eTELEMED 2012

The Fourth International Conference on eHealth, Telemedicine, and Social Medicine

ISBN: 978-1-61208-179-3

January 30- February 4, 2012

Valencia, Spain

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eTELEMED 2012

Forward

The fourth edition of The International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED 2012), held in Valencia, Spain, on January 30th – February 4th, 2012, considered advances in techniques, services, and applications dedicated to a global approach of eHealth.

Development of wireless homecare, of special types of communications with patient data, of videoconferencing and telepresence, and the progress in image processing and date protection increased the eHealth applications and services, and extended Internet-based patient coverage areas. Social and economic aspects as well as the integration of classical systems with the telemedicine systems are still challenging issues.

eTELEMED 2012 provided a forum where researchers were able to present recent research results and new research problems and directions related to them. The topics covered aspects from classical medicine and eHealth integration, systems and communication, devices, and applications.

We take this opportunity to thank all the members of the eTELEMED 2012 Technical Program Committee as well as the numerous reviewers. The creation of such a broad and high-quality conference program would not have been possible without their involvement. We also kindly thank all the authors who dedicated much of their time and efforts to contribute to the eTELEMED 2012. We truly believe that, thanks to all these efforts, the final conference program consists of top quality contributions.

This event could also not have been a reality without the support of many individuals, organizations, and sponsors. We are grateful to the members of the eTELEMED 2012 organizing committee for their help in handling the logistics and for their work to make this professional meeting a success.

We hope that eTELEMED 2012 was a successful international forum for the exchange of ideas and results between academia and industry and for the promotion of progress in eHealth and Telemedicine research.

We also hope the attendees enjoyed the beautiful surroundings of Valencia, Spain.

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Multicenter Support Network for CPAP Therapy Follow-up in Sleep Apnea

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Abstract— **Despite its fast penetration into many fields, the application of information and communication technologies in clinical practice is still limited, especially in respiratory medicine. The availability of tools such as the Internet has grown rapidly but it is rarely considered as an option for management of the Obstructive Sleep Apnea Syndrome (OSAS). We developed a novel multicenter support system for the follow-up of continuous positive airway pressure (CPAP) therapy in patients with OSAS. The system essentially consists of a support network that allows several sleep centers to perform online monitoring of their patients, whose data are stored in a secure central server. Patients interact with the system through a web-based interface that can be accessed from their home personal computer or tablets. By visiting the website, patients can answer a weekly questionnaire about their status and therapy, with access to continuously updated temporal trends in a graphic format. The system also provides easy communication with sleep center staff by e-mail and videoconference. After the development phase, the system has started to be put into operation. The positive preliminary results obtained show the potential usefulness of the Internet as a tool for supporting home monitoring of CPAP treatment in OSAS.**

Keywords-eHealth; Obstructive Sleep Apnea; CPAP; telemedicine; home monitoring.

I. INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is a serious disorder caused by partial or complete obstruction of the upper airway and it is associated with deterioration of quality of life, daytime sleepiness, neurocognitive impairment and cardiovascular disease [1]. OSAS is estimated to affect 2–4% of adult men and 1–2% of adult women in Western countries [2][3]. OSAS is strongly related to obesity even though it is also increasingly identified in non-obese subjects with a particular craniofacial structure. The incidence of OSAS is likely to grow in parallel with the spread of obesity now occurring in many countries. European and Spanish public health resources assigned to this problem have proved to be relatively inadequate and unlikely to handle the increase in OSAS cases [4], so cheaper and alternative management approaches are needed.

The most frequently used treatment for OSAS is continuous positive airway pressure (CPAP) applied through a mask to the nose or the mouth of the patient at home during sleep. This pressure in the mask is transmitted to the pharyngeal area, thereby avoiding upper airway obstruction. One critical factor in CPAP effectiveness is compliance. A minimum of 4 hours per night of CPAP use is recommended to avoid compromising outcomes. However, a number of patients suspend or underuse CPAP treatment, mainly due to the numerous side effects and lack of knowledge about possible solutions [5][6]. Some of these side effects could be easily solved by a close follow-up, especially during the first weeks, but busy sleep centers have difficulties in giving such support [7]. Accordingly, there is a clear need to improve patients' understanding of the expected advantages of CPAP use and to monitor and properly address side effects of CPAP therapy, as well as facilitate the communication of patients with sleep centers.

 ISBN: 978-1-61208-179-3

It has recently been recognized that telemedicine could have a valuable role in improving CPAP adherence and should be integrated into OSAS patients' care as fast as possible [8]. It has been shown that simple telemedicine interventions, such as weekly phone calls to clarify doubts and encourage CPAP use, can markedly improve compliance [9]. A randomized clinical trial showed that the use of a telephone-linked communication system providing feedback and counseling to OSAS patients at home improved CPAP adherence, patients' functional status and reduced depressive symptoms [6]. Furthermore, another previous study employed an Internet-based informational support service for problems experienced with CPAP use [10]. Despite the organizational limitations and poor differences between intervention and control group follow-up, they obtained good patients' acceptance of this monitoring approach. It is also remarkable that telehealth interventions, such as televisits, have been found to improve CPAP adherence in a small group of nonadherent patients versus a placebo-controlled group [11]. The cost of the interventions, including the telehealth monitor, home installation and telephone charges, was lower than the same number of presential visits. Nevertheless, larger studies are needed to generalize any conclusion.

Under the framework of an Investigation Project promoted by the Spanish Society of Pneumology and Thoracic Surgery (SEPAR) on sleep-related respiratory disorders, we developed a multicenter support system for the follow-up of CPAP therapy in OSAS patients. This system essentially comprises a support network that can be connected with several sleep centers to monitor and communicate online with their patients, whose data are stored in a secure central server. Patients interact with the system through a user-friendly web-based interface that can be accessed from their home personal computer or tablet. Moreover, videoconferencing is available to promote long-distance communication with the sleep center and provide non-presential visits.

This telemedicine application seeks to introduce a new approach to CPAP therapy monitoring, which focuses on enhancing patients' motivation and self-management skills and strengthening the professional-patient relationship, in order to improve CPAP compliance and reduce presential clinical visits.

In this paper, the telemedicine support system is described in detail and preliminary results of the practical application phase on OSAS patients are shown.

II. SYSTEM OVERVIEW AND FUNCTIONALITIES

The system was implemented using PHP language and all the user interface components were developed as dynamic server-side pages. In order to enforce completion and internal consistency of all the forms and surveys contained in the web application, Javascript components were employed. The system was developed with a focus on usability and structural simplicity. During each development stage, special effort was made to guarantee the maintainability and versatility of the tool. The system architecture was designed to allow frequent updating of the individual modules and easy adaptability to different clinical requirements. The web application functioning was successfully tested with the most important operating systems (Windows XP, Windows Vista, Windows 7, Mac OS X) and web browsers (Internet Explorer 6 and later versions, Mozilla Firefox, Google Chrome, Opera and Safari).

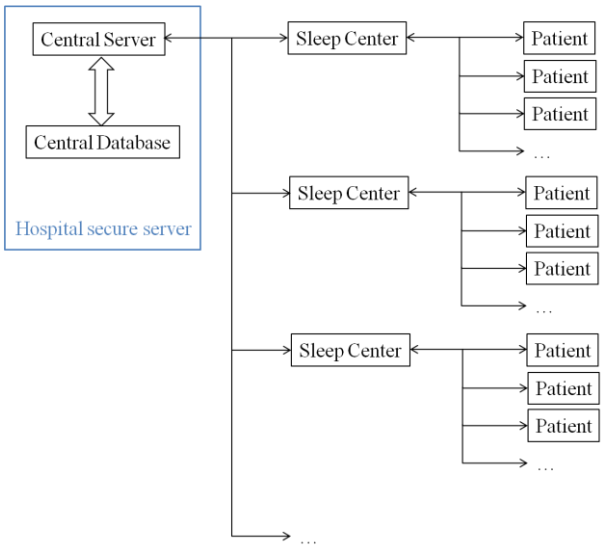

Figure 1. Network overview.

The system overview is shown in Figure 1. The main actors of this structure are: the patient, the Sleep Center and the Central Server.

A. *Patient interface to the system*

Patients included in the project are given access to an Internet-based application implemented as an interactive website. The equipment needed is nothing more than an Internet-connected computer or tablet, a microphone and a webcam. In order to ensure the confidentiality and preserve security, patients can access the website by logging in with their personal username and password, assigned during the enrollment. The system identifies the user by comparing inserted credentials to the ones stored in the Central Server and dynamically generates pages containing only the information available to each user. After logging in, patients are redirected to the website Home Page. The menu bar contains the links to the different sections of the website.

- The "Questionnaire" button in the menu bar of the website redirects patients to a short questionnaire they are asked to answer once a week. The questionnaire is composed of 6 questions about patients' weight, the amount and kind of physical activity they have done over the week, the time they have slept and used the CPAP device, the occurrence of sleepiness in daytime and problems caused by the use of the CPAP device. In order to ensure patients' compliance with the weekly questionnaire, an e-mail reminder is sent automatically to each patient once a week.

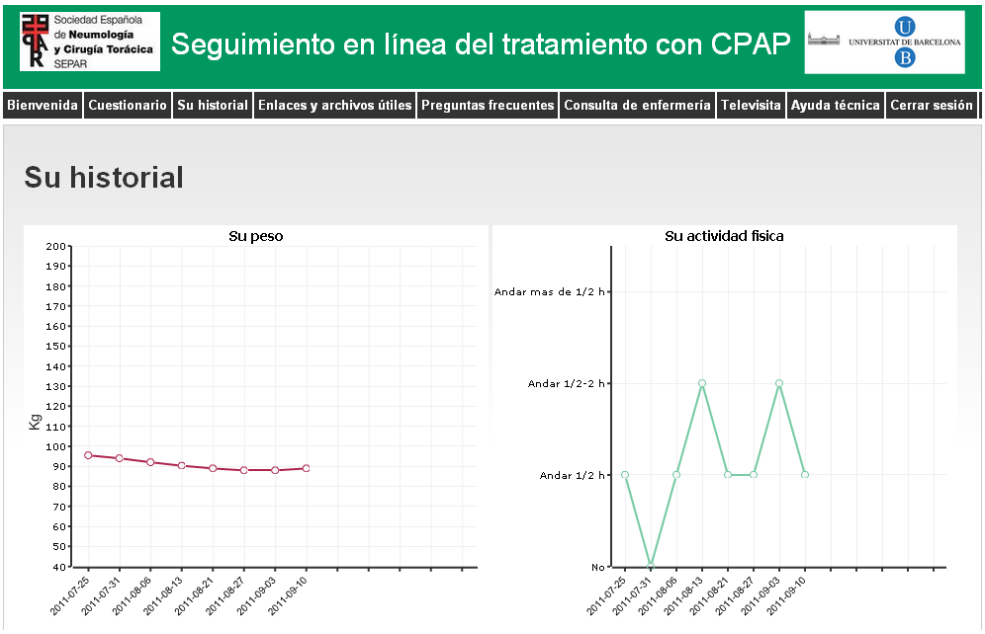

Figure 2. Screenshot of the "You record" page. Two of the six charts are shown here. Translation from original version in Spanish: *Header:* "Online follow-up of CPAP therapy". *Top menu-bar:* "Questionnaire", "You record", "Useful files and links", "Frequently asked questions", "Contact the sleep staff", "Televisit", "Technical support", "Log out". *Content:*"Your weight", "Your physical activity".

- In the "Your record" section, the patient's parameters, which correspond to the weekly questionnaire answers, are plotted in dynamic Flash charts and continuously updated. This section was created in order to give patients a visual feedback of their answers to the weekly questionnaire (Figure 2).
- In the "Useful files and links" section, high-quality informative documents about OSAS management and CPAP therapy are available for free download. Moreover, a list of links to the official websites of the most relevant OSAS patients associations is also provided. Educational videos that train patients in the correct use of the CPAP device and mask are accessible in this section.
- A validated list of answers to "Frequently asked questions" elaborated by sleep specialists is available.
- By clicking on the "Contact the center staff" button, the patients can easily communicate online with the sleep center staff by exchanging messages via e-mail to discuss doubts and ask questions regarding OSAS and CPAP therapy.
- In addition, the "Televisit" button gives patients access to an interesting function of the system which allows them to talk to the sleep center staff by videoconferencing. For this purpose, the LinkCare Videoconference Module was integrated into the system [12]. Videoconferences are scheduled by the sleep center staff and patients automatically receive a confirmation e-mail containing the day and time of the appointment. When a videoconference is undertaken, a new browser window opens, containing the videoconference client. The user enters the videoconference client application according to his/her user role in the system (professional or patient). Patients enter the videoconference application as simple participants and they are unable to activate or deactivate their webcam and microphone. This tool allows patients to see the healthcare professionals and receive teaching and support regarding their therapy.
- The application also provides continuous technical support. By visiting the section "Technical support", patients can directly contact the Webmaster, who is available to solve potential technical problems about the website functioning.

B. *Sleep center*

Several sleep centers can connect simultaneously to the support system. The healthcare professionals from each center can undertake the following management activities:

- Patients' status monitoring. Each center can access only the list of its own patients. The sleep center staff can observe patients' data, corresponding to their answers to the weekly questionnaire. Data are retrieved from a MySQL database connected to the Central Server and shown in dynamic Flash charts. After evaluating the patients' data, if necessary, professionals can write them a message with advice and comments about their status.
- New patient registration. The sleep center staff has to fill in a simple registration form inserting the identification data of each patient, such as the electronic health record (EHR) number, name initials and a contact e-mail address. To protect patients' personal information, their

 ISBN: 978-1-61208-179-3

name and surname are not included in the registration form. In addition, some initial medical data are requested, such as weight, height, apnea-hypopnea index (AHI), cumulative time with oxygen saturation less than 90% (CT90), etc. Once the registration is completed, a "welcome" e-mail is sent to the patients' contact e-mail address with the credentials needed for authentication by the website. The username is the contact e-mail address and the password is automatically assigned, with the possibility of changing it at any time. If necessary, professionals can also deregister a patient and prevent his/her access to the website.

- E-mailing and videoconferencing. Besides e-mail communication, sleep center staff can easily arrange a videoconference meeting with patients via a simple management interface that communicates with the LinkCare Videoconference Module. By filling in a short form, professionals schedule the videoconference for a time suited to both them and their patients. Professionals enter the videoconference application as coordinators, allowing them to activate or deactivate the webcam and the microphone of the different participants of the meeting.

C. Central Server

All network data, such as the patients' answers and authentication data, are stored in the system Central Server. Data storing is supported by a relational database developed with the MySQL management system, which is incorporated into the secure environment of the "Hospital Clinic" of Barcelona server. The central server administrator is responsible for all data management and system functioning supervision. Moreover, the administrator is in charge of the registration in the network of the sleep centers included in the project.

III. PRELIMINARY RESULTS

Once the development phase was finished, the system's practical application phase began. The support system is already operating in the main center for the project, the "Hospital Clinic" of Barcelona.

So far, the group of patients included has been selected from consecutive patients coming to the "Hospital Clinic" sleep center for a routine CPAP therapy monitoring visit. At the end of the visit, the nurse in charge of the patients proposed the enrolment in the study. The patients who declared they had good computer-Internet skills and were available to participate in the study were included. The sleep center staff took note of the patients' personal data and e-mail addresses. After being recruited, patients received a first e-mail containing information about the study and the personal credentials required to access the web interface. In order to ensure patients' compliance with the weekly questionnaire, an e-mail reminder was sent automatically to each patient once a week. Moreover, after the third completion of the weekly questionnaire a more personalized e-mail was sent in order to thank them for their collaboration and to encourage them to keep answering the questionnaire. At the end of the monitoring period, participants were invited to express their satisfaction about the website by answering an online questionnaire (Table 1). This questionnaire was developed from the Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ), a 5-point Likert questionnaire designed as part of the telemedicine project IDEATel and validated in English and Spanish [13].

Of a total of 163 consecutive patients from the Sleep Clinic, 66 reported basic knowledge of the Internet and agreed to participate. After 12 weeks of monitoring, the participation rate was high (82%). Thirty-five patients responded to the online satisfaction survey and the results are presented in Figure 3. Patients showed a level of agreement to the statement "Overall, I am satisfied with the web service" of 4.3 ± 0.58 points (mean ± SD, 1 = I strongly disagree, 5 = I strongly agree) and expressed their potential interest in participating in a long-term web-based monitoring.

IV. CONCLUSION

The multicenter support system we have developed represents a novel telemedicine approach to CPAP therapy follow-up in OSAS, where the main objective is patients' confidence and improved therapy adherence. The availability of easy communication tools with the sleep center staff can help patients to rapidly solve problems related to CPAP use

TABLE I. PATIENTS' SATISFACTION SURVEY

	Survey statement
1.	In general, I am satisfied with the CPAP follow-up web service.
2.	The CPAP follow-up web service has helped me to better manage my health and medical needs.
3.	I follow my doctor's advice better since working with the CPAP follow-up web service.
4.	The CPAP follow-up web service has been easy to use.
5.	The weekly questionnaire of the CPAP follow-up web service has been easy to fill.
6.	In the future I would like to use the CPAP follow-up web service as part of my treatment control.
7.	In the future I would like to receive comments from my doctor about my weekly questionnaire answers.
8.	In the future I would like my doctor use information from the CPAP follow-up web service for my medical visits.
9.	Files and information links about sleep apnea and CPAP therapy available on the website have been useful.
10.	The ability to review the progress of my parameters on the "Your record" page has been useful.

 ISBN: 978-1-61208-179-3

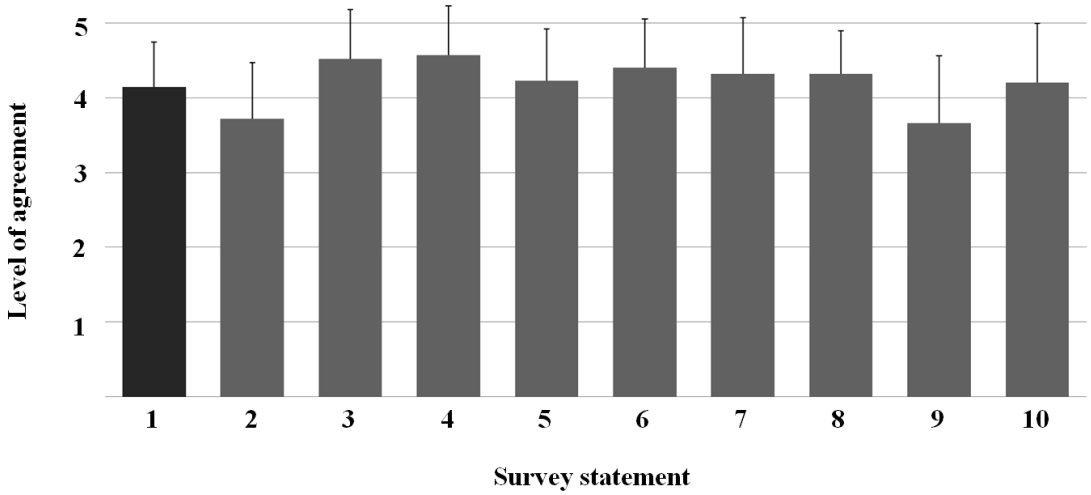

Figure 3. Results of patients' satisfaction survey (mean ± SD) where 1 means "I strongly disagree" and 5 means "I strongly agree". Survey statements are in Table I.

and consequently increase their satisfaction with community service. This system application can be particularly interesting for the management of difficult-to-treat patients, because they do not adapt easily to CPAP, and of special populations. Moreover, the possibility of carrying out non-presential visits via videoconference represents a valuable opportunity to release sleep clinics from a considerable amount of support interventions and extra visits, thereby enhancing the cost-effectiveness of CPAP therapy.

It is remarkable that this system can be readily applicable thanks to the widespread availability of Internet-connected home computers or tablets in the population [14].

ACKNOWLEDGMENT

The Spanish Society of Pneumology and Thoracic Surgery (SEPAR) and NEXES (CIP-ICT-PSP-2007-225025) partially supported this project. The authors wish to thank Esteve-Teijin for financial support for the clinical implementation of this telemedicine application.

REFERENCES

[1] Consenso Nacional sobre el síndrome de apneas-hipopneas del sueño Arch Bronconeumol 2005; 41(Supl.4):3-110.

[2] Gibson G.J. Obstructive sleep apnoea syndrome: underestimated and undertreated. Br Med Bull 2004; 72:49-65.

[3] Young T., Peppard P.E., and Gottlieb D.J. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med 2002; 165(9):1217-1239.

[4] Duran-Cantolla J., Mar J., de La Torre M.G., Rubio A.R., and Guerra L. [The availability in Spanish public hospitals of resources for diagnosing and treating sleep apnea-hypopnea syndrome]. Arch Bronconeumol 2004; 40(6):259-267.

[5] Rolfe I., Olson L.G., and Saunders N.A.. Long-term acceptance of continuous positive airway pressure in obstructive sleep apnea. Am Rev Respir Dis 1991; 144(5):1130-1133.

[6] Sparrow D., Aloia M., Demolles D.A., and Gottlieb D.J. A telemedicine intervention to improve adherence to continuous positive airway pressure: a randomised controlled trial. Thorax 2010; 65(12):1061-1066.

[7] Santamaria J., Iranzo A., Ma M.J., and de Pablo J. Persistent sleepiness in CPAP treated obstructive sleep apnea patients: evaluation and treatment. Sleep Med Rev 2007; 11(3):195-207.

[8] Kwiatkowska M. and Ayas N. Can telemedicine improve CPAP adherence? Thorax 2010; 65(12):1035-1036.

[9] Chervin R.D., Theut S., Bassetti C., and Aldrich M.S. Compliance with nasal CPAP can be improved by simple interventions. Sleep 1997; 20(4):284-289.

[10] Taylor Y., Eliasson A., Andrada T., Kristo D., and Howard R. The role of telemedicine in CPAP compliance for patients with obstructive sleep apnea syndrome. Sleep Breath 2006; 10(3):132-138.

[11] Smith C.E., Dauz E.R., Clements F., Puno F.N., Cook D., Doolittle G., and Leeds W. Telehealth services to improve nonadherence: A placebo-controlled study. Telemed J E Health 2006; 12(3):289-296.

[12] LinkCare. http://www.linkcarehs.es. 2011. (last access: November 2011)

[13] Bakken S., Grullon-Figueroa L., Izquierdo R., Lee N.J., Morin P., Palmas W., Teresi J., Weinstock R.S., Shea S., and Starren J. Development, validation, and use of English and Spanish versions of the telemedicine satisfaction and usefulness questionnaire. J Am Med Inform Assoc 2006; 13(6):660-667.

[14] Spanish Observatory for Telecommunications and the Information Society (ONTSI). The Networked Society 2009 Annual Report. 2010 Edition. 2010.

 ISBN: 978-1-61208-179-3

Human Centered Development of a Web-based Intervention for the Prevention of Depression

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***Abstract*—Web-based preventive interventions have shown to be effective for the prevention of depression, but high rates of non-use and drop-out, less than optimal implementation in the care organization and low acceptance rates cause interventions to be less effective in practice than in theory and research. The lack of a holistic overview where the human and technological context is given a prominent place, seems to be one of the main reasons for this less than optimal effectiveness. This study employs methods based on the holistic approach of the CeHRes roadmap to create a viable web-based intervention and to investigate the suitability of the chosen methods and the pitfalls that can be encountered. The study shows that it is possible to create a viable web-based intervention by including different stakeholders (users, designers, programmers, researchers) in different phases of the development process. The employed methods are suitable and yield complementary results, but made our approach more user and expert driven than fully stakeholder driven. Furthermore, our project team was organized with the researcher as the central hub. Although this worked well most of the time, we propose a more ideal organizational structure in which a formal project leader, who can be a researcher, has a mandate to make decisions and resources to be involved in all steps of the process.**

Keywords-Human Centered Development; Web-based Application; eHealth; Holistic; Design; Depression.

I. INTRODUCTION

To reduce the large public health burden of the high prevalence of depression, early interventions targeted at people at risk are essential and can be cost-effective [1, 2]. However, recruiting participants for interventions to prevent the onset of depressive disorders is quite a challenge [3]. Developing and implementing web-based preventive interventions might provide an opportunity to overcome this challenge [3, 4]. Advantages of web-based interventions can be seen not only in the broader reach, but also in increasing convenience for the users, the opportunity to provide information in an interactive and timely manner and cost-effectiveness [5-7]. Meta-analyses show that these interventions, on average, do have a positive influence on the severity of the complaints [8, 9]. Nonetheless, there are drawbacks of online interventions. High rates of non-use and drop-out, less than optimal implementation in the care organization and low acceptance rates cause interventions to be less effective in practice than in theory and research [10-13].

Many studies are done to investigate the effect of a web-based intervention solely on clinical outcomes, without attention for the organizational and technical context [13]. Especially the technology is seen as a given, only the effect can be subject to research. In development, this leads to a technology push: technology is developed because of the technological possibility, not because the target group needs the technology. The lack of a holistic overview where the human and technological context is given a prominent place, seems to be one of the main reasons that web-based interventions do not reach their full potential [13-15].

Recently, other approaches that take into account the context of the developed technology are gaining ground in the development of web-based interventions. Human centered design, which advocates the systematic, continuous consultation of potential users during the whole design process, is one of these approaches [16] and has been shown to have a positive effect especially on user satisfaction and fitting to user needs [17]. User satisfaction can be seen as an aspect of usability, which has been defined as: 'The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use' [18]. Fitting to needs of the users can be seen as an increased perceived usefulness of an application [19]. To ensure that these positive effects can be achieved, certain pitfalls should be avoided or dealt with in an appropriate manner. Common pitfalls that have been identified are: losing the focus on the user [20, 21]; a middle-of-the-road design [14, 22]; an uninvolved project leader [23].

 ISBN: 978-1-61208-179-3

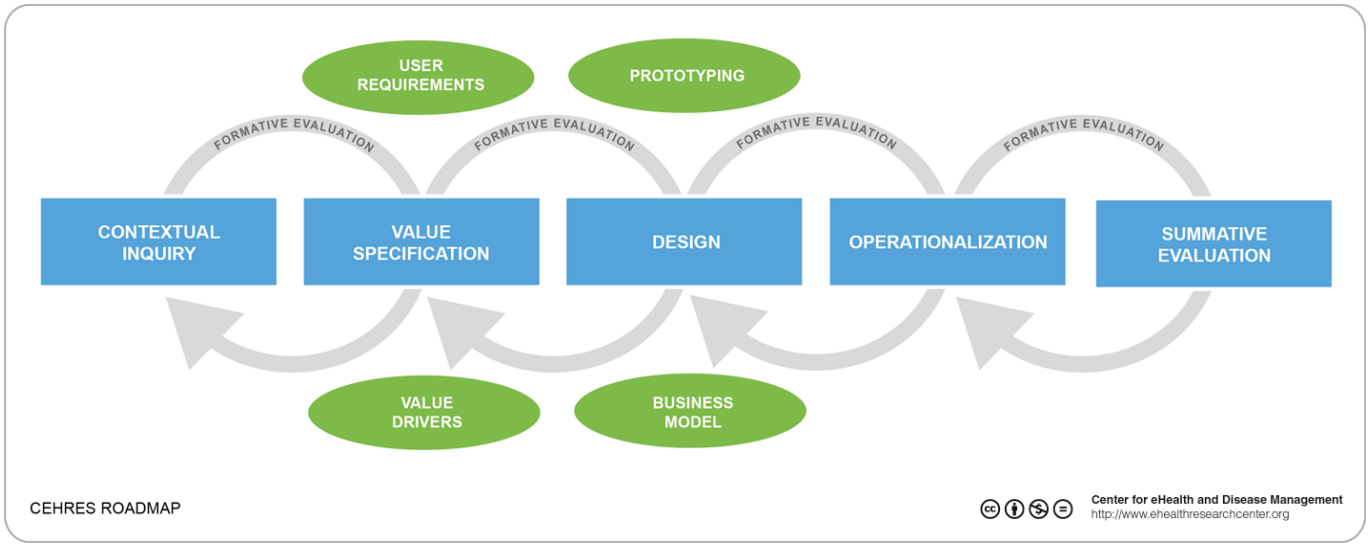

Figure 1. CeHRes roadmap

Another approach that is gaining ground in eHealth development is business modeling, which focuses on creating an optimal fit between the technology that is being developed and the organizational resources and capabilities to create a sustainable technology [24]. A framework that combines both approaches is the CeHRes (center for eHealth research) roadmap [15]. The roadmap with five main phases in the development process is shown in figure 1. The combination of human centered design and business modeling in this framework might provide a means to help achieve the full potential of a web-based intervention for the prevention of depression.

In this paper, we describe a study into the development of a web-based intervention for the prevention of depression, employing methods from the CeHRes roadmap. The goal of the study is twofold. The first goal is to create a viable web-based intervention, that is attuned to the needs and wishes of the end-users and fits the organizational context for which it will be developed. The accompanying research question is: What usability and usefulness issues are detected by employing a human centered design process? The second goal is aimed at the process: We aim to investigate the suitability of the chosen methods, the pitfalls we encounter and ways to cope with these pitfalls. The accompanying research questions are: How suitable are the employed methods? What pitfalls are encountered en what lessons can be learned from this?

The significance of the first aim of the study is obvious for the application being developed, but additionally, when developing similar web-based applications, the results can be used as a vantage point. The significance of the second aim is much broader. New web-based applications are developed at a startling rate, but there is no scientifically underpinned agreement on how to best develop these applications [14] (for example of an ad hoc development see [25]). The results of this study will provide a starting point for future development of web-based interventions.

II. METHODS

A. *Content of the Intervention*

The web-based intervention for the prevention of depression developed during this study is called 'Living to the full'. This intervention is based on acceptance and commitment therapy (ACT) and targets experiental avoidance that can be considered as a generic risk factor for mental illnesses [26]. The intervention as a group format and as a guided self-help format with email support by a counselor have both shown to be effective in reducing depressive symptoms [27-29]. The content of the web-based intervention has been adapted from the self-help book 'Living to the full' [30].

B. *Value Specification*

In this phase of the CeHRes roadmap it is determined which values the different stakeholders deem important. These values and prospective users' needs and wishes need to be translated into functional and organizational requirements. For this study we have chosen to employ interviews, rapid prototyping and a feedback session (Table I) to assess the needs and values of the target group and to translate them into requirements for the application. Interviews and rapid prototyping were conducted with prospective end-users, i.e., people with mild depressive symptoms who are willing to participate in a preventive intervention. The feedback session to translate the needs and values of this target group into requirements was conducted with researchers, designers and programmers.

1) *Interviews and Rapid Prototyping*

Semi-structured interviews were performed to identify the needs and requirements of the target group and the usefulness of various possible functionalities of the system. The interviews were combined with rapid prototyping [31]. In total, 18 interviews were conducted. The interview participants were recruited from a previous study into the

effectiveness of 'Living to the full' as a guided self-help format with e-mail support [28]. Our participants were not able to participate in that study because of an overwhelming number of responses, but were willing to participate in our study. All participants received a gift voucher for their participation. Prior to the interview, the interviewer explained the goal and process of the interview, obtained permission to audio record the interview and each interviewee signed an informed consent. A typical interview lasted about 45 minutes.

TABLE I. OVERVIEW OF RESEARCH ACTIVITIES AND INSTRUMENTS

Research phase	Research activity	Research method
Value specification	Assessment of needs and values of target group.	Interviews & Rapid prototyping
	Translation of needs and values in requirements.	Feedback session (researchers, designers & programmers)
Design	Usability assessment by target group.	Usability testing
	Usability assessment by experts.	Cognitive Walkthrough
	Prioritizing points for improvement.	Feedback session (researchers, designers & programmers)

The interview scheme was based upon eHealth and Human Centered Design literature [15, 21, 31, 32] and consisted of three parts. Part 1 focused on previous experience with the content of the intervention (ACT) and with web-based interventions in general. Furthermore, the needs and requirements were discussed by asking three cruxes that the web-based intervention has to satisfy and one thing that would be a reason to quit (or not start) the intervention. Rapid prototyping was part 2 of the interview and focused on the usefulness of three parts that were available as a paper prototype, i.e., text message coaching, online diary and feedback. Part three assessed demographics, such as age, education and internet experience.

The interviews were not transcribed, but were analyzed within 48 hours after the interview had taken place, according to the guideline of Holtzblatt [33]. We used a thematic analysis to identify patterns in the responses [34]. Part 1 was analyzed by translating the cruxes and reasons to quit into needs and values. Part 2 was analyzed by counting the number of respondents who would and would not like to use the different features. Further information was coded using a thematic analysis. All analyses were done by two independent coders.

2) Feedback session

The results of the interviews and rapid prototyping were communicated to the designers and programmers by means of a report written by the researchers. This report was presented and discussed with the development team of the web-based application to translate the needs and values into requirements. The researchers specified the most important needs and values and the development team used their expertise to implement these requirements into the prototype of the application.

C. Design

In this phase of the roadmap, (a prototypical version of) the technology is developed, based on the requirements. The framework advocates the application of cooperative design in which the design team creates the technology with prospective users and stakeholders together. For this study we have chosen to employ think aloud usability testing with the target group and a cognitive walkthrough with experts (Table 1) to assess the usability and usefulness of the web-based application.

1) Usability testing

Usability testing was used to assess the usability of the application by the target group. We employed a scenario-based think aloud protocol [35], i.e., respondents were guided through the application by means of scenarios that pose a problem or task that might be solved or completed by using the program and respondents were instructed to verbalize their thoughts during the whole process of the test. We conducted 10 usability tests. Participants were recruited using online advertisements and were part of the target group of the web-based intervention. All participants received a gift voucher for their participation. All usability tests were recorded and coded retrospectively. The material (audio and video) was reviewed and issues were identified by the researcher. Verbal comments as well as actions taken by the respondents could be coded as issues. These issues were analyzed using a coding scheme based upon the subconstructs of the ISO definition of usability [18] following the work of Hornbaek et al. [36].

2) Cognitive Walkthrough

The cognitive walkthrough method was used to assess the usability of the application by experts. This method was used in addition to usability testing by the target group to gain a broader overview of the usability of the application [35]. Eight experts of the University of Twente conducted the cognitive walkthrough. Issues were coded using the same coding scheme as used for the usability testing.

3) Feedback session

The results of the usability testing and cognitive walkthrough were communicated to the designers and programmers by means of a report written by the researchers. This report was presented and discussed with the development team of the web-based application to prioritize the points for improvement.

III. RESULTS

A. Value Specification

The mean age of the 18 respondents was 45 years (sd = 10), 78% (n = 14) was female and 78% (n = 14) has completed at least higher vocational education. The needs an values that arose from the interviews are presented in Table II.

67% (n = 12) respondents indicated that they would use text message coaching. 11% (n = 2) would not use this feature and for the remaining 22% (n = 4) using this feature depends on the content of the text messages. Reminders (n = 11) are seen as the most useful content for the text messages,

 ISBN: 978-1-61208-179-3

although assignments (n = 6) and motivation (n = 4) are also seen as useful content.

The possibility of an online diary was received with mixed reactions. 44% (n = 8) would definitely use it and thought of it as a pleasant addition. However 56% (n = 10) would only use the diary when it is part of an assignment in the course.

TABLE II. NEEDS AND VALUES

Needs and values	**n**
Functional design application	12
Feedback/contact with counselor	8
Added value of content	8
Flexible schedule of doing the course	6
Contact with others using the application	6
Attractive application	5
Fixed endpoint	3
Specific/clear instructions	3
Limited time investment (content and assignments to-the-point)	3
Personal attention	3
Encouragement to complete the course	3
Focus on 'real-world' of the users	1

All respondents indicated that feedback would be useful and even essential. Feedback is expected on assignments, but it can also be useful for gaining new insights, support and motivation. Several respondents (n = 5) stress the importance of the feedback being personal.

Based on the results of the interviews and rapid prototyping, a report with recommendations was written by the researchers and communicated with the design team. The recommendations were prioritized and an action plan was agreed on.

B. Design

The mean age of the 10 participants of the usability test was 38 years (sd = 11), 90% (n = 9) was female and 70 % (n = 7) has completed at least higher vocational education. The 8 participants of the cognitive walkthrough can be categorized as usability experts (n = 7) and target group experts (n = 1) [33]. In total, both methods yielded 476 issues, virtually equally distributed between the usability testing and cognitive walkthrough (respectively 52% (n = 242) and 48% (n = 225)). Table III shows the distribution of the issues over the subconstructs of usability and the amount of positive (+), neutral (+/-) and negative issues.

TABLE III. ISSUES DESIGN PHASE

	Usability testing				**Cognitive Walkthrough**				**total**
	+	+/-	-	total	+	+/-	-	total	
Effectiveness	12	3	76	91	0	0	85	85	176
Efficientcy	20	3	31	54	0	0	1	1	55
Satisfaction	45	5	47	97	29	3	107	139	236
Total	77	11	154	242	29	3	193	225	467

Issues ranged from the functioning of features (e.g., respondent cannot adjust the volume of the player of the mindfulness exercise; usability test, respondent 6); to layout (I like the colours, usability test, respondent 11); and to the lack of options (The mindfulness exercise should have the option to download the exercise as mp3-file; cognitive walkthrough, respondent 6). As can be seen in Table III there were differences in the sort of issues both methods detected. Usability testing yielded more positive issues and the issues were more evenly divided over the subconstructs. The cognitive walkthrough yielded only 1 issue in efficiency and most issues were found in satisfaction.

Based on these 467 issues, 109 unique points for improvement were formulated. Of these points, 38 came forward in both methods, 19 were uniquely based on the usability testing and 52 were uniquely based on the cognitive walkthrough.

The 109 points for improvement were communicated to the design team, by means of a report in which the improvements were categorized by feature of the application (e.g., signing up; the first lesson). During the feedback session with the researchers, designers and programmers, a prioritization was made, based on the study results and the estimation of the estimated effort (time and money) to implement the points of improvement.

IV. CONCLUSION AND DISCUSSION

A. Application

Our first research question was aimed at identifying usability and usefulness issues by employing a human centered design process. The study has shown that employing the chosen research methods yielded many issues related to the application. Regarding usefulness, our results show that the most important needs and values of the target group are a functional design of the application, feedback or contact with a counselor and the importance of added value of the content of the intervention. Furthermore, we have seen that text message coaching seems a viable feature of the web-based intervention, as long as the content of the text messages serves as a reminder, an assignment or is motivational. An online diary can be useful, under the condition that the diary is embedded in assignments. Moreover, feedback is essential for a web-based intervention for the prevention of depression. Regarding usability, the results yielded over 100 points of improvement on usability aspects of effectiveness, efficiency and satisfaction. Studies have shown the significance of a well attuned intervention to reduce non-use and dropout of an intervention [10-12]. By employing a human centered design process, we feel that we have succeeded in our goal to lay the foundation of a viable web-based intervention, that is attuned to the needs and wishes of the end-users and have thereby increased the expected future adherence to this intervention. However, the second part of our goal was to create an intervention that fits the organizational context for which it will be developed. Due to the methods we have used, our approach was more user and expert driven than fully stakeholder driven. The care professionals and the organizational context, might not have been given the appropriate attention. Nevertheless, the developed intervention seems to be viable for the end-users in their context.

 ISBN: 978-1-61208-179-3

B. Process

The research questions that accompany our second research aim were focused at the suitability of the employed methods, the pitfalls we encountered and the lessons we have learned. The methods used in the value specification phase seem to be suitable. They have yielded valuable information on the needs of the target group and the usefulness of different features. However, according to the CeHRes roadmap [15] and human centered design literature (e.g., [32]), participation of the target group should start before the value specification phase. In this study the researchers and the design team have decided in advance that the target group has a need for the intervention and the chosen mode (web-based). Therefore, other modes (e.g., mobile, devices) have not been considered and the actual *need* for a web-based intervention has not been researched. We feel that, for this topic, there is enough evidence to support the significance for web-based interventions [1-9], but it is important to always assess ones assumptions before trusting them blindly.

For the design phase we used a target group method (usability testing) and an expert method (cognitive walkthrough). Interestingly, the expert method yielded far more unique points of improvement than the target group method. This is in line with the overview of usability methods of Jaspers [35] that states that in a later stage of development expert methods might yield more usability results. An explanation might be that end-users find it harder to separate the content and context from functional characteristics of a system [14]. This might also explain the differences in the distribution of the issues over the subconstructs effectiveness, efficiency and satisfaction. Nevertheless, in line with the CeHRes roadmap, we feel it is important to view the system not as a stand-alone application, but in its context. Therefore, although the target group method did not yield as many unique points for improvement, it is still an important part of the design phase, especially because the end-users do not see the application separate from its context.

