, resource consolidation, business opportunities and Green IT are relevant and applicable to the healthcare sector.

Besides, PINCLOUD potentially will be responsible for the governance of a big volume of medical data. The protection and integrity of such data is vital for both the patients' privacy and their wellbeing. At this stage of the project the protection of these data is achieved with a Private Cloud delivery model. A Private Cloud model is operated by a single organization. In the private cloud, the technology resides within an organization's own data center and the resources are deployed as needed to the different departments. In our project, a private IT company, which is part of the consortium has provided the Private Cloud's infrastructure. Thus, the developers can overcome the challenges associated with other Cloud models (e.g., Public, Hybrid) since the ability to manage and control sensitive patient data remains within the organization.

PINCLOUD is based on the well-known Cloud-Computing three service models' structure, namely: (a) Software as a Service (SaaS), (b) Platform as a Service (PaaS) and (c) Infrastructure as a Service (IaaS). Respectively, PINCLOUD provides the user interaction through SaaS. In theory, SaaS is the capability provided to the consumer to use the provider's applications running on a cloud infrastructure. The applications are accessible from various client devices through either a thin client interface, such as a web browser (e.g., web-based email), or a program interface. PINCLOUD offers four applications, such as (a) E-prescription, (b) E-referral, (c) Home-Care and (d) PHR. These applications provide the main functionality required and are being consumed by End-Users (e.g., Patients, Doctors, Hospitals/Labs and Insurance Bodies). All these users access the PINCLOUD through user interface provided as a service. For example, a PINCLOUD registered user can have access to his/her medical record online.

In addition, PINCLOUD takes advantage of PaaS service model. Literature presents PaaS as the capability provided to the consumer to use and or deploy into the cloud infrastructure consumer-created or acquired applications

created using programming languages and tools supported by the provider (NIST). Accordingly, it takes advantage of the PaaS model and provides open source components as Web-Services and Application Programming Interfaces (APIs) that facilitate the integration with third (3rd) parties (e.g., Medical Data Providers, Hospitals). For example, when a hospital decides to be integrated in the PINCLOUD system, it can allocate and consume the Web-services' API created.

The processing and storage capability of PINCLOUD is based on IaaS model. IaaS is the capability provided to the consumer to provide processing, storage, networks, and other fundamental computing resources while the consumer can deploy and run arbitrary software, which can include operating systems and applications. PINCLOUD takes advantage of the IaaS and provides data processing and storage of medical data. IaaS consists of multiple Virtual Machines (VM), Medical Data Base and Network Infrastructure. In the given case, multiple VMs are utilized with each one dedicated to one service (e.g., Database, Access Control, Backup).

VI. E-REFERALL BUSSINESS PROCESS

This section familiarizes the reader with the PINCLOUD architecture and provides a detailed account for one of its main services, the E-referral service, as seen in Figure 2. In more detail, Figure 2 demonstrates the three service models, upon which PINCLOUD platform is based, namely: (a) Software as a Service (SaaS), (b) Platform as a Service (PaaS) and (c) Infrastructure as a Service (IaaS). Additionally, the E-Referral Service Business Process flow is exposed in its main functionality (e.g., Login, find, open etc.).

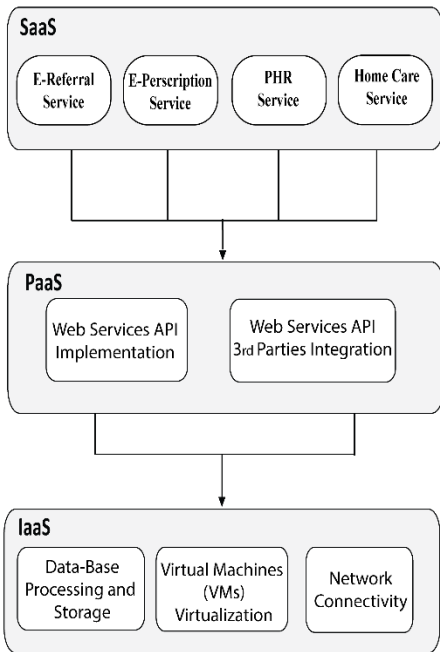
As shown in Figure 2, SaaS provides all the PINCLOUD's services such as: (a) Personal Health Record (PHR), (b) Home-Care, (c) E-referral and (d) E-Prescribe. The PHR is accessible by PINCLOUD's Services (E-Referral, E-Prescribe and Home-Care), but also by thirty party services and entities, which have access to the patient's PHR. Such thirty party services are the (a) Insurance Bodies, (b) Diagnostic Centers, (c) Trainers, (d) Medical Devices and manually submitted data by patient and access is granted with the patient's approval, as he is the owner of the PINCLOUD system.

The different web services (e.g., E-Referral, E-Prescription and Home-Care) are depicted in PaaS and can run independently and exchange information between each other. More specifically PICNLOUD provides two kinds of APIs, such as: (a) interconnectivity between the different provided services and storage and (b) providing access to thirty parties to connect with PINCLOUD, exploiting the advantages of PaaS Cloud models.

PINCLOUD is also using the IaaS Cloud model for: (a) Storage for the databases the platform is using, (b) The Virtual Machines where the PICNLOUD platform services are hosted and running and (c) The Network that is responsible for the interconnectivity between the different services and the different Virtual Machines of PINCLOUD.

It is worth mentioning that the PINCLOUD platform exploits several advantages from Cloud models such as the (a) Scalability (b) Elasticity and the (c) Lower Total Cost of Ownership (TCO), but also ensures the medical data integrity.

Figure 2. E-Referral implementation in PINCLOUD Platform



In a closer look of the E-Referral Service, an analysis of the Business Process flow is presented in the following paragraphs and depicted in Figure 3.

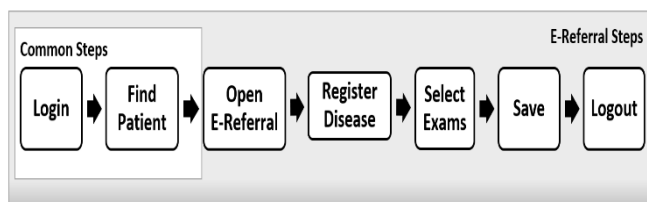


Figure 3. E-Referral Process

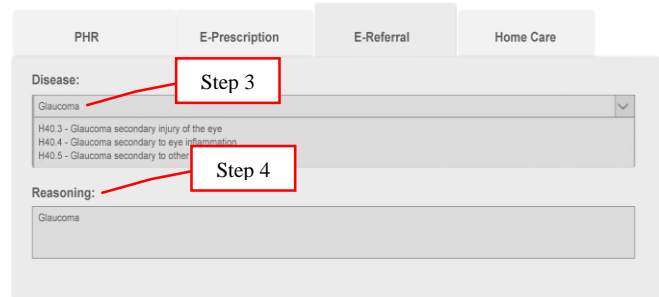
The E-Referral Service is one of the four main services the PINCLOUD platform offers as mentioned earlier in this section. The E-Referral Service is a complex web service consisting of several simple web services multiplexed together. In the diagrammatical flow shown in Figure 2, common (white border) and E-Referral steps (gray border) exist. The common steps referred to the steps which the doctor has to walk through despite the PINCLOUD service he/she executes (e.g., they are common for E-Prescribe as well). The first common step is “Login”, in which the doctor

provides his/her credential in order to gain access into the PINCLOUD platform. In the second step, “Find Patient” the doctor searches for the patient using the patient’s SSN number, which is a unique key identifier for each patient as it shown in Screenshot 1.



Screenshot 1. The Doctor initiates the search for the patient’s information

Moving on, the doctor selects between the offered services, such as: PHR, Home-Care, E-Referral and E-prescription, as depicted in Figure 2. In the next step (step 3), the doctor is able to create/open a new E-Referral (“Open E-Referral”). The “Open E-Referral” is followed by “Register Disease” in step 4, where the doctor obligated by the system to write the disease diagnosis with any comments (e.g., free text) as a guideline for the patient (Screenshot 2). The diagnosis for the patient’s disease is encoded based on the Worlds Healthcare Organization International Statistical Classification of Diseases and Related Health Problems that is now at its 10th Revision (e.g., ICD 10).



Screenshot 2. Diagnosis

Moving on in the E-Referral flow in step five, the doctor is able to select all the required exams for the patient in order to issue the E-Referral. This step named “Select Exams” by the authors as shown in Screenshot 3. The exams, which the doctor is able to select are also based on the ICD10 standard. It has to be mentioned at this point that, the PINCLOUD platform provides efficient mechanisms in order to prevent medical errors. To this direction in the current Service (E-Referral) the system is able to ensure the disease to medical exams interactions by providing appropriate alerts in such cases. Thus, the doctor is able to select up to ten different medical Exams for each E-referral. Finally, the doctor is

ready to issue the E-Referral and save it in step six “Save” and logout.

S/N	Description of Medical Exam	Medical Examination Preparation Notes	Quantity	Medical Examination Cost	Insured Participation	Total
1	Ultrasound (us) dor complete examination regardless of organ	-	1	8,28€	1,24€	7,04€
2	Ultrasounds (us) Doppler	-	1	8,28€	1,24€	7,04€
Totals			2		2,48€	14,08€

S/N	Description of Medical Exam	Directions for Exam Preparation	Quantity	Cost of Medical Exam	Insured Partitipation	Total
1	Complete Blood Exam	Empty Stomach	1	17,28€	2,59€	14,69€
Totals			1		2,59€	14,69€

Screenshot 3. Available Medical Exams

VII. EXPECTED BENEFITS

The project shall build a reliable, secure and extensible platform warranting stakeholder collaboration and enjoying public trust. The expected benefits for all participant organizations include amongst others: (a) the development of integrated healthcare services that improve quality of service and reduce costs; (b) business process reengineering, improvement, simplification and integration; (c) enhanced decision making for health organizations and significant reductions to medical errors; (d) standardization, automation, synchronization, better control and communication; (e) improved coordination, management and scheduling of specific health supply chains and services; (f) development of monitoring systems that improve quality of care of patients at home; (g) establishment of an infrastructure that provides up-to-date information; (h) development of an innovative organizational environment for the participating hospital using horizontal processes instead of the traditional hierarchical organization; (i) implementation of an extensible and maintainable infrastructure that can be enriched with other medical services; (j) development of an appropriate, sustainable technological framework that can be deployed and applied in other relevant situations and environments; (k) investigation of state-of-the art technologies and novel research that extends the body of knowledge; (l) significant research outcomes and publications of excellent quality; (m) production of new platforms, infrastructures and solution that can be further exploited, (n) knowledge and expertise gained can lead to competitive advantage and (o) production and export of technical know-how for all the participants.

The results of the proposed project are of great importance for the businesses that deal with the medical/health sector as they will increase the potential to gain competitive advantages through the project. The area of healthcare is

significant and the need for advanced and innovative IT solutions in this area is apparent too. Thus, the participant enterprises will have the opportunity to: (a) develop an integrated platform that can be used by other organizations in the future; (b) better understand and analyze the complexities of the Greek healthcare environment; (c) experiment and implement innovative integrated solutions that can be turned into products; (d) gain expertise and know-how on a complex area; (d) sell these products and know-how at national and international level since PINCLOUD seeks to develop an innovative solution; (e) obtain and reinforce experiences that can be used for the development of other network-oriented systems and (f) extend their business activities.

The benefits for both healthcare organizations include among others: (a) specifications of processes for the management of healthcare processes; (b) simplification and acceleration of business processes; (c) better management of healthcare tasks; (d) personalized disease monitoring and cost calculation; (e) more efficient operation and (f) economies of scale.

The academic institutions' participation in the project is equally important and include benefits, such as: (a) knowledge exchange and transfer; (b) engagement in innovative research; (c) investigation of state of the art technologies; (d) opportunity to publish research articles of high quality; (e) prospect to conduct applied research and combine theory and practice.

PINCLOUD will deliver the following benefits to the national economy and society: (a) enhancement of occupation and working activities for the participating partners; (b) the reinforcement of scientific research; (c) improved delivery of healthcare services at reduced cost; (d) patients' and next of keen satisfaction; (e) the development of innovative and state of the art healthcare systems; (f) more efficient allocation and management of computing resources; (g) the development of new products and jobs; (h) reduction of medical errors and consequently the amount of people that are affected or die due to them; (i) the reduction of the cost as an immediate effect of the reduction of medical errors; (j) technical, scientific and research benefits; (k) reduction of the amount of prescriptions and referrals and the associated cost; (l) improvement of the quality of life of people who live in islands or rural areas.

VIII. CONCLUSIONS AND FUTURE RESEARCH AGENDA

This paper introduces a Patient-Centered e-Health (PCEH) conceptual aspects alongside a multidisciplinary PHR project that combines state of the art technologies like cloud computing, Service-Oriented-Architecture (SOA), homecare telemedicine technologies, e-Prescribing, e-referral and e-learning in healthcare environment. The aim of the project is to create an integrated PHR platform that delivers many benefits to the society, the economy the industry and the research community. To this end, various technologies (e-health, cloud, etc.) and healthcare issues (e.g., complexity, PCEH, etc.) were presented. Additionally, our intentions on the way we propose to address and combine these issues were

explained and depicted. In the previous section, the benefits of such an endeavor alongside the steps taken so far to realize the implementation of a secure and reliable system, were analyzed. Yet, further research is required both in the testing and evaluation of our design and implementation.