In this study, we have made a first step in developing a web-based intervention for the prevention of depression following the CeHRes roadmap. Although we have included different stakeholders (users, designers, programmers, researchers), care professionals and the organization in which the intervention will be implemented have not been involved. This makes it hard to investigate whether the developed intervention fits the organizational context for which it is developed. Including these two important stakeholders in future research might lead to a better organizational fit. In the value specification phase, this could be realized by employing focus group methods and in the design phase by usability testing combined with interviews [15].

In the development process, we have encountered all of the common pitfalls described in the introduction (losing the focus on the user; a middle-of-the-road design; an uninvolved project leader) to a certain degree. Losing the focus on the user was seen most prominently in discussing and prioritizing the points of improvement in the design phase. Time and costs can quickly become more important than the needs and wishes of the users. It would have been better to involve the users in prioritizing the points for improvement. The pitfall of a middle-of-the-road design was also encountered in the design phase when users reacted differently on design ideas. For example, a sentence that was intended to rouse curiosity was found to be provoking for some participants and therefore tuned down. We did not encounter the pitfall of an uninvolved project leader as such, but we did encounter difficulties in the project team and interdisciplinary issues. Our project team consisted of researchers, designers and programmers. There was no formal project leader, instead one of the researchers took this role. The project team was organized with the researcher as the central hub. Although this informal project management worked well most of the time, there were instances where the informal project leader did not have the authority to make certain decisions or the resources to be involved in all aspects of the development process. These issues have led to time delays and confusion. A more ideal organizational structure based on our experiences and literature can be found in figure 2 [14, 23, 32]. In this figure, the project leader might be one of the researchers, provided that adequate resources and has a mandate to make decisions in the development process.

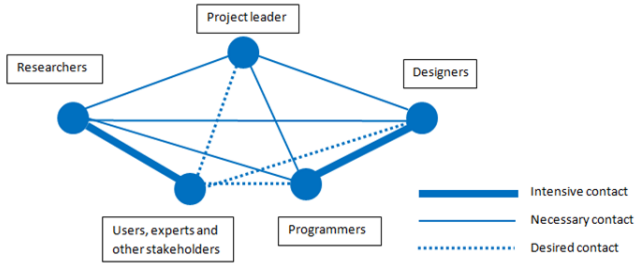

Figure 2. Ideal organizational structure

REFERENCES

[1] Andrews G., Issakidis C., Sanderson K., Corry J., and Lapsley H., "Utilising survey data to inform public policy: comparison of the cost-effectiveness of treatment of ten mental disorders," Br J Psychiatry 2004 Jun;184:526-533.

[2] Cuijpers P., van Straten A., Smit F., Mihalopoulos C., and Beekman A., "Preventing the onset of depressive disorders: a meta-analytic review of psychological interventions," Am J Psychiatry 2008 Oct;165(10):1272-1280.

[3] Cuijpers P., van Straten A., Warmerdam L., and van Rooy M.J., "Recruiting participants for interventions to prevent the onset of depressive disorders: possible ways to increase participation rates," BMC Health Serv Res 2010;10:181.

[4] Postel M.G., de Haan H.A., ter Huurne E.D., Becker E.S., and de Jong C.A., "Effectiveness of a web-based intervention for problem drinkers and reasons for dropout: randomized controlled trial," J Med Internet Res 2010;12(4):e68.

[5] Eysenbach G., "What is e-health?," Journal of Medical Internet Research 2001 Apr-Jun;3(2):E20.

[6] Griffiths F., Lindenmeyer A., Powell J., Lowe P., and Thorogood M., "Why are health care interventions delivered over the Internet? A

 ISBN: 978-1-61208-179-3

systematic review of the published literature," J Med Internet Res 2006;8(2).

[7] Tate D.F., Finkelstein E.A., Khavjou O., and Gustafson A., "Cost effectiveness of internet interventions: review and recommendations," Ann Behav Med 2009 Aug;38(1):40-45.

[8] Andrews G., Cuijpers P., Craske M.G., McEvoy P., and Titov N., "Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: a meta-analysis," PLoS One 2010;5(10):e13196.

[9] Barak A., Hen L., Boniel-Nissim M., and Shapira N.a., "A Comprehensive Review and a Meta-Analysis of the Effectiveness of Internet-Based Psychotherapeutic Interventions," Journal of Technology in Human Services 2008;26(2/4):109-160.

[10] Christensen H., Griffiths K.M., and Farrer L., "Adherence in internet interventions for anxiety and depression," Journal of medical Internet research 2009;11(2):e13.

[11] Eysenbach G., "The law of attrition," Journal of medical Internet research 2005;7(1):e11.

[12] Kelders S.M., Van Gemert-Pijnen J.E., Werkman A., Nijland N., and Seydel E.R., "Effectiveness of a Web-based intervention aimed at healthy dietary and physical activity behavior: a randomized controlled trial about users and usage," Journal of medical Internet research 2011;13(2):e32.

[13] Yusof M.M., Papazafeiropoulou A., Paul R.J., and Stergioulas L.K., "Investigating evaluation frameworks for health information systems," Int J Med Inform 2008 Jun;77(6):377-385.

[14] Pagliari C., "Design and evaluation in eHealth: challenges and implications for an interdisciplinary field," Journal of medical Internet research 2007;9(2):e15.

[15] Van Gemert-Pijnen J.E., Nijland N., Van Limburg M.A.H., et al., "A holistic framework to improve the uptake and impact of eHealth technologies," Journal of Medical Internet Research In press.

[16] Gould J.D. and Lewis C., "Designing for Usability - Key Principles and What Designers Think," Commun Acm 1985;28(3):300-311.

[17] Kujala S., "User involvement: a review of the benefits and challenges," Behaviour & Information Technology 2003;22(1):1.

[18] ISO, "Ergonomic requirements for office work with visual display terminals (VDTs)-Part 11: guidance on usability (ISO 9241-11:1998)," 1998.

[19] Davis F.D., "Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology," Mis Quart 1989 Sep;13(3):319-340.

[20] Carroll J.M. Making use : scenario-based design of human-computer interactions. Cambridge, Mass.: MIT Press; 2000.

[21] Kukafka R., Johnson S.B., Linfante A., and Allegrante J.P., "Grounding a new information technology implementation framework in behavioral science: a systematic analysis of the literature on IT use," J Biomed Inform 2003 Jun;36(3):218-227.

[22] Kreps G.L. and Neuhauser L., "New directions in eHealth communication: opportunities and challenges," Patient Educ Couns 2010 Mar;78(3):329-336.

[23] Göransson B. and Sandbäck T. Usability designers improve the user-centred design process. Paper presented at: INTERACT'991999; Edinburgh.

[24] Spil T. and Kijl B., "E-health Business Models: From pilot project to successful deployment," Innovation and Knowledge Management in Twin Track Economies: Challenges & Solutions, Vols 1-3 2009:437-448.

[25] Stevens V.J., Funk K.L., Brantley P.J., et al., "Design and implementation of an interactive website to support long-term maintenance of weight loss," Journal of medical Internet research 2008;10(1):e1.

[26] Biglan A., Hayes S.C., and Pistorello J., "Acceptance and commitment: Implications for prevention science," Prev Sci 2008 Sep;9(3):139-152.

[27] Bohlmeijer E.T., Fledderus M., Rokx T.A., and Pieterse M.E., "Efficacy of an early intervention based on acceptance and commitment therapy for adults with depressive symptomatology: Evaluation in a randomized controlled trial," Behav Res Ther 2011 Jan;49(1):62-67.

[28] Fledderus M., Bohlmeijer E.T., Pieterse M.E., and Schreurs K.M., "Acceptance and commitment therapy as guided self-help for psychological distress and positive mental health: a randomized controlled trial," Psychol Med 2011 Jul 11:1-11.

[29] Fledderus M., Bohlmeijer E.T., Smit F., and Westerhof G.J., "Mental health promotion as a new goal in public mental health care: a randomized controlled trial of an intervention enhancing psychological flexibility," Am J Public Health 2010 Dec;100(12):2372.

[30] Bohlmeijer E.T. and Hulsbergen M. Voluit Leven. Mindfulness of de kunst van het ervaren, nu als praktisch hulpboek [Living to the full. Mindfulness or the art of acceptance, now as a practical help book]: Boom: Amsterdam; 2008.

[31] Kinzie M.B., Cohn W.F., Julian M.F., and Knaus W.A., "A user-centered model for Web site design: Needs assessment, user interface design, and rapid prototyping," J Am Med Inform Assoc 2002;9(4):320-330.

[32] Gulliksen J., Goransson B., Boivie I., et al., "Key principles for user-centred systems design," Behaviour & Information Technology 2003 Nov-Dec;22(6):397-409.

[33] Holtzblatt K., Wendell J.B., and Wood S. Rapid contextual design: a how-to guide to key techniques for user-centered design: Morgan Kaufmann; 2005.

[34] Braun V. and Clarke V., "Using thematic analysis in psychology," Qualitative research in psychology 2006;3(2):77-101.

[35] Jaspers M.W.M., "A comparison of usability methods for testing interactive health technologies: Methodological aspects and empirical evidence," Int J Med Inform 2009 May;78(5):340-353.

[36] Hornbaek K., "Current practice in measuring usability: Challenges to usability studies and research," Int J Hum-Comput St 2006 Feb;64(2):79-102.

 ISBN: 978-1-61208-179-3

Guiding People with Early Dementia Home with the TalkMeHome Service

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***Abstract*—People suffering from mild dementia may get lost during a walk, which can be dangerous for them and adds to the anxiety felt by their informal caregivers. TalkMeHome is a new service that allows these people to get home safely in such situations using their mobile phone. They can call a remote care professional who will guide the lost person home. To accomplish this, the professional caregiver is able to follow the person's GPS-location on a map and in Google Streetview. This paper reports on four experiments with TalkMeHome to assess the effectiveness and user experience of the service. In all four cases the participants were guided home satisfactorily, even under suboptimal conditions. The experiments further revealed that talking people home is demanding for the care professional and that they need adequate ICT support. The contribution of our work is that we evaluated this new service with real patients and real professional care givers in a semi-controlled environment.**

Keywords-dementia; location-based services; global positioning system (GPS); remote care; lost person; care professional; user test.

I. INTRODUCTION

It has been estimated that in 2010 there were 35.6 million people living with dementia worldwide. Expectations are that this number will increase to 65.7 million by 2030 and 115.4 million by 2050 [1]. For people suffering from dementia, out-of-door mobility is an essential element of their quality of life [2]. However, these people are at considerable risk of getting lost during a walk, which can lead to hazardous situations [3, 4]. Moreover, the thought that their loved ones could be involved in an accident as a result of their disease adds to the burden felt by informal caregivers. To protect people suffering from dementia and to relieve the anxiety experienced by their informal caregivers, a number of interventions can be performed, such as locking doors to prevent a person with dementia (PwD) from leaving the house [5]. Such measures are however very disruptive and reduce the quality of life of people with dementia.

It has been recognized that the use of the Global Positioning System (GPS) may help to solve the problems experienced by caregivers and people with early dementia in a less disruptive manner [6]. Using this type of technology, the PwD typically carries a GPS tracking device. At home, an informal caregiver may then log into a secure environment (a website) to determine the location of the carrier of the GPS device [7, 8]. Some of the available trackers can be switched to two-way voice communications, which are commonly activated using the alarm button on the device. In case somebody suffering from dementia is unable to find the way home, an informal caregiver may, after obtaining the location of the PwD, go outside and bring the loved one home.

Despite the obvious benefits of the application of tracking devices (increased mobility for PwDs, fewer worries for informal caregivers), this technology has several shortcomings. For example, in many cases the main caregiver is an elderly person, often a spouse [1], who may not be able to physically get the PwD and take him home. Moreover, other informal caregivers such as adult children may not always be available because they live too far away or because they are bound by other obligations. Finally, not all caregivers may feel comfortable using new technology, such as a secure website.

TalkMeHome [9] is a new mobile service that overcomes these problems through a healthcare professional (see Figure 1). This person works from a care center and is specialized in remote care for people with dementia. PwDs can call the professional from their mobile phone when they are lost, which results in an "alarm" on the computer system that the professional uses. The professional accepts the call and talks someone home by providing instructions on how to walk ("turn left here", "turn right at next intersection"). To accomplish this, the professional's computer system provides a special dashboard that shows the PwD's location in real-time on a map and in Google Streetview. TalkMeHome works on a wide variety of mobile phones, as long as they have a GPS receiver and a UMTS data connection to stream the PwD's coordinates to the care professional. The service is primarily intended for people with early-stage dementia who live at home. TalkMeHome is a commercial service that PwDs will pay for. TalkMeHome also allows informal caregivers to follow the location of a PwD, but this part of the service out of scope for our work.

 ISBN: 978-1-61208-179-3

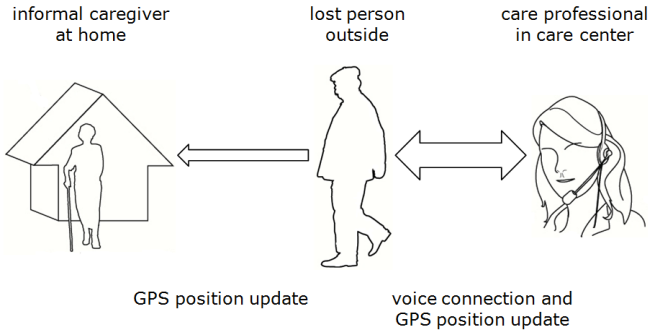

Figure 1. Main actors in the TalkMeHome service.

In this paper, we discuss the evaluation of TalkMeHome. The goal of the evaluation was to assess the effectiveness and user experience of this novel service before it will be made available commercially and to investigate how PwDs and care professionals experience the service.

The novelty of our work is that we evaluated the service with real PwDs and real professional care givers in a semi-controlled environment. In recent years, a number of pilot studies on the use of GPS for dementia patients have been carried out [7, 8, 10-13], but not for a service like TalkMeHome. These studies do however endorse the potential benefits of the use of GPS technology. At the same time, they also point out that the technology used should function sufficiently reliably. Furthermore, the need for a very simple tracking device is stressed [7] plus that these devices are mainly considered suitable for patients in the early stage of their illness [10]. It has been shown that not only informal caregivers who have experience with the use of tracking devices feel positive about the application of GPS technology, but formal caregivers as well [11]. Another application of GPS technology for lost people is the use of an adapted TomTom, which they can use to find the way back home [12, 13].

The remainder of this paper is structured as follows. Section II discusses the user requirements that served as an input for the development of the service. Section III presents the technical setup for our experiments, followed by the applied method in Section IV. Section V gives an overview of the results of our evaluation, followed by a discussion in Section VI. Section VII concludes the paper.

II. User Requirements

Before TalkMeHome was developed, we identified what the PwD (a possibly lost person) and the care professional guiding the PwD home would require from the service. To find these requirements, desk research was conducted, including a literature study and writing scenarios. Moreover a senior care professional was consulted, an employee of "Carint Reggeland", which is a care organization in the East of the Netherlands.

Also the researchers carried out a number of small experiments in which conventional trackers were used, combined with an additional mobile phone to simulate the anticipated implementation as close as possible [14].

A. Persons with Dementia

The requirements of the PwDs pertained to the mobile device they would have to use. Three options for such a device were discerned:

- A conventional tracking device, which enables the localization of the PwD as well as two-way voice communication.
- The combination of a mobile phone (not necessarily equipped with GPS) and a separate tracking device which the PwD may, for instance, wear on a belt.
- A mobile phone using the 3G standard (UMTS) and GPS.

To the best of our knowledge, no conventional tracking device was available which allowed voice communication and localization updates simultaneously, a conditio sine qua non for the TalkMeHome service. For that reason, the first option was rejected. The second option was regarded less desirable because in this case the informal caregiver must ensure that the PwD carries two devices, and both need to be charged as well, which was considered too cumbersome. Hence we chose the third option. An advantage of using a mobile phone is that such a device is not stigmatizing as nowadays almost everyone carries a mobile phone. Especially PwDs using a walker may want to carry the phone on a strap around the neck. For the same reason hands-free operation of the phone must be possible. It goes without saying that the mobile phone used should be as simple and as light as possible.

The second point of attention from the PwD's point of view were the GPS location updates. The aforementioned experiments with existing trackers showed that the typical interval of one minute between two GPS location updates was too long because even with a walker, walking velocities of elderly people may range from 0.9 to 1.1 m/s [12].

B. Care Professionals

The care professional who guides a lost person home must have a map showing the position of the person. This map should be extended with images of the surroundings of the guided person, when available, so that it becomes easier to formulate adequate instructions. A trace of the path taken thus far by the PwD as well as a route planner suitable for pedestrians were seen as needed to further support the professional in guiding the PwD home. These new functions should augment the basic functions available to a care professional, such as being able to answer a call (i.e., handle an alarm) and get (medical) information on the PwD who is calling.

III. Technical Setup

We ran the experiments with a prototype of TalkMeHome, which integrates into the Universal Alarm Receiver (UMO) from Verklizan, a company based in the Netherlands. The UMO is an existing commercial product for care centers that is widely in use across Europe, but as yet without support for guiding people home. It provides an

 ISBN: 978-1-61208-179-3

elaborate dashboard for care professionals to handle alarms, which we extended with TalkMeHome-specific functions. For the location updates, we used the services of FindWhere, also a Dutch company. We connected their location server to the UMO, thus making real-time location information available to care professionals.

Figure 2 depicts the implementation of the TalkMeHome service in more detail. The most important components are:

- A dashboard, used by the care professional to guide PwDs home. When an alarm is received, the dashboard displays (medical) information about the PwD as well as the location of the PwD. For this purpose, Google Maps with Street View was used. The dashboard also enables the voice connection with the PwD.
- A smartphone, used by the PwD to make contact with the care professional. For the test described below a Nokia 5230 was selected because of its uncomplicated user interface and favorable pricing. FindWhere's application iFindWhere (version 6.07.05) was installed on the smartphone and the red button of the Nokia served as the alarm button to be used by the PwD in order to establish the contact.
- A location server, which keeps track of the position of each smartphone, provided that the smartphone is registered properly. In the test version of the software used to update the GPS location, the time interval between two updates was set to 18 seconds.

IV. METHOD

The goal of our evaluation was to answer two questions: (1) how effective is the TalkMeHome service in guiding PwDs home and (2) what is the user experience during the process of talking someone home, both for PwDs and for care professionals.

A. Participants

As has been noted by other researchers, getting participants (people with dementia) was not easy [10]. The customer database of Carint Reggeland was consulted, medical coworkers were invited to recommend participants and local newspapers published information about the service tested. In addition, we used a set of inclusion criteria to determine if PwDs fall in the target group of TalkMeHome (see below).

Eventually four participants took part in the evaluation, as well as the two care professionals (Figure 3, taken from [15]). All participants came from the region of Twente, in the Eastern part of the Netherlands.

The inclusion criteria we used for the participants were:

- Suffering from mild dementia.
- Lives more or less independently at home.
- Is quite able to follow instructions.
- Must be able to use the available smartphone.
- Is able to walk a longer distance.
- Signed an Informed Consent (and the informal care giver as well).

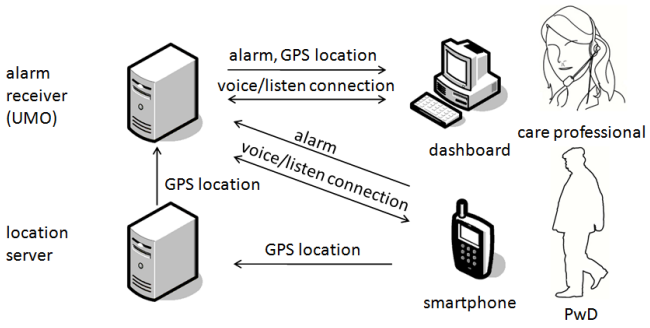

Figure 2. Organization of the TalkMeHome service.

Two experienced care professionals took part in the test. Both of them were employees of Carint Reggeland, one of whom also provided input during the user requirements phase (see Section II). It should be noted that prior to the tests the care professionals had not had an opportunity to gain experience in guiding a person with mild dementia home.

B. Talking Someone Home

For the actual evaluations, each participant was visited at home. Then it was determined first whether the participant met the inclusion criteria. If this was the case, the participant was invited to go out for a walk, accompanied by two researchers from our team. After walking a certain distance (typically 500 m.) the actual test began by pushing the alarm button, simulating the PwD being "lost". This established a connection with the care professional. After that, the care professional guided the participant back home. One of the researchers observed the participant while the main responsibility of a second researcher was to ensure the safety, for instance regarding traffic, of the participant.

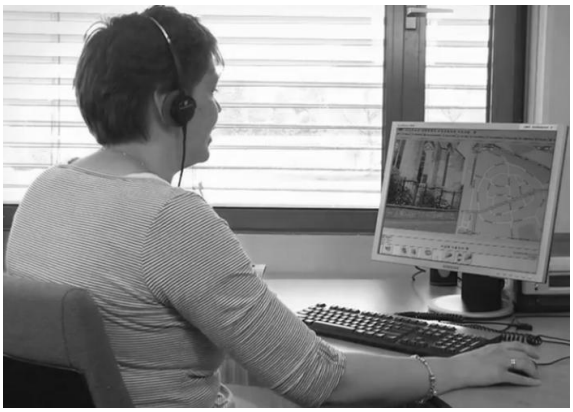

Figure 3. One of the care professionals guiding someone home.

While the participants were being talked home, data was collected in a number of ways. First, the observations made were written down. Moreover, the conversation between the participant and the care professional was digitally recorded.

After talking someone home, a short interview with each of the participants was conducted asking their opinion about the ease of use of the smartphone, their feelings regarding safety and security, and their motivation to use a smartphone. After each TalkMeHome session, the care professional also completed a questionnaire containing questions about the hardware and software used (e.g. the experienced usability), work load (e.g. whether it was possible to do other tasks while guiding somebody home), how the communication with the participant was experienced, and finally how comfortable the care professional felt when guiding a person home. After completion of all tests, the data were assembled, analysed and discussed by the researchers. In a second meeting the views held by the two participating care professionals were put forward.

V. RESULTS

In this section, we present a short summary of the results of the four TalkMeHome sessions. We discuss the effectiveness of the service and the user experience in Section VI.

A. Participant #1

The first participant was an elderly lady in her seventies. Together with her husband she lives in a small town with 7000 inhabitants. She was diagnosed with Alzheimer four years ago. Sometimes her right-left discrimination is poor.

Establishing a connection between participant and care professional took place without difficulties. But after a few minutes the transmission of GPS locations came to a halt, most likely due to insufficient UMTS coverage. However, this participant was able to describe her surroundings accurately, including street names and characteristic features such as buildings and parking lots. Based on this information, the map and corresponding satellite images, the care professional was able to satisfactorily guide the participant through her home town. Only once the participant took the wrong direction but this was corrected by the care professional after 20 meters. Right-left confusion occurred only once. The care professional knew on which wrist the participant wore her watch, which could have been helpful if necessary.

B. Participant #2

The second participant lives on her own in a larger city (130,000 inhabitants). She has been known to suffer from Alzheimer's disease for some time. She walks with a walker and for that reason the smartphone was used hands-free.

Despite this use of the smartphone, the communication between the participant and the care professional went smoothly during the test. Only once the participant took the wrong direction but again this could be corrected after 20 meters. The map used, however, turned out to be incomplete and inaccurate as the apartment of the participant was not on the map yet. But as she was familiar with the immediate vicinity of her home she still could be guided home successfully.

C. Participant #3

The third participant lives in a city of more than 70,000 inhabitants. She has suffered from dementia for some years. She already got lost once.

This test started under the trees of a small park. GPS locations got through to the care center only after a restart. The walk began with a straight road of about 100 meters with no crossroads. Because apparently no information was needed, the care professional stopped talking for a while. Then, somewhat confused, the participant stopped walking. When the conversation was resumed, the participant responded very well to instructions. Difficulties were observed at a road construction site. It took a while before the care professional understood the situation. After that, she guided the participant home taking a detour.

D. Participant #4

The fourth and final participant lives with his spouse in a village (over 7,000 inhabitants). He has been diagnosed with a mild form of Alzheimer's disease by a gerontologist.

Again, at the start of the walk, there were some difficulties establishing the connection between the care professional and the participant. Also, the participant broke the connection once unintentionally. As in the previous tests no technical problems were encountered after that. Contrary to the findings of the other three tests, this participant sometimes gave erroneous information, such as incorrect street names, which made the care professional's task harder, particularly since for this area Street View was not available. This participant interrupted the walk for a short chat with a friend.

VI. DISCUSSION

We discuss the results of our evaluation in terms of the two questions we are addressing: (1) how effective is TalkMeHome and (2) what is the user experience during the process of talking someone home. We also discuss the limitations of our results.

A. Effectiveness

In all four tests the participants were guided home satisfactorily. The start of a walk posed a specific problem: as the viewing direction of the participant was unknown, and the participant was not walking yet, the meaning of the terms left and right were not clear. In the experiments this was solved by asking the participant simply to start walking. If the direction turned out to be wrong, the participant was subsequently asked to turn around. Apart from this issue only a couple of easily corrected mistakes were observed during the tests.

The experiments showed that conditions for the TalkMeHome service are optimal if three conditions are met: a reliable map is available, GPS locations are updated frequently (preferably with interval of less than 10 seconds, as experiments showed), and PwDs are giving a good description of their surroundings during a walk. However, if only two of the three conditions are met, guiding a PwD home may still be possible. For example, the PwD's description is not really necessary as guiding a PwD home

 ISBN: 978-1-61208-179-3

based on a reliable map and GPS locations turned out to be possible as well. Moreover, it is still possible to guide a PwD home if the update of GPS locations should (temporarily) come to a halt, provided an initial location is available, the PwD is able to describe his or her surroundings sufficiently, and a reliable map is available, Finally, a small difference between reality and the map used is not necessarily insurmountable.

The test showed the value of relevant information, such as on which hand a (wedding) ring is worn in case of a right-left confusion. It should be investigated how such information can be made available to the care professional and how it can be kept up-to-date.

B. User Experience

The contact between the PwD and the care professional was found to be good as became apparent from the completed questionnaires and the digitally recorded conversations. There were few misunderstandings between them. If possible, the participant and the care professional had a chat, for example about the weather conditions, which contributed to a relaxed atmosphere while maintaining the necessary contact.

The evaluation further revealed that guiding somebody home is a demanding task for the care professional because a great deal of information needs to be processed quickly by them. As there is always a certain time delay the care professionals should anticipate the situation ahead. A higher update frequency for the GPS locations resulting in a more fluid motion, and more precise locations would be helpful. There appeared to be little time for other tasks, such as looking up additional information about the PwD. This suggests that the user interface of the dashboard needs to be optimized for TalkMeHome.

C. Limitations

The focus of the evaluation described in this paper is the actual process of guiding people home. How the TalkMeHome service will be incorporated into everyday life of the PwD, including the question whether PwDs are able to contact the care center autonomously, was not taken into consideration. A PwD who has difficulty to contact the care center may benefit from alternative scenarios, for instance a scenario in which a worried informal caregiver contacts the care professional, who then establishes the contact with the PwD.

The PwDs who participated in the evaluation were not really lost, but accompanied by researchers who paid attention to safety issues. It is unclear how PwDs would react to the TalkMeHome service in a more stressful situation. The meeting with the care professionals revealed the professionals' concerns regarding these matters. How should they act if a PwD is unable to respond properly? How can an unsafe situation (e.g. in traffic) be avoided? Issues regarding their (legal) responsibility should be looked into.

VII. Conclusion and Future Work

We discussed TalkMeHome, a novel mobile service that allows people with early-stage dementia to get home safely when they are lost. With the single press of a button, they can call a remote care who is specialized in (remote) care for people with mild dementia. This care professional uses the TalkMeHome dashboard to follow the lost person's location on a map and to provide instructions (directions) for this person how to get home safely. The service's added value is that it increases the quality of life of people with mild dementia (increased level of mobility) as well as that of the informal care giver (fewer worries). It also allows people to live at home longer, which reduces the load on intramural care facilities.

We evaluated the service with four people with early-stage dementia. Our goal was to assess how effective TalkMeHome is and how the users (PwDs and care professionals) would experience it. The novelty of our work is that it involved real PwDs and real professional care givers in a semi-controlled environment

As for effectiveness, all four participants were guided home satisfactorily, technical imperfections set aside. Only a few easily corrected mistakes were noticed. The evaluations further showed that guiding a PwD home is possible even under suboptimal conditions (unreliable information of the PwD, missing location updates or an incomplete map). This suggests that TalkMeHome is an effective service, which increases our confidence that it can be made available as a commercial service. It also shows that a technology that is not 100% accurate can still provide an added value. Regarding the experiences of the users, both PwDs and care professionals, we conclude that the contact between both was easy but guiding somebody home is a demanding task for a care professional.

Additional research may focus on optimizing the use of the service in everyday life as well as alternative scenarios.

In terms of user experience, our work revealed the difficulty of the care professional's task. This suggests that the user interface of the dashboard needs to be optimized for TalkMeHome and that it is of paramount importance to offer proper education for care professionals, both in regular education and continuing training. With an aging population the demand for appropriate support will only increase. For this reason the research group 'ICT-Innovations in Healthcare' will take the initiative for a 'Skills Lab', a laboratory equipped with the necessary hardware and software to facilitate research and training with regard to the skills of a care professional, for instance in terms of protocols for care professionals to guide someone home. This research and training will not be limited to the actual TalkMeHome service presented in this paper. The Skills Lab will support the necessary research and training facilities.

Acknowledgments

TalkMeHome was developed by Novay, Carint Reggeland Groep, Windesheim University of Applied Sciences, and Verklizan B.V. in cooperation with FindWhere. The project TalkMeHome is part of the innovation program for ICT-based services of the Province of Overijssel. The project website is at www.talkmehome.nl.

We thank Toke Bonekamp, Johannes de Boer, Henri ter Hofte, and Rob Hermans for their contributions. Above all,

we wish to express our gratitude to our test participants and their informal caregivers for their participation in the project.

REFERENCES

[1] A. Wimo and M. Prince, "World Alzheimer Report 2010," ed: Alzheimer's Disease International, 2010.

[2] N. Shoval, G. K. Auslander, T. Freytag, R. Landau, F. Oswald, U. Seidl, H.-W. Wahl, S. Werner, and J. Heinik, "The use of advanced tracking technologies for the analysis of mobility in Alzheimer's disease and related cognitive diseases," *BMC Geriatrics*, vol. 8, 2008.

[3] R. McShane, K. Gedling, J. Keene, C. Fairburn, R. Jacoby, and T. Hope, "Getting Lost in Dementia: A Longitudinal Study of a Behavioral Symptom," *International Psychogeriatrics*, vol. 10, pp. 253-260, 1998.

[4] M. A. Rowe, S. S. Vandeveer, C. A. Greenblum, C. N. List, R. M. Fernandez, N. E. Mixson, and H. C. Ahn, "Persons with dementia missing in the community: Is it wandering or something unique?," *BMC Geriatrics*, vol. 11, 2011.

[5] S. M. C. Rasquin, C. Willems, S. De Vlieger, R. P. J. Geers, and M. Soede, "The use of technical devices to support outdoor mobility of dementia patients," *Technology & Disability*, vol. 19, pp. 113-120, 2007.

[6] C.-C. Lin, M.-J. Chiu, C.-C. Hsiao, R.-G. Lee, and Y.-S. Tsai, "Wireless Health Care Service System for Elderly With Dementia," *IEEE Transactions on Information Technology in Biomedicine*, vol. 10, pp. 696-704, 2006.

[7] J. Van der Leeuw, C. Willems, and F. Van der Heide, "Zoeken en gevonden worden?! De inzet van gps voor mensen met dementie," ed: Vilans, 2009.

[8] F. Miskelly, "Electronic tracking of patients with dementia and wandering using mobile phone technology," *Age & Ageing*, vol. 34, pp. 497-499, 2005.

[9] C. Hesselman. http://www.talkmehome.nl/ . Retrieved: November, 2011

[10] S. Horjus, B. Willemse, and A. M. Pot, "Zorgen op afstand," ed: Trimbos Instituut, 2009.

[11] M. Runneboom, "GPS technologie: een ondersteuning voor verzorgers van mensen met dementie?," Masterthesis, Psychologie, Universiteit Twente, 2010.

[12] J. De Boer, "Auditory Navigation for Persons with Mild Dementia," Master thesis, Faculty of behavioral sciences, University of Twente, Enschede, 2008.

[13] M. Hettinga, J. De Boer, E. Goldberg, and F. Moelaert, "Navigation for People with Mild Dementia," in *Medical Informatics in a United and Healthy Europe*, K.-P. Adlassnig, B. Blobel, J. Mantas, and I. Masic, Eds., ed: IOS Press, 2009, pp. 428–432.

[14] H. Ter Hofte, L. Van den Bosch, M. De Jong, and J. Nauta, "Gebruikerseisen TalkMeHome," ed: internal report, 2010.

[15] *TalkMeHome. Veilig op pad met dementie.* http://www.youtube.com/watch?v=IDq7YpxLcVY. Retrieved: November, 2011.

 ISBN: 978-1-61208-179-3

Tele-Rehabilitation Therapy vs. Face-to-Face Therapy for Aphasic Patients

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***Abstract*— Though the application of telecommunication technology for rehabilitation of aphasic patients has been proposed as an appropriate mode for the delivery of speech and language services in general and for aphasic patients in particular, systematic research into the delivery of therapy via telerehabilitation (TR) is limited. The present study attempts to fill this gap by comparing the effects of TR to the effects of a conventional face-to-face (FtF) therapy. Eight patients with aphasia participated in a within-subject case study design (ABAC/ACAB). Patients received a 14-session block of TR at their homes via a custom-made Internet server, as well as a 14-session block of conventional FtF treatment in the clinic. Each patient was evaluated four times, before and after each of the two series of therapy. Patients also completed self-reported satisfaction questionnaires regarding the two treatment modes. All participants benefited from therapy, regardless of therapy mode. There was no significant difference in the effect of therapy on most measures in the formal assessment, as well as on the satisfaction measures. When a significant difference was found between the two treatment modes, TR was found to be more beneficial. Our results provide evidence that TR is not only feasible and suitable for the treatment of aphasic patients but that it may also be as effective as FtF therapy. Despite the promising results of the present study, future research is required in order to investigate the effect of TR in populations with more diverse speech and language disorders.**

Keywords-Tele-rehabilitation; Aphasia therapy

I. INTRODUCTION

Telerehabilitation (TR) is a branch of telemedicine, in which health services are delivered to patients from a distance through information technology and telecommunication systems. The main motivation for developing telemedicine in general and TR in particular was to offer accessible treatment to individuals who live relatively far from health centers, in geographically remote regions, as well as to individuals with physical disability for whom travel is difficult [9][13]. The earliest reports on treatment of speech and language disorders from a distance appeared in the 1980s. Since then, service delivery has been examined with the use of technologies such as telephone, television, computers, and satellite [1]. In the last decade, technological developments have enabled the use of videoconferences and internet-based features [1][2]. According to a recent review by Mashima and Doarn [9], these developments led to the implementation of tele-services in various areas within the speech language and hearing therapy. For instance, TR was examined as part of treatment of swallowing disorders, voice disorders, stuttering, and speech disorders in individuals with Parkinson's disease, cleft palate, autism, and hearing impairment.

Technologically-based rehabilitation of individuals with brain damage has great potential. Yet, this potential has to be established through careful research. It is important to study

 ISBN: 978-1-61208-179-3

the feasibility and effectiveness of both assessment and treatment from a distance. One of the main questions with which researchers have been concerned is whether assessment of language and speech disorders following brain damage could be as reliable as face-to-face assessment. Brennan et al. [3] and Gerogeadis et al. [4] reported that when using a picture description task, no difference was found between assessment from a distance through computer-based videoconference and conventional FtF assessment.

Further analysis that looked at the effects of background variables of age, gender, education level, and experience with technology on TR and FtF treatments revealed no significant differences between linguistic performances in either environment for TBI patients [3]. In addition, Palsbo [10] administered a more comprehensive assessment of functional communication, using three subtests from the Boston Diagnostic Aphasia Examination [5]. In this study, very high levels of agreement were recorded between stand-alone videoconference and FtF assessment.

Though these results were encouraging, the study did not control for impairment severity and type of communication disorder. In a later study, Hill et al. [6] showed that aphasia severity had little effect on assessment accuracy for the majority of tests.

The feasibility and reliability of technologically governed assessment from a distance are very important for planning and monitoring speech and language therapy programs. However, it is not enough to examine assessment if treatment is to be evaluated. There is some evidence regarding TR for people who suffer from voice disorders [8] as well as for people suffering from speech disorders in Parkinson's disease [12]. These studies used both objective measures and self-report to examine the efficacy of treatment. They documented no difference in outcome measures between patients treated via TR technology and those treated through conventional therapy.

Nonetheless, it is unclear whether the results of treatment to one population can be generalized to treatment of another population, especially when aphasia patients are concerned. If the goal is to develop and implement a TR protocol to aphasia patients, it is important to show that the mode of therapy delivery is not only feasible but that it is as effective as the traditional FtF therapy. Such research might promote the use of TR as the treatment of choice, and might help in allocating insurance funding to this line of treatment.

Thus, the present study aims at establishing the feasibility and effectiveness of TR to patients with aphasia. The study compares the outcome of speech and language therapy provided through both TR and FtF modes. The two treatment modes will be compared through both objective measures, mainly the change in scores in formal tests, and subjective measures that included self reported satisfaction. Our main question was whether TR via the Internet could be as efficient as is conventional FtF therapy.

The remainder of the paper is structured as follows: Section II describes the research method. Section III introduces the results of the comparisons between the two modes of therapy. First, we present scores on the objective assessment battery and then we present scores on the satisfaction questionnaires. Finally, Section IV presents the main conclusions of the study.

II. METHOD

Participants: Eight native Hebrew speaking individuals with aphasia participated in the study. Table 1 presents background characteristics of these patients. All participants were right handed with at least 11 years of education, between age 46 and age 72. They all suffered a single left cerebrovascular accident (CVA), most of them in the distribution of the middle cerebral artery. Lesions were confirmed by CT or MRI scans. Participants were 4-50 months post CVA. They all passed an audiometric hearing screening test that demonstrated normal hearing levels (< 35db HL 500-4000Hz).

The diagnosis of aphasia was determined on the basis of the Hebrew version of the Western Aphasia Battery [7][11]. Five participants were diagnosed with Anomic Aphasia, two participants were diagnosed with Conduction Aphasia and one was diagnosed with Broca's Aphasia. The WAB Aphasia Quotient at study entry ranged between 12.6 and 91, with a mean of 68.5 (SD = 24.14).

Study design: The study used a within-subject case study design (ABAC/ACAB). All eight participants received two types of treatment (TR and FtF). Each type of treatment included 14 therapy sessions that took place twice to three

TABLE I. BACKGROUND CHARACTERISTICS OF STUDY PARTICIPANTS

	P1	P2	P3	P4	P5	P6	P7	P8
Age (years)	63	70	46	64	71	72	68	54
Gender	M	M	F	M	M	M	M	M
Handedness	Right	Right	Right	Right	Right	Right	Right	Right
Education	17	12	11	15	15	15	12	16
MPO	50	30	30	21	32	12	4	28
Lesion location	Left MCA	Left MCA	Left MCA	Left MCA	Left Basal ganglia	Left MCA	Left parietal	Left Basal ganglia
AQ	12.6	72	73	91	76.6	87	66	69.8
Aphasia type	Broca's	Anomic	Conduction	Anomic	Anomic	Anomic	Conduction	Anomic

Note. P=participant; F=female; M=male; MPO=months post onset; MCA=middle cerebral artery; AQ=aphasia quotient

 ISBN: 978-1-61208-179-3

times a week. There was a six-week recess in between the two types of treatments to minimize the effect that the first treatment could have on the results of the next treatment. Four participants received TR first and then FtF (hereafter Group 1) and the other four participants received FtF first and then TR (hereafter Group 2). Each patient was evaluated four times, before and after each of the two series of therapy sessions (that is, before and after TR, before and after FtF).

Assessment: An independent clinician who did not provide therapy to a given patient evaluated him or her. The assessment was conducted in two sessions and included the Hebrew version of the Western Aphasia Battery [7][11], commonly used to diagnose aphasic syndrome and severity. For each patient a measure of Aphasia Quotient (AQ) was calculated as a summary of scores of the oral language subtests of the WAB: spontaneous speech (content and fluency), auditory comprehension, repetition, and naming. AQ scores can range from 0 up to 100, with 100 representing intact abilities.

In addition, an assessment of the participant's satisfaction with the therapy process was conducted at the end of each session series, using structured questionnaires designed for each type of treatment. Both questionnaires consisted of 13 identical questions. Following the TR session series, the questionnaire contained the same 13 questions plus five additional questions that focused on technical aspects. The questionnaires included both positive and negative statements about the treatment. Each patient was asked to specify his/her level of agreement with each statement, on a 1-4 scale. For example, the patients were asked to state their level of agreement with statements such as: "Using a computer for treatment is easy", "The treatment was stressful", "I was happy with the interaction I had with the clinician during the treatment".