To this end, the Research and Development (R&D) team engineered several mechanism to test and evaluate PINCLOUD and its components. For example, a proof-of-concept test will be implemented to check the communication of various sensors with the main PHR. The results of this test will be examined by healthcare professionals and provide initial evaluation of the technologies used. Additional, testing mechanism have been designed for other components (e.g., e-prescribing and e-referral) as well. Besides, PINCLOUD will be implemented in two different cloud IaaS providers so as to study the interoperability in two different settings. The results of this test will again provide insights into the utilized technologies and if needed reconfigurations and adjustments will be implemented. The authors expect the results of this test to be the subject of our next publication.

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An Extended View on Benefits and Barriers of Ambient Assisted Living Solutions

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Abstract— Motivated by the older adults' desire to age in their trusted home environment and the increasing financial pressure on the healthcare system, Ambient Assisted Living (AAL) technologies are designed to facilitate healthy and autonomous aging in place. To aid the acceptance of these still immature technologies, one first need to understand how prospective users perceive AAL technologies. Following this objective two studies were conducted. Study I contains an extensive literature of 26 AAL papers, which resulted in eight benefit categories and ten barrier categories. Study II attempted to validate and specify these benefits for a conceptual AAL application called SONOPA (Social Networks for Older Adults to Promote an Active Life). Focus groups and interviews were conducted with older adults and elder care professionals in Belgium, France and the UK. The results of these studies were translated into several design guidelines for SONOPA and related AAL applications.

Keywords-Ambient Assisted Living; elderly; benefits; barriers; design.

I. INTRODUCTION

With the rapid increase of Ambient Assisted Living projects, we need to put more focus on how these applications are perceived by their prospective users. Initial insights on this topic were presented at AMBIENT 2014 [1]. The current paper forms an extension to this paper and provides an extended view on the benefits and barriers of AAL technologies.

Worldwide the proportion of elderly people is increasing. With 18.2% of the population being 65 years or older in 2013, Europe has one of the highest shares of elderly people in the world [2]. It is expected that this proportion will rise to almost 30% by 2050 [3]. This goes along with a sharp increase in the old-age dependency ratio, meaning that the number of potential recipients of health and pension funds rises (65 years and older), while the number of potential providers of funds belonging to the working age population (15-64 years), continues to decline [3][4]. While global aging can be considered as a great accomplishment of today's socially and technologically advanced culture, it creates immense challenges for governments in terms of healthcare regulations, pension schemes and state budgets [3].

A. AAL Technologies

To meet these challenges, the concept of AAL was introduced. AAL is an umbrella term for innovative Information and Communication Technology (ICT) based products, services and systems, which support healthy and active aging at home, the community and at work [5]. AAL technologies cover a broad field of applications including smart homes, assistive robotics and mobile and wearable sensors. Various algorithms and computational techniques such as activity recognition, context modeling, location identification, planning and anomaly detection are used to support the older adults' physical (e.g., detecting falls, medication reminders) and psychological well-being (e.g., facilitate interaction with peers and family members) [6]. By promoting a healthy and autonomous lifestyle, AAL technologies meet both the older adults' desire to remain independent and age in place and the demand for controlling healthcare cost [7][8].

Despite the fact that AAL technologies offer a promising perspective on independent aging, it is uncertain if older adults are ready to adopt and use these technologies [9][10]. Usability problems [8][11], the lack of perceived benefits [7][10][12] and self-efficacy [10][13] can form, among other factors, severe barriers to technology adoption among elderly people. In addition, older adults form a highly diverse target group with regard to their health, activeness, social involvement and technological skills [9]. In our view, this heightens the need for a user-centered approach when designing AAL technologies, to access the wishes and needs of the intended user and identify potential benefits and barriers at an early stage of development.

B. SONOPA Project

The presented work is part of the SONOPA project [14] which is carried out in the framework of the AAL Joint Programme. The aim of the SONOPA project is to empower elders to stay active, autonomous and socially connected and consequently support and unburden family caregivers. SONOPA will achieve this objective by combining a social network with activity recognition techniques in a smart home environment to stimulate and support activities and daily life tasks. The SONOPA system consists of three major subcomponents (see Figure 1). Firstly, a simplified smart home environment for providing assistance to the older adults and obtain information about their activities.

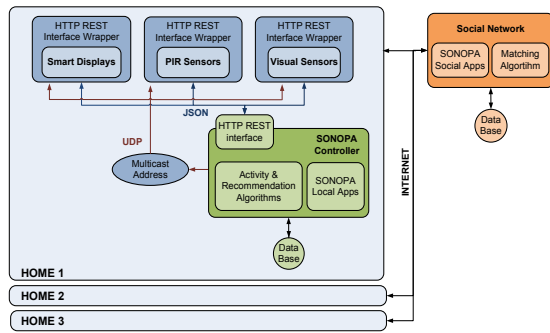


Figure 1. SONOPA System Architecture

Secondly, a module for intelligent behavior analysis which derives activity information from raw sensor data and finally, the social network application which manages the communications between users and their caregivers, and promotes activities. All these components communicate via a WLAN network setup in the home environment. The behavior analysis module, user interface and the middleware which connects with the social network are installed on a computer at the user's home – the SONOPA controller. The controller will collect the sensor data received from the visual sensors and passive infrared sensors. The user interacts with the smart home environment and the social network through the audio/video calling system and the smart wall displays. The smart wall displays are a touch-enabled display that provides spontaneous communication in any room in the home. The video messaging system enables a rich communication between the elder and their friends, relatives and caregivers. The SONOPA controller provides access to the social network application hosted in the cloud, which connects the different homes of the elders in the neighborhood.

C. Overview

In this paper, several design guidelines for AAL technologies are identified. Findings are based on both insights from an extensive literature study (study I) and a user-requirement study conducted as part of the SONOPA project (study II). Section II provides an overview of the conducted literature study. The design of the user-requirement study is described in Section III. The combined results of both studies with regard to the perceived benefits and perceived barriers of assisted living technologies are described in Section III. Together, these insights led to several design guidelines, that are directive for the development process of SONOPA and related AAL applications. These guidelines are described in Section IV. Section V provides general conclusions and implications for the future work with regard to the SONOPA system and related AAL technologies.

II. STUDY I: LITERATURE STUDY

To get an insight in the perceived benefits and barriers of AAL technologies, relevant literature about AAL and related technology applications designed for the purpose of healthy

and active aging in place was reviewed. We searched several scientific databases (Scopus, Web of Science, Google Scholar) with keywords such as 'older adult', 'assistive technology', '(ambient) assisted living', 'smart home', 'robots', 'monitoring', 'independent', 'adoption', 'use' or synonyms of these words. After initial screening of titles and abstracts, we included ($n = 26$) papers applying the following criteria :

- Peer – reviewed
- English language
- Published between 2000 - 2015
- Systematic review, qualitative study, quantitative study or mixed method approach
- Research focusing on factors which influence the adoption and use of technology applications designed for healthy and active aging

The selected papers studied different AAL applications such as sensor and monitoring technologies ($n = 11$), social network applications ($n = 2$), domestic robots ($n = 3$), smart health technologies ($n = 1$), an intelligent mobility aid ($n = 1$) or the more general concept of technologies for aging in place ($n = 8$) (see Appendix I). With a few exceptions, participants in the sample were aged above 60. The sample size ranged from 1-1518. Some of the included studies focused on older adults in good health, while other studies included participant with physical and cognitive limitations. Accordingly, the living situation of the sampled participants varied as well. Several studies ($n = 10$) also included the perspective of informal caregivers and health care professionals. While some studies investigated the technology in a more conceptual phase, some technologies (mostly prototypes) were tested in the field. We also included two systematic reviews. The selected studies were conducted in the US ($n = 12$), EU ($n = 10$), Australia ($n = 1$) and Canada ($n = 1$).

We extracted the perceived benefits and barriers from the selected papers and grouped them into categories. Consequently, eight benefit categories and ten barrier categories for AAL technologies could be identified.

III. STUDY II: USER-REQUIREMENT STUDY

To evaluate the perceived benefits and barriers identified from the literature study in the context of the SONOPA technology, a user-requirement study with older adults and elder care professionals was conducted.

Three focus groups (UK: $n = 8$; FR: $n = 5$; BE: $n = 9$) and semi-structured interviews ($n = 21$) were conducted in the UK, France and Belgium. In total, 28 older adults aged between 55 and 86 ($M = 71.36$, $SD = 9.45$) participated in the study. Six older adults participated in both focus-groups and in-depth interviews. Of all participants, twelve were male and sixteen were female. Nine participants lived on their own, while the other participants lived with a partner, family members or a friend. The older adults lived independently and without the regular help of a formal or an informal caregiver. A few seniors depended on their family members or external help for certain chores such as cleaning,

transport, grocery shopping or gardening. Although their self-reported physical well-being showed some variation, the majority felt fairly healthy. Overall, participants also felt fairly active, ranking their own activity level at an average of 7.06 (SD = 2.07) on a 10-point scale. Moreover, the majority of the older adults felt socially involved, ranking their own level of social involvement at an average of 7.32 (SD = 1,59) on a 10-point scale.

The Belgium focus group was conducted with four male and five female elder care professionals. The professionals were aged between 36 and 61 years (M = 46.50, SD = 9.89) and had an average of M = 14.44 years of work experience in the care sector (SD = 6.32).

A video was used to visualize two potential user-scenarios of the future SONOPA technology. Subsequent questions targeted the following topics:

- Problems related to ADLs and the level of social involvement
- Opinion about the SONOPA solution
- General level of technical skills and design requirements for technology for elderly

The recorded material was then coded according to the benefits and barriers perceived by the participants.

IV. RESULTS

Based on the conducted literature study (Study I), eight benefit categories and ten barrier categories for AAL technologies could be identified (see Table I). Almost all of these benefits and barriers were supported in the user-requirement study (Study II) with regard to the conceptual SONOPA technology. This section presents the combined results of both studies and provides a detailed description of all benefits and barriers.

A. Perceived Benefits

1) Health and Safety

Health and safety are prerequisites for aging in place [7]. Hence, the literatures study showed that responding to emergencies [7][8][16]-[21], detecting and preventing falls [7][8][16][18]-[23] and monitoring physiological parameters [7][8][19][24] were regarded as vital features of AAL technologies. Other valued features included health management tools such as fitness tracking and medication management [20][24], property security [8][18] and detection of safety hazards, e.g., fire or unlocked doors [18][25]. In sum, the literature study showed that AAL technologies can provide older adults with an increased sense of safety, security and peace of mind.

Safety was also a valued user-requirement with regard to the future SONOPA technology. Older adults and elder care professionals both felt that embedded sensors could provide added safety and security by detecting abnormal behavior such as falls or other emergencies, and automatically contact help. Thus, paralleling the findings from the literature study, fall-detection and emergency response were identified as key features. Another feature that was suggested to be incorporated to the SONOPA system was a reminder for turning off the stove.

TABLE I. BENEFITS AND BARRIERS OF AAL TECHNOLOGY

Benefits	Papers (n=)	References
health and safety	23	7, 8, 15-26, 32, 37, 39, 41-44, 48
independent living and aging in place	11	7, 16-19, 22-24, 26, 41, 44
support carenetwork	9	16-19, 22, 24, 26, 30, 32
social involvement	8	16, 26, 30-32, 37, 47, 48
support with daily activities	7	8, 18, 20, 24, 25, 37, 39
enjoyment and leisure	6	25, 26, 31, 32, 37, 47
education and information	2	24, 32
self confidence and status	2	21, 26
Barriers	Papers (n=)	References
privacy, intrusiveness and controle	18	8, 15-18, 20, 22-24, 26, 32, 37, 39-43
perceived need and perceived usefulness	15	7, 8, 16, 17, 19, 21, 22, 24, 32, 37, 39, 41, 43, 47, 48
Usability	13	7, 8, 17, 18, 22, 24, 32, 37, 39-41, 43, 47
lack of human interaction	10	7, 8, 19, 22, 24-26, 32, 37, 42
social stigma and pride	9	7, 8, 17, 19, 21, 39, 41-43
technology anxiety, technology experience and self-efficacy	8	7, 8, 17, 18, 24, 32, 41, 43
reliability and trust in technology	8	7, 8, 17, 18, 22, 41, 42, 44
cost	8	7, 8, 16,17, 22, 37, 41, 43
burden others	3	8, 17, 19
health concerns	2	7, 17

In the literature study automatic and around-the-clock monitoring was viewed as a major advantage of sensor-based assistive living technologies in comparison with existing solutions, such as an emergency button or a human caregiver [7][18][19].

The user-requirement study showed that automation was also regarded as a main advantage of the future SONOPA technology, as becomes clear in this statement by a female older adult participant: "I have a panic button on my mobile [...]. But as far as I'm concerned it is practically useless. Because if something serious happens it is either going to be on the other side of the room, or in your hand bag, or you're not capable to press the button. So really what you are talking about, is a lot more helpful".

2) Support Care Network

According to the literature study, both informal caregivers and the elderly people themselves perceived AAL technologies as good tools to support the care network because they can provide some peace of mind and can reduce the overall burden of family caregivers [16]-[18][22][24][26]. With the help of in-home monitoring, professional and family caregivers can gain a better overall understanding of the elderly person's well-being,

immediately react in emergency situations and detect functional and cognitive decline at an early stage [19].

Similar findings resulted from the user-requirement study. The older adults stated that SONOPA could be very valuable to support the care network and provide peace of mind for the relatives. One male senior participant regretted that a similar technology was not available when he was an informal caregiver: "When my mother was older I looked after her to be sure she is well. And I think this kind of solution would have been very valuable in that situation".

3) *Social Involvement*

Another benefit of AAL technologies which resulted from the literature study concerns the improvement of the user's social involvement. Social connectedness has been described as a key element of a good quality of life [27][28] and successful aging [29]. Several of the reviewed projects demonstrated that AAL technologies can help elderly to feel closer to family members and combat social isolation and loneliness [26][30][31]. Huber et al. [26] showed that the tested technology gave the elderly and their family members "windows into each other's daily lives" (p. 450) and provided new topics of communication while eliminating monitoring questions. Similarly, the field trial of the 'Digital Family Portrait' project [30], revealed that the female participant felt less lonely, knowing a family member was watching over her. AAL technologies can also provide opportunities to connect with peers. In the 'Building Bridges' project [32], elderly people met fellow seniors via online calls and chat to discuss a broadcast they had commonly listened to. Participants stated that they were very keen to arrange real-life meetings and get to know their conversations partners.

In the user-requirement study, social involvement was also perceived as an important advantage of the future SONOPA technology. The participating older adults and professional caregivers liked that the social network feature of the technology would allow elderly people to make new friends and strengthen the neighborhood network, as stated by one male senior: "It's like a social club." They also valued that one could stay in touch with family and other existing contacts. Participants appreciated that contact would be one-on-one and could lead to real-life interaction. They concluded that SONOPA could prevent social isolation by getting people outside the house, motivate them to participate in social life and therefore, give them back a sense in life. By aiding social involvement, SONOPA could simultaneously stimulate the elderly people's activity level. As stated by one female senior participant: "If you meet someone, you get ready, you clean the house and you get busy with other daily chores. And in this way this kind of technology could contribute to staying active". While this is in line with some studies from the literature study, it contradicts findings from Steele et al. [7] who found that their elderly participants strongly rejected the suggestion to incorporate social aspects in an assisted living technology. However, one female elder care professional in our user-requirement study argued that particularly these social aspects could be the reason that the more healthy and active elderly people would be interested in SONOPA: "For some

people safety would not be such a big problem at first, and if that is all there is, they probably would not get [the technology] installed. But it also includes some social elements which could maybe convince people to get it installed anyway. This way they get familiar with [the technology] [...] and by the time it is needed for safety purposes than there is already a good [activity] profile of this people and that I consider a strength". Mynatt and Rogers [46] also implicated that the more technologies can be incorporated in the homes of fit elderly, the more likely they will be to adopt more advanced assistive technologies when their health declines.

4) *Support with Daily Activities*

With older age physical, cognitive and sensory impairments such as muscle stiffness, memory decline and poor vision increase [33]-[36]. AAL technologies can help elderly people to compensate for these deficits and help them with their daily activities. Indeed, Smarr et al. [25] found that elderly people would value the assistance of domestic robots in helping them with chores such as cleaning, fetching objects or reminders. With those tasks robotic assistance is even preferred over human assistance. Similarly, Demiris et al. [8] found that older adults identify assistance with impairments and a reminder function as potential advantages of assisted living technologies.

In line with these findings from the literature study, assistance with chores and reminders (e.g., medicine, important appointments) was a much appreciated feature among older adults and elder care professionals in the SONOPA user-requirement study. A few older adults liked the possibility to get personal advice from peers or family members via video-chat. One female senior participant even suggested to use SONOPA to recruit help for chores through the social network feature: "But imagine if you want to decorate your kitchen and you put it on there, you could have five people come around and you could go shopping and come back and it would all be done".

5) *Enjoyment and Leisure*

According to the literature study, enjoyment was identified as another benefit of AAL technologies. Several older adults reported to have fun when interacting with the tested technologies [26][32]. They also recognized that AAL technologies could stimulate leisure activities. For example, in the study of Beer and Takayama [37] older adults suggested to use the tested virtual presence robot to attend concerts or sport events from the comfort of their own home.

When discussing the conceptual SONOPA technology during the user-requirement study, several participants imagined that using SONOPA would be fun and enjoyable. Several older adults also saw the SONOPA social network feature as an opportunity to share common interests. As one female participant stated: "I do watercolor painting, I might find somebody who wants to come in with me once a week and sit."

6) *Education and Information*

Opposed to common stereotypes, a good proportion of elderly people are still capable of learning new things and is still fairly active and productive [38]. This was confirmed by the results of the literature study. In the 'Building Bridges'

Project [32], participants were very excited about the educational element of the tested device. Similarly, Joe et al. [24] found that elderly people would like their tested AAL technology to include features like ‘learning something new’ and ‘keep up with the news’.

In line with these findings some of the user-requirement study participants were interested in informational and educational features for the future SONOPA technology. For instance, one participant suggested to incorporate online classes or educational videos in the SONOPA system.

7) *Independent Living and Aging in Place*

In the literature study, independent living and aging in place were perceived as essential benefits of AAL technologies. Several studies reported that independence is of utmost importance to elderly people, and technology which can facilitate autonomous living is therefore perceived as useful, e.g., [7][18][19]. Many elderly people are attached to their own homes because of their possessions, past memories and the familiar neighborhood [17][18]. Consequently, they often have a negative view on nursing homes and regard institutionalization as a last resort [7][17][18]. The desire for independent living was so strong, that it often superseded other concerns, such as privacy and intrusiveness [19].

Independent living and aging in place was not explicitly mentioned in the user-requirement study with regard to the future SONOPA technology. A possible explanation is that SONOPA was already presented as a conceptual technology for healthy and independent aging at home. Consequently, participants might have felt that this was an obvious advantage and therefore, unnecessary to recall. However, various statements made clear that independence is very important to the participants. This and the fact that it was a major advantage in previous studies lead to the conclusion that independent living and aging in place indeed should be emphasized as a benefit of AAL technologies

8) *Self confidence and Status*

Finally, it was recognized in the literature study that AAL technology could built up the self-confidence of older adults [21] and even serve as a status symbol [26]. However, ‘self-confidence and status’ was not a very prominent benefit.

Therefore, it is not surprising that it was not mentioned in the SONOPA user-requirement study. However, we still think it would be a desirable benefit for AAL technologies as low self-esteem is a common problem among older adults [45].

B. *Perceived Barriers*

Besides benefits, several barriers that could interfere with the successful adoption of AAL technologies were extracted from both studies. The insights on those barriers are discussed below.

1) *Privacy, Intrusiveness and Control*

Concerns about privacy, security and possible intrusion were perceived as important barriers to the adoption of AAL technologies. Elderly people were worried that their personal information can get in the wrong hands and be misused [15][24]. Some were reluctant to the monitoring aspect of

assisted living technologies, as it felt like surveillance to them [22][23]. Especially, the use of cameras, was strongly rejected [8][20]. In contrast, some studies found that privacy is just a minor concern to their elderly participants [7][19]. They regarded some loss of their privacy as a valid trade-off for their safety, independence and health. Another reason could be the lack of awareness of potential security risks. Moreover, older adults were worried that technologies are too visible in their home environment [17][39], and could interfere with their normal routine [23][32][39]. Indeed, some participants in the study by Van Hoof, Kort, Rutten and Duijnste [18] complained about visible cables, annoying sounds and interference with other devices, such as the TV. Others worried about having to dress up and keeping their home clean for video calls [23].

Following these findings, the participants of the user-requirement study considered the loss of privacy as a negative aspect of the future SONOPA technology. Some of SONOPA’s potential functionalities were also regarded as intrusive. Several senior participants felt that the SONOPA technology would invade their personal space, and that they would feel observed as becomes clear in this statement by a female participant : “I think it is big brother, being watched all the time”. The older adults worried that they would feel restricted in their freedom and loose spontaneity as argued by another female older adult: “But I don’t know whether you would creep around the house, thinking oh dear they can see me [...] That would be horrible, sort of spy on the wall”. Some of the older adults were concerned that the data could get in the wrong hands. However, the majority of the older adults found the idea of sensors acceptable because they perceived them to benefit their personal well-being and safety at home, as this male participant stated: “When I know that the sensors are installed in my home for my well-being, I don’t have any problems with them being in my home”. Furthermore, most of the participants who were comfortable with sensors, were comfortable to have them in every room of the house as falls could happen everywhere. However, a few older adults would not like to have sensors in the toilet, bathroom and bedroom.

According to the literature study, the level of user control was a matter of concern to the elderly user. Most elderly people wanted to have some level of control about the technology, e.g., turn it off manually [17][40]. Consequently, the lack of user control is perceived as a barrier. On the other hand, some elderly people argue that a monitoring system cannot assure safety, unless it is switched on all the time. Emergencies could happen when the system is switched off or when users forget to switch it back on [7]. A low level of user-control would also be more suitable for people who are not very confident in interacting with technologies [8].

In line with these findings, most older adults from our user-requirement study wanted to be able to switch the future SONOPA system on and off, be aware of which data are shared and decide with whom the data are shared. On the contrary, other participants thought that the system would only work to its full potential, when it could not be switched off.

2) *Perceived Need and Perceived Usefulness*

The subjective need and the perceived usefulness of a new technology are essential for elderly people to adopt it. Consequently, the literature study showed that the lack of subjective need and perceived benefits forms a major barrier to accepting assisted living technologies. The subjective need for AAL technologies seems to be influenced by the elderly person's perceived well-being in terms of health, activity and social involvement. Steele et al. [7] found that elderly persons with good social ties were less likely to feel the need for such a technology. Greenhalgh et al. [39] discovered that their participants saw no value in assistive technologies if they had never needed to use it before. However, many elderly people struggled to imagine future deterioration where they might benefit from features such as monitoring [19]. Others simply did not want to admit the need for assistive technology [21]. This is confirmed by Peek et al. [17] who concluded that many elderly people talk about a hypothetical older person who could benefit from assisted living technology rather than themselves. The use of existing technologies, such as an emergency button and the help of family members or a spouse can also reduce the perceived need for assisted living technologies [17]. This is contributed by the fact that many elderly people did not fully understand the additional benefits assisted living technologies can provide [7][39]. While the perceived benefits were more abstract, the concerns related to those technologies were very specific [17].

Similar results were found in the user-requirement study. Although the majority of the older adults liked the general idea of SONOPA, many felt no need for it in their current situation. They found the concept of SONOPA more beneficial for people who are less independent, active and healthy; and who are more isolated as becomes clear in this statement of an older couple: "I mean we're not in the position at the moment to need any of those things. But thinking of other people, I think it is marvelous". They also found it hard to imagine that they might feel less healthy in the near future and would need more assistance. Like in the study of Peek et al. [17], it was observed that many older adults talked about a hypothetical older person who could benefit from SONOPA, rather than themselves. However, eleven older adults indicated that they have no need for it at the moment, but could imagine to use it in the future, when they felt less healthy and active, or in case they would lose their partner. Some older adults found that the future SONOPA technology would not offer a lot of added benefits. Several older adults indicated to already use a paper diary for overlooking their appointments, or a pill-box to remember to take their medications. However, it also became clear that the concept of the technology was still quite abstract and therefore, some of the participants did not fully understand all benefits the SONOPA technology could offer to them.

3) *Usability*

In the literature study, many elderly were worried about the user-friendliness of AAL technologies. They feared that those technologies will be difficult to use and not adapted to their specific needs as older adults [17][24]. Indeed several

field studies encountered usability problems with regard to the tested AAL technology, e.g., [18][32].

As in many previous studies from the literature review, older adults in the SONOPA study were worried about the potential complexity of the SONOPA interface, and how much user participation is needed to operate the system as becomes clear in this statement by a female participant: "But if you got to go to an iPod thing and should do tutututu [push buttons] before you find out what you are supposed to do, that is not helpful".

4) *Lack of Human Interaction*

According to the literature study, the lack of human interaction was also a matter of concern to the elderly target group. They thought that AAL technologies cannot and should not replace human assistance and human interaction, but should be used as a supplement to human care [7][8][19][22][26][32][37]. Indeed, Smarr et al. [25] revealed that while robot assistance is accepted for certain tasks, human assistance is preferred for personal care tasks (e.g., wash hair), leisure activities (e.g., entertaining guests) and most health related tasks (decide which medication to take). Similarly, Joe et al. [24] found that their participants preferred in-person communication with their physician over technology-mediated contact. On the other hand, in the study of Huber et al. [26] it was found that despite concerns about monitoring technologies reducing the contact with family caregivers, the quality and quantity of communication actually improved during the field trial with the technology. However, this does not change the fact that older adults are concerned about technology replacing human care.