In addition, six weeks following the completion of the second treatment series, each patient was requested to fill a questionnaire that contained 17 statements. The patient was asked to indicate for each statement which mode of treatment s/he would prefer. Responses could be TR, FtF, both or neither. The patient was encouraged to explain his/her decision. For example, the patient heard statements such as "I understood the clinician better", "I made greater progress". After each statement the patient was asked to choose TR or FtF, or to say "both" if s/he thought that both treatments were equally good or "neither" if no treatment could be selected.

Treatment: At the beginning of the treatment session series each person was presented with a set of pictures and was requested to name them. A different set of pictures was used in each treatment program. Following this initial naming test, a set of 20 pictures that the patient failed to name was defined separately for every person. This set was then divided into two subsets of ten pictures – one set was used for training and the other set was used to assess generalization following all therapy sessions. Each treatment session lasted 45 minutes. The session began with a short spontaneous conversation, followed by a diagnostic naming test of the ten words. The next twenty minutes were dedicated to improving naming of these 10 pictures. In the remaining time, several other language tasks were chosen and tailored by the SLP to fit the patient's individual needs and personal goals. The same structure applied in both the TR and the FtF protocols. During the period of the study none of the participants received any other treatment for aphasia.

System: A custom-made web application that provides videoconference along with a shared whiteboard was used for the TR. This system contains more than 50 various language-related tasks, such as naming, semantic relations, hearing comprehension, reading and so on.

III. RESULTS

This section first presents scores on the aphasia assessment and then scores on the satisfaction questionnaire

A. *Aphasia assessment*

For each patient, we calculated the difference between score before and after each treatment in AQ as well as in each of the four subsets scores of the WAB. Differences were then averaged across participants, separately for the TR mode and FtF mode. Figure 1 presents the percent of improvement following treatment in both AQ and in the four WAB sub-scores.

As can be seen in Figure 1, there was improvement in all skills in both modes of treatment. A paired t-test that examined improvement in both modes of treatment showed no significant differences on any of the assessment subsets (speech, auditory comprehension, repetition, naming). The difference between improvement in AQ following TR and following FtF was significant ($t_{(DF=7)} = 2.606$, $p = 0.035$) (see also Table 2). It should be noted that the AQ score is combined of the other four sub-scores, and thus, the difference in AQ was stronger than the differences in each subtest.

In order to further estimate the effect of treatment mode (TR vs. FtF) and treatment order (1st vs. 2nd), we used linear regression model for panel data, with person as a subject (panel) and period and treatment mode as factors (covariates).

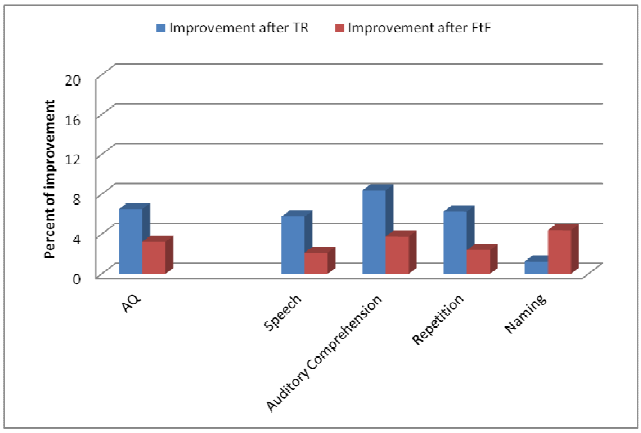

Figure 1. Improvement in language skills, by treatment mode

TABLE II. MEAN IMPROVEMENT (AND SD) ON ASSESSMENT SCORES BY MODE OF TREATMENT, AND PERIOD

	Paired t-test				Regression	
Scale	Effect of TR Mean (SD)	Effect of FtF Mean (SD)	t* (df=7)	p-value	Period effect (SD, p-value)	Mode effect (SD, p-value)
AQ	6.51 (2.82)	3.21 (2.59)	2.6	0.04	-1.67 (SD=1.02, p=0.1)	3.3 (SD=1.02, p=0.001)
Speech	0.25 (2.49)	0.87 (1.24)	-0.72	0.49	-1.37 (SD=0.75, p=0.03)	-0.62 (SD=0.75, p=0.33)
Auditory comprehension	0.62 (0.73)	0.29 (0.83)	0.96	0.36	-0.45 (SD=0.35, p=0.19)	0.39 (SD=0.35, p=0.26)
Repetition	8.37 (10.42)	3.75 (13.08)	1.55	0.16	0.87 (SD=2.78, p=0.75)	4.62 (SD=2.78, p=0.096)
Naming	0.57 (0.63)	0.21 (0.69)	0.9	0.39	-0.24 (SD=0.30, p=0.43)	0.36 (SD=0.30, p=0.23)

* t-test compared improvement in TR to improvement in FtF. Df = degrees of freedom

Table 2 presents the regression analyses (effect and SD of mode and period and the p-value). As can be seen in Table 2 there was no effect of treatment order for most of the sub-scores, except for the Speech subtest which had significant order effect (that is, there was greater improvement after the first treatment than after the second one). The regression showed significant effect of treatment mode for the AQ score only, as did the t-test analysis.

In sum, TR led to a greater improvement in AQ than did FtF therapy. Improvement in scores on the Speech subtest were higher following the first treatment session series than following the second session series, regardless of treatment mode.

Next, we examined whether the order of treatment affected the carry over between the two treatments. A paired t-test analysis compared the total change in AQ scores between the two groups. That is, we computed the difference (delta) in AQ scores between the 4th and the 1st assessments for each group separately (Group 1: TR then FtF; Group 2: FtF and then TR) and then compared those deltas. This test is based on an assumption of no interaction between period and treatment mode. Any possible interactions were examined through an analysis of variance (ANOVA) with period and mode as factors, which resulted in these p-values for the AQ score: period p=0.25, mode p=0.034 and interaction period*mode p=0.97. The t-test analysis showed no significant difference in deltas between groups: Group 1 mean delta=10.2 (SD 3.51) and Group 2mean delta=7.35 (SD. 6.09), $t_{(6)}$ =0.81, p=0.45. Therefore, there was no significant difference between the two groups in the carry over effect. That is, in both groups, improvement between testing times was similar and the order of treatment mode had no effect on scores on the aphasia test battery.

B. Satisfaction questionnaires

In this section, we present participants' answers on the satisfaction questionnaires, as provided at the end of each 14-session treatment series (at the end of either the TR tor the FtF treatment). We also present the answers that were provided at the end of both treatments regarding the comparison between the two modes, as collected a month and a half after the end of the second treatment.

1) Satisfaction from each treatment mode separately

Overall, the participants showed similarly high satisfaction from both treatment modes. They felt that each treatment was as simple to understand, as comfortable, as available, as interesting, and as helpful as the other.

a) Satisfaction regarding common questions for TR and FtF

For each of the 13 common questions, we estimated agreement between answers for TR and FtF using Kappa statistics (that is, testing the relation between the observed agreement and the expected agreement according to the given distribution of answers). We analyzed cases of disagreement between satisfaction ratings using exact generalized McNemar statistic. This test analyzes each pair of symmetrical cells and compares the observed distribution with a uniform (50%-50%) distribution. No result was significant (as might be expected because of the small sample size). Table 3 presents the distribution of answers to the satisfaction questionnaire in each treatment mode, as well as the agreement between treatment modes (in percent), Kappa score, and p-value.

As can be seen in Table 3, there was high agreement between ratings of the two treatments, with 5 out of 13 questions receiving the same ratings by all participants (Agreement=100%), and the remaining questions receiving highly similar ratings.

 ISBN: 978-1-61208-179-3

TABLE III. DISTRIBUTION OF ANSWERS TO SATISFACTION QUESTIONNAIRE IN EACH TREATMENT MODE, AGREEMENT BETWEEN TREATMENTS, AND KAPPA SCORES

No.	Question	Mode	Grades (n) **				% Agreement	Kappa (p^)
			1	*2*	*3*	*4*		
1	I would recommend this treatment to someone else	TR FtF	0 0	0 0	0 0	8 8	100%	-
2	I felt uncomfortable during treatment	TR FtF	8 8	0 0	0 0	0 0	100%	-
3	The treatment was too complicated	TR FtF	7 3	0 2	1 3	0 0	37.5%	0.0 (0.5}
4	I would like to participate in this treatment again	TR FtF	0 0	0 0	0 0	8 8	100%	-
5	The treatment was interesting	TR FtF	0 0	0 0	0 1	8 7	87.5%	0.0 (-)
6	The treatment was stressful	TR FtF	8 6	0 0	0 2	0 0	75%	0 (-)
7	I was satisfied with the quality of the pictures	TR FtF	0 0	0 0	1 1	7 7	75%	-0.14 (0.66)
8	There was a change in my speech after treatment	TR FtF	0 0	1 0	3 3	4 5	75%	0.54 (0.03)
9	The quality of speech therapy was (choose from options)	TR FtF	0 0	0 2	4 1	4 5	50%	0.2 (0.16)
10	The clinician helped me	TR FtF	0 0	0 0	1 3	7 5	75%	0.38 (0.08)
11	The treatment met my expectations	TR FtF	0 0	0 0	7 7	1 1	100%	1 (0.002)
12	The interaction with the clinician was (choose from options)	TR FtF	0 0	0 0	8 8	0 0	100%	-
13	The availability of treatment was (choose from options)	TR FtF	0 0	0 0	0 1	8 7	75%	0.0 (-)

**1=Not at all / poor, 2=Low / Adequate, 3=Medium / Good, 4=High / Excellent

^ One tailed: Agreement higher than expected

b) Satisfaction regarding TR treatment

Table 4 presents the distribution of answers that participants gave on the five questions that addressed the TR alone.

As can be seen in Table 4, most responses indicated high satisfaction from TR. Participants reported no difficulty in learning how to use the TR system, they felt that the TR system was easy to use, and they were satisfied with the quality of the materials.

2) Comparing satisfaction between treatment modes

Next, we analyzed responses on the satisfaction questionnaire filled a month and a half after the end of second treatment. Figure 2 presents participants' preferences of either on of the treatments or answers that indicated no preference.

TABLE IV. NUMBER OF PARTICIPANTS WHO ENDORSED SPECIFIC ANSWERS ON TR SATISFACTION QUESTIONS

Question	High	Medium	Low	Not at all
Easy to use	4	2	1	1
Learning how to use is effortful	2	1	1	4
Need technical assistance	1	0	3	4
Most people will learn easily	7	1	0	0
	Excellent	**Good**	**Adequate**	**Poor**
Audio quality	5	3	0	0

The overall agreement and asymmetry tests between the two modes showed 68.4% agreement with Kappa=0.193 (p=0.0095) and asymmetry of 29 vs. 14 (p=0.03).

As can be seen in Figure 2, for most statements (93/136) participants had no preference for either treatment (chose "both" or "neither"). For example, for statements such as "There was more frustration in the treatment" all participants chose "neither" or "both", and for statements such as "I will recommend to people in my condition to participate in this kind of treatment", most participants chose "both".

When showing a preference for one treatment over another, FtF was more favorable (29/136) than TR (14/136).

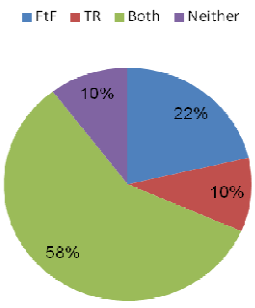

Figure 2. Comparing satisfaction between treatment modes

For example, when asked to rate statements such as "I was satisfied from the interaction with the clinician", and "I advanced more through treatment", more participants chose FtF than TR. When asked to rate a statement such as "I was satisfied with the treatment availability", more participants chose TR than FtF. When examining the content of the statements on which no agreement was found, we saw that most of these statements revolved around the interaction with the clinician. In those statements participants preferred FtF over TR.

In sum, when examining satisfaction levels, participants had no preference of one mode over another, except when asked about the interaction with the clinician, which they rated as more favorable in the FtF mode.

IV. CONCLUSION AND FUTURE WORK

The current study sought to explore whether speech and language therapy delivered via telerehabilitation had similar effects as did conventional face-to-face therapy. The effect of therapy was examined by using objective scores obtained from a formal assessment of aphasia, as well as by collecting subjective satisfaction data.

Overall, the results show that the delivery of speech and language therapy via telerehabilitation at home yields at least the same results as similar therapy delivered in the clinic. The results of the present study add to former reports about the reliability of the assessment of speech and language difficulties [4][6][10]. In addition, the results suggest that the technology is not only suitable for assessment but that it is also effective when used for therapy. Theses results are similar to several earlier reports that found that TR was effective in treating people with voice disorders [8][12]. The novel contribution of the current study is that it shows for the first time the beneficial effects of TR in the treatment of aphasia.

It is important to note that TR resulted in higher general aphasia scores relative to FtF treatment. It could be the case that the technological novelty of the TR added both to the participant's motivation and to the therapist's motivation. As for the subjective report, we found that participants were satisfied from both modes of treatment. However, when asked to choose between the two modes, participants showed a preference toward the FtF mode, mainly in reference to questions that addressed personal contact with the clinician. As in an earlier report [3], participants were generally satisfied with TR with regards to audiovisual quality, and ease of use, yet some individuals may still require help in solving technical problems during TR sessions at home.

Despite of the small sample in the present study, we believe that our results are promising. They add evidence regarding the efficiency of TR and thus make it possible to offer such treatment either alone or in combination with FtF therapy to people suffering from aphasia. TR expands the accessibility of speech and language therapy to this population, overcoming obstacles such as lack of rural services, geographical distance, transportation difficulties, or lack of mobility.

Although the results of the present study are encouraging, future research is still needed to investigate the effect of TR in diverse populations in terms of the nature and severity of the speech and language disorders.

V. ACKNOWLEDGMENTS

The authors acknowledge Dr. Ilia Novikov and Prof. Laurance Freedman from Gertner Institute for Epidemiology and Public Health Policy for the statistical analyses. The authors also acknowledge Yuri Fayans for his assistance in development of the custom-made web application.

VI. REFERENCES

[1] American Speech-Language-Hearing Association. (2005). Speech-Language Pathologists Providing Clinical Services via Telepractice: Technical Report. Available from www.asha.org/policy <retrieved: December, 2011>

[2] Brennan, D., Georgeadis, A., and Baron, C. (2002). Telerehabilitation tools for the provision of remote speech-language treatment. Topics in Stroke Rehabilitation, 8, 71-78.

[3] Brennan, D. M., Georgeadis, A. C., Baron, C. R., and Barker, L. M. (2004). The effect of videoconference-based Telerehabilitation on story retelling performance by brain injured subjects and its implications for remote speech language therapy. Telemedicine Journal and E-Health, 10, 147-154.

[4] Georgeadis, A. C., Brennan, D. M., Barker, L. M., and Baron, C. R. (2004). Telerehabilitation and its effect on story retelling by adults with neurogenic communication disorders. Aphasiology, 18, 639-652.

[5] Goodglass H., Kaplan, E. and Barresi B. (2001) Boston diagnostic aphasia examination (3rd ed). Baltimore, MD: Lippincott Williams and Wilkins.

[6] Hill, A. J., Theodoros, D. G., Russell, T. G., Ward, E. C., and Wootton, R. (2009). The effects of aphasia severity on the ability to assess language disorders via telerehabilitation. Aphasiology, 23, 627-642.

[7] Kertesz, A. (1982). Western Aphasia Battery. Orlando, FL: Grune and Stratton.

[8] Mashima, P. A., Birkmire-Peters, D. P., Syms, M. J., Holtel, M.R., Burgess, L. P. A., and Peters, L. J. (2003). Telehealth: Voice therapy using telecommunications technology. American Journal of Speech-Language Pathology, 12, 432-439.

[9] Mashima, P. A., and Doarn, C. R. (2008). Overview of telehealth activities in speech-language pathology. Telemedicine and E-Health, 14, 1101-1117.

[10] Palsbo, S. E. (2007). Equivalence of functional communication assessment in speech pathology using videoconferencing. Journal of Telemedicine and Telecare, 13, 40-43.

[11] Soroker, N. (1997). *Hebrew Western Aphasia Battery.*Ra'anana, Israel: Loewenstein Hospital Rehabilitation Center.

[12] Theodoros, D. G., Constantinescu, G., Russell, T. G., Ward, E. C., Wilson, S. J., and Wootton, R. (2006). Treating the speech disorder in Parkinson's disease online. Journal of Telemedicine and Telecare, 12, 88-91.

[13] Theodoros, D., and Russell, T. (2008). Telerehabilitation: Current perspectives. Studies in Healthtechnology and Informatics, 131, 191-209.

 ISBN: 978-1-61208-179-3

Towards a Mobile, Assistive and Intuitive Videoconferencing

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***Abstract*—In this paper we present TAM-TAM (Tele Assistance and Monitoring), a tool devised to provide assistive and intuitive videoconferencing. It can be used to provide social support, remote consultation, remote monitoring and training or rehabilitation group sessions through multi-user videoconferencing. TAM-TAM relies on a simple and minimalist interface based on accessible standard web technologies and open video streaming solutions. We also describe our progress for bringing TAM-TAM mobile, targeting Android and iOS tablet PCs and mobile market.**

Keywords–videoconferencing; teleconsultation; social care; nursing home; group home; elderly.

I. INTRODUCTION

The accelerating pace of the world's population aging is remarkably changing the demographic distribution of population, as predicted by the last International Population Report issued by the U.S. National Institute on Aging [1], which foresees that the global population aged 65 and over (about 7 percent of the world's population in 2008) will rise to 14 percent of the total by 2040. In Europe, the number of Europeans aged over 65 will increase by 52.3% from 2005 to 2030, with more than 100 million people older than 80 years by 2020 [2].

The ageing of the population together with changes in lifestyle become two key factors in the growing prevalence of chronic disorders [3], which put in risk the current healthcare system since it is more focused on the treatment of acute diseases. In 2002, the World Health Organization (WHO) launched the Innovative Care for Chronic Conditions (ICCC) initiative, which formulated the basic principles and strategies to improve the management of chronic patients: disease prevention, an increasing implication of the patient and relatives in the management of the disease and a joint work between primary, secondary care and all the actors involved in healthcare.

In this context, there is a need for technological tools that help to deploy this integrated care for chronic patients, who are mainly composed by the elderly, impaired and long-term care patients. Hence, videoconferencing postulates as a very powerful technology to enhance social support, loneliness and depressive status of those collectives [4].

However, there is still a lack of intuitive applications for those collectives. According to [5], Internet technologies would be more used if they were better adapted to the elderly. On the other hand, the main reasons adduced by non-cybernauts for not using the Internet are the difficulty (71%) and the effort required for learning how to use it (60%). Among the proposals for improving the usage of Internet technologies, price and simple interfaces are considered to be prominent.

In this paper we present TAM-TAM (Tele Assistance Monitoring), a tool that offers an intuitive interface for the elderly, impaired and long-term care people as well as for health professionals to provide social support, remote consultation, remote monitoring and training and rehabilitation group sessions through multi-user videoconferencing.

II. RELATED WORK

Although there are several initiatives and projects dealing with devices and applications devised for the aforementioned collectives, whenever a hardware device is needed but not produced in mass, it results in a relevant increase of the cost of the system, which is not affordable by public health systems. That's why TAM-TAM focuses on standard hardware such as PCs and tablet PCs, as discussed in subsequent sections. Some related projects do not include videoconferencing functionality (ALZ-AVANZA project [6]), they rely on the use of a specific set top box connected to a TV display (ATTENTIANET project [7) or they have built their specific tactile hardware and specific software (Colabor@ project [8]).

On the other hand, there is also a wide range of videoconferencing applications, either open or proprietary that could be adopted for being integrated in a new application. In general, videoconferencing solutions can be classified into two types: dedicate systems and desktop systems.

Dedicate systems consist of an integrated equipment including all the interfaces with external devices (i.e. camera, microphone, speakers, display) and a hardware or software codec for the audiovisual digital transmission. Some examples of manufacturers are Sony, Tandberg, Polycom and Cisco, amongst others. These systems are, in general, expensive and rely on specific proprietary hardware. Moreover, changes in their interfaces are not easy to implement.

Desktop systems are applications that can be installed or run on a computer and are very diverse in nature and number. Some relevant free tools include Ekko, TokBox and Vawkr, which can be easily embedded in a web site or as part of another application. However, they lack some functionality such as recording conferences or sharing documents, and they are not open source, so they cannot be freely modified or improved to be adapted to specific medico social environments (see section III.A). Among payment solutions it is worth mentioning Adobe Acrobat Connect Pro and ViewCat, both flash-based, and Skype, which currently supports videoconferencing in iOS (4.0 or above) and a subset of Android (2.1 or above) devices. Regarding open source solutions, the most relevant is OpenMeetings, a flash-based

 ISBN: 978-1-61208-179-3

tool that includes shared desktop, blackboard, and multi videoconferencing. However, the complexity of the application odds with the goal of providing a very intuitive interface and makes it difficult to run it on tablet PCs.

Finally, we need not forget about HTML5, a recent standard that could be used in the next future for developing videoconferencing solutions. Currently, the specifications and implementations of HTML5 in different browsers support the rendering of video streams in the same browser without the need of external plugins. The main unsolved issue is the access to the local camera for streaming the video, although some lab experiments have already proven its feasibility [9].

III. REQUIREMENTS AND FUNCTIONALITY

A. System Requirements

TAM-TAM has been developed in the context of a working group lead by the BCDS research group [10] in coordination with the Social Services Cohesion Board depending of the Girona's Council. This working group, called "ICT, socialization and active ageing" explores and promotes new efficient ways for supporting the elderly, dependent and impaired people through the use of ICT technologies. This collaboration relies in the collection of the requirements from end users but also in testing with real users in a real environment, which includes nursing and group homes as well as particular homes involving the target collectives.

Five scenarios have been identified for the provision of videoconferencing services in medico social environments.

1) Rendezvous: Given an appointment, the patient accesses the application and waits until the professional is ready to assist them. Only when the professional is ready, the videoconference is started. This is the typical operation in real life, where patients wait for the doctor to be available for the consultation. The professional constantly monitors waiting patients and selects who is to be attended next.

2) Remote camera control: The patient is contacted by a professional or call center. This scenario is foreseen for cases where alarms are involved, where the patient's impairment is a barrier to use technology or when an intensive monitoring is needed. Since the videoconference is not started by the patient, it involves privacy issues that should be formalized in an agreement with the patient or their family.

3) Call center: The patient contacts an intermediary, which redirects them to the appropriate professional if needed. Here the patient may or may not have an appointment with the professional. The call center may act as the receptionist of the professional or as an integrated service that can be used to manage emergency calls and filter user requests according to the criteria of an intermediate health or social professional.

4) Single videoconferencing: This is the typical scenario present in most of videoconferencing tools. A user has a set of contacts with which they are able to interact as long as they are all connected at the same time. This set of contacts may be static (not modifiable by the user) or dynamic (modifiable) depending on the requirements of the application and the skills of the target user.

5) Multi videoconferencing: This scenario is foreseen to enable the practice of training or rehabilitation group sessions for patients (e.g. occupational therapy), improving the feeling of belonging to a group of people with similar problems and concerns. Moreover it is also useful for holding medical or training sessions among professionals and/or the members of the patient's support group, as their familiars and carers.

B. System Functionality

Current main functionalities present in TAM-TAM are described in detail next.

Videoconferencing. It is the central element in TAM-TAM, as it is needed for providing telemonitoring and teleassistance health and social services. Videoconferencing has proved to be very useful both from the medical and social perspective. On one hand, from the medical point of view, it enables a closer monitoring of the patients while improving their compliance to the prescribed treatment or therapy [11]. On the other hand, from the social perspective, it alleviates the patients' loneliness and depressive status and improves their emotional and social support thanks to their interaction with their families, social carers or psychologists [4]. TAM-TAM currently supports scenarios 1, 2, 4 and 5 from those identified in section III.A, all of which rely on the same core. This fact proves how versatile the system can be by adapting the front-end operation and interface. The video quality can be dynamically tuned to fit the available bandwidth and avoid delays in the transmission.

Calendar, messages and notifications. A relevant feature in some environments is the presence of a reminder mechanism for activities or actions that need to be carried out punctually or periodically, such as drug administration, exercises to be carried out, medical appointments (physical or by videoconference). TAM-TAM offers different interfaces for that purpose. First, it provides a calendar-like interface for editing and consulting any activity or action that is linked to a certain date, time and periodicity, what we call a notification. Each notification can be configured with an urgency degree (low, medium and high), which determines whether it will trigger a visible warning when the user accesses TAM-TAM or whether it will be kept in the calendar with no visible warning. Then, we also provide a mailbox-like interface for enabling users to send customized messages to any other user associated to them. Calendars become a very powerful tool when people belong to nursing or group homes, which are monitored by specific associations, as they can be used to manage the patient's agenda from the association itself. Edition interfaces can be configured to be accessible to all or part of the application users, depending on their profile and skills.

Instant messaging and chat. These features introduce a higher complexity in the use of telemonitoring and teleassistance applications, since they need a direct interaction of users with physical or tactile and virtual keyboards, which might be something not affordable when dealing with some types of patients. However, in some occasions when the audiovisual interaction between two parties becomes not feasible due to temporal bandwidth constraints, it may act as a backup means of communication. Moreover, for users that do not have difficulty in using technology, this may act as an added value to establish and maintain a less formal

 ISBN: 978-1-61208-179-3

communication with other users. Therefore, TAM-TAM can be configured to provide instant messaging and chat functionalities depending on the user profile.

User authentication. Since user authentication needs to be kept as simple as possible, a user and password approach has been adopted, offering the possibility to remind them for future accesses. In tablet PCs or if the user device is to be used by a single patient, authentication can be highly simplified by following an initial setup that bundles the application to the user.

User contacts. TAM-TAM enables bundling a set of predefined contacts to a user by the system administrator as well as adding new users by sending invitations. The user's contact list is available to determine whether a user is connected so that a communication can be started.

IV. ARCHITECTURE

A. Architecture

TAM-TAM consists of two main parts: the portal or front-end, and the server or back-end, as depicted in Fig.1.

The front-end is the application that users access, either from their web browsers or as an installed application. It offers the interface for the whole system functionality, i.e. videoconferencing, calendar, messages and notifications, instant messaging and chat, authentication, user contacts, etc.

The back-end is composed of the modules that obtain and manage the information stored in the system's databases. TAM-TAM currently uses two different relational databases, one for users, contacts and profiles and a different database for managing the calendar, messages and notifications. Regarding the modules, they provide the intelligence for the functionalities offered by TAM-TAM and the interfaces with the corresponding databases. For example, there is a module responsible for managing notifications, messages and the user's calendar. This module is implemented as a web service that offers the functions to store create new events, messages and notifications as well as to consult them for a specific user. The front-end makes use of those functions whenever a new notification is to be created or when a user logs into the system to consult any pending urgent notification. There is also a module dealing with videoconferencing, which receives all the audio and video streams and forwards them to those users that belong to the same audiovisual single or multi videoconferencing. This module is a servlet running on the multimedia server. Fig. 2 identifies the technologies being used in TAM-TAM, described in subsequent sections.

B. Client Technology

TAM-TAM client technology is based on the Adobe Flash and Adobe AIR technologies. While the first is used for generating a Rich Internet Application (RIA) to be run on a web browser, the latter is used to build native applications for mobile and tablet devices (see section V).

RIA technologies offer in the web browser some features of traditional desktop applications, while making the update process transparent for the user, avoiding the reload of web pages and offering capabilities for designing intuitive interfaces.

Among the available frameworks used for the development of RIAs, JavaFX, Microsoft Silverlight, AJAX, Google Web Toolkit and Adobe Flash are the most relevant and adopted. Adobe Flash was chosen for TAM-TAM, since it enables the development of web applications in a simple manner by means of the Adobe Flex framework. Adobe Flex is an open source compiler and SDK based on two underlying programming languages: MXML and ActionScript (AS). While the first is used for easing the design of user interfaces, which can be based on Cascading Style Sheets (CSS), the latter offers an API that can be used for achieving interactivity and, in our case, for integrating audio and video conferencing in a simple way. AS is an open source object-oriented language that can be compiled into a SWF file to be run on the Adobe Flash Player.

The control of multimedia flows in Flex is achieved by using the NetConnection and NetStream classes offered by the AS API to create a RTMP connection to the media server and stream an audio and video transmission over that connection.

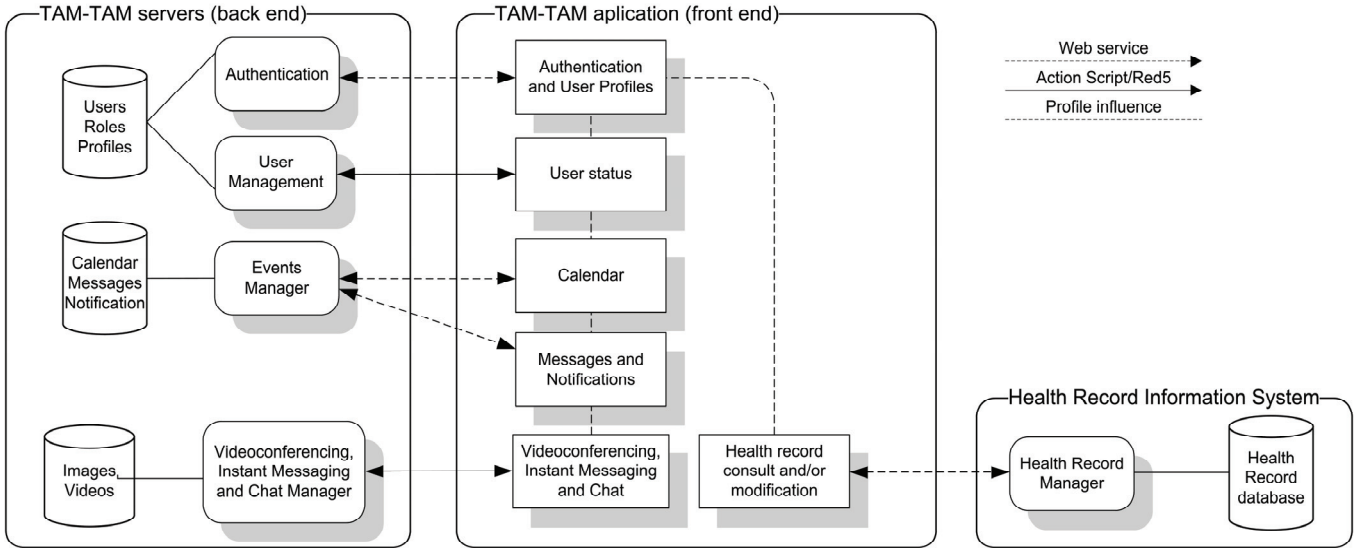

Fig. 1. TAM-TAM architecture components

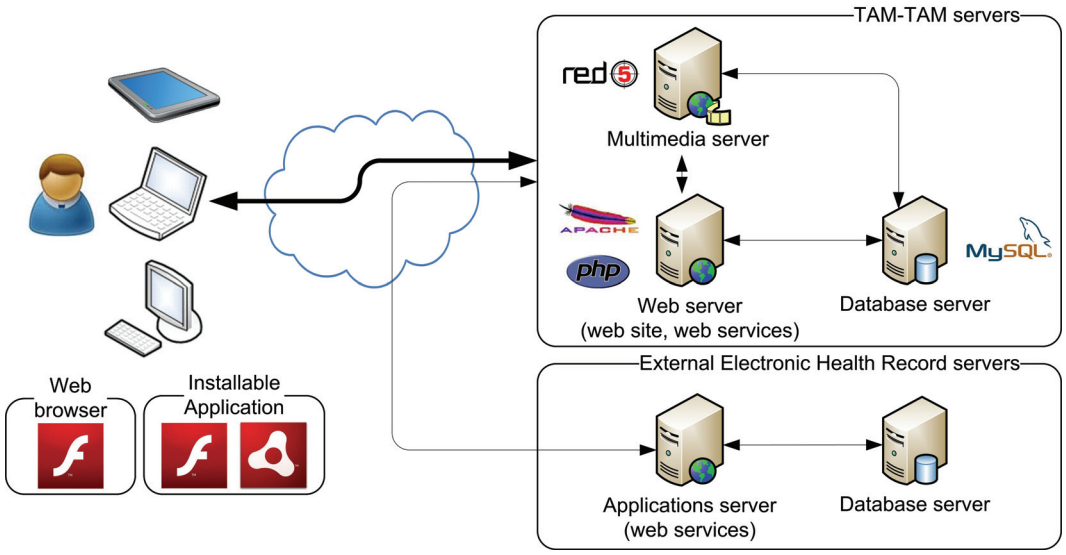

Fig. 2. TAM-TAM technologies

Moreover, the possibility of invoking web services from the AS language simplifies the extension of current functionalities and its integration with external services. This has been the approach followed to generate and consult calendar events, notifications and messages, implemented as a PHP web service. The same approach will be used to consult and modify the patient's electronic health record, presumably stored in remote Hospital Information Systems.

C. *Server Technology*

The multimedia server architecture is based on Red5 [12], an open source Flash server written in Java and hosted on Google Code. Red5 supports the delivery of multimedia content through the RTMP, RTMPT and RTMPS protocols, whose specification is open for the public use.

The fact that Red5 is an open source project eases the modification of the server and enables the development of cheaper and open solutions with respect to other proprietary server alternatives as Adobe Flash Media Server and Wowza.

Red5 contains an HTTP and application server that can host a custom-made servlet managing the multimedia streams and generating specific events for the connected clients to notify any change produced in the shared objects.

On the other hand, the server part also consists of an AMP server, which combines an Apache web server, a MySQL database server and PHP. Whereas the web server hosts the Flash web application, the MySQL database server is needed for the different databases regarding users, contacts and profiles and the calendar, messages and notifications.

Finally, it is important to remark that both Red5 and AMP servers are available for GNU/Linux, Windows and Mac OS X operating systems, which eases the deployment of TAM-TAM in different production environments.

V. TOWARDS MOBILE VIDEOCONFERENCING

In the last years, with the increasing development of the tablet PC market, very few companies or initiatives have taken benefit of the new capabilities provided by those devices for developing videoconferencing applications other than video calls [13][14]. Tablet PCs have long-lasting batteries and capacitive screens that ease their use with respect to PCs and portable PCs. They can be easily transported and charged, sustained and connected to external displays by using docks. Main operating systems running on tablet PCs are iOS, Android and Windows 7, being Android the most adopted in mobile devices and tablet PCs other that the Apple iPhone and iPad.

Next, we describe the progress for bringing TAM-TAM mobile in different operating systems in the mobile context. Since TAM-TAM is to be run on the Adobe Flash Player, any operating system (OS) or device supporting Flash will be suitable for running the client application, as long as it has a microphone, a front webcam and a fixed, Wi-Fi or mobile Internet access.

Currently, the use of Adobe Flash technology enables the development of applications to be run on the browser targeting a very large part of the market, excluding iOS and some old versions of the most common OSs. In order to be run on the browser, Adobe has specific versions of the Flash Player for different OSs and browsers [15].

From our experience and tests, Flash-based videoconferencing performs well on all Windows, Linux and Mac OS X PCs, tablets and/or mobiles, but it still has some limitations when running on Android and is not compatible with iOS.

When an Adobe Flash (version 10.3 or higher) application is run in the browser on an Android 3.0 (Honeycomb) device, the execution sandbox does not allow it to access the local camera for streaming the local video and audio. While in other operating systems the Flash player asks the user for permission to get access to the local camera, in Android this feature is disabled, thus preventing the user to send his own video stream. This issue will presumably not be solved in future releases since Adobe has recently announced that the Adobe Flash player plugin for mobile browsers will not be continued.

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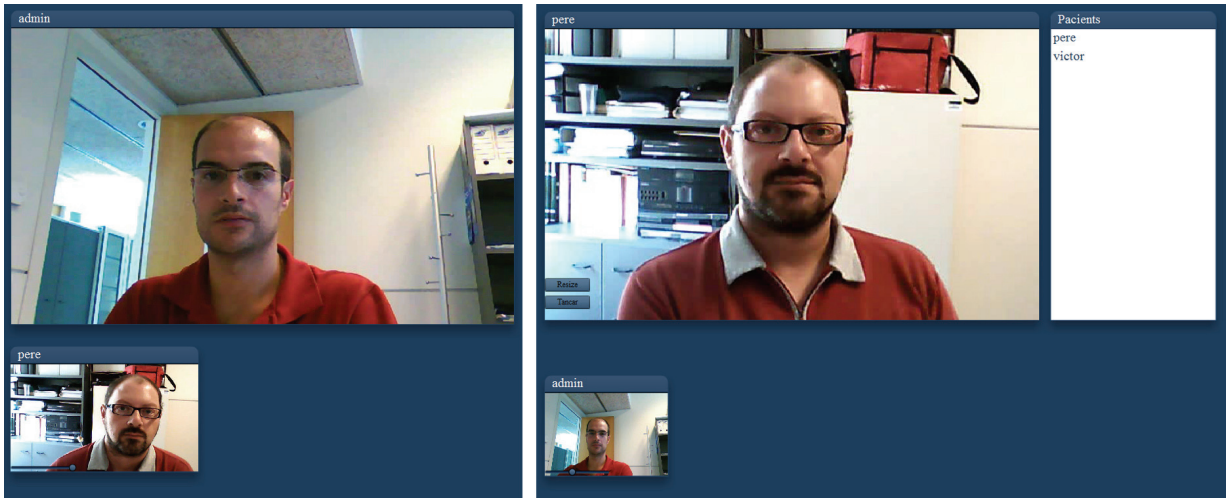

Fig. 3. TAM-TAM "Rendezvous" operation mode screenshots (left: patient view, right: professional view)

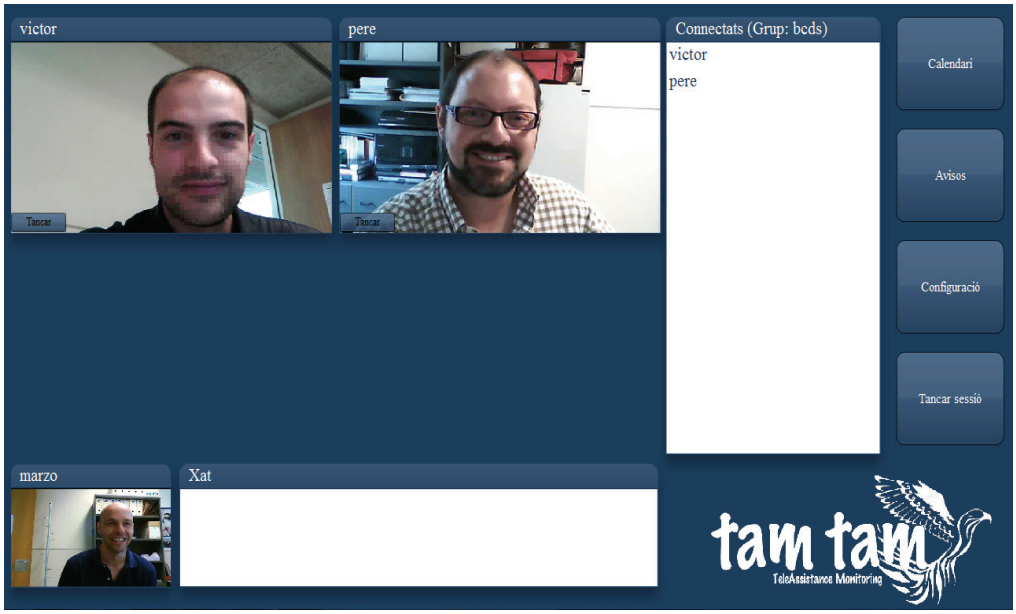

Fig. 4. TAM-TAM "Multi videoconferencing" operation mode screenshot

The solution to deal with the aforementioned limitations relies on the use of the Adobe AIR middleware, which enables to build standalone Flash-based client applications that are run like native applications. Adobe AIR is available for different operating systems, including Android and iOS. Whenever installing an AIR-based application in iOS or Android, if Adobe AIR is not installed or embedded into the application, the user will be required to do so. When developing AIR applications for Android, a manifest file needs to be configured for stating which are the local resources the application will have access to, such as the camera, microphone, contacts, etc. This step is not required for iOS applications, since applications are trusted. Whenever the user installs the AIR-based Android-enabled application, they will be asked to accept the security permissions required by the application, which, from that moment, will be capable of accessing those resources without any further explicit authorization. Our experience and findings using Adobe AIR shows that current release (AIR 3.0) fully supports the access to the front camera in Android 3.0 or higher, which was not possible on previous releases. On the other hand, Adobe AIR is perfectly suitable for flash-based iOS videoconferencing.

A reduced version of TAM-TAM has been successfully tested as a standalone application on three tablet PCs: Acer Iconia A500 (Android 3.0), Acer Iconia W500 (Windows 7) and Apple iPad (iOS).