In line with these findings, older adults and professional caregivers from the user-requirement study stated that SONOPA could not and should not replace human care and human interaction, as becomes clear in this statement by a male older adult: "For me human contact is still most important [...] Thus, I prefer no computer". A female senior participant pointed out: "The negative point is that this person's family and the environment cannot fully rely on this application. Because the application cannot replace the human".

5) *Social Stigma and Pride*

The literature study showed that social stigma was also a potential barrier to the acceptance of AAL technologies. Many elderly people were hesitant to use technologies that could stigmatize them as frail or needing assistance [8][17][21][41]. Pride and embarrassment were often the reason for not using assistive devices [7][19][21]. Consequently, older adults indicated that AAL technologies should be as discreet and unobtrusive as possible [7][42][43].

Similar findings resulted from the user-requirement study. While assistance with chores was well perceived by a few older adults, others felt no need for assistance and almost felt insulted by the idea as this statement by a female participant indicates: "I don't need anybody to tell me how to make a stew". We observed that some older adults were very proud of their independence and therefore, rejected anything which would imply otherwise. Indeed, one older adult pointed out that seniors might be resistant to accepting that

they need assistance and therefore, would not want to use technology that stigmatizes them as frail and dependent.

6) *Technology Anxiety, Technology Experience and Self-Efficacy*

According to the literature study, several elderly people were apprehensive towards technology and worried about their abilities concerning technology use [7][8][24]. They perceived technology to be very complex and inaccessible for elderly people who miss the necessary skills and experience [32]. Making mistakes when interacting with the technology, was a major concern. However, some of them were willing to undertake training and believed that this knowledge could make the interaction with the technology easier [7].

In line with these findings, the older adults from our user-requirement study were worried about the complexity of the future SONOPA technology. It was repeatedly emphasized that they did not grow up with technology and therefore, might lack the necessary skills, experience and confidence as this statement by a male senior participant shows: "I think a lot of our generation are computer shy".

7) *Reliability and Trust in Technology*

The literature study showed, that many elderly people worried about the reliability of AAL technologies and questioned the accuracy and ability of those technologies in ensuring the health and safety of the user [7][17][22][41]. They worried about interruptions in energy supply [7][44] and the occurrence of false alarms [7][17][18][42]. Indeed, several studies testing monitoring systems reported false emergency alarms during field trials, e.g., [18][22]. While some participants were annoyed by these false alarms [18][22], other participants perceived false alarms as a reassurance that the systems is actually working [18][30].

In accordance with these findings, older adults in our user-requirement study were concerned about the reliability of the future technology, especially the sensors. They worried that SONOPA could give false alarms as becomes clear in this statement by a female participant: "It might just go off with your natural things". Two seniors regarded the activity recommendations as ineffective: "I am not convinced that a single technology application and especially a screen can motivate people to do stuff". Older adults also wondered if all parts of the system could be installed in different domestic environments as becomes clear in this statement by a female participant: "I can't honestly visualize it to be a possibility. Not in an old house".

8) *Cost*

Another barrier concerns the cost of assisted living technologies. In the literature study, several elderly people have stated that, due to their limited income, such systems would either not be affordable to them [7][8][22][37][41], or they would not be willing to spend a lot of money on such technologies [7][22]. Elderly people also mentioned that cost should be subsidized by the government [7].

Although cost came not up as a top-of-the-mind concern among the older adults in the user-requirement study, it became clear that the SONOPA technology has to be affordable for a person living on a pension. Several French

and Belgium seniors demanded that the government would have to cover parts of the costs.

9) *Health Concerns*

Finally, the last barrier regards health concerns. In the literature study, several elderly people worried that electromagnetic radiation caused by wireless sensors could cause health problems [7][17].

Although our user-requirement study participants were not worried about electromagnetic radiation, one older adult stated that SONOPA could potentially provide too much assistance and make people less active and healthy because then they do not have to go outside the house to have social contact: "It could be that you shackle them behind the computer".

10) *Burden Others*

The literature study showed that, while support for caregivers was identified as a potential benefit of AAL technologies by several older adults, others perceived AAL technologies to put an additional burden on relatives as family caregivers [8][17][19].

This barrier was not mentioned in the context of the SONOPA user-requirement study. Nevertheless, we should keep in mind that some older adults might worry to burden their family when using AAL technologies.

V. DESIGN GUIDELINES

Based on the findings from the literature study and the SONOPA user-requirement study, we formulated several design guidelines which are discussed below.

A. *Clear, Specific and Flexible Benefits*

To stimulate older adults and their caregivers to use AAL technologies, these technologies must not just offer added benefits to its users, but at the same time those benefits have to be clear, specific and profound. The benefits that should be targeted by AAL technologies include the following areas: health and safety, independence, support for the care network, social involvement, support with daily activities, enjoyment and leisure, education and information and self-confidence. Especially, social, leisure and educational benefits should not be overlooked, as some older adults are still very active and fit, and therefore, might not feel an immediate need for a technology which is mainly focused on health, safety and support. Because the concept of AAL technologies is often perceived as abstract, elderly should be able to try out or experience a technology without being obliged to buy it first.

In the context of SONOPA, a central element of the first prototype is the social network which helps the user to connect with peers and family members and offers leisure and informational features such as personal interests groups and event information. By emphasizing social, leisure and educational benefits we try to target the still healthy and active, older adults. During the upcoming pilot phase, two demo sites will be equipped with the SONOPA prototype, so a large number of potential users can experience the system and get a better understanding of its benefits.

B. Ensuring Privacy, Security and Unobtrusiveness

AAL technologies often collect sensitive data such as personal health and activity records. Therefore, measures must be taken to ensure the secure storage of this sensitive information. By giving the user control over whether the system is active, where potential sensors are placed and which data are shared and with whom, privacy concerns can be reduced. However, the level of user control has to be weighed against the proper working and reliability of the AAL technology. In case of a monitoring system, a time limit for deactivation could be applied, to avoid that people forget to switch the system back on. Furthermore, caregivers could be informed when the system is switched off for a longer period of time. To counter obtrusiveness, it is recommended to embed the hardware in the elderly people's home environment and blend it with the surroundings. Moreover, the system should be able to communicate wirelessly, without noise, and no interference with other devices in the home environment.

For the SONOPA pilot phase we will take all necessary measures to ensure safe data storage. Moreover, we will try to reduce the number of sensors and collect feedback on the design to make the system less obtrusive. Within the social network environment the users can control which data they want to share and with whom.

C. Simplicity and Familiarity

The interaction with an AAL technology should be simple, consistent and easy to use and learn. The interface has to be intuitive and clearly structured. Technical slang should be avoided and textual elements should fit the elderly's frame of reference. The challenge is to create a simple design but not limit the functionality [32].

The SONOPA prototype is designed to be simple and easy to use. During the pilot phase we aim to collect detailed feedback to further improve the user-friendliness of the system.

D. Training and Low Level of Active Interaction

To simplify the interaction with AAL technologies, it is suggested to automate most processes and to opt for a minimal level of active user interaction, if desired by the user. Special training programs should be designed to teach the elderly how to use a technology and thereby improve the perceived ease of use and the confidence in their skills.

Many features of the SONOPA prototype are automated and require little user interaction. During the pilot phase the participants will receive a short training for using the more 'active' features such as the social network environment. Moreover, we will try to improve the usability of these features with the help of the user's feedback.

E. Emphasizing Abilities rather than Disabilities

When designing and marketing AAL technologies like SONOPA, emphasis should be put on the abilities rather than the disabilities of the target group. This can be achieved by further developing and embedding social, leisure and educational features and positioning AAL technologies as a wellness tool rather than a assistive device. Functionalities of

AAL technologies should be helpful but not patronizing and be flexible to the wishes of the still healthy and active user.

As mentioned earlier, social, leisure and educational features are a central element of the SONOPA prototype. This features will help to market SONOPA as a wellness tool rather than a assistive device. During the pilot testing, we will investigate if the recommendations provided by SONOPA are perceived as patronizing and adapt this feature accordingly.

F. Reliability and Technical Support

Given that the average experience with technology in the elderly target group is rather low, robustness to mistakes is another important demand for designers to keep in mind. Furthermore, sensors should be accurate and reliable to avoid false alarms. Technical support in form of a helpline or a well-written manual should be available to all users to minimize technology anxiety and promote a successful interaction with the technology.

For SONOPA, we conducted a technical test in two home environments prior to the pilot studies, to test the integration between the different technical elements and ensure that all elements are working properly and in a reliable manner. During the pilot phase, the technical installation in each pilot site will be monitored remotely by the responsible technical partners and if technical problems occur, they will intervene directly at the pilot sites. The participants can contact their end-user contact person at any time if they experience technical problems. The insights from the pilot study will be used to further improve the reliability and proper functionality of the SONOPA system.

G. Flexibility and Adaptiveness

AAL technologies should be adaptive to differences in physical constraints, personal preferences, technological skills, context and environment. By offering high flexibility in content, functionalities and level of control, AAL technologies can appeal to the different needs of this highly divers target group.

With regard to SONOPA, we aim to offer the system in different modes. One mode is tailored to the active and healthy older adults with an emphasis on the social aspects and only a few sensors. The other mode will target the older adults who start to experience physical problems and put more emphasis on health and safety with a denser sensor installation.

H. Promoting not Replacing Social Interaction

AAL technologies should promote and not replace social interaction. For instance, it is recommended to use a local social network so that face-to-face interaction is a possibility.

We expect that the SONOPA social network and event recommendations will improve the contact with family and peers and stimulate the creation of new social connections online and offline.

I. Low Cost and Spread Payments

Keeping in mind that the average income in parts of the intended target group is rather low, costs should fit into the

available resources of the users. Also, a monthly payment scheme is recommended. Furthermore, one should keep in mind that users might expect that costs are partially covered by social security means.

By offering different modes of the SONOPA system and keeping the hardware requirements to a minimum we try to minimize the costs of the SONOPA system. We also plan to use a different monthly payment scheme for the different modes of the SONOPA system. This way, we can adapt to different user needs.

VI. CONCLUSION AND FUTURE WORK

AAL technologies offer a promising prospect on independent aging and managing health care costs. However, it remains unclear if older adults are ready to adopt these new technologies. In this paper, we identified eight benefits and ten barriers of AAL technologies as perceived by the elderly user and their caregivers. These benefits and barriers were the result of an extensive literature study and a user-requirement study of a conceptual AAL application called SONOPA. Together the results of both studies led to the following design guidelines: (1) clear, specific and flexible benefits, (2) ensuring privacy, security and unobtrusiveness, (3) simplicity and familiarity, (4) training and low level of level of active interaction, (5) emphasizing abilities rather than disabilities, (6) reliability and technical support, (7) flexibility and adaptiveness, (8) promoting not replacing social interaction, (9) low cost and spread payments.

Our approach is not without limitations. The benefit, barriers and consequent design guidelines are still based on qualitative data. However, the initial study was extended [1] and our preliminary results were verified. Moreover, recently another SONOPA user-study was conducted, and the first results seem to confirm the findings of this paper. Also, a recent content analyses of AAL deliverables, showed similar benefit categories and also provided some theoretical background for these found benefits [49].

Future work will focus on integrating the found benefits and barriers into a model for AAL acceptance and gather quantitative data to test the conceptual model. The SONOPA system will be tested in the field and the user feedback will be used to further adapt and improve the system according to the user's needs.

Although design guidelines need further evaluation, they form a valuable directive for the developers of SONOPA and other AAL technologies.

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APPENDIX I OVERVIEW SELECTED PAPERS

Ref.	Technology Category	Test User Characteristics						Test Country	Applied Method
		Number	Age	Gender	Health Status	Living Situation	Caregivers involved		
7	sensor network/monitoring	n = 13	65+	6 males 7 females	n/a	independently	no	Australia	focus groups
8	technologies for aging in place	n = 15	65+	7 males 8 females	n/a	independently and assisted living and nursing home	no	US	focus groups
15	sensor network/monitoring	n = 119	80+ m = 83	22% males 78% females	average or better health n = 92 with normal cognitive function n=27 with MCI	independently	no	US	field trial with questionnaire
16	technologies for aging in place	n = 9	70+	2 males 7 females	normal cognitive function	assisted living	no	US	focus groups
17	technologies for aging in place	sample size range: 7-1406	60+	n/a	n/a	independently	n/a	mostly US (67%)	systematic review
18	sensor network/monitoring	n = 18	63+	4 males 14 females	The majority of participants deal with a variety of comorbidities, n = 7 mild to moderate psychogeriatric health problems including dementia	independently and assisted living	informal caregivers	Netherlands	field trial with observational data and interviews
19	sensor network/monitoring	n=23 elderly n=16 informal carers	66-91 m=80.6	n/a	stable health, no signs of dementia	n/a	informal caregivers	US	focus groups
20	sensor network/monitoring	n = 6	60-85+	n/a	some participants had partial physical or cognitive impairments	assisted living	no	Netherlands	participatory design activities, interviews, questionnaire
21	Intelligent mobility aid	n = 19	67-86	n/a	mobility problems	n/a	informal carers	UK	focus groups, observation and interviews
22	sensor network/monitoring	focus groups: n = 28 field trial: n = 22 elderly and n = 20 informal caregivers	65+	Equal gender distribution	n = 8 had a significant health problem and n = 9 reported minor health problems	assisted living	informal caregivers and care professionals in focus groups and informal carers in field trials	UK	focus groups and field trial with interviews and questionnaires

Ref.	Technology Category	Test User Characteristics						Test Country	Applied Method
		Number	Age	Gender	Health Status	Living Situation	Caregivers involved		
23	sensor network/monitoring	n = 12	61-95 m = 75.6	3 males 9 females	mean of 3.75 chronic conditions and n = 5 relying on an assistive device to function within the home	n/a	no	Canada	interviews
24	sensor network/monitoring	Three group with 7-15 participant n = 7 sheltered housing wardens	n/a	n/a	Some studies included healthy older adults, while others included participants with neurological deficits.	n/a	informal carers and sheltered housing wardens	UK	focus groups with scenario based drama
25	domestic robot	n = 21	65-93 m=80.25	6 males 15 females	good health	independently	no	US	focus groups, questionnaires
26	sensor network/monitoring	n = 6	73-86 m = 82.17	6 females	good to excellent (self-rated)	retirement community	informal carers	US	field trial with datalogs and interviews
30	sensor network/monitoring	n=1 elderly n=1 informal caregiver	76	1 female	good health	independently	informal caregivers	US	field trial with interviews, diaries
31	technologies for aging in place	n = 14	62+	6 males 8 females	n/a	retirement community	no	US	focus groups and questionnaires
32	social network application	field trial n=15	60+	n/a	n/a	n/a	Professional carers	Ireland	home visits interviews focus groups workshops field trial
37	domestic robot	n = 12	63-88	5 males 7 females	excellent:17% very good: 33% good: 42% fair: 8% poor: 0%	independently	no	US	interviews
39	technologies for aging in place	n = 40	60 – 98 m=81	13 males 27 females	various medical conditions	independent and sheltered housing	no	UK	Various ethnographic techniques: interviews cultural probes field notes home tour
40	smart health technology	group 1: n = 7 group 2: n = 35 group3: n = 40	group 1: 40-50, m = 45.5 group 2: 51-65, m = 58.6 group 3: 66-92, m = 74.1	group 1: 45% males and 55% females group 2: 43% males and 57% females group 3: 45% males and 55% females	n = 39 suffer chronic diseases	n/a	no	Germany	questionnaire

Ref.	Technology Category	Test User Characteristics						Test Country	Applied Method
		Number	Age	Gender	Health Status	Living Situation	Caregivers involved		
41	technologies for aging in place	n = 30 aging service leaders and policy advocates	40-75	13 males 17 females	n/a	n/a	aging service leaders and policy advocates	US	workshop and focus groups
42	ambient display with social network application	n=1 elderly n=8 informal carers	88	1 female	n/a	n/a	informal carers	n/a	field trial with interviews
43	technologies for aging in place	group 1: n = 762 group 2: n = 756	group 1: 45-64 group 2: 65+	499 males 1019 females	both disabled and nondisabled adults	n/a	no	US	survey
43	technologies for aging in place	sample size range: 1-78	mostly 65+	n/a	heterogenous	heterogenous	4 studies included informal carers and care professionals	Mostly North America and Europe	Systematic review, interviews
47	domestic robot	Exp. 1: n = 40 Exp. 2: n = 88 Exp. 3: n = 30 Exp. 4: n = 30	Exp. 1: 65-89 Exp. 2: n/a Exp. 3: 65-94 Exp. 4: 65-89	Exp. 1: 18 males and 22 females. Exp. 2: 28 males and 60 females. Exp. 3: 8 males and 22 females. Exp. 4: 16 males and 14 females.	n/a	n/a	no	Netherlands	4 experiments
48	sensor network/monitoring	n = 40	56-88 m = 70.3	n/a	n/a	n/a	no	Italy	experiment and questionnaire

FutureBody-Finger

A Novel Alternative Aid for Visually Impaired Persons

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Abstract—We have developed a sensory substitution device (SSD), called FutureBody-Finger (FB-Finger) based on a “smart” mechanism with an ecological interface. The primary aim of FB-Finger is to enable visually impaired persons to “recognize” their surrounding environment, specifically in terms of distance. FB-Finger comprises a position-sensitive device (PSD) sensor unit and a small actuator unit and is used to sense the distance as follows: (1) The distance between a (visually impaired) user and an object is measured via ultrasonic waves or infrared rays radiated from the PSD sensor unit; (2) Information on the measured distance is transformed in the actuator unit into haptic stimulation (“somatosensory stimulation”) and then sent to a servo motor incorporated in the actuator unit; and (3) A lever connected to the servo motor catches the stimulation and creates angular motions to convey the information to the user’s finger. In order to afford the device simple use and portability, FB-Finger was designed with a shape such that the forefinger skin/joints receive somatosensory stimulation. In this paper, we outline the concept underlying FB-Finger, describe its underlying mechanism, and report on two psychological experiments conducted. The results of the experiments show that FB-Finger estimates the distance between two objects (i.e., the user and an object) more accurately, and the somatosensory interface enclosed in the device performs better, than commercially available SSDs. On the basis of these findings, we also discuss the effectiveness, possible future improvements, and applicability of FB-Finger to electric travel aids and other assistive aids.

Keywords—*haptic interface; somatic sensation; ecological interface; assistive technology; electric travel aid.*

I. INTRODUCTION

A. Purpose

In general, human beings are thought to obtain information via visual modality, but it is natural that nonvisual modalities also provide people with a significant

amount of information. Thus, it is important to shed some light on the role of nonvisual modalities in exploring the surroundings. On the basis of the philosophy and psychology associated with human perception and behaviors, we hypothesize that people are able to subjectively have an “extended body” experience (hereafter referred to as “FutureBody”) that endows them with a sense of effectivity in their surroundings if a device functions as a part of their bodies to enable them to recognize an unfamiliar environment by using that device. We have been working on the development of a device that proves our hypothesis. In particular, our research has been focused on developing a new type of sensory substitution device (SSD) for visually impaired persons to enable such persons to enhance the quality of their lives in terms of utilizing their nonvisual modalities. This paper is an extended version of a paper we presented at AMBIENT2012 [1]. In this extended version, we explain the key concept underlying the FutureBody device, give an outline of our developed device, FutureBody-Finger (hereafter referred to as FB-Finger), describe its hardware configuration, and discuss its efficiency. Finally, we present the latest improvements to FB-Finger (FB-Finger2). However, before delving into those areas, we give a general overview of previous and current aid devices for the visually impaired.

B. Assistive devices for the visually impaired

Devices called sensory substitution devices (SSDs) and electric travel aids (ETAs) have been developed in both academic and industry fields [2-9]. SSDs and ETAs [10, 11] are intended to assist the visually impaired with their activities, such as exploring their surroundings and locomotion. To ensure the safety of these activities, these devices have sensor(s) installed that detect a user’s location, the direction in which the user is moving, and the distance between himself/herself and nearby objects.

SSDs and ETAs obtain information about the surroundings via two major methods. In the first method, a small camera is used to capture images that are then analyzed, and the results of the analysis output to an electro-tactile display or vibration display. OPTACON [12, 13] adopted this method to help the visually impaired read printed letters, and the Forehead Retina System [14, 15] utilizes it to assist users with search of their surroundings. The second method utilizes supersonic wave sensors, which makes it suitable for measuring the distance between a visually impaired person and an object. Products equipped with supersonic wave sensors include Sonicguide [16-18], Miniguide [4], and Palmsonar [6].

SSDs and ETAs are categorized in terms of their output feedback interface as either “auditory” or “haptic.” Auditory type devices transform spatial information into audible sound. Sonicguide, for example, measures the distance between an object and a user with ultrasonic waves, converts the data into sound, and conveys the sound to the user. This type of device typically emits a low-pitched sound when an object is distant from the user and an increasingly higher-pitched sound as the object approaches.

Haptic type devices convert distance information into mechanical vibration or electrical-tactile stimulation and convey it to the skin (haptic sense). The intensity/frequency of the mechanical vibration varies according to distance: it increases when a user approaches an object.

However, in order for users to handle such devices, a number of problems need to be solved. Users are required to be trained to effectively use their cognitive inference and memory to comprehend what a stimulus means; that is, how much distance a certain stimulus equates to. To make full use of a device equipped with an interface that outputs the data in the form of sound pitch or vibration, visually impaired adults and children must use the device repeatedly to become expert users. Thus, visually impaired persons have to learn to associate a specific pitch/vibration with a corresponding distance. Such a practice has to be carried out because an arbitrary frequency or an arbitrary intensity from a stimulus is by itself a meaningless signal. Success with associative learning depends on cognitive abilities including inference and memory capabilities. Cognitive abilities take on the leading role in processes where users interpret a pitch/vibration signal correctly, understand the meaning of such a stimulation, and associate it with the distance to an object. This problem applies to the visually impaired, whether congenital or adventitious. If they hope to master one of these devices completely, they have to improve their cognitive abilities; otherwise, training will take a long time, or they will have to give up on actually mastering the device. Furthermore, visually impaired children are unlikely to develop enough high-level cognitive processing abilities, and adventitious visually impaired persons may have more difficulty discriminating pitches of sound and the intensity/frequency of vibration than congenitally visually impaired persons. To enable visually impaired users to receive spatial information more “intuitively” (directly), we developed our device, FB-Finger, with a novel haptic interface.

II. OUTLINE OF FUTUREBODY DEVICE: “SMART” MECHANISM WITH ECOLOGICAL INTERFACE

A. Key concept underlying FutureBody

The key concept underlying FB-Finger is adoption of a “smart” mechanism. As suggested by Runeson [19], we define a “smart” mechanism as a mechanism that directly registers complex variables. The operation of a polar planimeter can be used to give an indication of how this “smart” mechanism operates. A polar planimeter is a tool that is used to measure the area of irregular shapes, which necessitates calculation of complex variables. A representative polar planimeter is shown in Figure 1. When a user moves the tracer arm, the attached measuring wheel carefully traces the outline with the index to calculate the area (a complex variable) automatically. The length and angle measured by the polar planimeter are directly proportional to the area. The device is sufficiently simple to use such that those who have no knowledge of the calculations, e.g., summing up small pieces of a figure, can easily determine the area. This “smart” mechanism does not require any computational skills, higher cognitive inference ability, or excellent memory capability.

Extending the discussion of smart mechanism to human perception and performance, we assume that the human body operates in a manner similar to the polar planimeter. The polar planimeter uses a tracer arm with an index to register the summation of the area; analogously, the human body registers information on the surroundings by moving legs, arms, fingers, and joints and by stimulating their bones and muscles (called somatosensory stimulation). Whether they are conscious or unconscious, people are always exposed to such somatosensory stimulations from birth. To directly and intuitively register spatial information for surroundings, humans need to develop somatic sensations that underlie a person’s higher cognition and behavioral regulatory systems.

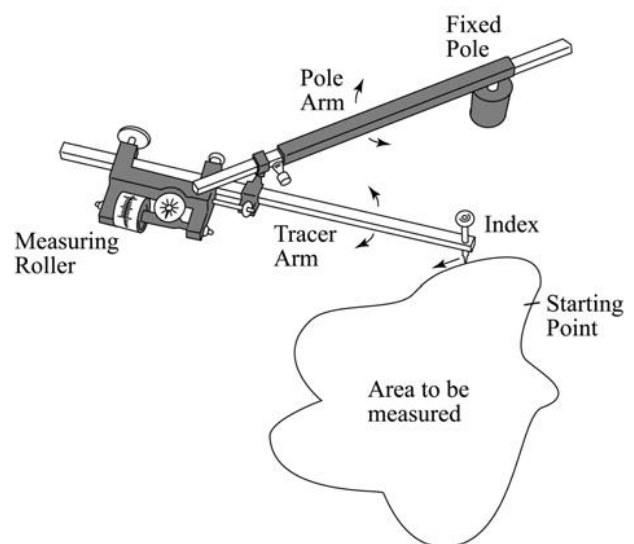


Figure 1. Polar planimeter as a tool for measuring the dimensions of irregular shapes.

Following this assumption, somatosensory stimulation plays an important role in devices that convey information to users directly or intuitively. Thus, we hypothesize that using a somatosensory/haptic interface would enable us to solve the problems outlined in the previous section.

Further, a smart mechanism is required to be equipped with an ecological interface. Here, the term “ecological” originates from “Ecological Psychology” [20] — a subfield of psychology aimed at revealing the human-environment interrelationship from the viewpoint of human’s perception and behavior in the environment. An ecological interface is designed to “reflect” the surroundings, in which information is directly and perceptually available to the persons who use it [21]. Design of ecological interfaces is mainly focused on interfaces for large and complex systems, such as power plants and medical equipment in order to avoid human errors. In this paper, we extend the discussion of ecological interface design to SSDs (or ETAs). The ecological interface of the device functions as a part of the user’s body so that they feel as if their bodies are extended by using it. Furthermore, they are directly exploring and connected to the surroundings so they are able to take effective actions with the interface. An example of a tool with an ecological interface is a pen. When we write letters with a pen, we feel the texture of the paper surface in which the pen is in contact. There are no touch receptors on top of a pen, but the skin of the hand holding the pen has a sense of touch. This sense of touch extends from the skin, through the hand, to the top of the pen. The shape of the pen is such that it is easy to hold with the fingers to help its users easily feel the smooth texture of the paper surface. This can be termed an “incarnation,” as argued by Merleau-Ponty [22]. On the basis of the above arguments, FutureBody should satisfy two requirements. First, it must operate as a smart mechanism with which users can directly or intuitively register spatial information without higher cognitive abilities. Second, it should be equipped with an ecological interface by which the device can function as a part of the bodies of users, and consequently allow users to have a sense of extending their bodies.