VI. INTUITIVE VIDEOCONFERENCING

Making videoconferencing intuitive is one of the major goals when designing medical and social applications, since they need to deal with a large diversity of users and different degrees of technology knowledge. For that purpose, TAM-

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TAM has been designed to be intuitive, as in the operation modes illustrated in Fig. 3 and Fig. 4, which present different views of the rendezvous and multi videoconferencing modes implemented in TAM-TAM.

In the rendezvous operation mode, the role of the user determines the presentation and functionality being displayed to the user. On one hand, the professional has the full control over the system, since he is responsible for selecting the user to be attended from a patient's queue, controlling the video quality whenever needed and pausing or ending the consultation. The videoconference is started, paused and finalized according to the professional's decisions. On the other hand, the patient just logs into the application and waits for the professional, which will conduct the teleconsultation. When the videoconference is not active the user views notification messages like "Your doctor is online, please wait to be attended", "Your doctor is currently busy, please wait to be attended" and "Your consultation has been finalized".

In the multi videoconferencing mode, a group of users belonging to the same group interact with each other. When logged, they all can see who else in the group is already available and start videoconferencing by just a single click on the user's name or picture.

Regarding authentication, when running TAM-TAM in a browser, login information can be saved for further accesses. Additionally, when dealing with tablets, the application can operate in the same manner or even be individually bundled to a single user.

This simple user interfaces ease very much interaction for people for which technology may be an impairment. Moreover, when using tablets or mobile devices, the possibility to access videoconferencing applications by just a single touch on the screen makes the difference with respect to other type of devices.

VII. CONCLUSIONS AND FUTURE WORK

We have presented TAM-TAM functionalities, architecture and underlying technology. TAM-TAM uses the Adobe Flex framework, which enables the design of usable interfaces and provides videoconferencing support, while opening the door to the development of portable health applications on iOS and Android mobile phones and tablet PCs.

The multi videoconferencing and rendezvous operation modes of TAM-TAM are accessible for demonstration at [16], where additional videos and resources can be also found.

Currently, we have started small-scale tests with selected users who are running standard PCs in their homes. Next step will include the usage of tablet PCs. This work is being done in the context of the "ICT, socialization and active ageing" working group depending on the Girona's Council. The results are being taken into account for improving the usability of the TAM-TAM application. Additional clinical assessment as well as non-functional tests and measurements need to be carried out, including the cost-effectiveness assessment, videoconferencing performance, delay, scalability and jitter depending on the type of connectivity (WiFi, mobile, etc.).

Other relevant features that will be adopted in the future include audio and video recording, to take pictures of the patient's aspect or some types of lesions and to adopt more secure authentication mechanisms, mainly when dealing with health professionals, through the use of X.509 digital certificates. Moreover, we also foresee the integration of TAM-TAM with Hospital Information Systems, so that health professionals have access to the patient's electronic health record.

ACKNOWLEDGMENT

This work was partially supported by the Spanish Ministry of Science and Innovation Project TEC 2009-10724, and by the Generalitat de Catalunya Research Support Program SGR-1202.The authors thank Raul Romero for his collaboration.

REFERENCES

[1] K. Kinsella and W. He. International population reports. "An aging world: 2008". Washington, DC: U.S. Government Printing Office, 2009, retrieved: November, 2011.
http://www.census.gov/prod/2009pubs/p95-09-1.pdf

[2] European Commission's Green Paper on Demographic Change, 2005.

[3] J. Roca, A. Alonso, and C. Hernandez. "Integrated care for COPD patients: time for extensive deployment". Breathe, vol. 5, n. 1, pp. 27–35, 2008.

[4] H. Tsai, Y. Tsai, H. Wang et al. "Videoconference program enhances social support, loneliness, and depressive status of elderly nursing home residents". Aging & Mental Health, vol. 14, n. 8, pp. 947–954, 2010.

[5] H.R. Schelling and A. Seifert. "L'utilisation de l'internet par les personnes âgées". Centre de gérontologie sur mandat de Pro Senectute Suisse, en collaboration avec l'Office fédéral de la communication (OFCOM) et l'Institut für Publizistikwissenschaft und Medienforschung de l'Université de Zurich.

[6] ALZ-AVANZA Project, retrieved: November, 2011.
http://www.aideca.net/alz_avanza.php

[7] ATTENTIANET project, retrieved: November, 2011.
http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&project_ref=ETEN-517316

[8] Colabor@ project, retrieved: November, 2011.
http://grandesclientes.telefonica.es/articulo.php?id=56&id_submenu=.

[9] Ericsson Labs, retrieved: November, 2011.
https://labs.ericsson.com/developer-community/blog/beyond-html5-conversational-voice-and-video-implemented-webkit-gtk

[10] Broadband Communications and Distributed Systems research group. Universitat de Girona, retrieved: November, 2011. http://bcds.udg.edu/.

[11] R. Antonicelli, P. Testarmata et al. "Impact of telemonitoring at home on the management of elderly patients with congestive heart failure". Journal of Telemedicine and Telecare, vol. 14, pp. 300–305, 2008.

[12] Red5 website, retrieved: November, 2011.
http://red5.org/, http://code.google.com/p/red5/

[13] Cisco Cius, retrieved: November, 2011.
http://www.cisco.com/en/US/products/ps11156/index.html

[14] Apple Facetime for iPad, retrieved: November, 2011.
http://www.apple.com/ipad/built-in-apps/facetime.html

[15] Adobe Flash system requirements, retrieved: November, 2011.
http://www.adobe.com/products/flashplayer/systemreqs/

[16] TAM-TAM, retrieved: November, 2011.
http://tamtam.udg.edu/

 ISBN: 978-1-61208-179-3

The Potential of Telemedicine for Patients with Chronic Disorders Experiencing Problems with Their Functioning

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***Abstract*—It is hypothesized that telemedicine applications can make rehabilitation care more effective and efficient. Besides the demonstrated potential of image/audio-based technology, it is expected that telemedicine applications, which use biomedical and ICT technology, to support physical and cognitive behavioral rehabilitation at home or daily life style management, both under remote supervision of professionals, are considered very promising. Compared to traditional rehabilitation methods, these telemedicine applications enable the patient to receive more intensive treatment at moments they prefer, or when care/coaching is needed, instead of when scheduled. In addition they also have the advantage that no translation of the learned skills to everyday life is needed. However, these telemedicine applications are often too much technology driven and insufficiently guided by the need of end users and the added value of these applications is still insufficiently known as a proper evaluation methodology is scarcely applied and large studies are lacking. This paper addresses these two aspects by describing a concept for development of end user driven telemedicine applications followed by an evaluation methodology that enables us to show the added value when applied in every day care. This is illustrated for telemedicine applications that focus on physical rehabilitation of patients with a chronic disease who are experiencing problems with physical functioning. Based on the results available so far, it can be concluded that these telemedicine applications are well accepted by patients and are at least as effective as traditional care.**

Keywords-telemedicine; chronic disease; physical reconditioning; ambulant monitoring; home treatment; feedback.

I. INTRODUCTION

Both the European and American population is aging. With regard to The Netherlands, it is expected that the number of people aged over 65 years will increase to about 24% of the total population by 2050. Besides the increase in the proportion of elderly in the population there is also an increase in the number of people suffering from one or more chronic illnesses. Currently in The Netherlands, 1 of 4 people suffers from a chronic disease and it is expected that this number will rise sharply in the coming years. Since both the elderly and those with chronic diseases have higher care consumption this increase means a surge in pressure on our healthcare system.

Treatment of chronic diseases focuses on the relief of symptoms and related complaints as well as on increasing self-management by patients; this with the overall aim of increasing quality of life and level of participation in society. There are various treatments for patients with chronic disorders: such as drug treatments but also non-pharmaceutical treatments, like physiotherapy and multidisciplinary treatments are becoming increasingly important. It is however not realistic to continue these treatments in the way they are currently provided. This is due not only to the growing number of people in need of such care, but also due to the decline in labor capacity and the rise in costs that the care system is facing. In addition, our current way of care provision is strongly geared towards professional guidance with the patient not sufficiently in the driver's seat.

Prompted by these trends, but also facilitated by the new possibilities of technology, it is expected that telemedicine can contribute to more cost-effective patient centred care. This style of care provision is considered of utmost importance for our current and future care.

According to the Dutch Technical Appointment (NTA) telemedicine is defined as a process in healthcare, characterized at least by the following two features (NTA 8028; [1])

 ISBN: 978-1-61208-179-3

- Distance is bridged by using Information and Communication Technology (ICT)
- There are at least two actors involved, at least one of them is an approved care professional or acts on behalf of an approved care professional

The use of ICT in healthcare is a relatively recent development. In 1906, the Dutch physiologist Willem Einthoven transmitted Electrocardiograph (ECG) signals over telephone lines. He investigated ECG signals from patients in the Hospital from his laboratory located 1.5 km away. However, this was for research purposes only [2]. Medical care on a distance started in the 1920s when physicians were linked by radio to ships at sea to assist in medical emergencies [3]. Nowadays a Google search using the term 'ICT and healthcare' results in about 16.820.000 hits.

One of the areas in healthcare where telemedicine applications are considered to be of potential is the rehabilitation that merely aims at supporting patients in acquiring and maintaining an active lifestyle. Recently, the first systematic reviews related to telemedicine in this field have been conducted. Kairy et al. [4] performed a systematic review on clinical outcomes, clinical processes, such as attendance and compliance, healthcare utilization and costs associated with tele-rehabilitation for individuals with physical disabilities. They included 28 papers, published between 1993 and 2006, that used an experimental or observational study design. They concluded that tele-rehabilitation can lead to similar clinical outcomes compared to traditional rehabilitation programs, with possible positive impacts on some areas of healthcare utilization. However, the majority of the reviewed papers concerned technology that focused on image/audio-based technology. Other more advanced technologies such as sensor based technology and virtual environments, are hardly considered. LaPlante and Peng [5] published a systematic review in 2011 that included 31 articles which they analyzed in terms of study design quality, intervention characteristics and support for e-health in physical activity interventions. This review demonstrated that it is increasingly common to use various e-health technologies to address physical activity, but they also concluded that it is impossible at this moment to give definitive evidence for the effectiveness of e-health technologies as insufficient systematic and proper evaluation studies have been performed. In addition, a recent review [6] concluded that there is even less evidence regarding the costs or cost-effectiveness of telemedicine applications, as well as the fact that there is insufficient evidence of the added value. The fact that telemedicine applications are still too technology driven and insufficiently guided by the needs of end users is also considered to hamper implementation and successful uptake of telemedicine applications by its stakeholders, including healthcare institutes, health professionals and health insurance companies [7].

This paper focuses on these two aspects, a concept for development of end user driven telemedicine applications and an evaluation methodology which enables us to show the added value of telemedicine when applied in every day care. This is illustrated by reference to telemedicine applications which focus on physical rehabilitation of patients with chronic disease who are experiencing problems with physical functioning. Firstly, the telemedicine applications will be addressed by describing the overall concept as well as some examples for physical rehabilitation. Subsequently an evaluation methodology is described as well as results of evaluation studies using this methodology on telemedicine applications that are used in the care of patients with chronic low back pain, chronic fatigue or a pulmonary disease.

II. POSSIBLE TELEMEDICINE APPLICATIONS FOR PHYSICAL REHABILTIATION

A. *The concept of telemedicine*

Looking at rehabilitation in a broad sense, the aim is to enable a patient to participate in our society at the highest possible level of activity. There are different rehabilitation methods available to achieve this and they have certain key aspects in common, namely (re)learning adequate motor skills, regaining important functions such as force and, mobility and improving a patient's activity level. In traditional care, these treatments are performed during patient visits to the professional's premises where the patient receives feedback from the professional on how the patient performs and tips on how to further improve. Opportunities for introducing telemedicine in this rehabilitation process lie in applications that enable patients to train at home and work on their recovery more independently while being remotely supervised by their healthcare professional. Such telemedicine applications can be realized by means of biomedical technology used in combination with ICT. Hermens and Vollenbroek-Hutten [8] described an overall concept for these telemedicine applications, which is graphically presented in Fig 1.

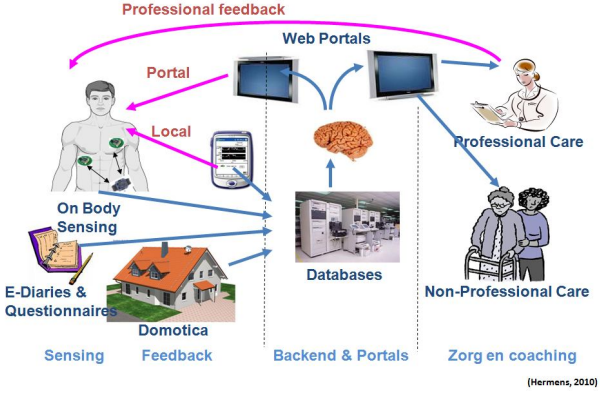

Figure 1. The concept of a telemedicine service

This figure shows that different building blocks are needed for a telemedicine service.

Sensing:

In traditional treatment, a professional assesses the performance of the patient during training and, based on this, feedback is provided. In the case of telemedicine applications, where face to face treatment is at least partly replaced by technology, it is required that performance can be quantitatively assessed within the patient's daily environment and therefore some kind of sensing is usually needed. Which parameters to use for sensing the patients' performance depends on the diagnosis and the aim of the telemedicine application. Examples are: range of motion if mobility is being trained; muscle activation patterns where treatment aims at reduction of tension or at coordination, or activity levels when the goal is improvement of physical activity. The techniques useful for assessing performance can also differ. Some possible techniques are: subjective information (e.g. diaries), sensors temporarily attached to the body (e.g. ECG, EMG) and environmental sensors (e.g. wireless sensor networks [8].

Feedback

Once insight into a patient's performance is gained, the next step is to give the patient insight into his own performance by providing adequate extrinsic feedback. Extrinsic feedback is feedback provided on top of intrinsic feedback and mostly provided by an external source [9]. Feedback in treatment of patients with chronic disorders can serve different goals such as motor skills learning, creating awareness, motivating the patient to change, changing into and maintaining new performance levels [10]. In the case of telemedicine applications, feedback can be provided via different loops as also shown in Fig. 1. The shortest loop is local feedback provided directly on the monitored information. The second loop is feedback provided via a portal. This loop enables integration of data from different sources as well as over longer period of time. The third loop is professional feedback in addition to feedback received via the first two loops. Research shows that both patients and professionals prefer a combination of feedback via the first two loops, namely feedback by technology with feedback by professionals (third loop) [11].

Backend and portals

Backend and portals concern transport and storage of the measured signals, the processing of these signals as well as support of secured access to the data via internet. In most of the cases a 'decision-support system' is needed in order to extract relevant characteristics from the data and to adequately inform or warn patients and professionals as well as to trace technical failures [12]. The portals that provide access to the data are most often built around databases and this kind of 'decision-support system' and enable the user to get access to the data in a user friendly and secure manner. In case multiple professionals are involved in the care of a patient it is important that the system, supported by a good policy management, can decide who needs to be warned and, which information needs to be presented to which healthcare professionals.

Care and coaching

Formal and informal care givers may be involved in the care process to coach/support the patient. In order to adequately support them it is important to ensure that telemedicine applications are implemented in this daily care process in a proper manner. Telemedicine applications can be implemented as aftercare, as partial replacement of traditional care or as an addition alongside regular care. Considering the challenge to decrease the pressure on our healthcare in terms of costs and required labor capacity it is important that implementation as partial replacement is pursued.

B. Examples of telemedicine applications

Starting from this overall architecture different kinds of telemedicine applications can be realized for physical reconditioning of patients with chronic diseases. Below some examples are given.

Rehabilitation exercises at home

Patients with chronic disorders need to exercise and keep exercising a lot to improve and/or maintain their condition and motor skills. Rehabilitation at home refers to telemedicine applications that enable patients to perform these exercises at times and places they prefer while still being adequately supervised by professionals. Patients get access to individually tailored exercise programs through technology. Examples of these are presented in Fig. 2.

The picture on the left shows web-based exercise programs as developed in the FP7 project Clear (ICT: PSP CLEAR 224985) [13] and the Dutch project CoCo (CALLOP9089) [14]. A healthcare professional, often a physiotherapist, creates an individually tailored exercise program for each patient by making a schedule with the patient showing what exercises to execute and when. Exercises are chosen out of a data base of exercises. At home the patient logs into the system with a username and password and gets access to his personalized exercise program. Exercises are presented to the patient by means of video, spoken word and text. The patient has the opportunity to send text messages to the professionals or a teleconference can be scheduled.

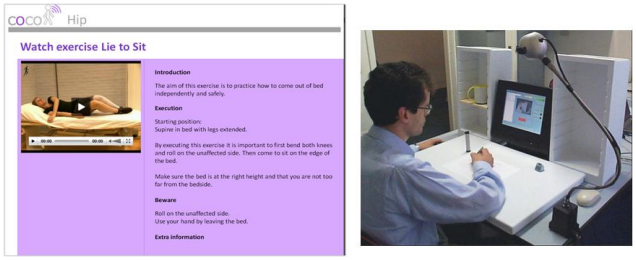

Figure 2. Examples of telemedicine applications for active rehabilitation at home

The picture on the right shows a Home Care Activity Desk (HCAD) equipped with sensors for arm-hand function training. This application was developed by the European project HELLODOC (FP6 ETEN, 517508) [14]. This system consists of a portable unit with seven sensorized tools, which is installed in the patient's home. The seven sensorized tools are: a key, light bulb, book, jar, writing, checkers and keyboard. With this portable unit a set of exercises can be performed such as reaching, grasping, lateral pinch, pinch grip, holding, manipulation and finger dexterity. The unit is also equipped with two webcams, which allow videoconferencing and recording. The videos and the results of the exercises were uploaded to the hospital server where all the data and videos were collected. The therapist used this information for the weekly videoconference with the patient [15].

Life style management

Patients with a chronic disease often need to change their lifestyle to prevent deterioration or recurrence of complaints. An example of this is deploying and maintaining an active lifestyle. Telemedicine applications for life style coaching support patients in the development and maintenance of healthy behaviour by monitoring the patient's daily lifestyle and giving direct feedback on this to the patient. The monitored data can also be stored in databases and made accessible to his formal and informal care professionals via web-portals to adequately support the patient in this process. An example of such a telemedicine application is shown in Fig. 3.

The picture on the left shows the sensor for activity monitoring. In the middle of the illustration, an example can be seen of the direct feedback that is provided to the patient on his mobile phone. On the right is a screenshot of the portal that gives both the patient and professionals insight into the data and changes over a longer period of time.

Remote monitoring and alarming

For many patients it is difficult to recognize important disease-related symptoms and complaints and to act adequately on them. For example a worsening of complaints for patients with a pulmonary disease can be a reason to start an antibiotic or Prednisolon treatment.

Figure 3. Examples of a telemedicine application for lifestyle management

Remote monitoring and alarm applications focus on guarding the (changes in) health status of a patient by monitoring and interpretation of his vital body signs or primary complaints. This should be achieved as far as possible without affecting the patient's daily life but ensuring that help is provided if necessary. Fig. 4 gives an example of a remote monitoring and alarm service.

This application for patients with pulmonary diseases monitors the patient's changes in complaints on a daily basis by asking the patient whether the most relevant aspects of their complaints are different than usual. Based on the patient's scores over consecutive days an advice is given to the patient whether or not to start a medication treatment. Data of the patient are made accessible for his healthcare professional who is alerted in case a medication treatment has to start. This enables him to adequately advise the patient.

III. EVALUATON

A. *Methodology*

Once a telemedicine application has been developed, the next step is to demonstrate the results when the system is used in everyday practice. Outcome measures usually focus on the technical feasibility of the system and on user satisfaction. In general, the results of such studies show that telemedicine applications are technically stable and that patients and professionals have a positive attitude towards using them. This type of evaluation is however not sufficient to justify subsequent large scale implementation. For this, a broader evaluation is necessary [9]. DeChant et al. [16] proposed a staged approach for the evaluation of telemedicine applications, starting early in the development phase and dependent on the maturity of an application. The first phase evaluation is aimed at investigating whether the requirements of the patients are met and whether the application is technically stable. At this stage the user group is small, because the results are mainly used to develop a more mature application. After the first phase evaluation, evaluation of a mature application (stage 2) focuses on the clinical outcome. If these results are positive, evaluation becomes even more extensive, using multiple endpoints such as effectiveness, efficiency or accessibility of care (stage 3). The last evaluation phase (stage 4) focuses on external validity and investigates whether the application is as effective when implemented in places other than where it was developed.

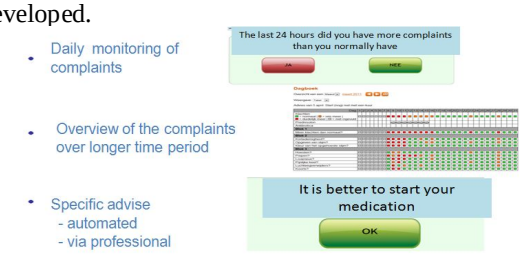

Figure 4. Examples of a telemedicine application for remote monitoring and alarming

B. *Clinical studies*

Taking the DeChant [16] framework as starting point evaluation studies have been performed for the rehabilitation-at-home applications and the life style management applications. Results of these studies are presented below.

Rehabilitation exercises at home

After a small positive prognostic cohort study, a further developed version of the web-based exercise program was implemented at The Roessingh Center for Rehabilitation (RCR) (The Netherlands) in outpatient pain and pulmonary rehabilitation programs in two different modalities: as addition to and as partial replacement of the traditional rehabilitation. For evaluation a study was performed in which eligible patients were divided into a control and an intervention group. The control group followed the traditional rehabilitation program. The intervention group followed the same program but with the web-based exercise program implemented, dependent upon patient's ability to train as addition or as replacement of one visit to the rehabilitation center per week. The large scale evaluation focused on multiple outcome parameters namely experiences (satisfaction, compliance and usability) and clinical benefit. Clinical benefit was assessed by using a Visual Analogue Scales; pain intensity for chronic pain patients and level of dyspnoea for COPD patient. The trial is ongoing; currently 212 patients are informed about the service and 187 patients have given written informed consent to participate. Eighty-four patients were allocated to the control group and 103 patients were allocated to the intervention group. Preliminary results for the first 125 patients who have finished the treatment show that the overall grading of the web-based telemedicine exercise service was sufficient and that the ease of use was rated good. On average, these patients scored 7.2 on a scale of 0-10 indicating that usability is good. The first results on clinical benefit show that both implementation modalities (as addition / as partial replacement) are at least as effective as traditional care. In the telemedicine (n= 66) and the traditional care group (n= 69) about 55% and 49% of the patients show a clinically relevant improvement on the primary outcome parameter, respectively. However, these percentages are not significantly different from each other.

The Home Care Activity Desk (HCAD), which was also redesigned after an initial demonstration study, was evaluated in a randomized multicenter trial within the European project Hellodoc [17]. In this study usual care was compared to the HCAD intervention for arm/hand training. The intervention with the HCAD system at home lasts one month, whereby the patients had to train at least once a day, 5 days a week for an average of 30 minutes. Usual care (control group) consisted of regular physical and ergonomic therapy with an average of three times a week for 45 minutes. Follow up measurements were performed after one month of treatment. Eighty-one patients with chronic Stroke, TBI and MS patients were recruited in Italy, Spain and Belgium. Outcome measures used were the Action Research Arm Test and the Nine Hole Peg Test. Results showed that the overall satisfaction of patients and therapists concerning the HCAD system was high. The outcome measures do not differ significantly between the two groups; and patients maintain or even improve on their arm/hand function.

Life style management

Evaluation of the activity-based feedback application for supporting the patient in deploying a better activity pattern during the day started with a prognostic cohort study of 17 patients with chronic low back pain who carried a tri-axial accelerometer and a PDA for 15 days (baseline and 2 weeks of feedback [18]. Patients received continuous and time-related personalized feedback and were instructed to follow the activity pattern as displayed on the PDA (norm value). Results showed that the technical performance was rated good in nine patients (56%), moderate in four patients (25%) and bad in three patients (19%). The overall compliance was rated good in seven patients (44%), moderate in five patients (31%) and bad in four patients (25%). A positive trend was seen in the activity pattern of the patient that moved towards the norm value during the feedback weeks, however the difference failed to reach the level of significance ($F=1.932$; $p=.149$). In contrast, the pain intensity levels decreased significantly in the second week of feedback compared to baseline and the first week of feedback ($F=5.401$; $p=.005$).

In addition to this study, a second study was performed on 30 patients with chronic fatigue syndrome with the aim determining the compliance with the system and the amount of change in physical activity patterns of those who comply [19]. For this a longitudinal study was performed as part of a randomized controlled trial in which a feedback program was introduced in an existing rehabilitation program. The existing rehabilitation program comprised 9 weeks of inpatient cognitive behavioural therapy in weeks 1, 3, 5, 7 and 9. The feedback application was implemented during the four periods when patients were at home in between the weeks of inpatient treatment. Compliance with the feedback system was around 90% during each of the four feedback periods, however only fifteen patients (50%) complied with all four feedback periods (compliers). The Wilcoxon signed ranks test showed that for the group of compliers the physical activity level, expressed as percentage of the goal value, during feedback period 1 (103%), feedback period 2 (98%), feedback period 3 (94%) and feedback period 4 (98%) were significantly higher ($p<0.01$) and closer towards the goal compared to the baseline period (84%) and these changes were most obvious in the morning and afternoon.

IV. CONCLUSION AND FUTURE WORK

The results of the present paper show that patients and professionals are positive about telemedicine services for

 ISBN: 978-1-61208-179-3

rehabilitation purposes. In addition, the clinical benefits achieved with telemedicine applications are promising as the clinical benefits appear to be at least as good as the results achieved with traditional rehabilitation care. However, the level of evidence to date is, also according to the DeChant [13] framework, not sufficient and needs attention in future. Next to this, another aspect that is considered important for future work is the technology used. The technology should be relegated even more to the background as is currently the case. For this, the technology should be more adaptive, intelligent and become a real buddy of the patient. Concerning the telemedicine applications itself the integration of social media, group dynamics but also serious games are considered important, especially for long term adherence to exercising.

To finalize, although there are still many challenges, the potential of telemedicine in rehabilitation care becomes conspicuous on a daily basis and the positive effect of our methodology is evident.

ACKNOWLEDGMENT

The work presented in this paper is made feasible with different grants. HELLODOC (FP6 ETEN, 517508) [13] CLEAR (FP7, ICT: PSP 224985) [12], The Dutch ZIP project CoCo (CALLOP9089) [13], ZonMw project Chronisch Vermoeidheidssyndroom (56100001), BSIK Awareness project [13]

REFERENCES

[1] http://www.nen.nl/web/Leven/Telemedicine.htm, <retrieved, dec, 2011>

[2] W. Einthoven, “Le telecardiogramma,” Arch Int de Physical, vol. 4, 1906, pp. 132-134 (translated into English, Am Heart J 1957; 53: pp. 602-615).

[3] S. Tachakra, Z.H. Wang, R.S.H. Isepanian, and Y.H. Song, “Mobile e-Health: The unwired evolution of telemedicine,” Telemedicine journal and e-health, vol. 9(3), 2003, pp. 247-257.

[4] D. Kairy, P. Lehoux, C. Vincent, and M. Visintin, “A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation,” Disabil Rehabil, vol. 31(6), 2009, pp. 427-447.

[5] C. Laplante and W. Peng, “A systematic review of e-health interventions for physical activity: an analysis of study design, intervention characteristics, and outcomes,” Telemed journal and e-Health, vol. 17(7), 2011, pp. 509-523.

[6] A.G. Ekeland, A. Bowes, and S. Flottrop, “Effectiveness of telemedicine: a systematic review of reviews,” International journal of medical informatics, vol 79, 2010, pp. 736-771.

[7] T.F. Broens, M.H.A. Huis in ‘t Veld, M.M.R. Vollenbroek, H.J. Hermens, A.T. van Halteren, and L.J.M. Nieuwenhuis, “Determinants for successful telemedicine implementation; a literature study,” Journal of Telemedicine and Telecare, vol. 13(6), 2007, pp. 303-309.

[8] H.J. Hermens HJ and M.M.R. Vollenbroek-Hutten, “ Towards remote monitoring and remotely supervised training,” Journal of Electromyography and Kinesiology, vol. 18(6), 2008, pp. 908-919.

[9] C.J. Winstein, “Knowledge of results and motor learning – implications for physical therapy,” Phys Ther, vol 71, 1991, pp. 140–149.

[10] M.M.R. Vollenbroek-Hutten and H.J. Hermens, “Remote care nearby,” J Telemed Telecare, vol 16(6), 2010, pp. 294-301.

[11] K. Cranen, C.H. Drossaert, E.S. Brinkman, A.L. Braakman-Jansen, M.J. Ijzerman, and M.M.R. Vollenbroek-Hutten, “An exploration of chronic pain patients' perceptions of home telerehabilitation services,” Health Expect, vol 17(7), 2011, pp. 530-535.

[12] V. Jones, R. Batista, R. Bults, H. Op Den Akker, Y. Widya, H. Hermens, M. Huis In' t Veld, T. Tonis, and M.M.R. Vollenbroek-Hutten, “Interpreting streaming biosignals: in search of best approaches to augmenting mobile health monitoring with machine learning for adaptive clinical decision support,” In Learning from Medical Data Streams Workshop, 13th Conference on Artificial Intelligence in Medicine (AIME'11), July 2-6, 2011, Bled, Slovenia. eds. P.P. Rodrigues, M. Pechenizkiy, M.M. Gaber, and J. Gama.

[13] http://www.habiliseurope.eu/ <retrieved:dec,2011>

[14] http://www.rrd.nl,< retrieved: dec, 2011>

[15] B.C. Huijgen, M.M.R. Vollenbroek-Hutten, M. Zampolini, E. Opisso, M. Bernabeu, J. Van Nieuwenhoven, S. Ilsbroukx, R. Magni, C. Giacomozzi, V. Marcellari, S.S. Marchese, and H.J. Hermens, “Feasibility of a home-based telerehabilitation system compared to usual care: arm/hand function in patients with stroke, traumatic brain injury and multiple sclerosis,” J Telemed Telecare, vol. 14, 2008, pp. 249–256.

[16] H.K. DeChant, W.G. Tohme, S.K. Mun, W.S. Hayes, and K.A. Schulman, “Health systems evaluation of telemedicine: a staged approach,” Telemed J, vol 2, 1996, pp. 303–312.

[17] H.J. Hermens, B.C.H. Huijgen,C. Giacomozzi, S. Ilsbroukx, V. Macellari, E. Prats, M. Rogante, M.F. Schifini, M.C. Spitali, S. Tasies, M. Zampolini, and M.M.R. Vollenbroek-Hutten, “Clinical Assessment of the HELLODOC tele-rehabilitation service,” Ann Ist Super Sanita, vol 44(2), 2008, pp. 154-163.

[18] M.G.H. Dekker-van Weering, M.M.R. Vollenbroek-Hutten, and H.J. Hermens, “Potential value of an activity based feedback system for treatment of patients with chronic low back pain,” Unpubslished.

[19] R.M.H. Evering and M.M.R. Vollenbroek-Hutten, “Ambulatory activity-based feedback for improving daily physical activity patterns in patients with the chronic fatigue syndrome: a longitudinal study,” Unpublished.

 ISBN: 978-1-61208-179-3

Repeatable Experimental Framework for Wellness Indicator Testing/Evaluation: Environmental Setup

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***Abstract*—This paper presents more detailed information relative to an experimental framework for evaluating a wellness visualization system, mainly focuses on setting up an appropriate environment for conducting a testing session. Relative issues and considerations, e.g., selecting a testing location, suggested list of equipments and survey tools, and privacy issues, are also discussed.**

Keywords-testing methodology; system testing; wellness visualization system; information visualization.

I. INTRODUCTION

An agent-based wellness visualization system was presented in the previous publications [1-3] as a proof of concept of personal wellness indicator that is designed to assist a person to monitor, learn, and therefore promote their state of well-being; plus, providing decision support information to a caregiver with an alternative communication channel between a patient and a caregiver. The wellness indicator is constructed in accordance with the concept of the operational wellness model, as described in [2]. In order to verify and confirm the validity of the agent-based wellness visualization system, a repeatable framework for evaluating a wellness visualization system was developed. Two sets of questionnaires and evaluation metrics have been constructed from this framework. The wellness indicator will be evaluated by following the protocols described in the framework. Detailed information relative to the framework for testing a wellness visualization system can be found in [3].

The protocols, sets of questionnaires, and evaluation metrics are not enough for pursuing an effective measurement. There are other factors that can support and lead us to a well-performed testing session with high possibility of success; for example, location, equipments, number of volunteers per staffs per one testing session, etc. In this paper, we discuss the issues and solutions relative to setting up an appropriate environment for testing a wellness visualization system.

The paper is organized as follows. Next section gives background information relative to the operational wellness model and agent-based wellness visualization system. Section III provides the summary of the testing framework. The issues relative to setting up a testing environment are discussed in Section IV. Conclusions and future work are provided in the last section of the paper.

II. BACKGROUND INFORMATION

This section provides summarized information relative to the operational wellness model and agent-based wellness visualization system. More information is available in [1-3].

A. Operational Wellness Model

The operational wellness model is a wellness model that is created for an automatic measuring system and it is also a fundamental for developing our wellness indicator [2]. The model includes the operational definition of wellness and operational wellness evaluation model [2].

In this research, the term *wellness* is defined as "*a state of achieving best possible state of physical health and lifestyle within a person's capability*" [2]. Each person can have personal sets of wellness indicators; and each indicator has a certain target value or range [2]. A person might not be able reach the highest level of wellness but still can achieve their desirable level of wellness; in which case we consider them as being well [2]. A person having disability can be considered as being well (in certain areas), if they can manage to achieve the targets/goals of their wellness indicators. The visualization system supports monitoring of three sets of parameters, mainly focused on physical health, and to their improvement towards the target values/ranges [2]. The three sets of parameters are as follows:

1. Case-based indicator: initial sets of clinical objective parameters that are relative to certain cases. These parameters are predefined and provided to the end-users to choose. [2]

2. User defined indicator: a set of indicators defined by a user. The user can define personal indicators with target values or target ranges by following certain instructions and rules. [2]

3. Healthcare-professional defined indicator: a set of indicators defined for a patient by caregivers. [2]

A person can have a personal set of indicators for monitoring their personal wellness level and can expand/modify it as need. Thus, the operational wellness model is flexible, customizable and expandable.

The operational wellness evaluation model is

 ISBN: 978-1-61208-179-3

constructed based on the operational definition of wellness. Both single indicator wellness and overall wellness level are measured [2]. Single indicator wellness indicates the wellness level as perceived through a single indicator [2]. The results from a series of case-based indicators and healthcare-professional defined indicators are combined to become the overall wellness level of a person [2]. The latest results can be compared with the previous evaluations to find the progress and trend.

B. Agent-Based Wellness Indicator

The agent-based wellness indicator is an information visualization system and a physician/patient support system that employs the benefits of the information provided by existing electronics resources such as personal health monitoring devices and e-Health services [1-3]. The visualization system supports a person to enhance their knowledge relative to personal state of well-being and encourages the user to improve their wellness level [1-3]. The wellness indicator also assists a caregiver to gain access to a patient's wellness and analyzed information, including utilizing decision supporting tools provided by the system [1-3]. The wellness indicator employed the results from both types of wellness evaluation to visualize the state of wellbeing of a person in simple graphical formats [2].

A user can access to the system through personal computers, small form factors, and, in the future, televisions. The content presented on all types of devices is the same but on different layouts; mainly because of the screen size and the limitation of those devices.

The wellness indicator has various screens designed for supporting the two types of users who have different backgrounds and requirements [1]. A general user can access both regular and advanced modes [1]. The advanced mode allows a general user to view how their information is presented to the authorized caregivers [1]. A healthcare professional user has advanced screens only because these are specifically designed for supporting caregivers' tasks and the information provided in this mode covers the content in the regular mode.

For more detailed information of the agent-based wellness indicator, please refer to [1-3].

III. TESTING FRAMEWORK

Standard and de facto methods for measuring a wellness visualization system are not available at the time of writing. Therefore, a testing framework for evaluating a wellness visualization system is created to support the need [3]. The following information gives a brief summary of the testing framework.

The framework is created by following the Goal-Question-Metric approach [3-5]. The framework covers benchmarking in term of software quality, usability, and user's impression [3]. A wellness visualization system is measure in seven major aspects: system verification, system validation, verification of system's functionalities, validation of system's functionalities, usability of the GUI and graphical presentations, accessibility, and impression [3]. In other words, technical requirements, user's impression, feeling, and satisfaction are all measured. Both technical-oriented and user-oriented tools/methods are employed in this framework [3]. Examples of the employed testing tools/methods are questionnaires, comparative methods, and peer review [3].

We have created two sets of questionnaires and evaluation metrics from the framework [3]. Both questionnaires contain a combination of scale, forced choices, and open-end questions; a series of tasks; and instructions. The questions are formed in regard to the testing goals [3]. Each testing goal is created from the research's goal [3]. The questionnaires will be employed to collect information from both general and healthcare professional users. The collected data and the evaluation metrics will be used for measuring the agent-based wellness indicator.

IV. SETTING UP A TESTING ENVIRONMENT

As mentioned earlier, there are other issues and factors that we need to take into consideration to conduct an effective testing session. The followings are the important issues that we have encountered in our preparation phase of the testing process.

A. Selecting a Testing Location

It is important to select an appropriate testing location because good location allows a testing session to go smoothly and supports all relevant activities when conducting a study. It would be best if the location can represent where people normally do tasks and has no or, at least, minimum distraction. Therefore, some difficulties and problems caused by a real-life situation can be easily identified.

When selecting a testing location, one of the most important questions is "what do we need?". A list of tasks and activities, required equipments, survey tools, and supporting things must be created. Then, we can compare the list with the facilities and functionalities provided by each potential location. In addition, the following issues should be taken into consideration: volunteers, budget, accessibility, and timeline.

During a testing session, a user will be asked to follow a series of tasks, explore the wellness indicator, and answer the given questions [3]. A user can access to the GUI of the agent-based wellness indicator through both personal computer and small form factor [1-3]. Thus, the location must have enough space for at least one personal computer, one mobile device, one volunteer, one staff, a set of table and chairs, computer network connection tools/accessories, and survey tools. A space for a staff to make observation is also required.

Since there are two groups of volunteers, i.e., general and healthcare professional users, there might be special requirements from each of the groups. For both groups, we have to ensure the availability of the selected location matches with the schedule of our volunteers and can be accessed by all of them. In case of the general users, the user

 ISBN: 978-1-61208-179-3

can be a healthy, unhealthy, older, or disable person. Thus, accessible location is preferred.

For the healthcare professional user, asking them to leave their daily routine to participate in the study could be difficult because of their work and schedule. The testing location should be close, easy to access for this type of users, in order not to interfere with their tasks. It might be a good idea to make the testing site be able to relocate when it is necessary.

Moreover, we need to ensure that the location is in a private area. It should not be easy to access by an outsider. The private area can isolate the testing session from an unwanted distraction and unauthorized person. It also ensures the volunteers that we do respect their privacy.

In case of this research, testing session will be conducted in the University of Regina's area. One of the reasons is that the university provides an easy access to the locals and others; including people with special needs. The university is a place designed for studying, meeting, and performing an experiment and research; thus, it offers a good environment, i.e., appropriate lighting levels, well equipped rooms, privacy supported area, internet connection, parking area, etc. The university is also close to major hospitals and clinics. However, in case that the chosen location is not convenient for a participant, performing a test at the user's site is possible if permission is granted.

B. *Equipments and Survey Tools*

The followings are the major equipments and survey tools that are needed for this study and can be adopted by other research in the same area:

- Scripts and consent forms
- Researcher's contact information or business card
- Questionnaires
- The prototype
- Personal computer and/or laptop
- Mobile device
- Cables and extension cords
- Router or network hub
- Audio recorder with relevant accessories
- Video recorder with relevant accessories
- Secured data storage
- Stationary, e.g., pen, paper, and clip board
- Stop watch
- Compensation for volunteers, if provided

Providing some refreshments is also a good idea as they help people feel refreshing and comfortable, and sometimes can relieve frustration. Thus, the volunteers and staffs trend to be more comfortable and cooperative during a testing session; which leads us to an effective testing session.

When conducting a test at the user's site, there might be more stuff that we need to take with us and some arrangements are also required. A useful list, plan, and tips for taking a test at user's site can be found in [7].

C. *No. of volunteers vs. no. of staffs per one testing session*

Since we have limited number of observers, we have to limit the number of volunteers per one testing session for effective results. Krug suggested that the ideal number of participants in a usability testing session is three people or not more than four people because it guarantees that there will be more rounds of testing; which gives a possibility in detecting more problems [6]. In addition, a researcher will spend less time to process the collected data after each testing session [6].