B. Preliminary version of FutureBody device (CyARM) and its mechanism

Our first step in the development of FutureBody was CyARM [23, 24]. CyARM is characterized by its “smart” user interface. Users do not need calculations, inference, or higher-level cognitive processing to determine the distance between them and an object, whether or not it is moving. Figure 2 depicts the structural diagram of CyARM. The strength of the device’s wire tension enables users to specify distance as well as direction. Connected to the user by a wire, CyARM measures the distance between the user and an object. CyARM emits ultrasonic waves, spotting an object and measuring the distance between the user and the object. At the same time, it also controls the tension of the wire connecting the device to the user. The wire’s tensile strength is directly proportional to this distance. When an object is a short distance away, CyARM pulls the wire tightly, and the user understands that the object can be reached by bending

the arm. When the object is far from the user, CyARM slackens the wire, indicating to the user that the object is not within reach. The user can thus explore his/her surroundings with the device.

Ultrasonic sensors measure the distance between the user and an object, and CyARM’s motor slackens or tightens the wire in accordance with the measured distance. The wire is rewound to the initial default position, and the rewinding tension is regulated in accordance with the measured distance. High tension signifies a short distance, while low tension signifies a longer distance. CyARM uses a somatosensory stimulation user interface such that users can obtain distance from themselves to an object via bending or extending their arms.

The basic mechanism underlying CyARM is as follows: The motor is Maxon GP16 (4.5W) with a 29:1 gear head and magnetic rotary encoder; the motor driver is iXs iMDs03-CL; the MPU is Renesas H8/3664, and the ultrasonic frequency used is 38 kHz.

The results of our previous studies indicated that CyARM is feasible for visually impaired persons. Psychological experiments conducted in which CyARM was used to estimate the distance to an object showed high accuracy and correlation to the actual distance. In addition, another psychological experiment also found that CyARM is effective in perceiving the shapes of objects [25, 26]. However, CyARM is too large to carry for daily use and its mechanism inhibits the user’s arm and trunk movement. In addition, its ultrasonic sensor has only low resolution for measurement of distance. Thus, CyARM is impractical for daily use. In order to overcome those usability and portability issues, we developed a novel “FutureBody” device called FutureBody-Finger (FB-Finger).

III. FUTUREBODY-FINGER: BASIC MECHANISM AND HARDWARE CONFIGURATION

FB-Finger was developed to enable users to recognize the direction of, and distance from, an object. Using it, people do not require higher cognitive abilities such as mathematical calculations, inference, and excellent memory to recognize the distance to an object. The device has been verified to solve some of the usability problems discussed in

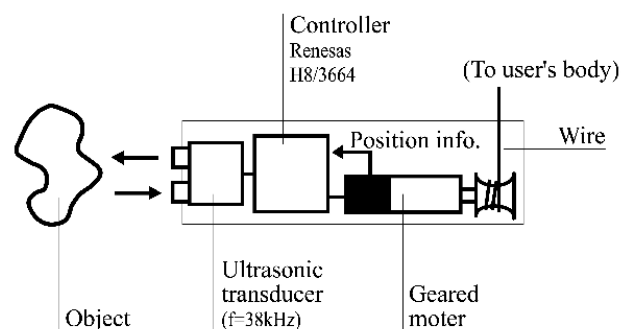


Figure 2. Structural diagram of the prototype CyARM, developed by us.

the previous sections.

The hardware architecture of the prototype FB-Finger is shown in Figure 3. The developed FB-Finger consists of three functional blocks: a controller, a sensor, and actuator units, all of which are connected to a common communication channel. Each unit has a microcontroller (MCU, Cypress CY8C21123).

The sensor unit acquires information about the environment via an adequate sensor device, and converts it to a digital value. We developed four types of sensor units with different sensor devices. The first and the second equip a position-sensitive device (PSD)-type distance sensor that radiates infrared rays toward an object; it detects the reflected position of the received rays using a PSD that implements a trigonometric distance measurement technique. We employed two different PSD devices: GP2Y0A21YK and GP2Y0A02YK by Sharp Inc. They have different distance measurement ranges: 100 mm – 800 mm for GP2Y0A21YK, and 200 mm – 1500 mm for GP2Y0A02YK. They output voltage signals corresponding to the measured distances. The supply voltage used is 5 V, and their physical dimensions are 30 mm (W), 13 mm (H), 14 mm (D) and 30 mm (W), 13 mm (H), 22 mm (D), respectively. The microcontroller is installed on the sensor unit, and calculates the distance from FB-Finger to an object; with an adequate conversion equation for each PSD sensor.

The third sensor unit equips the ultrasonic distance sensor of PING by Parallax Inc. It measures the distance to the target object in the range 20 mm – 30 mm, and has physical dimensions 22 mm (W), 46 mm (H), and 16 mm (D). It outputs a pulse with a modulated signal according to the measured distance. The microcontroller installed on the sensor unit converts the distance from FB-Finger to the object.

The fourth sensor unit equips the light sensor to measure the intensity of the incoming light, with lens for focusing. It measures luminance intensity at the narrow point on the surface of the target object.

The microcontroller installed in each sensor unit converts the sensor signal to the “distance” information in the same signal format. This enables the system to easily exchange the sensor unit with the same controller unit and actuator unit. In other words, the user can exchange the sensor unit for suitable applications with the one for FB-Finger body with the controller unit and the actuator unit. We here emphasize that the user can select a type of sensor unit according to the purpose of use. This is an important advantage of FB-Finger. We employ a 2.5 mm stereo plug and jack for physical connection between the sensor unit and the FB-Finger body, including the controller unit and the actuator unit. The stereo plug and jack provide the power, the ground, and the signal terminals.

The user can also apply the adequate distance sensor unit for the purpose based on its characteristics. For example, the ultrasonic distance sensor can steadily measure the distance to the object regardless of the material, while the infrared reflection used in the PSD sensor tends to be weak for black objects because of light absorption. On the other hand, the PSD sensor can measure the distance beyond a transparent

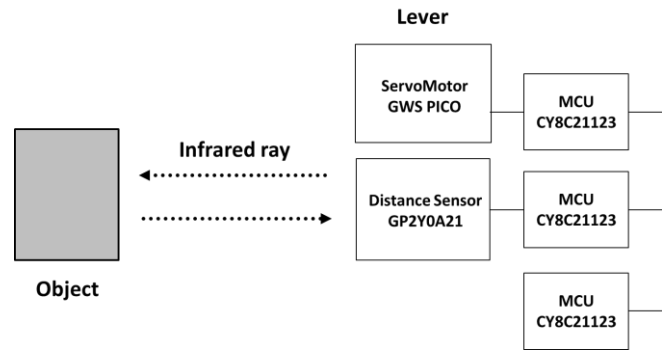


Figure 3. Block diagram of FB-Finger, developed by us, with infrared ray sensor.

wall, which is impossible for an ultrasonic sensor. In terms of the distance range available, the ultrasonic distance sensor can be applied to long distances, such as 3 m compared with the PSD sensor. In terms of physical size of the distance sensor devices, the ultrasonic distance sensor tends to be larger than the PSD device for the physical wavelength of the ultrasonic waves.

The actuator unit has a servo motor equipped with a 55-mm-long lever to form a one degree-of-freedom (1-DOF) link. The microcontroller on the actuator unit controls the servo motor according to the angular information received.

The controller unit periodically requests distance information from the sensor unit, converts the measured distance to angular information, and transmits it to the actuator unit; this chain of operations forms the sensor-actuator system. The angle of the link increases when the distance between FB-Finger and the object decreases (i.e., when the object is approaching), whereas it decreases when the distance increases.

Figure 4 illustrates the method by which FB-Finger is operated. A user holds FB-Finger and places his/her forefinger on the link. The finger bends or extends depending on the link's angular motion. The angle changes from zero to 70 degrees in correspondence with the metric distances between the user and an object. The extent that the user bends his/her forefinger is directly associated with the link movements, such that a finger motion allows a user to “directly,” and “intuitively” perceive the distance to an object. In this sense, FB-Finger has a somatosensory (haptic) interface that is ecologically designed.

The hardware specifications of the prototype FB-Finger are as follows: weight = 60 g; height = 75 mm; width = 45 mm; and depth = 35 mm. The body and the lever are composed of aluminum. The measurable distance ranges from 300 mm to 1400 mm for the PSD-short range sensor, and 1000 mm to 2800 mm for the PSD-long range sensor as the link angle changes from 70 to zero degrees in both sensors. The distance-angle coefficients are 7 deg/110 mm for the PSD-short range sensor and 7 deg/180 mm for the PSD-long range sensor. The output of the PSD is converted by an analog-to-digital converter, and then transformed to

the angle of the lever, which is controlled by the width of the control pulse. The theoretical minimum resolution for the distance measurement is approximately 1 mm.

IV. PSYCHOLOGICAL EXPERIMENT 1: ACCURACY OF ESTIMATED DISTANCE

A. Purpose

To demonstrate that FB-Finger enables users to perceive the distance between them and an object more accurately than commercially available products, we performed a psychological experiment as follows.

B. Method

1) *Participants*: 16 persons, visually impaired and sighted, participated in the experiment. Eight visually impaired adults, four congenitally and four adventitiously, participated in the visually impaired group. Their ages were between 28 and 57 years (mean = 43.0 years). Eight sighted adults with ages in the range 20 to 22 years (mean = 20.8 years), participated in the sighted group.

2) *Distance Range*: Two separate FB-Finger devices were used in order to test for a short range stimuli set ("Short Range") and a long range stimuli set ("Long Range"). The device designated to test for Short Range was equipped with a short distance sensor whereas the other was equipped with a long distance sensor.

3) *Object for Stimuli*: A piece of cardboard adhered to a whiteboard (1.6 m × 1.0 m × 0.02 m) was used as the standard stimulus and the test stimuli. We used a standard stimulus and four test stimuli in the Short Range and five test stimuli in the Long Range scenarios.

4) *Stimuli presentation*: In the Short Range stimuli set, the standard stimulus was presented at a distance of 0.4 m from a device affixed to a table. One test stimulus was presented at each of four positions, specifically, 0.4, 0.6, 0.8, and 1.0 m. In the Long Range stimuli set, the standard stimulus was presented at a distance of 1.0 m in the same manner as the Short Range standard stimuli set. One test stimulus was presented at each of five positions, specifically, 1.0, 1.4, 1.8, 2.2, and 2.6 m.

5) *Device Conditions*: Three types of SSDs (FB-Finger, Vibratory device, and Sonar device) were used as a within-subject factor. Participants were asked to estimate the distance to the stimuli using each SSD in turn. The Vibratory and Sonar devices used are commercially available ETAs. The Vibratory device (70 mm × 40 mm × 25 mm) was equipped with a haptic interface that transformed measured distances into vibration signals. The Sonar device (60 mm × 35 mm × 15 mm) transformed measured distances into audible sounds (i.e., sounds with a specific pitch). Both devices use ultrasonic waves to determine the distance to an object.

6) *Procedure*: Figure 5 shows the experimental setup. In each trial, participants were asked to use an SSD to detect

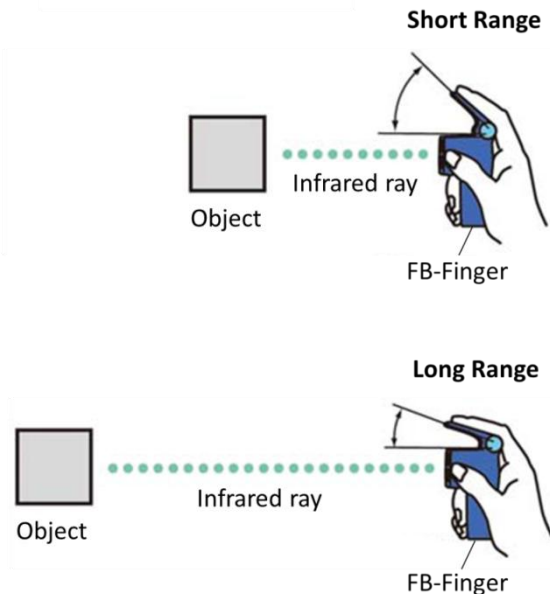


Figure 4. Illustrations showing how to operate FB-Finger with PSD-short range sensor (upper panel) and with PSD-long range sensor (lower panel).

the distance to a stimulus that was presented for 3 s. Initially, the standard stimulus was presented, after which one of the test stimuli was randomly presented at a certain distance in each distance range stimuli set.