The authors of [7] also indicate that research found four to five participants is an effective number. However, they feel uncomfortable with small group of participants. Therefore, they suggest at least eight people per testing session instead. The authors also recommend balancing requirements with the practical constraints relative to time and resources [7].

We agree with Krug's idea about having multiple rounds of testing sessions will reveal more problems and it is easier to control the flow and make an observation with smaller number of participants. However, it is quite difficult to follow when we have some limitations. Thus, we combine Krug's suggestion with the criteria given in [7].

When taking budget; availability of our volunteers, resources, and staffs; and research timeline into consideration, it turns out that when the number of rounds of testing sessions increases, the more money, resources, and time are needed. Adding the number of rounds also gives an opportunity for a volunteer to select the best available date and time within limitation, since the availability of the selected location and staffs are also counted.

Another important factor is the timeline of a research. When adding more rounds of evaluation, the total length of time to be spent on the testing process will be longer; this could affect a research's timeline or extend the finish line of a research.

In conclusion, multiple rounds of testing will be conduct and the number of volunteers in one testing session should be closest to Krug's suggested number while respecting the availability of the budget, volunteers, resources, and staffs; and the research's timeline.

D. *Data Collection and Protection*

Since we decided to perform one testing session with a group of volunteers and staffs, it is important to determine on how to collect the data while respecting the privacy of an individual; including how to protect those collected information.

In case of our team, it is wise to set up policies and explain them clearly along with the ethics considerations and protocols to the team members beforehand. It must be clear who have/don't have an authorization to access to the data, how to collect the data, how to keep the data safely, and how to protect the data from an unauthorized person. For example, a person who collects volunteer's contact

 ISBN: 978-1-61208-179-3

information must not copy, reveal, and distribute the information for both personal usage and any reason that is not related to the research. The volunteer's identification and personal information must be separated from their answers.

Moreover, there should be enough distance among volunteers during a testing session. Thus, peeking and unauthorized recording will be difficult to be done. In addition, there should be some spaces between each volunteer and an observer as well. Not only to respect their privacy but also create a comfortable atmosphere during a testing session.

All form of collected data must be kept in secured places. For hard copies, a locked cabinet or safe is preferred. In case of digital records, they must be password protected, encrypted, and must not be able to access through an unsecured connection.

E. Other Consideration and Limitations

The following are the issues and limitations that we have not encountered at the time of writing but they could affect the testing process of a wellness visualization system.

1) Testing environment management: performing a rehearsal is recommended as to review all relevant procedures and activities, and complete the checklist [6-7]. This includes making an agreement on the responsibility of each staff, verifying that they understand all steps and accept the policies, and confirming their availability. During a rehearsal, it is important to identify all the problems that we might face during a real testing session and what we have missed during the planning phase. Then, find the solutions to those problems before moving to the further steps. Performing more than one round of rehearsal is also an advantage.

2) Time management: time is a limitation that can be overcome by effective management and utilization. Timing all rounds of rehearsal is recommended. Both volunteers and staffs have their own schedule. If we have an approximate testing duration, it is easier to create a testing schedule and to make an appointment with both volunteers and staffs. Moreover, we have to ensure that we spend the testing time wisely by getting information as much as possible within a shortest period of time. One of the possible solutions is to prepare a list of interview questions along with the scripts and bring them on the testing day [6-7].

3) The prototypes: the prototype is tested in the laboratory isolated from outside connection during and after the implementation process by the researchers. However, it is possible that the prototype will not work properly on the testing day due to unexpected problems such as hardware problems and human errors. Thus, performing a rehearsal and having a backup on the testing day is a must.

4) Ethics and other privacy related issues: it is important to have permission before audio taping and video recording. When conducting an orientation, other than explaining about the research and the testing process, we should clarify what we are going to do with the collected data and records and how do we secure them before presenting a consent form. Also, all relative risks must be explained. Moreover, each volunteer has their right to opt out from the testing process anytime without any obligation. The data received from the withdrawn person must be destroyed immediately.

V. CONCLUSIONS AND FUTURE WORK

Currently, our research is at the stage of applying for a research ethics approval from the University of Regina's ethics board. While we are waiting for the results, we are concurrently preparing for the evaluation process as to start the testing sessions right after receiving the approval.

This paper gives people, who are preparing or conducting an evaluation for a wellness visualization system, some ideas relative to setting up a testing environment and relevant issues from our experiences. We wish that the information provided in this paper can give an insight to those who work in the same area and people who are interested in this research.

ACKNOWLEDGMENT

We would like to thank Thailand's Office of Educational Affairs and Telecommunication Research and Laboratories (TRLabs), Regina for giving financial support to this research.

REFERENCES

[1] L. Benedicenti and C. Soomlek, An Agent-Based Modeling System for Wellness, in Multi-Agent Systems for Healthcare Simulation and Modeling: Applications for System Improvement, 1st ed., Medical Information Science Reference, IGI Global, 2009, pp. 137-163.

[2] C. Soomlek and L. Benedicenti, "Operational Wellness Model: A Wellness Model Designed for an Agent-Based Wellness Visualization System," the 2nd Int'l Conf. eHealth, Telemedicine, and Social Medicine (eTELEMED2010), Feb., 2010, pp. 45-50, doi:10.1109/eTELEMED.2010.14.

[3] C. Soomlek and L. Benedicenti, "Creating a Framework for Testing Wellness Visualization Systems," the 3rd Int'l Conf. eHealth, Telemedicine, and Social Medicine (eTELEMED2011), Feb., 2011, pp. 83-88, ISBN: 978-1-61208-003-1.

[4] R. S. Pressman, Software Engineering: A Practitioner's Approach, 6th ed., McGraw-Hill, 2005.

[5] N. E. Fenton and S. L. Pfleeger, Software Metrics: A Rigorous and Practical Approach, 2nd ed., PWS Publishing Company, 1998.

[6] S. Krug, Don't Make Me Think: A Common Sense Approach to Web Usability, 2nd ed., New Riders, 2005.

[7] J. Rubin, D. Chrisnell, and J. Spool, Handbook of Usability Testing: How to Plan, Design, and Conduct Effective Tests, 2nd ed., John Wiley & Sons, 2008.

 ISBN: 978-1-61208-179-3

m3DICOM: A Platform for Mobile DICOM Visualization Based on X3D

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***Abstract*—The authors propose a platform suitable for mobile DICOM visualization and segmentation processing, that overcomes some of the current limitations of web-based DICOM viewers by integrating 3D modeling on the cloud and dynamic generating an X3D file for visualization on a mobile device. Web based DICOM viewing in real-time is a desirable application for physicians/radiologists, but the limitation of high volume data and large bandwidth requirements is a barrier for adoption. With the new tablet / smartphone technologies, and the new generation of WebGL-based browsers with GPU accelerated graphic visualization, it is possible to explore possible alternatives. The proposed approach segments the DICOM file on the server side, and delivers a dynamic X3D model to the mobile device for visualization and interaction with the user. Processing is carried out on the cloud, but final 3D rendering is done on the mobile device, with communication bandwidth requirements reduced in the order of 3 to 5 times.**

Keywords*—DICOM; X3D; WebGL; HTML5; 3D graphics; mobile medical applications; render on the cloud; GPU segmentation on the cloud; X3DOM.

I. INTRODUCTION

There has been extensive research on using the web for medical image processing, remote diagnosis and visualization [1][2]. Unfortunately, the large amount of data of DICOM files limits the applicability on mobile devices. Several applications currently available for mobile device DICOM visualization require to download the whole DICOM file, that could be time consuming for large studies, i.e., 50 Mbytes. On the other hand, the adoption of WebGL [3] and HTML5 standards for the new generation of browsers brings back the interest of web based 3D rendering with WebGL and declarative X3D [5], since it will be supported without plug-ins. Further, WebGL will make possible to render 3D models in real time with the computational capabilities of the new smartphones and tablets. Some attempts to build WebGL-based medical visualization systems have been reported [4], but only considered the X3D model creation from DICOM on the server side for visualization in a remote platform. In this work, we propose an extended approach where the 3D model is a hybrid representation of the DICOM extracted model, and other features (like 2D slices for close inspection) and a flexible user interface to control position and transparency of 3D features. Our approach gives more flexibility and visual information to the user than previous approaches. The short paper is organized as follows: section II gives an overview of the architecture, from the server and client sides. Section III details the implementation and preliminary results, and we give some conclusions and directions in section IV.

II. PROPOSED ARCHITECTURE

The proposed platform is based on a client – server architecture, which allows doctors/radiologists to visualize, analyze and interact with patient information stored in a DICOM web repository, using a mobile device and a WebGL enabled browser. The general architecture is depicted on Figure 1.

A DICOM server contains a patient database, and applications to process on the cloud the files to extract an X3D model from the data. The 3D model is created by a segmentation and slicing process on the DICOM data. Later, a complex model is assembled and converted to HTML5 format to be visualized on the client side with a WebGL compliant browser. The client device could integrate hardware graphics acceleration for local 3D rendering.

Since the segmentation process could range from simple thresholding to complex segmentation algorithms, the platform is open to integrate GPGPU acceleration.

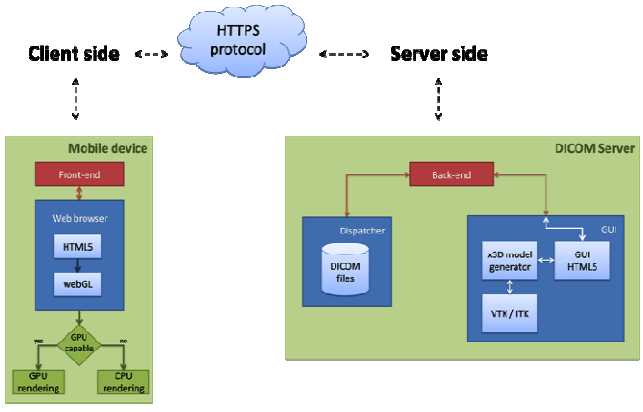

Figure 1. General Server/Client architecture

 ISBN: 978-1-61208-179-3

A. *Server processing*

Most of the processing is carried out on the server side. The server contains a DICOM repository where the patient data is stored. A file subsystem and access is supported for file upload, storage, management and traditional DICOM access for visualization through the net.

Several medical visualization applications carry out some kind of preprocessing to the DICOM files. The most elaborate and complex processes are based on advanced segmentation algorithms that locate specific organs or tissue in the data. Unfortunately, the processing capabilities of current computers are limited, so cloud processing (i.e., large computer arrays or GPU hardware acceleration on the cloud) has become an alternative to a data center in the hospital. The proposed architecture is open to combine cloud processing for data segmentation and the creation of the X3D model for visualization.

For our proof of concept system, we are using the VTK/ITK libraries for exploring basic segmentation and data slicing on the server side. Furthermore, the dynamic X3D creation is composed of a segmented model of the DICOM data with 2D slices from the DICOM set for close comparison of details by the radiologist/doctor.

The 2D slices are extracted from the DICOM file and combined with the general 3D model as a hybrid visualization model that contains the segmented organ or structures, and 2D slices for close visualization of the original scan. User retains full control on the X3D model control on the web browser, but the slices are dynamically generated and streamed from the server into the web client.

Figure 2 gives more details on the libraries and subprocesses carried out on the server side, and the client WebGL requirements.

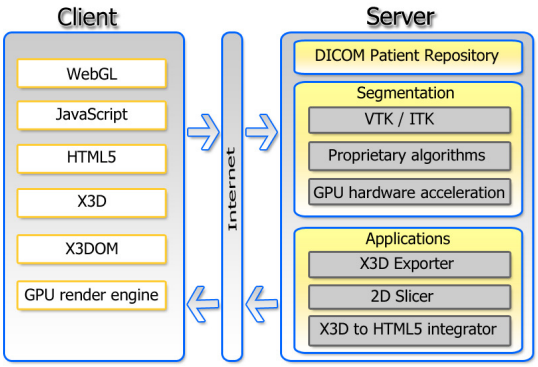

Figure 2. Server-Client architecture of the DICOM/X3D System

B. *Client – web user interface*

On the client side, we are proposing a web interface using HTML5 and JavaScript. X3D files are integrated into html using embedded X3D as mixed-namespace document (X3DOM implementation [5]), which makes it possible simple interaction (HTML events) and navigation (zoom, rotate) on 3D objects. The interface is designed to provide cross-browser support (for both desktop and mobiles), using JQuery Mobile framework [6].

Through the user interface, it is possible to set up segmentation parameters (algorithm, thresholding, and reducing factor), which are used by the segmentation application on the cloud.

There are some initial parameters for the X3D object generation, such as transparency, shininess, diffuse color, and so on. These can be later on changed via JavaScript directly on the generated X3D file.

Figure 4 shows a view of the mobile device web interface with a 3D model rendered on the server side.

C. *X3D model creation*

Figure 3 presents a diagram of the hybrid model creation process. There is a set of default parameters, which the user can update interactively from the web interface. The DICOM file is segmented and a mesh is created. The segmentation process is dependent on the kind of visualization required by the user; for our experiments, we are using simple threshold to isolate bone from other tissues. Once the mesh is created, it is exported as a X3D model.

On the other hand, a set of slices is extracted from the DICOM, and individual X3D models are generated, and integrated into a single X3D model that is then integrated using the X3DOM libraries into HTML5. The selection of the slice is activated based on user interaction by a slide control to visualize the 2D cut details of the 3D model.

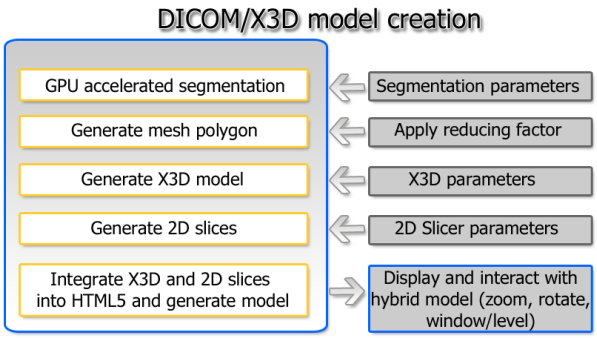

Figure 3. DICOM/X3D hybrid model creation

III. PRELIMINARY RESULTS

An implementation of the platform was carried out. On the server side, the DICOM files are stored in a basic file system, where they can be accessed and processed by a server application. The application communicates with the client to receive the visualization parameters and performs the DICOM segmentation, optimization and delivery of the

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X3D model. Processing is carried out using the visualization toolkit libraries VTK [7], ITK [8] and proprietary algorithms used to segment the 3D model from the DICOM data. The application integrates the X3D and 2D slice models into a HTML5 web interface, using JavaScript and declarative X3D.

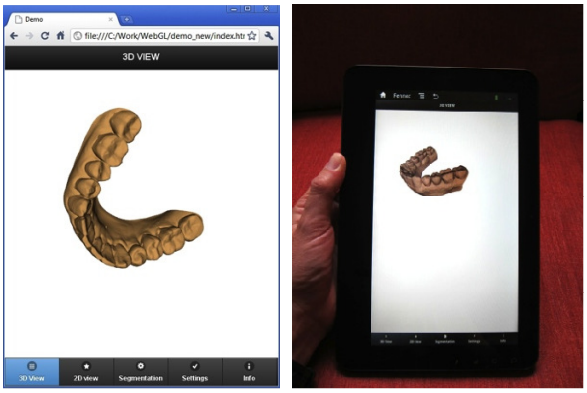

Figure 4. View of the mobile device interface showing a 3D model segmented on the server side.

On the mobile device, the user can access the interface web page through an HTML5 compliant browser. We are using a Viewsonic G-Tablet running Android 2.2 and the Fennec 4.0b6pre browser. Figure 4 shows the interface and the user interaction on the tablet. The Fennec browser still has some limitations (i.e., only single touch event detection) that limits interaction on the image) that had to be hand programmed to allow full interaction with the user.

The following table summarizes the file size and transfer times compared to a pure DICOM download. Since the file size is 2-3 times smaller than a DICOM down-sampled file, the download time is improved in the same proportion, allowing the user to experiment with other segmentation parameters. Furthermore, the user keeps full interaction of the 3D model (transparency, window/level, 3D rotation, zoom) as well as position of the 2D slices that allow the physician to see and verify original details extracted by the 3D segmentation process.

TABLE I. COMPARED SIZES OF DIFFERENT MODELS

Model	Original DICOM size	Reduced size	X3D model	X3D Hybrid model
Dental file	62 MB	10 MB	1 MB	1.5 to 4 MB
Thorax file	20MB	5 MB	500 KB	1.5 to 2 MB
Comments	Too large for mobile	Reduced resolution	Only 3D model	3D model and 2D slices

IV. CONCLUSION AND FUTURE WORKS

We have presented a proof of concept of a hybrid DICOM/X3D visualization platform that efficiently delivers high resolution data to a mobile device optimized bandwidth. The platform visualize a WebGL-based render 3D model from a large DICOM model stored on the server side, with high resolution slices of the scan intersected with the 3D model. The platform is extensible to allow further processing and segmentation on the server side, but flexible enough to allow the mobile user to interact with the visualization and segmentation parameters. In the context of cloud computing, the cloud server will preprocess the DICOM files to generate the X3D models, so they will be ready for user interaction. As future work, we are exploring using GPU based segmentation on the server side, combined with WebGL on the mobile device, to enhance the quality and flexibility of the segmented data.

REFERENCES

[1] S. K. Yoo, J. Key, K. Choi, and J. Jo, “Web-Based Hybrid Visualization of Medical Images,” Image and Video Retrieval, LNCS, Vol 3568. 2005, pp. 588

[2] A. Poliakov, E. Albright, K. Hinshaw, D. Corina, G. Ojemann, R. Martin, and J. Brinkley, “Server-based Approach to Web Visualization of Integrated Three-dimensional Brain Imaging Data,” Journal of the American Medical Informatics Association, 2005 Mar–Apr 12(2), pp. 140–151

[3] WebGL, „OpenGL ES 2.0 for the Web,“ 2011. Available: http://www.khronos.org/webgl/ <retrieved: November, 2011>

[4] D. Cantor-Rivera, R. Bartha, and T. M. Peters, “Efficient 3D rendering for Web-based medical imaging software: a proof of concept,” SPIE Medical Imaging 2011: Visualization, Image-Guided Procedures, and Modeling, Volume 7964 Feb 2011, pp. 79643A-79643A-4

[5] J. Behr , Y. Jung , J. Keil , T. Drevensek , M. Zoellner , P. Eschler and, D. Fellner, “A scalable architecture for the HTML5/X3D integration model X3DOM”, Proc. 15th International Conference on 3D Web Technology (Web3D 2010), ACM Press, 2010, pp. 185-193

[6] JQuery, “JQuery Mobile Framework,” 2011. Available: http://jquerymobile.com/ <retrieved: November, 2011>

[7] VTK, “Visualization Toolkit, v5. Open Source for 3D computer graphics,” 2011. Available: http://www.vtk.org <retrieved: November, 2011>

[8] ITK, “Insight Segmentation and Registration Toolkit, v4. Open Source library of image analysis algorithms,” 2011. Available: http://www.itk.org <retrieved: November, 2011>

 ISBN: 978-1-61208-179-3

Region Marking Software Tool for Medical Images

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***Abstract*—Subjective quality evaluation of medical images is mostly achieved using some version of ROC (Receiver Operating Characteristic) evaluation. In the majority of studies ROC analysis is the focus of research. The software tool used to mark medical images and to gather diagnostic data is either not described or described only briefly. During our research on quality evaluation system for medical images used in PACS system (Picture Archiving and Communication System), we decided to implement such a software tool. We decided to base our solution on web technologies. One of our goals was to enable in a single application on site evaluation of medical images in a local hospital and remote evaluation of medical images. In the paper, we report our goals, design decisions, and we describe the current version of the region marking software tool. The presented software tool is more than just an additional tool for subjective quality evaluation of medical images because it can be used as a software platform for education in diagnostic imaging.**

Keywords-eHealth application; medical image quality; ROC evaluation; medical image marking

I. INTRODUCTION

The quality of a digital medical image (henceforth, medical image) is an important issue in medical imaging because it directly influences the procedures based on medical images. Medical image quality can be degraded due to several sources, from the acquisition process to image compression, noisy channels and so on [1]. Therefore, it is useful to evaluate the quality of medical images.

In medical imaging, quality is evaluated using domain specific subjective evaluations [2]. Medical image accuracy in a diagnostic task is measured and quantified. Medical image influence on diagnostic accuracy is evaluated by measuring whether the same results are achieved compared to some form of gold standard [3]. The same diagnostic task is conducted using an original reference image and the evaluated medical image. The results are usually quantified using ROC analysis or some of its variations [4]. ROC evaluation is the most frequently used subjective evaluation of medical image quality [5][6]. It is conducted in two phases:

1) Data gathering – observers performe a diagnostic task on medical images by markin regions of interest.
2) Data analysis – gathered data are processed using ROC analysis**.**

In the *data gathering* phase of the ROC evaluation, depending on the variation of the ROC analysis used, it is necessary to use additional software for performing observers' diagnostic task in the manner suitable for ROC evaluation [7]. What surprised us during our evaluation of technical literature is the lack of description for this kind of software [4][8]. Also, we did not manage to find any free software for the *data gathering* phase of the ROC evaluation. Therefore, during our research on a quality evaluation system for medical images in PACS systems [9][10] we were forced to implement a region marking software tool for ROC evaluation of medical images. We had several goals in mind:

- It should resemble software tools used in everyday clinical tasks.
- It should be accessible from many places.
- It should be usable in education.
- It should be free.

Therefore, we decided to implement it using web technologies. In the paper we describe our ideas and present the current version of the software tool.

The organization of the paper is as follows. The background is described in Section 2. Software design and tools used in implementation are presented in Section 3. The current version of the region marking software tool for medical images is described in Section 4. Section 5 concludes the paper.

II. BACKGROUND

There are two approaches to evaluate image quality in general [5][8]:

- Objective evaluation – based on a mathematical or a statistical model, which is easy to compute, rate, and implement on a computer.
- Subjective evaluation – based on a subjective evaluation of restored images by single or multiple observers.

However appealing, objective evaluation did not replace subjective quality evaluation in medical imaging [2][11]. Even today, the quality of medical images is tested using subjective quality evaluation. Generally, subjective quality evaluations can be broadly categorized into two types [12]:

- Fidelity subjective evaluation. Quality of the image is defined in comparison to another, referenced image, and difference between the images is measured.

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- Domain specific subjective evaluation. Quality of an image is defined by the image usability in some domain specific task.

ROC evaluation is a representative of domain specific subjective evaluations and is one most often employed in medical imaging [3]. Qualified observers evaluate medical images as they would in a clinical task. For every medical image they have to provide a decision if an abnormality is present or not and to quantitatively describe their degree of certainty. This is usually a number from 1 to 5, where 1 means definitely negative confidence and 5 means definitely positive confidence [13]. The resulting diagnostic accuracy is compared with original image or to the gold standard which defines the truth. Therefore, observers can either correctly identify the anomaly (*true positive*), or miss it (*false negative*). For each of anomaly detected by the observer, either it agrees with the gold standard (*true positive*) or not (*false positive*). Also, the observer can correctly identify the absence of the anomaly (*true negative*). A subjective confidence rating of the diagnoses is then used as if it were a threshold to adjust for detection accuracy [2][4]. This threshold is used for plotting ROC curves which describe detection accuracy, Fig. 1. The plot is a summary of the trade off between true positives and false positives. The area under the curve can be used to summarize the overall quality or the efficiency of the detection process [13]. The size of the area under the curve directly corresponds to the image quality.

ROC analysis is used in medicine frequently, wherever there is a need to describe a binary decision (detection) problem. However, conventional ROC evaluation has its limits and drawbacks when used for medical image evaluation [13]:

- It can be used only to describe binary decisions. It cannot be used for evaluating an image with more than one anomaly.
- It is not location specific. It is possible for the observer to miss the anomaly in a correct spot, but to mistakenly identify it in another. This would be scored as a *true positive* when it should be scored as a *false positive*.
- Observers are forced, unnaturally, to indicate their confidence. When making decisions, clinicians usually use qualitative ways for describing their confidence rather than numerical rankings.

Several variations of ROC evaluation have been proposed to overcome the limits of the conventional ROC form. They address localization and binary decision issues because the confidence rating is not easy to overcome. The most popular variations of ROC medical image evaluation are [14][15]:

- Localization ROC (LROC). Observers are required to specify the single location, if any, at which an anomaly is judged to be present.
- Free-Response Operating Characteristic (FROC). In a sense, this is a generalization of LROC because the observer can specify more than a single anomaly and locations. This approach is limited because the results depend on the number of the locations allowed by the data analyst.
- Alternative FROC (AFROC). It is similar to FROC but enables a mandatory number of anomalies detected.
- Jack-knife analysis of FROC (JAFROC). A re-sampling method that does not assume independence of responses within the same study applied to FROC. Very stable method but it requires multiple readers and a substantial number of images for good results.
- Differential ROC (DROC). Determines the differences between modalities.

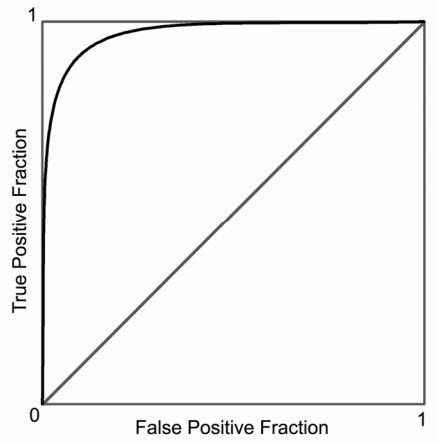

Figure 1. Example of ROC curve

A detailed description of ROC evaluations can be found in the aforementioned literature.

There is no standard for the *data gathering* phase of the ROC evaluation [7]. But it is possible to distinguish two approaches:

1) Based on *conventional software* used in everyday diagnostic tasks.
2) Based on *additional software* for performing observers' diagnostic task in the manner suitable for ROC evaluation.

The *Conventional software* approach enables the observers to work in familiar surroundings and in a familiar way, because they work with software tools used in everyday clinical practice. It is the cheapest way as it is not necessary to develop new software. However, this approach relies heavily on persons conducting the test. They follow observer performance and note the answers (detected anomalies and confidence rates). This approach is manageable for conventional ROC evaluation because it is only necessary to note the presence of an anomaly and the confidence rating. However, it is not suitable for ROC variations because the observers are forced to verbally describe the location of anomalies detected and there is a larger margin for error. The evaluator has to estimate if the answer is a *true* or *false positive*. This approach has been used in [16][17][18].

The *Additional software* approach is expensive and the clinical practice is only simulated. But it is easier to conduct ROC evaluation and gather data this way, especial in the case of the ROC variations. Observers mark the anomaly

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directly on the image evaluated, pinning its location. This data is immediately compared against the gold standard and memorized as a *true/false positive* or a *true/false negative* for latter analysis. This approach has been used in [19][20], but the software is only mentioned (it is not described) and it is not publicly available.

III. DESIGN CONSIDERATIONS AND SOFTWARE TOOLS

As we described it in the Introduction, we had several goals in mind. The first goal, resemblance to software tools used in everyday clinical tasks, is very important for the success of ROC evaluation [13]. This means that GUI (Graphical User Interface) should resemble software tools used in everyday practice. The region marking software tool should be based on technologies supported in examination rooms because, the software is meant to be used in everyday clinical tasks.

But our decision to choose the underlying technologies that we did is additionally influenced by another fact. Clinicians are the primary persons undertaking the role of the observers in evaluation. Their schedule has few openings. It is hard for them to devote their time to ROC evaluation (at least it was like this in our case). It would be a good decision to allow the observers to evaluate medical images outside of examination rooms, in fact from any (even from their home if this is necessary and they are willing), at the time which is convenient to them. Although this does not correspond perfectly with clinical practice, it would enable far more clinicians to participate in the evaluation and it would help gather more statistical data. It is possible for several observers to evaluate images at the same time, thus greatly increasing the efficiency and, at the same time, reducing the cost of the ROC evaluation.

The region marking software tool should be accessible from many places by supporting remote access based on web technologies. This is the most common way for achieving access from several remote locations. The ultimate decision, whether the ROC evaluation will be conventional (constrained to examination room only), or it will support remote evaluation, is up to the persons conducting the test. It is only a matter of whether remote access is allowed or not which is set in the configuration files.

Our third goal, that it should be usable in education, dovetails well with our second goal. With little modification the software tool is suitable for remote education. The same principle used in ROC evaluation can be used in education. The difference lies in fact that it is not the image quality that is tested. Students will evaluate images remotely. They will mark anomalies they think are present in the image and they will describe their degree of certainty. Educational use differs from ROC evaluation in a way that the values of the gold standard will be shown at the end of the evaluation. Detailed explanations of clinical decisions will be presented for each anomaly and they will be compared to the answers of the students.

To achieve our last goal, a free software tool, we had to base our solution on technologies and software tools freely available. Fortunately for us, many of the web technologies belong to this category.

In line with previous explanations, we decided to use web technologies and we implemented the region marking software tool for medical images using HTML (Hyper Text Markup Language), PHP [21], and MySQL [22]. Web technology is supported almost everywhere and a web based solution can be used anywhere from an examination room to a handheld device. PHP is a general-purpose server-side scripting language used for Web development and for producing dynamic Web pages. In our solution PHP is used for generating parts of the GUI and for communicating with the MySQL database. MySQL is a relational database management system. We used MySQL for storing observers' answers, ROC evaluation data and image info. A good part of the GUI relies on JavaScript [23]. It is a weakly typed, prototype scripting language primarily executed in a Web browser. Multi-browser development can be an issue when pure JavaScript is used. As it is not possible to predict which Web browser will be used in evaluation, we decided to build the JavaScript part of the code through the JQuery library [24]. It is a cross-browser JavaScript library specifically designed to simplify client-side scripting of HTML and to enable, as much as possible, the same look for different Web browsers.

The application flow diagram of the region marking software tool for medical images is described in Fig. 2. There are two flow branches:

- ROC evaluation (right branch of Fig. 2).
- Educational use (left branch of Fig. 2).

Which branch in application flow diagram will be active depends on the user type. When the user logs into the application, hers/his type is determined (first step in Fig. 2) and appropriate branch is executed. User type is defined in user's profile stored in MySQL database.

Next step is the same in both cases. Users evaluate the medical image. They can insert more than one mark, modify previously defined marks, or completely delete a mark. Results of the observer's actions are memorized in MySQL database. The AJAX (Asynchronous JavaScript and XML) methods of JQuery library are used for data updating. This means that Web page is not reloaded every time observers

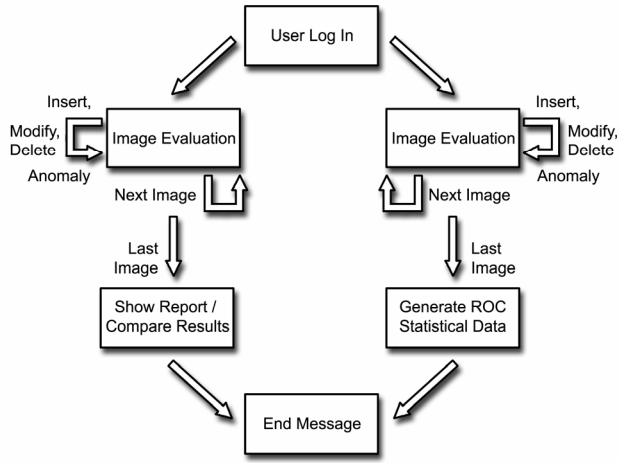

Figure 2. The application flow diagram of the region marking software tool for medical images

make some change. At any time, the observer can progress to the next medical image in the series. This effectively ends all actions on previous medical image meaning that it is not possible to modify observations made on the previous image.

It should be noted that observer can stop the evaluation at any given time. Next time, she/he logs to the application, medical image evaluation will continue from the last evaluated image.

When the observer reaches the end of the ROC evaluation, hers/his answers are converted to ROC statistical data, *positives* and *negatives*. The results are not reported to the observer. At the very end, user is presented with a message which designates the end of evaluation.

The end of evaluation in the educational version of the region marking software tool for medical images differs from the end of ROC evaluation. The observer's results are compared to the gold standard, a report is generated, and the results are presented to the observer. It is possible to view each of the images evaluated with observer's marks compared to the gold standard. At the end, observer is presented with the same message as in the ROC evaluation.

IV. THE REGION MARKING SOFTWARE TOOL

At the moment of writing the ROC evaluation version of the software tool has been finished and prepared for clinical testing as it was needed for our quality evaluation system of medical images in PACS systems. This software version follows the right branch of application flow diagram described in Fig. 2.

The primary version of the software is written in the Serbian langue. However all language configurations are located in a PHP configuration file and are easily replaced with another language. We did this for the sake of presentation as all the images of the software tool contain English user interface labels.

The first step in the application is user identification

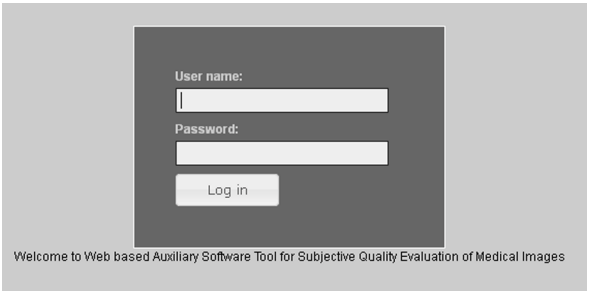

Figure 3. AST log in page

through login page, Fig. 3. Only observers registered for ROC evaluation may log into the system.

After login, observer starts/continues medical image quality evaluation by marking the places of anomalies on the image. Observer should left click on the approximate center of the anomaly. This action brings up a dialog for defining new anomaly, Fig. 4. Observer sets the size of anomaly and hers/his degree of certainty. Because of the technology limitations it is not possible to define custom sized anomaly in the current version of the application. Instead it is necessary to choose some of the predefined sizes: 50, 75, 100, 150, 200, and 300 pixels. This permits only basic overlap between the detections and the gold standard. We intend to improve on this in further software versions.

We decided to use the same scale for defining the degree of certainty as described in [13]. Instead of numbers, the observer chooses one of the answers which corresponds the best to hers/his degree of certainty. A different color is assigned to each of the answers. When the size of anomaly and degree of certainty are chosen, a circle is drawn around the place where observer left clicked, Fig. 5. The circle is drawn in the color corresponding to the chosen degree of certainty. Circles are drawn as an image overly using AJAX methods. Web page is not redrawn completely, but only part

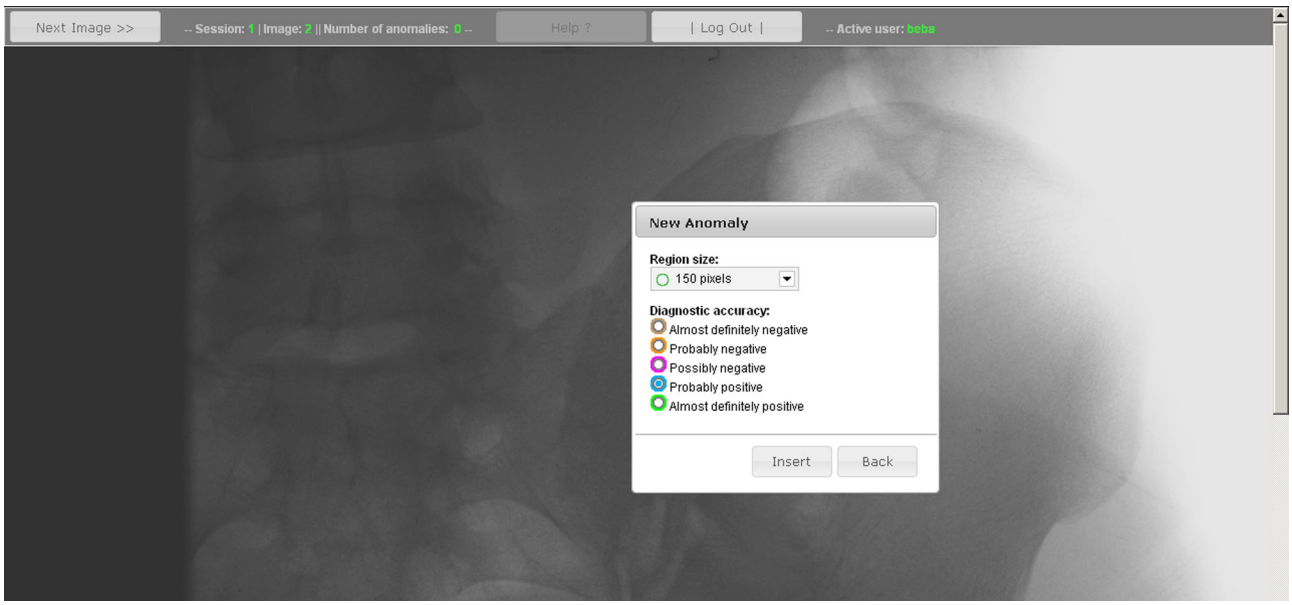

Figure 4. Dialog for defining new anomaly in the region marking software tool for medical images

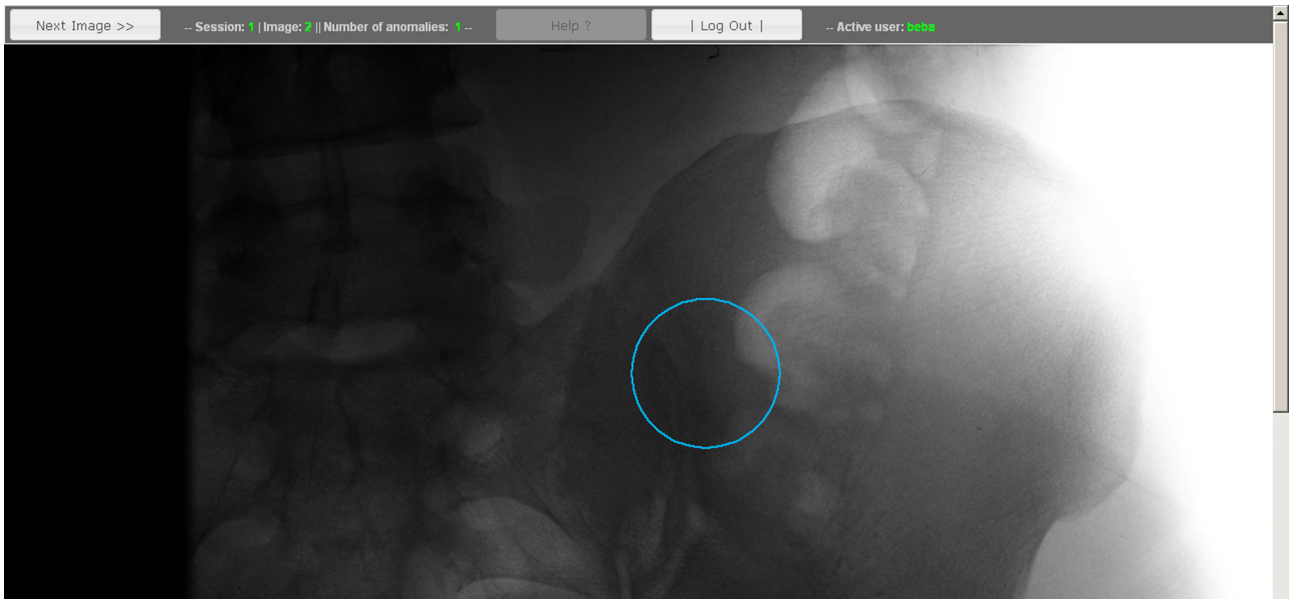

Figure 5. Example of Drawn circle around an anomaly in in the region marking software tool for medical images

of the image containing the circle. Also, AJAX methods are used in background to send updated data to MySQL database. These operations are fast and not noticeable by observers even on low end configurations.

It is possible to mark multiple anomalies on the image evaluated. But it is not possible to mark them on the same spot. If observer clicks on the already marked anomaly a dialog similar to the one described in Fig. 4 will display, Fig. 6. This dialog is used to modify the chosen anomaly or to completely remove it.

The observer may leave the evaluation by clicking the *Log Out* button. By clicking the *Next Image* button, observer will proceed to evaluate the next image. She/he cannot return to previous images evaluated. Absence of anomalies means that observer did not find any anomaly in the medical image evaluated. After the last medical image of the series is evaluated, the observer is presented with the ending message in which she/he is informed of the end of the evaluation and thanked for participating in the ROC evaluation.

After the last medical image is evaluated the background process is triggered. Observer's markings are converted into ROC statistical data used in ROC evaluation. Marked anomalies are compared to the gold standard. The center and size of the marked anomaly are compared to the data of the gold standard. If there is a match, a *true positive* is scored, if not a *false positive* is scored. Data gathered with the region marking software tool are statistically analyzed using some ROC analysis software tool.

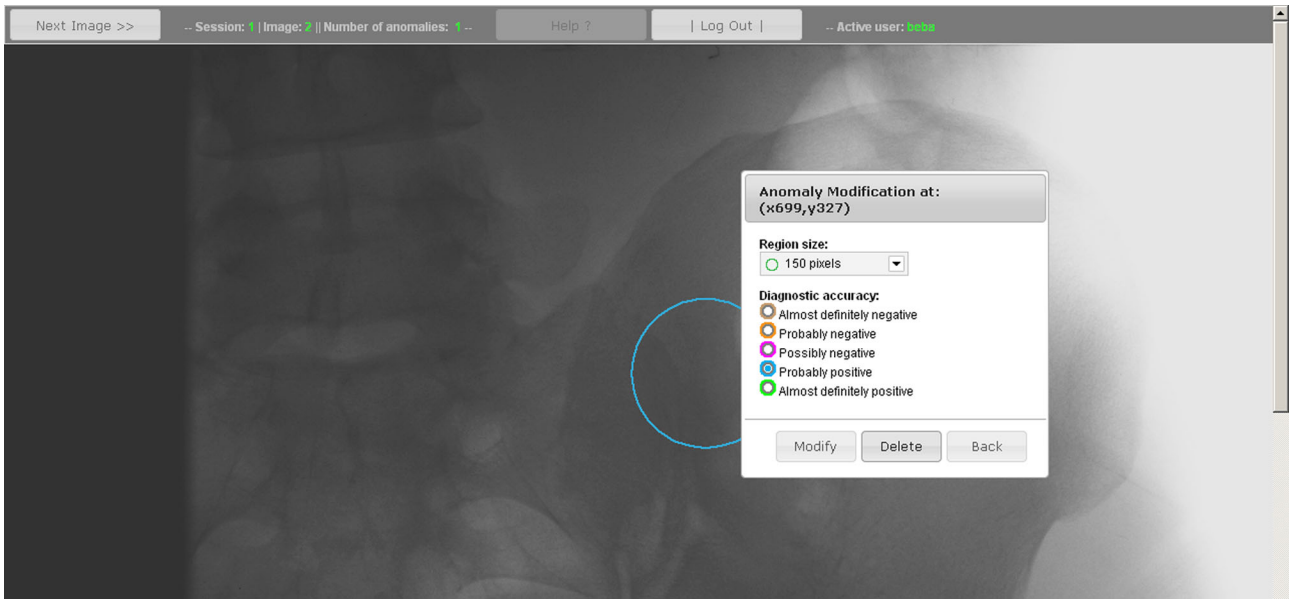

Figure 6. Dialog for modifying/deleting marked anomaly in the region marking software tool for medical images

 ISBN: 978-1-61208-179-3

V. CONCLUSION AND FUTURE WORK

In the paper we described the region marking software tool for ROC evaluation of medical images. It is designed to be used with all versions of ROC evaluation. Therefore, an arbitrary number of anomalies and their location can be marked using this software tool. Also, the observers' degree of certainty is stored for every anomaly marked. It is designed for the on site evaluation (in accordance with everyday clinical tasks) and for the remote evaluation of medical images as well. The region marking software tool is designed to resemble similar software used in every day clinical practice, but it has one addition: remote accessibility. It is developed using web technologies such as HTML, PHP, JQuery for JavaScript, and MySQL. Internet access and a Web browser are the only requirements.

The region marking software tool for medical images is developed with an eye towards educational use. Training in diagnostic imaging does not differ much from ROC evaluation. Students need to mark the places they think anomalies exist and need to describe their degree of certainty. The only difference exists at the end. ROC observers are not presented with the results while students are. It is easy to extend the region marking software tool to support educational use as it is described in the paper. It is our intention to expand the software with this feature.

At the moment all the data gathered and processed are stored in a MySQL database. However, handling a MySQL database requires some computer skills. We intend to expend data management so that XML (Extensible Markup Language) files are used as an alternative to a MySQL database. Textual form of XML is easier to handle for inexperienced users. XML will contain description of the software interface. In this way it is possible to change the description of diagnostic accuracy and anomaly size.

As it is based on free technologies, the region marking software tool for medical images is practically free. It is our intention to make it freely available for the general public, after extensive clinical trials.

ACKNOWLEDGMENT

This research is financially supported by Ministry of Science and Technological Development, Republic of Serbia; under the project number TR32044 "The development of software tools for business process analysis and improvement", 2011-2014.

REFERENCES

[1] S. Aja-Fernández, R. S. Estépar, C. Alberola-López, and C. F. Westin, "Image quality assessment based on local variance," Conference Proceedings of the IEEE Engineering in Medicine and Biology Socciety 2006, Vol.1, pp. 4815-4818, 2006.

[2] D. Smutek, "Quality measurement of lossy compression in medical imaging," Prague Medical Reports, Vol. 106, No. 1, pp. 5-26, 2005.

[3] B.J. Erickson, "Irreversible compression of medical images," Journal of Digital Imaging, Vol. 15, No. 1, pp. 5-14, 2002.

[4] D. Dragan and D. Ivetic, "Quality Evaluation of Medical Image Compression: What to Measure?," Proceeding of the 2010 IEEE 8th International Symposium on Intelligent Systems and Informatics, pp. 37-42, 2010.

[5] B.J. Erickson, "Image Compression," PACS: A Guide to the Digital Revolution, K.J. Dreyer, D. S. Hirschorn, J. H. Thrall, and A. Mehta, (Eds.), Springer-Verlag New York Inc., pp. 229-247, 2006.

[6] R. K. W. Schulze, et al, "|Diagnostic yield of ink-jet prints from digital radiographs for the assessment of approximal carious lesions: ROC-analysis," European Journal of Radiology, Vol. 79, No. 2, pp. 277-282, 2011.

[7] D. P. Chakraborty, "Recent advances in observer performance methodology: jackknife free-response ROC (JAFROC)," Radiation Protection Dosimetry, Vol. 114, No. 1-3, pp. 26-31, 2005.

[8] D. Dragan and D. Ivetic, "A Comprehensive Quality Evaluation System for PACS," Ubiquitous Computing and Communication Journal, Special Issue on ICIT 2009 Conference - Bioinformatics and Image, Vol. 4, No. 3, pp. 642-650, 2009.

[9] D. Ivetic and D. Dragan, "Medical Image on the Go!," Journal of Medical Systems, Vol. 35, No. 4, pp. 499-516, 2011.

[10] D. Dragan and D. Ivetic, "Request redirection paradigm in medical image archive implementation," Computer Methods and Programs in Biomedicine, In Press, doi: 10.1016/j.cmpb.2011.06.001, 2011.

[11] S. Winkler, "On the properties of subjective ratings in video quality experiments," Proceedings of the International Workshop on Quality of Multimedia Experience (QoMEX), doi: 10.1109/QOMEX.2009.5246961, 2009.

[12] A. Pommert and K. H. Hohne, "Evaluation of Image Quality in Medical Volume Visualization: The State of the Art," Proceeding of Medical Image Computing and Computer-Assisted Intervention (MICCAI 2002), Part II, T. Dohi and R. Kikinis (Eds.), Lecture Notes in Computer Science, Vol. 2489, pp.598-605, 2002.

[13] P. Cosman, R. Gray, and R. Olshen, "Chapter 49: Quality Evaluation for Compressed Medical Images: Fundamentals," Handbook of Medical Imaging, Processing and Analysis, Isaac N. Bankman (Ed.). Academic Press Inc., pp.803-819, 2000.

[14] C. Metz, "Receiver Operating Characteristic Analysis: A Tool for the Quantitative Evaluation of Observer Performance and Imaging Systems," Journal of the American College of Radiology, Vol. 3, No. 6, pp. 413-422, 2006.

[15] F. Zarb, L. Rainford, and M. F. McEntee, "Image quality assessment tools for optimization of CT images," Radiography, Vol. 16, No. 2, pp. 147-153, 2010.

[16] F. Li, et al, "Computer-Aided Detection of Peripheral Lung Cancers Missed at CT: ROC Analysis without and with Localization," Radiology, Vol. 237, No. 2, pp. 684-690, 2005.

[17] L. Zhigang, L.I. Kuncheng, Z. Jinghong, and L Shuliang, "The study of diagnostic accuracy of chest nodules by using different compression methods," European Journal of Radiology, Vol. 55, No. 2, pp. 255-257, 2005.

[18] D.H. Kim, et al, "Comparison and Evaluation of JPEG and JPEG2000 in Medical Images for CR (Computed Radiography)," Journal of the Korean Physical Society, Vol. 56, No. 3, pp. 856-862, 2010.

[19] M. Kallergi, et al, "Improved interpretation of digitized mammography with wavelet processing: a localization response operating characteristic study," American Journal of Roentgenology, Vol. 182, No. 3, pp.697-703, 2004.

[20] M. Kallergi, et al, "High-Performance Wavelet Compression for Mammography: Localization Response Operating Characteristic Evaluation," Radiology, Vol. 238, No. 1, pp. 62-73, 2006.

[21] PHP, general-purpose scripting language. [Online] Available at: http://www.php.net/, 11/26/2011.

[22] MySQL, open source database. [Online] Available at: http://www.mysql.com/, 11/26/2011.

[23] S. Suehring, "JavaScript(TM) Step by Step," Microsoft Press, p.432, 2008.

[24] JQueery, cross-browser JavaScript library. [Online] Available at: http://jquery.com/, 11/26/2011.

 ISBN: 978-1-61208-179-3

Developing Nations' eHealth and Telemedicine: Lessons Learned, Especially for Africa

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Abstract—**Telemedicine is being steadily introduced into African and other developing countries. The associated problems encountered often differ markedly from those in developed countries and merit study to facilitate application in all emerging nations. An overview and analysis of lessons learned from such pilot and other telemedicine projects is given in this communication and the consequent application to future programmes will be outlined. From this survey telemedicine and eHealth projects are deemed appropriate for developing nations, if allowance is made for their special conditions in the projects' strategic planning.**

Keywords-component; telemedicine; eHealth; developing country

I. INTRODUCTION

Developing nations are starting to apply increasing numbers of telemedicine (TM) and eHealth projects to provide partial solutions to their problems of providing appropriate public health service. This provision must serve many socio-economically deprived persons living in remote rural areas, with poor infrastructure, often far from doctors, hospitals and specialist medical services. Very frequently few funds are available for any health services and the health-care personnel often lack experience and knowledge of information and communication technology (ICT). This challenging base necessitates careful thought in initiating TM projects, normally inspired by, or in collaboration with, advanced nations' TM. eHealth is the use of ICT to convey medical information and permit certain medical services. Since it can involve many aspects of health services, such as health education, management, promotion, disease prevention, research and relevant population data collection, it is sometimes considered a broader activity than TM, which has a generally accepted definition as concerned with medical activity, or a function related to healthcare practice, where participants are not at the same physical location and they communicate using ICT.

The general ICT status of a developing nation is no guarantee that a country's eHealth will be adequate. A Thai comment on its eHealth foundations describes them as inadequate, even though ICT applications are in general of a high standard and widespread throughout Thailand [1]. But whatever the overall ICT situation, TM practitioners must have appropriate knowledge of ICT. This often lacks and in both Venezuela [2] and India [3] it has been noted that such basic knowledge frequently is deficient in primary health-care centres. There is a similar situation in South Africa where ICT expertise is overall of a standard comparable to most Western nations. However its distribution (as is true of the distribution of public health service facilities) is concentrated in urban regions. In rural areas primary health-care is usually supplied by clinics (over 4000 in all), directed by nursing sisters. Their ICT experience is often woefully inadequate for effective operation of a TM link, for there is currently insufficient material in the national nursing curriculum. This situation is reflected in most developing countries. When the eHealth of a region of emerging nations is studied, the lack of effective inter-nation TM links can be due to a deficiency in fruitful contacts between the relevant researchers, practitioners and policy makers. This was the conclusion of a Canadian study of the TM in 12 East Asian countries [4]. Although many TM projects have been reported in developing countries, most are not sustainable. For example the South African Minister of Health announced in 2010 that of 86 TM projects initiated, only 38 were functioning, because of inadequate connectivity and insufficient "coordination and management of the necessary work" [5]. In India there is a similar sentiment and in part this is because of inadequate evaluation and analysis of TM, for "no studies have been conducted to identify precise reasons why eHealth solutions have not been adopted in the Indian primary health centres" [3]. Evaluation of such projects is universally acknowledged as a very difficult undertaking, although a suggestion has been made that application of a suitable mathematical model may aid in providing useful information [3]. Another difficult, though necessary, consideration is the question of quantitative cost benefits and cost effectiveness. Although some economic advantages of TM are clear, such as reduced transport costs for patient referral and obtaining radiology and pathology opinions easily, in developing and other nations, elucidation of economic impacts is often not straightforward. Reasons for their complexity include the difficult estimation of cost advantages of TM, which provides services totally unavailable previously.

 ISBN: 978-1-61208-179-3

This paper considers recent, selected, representative eHealth activities in developing countries, emphasising Africa, with a view to establishing principles for successful introduction of specific programmes. To do so there are considerations of collaborations with developed countries, how and why evaluations are essential, contributions of technology and distance education in medicine.

II. eHEALTH PLANNING FOR A DEVELOPING COUNTRY

A crucial attitude for the introduction of TM anywhere is to respond to "the pull of needs, not the push of supply" [6]. Regrettably in emerging countries some donor nations, which manufacture TM equipment or individual vendor companies, may encourage, or insist upon, purchases of unsuitable devices and render the TM projects unsustainable. So attention should be paid to "local experts, rather than external commentators" when disagreement occurs [6]. All potential stakeholders should be involved, for obstacles to successful eHealth can be "as simple as ignorance or as complex as political or national lack of vision and leadership" [7]. An example of extensive ignorance comes from a survey of Libyan physicians concerning TM. Those 'confused' or 'unaware' in 2008 were respectively 54% and 15% [8]. In such cases corrective action must be taken. A useful and most acceptable first application of TM is often the provision of a second opinion, as was found in the UAE in 2007 [9] When a developing country TM network is being planned, it is important to consider any existing regional networks of all forms of health-care and to coordinate them [10]. An example of where this was not done sufficiently well exists in South Africa (which has the world's highest number of HIV infected persons) where some of the 9 provincial databases for HIV patient information, etc., were found to be incompatible and unable to exchange data [11]. This clearly can be remedied, but only after considerable and unnecessary expense and effort.

An overall strategy to set up a TM project is first to identify the service or other activity required in terms of needs, then to commence properly controlled pilot studies to establish feasibility and to quantify health-care benefits, if practical, and with these data to estimate the consequences of large scale deployment, in terms of cost, benefits, etc [12]. Often, as found in Pakistan, there will be a need for eHealth readiness tools and an appropriate "process of change management" [13]. Another approach was used in the Balkans after 10 years' of war, which destroyed much of the existing medical system [14]. An initial healthcare assessment, an e-learning programme and 7 years' experience with a virtual hospital, together were confirmed as very successful [15]. Objectives of a TM project should be to delineate it in terms of small modules and "to keep the deliverables within sight" [16]. In all nations when there are eHealth programmes set up, licensure and practice regulations must be reviewed for all those health professions, which are involved [17]. However although in China there are now 3 large, wide-ranging TM networks functioning [18], there have not been any resultant changes in legislature [19], which could affect teleconsultations. These Chinese projects are associated with extensive medical distance learning programmes administered by 13 medical universities, in which 1.6 million persons had participated by 2010. In contrast to the teleconsultation situation, the distance learning is controlled by appropriate legislation and the necessary accreditation [19].

III. NORTH-SOUTH COLLABORATION

A frequent way for developing countries to enter the TM world is to collaborate with a nation that already has established TM. This contrasts with the way TM initially grew in developed nations, where there was no networking with foreign centres of excellence, as is indicated in a German-Estonian project [20]. The European Union has such an agreement with India and this emphasises distance medical education. However one difference between the two parties is that the participating European healthcare and TM are usually public while the Indian partners are mainly private and there are consequent European "sensitivities associated with commercialising healthcare". [21]. A wide range of disciplines has benefitted from such initial mentoring. These include surgical pathology, between Italy and Zambia [22], dermatology between USA and Egypt [23], paediatric neuro-oncology between Canada and Jordan [24], pathology between Germany and Iran [25] and retinopathy diagnosis and care between USA and Peru [26]. Important points are that for the Peruvian project non-ophthalmologists were trained to provide images, the Jordanians found "videoconferencing is a feasible and practical twinning tool in paediatric neuro-oncology with a potentially major impact on patient care" [24] and the Egyptian participants needed only a 5Mp mobile phone camera and access to Email. This gave about 75% agreement with face to face consultations and was the first report of m-teledermatology. All these projects were successful. An extensive Swiss TM partnership, the RAFT project, was initiated in 2000 by the University of Geneva, with collaboration from UNESCO and the WHO, as a French Language African Telemedicine Network in Mali. It was rapidly extended to 17 other Francophone African countries and then more slowly to 5 English speaking African nations. It links 45 healthcare institutions (mainly tertiary and district hospitals) allowing a wide range of tele-education interactive courses and teleconsultations and also supports medical laboratory quality control support, cooperative data bases, satellite enabled rural TM and tele-echography. It uses the iPath platform for pathology and other asynchronous consultations, mainly for difficult cases. The RAFT network has proved sustainable for individual healthcare districts, with 50 000 to 200 000 inhabitants [27].

 ISBN: 978-1-61208-179-3

When any form of healthcare is transferred between different nations, cultural differences must be taken into \consideration. Even between two western nations this was demonstrated as essential after a phone based USA project for chronic care was made available in the UK and Italy. In both the USA and UK the use of phone and care managers proved successful, but in Italy additional face to face consultations proved essential for cultural reasons [28]. Chronic conditions account for about 60% of deaths worldwide and, according to the WHO, are largely preventable So since mobile phone usage in Africa and other developing areas is increasing very rapidly it is likely that such programmes, with appropriate cultural modifications, will be introduced there too, for they both significantly improved health and reduced need of other medical facilities.

IV. SOUTH-SOUTH COLLABORATIONS

The pan-African e-Network, an extensive TM network linking Indian and African medical institutions, mainly concerned with tele-education but also with teleconsultations, is described in the next section. There are also some Indian TM links, dealing with tele-education, to emerging countries in South Asia. A smaller Chinese eHealth programme is planned with Africa, but it has not been formalised yet. The Balkans eHealth network, mentioned above, is active in Kosova, Albania, Macedonia and Montenegro and includes healthcare assessment tele-education and establishing national TM networks. Extensions to other nearby nations are planned [14]. South Africa has a few individual links to nearby nations and more are planned. However there is also a regional network being established to make available surveillance for communicable diseases (HIV, TB, etc) and notification. This results from cooperation with the Southern African Development Community, the African Development Bank and WHO/AFRO. The power of such a surveillance network has been proven on a much smaller scale, with previous success of an Indian Ocean Island TM network, which provided early recognition of an outbreak of bubonic plague in Madagascar and so prevented an epidemic.

V. TECHNOLOGY

India, alone amongst emerging nations, has a satellite, "exclusively for purposes of healthcare" [29] and this is used in an ambitious south-south TM project, the pan-African e-Network, associating India with 47 of the 54 nations in the African Union. It involves 5 medical universities for tele-education and 15 super speciality hospitals in India. Participants in Africa are 4 medical universities for tele-education, 45 learning centres, 4 super speciality hospitals plus 40 other hospitals. Currently there is 1 hour per day for teleconsultations, which will be available for 5 years and so far $125 million have been spent on this project [30]. A lesser TM collaboration, which exists with emerging South Asian nations, is concentrating on distance learning and the provision of digital medical libraries [31]. TM equipment used in advanced countries is often insufficiently robust for use in remote regions of developing countries and this is an important consideration when setting up TM links.

Electronic medical records (EMRs) have greatly aided effective practice of medicine, especially when associated with TM. However it is not necessary to invest in elaborate and costly software to set up an EMR data base. A home-made, modular and effective system has been described in Serbia [32] and another for use in primary health-care facilities in Indonesia, that uses only open source software [33]. As everywhere in the developing world, the reliability of electrical power supplies is important, with ways of coping with power outages are often required, as has been reported from Haiti, for a HIV patient data base [34]

As mentioned, evaluation of any TM project is usually difficult to do and especially so in developing countries. But sometimes there are clear benefits indicated. One such is the reduction of the burden of eye disease in South Africa, as the result of a collaborative project with the UK [35]. More typically an extensive review of 43 projects involving 650 institutions, which have served over half a million patients in Colombia found that although "many projects seem to have had a positive effect, none of them had been rigorously evaluated" [3]. Even in the USA, whose eHealth activities are legion and have inspired and parented many projects in developing countries, when 250 eHealth programmes were examined it was concluded that they needed a detailed evaluation to determine their impact on quality, safety and efficiency and how to ensure such impact could be positive, in terms of value and sustainability [36].

VI. TELE-MEDICAL EDUCATION

Tele medical education can range widely from use of minimal web-based tools to virtual reality and a telepresence-based collaborative learning environment and even the simplest techniques have proven very useful indeed in developing nations. Indian policy in this respect is to ensure that use of the Indian satellite and free bandwidth supplied by the government, will significantly aid social development through eHealth [37]. In Australia there is much use of such training for all types of allied health professionals working in remote areas, who previously learned on-the-job. A videoconferencing programme, initially intended for therapy assistants and extended to others, has proved successful and it indicated that a standardised qualification is frequently not the best approach for therapy assistants [38]. Necessary flexibility in training can be built into distance learning programmes and this can be extended elsewhere. The RAFT tele-education service is now available for 16 hours monthly,

 ISBN: 978-1-61208-179-3

with an average of 18 institutions participating per course. About 75% of the courses are now produced in Africa and there have been over 300 courses offered since 2003. Recent RAFT educational activities include the training of remotely located non-radiologist healthcare workers in use of ultrasound [39] and successful use of a computerised patient simulator in continuing medical education for health professionals as part of a pilot study [40]. The simulator has been appropriately adapted for African usage. Many other tele medical education programmes have been successfully completed throughout the world and some in developing countries have been reviewed elsewhere, together with an analysis of their benefits [41]. There is a general consensus that tele-education is a very valuable and practical application of eHealth techniques in developing countries.

VII. DISCUSSION

There are shortages of doctors, nurses and other allied healthcare professionals in developing countries, especially in Africa. This presents great difficulties in establishing and maintaining acceptable healthcare and is an important matter with serious consequences. Also available funds and health associated infrastructure are often lacking and serious diseases are prevalent there. eHealth is considered an important means of alleviating this dismal situation. But it is not usual for developing nations to have a general eHealth strategy, particularly in Africa, so experience from previous work can be beneficial. Since there are few local funds for capital costs to set up TM, the approximately 300 eHealth projects now underway in Africa usually receive external funds. So it is rare for them to have built-in sustainability or scalability. Many have started as research projects and so will probably last only as long as the donor funds remain available. Few African TM activities are funded by their governments. Hence it is clear that before an eHealth project is introduced, there must be careful planning to avoid unsustainability, with all potential participants to be consulted [42]. In developing countries appropriate legal and regulatory issues related to TM must be considered [43], but this has not always been done. In China, with major eHealth activity, there is virtually no specific legislation concerning TM, although in contrast for over a decade there has been strict control concerning tele-education and necessary accreditation [19]. However a detailed treatment of legislation, ethics, confidentiality, etc., will be given elsewhere.

The medical conditions managed by emerging nations' TM are varied and naturally they often tend to concentrate on those conditions most prevalent there (e.g., HIV, TB, malaria and other infectious conditions). These often differ from those of developed nations, but medical afflictions associated with modern western life are also steadily increasing throughout the world (e.g,. cardiovascular and neoplastic conditions, non-communicable illnesses reflecting life style, etc.). These, and many rarer medical problems, have benefitted from TM. A drawback in Indian oncology care is poor infrastructure and teaching. There is improvement for this in the Uttar Pradesh province of India (where over 100 000 new oncology patients present annually and about 70% of them need radiotherapy), according to the results of a recent 2 year audit of a videoconference based tele-education scheme for registrars [44]. TM can also be most effective in out-patient pulmonary medicine. A videoconferencing link with a telenurse resulted in satisfactory remote physical examination and management of 92% of patients who presented at the remote site [45]. There is recent interest in neuropsychiatric disorders, which account for over 20% of adult global disease. One form of coping with this is due to consultative-liaison psychiatry ("the psychiatric subspeciality devoted to practice of psychiatry in non-psychiatric settings".) After a pilot introduction using non-physician mental health-care providers in rural South Australia who liaise with psychiatrists using telepsychiatry, this was found to be a feasible form of care. Then it was successfully introduced into Ethiopia, to aid training of mental health-care providers and to offer a rudimentary psychiatric service [46]. A recent additional important finding, from rural California [47] is that a pilot asynchronous telepsychiatric service has been shown to be feasible, with clear relevance for developing countries [48].

The need for a specific eHealth project must be unambiguously identified and its aims scrupulously detailed. Equally essential are the practical matters of ensuring thorough preparation and training of all personnel involved and that technical and other backup are made available, while the project continues. A local champion is an ideal part of its management, as is prevention of the impression that the project will simply increase the workload, without additional remuneration. (The latter perception is a frequent consequence of inadequate preparation of those associated with the TM project.) An audit of the pre-TM situation is also necessary, if practical, in order to facilitate later appraisal. After the introduction it is necessary to monitor progress. These injunctions are related to lessons learned from projects mentioned and many others, which confirm this experience and have been described elsewhere [41].

Telemedical disciplines of a developing country eHealth project frequently differ from those of wealthier nations, which now usually have an emphasis on sophisticated radiology, access to patients' EMRs, home care and teleconsultations seeking specialist opinions for those in remote areas. All these have a place in poor countries, where there is usually more concern to support primary health-care, which, before the advent of a TM facility, was rudimentary or often absent. In South Africa, for example, most rural health-care is provided by simple clinics staffed by nurses, perhaps with an assistant. Such clinics are visited rarely or never by a doctor. Transport facilities for medical consultations are often poor and expensive with the

 ISBN: 978-1-61208-179-3

destination distant, perhaps over a hundred km. So TM is seen by the government as an important aid to improve the situation. Tele-education is another valuable eHealth activity, which can be commenced soon after the establishment of TM links.

Benefits obtained from a developing country's TM project in its early stages can include the provision of second opinions [49]. But even when the project is running it often does not result in a general increase in referral rates and only about 1/100 of 1% of the potential demand for those in developing countries who could benefit from TM are believed to do so [49]. Various explanations for this have been given and include the professional participants being overworked and too busy to refer, or their fear of losing control of their patients' care. This can possibly be countered in developing countries by vigorous demonstration of the results of better training and having eHealth networks within the country, which indubitably improve health outcomes, are cost effective and sustainable [11]. Lessons learned for application to future programmes are many and, as sketched above, include thorough preparation, adaptation of equipment to local needs, appropriate choice of eHealth applications, inclusion of distance learning and provision for monitoring. eHealth has been shown to be a complex subject and to ensure its success the factors which must be considered in developing countries (and elsewhere) include primarily healthcare benefits, but also sustainability, scalability, costs, careful consideration of local needs and customs, safety and effectiveness. Considerations of all these factors must be part of the planning and execution of early stages of any eHealth project to determine that it will succeed. Taking note of all this can ensure that eHealth has a bright future in developing countries.

VIII. CONCLUSION

To avoid the failure of a developing country's eHealth project, very careful preparation must be made, to ensure it meets a valid need, is sustainable and appropriately monitored. Then it is clear that projects appropriate for emerging nations can be successful in their specific situations, which may differ from those of more wealthy and technically advanced countries.

REFERENCES

[1] B. Kijsanayotin, N. Kasitipradith, and S.Pannarunothai, "eHealth in Thailand: the current status," Stud Health Technol Inform. 2010;160(Pt 1):376-80.

[2] A.Zambrano, M. Huerta, M. Diaz, and T. Vivas, "Telemedicine network physical connection design for remote areas. Case Baruta—El Hatillo," Conf Proc IEEE Eng Med Biol Soc. 2008;2008:759-62.

[3] S. Chattopadhyay, "A framework for studying perceptions of rural healthcare staff and basic ICT support for e-health use: an Indian experience," Telemed J E Health. 2010 Jan-Feb;16(1):80-8.

[4] S. Varghese, and R.E. Scott, "Categorizing the telehealth policy response of countries and their implications for complementarity of telehealth policy," Telemed J E Health. 2004 Spring;10(1):61-9.

[5] A. Motsoaledi. "Opening remarks," 1st South African Telemedicine Conference", Sept 2010, Cape Town, South Africa.

[6] S. M. Edworthy, "Telemedicine in developing countries: May have more impact than in developed countries," BMJ. 2001 September 8; 323(7312): 524–525.

[7] R. Latifi, "The do's and don't's when you establish telemedicine and e-health (not only) in developing countries," Stud Health Technol Inform. 2008;131:39-43.

[8] R. Wootton, and M. L.Bonnardot, "In what circumstances is telemedicine appropriate in the developing world?" JRSM Short Rep. 2010 Oct 1;1(5):37.

[9] N. Al-Qirim, "Realizing telemedicine advantages at the national level: cases from the United Arab Emirates," Telemed J E Health. 2007 Oct;13(5):545-55.

[10] J. M. Overhage, L. Evans, and J. Marchibroda, "Communities' readiness for health information exchange: the National Landscape in 2004," J Am Med Inform Assoc. 2005 Mar-Apr;12(2):107-12.

[11] T. Sørensen, U. Rivett, and J. Fortuin, "A review of ICT systems for HIV/AIDS and anti-retroviral treatment management in South Africa," J Telemed Telecare. 2008;14(1):37-41.

[12] R. Wootton, "The possible use of telemedicine in developing countries," J Telemed Telecare. 1997;3(1):23-6.

[13] S. Khoja, R. Scott, and S. Gilani, "E-health readiness assessment: promoting "hope" in the health-care institutions of Pakistan," World Hosp Health Serv. 2008;44(1):36-8.

[14] Doarn CR, et al., "Third intensive Balkan telemedicine and e-health seminar: current principles and practices of telemedicine and e-health--clinical applications and evidence-based outcomes," Telemed J E Health. 2009 May;15(4):379-86.

[15] R. Latifi, "'Initiate-build-operate-transfer' - a strategy for establishing sustainable
telemedicine programs not only in the developing countries," Stud Health Technol Inform. 2011;165:3-10.

[16] S. P. Sood, "Implementing telemedicine technology: lessons from India," World Hosp Health Serv. 2004;40(3):29-30.

[17] S. Hardin, and D. Langford, "Telehealth's impact on nursing and the development of the interstate compact," J Prof Nurs. 2001 Sep-Oct;17(5):243-7. .

[18] Z. Wang, and H. Gu, "A review of telemedicine in China," J Telemed Telecare. 2009;15(1):23-7.

[19] J. Zhao, Z. Zhang, H. Guo, L. Ren, S. Chen, "Development and recent achievements of telemedicine in China," Telemed J E Health. 2010 Jun;16(5):634-8.

[20] F. Köhler, et al., "Health telematics/telemedicine in the republic of Estonia," Dtsch Med Wochenschr. 2004 Apr 30;129 Suppl 1:S17-20.

[21] R. Chanda, "India-EU relations in health services: prospects and challenges," Global Health. 2011 Feb 10;7(1):1.

[22] F. Pagni, F. Bono, C. Di Bella, A. Faravelli, and A. Cappellini, "Virtual surgical pathology in underdeveloped countries: the Zambia Project," Arch Pathol Lab Med. 2011 Feb;135(2):215-9.

[23] K. Tran, et al., "Mobile teledermatology in the developing world: implications of a feasibility study on 30

 ISBN: 978-1-61208-179-3

Egyptian patients with common skin diseases," J Am Acad Dermatol. 2011 Feb;64(2):302-9.
[24] I.Qaddoumi,et al., "Impact of telemedicine on pediatric neuro-oncology in a developing country: the Jordanian-Canadian experience," Pediatr Blood Cancer. 2007 Jan;48(1):39-43.
[25] M. Mireskandari, G. Kayser, P. Hufnagl, T. Schrader, and K. Kayser, "Teleconsultation in diagnostic pathology: experience from Iran and Germany with the use of two European telepathology servers," J Telemed Telecare. 2004;10(2):99-103.
[26] A.H. Skalet, et al., "Telemedicine screening for retinopathy of prematurity in developing countries using digital retinal images: a feasibility project," J AAPOS. 2008 Jun;12(3):252-8.
[27] A.Geissbuhler, C. O. Bagayoko, and O. Ly, "The RAFT network: 5 years of distance continuing medical education and tele-consultations over the Internet in French-speaking Africa," Int J Med Inform. 2007 May-Jun;76(5-6):351-6.
[28] P. Azarmina, G. Prestwich, J. Rosenquist, and D. Singh, "Transferring disease management and health promotion programs to other countries: critical success factors," Health Promot Int. 2008 Dec;23(4):372-9.
[29] K. Ganapathy, "Telemedicine in the Indian context: an overview," Stud Health Technol Inform. 2004;104:178-81.
[30] K. Ganapathy, A. Ravindra,"Telemedicine in India: the Apollo story," Telemed J E Health. 2009 Jul-Aug;15(6):576-85.
[31] S. K. Mishra, L. Kapoor, and I. P. Singh, "Telemedicine in India: current scenario and the future," Telemed J E Health. 2009 Jul-Aug;15(6):568-75.
[32] S. Sucurovic, "Implementing security in a distributed **web**-based EHCR (Electronic Hlth Care Record)," Int J Med Inform. 2007 May-Jun;76(5-6):491-6.
[33] I.T. Pambudi, T. Hayasaka, K Tsubota, S. Wada, and T. Yamaguchi, "Patient Record Information System (PaRIS) for primary health care centers in Indonesia," Technol Health Care. 2004;12(4):347-57.
[34] W. B. Lober, et al., "Three years experience with the implementation of a networked electronic medical record in Haiti," AMIA Annu Symp Proc. 2008 Nov 6:434-8.
[35] K. Johnston, C. Kennedy, I. Murdoch, P. Taylor, and C. Cook, "The cost-effectiveness of technology transfer using telemedicine," Health Policy Plan. 2004 Sep;19(5):302-9.
[36] J. M. Marchibroda, "Health information exchange policy and evaluation," J Biomed Inform. 2007 Dec;40(6 Suppl):S11-6.
[37] A.K. Mahapatra, S. K Mishra, L. Kapoor, and I. P. Singh, "Critical issues in medical education and the implications for telemedicine Technology," Telemed J E Health. 2009 Jul-Aug;15(6):592-6.
[38] B.J. Goodale, S. Spitz, N. J. Beattie, and I. B. Lin, "Training rural and remote therapy assistants in Western Australia," Rural Remote Health. 2007 Jul-Sep;7(3):774.
[39] C. O. Bagayoko, et al., "Deploying portable ultrasonography with remote assistance for isolated physicians in Africa: lessons from a pilot study in Mali." Stud Health Technol Inform. 2010;160(Pt 1):554-8.
[40] G. Bediang, C. O. Bagayoko, M-A Raetzo, and A. Geissbuhler, "Adaptation of a Computerized Patient Simulator for Continuous Medical Education of Isolated Care Professionals in Sub-Saharan Africa," Yearb Med Inform 2010:47-54.
[41] S Wynchank, and J Fortuin, "Africa's Telenursing today (and tomorrow?)," Int J Advances Life Sci. 2010; vol 2: pp 165-174.
[42] P. Yellowlees, "How not to develop telemedicine systems," Telemed Today. 1997 May-Jun; vol 5(3): pp 6-7.
[43] A.M. El Gatit, et al., "Effects of an awareness symposium on perception of Libyan physicians regarding Telemedicine," East Mediterr Health J. 2008 Jul-Aug;14(4):926-30.
[44] S. Agrawal, et al. "Training the trainees in radiation oncology with telemedicine as a tool in a developing country: a two-year audit," Int J Telemed Appl. 2011; 2011: 230670.
[45] T. Raza, M. Joshi, R. M. Schapira, Z. Agha, "Pulmonary telemedicine--a model to access the subspecialist services in underserved rural areas," Int J Med Inform. 2009 Jan;78(1):53-9.
[46] A.M. Bauer, et al., "Tackling the global mental health challenge: a psychosomatic medicine/consultation-liaison psychiatry perspective," Psychosomatics. 2010 May;51(3):185-93.
[47] A.Odor, et al., "PsychVACS: a system for asynchronous telepsychiatry," Telemed J E Health. 2011 May;17(4):299-303.
[48] A.Bauer, et al., "The role of psychosomatic medicine in global health care," Curr Psychiatry Rep. 2011 Feb;13(1):10-7.
[49] R. Wootton, "Telemedicine support for the developing world," J Telemed

 ISBN: 978-1-61208-179-3

Telenursing Service for Neonatal Post-discharge Home Care

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***Abstract*—The application of Information and Communication Technology (ICT) in nursing care is becoming more widespread but few examples have been reported in neonatal care. The post-discharge period of sick newborns from a Neonatal Intensive Care Unit (NICU) is a challenging time for young families. Neonatal Home Care Programs offer home support after discharge but clinical and geographical constraints render this service inaccessible to many families that could benefit from it. This paper describes a new web-based application that provides online monitoring of babies after discharge from a NICU. By accessing to a personal area on the website, parents are asked to periodically answer a questionnaire about the newborn's health status (weight, feeding, sleep, etc.). The answers are continuously monitored by professional nurses, who can communicate online with parents to advise them about good baby care. Moreover, high-quality informative documents of use to babies' families are available online. The aim of this tool is to ease pressure on the healthcare system from additional visits, reduce hospitalization and improve parents' satisfaction. The results of a usability test with potential users are shown.**

Keywords-eNurse; neonatology; telemedicine; home monitoring.

I. INTRODUCTION

The pressure to contain health costs, particularly by avoiding hospitalizations and promoting the early discharge of patients, is generating a greater demand for home healthcare at a time when this resource is rapidly becoming less available. Telemedicine involves the use of information technology that facilitates communication between patients and healthcare professionals. This technology has been increasingly considered to potentially have a key role in closing the gap between the demand for and availability of home healthcare services [1].

In the last decade, the telemedicine concept has been expanded to nursing care because it can provide efficient, long-distance healthcare. Telenursing offers easy access to high-quality care and reduces the costs and problems related to travel to health facilities. Patient satisfaction with telenursing is based on prompt, expert care from professional nurses that enhances patients' involvement in their own care and strengthens the nurse-patient relationship [2]. Most nurses recognize the contribution that Information and Communication Technology (ICT), and in particular the Internet, can make to their practice and their patients' understanding of their health and care [3]. Telenursing is progressively becoming more extended as a valuable technique for delivering nursing care, particularly in home healthcare.

Examples of telenursing applications include the use of different telecommunication tools, particularly the telephone and, more recently, the Internet. Telephone triage is already a well-established application in many clinical fields, allowing nurses to determine whether the caller is in need of healthcare and, if necessary, refer him/her to the proper care source [4][5]. In order to provide a health service built around patients' needs, including the need for knowledge and information, the Internet is increasingly preferred over the telephone. A

 ISBN: 978-1-61208-179-3

Figure 1. eNHCP home page screenshot. Translation from original version in Catalan: *Header:* "Babies at home". *Menu-bar:* "Home", "Tips for baby care", "Useful links", "Online baby follow-up", "About us". *Content:* " Congratulations, parents, and thank you for your visit to 'Babies at home'! You as parents, and we as health professionals, know that the most important thing is the health of your children. From the Neonatal Unit at the Hospital de la Santa Creu i Sant Pau we have created a page where the babies are the stars and you will find tips, links and answers to frequently asked questions regarding baby care. Use the menu to navigate to different sections of the website.", "Project developed with the collaboration of the Unit of Biophysics and Bioengineering, Faculty of Medicine, University of Barcelona."

pilot experiment with a Nurse-led Web Chat Triage produced positive reactions from patients [6]. Web-based tools for the support of chronic disease management, such as dyspnea in COPD patients [7], or for educational intervention, such as Web-assisted tobacco control [8], are recent examples of successful telenursing applications using the Web.

Neonatal care is a field where telenursing could be an interesting support tool, but there have been only a few studies to date. The admission of a newborn into a Neonatal Intensive Care Unit (NICU) and the period just after the discharge pose emotional, educational, and logistic problems for a parent. Young families without experience in critical care medicine need not only high-quality medical care but also effective and resourceful information sharing with health professionals.

One previous study described a program in which nurses provided updates to family members of NICU patients on the Internet [9]. The authors reported significant improvements in family satisfaction with NICU in-patient very low birth weight (VLBW) care and pointed out the need to extend this service to the post-discharge period. Programs of neonatal post-discharge home assistance, or transitional care, are already established in many neonatal departments. Typically, they provide in-home and telephone support delivered by clinical nurse specialists for a period after infants are discharged. Wide-ranging program evaluations have revealed a decreased demand in health care resources (mainly emergency departments and pediatricians' consulting rooms) and improved maternal confidence and satisfaction with community service [10]. However, this kind of service is expensive and difficult to maintain with the resources currently available to public health. Therefore, it would be of great interest to have a support tool which can establish a direct contact between parents and NICU staff after baby's discharge, increase parental involvement in baby's care as well as guarantee the cost-effectiveness.