The magnitude estimation method was used to estimate the distance to the presented stimulus. Using this method, each participant was asked to report the magnitude of a stimulus that corresponded to some proportion of the standard. The participant then assigned numbers reflecting the adjudged magnitude of his/her subjective experiences to each stimulus. In the magnitude estimation practice, each stimulus was assigned a number that reflected its distance as a proportion of the standard. The standard stimulus was set as "100." Thus, if a test stimulus was subjectively twice as far as the standard, a participant was expected to assign it a magnitude of "200." Under the three device conditions, each participant performed five trials for each of the four test stimuli in Short Range, and five trials for each of the five test stimuli in Long Range.

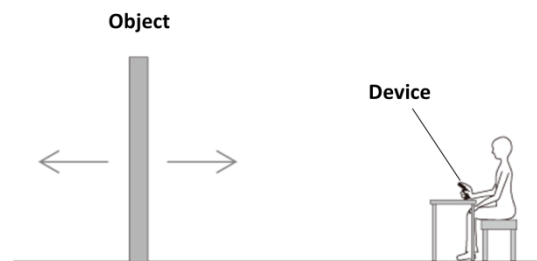


Figure 5. Setup used in Experiment 1: participants sat in front of a table on which one of three devices remained fixed. Experimenters randomly moved the object to change the distances between the object and the device.

C. Result and discussion

The product-moment correlation coefficient (r) between the presented distance (the presented stimulus) and the estimated distance (the distance participants estimated) by each device was computed. It was computed for each group, each device, and for both the Short and Long Range scenarios. We categorized both congenitally impaired and adventitiously impaired adults as “visually impaired group,” because there was no significant difference between them, and compared the group with “sighted group.” In the Short Range scenario, the product-moment correlation coefficients when the visually impaired group used FB-Finger, Vibratory device, and Sonar device were 0.918, 0.742, and 0.763, respectively. When the sighted group used those devices, the correlation coefficients were 0.882, 0.730, and 0.740, respectively. In the Long Range scenario, the correlation coefficients when the visually impaired group used FB-

Finger, Vibratory device, and Sonar device were 0.908, 0.663, and 0.461, respectively. When the sighted group used those devices, the correlation coefficients were 0.928, 0.777, and 0.422, respectively. Without regard to each device, each group, or each range, the estimated distances were correlated with the presented distances. Remarkably, FB-Finger exhibited the highest correlation between the presented and estimated distances.

Figures 6 and 7 show the regression lines for the overall data of each device, calculated using the least squares method. These figures indicate that the farther away a stimulus was presented, the farther the distance was estimated. From the abovementioned correlation coefficients and the regression lines, it was found that FB-Finger provided participants with the most accurate estimation of the distance to the presented stimuli.

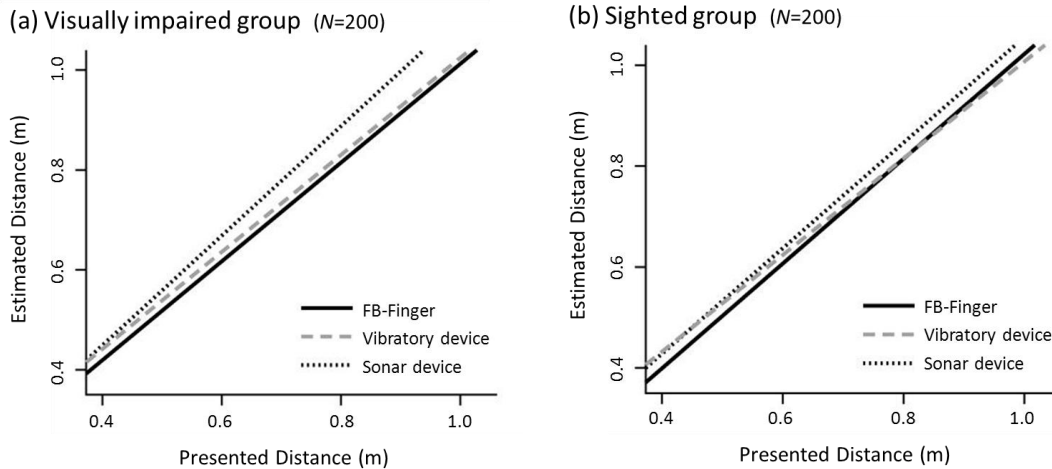


Figure 6. Regression lines for the overall data in the Short Range setup, calculated using the least squares method.

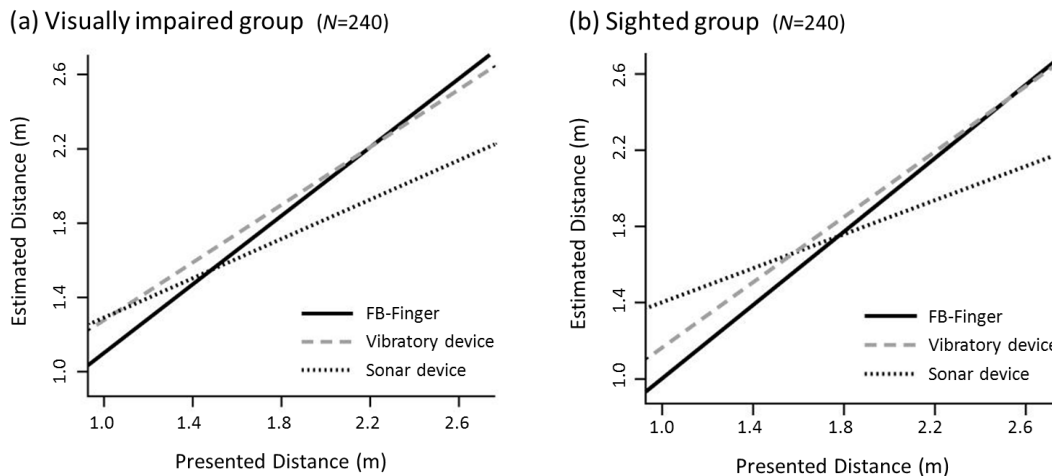


Figure 7. Regression lines for the overall data in the Long Range setup, calculated using the least squares method.

Determination coefficients (square of r) were also computed for each participant. Figures 8 and 9 show the mean determination coefficients of each group in the three device conditions. In the Short Range scenario, the mean determination coefficients of FB-Finger, Vibratory device, and Sonar device were 0.872, 0.622, and 0.660, respectively, for the visually impaired group. They were 0.813, 0.647, and 0.744 for the sighted group, respectively. In the Long Range scenario, the mean determination coefficients of each device were 0.878, 0.608, and 0.294 for the visually impaired group, and 0.884, 0.746, and 0.255 for the sighted group, respectively.

A two-way analysis of variance was performed on both the Short and Long Range scenarios by setting both visually impaired and sighted groups as a between-subject factor, and three device conditions (FB-Finger, Vibratory device, Sonar device) as a within-subject factor. The results indicated the same significant main effects of device condition ($ps < 0.01$) for both the Short and Long Range scenarios. Similarly, multiple comparison tests between the three devices found that the distance estimated using FB-Finger was positive proportional to the presented distance with the highest linearity compared to the other two devices. By contrast, there was no significant difference between the visually impaired and sighted groups. These results demonstrate that FB-Finger endows users with two advantages that cause it to excel above other devices: (1) better estimation of distance, and (2) capability of assisting users with accurate detection of distance.

Evaluation of the output interfaces of Sonar device (pitch of sound), Vibratory device (mechanical vibration), and FB-Finger (lever motion) showed that they all required users to use their bodies/senses to hear sound, feel vibration with skin, and feel finger movement. The findings from Experiment 1 suggest that finger movements, or finger joint motions, most effectively transfer distance information to users.

V. PSYCHOLOGICAL EXPERIMENT 2: FINGER FIXATION ON ACCURACY OF DISTANCE ESTIMATION

A. Purpose

In Experiment 1, the participants placed a finger on the lever of FB-Finger but the finger was not fixed to the lever. This may lead them to have a wrong perception of the angular motions of the lever. Hypothesizing that the participants may be able to estimate distances entirely based on the information conveyed from FB-Finger, we conducted another experiment (Experiment 2) to demonstrate the effect of fixing finger joints on the lever of FB-Finger to estimate the distance.

B. Method

1) *Participants*: 16 sighted adults participated in the experiment. Their ages ranged from 21 to 23 years. Of the 16, eight participants were asked to wear blindfolds and were randomly assigned to each experimental condition (given below).

2) *Object for Stimuli*: We used the same object for stimuli as Experiment 1.

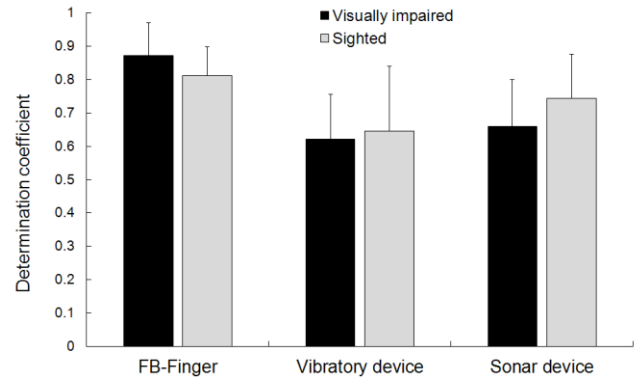


Figure 8. Mean determination coefficients in Short Range setup in the three device conditions for each of the visually impaired and the sighted groups. Standard deviations are shown as error bars.

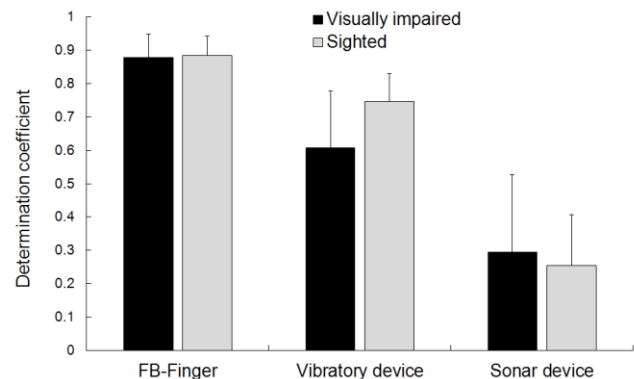


Figure 9. Mean determination coefficients in Long Range setup in the three device conditions for each of the visually impaired and the sighted groups. Standard deviations are shown as error bars.

3) *Experimental condition*: We adopted two experimental conditions: Fixing condition and Non-fixing condition. In the Fixing condition, shown in Figure 10, each participant's forefinger was affixed to the lever of FB-Finger using a Velcro touch fastener. In the Non-fixing condition set, the forefinger was not affixed to the lever (the same condition as in Experiment 1).

4) *Procedure*: FB-Finger was used to estimate distances. The standard stimulus was set at a distance of 0.4 m, and one test stimulus was respectively positioned at 0.4, 0.6, 0.8, 1.0 and 1.2 m. Each participant performed six trials for each of the five stimuli. Other procedures (experimental setup and magnitude estimation method) were the same as in Experiment 1.

C. Result and discussion

Product-moment correlation coefficients (r) were computed for each condition. The r values of the Fixing condition and the Non-fixing condition were 0.965 and 0.938,

respectively. This suggests that the distances estimated were more correlated with the presented distances in the Fixing condition than in the Non-fixing condition. Statistical analysis found that there was a significant difference between the Fixing condition and the Non-fixing condition ($z = 2.515$, $p < 0.01$). From this result, it is clear that an FB-Finger user is able to estimate the distance between himself/herself and an object more accurately when his/her finger is properly affixed to the lever.

In the Fixing condition, the forefinger was affixed sufficiently tightly that the finger was likely to follow a link-angular motion completely and its joint(s) and skin become more sensitive to somatosensory stimulation with their haptic sense. A finger's haptic sense to somatic stimulation is considered to be effective to obtain distance information. It is remarkable that FB-Finger enabled blindfolded, sighted participants to correctly determine the distance to an object, even though the individuals had little experience with haptic exploration of the surroundings using FB-Finger. Taking into account the fact that the visually impaired have higher somatic sensitivity than the sighted, it is conceivable that the results from Experiment 2 will lead to the development of some promising applications of FB-Finger for the visually impaired.

VI. "TWO DEGREES-OF-FREEDOM" PROTOTYPE OF FB FINGER2

Toward upgrading of the functionality of FB-Finger to perceive shapes, we developed an FB-Finger designed with 2-DOF (Figure 11, hereafter "FB-Finger2"). A user holds this device with forefinger on the lever, as can be seen in Figure 12(b). The lever consists of two components with two servo motors attached for each. One servo motor controls the distal interphalangeal (DIP) joint of the forefinger, and the other the proximal interphalangeal (PIP) joint of the finger. The distances from FB-Finger2 to three points (p_1 , p_2 , and p_3) on the surface of the object, as can be seen in Figure 12(a), were measured using a depth camera (ASUS Xtion Pro Live, hereafter referred to as "Xtion"). This was connected to a Microsoft Kinect to show the depth image of the measured object. On the basis of the measured distances between Xtion and p_1 , p_2 , and p_3 (referred to as d_1 , d_2 , and d_3), the angles of the finger's DIP joint (θ_1) and PIP joint (θ_2) were calculated using the following equations:

$$\theta_1 = \arctan \frac{d_1 - d_2}{v_1}$$

$$\theta_2 = \arctan \frac{d_3 - d_2}{v_2}$$

Here,

v_1 : vertical distance between p_1 and p_2 ,

v_2 : vertical distance between p_2 and p_3 .

The distance was set as 20 mm with adequate selection of the acquired depth image by Xtion. To cover the user's

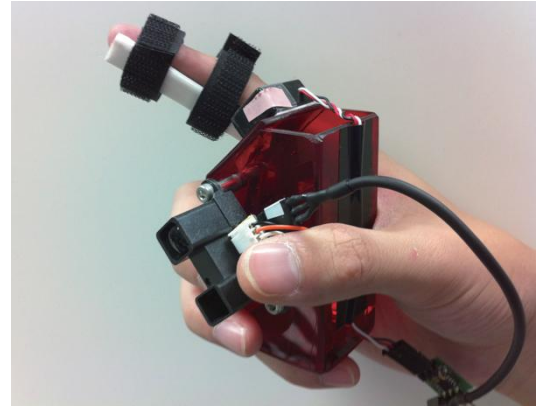


Figure 10. A finger affixed to the lever of FB-Finger.



Figure 11. Prototype of FB-Finger2, designed with 2-degrees-of-freedom.

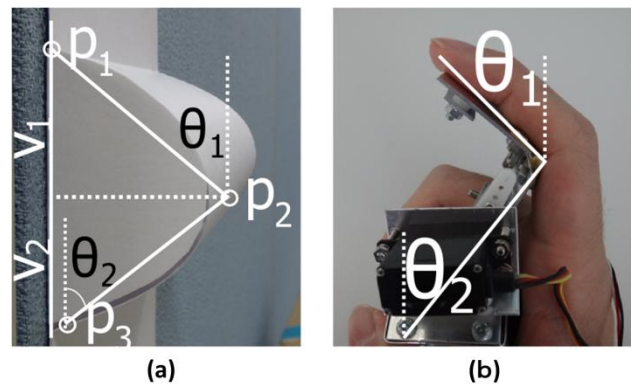


Figure 12. Measuring the distance to an object using the depth camera of FB-Finger2: (a) three points on the surface of the object were measured, (b) a user holds FB-Finger2 with forefinger on the lever.

finger motion, θ_1 ranged between -10 deg and 90 deg, and θ_2 ranged between -40 deg and 90 deg.

Figure 13 shows the system configuration of the FB-Finger2 prototype developed. The distance to the targeted object is measured using a PC-controlled Xtion. The PC also controls two servo motors that are attached to levers 1 and 2. The levers correspond with the movements of the DIP and PIP joints of the user's forefinger. The servo motors are controlled by microcontroller (Cypress's CY8C24123) from the PC control command. To accommodate various finger sizes, the lengths of levers 1 and 2 are set at 25 mm and 30 mm, respectively. The weight of the developed FB-Finger2 is 100 g (without Xtion). The distance range measurable by Xtion is between 0.8 m and 3.5 m, and its depth resolution is 10 mm.

To verify the performability of FB-Finger2, we conducted a preliminary experiment with 12 sighted adult participants. The participants were asked to wear blindfolds and use either FB-Finger or FB-Finger2 to identify the shape of objects (triangle, rectangular, trapezoid, semicircle). All participants identified triangular and rectangular objects more accurately when they used FB-Finger2 than when they used FB-Finger, but no such difference was found when they tried to identify trapezoidal and semicircular objects. The results of this experiment partially verify the performability of the 2-DOF in FB-Finger2. However, further studies on the method for measuring the depths of an object and for outputting information are necessary.

VII. CONCLUSION

The development of FB-Finger was inspired by the "smart" mechanism and the ecological interface design. As a novel SSD, FB-Finger is primarily aimed at helping the visually impaired to "feel" and "recognize" their surrounding environment. The current device comprises a sensor unit (one of two different types of sensor units) and a small actuator. One type of sensor unit radiates ultrasonic waves or infrared rays to measure the distance between the user and an object. The other type of light sensor unit measures luminous intensity. An actuator transmits the distance or luminance level into the haptic sense of a finger as somatosensory stimulation via a link-angular motion. This represents a form of ecological interface, in that information on distance and brightness is directly converted to another sensory modality. This paper focused on forefinger skin and joints to determine

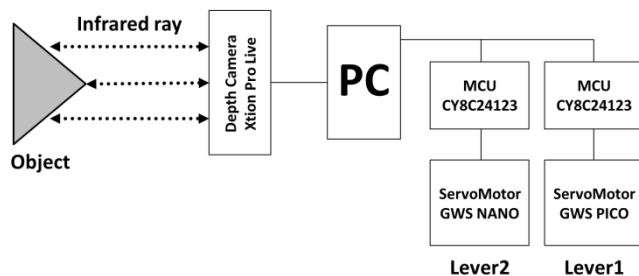


Figure 13. Block diagram of FB-Finger2, which we developed, with depth camera.

how somatosensory stimulation helps to improve the performance of FB-Finger.

Two experiments were conducted to verify the feasibility of FB-Finger. The results of Experiment 1 demonstrate that FB-Finger is more accurate than commercial products, and has the highest linearity in estimating distances. The results of Experiment 2 clarified that users are able to estimate distance more accurately when the joints of their forefinger are fixed at a 1-DOF link with FB-Finger.

The findings obtained from these two experiments suggest the following: First, finger joints motion ("somatosensory feedback") provides users with richer spatial information than tactile or auditory feedback. Second, FB-Finger can serve as a useful travel aid. It can help the visually impaired avoid obstacles and find landmarks such as poles, bus stops, and trash cans, while walking, particularly when used along with a cane or a guide dog. In order to verify its usefulness, we will ask visually impaired participants to use FB-Finger along with a cane and walk on roads, avoiding obstacles or detecting landmarks in a more real environment like city streets, where the obstacles and/or the users are moving. Third, FB-Finger can help to enhance quality of life for visually impaired persons.

We conducted two further case studies in accordance with the progress of our research. From the first case, we found that FB-Finger, when equipped with an infrared ray sensor, enables users to "feel" the outline of objects in display windows. In a test at a museum, FB-Finger users managed to feel the contour of exhibits contained in glass cases without touching and seeing them, as illustrated in Figure 14.

In the second case study, in order to obtain suggestions regarding the potential for a variety of applications, we conducted a small workshop in which visually impaired participants were asked to use FB-Finger with a light sensor

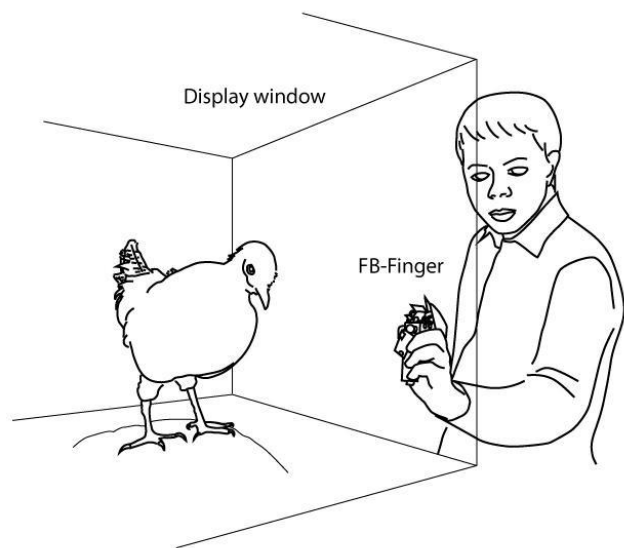


Figure 14. "Feeling" an exhibit in a display window using FB-Finger: A scene from a demonstration in a museum.

unit (see Section III) to “feel” several events, such as a flame of fire, pendulum motion, and a rolling ball, without touching. The results were better than what we expected; visually impaired children as well as visually impaired adults were able to “feel” and recognize a flame, as illustrated in Figure 15, the direction of pendular motion, and an approaching ball. Thereby, we confirmed that FB-Finger can be applied to devices that allow visually impaired users to obtain knowledge of events that are impossible to touch, even though we do not yet have quantitative evidence. In other words, these findings indicate that FB-Finger can facilitate recognition of the surroundings without visual modality.

FB-Finger currently still needs improvements. First, its distance measurement capabilities need to be consistent when nearby objects emit infrared rays.

Second, though the sensors have a theoretically high resolution in daily use, the actual resolution of our device is lower for a few reasons. These reasons include a servo motor’s control noise (small vibrations even in stable condition), analog-to-digital converter’s noise, and quantization error. In real situations, we expect that a user will move around his/her hand holding the FB-Finger to perceive the distance of surrounding objects and their direction, so that such activities enhance the perceptual resolution of our device such as “active touch” [27]. We will continue to improve FB-Finger to eliminate factors that disrupt the device’s resolution. We will finally improve FB-Finger so that it can convey information for various textures of objects.

Third, the sensor needs to be replaceable between infrared rays and ultrasonic waves, so that users can use an appropriate sensor depending on the scenario. In order to

allow the use of more than two sensors, there are some alternative methods. One is to let the user manually select an individual sensor, and the other is to select or integrate a sensor automatically, which is called “sensor fusion.” We hypothesize that the manual switching has an advantage in normal use, because humans are smarter and more flexible as compared to artificial intelligence, and can adjust to complex and various environments. Consequently, users will be able to handle FB-Finger effectively. In one of our future works, we will develop two versions of FB-finger: one with manual sensor switching, and the other with “sensor fusion,” in order to compare their usability.

Fourth, the distance sensors need to be applicable to both Short and Long Range scenarios to allow for measurement of more expansive locations.

Fifth, we will take the output interface into account. It should be possible to have another method of conveying distance information via somatosensation, besides finger joints motion. A laparoscopic surgery simulator with the haptic device, employing force sense feedback, has been commercially available recently [28]. This product ensures that force sense can be used for the feedback interface. In the further improvement of our device, we will consider multiple somatosensory feedback interfaces by adding force sense to lever angular motion.

FB-Finger2 was developed to capitalize on the movements of finger joints for more accurate distance estimation, but it also needs to be improved. The prototype system is too large to be portable. Consequently, it is necessary to downsize it to a size similar to that of FB-Finger. Moreover, in order to obtain information on surrounding objects or their textures, Microsoft Kinect should be used effectively. Zöllner et al. recently developed Mobile Navigational Aid for visually impaired persons based on Microsoft Kinect [29]. This Aid system uses two cameras of a Kinect separately. An RGB camera is used in “micro navigation,” and a depth camera is used in “macro navigation.” In a similar manner, we will improve FB-Finger2 so that it can be equipped with sensors and information processing system available in Kinect.

To ensure availability, applicability, and ease of use, SSDs and ETAs should be capable of being held in one hand. They should be capable of assisting users with exploration of their surroundings, i.e., detection of distance and direction to nearby objects, accurate perception of the shape of objects, and recognition of events or objects that cannot be physically touched. Such spatial information will help users to avoid collisions with obstacles and to approach objects. FB-Finger encourages visually impaired persons to acquire knowledge about events that they have not experienced before. Additionally, FB-Finger devices should be manageable by anyone, regardless of age or cognitive ability, and they should require little knowledge or skills in understanding the signals emitted by the devices. If a user can easily replace the sensor with a different one, FB-Finger can respond to demands under various situations. On realizing this improvement, we guarantee that users will receive full benefit from our developed device.

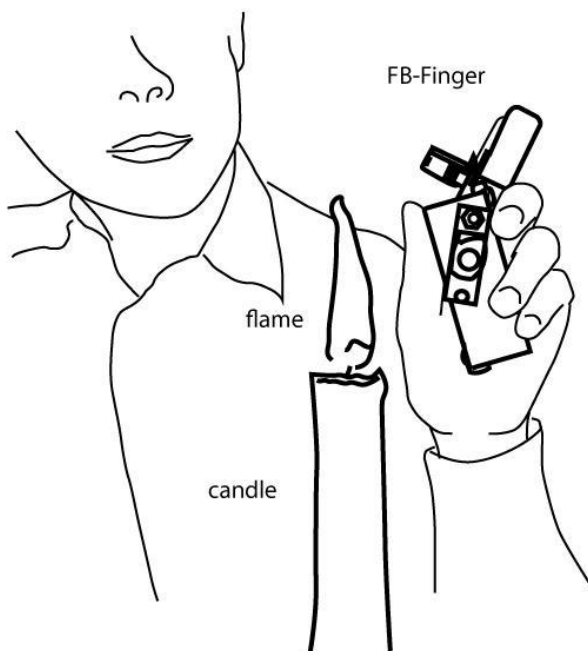


Figure 15. “Feeling” a flame using FB-Finger: A scene from a demonstration in the exhibition in 2013.

In this study, we verified that FB-Finger can fulfill the requirements of visually impaired people. To enhance the usability of FB-Finger or FB-Finger2, we will continue experimental studies, analyze the results, make necessary improvements, and enhance the performance in traveling and exploring environments. The device presented in this paper is functionally promising and we expect to make the device function as a part of the body for both visually impaired and sighted people to develop their potential capabilities. If this idea of "Extended Body" is realized, our device can assist users in improving the quality of life.

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