In 2004, the Hospital de la Santa Creu i Sant Pau (HSP) of Barcelona launched the Neonatal Home Care Program (NHCP), which provides home assistance delivered by neonatal nurses and has demonstrated its effectiveness in reducing hospitalization and increasing users' satisfaction. The NHCP established clinical criteria and a maximum distance from a patient's home, which necessarily limit the number of patients that can be included. To overcome these geographical and clinical limitations of the NHCP, the HSP Neonatal Care Department decided to expand it, implementing the eNHCP, an Internet-based support and monitoring

 ISBN: 978-1-61208-179-3

Figure 2. eNHCP "Online baby follow-up" page screenshot. By logging in, parents can access to their exclusive area. Nurses and healthcare professionals can access to their special area by clicking to the link in the lower right corner of the page. Translation from original version in Catalan: *Header:* "Babies at home". *Menu-bar:* "Home", "Tips for baby care", "Useful links", "Online baby follow-up", "About us". *Content:"*Online baby follow-up. Access to this section is exclusively for parents registered to the online baby follow-up service.", "Login. Your e-mail address. Your password. Enter.", "Forgot your password?", "Healthcare professionals".

program for newborn patients after discharge. The application developed essentially comprises a web service managed by the NHCP nurses, which provides high-quality educational information about neonatal care to new parents and baby monitoring through a survey that parents fill in periodically. The aim is to relieve the pressure on the healthcare system caused by additional visits, reduce hospitalization and enhance parents' empowerment and satisfaction.

The eNHCP web tool, described in detail in this paper, was developed in close collaboration with the Unit of Biophysics and Bioengineering, Faculty of Medicine, University of Barcelona. A preclinical validation of the tool was performed by a usability validation test with potential users, the results of which are shown.

II. TOOL DESCRIPTION

The web tool was implemented using PHP language and MySQL database on a Linux/Apache server. All user interface components were developed as dynamic server-side pages. Javascript components were implemented in order to enforce completion and internal consistency of all forms and questionnaires contained in the web tool.

The application was developed with a focus on usability and structure simplicity. In each development stage, special efforts were made to guarantee the maintainability and versatility of the tool. The system architecture was designed to allow frequent updating of the individual pages and easy adaptability to different clinical applications.

The web application functioning was successfully tested with the most important operating systems and web browsers.

The application consists of three main areas:

- Free-access area;
- eNHCP Parents Area;
- eNHCP Staff Area.

A. *Free-access Area*

This area is an open platform that all parents can freely access to find useful information about newborn care. A screenshot of the home page is shown in Figure 1.

The top menu bar contains the links to the different sections of the website. The main sections are:

- "Tips for baby care", which contains several informative documents available for free download written by the NHCP nurses and pediatricians. These documents contain helpful advice about newborn care, such as feeding, bathing, sensory stimulation, massage, how to avoid hazards, primary care, when to go to the

 ISBN: 978-1-61208-179-3

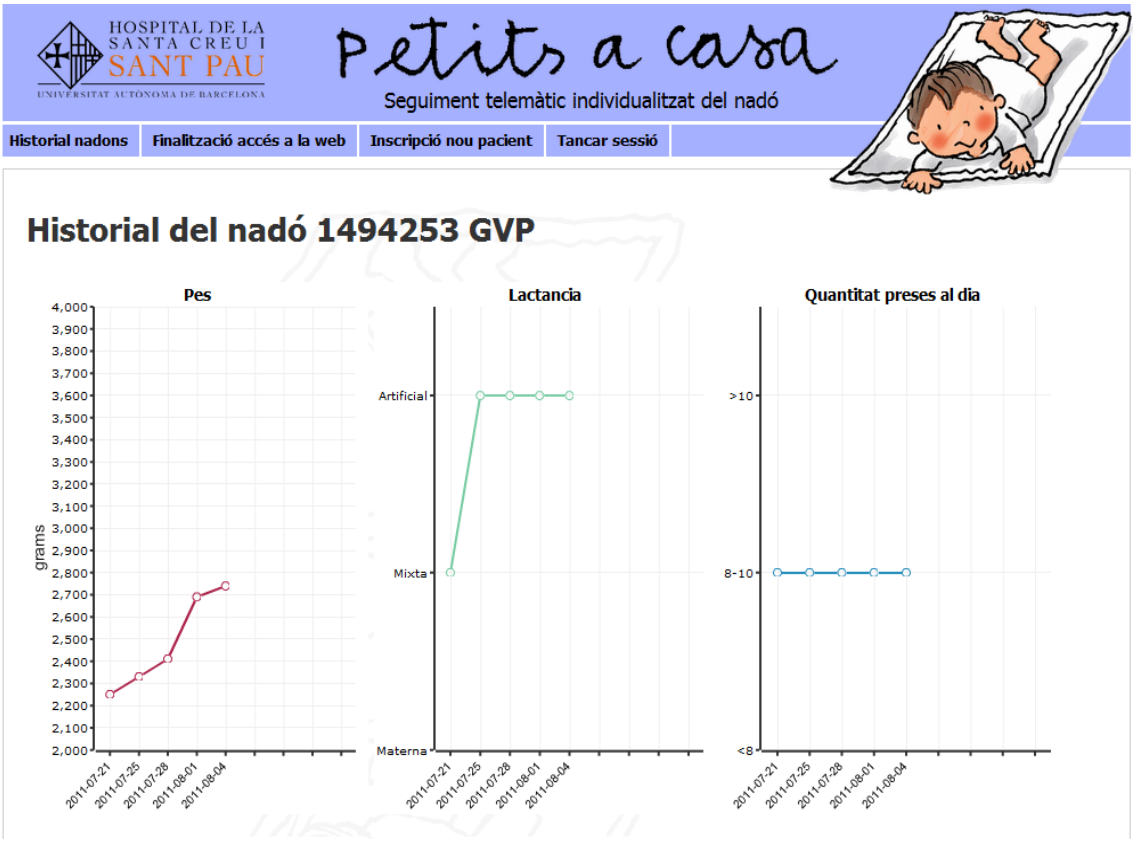

Figure 3. eNHCP nurse page screenshot. Visualization of parents' answers to the periodic questionnaire by dynamic Flas charts. Translation from original version in Catalan: *Header:* "Babies at home. Online baby follow-up". *Menu-bar:* "Baby record", "Deregister a baby", "Register a baby", "Log out". *Title:* "Data of baby number…". *Graphs:* "Weigth", "Feeding", "Intakes per day".

pediatrician, etc. Instructive videos are available in the multimedia section;

- "Useful links", where parents can find a comprehensive list of breastfeeding and neonatal nursing association websites;
- "Online baby follow-up", where parents and nurses can access, after authentication, their respective restricted areas of the eNHCP website (see Figure 2). By clicking on the link "Forgot your password?" users can retrieve their password, which will be automatically sent to their e-mail address.

B. eNHCP Parents Area

Once their eligibility has been established, parents are informed about the web tool and their informed consent is obtained. In order to guarantee the confidentiality of all patients and preserve security, parents included in the eNHCP can access this private area by logging in with their personal username and password, assigned by the NHCP nurse during the enrollment. The eNHCP web tool identifies the user and dynamically generates pages containing only the information available to each user.

In this section all parents find a periodic questionnaire formulated by the NHCP nurses about the baby's conditions (weight, feeding, sleeping, body temperature, skin color, etc.).It comprises 18 questions covering the essential topics that NHCP nurses usually investigate and assess during home visits. The questionnaire has been carefully designed to be autonomously answered by parents, who are recommended to respond it every four days. Their answers are stored, together with the patient authentication data, in a relational data base developed with the MySQL management system. All data are stored in the secure environment of the hospital server.

Furthermore, the baby's weight trend is plotted and continuously updated on the basis of the periodic questionnaire answers. This section was created in order to give parents a visual feedback of their baby's progress.

Another important function integrated into the website is the possibility of exchanging messages via e-mail with the eNHCP nurses, in order to clarify doubts and answer questions about baby care. In the same way, parents can make direct contact with the Webmaster, who is available to solve potential technical problems related to the website's functioning.

 ISBN: 978-1-61208-179-3

C. eNHAP Staff Area

By clicking on the link "Professionals" (see the lower right corner of the screenshot of Figure 2), the eNHCP nurses and pediatricians can enter their own authentication page, similar to that of the parents (as shown in Figure 2). By logging in, they can access the special staff area, where they can undertake three main management activities:

- Monitoring eNHCP babies' status. In this section the eNHCP patients list is displayed and, by selecting one, nurses can observe a baby's data corresponding to parents' answers to the periodic questionnaire. Data are retrieved from the MySQL database and shown in dynamic Flash charts (see Figure 3). After the baby's data evaluation, nurses can, if necessary, write a message directly to the parents with advice and comments about the newborn's care;
- Registering a new baby on the eNHCP. Nurses have to fill in a simple form with the identification data for each baby, such as his/her electronic health record number, name initials and contact e-mail address. The parents of twins or triplets are asked to provide an e-mail address for each baby. In order to protect the newborns' personal information, the baby's name and surname are not included on the registration form. When the registration is complete, a "welcome" e-mail is sent to the contact e-mail address with the parents' credentials needed for authentication by the web tool. The username is the contact e-mail address and the password is automatically assigned, with the possibility of changing it at anytime;
- Deregistering a baby when he/she meets the clinical criteria for final discharge. In order to obtain feedback of users' acceptance of the eNHCP web tool, a concluding satisfaction survey is automatically sent to the parents just after the deregistration. Parents' answers are automatically sent via e-mail to the eNHCP e-mail box to be evaluated by the nurse; they are also stored in the MySQL database to be available for further analysis.

III. PRE-CLINICAL VALIDATION

Before being introduced into routine clinical use, the web tool described above was assessed by a usability test with potential users, in accordance with the UNE-EN 62366 rules. This standard, entitled "Medical devices - Application of usability engineering to medical devices", defines the process of development and testing that should be followed to identify and validate the usability features of a medical device with respect to its security and normal use. Specifically, the aim of this test was to assess the opinion of potential users on the usability and usefulness of the web tool.

A questionnaire similar to the final satisfaction survey proposed on the eNHCP site was given to 15 parents of patients admitted to the HSP NICU. An NHCP nurse had already explained them the eNHCP concept by showing them a website prototype.

The survey comprised 8 statements about the usefulness of the eNHCP contents and functions, and possible answers were distributed on a scale from 0 (I strongly disagree) to 5 (I strongly agree). The results are shown in Table 1. The potential users showed a level of agreement of 4.67 ± 0.49 (mean ± SD) to the first statement, corresponding to an overall positive evaluation of the helpfulness of the eNHCP website.

IV. CONCLUSION

The web tool described in this paper represents a cheap and straightforward approach to support home healthcare. Its application to neonatal care opens up new horizons in the follow-up of NICU patients after discharge. Besides providing high-quality educational contents about neonatal care to parents, the novelty of this tool resides in offering to nurses a valuable and easy procedure for the home monitoring of newborns, as well as fast long-distance communication with families. Furthermore, the questionnaire periodically answered by parents is a monitoring approach which promotes a higher involvement of parents in their baby's care and, consequently, enhances their care skills and self-confidence during a usually stressful period such as the one of post-discharge from NICU.

The concept of this tool as an interactive website is a very convenient method, due to the wide availability of

TABLE I. USABILITY TEST WITH POTENTIAL USERS

Survey statement	Answer (mean ± SD)*
1. In general the Web service "Babies at home" could be helpful.	4.67 ± 0.49
2. The available information could help me take care of the baby.	4.27 ± 0.80
3. The information available on the website could clarify my doubts.	4.00 ± 0.76
4. The e-mail service with nurses available on the website could be useful.	4.37 ± 0.76
5. The files and recommended links could be useful.	4.07 ± 0.70
6. The use of the website could avoid visits to the primary care center.	4.47 ± 0.64
7. The use of the website could avoid visits to the emergency department.	3.87 ± 0.64
8. I would recommend this website.	4.67 ± 0.49

*0 = I strongly disagree, 5 = I strongly agree.

 ISBN: 978-1-61208-179-3

Internet-connected computers among healthcare consumers, especially in the homes of young families. Moreover, as usability and structural simplicity were crucial to the development of the application architecture, the training required by nurses and parents is minimal. Concerns about security and personal data confidentiality have been minimized, as this kind of application can be easily incorporated into the secure environment of a hospital server.

By using this tool, well-established neonatal home care programs could be effectively integrated, reducing costs and overcoming clinical and geographical limitations. Its routine use would be expected to reduce visits to primary and emergency care centers resulting from lack of information and insecurity on the part of parents, thereby improving the cost-effectiveness of the NHCP service.

Given the highly positive reactions obtained from the usability test with potential users, in July 2011 the website started to be used as part of a pilot test with real patients. At the end of pilot period the impact of the eNHCP web application will be formally assessed in terms of cost-effectiveness and users' (both parents and NICU staff) satisfaction.

REFERENCES

[1] Jenkins R.L. and White P. Telehealth advancing nursing practice. Nurs Outlook 2001; 49(2):100-105.

[2] Lorentz M.M. Telenursing and home healthcare. the many facets of technology. Home Healthc Nurse 2008; 26(4):237-243.

[3] Lupianez-Villanueva F., Hardey M., Torrent J., and Ficapal P. The integration of Information and Communication Technology into nursing. Int J Med Inform 2011; 80(2):133-140.

[4] Kaminsky E., Carlsson M., Hoglund A.T., and Holmstrom I. Paediatric health calls to Swedish telenurses: a descriptive study of content and outcome. J Telemed Telecare 2010; 16(8):454-457.

[5] St George I., Cullen M., Gardiner L., and Karabatsos G. Universal telenursing triage in Australia and New Zealand - a new primary health service. Aust Fam Physician 2008; 37(6):476-479.

[6] Eminovic N., Wyatt J.C., Tarpey A.M., Murray G., and Ingrams G.J. First evaluation of the NHS direct online clinical enquiry service: a nurse-led web chat triage service for the public. J Med Internet Res 2004; 6(2):e17.

[7] Nguyen H.Q., Donesky-Cuenco D., Wolpin S., Reinke L.F., Benditt J.O., Paul S.M., and Carrieri-Kohlman V. Randomized controlled trial of an internet-based versus face-to-face dyspnea self-management program for patients with chronic obstructive pulmonary disease: pilot study. J Med Internet Res 2008; 10(2):e9.

[8] Norman C.D., McIntosh S., Selby P., and Eysenbach G. Web-assisted tobacco interventions: empowering change in the global fight for the public's (e)Health. J Med Internet Res 2008; 10(5):e48.

[9] Gray J.E., Safran C., Davis R.B., Pompilio-Weitzner G., Stewart J.E., Zaccagnini L., and Pursley D. Baby CareLink: using the internet and telemedicine to improve care for high-risk infants. Pediatrics 2000; 106(6):1318-1324.

[10] Lasby K., Newton S., and von Platen A. Neonatal transitional care. Can Nurse 2004; 100(8):18-23.

 ISBN: 978-1-61208-179-3

Evaluation of HelloDoctor 24x7 Healthcare Services in Rural India: A Case Study

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***Abstract*—The poor state of healthcare systems and outcomes in developing countries is widely known. There has been a growth in telephone consultation to assess patients' symptoms, providing health information and referring patients to appropriate levels of care. In this case study, we evaluate the utilization of HelloDoctor 24X7 health hotline services aimed to facilitate health information, consultation and referral services over a three month period (June-Sep 2011) in the State of Orissa, India. A total of 1900 calls were received during this three month period. Gender data was available on 1377 callers of which 74% calls (n=1023) were made by males. 68% of the calls were made in the evening. Health information was delivered in 11% of the cases, doctor information was provided in 6%, and hospital information and medicine related general information was delivered in 6% of the cases. Of the total 1900 calls made, only 94 were referred during this time period that included 17% of the calls being actually referred to the specialists. 48% of the calls were made to gather information about treatment and 8% gathered information about medicines. Common ailments for which the calls were made included fever, diarrhea and vomiting, diet and weight management, allergies and women health related issues.**

Keywords-health hotlines; evaluation; rural; triage; information.

I. INTRODUCTION

There has been an increase in the use of telephone consultation and triage; the process where calls, from people with a health care problem, are received, assessed and managed by giving advice or by referral to a more appropriate service [1]. These systems, in general, aim to help with the provision of out of hours care, manage demand for care, or provide an additional source of help and advice that is not limited to out of hours care alone.

Health hotlines are medical call centers that provide health-related information, advice, referrals, and sometimes prescriptions to individual callers over a phone line [2]. Callers are connected to health professionals such as nurses, paramedics, or physicians, who usually follow standard protocols to assess medical situations and provide information and advice. Health hotline is described as a service whose main goal is to provide medical advice and information over the telephone and has following four characteristics [2]: (a) it primarily gives information to callers who are individual patients, but many also serve as medical personnel or health workers, delivers information to callers mainly through a voice call, over the caller's wireless or landline telephone connection, (c) more inbound service as it receives many more calls than it makes; the limited number of outbound calls may be for follow up or reminders and (d) callers may be anywhere and need not be at a specific location such as a telemedicine center, a health clinic or with a health worker. Health hotlines provide several services such as medical information, triage, consultation, diagnosis, referral, treatment and counseling.

The poor state of healthcare systems and outcomes in developing countries is widely known. There are more than four billion mobile connections-most in developing countries-health hotlines accessible to mobile phone basic health information [2]. This can provide care even to people in sparsely populated or low income areas where there are few health care facilities and doctors. There are several factors that might hinder achieving good health outcomes and these include lack of primary care physicians, lack of financial resources to consult better quality providers, high cost of health facilities and presence of low quality primary care facilities and personnel are often not highly skilled.

People lack basic information about the location and availability of pharmacies, clinics and laboratories and about prescription medicines. People widely consult with informal, sometimes traditional, healthcare providers who may not be trained or ethical [3]. Poor information leads to poor healthcare outcomes. Individuals spend time and money to go to the doctor because they don't know the

 ISBN: 978-1-61208-179-3

condition and travel long distances to find that the healthcare provider is unavailable. Health hotline providers in developing countries have been and utilize diverse approaches to deliver healthcare services. These include deploying of phone and video units at pharmacies linked to health hotline [4], multiple interventions in rural areas to strengthen and supplement health system [5], integration of patient records with existing facilities and build new clinics [6] and expansion of rural telemedicine facilities [7]. The hotlines utilize health call agents from diverse backgrounds and roles and responsibilities and can include doctors, nurses, paramedics and non medical personnel. Several health hotlines have been developed in developing countries including Pakistan [4], India [5], Mexico [6] and Bangladesh [7]. Health Management Research Institute (HMRI) is a not for profit organization and offers free services includes phone consults, counseling and complaints, information on facilities and drugs and mobile health clinics [5]. The top caller complaints in this case were recurring abdominal pain and back and knee pain [5].

However, Health line is for profit organization offering phone consults information on facilities and drugs, test results interpretation and discounts on hospital visits. The major caller complaints included chronic diseases, ENT, early pregnancy, and diarrhea [7]. Health hotlines may be sponsored by a government, a healthcare provider, or a Mobile Network Operator (MNO) and some are independent. Health hotline providers can provide proper information at right times that can significantly reduce the overall cost associated with healthcare. Informed individuals can prevent adverse health outcomes, treat some conditions themselves, and make the right decisions during medical emergencies. A health hotline can create a low-cost, widespread, infrastructural model for the delivery of health information. Health hotlines face several challenges such as difficulty in identifying who and what services to offer, reimbursement model associated with these services, measures of effectiveness of these services, associated medical liabilities and how can these services be sustainable. Another major limitation of existing Health hotlines is the limited evaluation of these services especially in developing countries. There is a continuous ongoing need to evaluate and gauge effectiveness of Health Hotline programs.

The objective of our study is to evaluate ―Hello Doctor 24X7 healthcare services, a health hotline aimed to deliver health information, consultations, and triage and referral services to individuals from diverse settings such as urban, rural and tribal in the State of Orissa, India.

HelloDoctor 24x7 healthcare services

HelloDoctor 24X7 [8] provides an opportunity for healthcare service providers to extend their services and facilities to the patients in need. As a result, general public is empowered to make informed decisions. People anytime, anywhere can dial on *0674-66 55 555* and can have necessary information to take proper healthcare decisions free of cost. It uses a Peopletech call center [9] package that sends calls to a health call agent and allows an agent to place calls. It can run in an inbound, outbound (as predictive or manual dialing) or blended capacity (handling inbound and outbound calls in the same agent session). There is also the ability to allow for Interactive Voice Response (IVR) applications interacting with customers' calls. The HelloDoctor 24X7 services have both individual and institutional members. The program is managed by individuals with two roles: health advice officers and healthcare associates.

These individuals had diverse backgrounds and included healthcare professionals including medical trained allopathic doctors, other professionals including (Ayuvedic / Homeopathic / Physiotherapy), nurses or other paramedical staff. The professionals were trained in addressing the needs of the health information seekers. An initial training was provided to the different health advice officers and healthcare associates. The Hello Doctor 24X7 has developed clinical protocols for the management of minor ailments and while initial support can be provided by the health advise officers and if needed the calls can be triaged to the specialists. The health information service providers support for providing health information relevant to specific hospitals, nursing homes, clinics, consultants, blood donors, ambulance and information about the doctors on call.

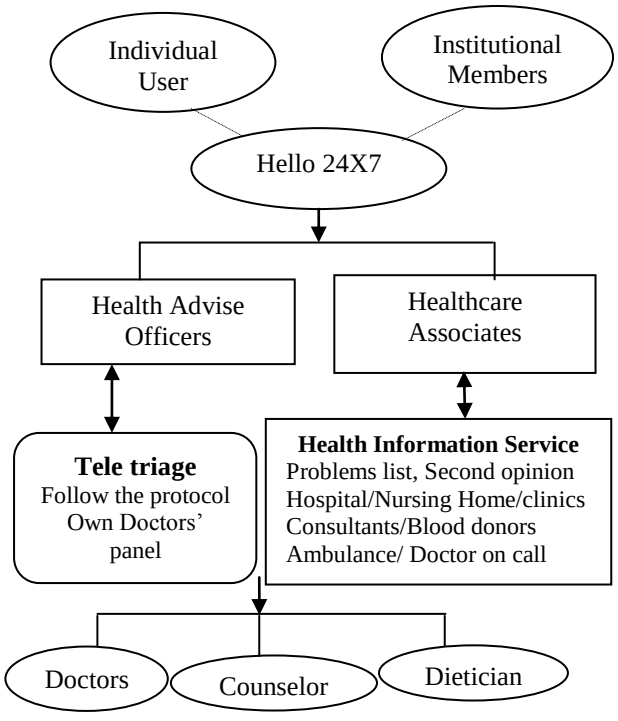

Figure 1. Hellodoctor 24X7 healthcare delivery services

II. METHODS

Analysis was performed on the data gathered during June 2011-Sep-2011 using the HelloDoctor 24X7 services. The data recorded during every call included caller id, date and time of the call, age, gender, purpose and if the call was triaged or not. The entire data gets stored in the Microsoft SQL database. For the purpose of this study we particularly explored the utilization of HelloDoctor 24X7 services over 3 month period (June-Sep 2011). The date and time variable was further stratified into month, day (Monday to Sunday) and time (morning/afternoon) to explore and better understand the temporal utilization of these services.

III. STATISTICAL ANALYSIS

Descriptive analysis was performed and means and standard deviation was reported for the continuous variables and frequency distribution for the categorical variables. Stratified analysis was performed to examine the average number of calls during different days and time. Further stratified analysis was performed to determine differences in the number of health information calls made either by males or females during this time period. Correlation analysis was performed to determine association between the number of calls and the day (i.e. Monday to Sunday) and time (morning/afternoon) of the calls. All analysis was performed using SAS version 9.1

IV. RESULTS

Overall 1900 calls were made during a 3 month period (June-Sep 2011) (Figure2). There has been a consistent increase in the total number of calls over these months. The average age of the callers was 20 years (SD=20.6). Gender data was available on 1377 callers of which 74% (n=1023) were males and 26% (n=354) were females. 68% (n=1345) of the calls were made in the evening as compared to the remaining 32% calls that were made in the morning (n=554). Fifty three calls have been received for the month of September (Till September 3, 2011).

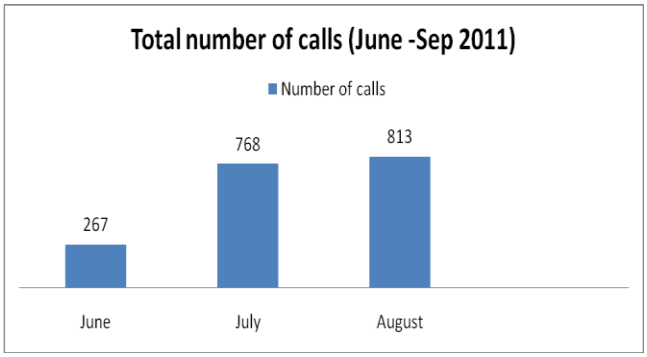

Figure 2. Total number of calls during June-Sep 2011

We also performed analysis to explore temporal utilization of these health information calls. Figure3 illustrates that the majority of calls were made on Friday (n=300/1900), followed by Wednesday (n=273/1900) and Saturday (n=272/1900). Our results reflect a change in the utilization of health information calls using the HelloDoctor 24X7 services.

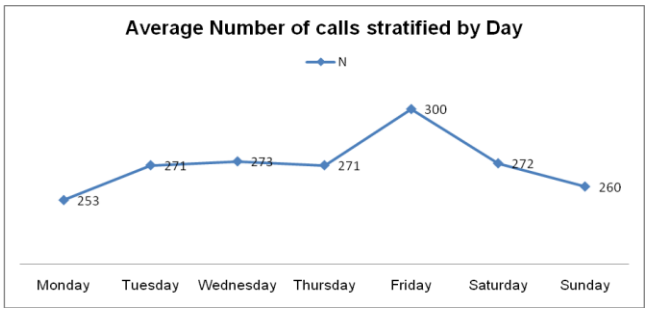

Figure 3. Average number of calls stratified by days of the week

Results also show that majority of the calls were made in the afternoon for the different days of the week (Figure4). Majority of the calls were made on Thursday afternoon (n=204) followed by Friday afternoon (n=203). Results showed that the lowest number of calls were made on Thursday morning (n=67)

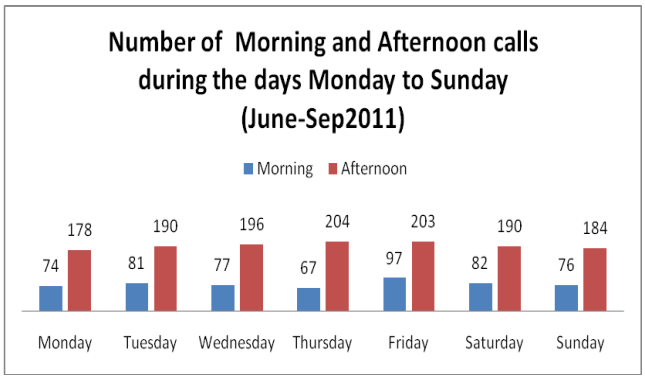

Figure 4. Calls stratified by the time of the day

Our results also showed gender disparity in the utilization of HelloDoctor 24x7 healthcare services (Figure5). Males were consistently making use of these services than females for all the days of the week. Most of the calls by males were made on Sunday while most of the calls by females were made on Monday.

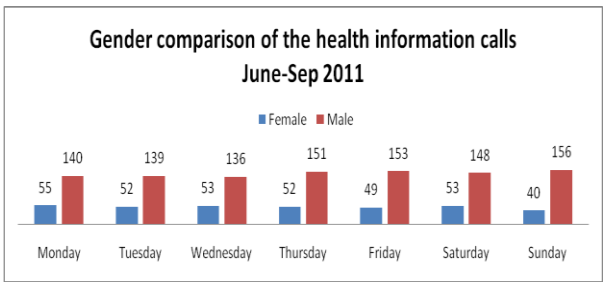

Figure 5. Gender comparisons of health information calls

 ISBN: 978-1-61208-179-3

Additional analysis was performed to determine the characteristics of the calls during the time period from June-Sep2011. Results found 18% (n=340) of the calls to be prank calls. In 11% (n=210) of the cases, health information was received, doctor information was provided in 6% (n=121), hospital information and medicine related general information in 6% (n=108) cases. Additional calls gathered neurologist (4%; n=73), orthopedic, obstetrics and skin and venereal disease related information (3%; n=63).

We also performed triage analysis to determine the frequency of calls that were referred to the specialists. Of the total 1900 calls made during this time period, 94 were referred. Of these calls, only 17% (n=16) of the calls were actually referred to the specialists. 46% (n=43/94) of the calls were made to gather information, 48% (n=45/94) of the calls focused primarily on treatment and the remaining 8% (n=6/94) was to gather information about medicines. Common ailments for which the calls were made included fever, diarrhea and vomiting, diet and weight management, allergies and women health related issues.

V. DISCUSSION

Telephone access and consultation can be used to overcome geographical barriers. Health hotline provides health information and can help the public make informed decisions. They can also help in providing information and handling surges during specific emergency responses.
Previous studies have shown that people from the remote areas in Bangladesh, now find it convenient to pick up their mobiles and call for help. The rural areas, where 80% of the populations inhabit, lack hospitals, clinics, health facilities and particularly qualified doctors. To be able to talk to a doctor is a unique privilege for the villager or an individual in a regular medical situation or emergency. However, there is a significant need to continuously evaluate health hotlines programs so that greater adoption and dissemination of these services can be done.

The results of our study present an overview of the utilization of the health hotline program HelloDoctor 24X7 serving the rural areas of Orissa. The program facilitates delivery of health information, consultation, triage and referral services. Results of our study show significant age and gender variation in seeking HelloDoctor 24X7 healthcare services. Males were likely to utilize these services. Results showed significant variation in the times when these calls are made. Majority of the calls were made during afternoon than morning that might reflect a need of more trained staff when the call load is more. Health hotlines is an excellent way to answer and be in touch with those who consider this service as a place where to find somebody interested in their requests, for not having, sometimes, the possibility to access to information otherwise.

However, there are several limitations of the study. The health hotline delivery model is not a full substitute for traditional, in person modes of health information delivery. Several factors also limit the ability of health hotlines to provide information and advice to callers. First, some callers require in-person consultations, prescription drugs, or other treatments that may not be affordable even if they are available nearby. Second, health hotlines have limited ability to follow up with callers to understand the results of their information and advice. Patients do not regularly call to report the results after they complete a course of treatment or act on the hotline's advice. This makes it difficult for hotlines to judge how successful their interventions have been and how to adapt their protocols or recommendations. If anything, the patient is more likely to call back if the advice or prescription has not worked. Another limitation of the study was that it did not really gauge the effectiveness of the health hotlines in improving health outcomes.

There is a need to develop health call center protocols, algorithms and tools for specific scenarios to advise the community on how to self-triage, identify symptoms and call for help or advice. There is a significant need to provide consistent, accurate information, collecting/maintaining structured data to characterize events/responses (situational awareness) and developing capability and capacity to adapt to public health emergencies (technology tools can assist with this).

ACKNOWLEDGEMENT

We would like to acknowledge Dr. Manik, Dr. Devendra Tewari and Ashok Mallick from HelloDoctor 24X7 services for providing support in providing the data and description of the program.

REFERENCES

[1] Bunn F., Byrne G., and Kendall S. Telephone consultation and triage: effects on health care use and patient satisfaction. Cochrane Database of Systematic Reviews 2004, Issue 4. Last accessed 1 September, 2011.

[2] Ivatury G., Jesse M., and Alison B. A Doctor in Your Pocket: Health Hotlines in Developing Countries, GSMA Development Fund, 2009, 119-152. Last accessed 2 September, 2011.

[3] Bagchi S. Telemedicine in rural India. PLoS Med, 2006, 3 (3): e82. Last accessed 8 September, 2011.

[4] Akter., Shahriar., D'Ambra., John., Ray., and Pradeep. User Perceived Service Quality of mHealth Services in Developing Countries. 18th European Conference on Information Systems http://aisel.aisnet.org/ecis2010/134. Last accessed 10 September, 2011

[5] Bergkvist Sofi. Human Resources in Healthcare, Health Informatics and Healthcare Systems, 2010, 127-153. Last accessed 10 September, 2011.

[6] MedicalHome http://www.mhealthinfo.org/project/medicallhome-hotline. Last accessed 13 September, 2011.

[7] Mohammad R. Health-Line Medical Call Center Using Cellular Phone Technology in Bangladesh: Lessons Learned in Breaking Economic and Social Barriers in Accessing Healthcare. 135th Annual American Public Health Association

 ISBN: 978-1-61208-179-3

Scientific Conference Nov 3-7, 2007. Last accessed 9 September 2011.

[8] Hello Doctor 24x7 http://www.hellodoctor24x7.com/index.html. Last accessed 13 September, 2011

[9] Peopletech. http://peopltech.co.in/case01.htm. Last accessed 13 September, 2011

[10] Wetta-Hall., and Ruth. Help on the Line: Telephone Traige Use, Outcomes, and Satisfaction within an uninsured population. Evaluation and the Health professions, 28 (4), 414-427. Last accessed 11 September 2011.

 ISBN: 978-1-61208-179-3

HIV Self-testing Combined with Internet Counselling: A Low Threshold Strategy to Increase Diagnoses of HIV-infections

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***Abstract*—The proportion of undiagnosed HIV infections in the Netherlands is substantial. Increasing the HIV test uptake is important to improve individual health outcomes and reduce further spread of HIV. Self-tests for HIV have become available. Self-tests allow individuals to test at the privacy of their home, without involvement of any health care professional or laboratory, and may help to increase HIV test uptake. However, there are many concerns with respect to test quality, test procedures, and medical follow up. This project aims to develop and evaluate a service that offers high quality HIV self-tests in combination with internet pre- and post-test counseling to individuals at high risk for HIV. The usage of the service, its effectiveness in identifying unrecognized HIV infections and their follow-up in care, perceived usability and acceptability, and cost effectiveness will be evaluated.**

Keywords-HIV; screening; self-test; online counseling.

I. BACKGROUND

HIV infections remain a major public health issue in Western countries [1]. The most important risk groups for HIV are men who have sex with men (MSM) and migrants from HIV-endemic countries [2-5]. Recent estimations indicate that 40% of 21,500 HIV-infected individuals in the Netherlands do not know their HIV status [6]. Earlier diagnosis of these individuals will lead to timely treatment which improves the prognosis and assists in controlling the HIV epidemic [7,8].

The need for increasing the uptake of HIV testing did not elude commercial medical entrepreneurs in developing self-test packages for HIV. In recent years the availability of such tests has increased. These tests are bought and performed by a consumer, usually at home without the involvement of medical staff or a laboratory. For some individuals HIV self-tests appear to be a convenient alternative for testing as they enable them to overcome several barriers related to HIV testing.

However, several concerns regarding the quality and effect of the self-testing procedures have been raised. The accuracy of many of the currently available HIV self-tests is not proven, and there are concerns related to the correct application of the test, the follow-up trajectory for those who test positive, and the loss of counseling opportunities for HIV positives and negatives. Further, by choosing to only test for one infection (e.g., HIV) one looses the more inclusive approach currently used in the Netherlands to screen for a broad spectrum of sexually transmitted infections (STI) in each screening contact. Therefore, health care providers are reluctant to promote the usage of self-tests despite the increasing number of outlets offering such tests.

Nevertheless, the quality and robustness of self-tests for HIV are continuously improving. Recently, a highly reliable HIV rapid test has become available that uses oral fluid instead of blood, making it easier for self-use by consumers. In potential, the availability of such a low-threshold testing method can help us in the long run in increasing HIV test uptake. The proper integration of such self-testing options within the health services is certainly worth examining.

II. AIM

The project aims to develop and evaluate a service that provides reliable HIV self-tests using oral fluid in combination with an Internet counseling strategy to individuals at risk for HIV, especially MSM and migrants from HIV endemic countries.

III. METHODS

Following strategies of human-centered design and business modeling, a website and logistic infrastructure will be developed that inform individuals about HIV self-testing, enable individuals to purchase an HIV self-test online, and offer user-friendly instructions, pre- and post-test counseling and low-threshold contact options with health care professionals. The website will contain an online triage system using an interactive intake questionnaire and risk assessment algorithm that will enable us to distinguish between those at risk for HIV and those not at risk for whom testing is not necessary.

Those not at risk for HIV will be discouraged from using the self-testing service; those at risk for HIV will be encouraged to test for HIV. The STI-clinic and general practitioner (GP) will be referred to as the preferred locations for testing considering their inclusive testing for multiple STIs. Those who indicate that they do not want to involve their GP or STI clinic, will have the possibility to order an HIV self-test. With the test, they will receive a code to access an elaborated pre-test trajectory including step-by-step instructions and counseling. Interactive movies and information modules will be used, and low-threshold contact

 ISBN: 978-1-61208-179-3

options with health care professionals will be offered (e.g., using Skype, telephone, or web cam). After testing, a post-test counseling procedure will be offered online for both positives and negatives. For individuals who test positive, a follow-up procedure will be setup in order to motivate them to access regular health care as soon as possible for confirmation testing and referral to an HIV outpatient clinic.

The project will start with a pilot phase of three months in the beginning of 2013 in which the service is offered on a relatively small scale (i.e., without campaign activities) to identify and solve potential technical or logistical difficulties that might arise. Early users of the service will be interviewed about their experiences to further improve the service. After successfully completing the pilot phase, a media campaign targeted at high risk groups for HIV (e.g., MSM, migrants) will be launched nationally. A total of 2,000 tests are estimated to be sold within a 12-month period. We aim to reach an HIV prevalence of newly diagnosed individuals of 2.5-5% (n=50-100 individuals).

IV. EVALUATION

The evaluation will focus on the following outcome measures:

- The proportion of individuals at risk for HIV among those who completed the intake questionnaire, and their characteristics and reasons for preferring to test via an HIV self-test.

- The frequency of use of the website's features and functions (e.g., ordered tests, logins to the website's counseling program), the duration of use (e.g., per web session, and online module), the registered number of contacts with health care professionals during the project, an overview of the feedback of users and stakeholders during the project; the feasibility, and perceived usability and acceptability of the testing and online counseling procedures as measured both qualitatively and quantitatively.

- The proportion of individuals belonging to the HIV risk groups that use an HIV self-test, the HIV prevalence among these individuals and their determinants; the number of individuals that show up for confirmation testing, the time from testing positive via a self-test to confirmation testing, the proportion of confirmed positive test results, the number of individuals that are referred to the hospital, and the moment of diagnosis in their infection (using CD4 cell counts and viral load measurements).

- The cost-effectiveness of the proposed testing strategy.

ACKNOWLEDGMENTS

This project is funded by the Netherlands Organisation for Health Research and Development (ZonMw; grant no. 50-51515-98-176).

REFERENCES

[1] M.J. van de Laar. HIV/AIDS and other STI in men who have sex with men - a continuous challenge for public health. Euro Surveill. 2009;14(47):pii=19423.

[2] L. Gras, A. van Sighem, C. Smit, S. Zaheri, M. Prins, et al. Monitoring of human immunodeficiency virus (HIV) infection in the Netherlands. HIV Monitoring Foundation: 2010.

[3] European Centre for Disease Prevention and Control/WHO Regional Office for Europe. HIV/AIDS surveillance in Europe 2009. Stockholm: European Centre for Disease Prevention and Control; 2010.

[4] European Centre for Disease Prevention and Control/WHO Regional Office for Europe. Migrant Health: Epidemiology of HIV and AIDS in migrant communities and ethnic minorities in EU/EEA countries. Stockholm: European Centre for Disease Prevention and Control; 2010.

[5] M. Xiridou, M. van Veen, R. Coutinho, and M. Prins. Can migrants from high-endemic countries cause new HIV outbreaks among heterosexuals in low-endemic countries? AIDS 2010; 24(13), pp. 2081-2088.

[6] M. van Veen, A.M. Presanis, S. Conti, M. Xiridou, A.R. Stengaard, et al. National estimate of HIV prevalence in the Netherlands: comparison and applicability of different estimation tools. AIDS 2011; 25(2), pp. 229-237.

[7] M.M. Kitahata, S.J. Gange, A.G. Abraham, B. Merriman, M.S. Saag, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. N Engl J Med 2009; 360(18), pp. 1815-1826.

[8] J.A. Sterne, M. May, D. Costagliola, F. de Wolf, et al. for the When To Start Consortium. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. Lancet 2009; 373(9672), pp. 1352-1363.

 ISBN: 978-1-61208-179-3

Designing Physical Telerehabilitation System for Patients with Multiple Sclerosis

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***Abstract*—Physical rehabilitation positively affects clinical outcomes in multiple sclerosis (MS) however it is limited by delivery modes, cost and distance. Telemedicine approaches can potentially facilitate home-based rehabilitation however they were not systematically implemented for patients with MS. We developed a Home Automated Telemanagement (HAT) system for computer-guided management of patients with MS providing individualized instruction and monitoring of physical therapy exercise at patient homes. The HAT home unit runs on a netbook in the patient's home connected to a remote server via internet. The system questions the patient on their condition, gives detailed step by step exercise instructions, records their daily exercise log, and informs and quizzes the patient on their knowledge of multiple sclerosis. The exercise log is transmitted to the remote HAT server where it is analyzed using decision support algorithms to facilitate MS management. The exercise logs are available on-line for review by patient providers. Patient exercise regimen is determined by their physical therapist and can be updated on-line, keeping a personalized approach to disease management while taking advantage of the convenience the technology supplies. This telemanagement system has been successfully designed and implemented to optimize the care of patients with multiple sclerosis.**

Keywords-telerehabilitation; eHealth; multiple sclerosis

I. INTRODUCTION

Multiple sclerosis (MS) is a chronic debilitating disease of the central nervous system that may result in significant damage of the neuromuscular system, vision, and affective and cognitive functions [1]. Approximately 400,000 persons in the United States have MS [2]. Lifelong rehabilitation measures, along with medication treatment, are the major components of patient management [3–4]. Physical exercises positively affect patients' quality of life and their functional capacities [5–6]. Poor adherence to rehabilitation, limited patient education, and access to specialized care can be barriers to treatment [7–8]. Removing those barriers is an important step towards improving patient care for multiple sclerosis.

Current technology allows for remote information transfer in a variety of circumstances. Information can be easily transferred to and from a person's home through the existing telephone and internet infrastructures. Our goal was to design a telemanagement system for patient use in MS. This paper reports the success of design and implementation of the Home Automated Telemanagement (HAT) software in patients with MS. We describe the software and hardware used, website design, and overall interactions of the HAT system design.

II. SYSTEM DESIGN

The HAT system is based on Wagner's model of chronic disease care [9]. The HAT system supports the major components of this model including patient self-care, tailored education and counseling, individualized treatment plan, guideline-concordant decision support, comprehensive patient provider communication, and multidisciplinary care coordination [10-12]. Using this model, the HAT system has been successfully implemented and tested in various health conditions [13-17].

The HAT system consists of home unit, HAT server and clinician unit [18]. The previous applications utilized laptops, PDA, IVR, and cell phones for patient home units [19-22]. The HAT system for MS takes advantage of the current technology to provide patients with a convenient treatment plan and exercise regimen as well as enforcing adherence to rehabilitation through more frequent monitoring.

The home unit was developed using Visual Basic and runs on netbooks with Windows operating systems. Visual Basic is a programming language and development environment from Microsoft derived from the BASIC programming language. The language allows for quick development and has extended Microsoft Windows functionality for more complex projects. Visual Basic is also well supported by older operating systems, making it ideal for projects utilizing less expensive computers with limited system resources.

The patient home unit sends patient self-report information via internet to a HAT server running Windows 2008. A server running Internet Information Services (IIS) collects the patient's data and integrates it into a website to be accessed by the patient's physician and physical therapist. IIS is one of the most widely used web servers and provides a stable and widely compatible system for receiving and editing patient information.

The webpage was developed using Microsoft's .NET framework. This is a framework for developing dynamic websites which offers extensive built-in functionality and is supported by most browsers.

The patient home unit allows a patient to run a self-test and exercise program which asks the patient a series of symptom questions, instructs them on exercise routines,

 ISBN: 978-1-61208-179-3

records exercise completion and attempts, then questions and educates the patient on multiple sclerosis. The system then sends the symptom and exercise information to the server. Once a report has been sent to the server it can be viewed by the patient's physician through the MS HAT website.

The system is designed so that each patient has an individual exercise plan decided by their physical therapist. The exercise plan specifies a set of exercises chosen by their physical therapist to optimize treatment and can be reviewed on the laptop system and the website. Prior to beginning home unit use, a physical therapist creates the patient's exercise plan. The physical therapist chooses from a library of 47 predefined stretching and strengthening exercises, each with their own step by step instructions, illustration, safety tips, and instructional video. During the self-test the patient records how many times they completed each exercise, along with the number of attempts made. This allows the physician to determine which exercises are more challenging to the patient. The exercise plan can be updated through the website by the physical therapist and will update on the home system the next time it connects to the server or when the patient chooses the "Update Exercise Plan" from the main menu on the home unit. There are also general exercise safety tips as well as specific tips for each exercise designed to minimize the risk of injury during exercise. Information flow for the exercise plan can be seen in Fig. 1.

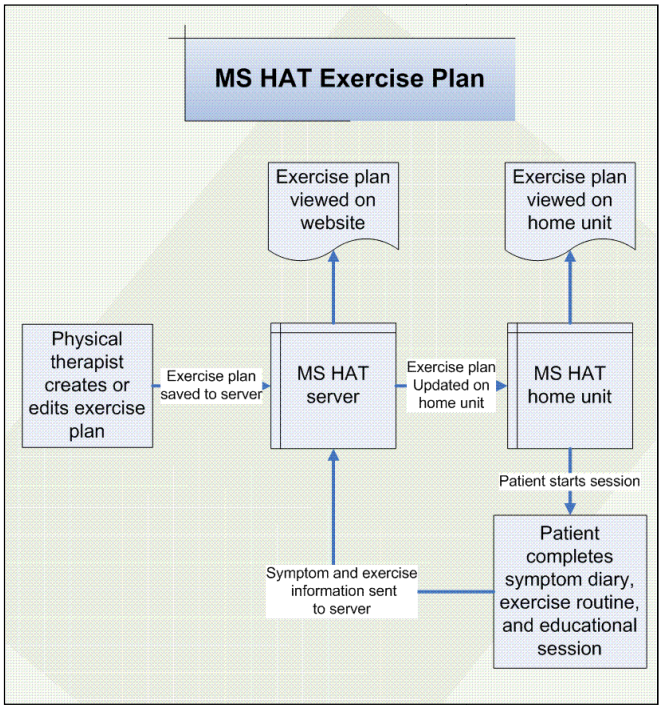

Fig. 1. Exercise plan information flow

III. RESULTS

The MS HAT system was successfully designed and implemented on low-cost touch-screen netbooks running Windows operating system. Information was successfully sent and received from a remote location to the server using wireless internet. The website was successfully launched and provides full system functionality.

The patient home unit runs the MS HAT program when it starts up and the user can navigate through the menu using the enter, space, and backspace keys along with the arrow keys. These keys are marked clearly with their function to avoid any confusion. There is also the option of using a wireless keypad to navigate the program. The wireless keypad is clearly marked like the keyboard and allows the patient to navigate the different exercises without having to go back the unit and make selections between exercises or exercise steps. This functionality is especially important in MS where the patient's mobility may be limited.

The text is large and easy to read while all the instructions are kept simple. The program is designed to be simple enough for someone with no previous computer experience to use.

The home unit main menu options five different options. The first section is "Start Exercises". This portion of the program is broken into 3 parts, the symptom diary, the exercise plan, and the educational portion. This section begins with a self-testing portion where the patient answers a series of 16 questions pertaining to their multiple sclerosis. One of these questions is shown in Fig. 2.

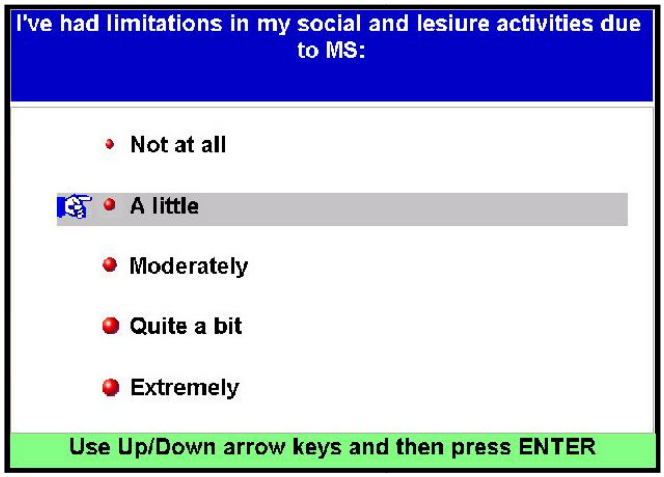

Fig. 2. Patient symptom diary question

The responses are used to gauge the overall health of the patient, as well as to raise flags when the patient may be experiencing multiple sclerosis symptoms that require attention and treatment.

After the self-test portion of the session, the patient enters the exercise portion of the session. First the patient is asked whether they would like to view general exercise safety tips, then the patient is presented with their specialized list of exercises. The patient can then navigate to any exercise on the list and select it. This brings the patient to a screen with a diagram of the exercise and step by step instructions. The screen also lists the amount of times the exercise is supposed to be completed as specified by a physician. This screen can be seen in Fig. 3.

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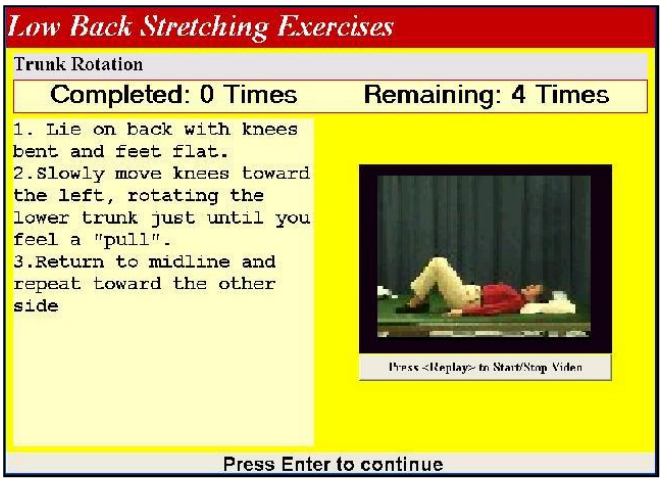

Fig. 3. Trunk rotation exercise instruction screen

If the patient still needs more instruction about the exercise, they can choose to view a video of an instructor giving detailed directions and performing the exercise.

Once the patient has completed the exercise to their satisfaction, they are questioned about the number of times they performed the exercise. If this number is equal to or more than the amount specified by the physician then the exercise is highlighted red in the exercise menu, otherwise it remains green, indicating it is not completed as seen in Fig. 4.

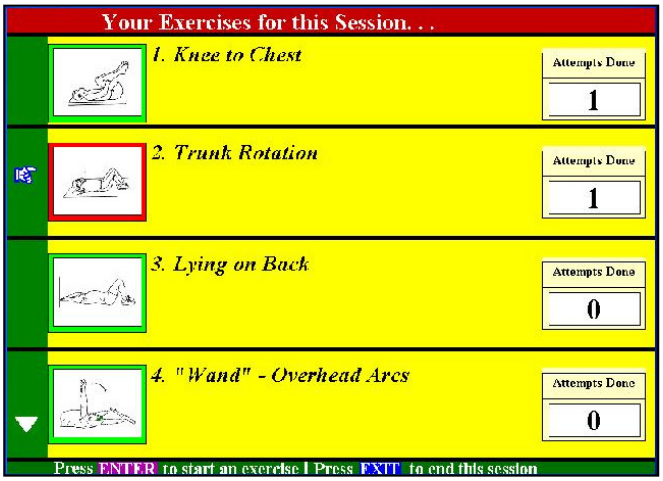

Fig. 4. Patient exercise list screen

The patient may leave the exercise screen at any time by hitting the key marked "Exit". If all exercises are not completed when the patient tries to exit they will be presented a dialog box telling them the exercises are not completed, asking for confirmation that they wish to exit to the main menu.

When the exercise portion is completed, the patient begins the education portion of the program. The patient is asked a question about MS and then shown an educational tip about the disease. Each question is based upon the tip given during the previous exercise session and if a question is answered wrong the tip for the question is repeated and the question is repeated the next time the session is completed.

Once the patient completes the educational portion, the program attempts to send the collected data to the server through the phone connection. If there is no connection or the data can not be sent to the server, the data is stored on the home unit and sent to the server the next time a successful connection is made.

From the main menu the patient may also review general exercise safety tips and view their prescribed exercises without having to start a self testing session. There are also options to check for an updated exercise plan and to shut down the system. The main menu is shown in Fig. 5.

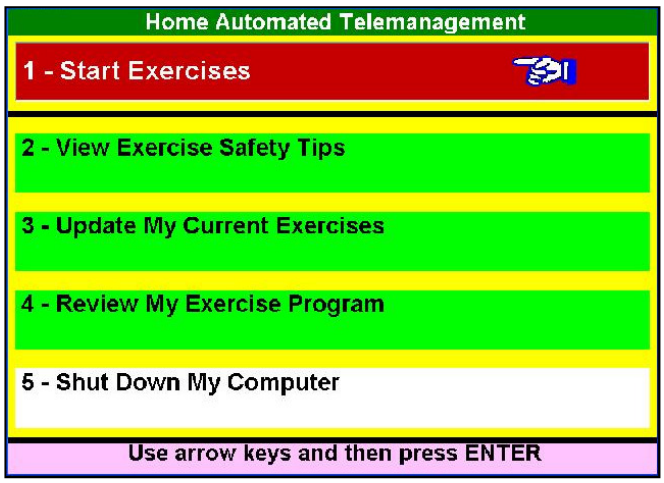

Fig. 5. MS HAT main menu

The MS HAT website is hosted on our servers and can be accessed by a patient's physical therapist using any computer with a web browser and an internet connection. The physical therapist can view and edit the patient's current exercise plan as seen in Fig. 6.

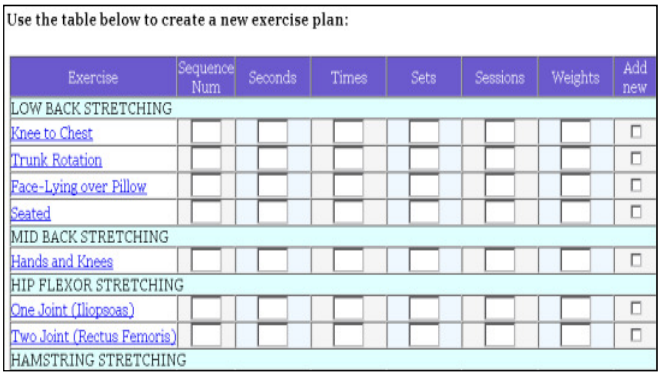

Fig. 6. Exercise editing on the website

The physical therapist can also change their exercise plan for the patient, send a message to the patient, record clinical notes, and view completed exercise data as shown in Fig. 7.

IV. DISCUSSION

The MS HAT system was pilot tested in patient's homes. The patient's response was positive and the system design shows great potential for providing multiple sclerosis patients better care. The system's ease of use and convenience can provide reluctant patients with an

alternative to frequent doctor visits as well as provide them with a strict and easy to follow exercise regimen for disease intervention. While face to face visits would still be important to the patient's care, allowing the patient to monitor their health frequently, educating them on their condition, and walking them through a tailored exercise routine will hopefully increase their awareness, quality of life, and rehabilitation adherence.

Patient Summary — Patient Name: Phone:

Home Monitoring

Exercise	Attempts	Times	
11/6/2006			
Knee to Chest	1	0	Details
Trunk Rotation	1	0	Details
Face-Lying over Pillow	1	0	Details
Seated	1	0	Details
One Joint (Iliopsoas)	1	0	Details
Passive - Seated with Towel Assist	1	0	Details
Calf Muscles: Gastroc Stretching-Standing	1	0	Details
"Wand" - Overhead Arcs	1	0	Details
"Wand" - Circles	1	0	Details
Wall-Sitting	1	0	Details

Figure 7. Exercise home monitoring on the website

The proposed system can be adapted for other chronic diseases such as chronic obstructive pulmonary disease [23] where the same principles have been applied to facilitate patient-centered care [24].

We are also looking toward expanding the HAT system to other electronic platforms [25-26]. Mobile computing is becoming smaller, faster, and cheaper, creating more potential environments for the HAT disease management system. Systems such as the Apple iPhone and mobile phones are rapidly becoming viable options for implementing HAT systems.

V. CONCLUSION

The HAT system is a viable platform to facilitate management of multiple sclerosis. This system can be expanded to support rehabilitation in other chronic cardiovascular, respiratory, and neurodegenerative conditions. Including means to monitor blood pressure, oxygen saturation and heart rate can improve safety of home exercise. Adding Kinect-like sensors may enhance user interface, exercise assessment, and data collection.

REFERENCES

[1] Vickrey B.G., Hays R.D., Harooni R., Myers L.W., Ellison G.W. A health-related quality of life measure for multiple sclerosis. Qual Life Res. 1995;4(3):187–206. [PMID: 7613530]

[2] Anderson D.W., Ellenberg J.H., Leventhal C.M., Reingold S.C., Rodriguez M., Silberberg D.H. Revised estimate of the prevalence of multiple sclerosis in the United States. Ann Neurol. 1992;31(3):333–36. [PMID: 1637140]

[3] Brown T.R., Kraft G.H. Exercise and rehabilitation for individuals with multiple sclerosis. Phys Med Rehabil Clin N Am. 2005;16(2):513–55. [PMID: 15893685]

[4] Wiles C.M., Newcombe R.G., Fuller K.J., Shaw S., Furnival-Doran J., Pickersgill T.P., Morgan A. Controlled randomised crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis. J Neurol Neurosurg Psychiatry. 2001;70(2):174–79. [PMID: 11160464]

[5] Solari A., Filippini G., Gasco P., Colla L., Salmaggi A., La Mantia L., Farinotti M., Eoli M., Mendozzi L. Physical rehabilitation has a positive effect on disability in multiple sclerosis patients. Neurology. 1999;52(1):57–62. [PMID: 9921849]

[6] Romberg A., Virtanen A., Ruutiainen J., Aunola S., Karppi S.L., Vaara M., Surakka J., Pohjolainen T., Seppänen A. Effects of a 6-month exercise program on patients with multiple sclerosis: A randomized study. Neurology 2004;63(11):2034–38. [PMID: 15596746]

[7] Petajan J.H., White A.T. Recommendations for physical activity in patients with multiple sclerosis. Sports Med. 1999;27(3):179–91. [PMID: 10222541]

[8] Río J., Porcel J., Téllez N., Sánchez-Betancourt A., Tintoré M., Arévalo M.J., Nos C., Montalban X. Factors related with treatment adherence to interferon beta and glatiramer acetate therapy in multiple sclerosis. Mult Scler. 2005;11(3):306–9. [PMID: 15957512]

[9] Wagner E.H., Austin B.T., Von Korff M. Organizing care for patients with chronic illness. Milbank Q. 1996;74(4):511–44.

10] Finkelstein J., Wood J., Cha E., Orlov A., Dennison C. Feasibility of congestive heart failure telemanagement using a Wii-based telecare platform. Conf Proc IEEE Eng Med Biol Soc. 2010;2010:2211-4.

[11] Finkelstein J., Cha E., Dennison C.R. Exploring Feasibility of Home Telemanagement in African Americans with Congestive Heart Failure. Stud Health Technol Inform. 2010;160(Pt 1):535-9. [PMID: 20841744]

[12] Finkelstein J., Cha E. Hypertension telemanagement in blacks. Circ Cardiovasc Qual Outcomes. 2009;2(3):272-8. [PMID: 20031848]

[13] Finkelstein J., Hripcsak G., Cabrera M. Telematic system for monitoring of asthma severity in patients' homes. Stud Health Technol Inform. 1998;52 Pt 1:272-6. [PMID: 10384460]

[14] Finkelstein J., Khare R., Ansell J. Feasibility and patients' acceptance of Home Automated Telemanagement of oral anticoagulation therapy. AMIA Annu Symp Proc. 2003:230-4. [PMID: 14728168]

[15] Cross R., Cheevers N., Finkelstein J. Home Telemanagement for Patients with Ulcerative Colitis (UC HAT). Digestive Diseases and Sciences 2009;54(11):2463-72. [PMID: 19104937]

[16] Cross R.K., Finkelstein J. Feasibility and acceptance of a home telemanagement system in patients with inflammatory bowel disease: a 6-month pilot study. Dig Dis Sci. 2007;52(2):357-64. [PMID: 17211702]

[17] Cross R.K., Arora M., Finkelstein J. Acceptance of telemanagement is high in patients with Inflammatory Bowel Disorder. Journal of Clinical Gastroenterology 2006;40:200-8. [PMID: 16633120]

[18] Finkelstein J., Khare R., Vora D. Home Automated Telemanagement (HAT) system to facilitate self-care of patients with chronic diseases. Journal of Systemics, Cybernetics and Informatics 2003;1(3):78-82.

[19] Farzanfar R., Finkelstein J., Friedman R.H. Testing the usability of two automated home-based patient management systems. J Medical Systems 2004; 28(2): 143-153. [PMID: 15195845]

[20] Samal L., Hutton H.E., Erbelding E.J., Brandon E.S., Finkelstein J., Chander G. Digital divide: variation in internet and cellular phone use among women attending an urban sexually transmitted infections clinic. J Urban Health. 2010;87(1):122-8. [PMID: 19941085]

[21] Wood J., Yablochnikov I., Finkelstein J. Interactive asthma learning system utilizing a mobile phone platform. AMIA Annu Symp Proc. 2008 Nov 6:1181. [PMID: 18999060]

[22] Skinner C., Finkelstein J. Using cell phones for chronic disease prevention and management. AMIA Annu Symp Proc. 2008 Nov 6:1137. [PMID:18999018]

[23] Finkelstein J., Khare R., Vora D., Arora M. Design and implementation of home automated telemanagement in chronic obstructive pulmonary disease. Proceedings of the 16th IEEE Symposium Computer-Based Medical Systems (CBMS 2003), 2003:207 – 212.

[24] Finkelstein J., Barr M.S., Kothari P.P., Nace D.K., Quinn M. Patient-centered medical home cyberinfrastructure: current and future landscape. Am J Prev Med. 2011;40(5 Suppl 2):S225-33. [PMID: 21521598]

[25] Finkelstein J., Friedman R.H. Potential role of telecommunication technologies in the management of chronic health conditions. Dis Manage Health Outcomes 2000;8(2):57-63.

[26] Cross R.K., Cheevers N., Rustgi A., Langenberg P., Finkelstein J. Randomized, controlled trial of home telemanagement in patients with ulcerative colitis (UC HAT). Inflamm Bowel Dis. 2011 Jun 17. [Epub ahead of print] [PMID: 21688350]

 ISBN: 978-1-61208-179-3

Improved Treatment of Cerebral Stroke Patients in Small Hospitals? Reporting from a Telestroke Service in North Norway

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Abstract - **In 2010, Norwegian Centre of Integrated Care and Telemedicine (NST), in collaboration with Northern Norway Regional Health Authority (Helse Nord RHF), initiated a project to establish and explore a telestroke service for diagnosing and treatment of cerebral stroke patients. The first step was to set up a video-conference system between the three hospitals that constitute The Nordland Hospital (in Norwegian: Nordlandssykehuset, NLSH). This service connects the neurological department at NLSH Bodø with the two small rural hospitals; NLSH Lofoten and NLSH Vesterålen. The telestroke service was made available between NLSH Lofoten and NLSH Bodø from September 2010. At NLSH Vesterålen, the telestroke equipment was made available, but the usage was postponed due to reorganization of the local cerebral stroke care. The second step of our study was to explore the significance of the context when establishing a telestroke service in North Norway. This article is based on telestroke log data, semi-structured interviews, and focus group discussions with involved health personnel. We report from the implementation of the service, and the preliminary experience from the first year of use.**

Keywords-cerebrale stroke, rural hospitals, video conference consultation, telestroke

I. INTRODUCTION

The volcano ash incident in Iceland in April 2010, gave a reminder of how vulnerable the health services in Norway are without air transport. In May 2010, Northern Norway Regional Health Authority (Helse Nord RHF), decided to establish a telemedicine service for diagnosis and treatment of cerebral stroke patients in The Nordland Hospital (from now on we will use the Norwegian name, Nordlandssykehuset, NLSH), connecting the two rural hospitals; NLSH Lofoten and NLSH Vesterålen, to the Neurology and Radiology departments at NLSH Bodø. The two rural hospitals receive approximately two patients with stroke symptoms every week; NLSH Lofoten (1.6) and NLSH Vesterålen (1.25). NLSH Bodø receives an average of one stroke patient every two days. As the numbers are small, a fully specialized stroke unit is difficult to maintain with stroke specialists physically present (day and night, seven days of the week) at the small hospitals in Lofoten and Vesterålen.

A "VAKe" -compatible video-conference system [1] was installed in June 2010. After completion of common procedures and on-site training, the telestroke service was operational from September 2010. It was utilized immediately between Lofoten and Bodø, but the use was postponed in NLSH Vesterålen waiting for the employment of a specialized stroke nurse and the refurbishment of the intensive care unit.

Telestroke implies that the stroke specialist examines the patient in cooperation with the physicians and nurses at the local site, through video- and sound communication systems. Radiology images are transmitted using the RIS/PACS system [2]. When a patient with stroke symptoms is expected to one of the two local hospitals, the procedures are as follows: In Bodø, the stroke specialist is notified by phone, and moves quickly to a dedicated room for telestroke conferences. At the relevant local hospital the involved staff is gathered at the intensive care unit, waiting for the patient to arrive. The "VAKe" video-conference system is also prepared.

This article addresses treatment of cerebral stroke patients. We report from the implementation of a telestroke service in North Norway, and the preliminary experience from the first year of use.

 ISBN: 978-1-61208-179-3

II. BACKGROUND

Cerebral stroke is the third most frequent cause of death in Norway, and the most common cause of severe disability in adults. The annual incidence is about three per thousand inhabitants, where 85-90% is due to ischemic stroke. The average cost of one stroke incident is approx. NOK 600,000, adding up to a total annual cost of NOK 7.8 billion. Timely treatment and rehabilitation can reduce disability after stroke, improve quality of life and reduce costs [3, 4]. Hospitalization in a specialized stroke unit leads to a 10 % absolute reduction in mortality in the acute phase [3]. The prognosis for patients with ischemic stroke is further improved by thrombolytic treatment in the acute phase. The challenge is the narrow time window: Thrombolytic treatment should be given as soon as possible, and not later than 4.5 hours after the first symptoms. The national numbers on thrombolytic treatment indicates that only 5.9 % of all stroke patients in Norway receive such treatment (the numbers for NLSH is 2.7%), whereas 20 % is expected to benefit from thrombolytic treatment [4] The low rate could be due to geographical conditions with long travel distances, lack of awareness in the population, but also limited experience with the treatment in local hospitals may play a role [5].

It is crucial to decide the diagnosis and indication for thrombolytic therapy as soon as possible after the patient with suspected stroke reaches the emergency unit. If the local hospital is without specialists with adequate experience and competence in the field, telemedicine can guide and support the clinician remotely [6-10].

Organization in telestroke networks includes [6, 7]:

1. Specialized stroke units in all hospital.
2. Comprehensive and continuous education and training of the entire staff in the units,
3. Stroke specialists available 24/7 on videoconference combined with teleradiology,
4. Centralized organization of patient transfers. This is in consistence with The Norwegian Directorate of Health's national guidelines for treatment and rehabilitation of stroke [4].

Telestroke consultations may be useful to assess whether patients need more advanced specialist neurological or neurosurgical emergency treatment, by supporting quick triaging and transfer to the appropriate unit. Although the decision to give thrombolytic treatment is seen as the end-point of the telestroke consultation, this is just the beginning of care for the patient [5]. Post-thrombolytic care requires intensive cardiovascular and neurological monitoring, neurosurgical backup, and decision whether to keep the patient or to "drip-and-ship". Tele-consultation may also be useful for follow-up after the acute phase [5].

There is limited experience with telestroke in Norway. Many hospitals use teleradiology image transfer combined with phone advice to support local hospitals for stroke patients. A telestroke service established between Haukeland University Hospital and local hospitals in Voss and in Førde reports an increase in thrombolytic treatment [11].

There is substantial scientific evidence of the medical impacts of telestroke [12]. A meta-analysis shows that a telestroke network, where the experienced stroke specialists perform an evaluation and examination of the patient through a video-conferencing system, and considers the indication for initiation of thrombolytic treatment, is comparable with face-to-face consultations [10]. There is also evidence that video-conferencing counseling is more effective than telephone counseling in the acute treatment of stroke. Several studies of telestroke solutions including video, versus solutions without video, show that video conferencing may [13, 14]:

1. Reduce the number of wrong diagnoses.
   7.1 % vs 17.6 %, $p < 0.05$
2. Reduces death rate.
   1.3 % vs 6.8 %, $p < 0.05$
3. Reduces needs for nursing homes.
   2.6 % vs 5.4 %, $p = 0.58$

In this project we aim to implement and organize a telestroke service, and explore whether the same benefits that are reported internationally, are possible to obtain in a North Norwegian context.

III. MATERIALS AND MEHTODS

In this section, we present the research settings, the materials and the methods used.

A. Research settings

The research was conducted at three hospitals within Northern Norway Regional Health Authority, more precisely Nordlandssykehuset, NLSH, in Nordland County. NLSH serves a geographical area of 131,000 inhabitants, and consists of three local hospitals, Bodø, Lofoten and Vesterålen. NLSH Bodø is the largest hospital in the county and act as the central hospital of NLSH [15]. NLSH Lofoten and NLSH Vesterålen are two rural hospitals, situated in a geographical area known for its wild and beautiful nature, long distances, dispersed settlement and extreme rough weather conditions. The weather conditions often make it difficult or even impossible to use air transport for severe ill patients. Other types of transport take between five to ten hours to reach Bodø. NLSH Vesterålen, covers a geographical area of approximately 30,000 inhabitants, and employs about 400 people. The hospital has a full surgical and medical emergency unit and a maternity ward. A new hospital is under construction in Vesterålen. NLSH Lofoten is placed on the island Vestvågøy, in the middle of Lofoten, and serves approximately 24,000 inhabitants.

The telestroke service was implemented and has been operative since September 2010. When a potential stroke patient arrives at one of the two rural hospitals, the standard procedure is to conduct a Computed tomography (CT) scan and collect the necessary blood samples. At NLSH

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Vesterålen, the patient is then transferred to the intensive care unit, where a telestroke conferencing is prepared for a potential collaboration with stroke specialists in Bodø. At NLSH Lofoten, the patient is transferred to the emergency room for telestroke conferences and given thrombolytic treatment if relevant.

To ensure that the technology is operational and works flawlessly, as well as maintain the users' expertise, NST has recommended that each hospital test the telestroke solution regularly, and preferably once a week. The staff agreed on being abundant in using the system in the initial phase in accordance with this.

B. Materials

To implement a telestroke service it is necessary to obtain video-conferencing equipment, at least one for each site. In this project, we decided to supply each of the hospitals with the same type of equipment, which reduces possible sources of error. Only minor local adjustments were made due to room configuration. The video conferencing equipment consists of a Tandberg Quick set C60 and a Sony full HD (1080p) television, mounted on a mobile rack (see Fig. 1). The Tandberg Quick set C60 has the possibility to connect medical equipment like: Electrocardiography (ECG) together with two full HD (1080p) cameras. The system is also made ready for multipart conferences for communication between more than two locations. The total cost of each unit ready for use is approximately NOK 200,000.

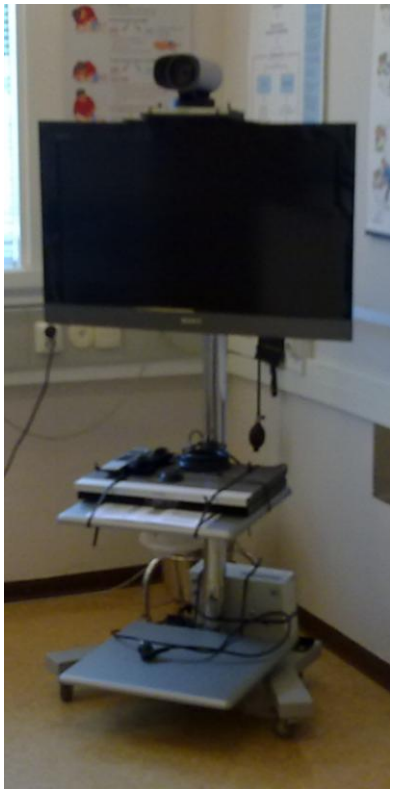

Figure 1. Telestroke equipment

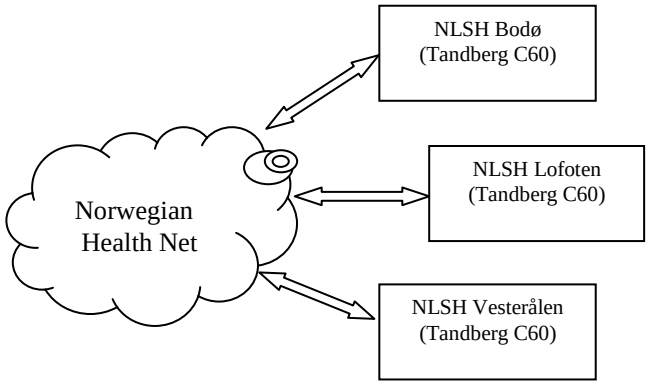

Figure 2. NLSH Telestroke service

At NLSH Bodø, the telestroke system is installed in a dedicated room connected to the neurology department. This room has also a computer equipped with two 24 inch displays; one display devoted to the electronic patient record, and one to the CT images.

At NLSH Lofoten and Vesterålen, the telestroke equipment (Fig. 1.) is mobile. When not in operation, it is stored in the intensive care clinic. However, when the local hospital is notified about a possible cerebral stroke patient, the equipment is brought from storage and moved into position. The video conference unit is then prepared for a telestroke session. The 3 telestroke units are connected through the Norwegian Health Net [16], which is a dedicated secured network for health information between hospitals and different health care institutions, see Fig. 2. All institutions require authorization before connection to ensure data protection and security [17]. This solution is approved by the Norwegian Data inspectorate and Privacy Protection Committee [16].

C. Methods

We have used a qualitative, multi-method research approach to gather relevant data on the telestroke service in North Norway, in this case Nordlandssykehuset. Quantitative methods with control-groups have been considered, but found not ethical since the telestroke equipment is already installed in the hospitals. We have also considered including more hospitals as control-groups, but found difficult within the framework of the project. The methods used are:

- Analyzing telestroke log data
- Video conference and phone interviews with involved health personnel
- Focus group discussions

This approach does not only capture research data, it also ensures that the telestroke system is working according to the plan, and reveals potential need for follow-up actions like training and revision of procedures.

 ISBN: 978-1-61208-179-3

1) Analyzing telestroke log data

Exploring telestroke log data is an adequate approach to gather an understanding of the usage of the telestroke service. Telestroke log data indicates the frequency and length of the telestroke sessions between the hospitals. Log data is sufficient to observe which hospital that has been connected, and which hospital that are more reluctant with telestroke collaboration. This data includes the year, season, time and length of the video and sound communication between the collaborating hospitals. Analyzing log data is an adequate approach to map out the actual telestroke collaboration. It is also a useful approach to visualize the numbers and the length of the training sessions, and how often the different hospitals are testing the equipment. Analyzing log data also captures potential changes in the organization of stroke treatment over time.

2) Semi-structured interviews

Semi-structured interviews with involved health personnel are a constructive approach for gathering the users' satisfaction and experiences with the telestroke system. Health personnel can share their knowledge from specific cases where the telestroke service has been used. For instance, information about medical results like; time from onset of symptoms to thrombolytic treatment or proportion of thrombolytic treatment. The method is also sufficient to gather information about health personnel experiences with the technology and the online collaboration between the hospitals. Semi-structured interviews can reveal potential differences between users, for instance between the remote neurological experts and the onsite local hospital staff. The approach is also useful to detect technological obstacles or organization challenges with the telestroke service. We have conducted the interviews by phone and video-conferencing systems.

3) Focus group discussions

Focus group discussions with participants from all three hospitals are an adequate approach to get in contact with the everyday practice of cerebral stroke treatment. Similarities, differences and the dynamic character of the local practices are often revealed in group discussions [18]. Focus group discussions between health personnel from different institutions are also suitable to expose contextual and organizational aspect of the telestroke service.

D. Ethical considerations

The study has been approved by the North Norwegian Regional Medical Ethics committee (REK).

IV. RESULTS

The telestroke service has so far been used for treatment of a few cerebral stroke patients at NLSH Lofoten, but until now, none from NLSH Vesterålen. After approximately one year of service, the frequency of telestroke conferences has been considerable lower than expected. However, the few conferences that have been carried out were reported as constructive and valuable. The conference quality has been characterized as excellent: The video quality was good enough to detect pupil contraction and eye movements like nystagmus (a rapid, involuntary, oscillatory motion of the eyeball). Despite the high video and sound quality, health personnel at both the rural hospitals have expressed concerns about the low frequency of use, which might be a threat to the long term success of the telestroke service. Low frequency of use can result in ambiguity and hesitation on how to operate the telestroke equipment, and thereby result in even fewer telestroke consultations. Even though NST recommended that the hospitals tested the telestroke system regularly, preferably once a week to maintain the users' expertise, the log data shows that the recommendations has not been followed. This has not been done regularly, and far from once a week.

It also needs to be emphasized that the involved staff at NLSH Vesterålen, in general, were perceived as more reluctant to adopt the new service than the involved staff at NLSH Lofoten.

Health personnel also reported that the telestroke system could be useful for other clinical consultations. This could be other acute neurological sufferings, but also in none acute situations with uncertain diagnoses or treatment. At NLSH Lofoten some of the local staff also suggested to use the telestroke system for collaborations with other departments, for instance, dermatologists at NLSH Bodø.

The two rural hospitals have developed different telestroke procedures. At NLSH Vesterålen the second-call physician is always consulted first, if there are any doubts about whether thrombolytic treatment is adequate or not. If the local team still is uncertain about the best treatment, the telestroke service should be used. This differs from NLSH Lofoten where the procedure is to always seek guidance from neurologist at NLSH Bodø, if thrombolytic treatment is considered. The telestroke service replaces the phone as a collaboration tool at this hospital. None of the three involved hospitals indicated any delays in thrombolytic treatment when using the telestroke service compared to ordinary phone conferences.

As already mentioned the telestroke service has only been used for treatment of a few cerebral stroke patients at NLSH Lofoten. Here we report from three cases where the telestroke service has been used for patients hospitalized with cerebral stroke symptoms. As we will show, all three cases had different outcomes.

1) The first patients arrived at the rural hospital with a diagnosis of possible cerebral stroke. After using the telestroke service, this diagnose was dismissed and changed. No thrombolytic treatment was given, and the patient was discharged from the rural hospital two days later.

2) The second patient who arrived with cerebral stroke symptoms was a person with a heart transplant. After using the telestroke service, this patient was diagnosed with a possible severe rejection of the transplant. The patient was transferred by air ambulance directly to national expertise in Norway, located in Oslo. No thrombolytic treatment was given.

3) The third patient who arrived with a possible cerebral stroke diagnosis had a former diagnose of cerebral stroke. The patient had successfully received thrombolytic treatment

 ISBN: 978-1-61208-179-3

one and a half year earlier. After using the telestroke service, the patient received thrombolytic treatment successfully.

V. DISCUSSION

The results presented here indicate anecdotally how a telestroke service might be useful in rural hospitals for diagnosing and treating patients with suspected cerebral stroke. The collaboration was described as constructive and valuable by the involved health personnel. Despite successfully implementation and positive feedback from the few telestroke conferences that has been conducted, the frequency of telestroke conferences has been considerable lower than expected. This interesting paradox needs further investigation.

The preliminary results from NLSH Lofoten question the estimated number of potential stroke patient in the Lofoten region. This number might be too high. The next step in our study will include data from patient records to reveal both actual numbers of stroke patients last year, and the patients that arrived with a suspected stroke diagnosis. This data will then be compared with the numbers from the telestroke log data.

The results also question the frequency of thrombolytic treatment in Lofoten. In general only 2% of all Norwegian stroke patients receive thrombolytic treatment, whereas 20 % is expected to benefit from such treatment (Helsedirektoratet, 2010). The low rate could be due to geographical, environment or organizational conditions. Hazard weather conditions, long travel distances and lack of stroke awareness in the population, might be of importance for how quickly patients arrive at the hospital. The established practice of shipping patients to the central expertise, rather than giving local treatment, might also affected on the frequency of use.

The preliminary results from NLSH Vesterålen point in direction of organizational or technological challenges. A new hospital is under construction, and the staff is naturally eager to move into a new building. New procedures and training might be put on hold until the new facilities can be used.

It also needs to be highlighted that the involved staff at NLSH Vesterålen, in general, seems more reluctant to adopt the new service than the involved staff at NLSH Lofoten. NLSH Vesterålen is a bigger hospital than NLSH Lofoten, which means that they have more staff and local expertise present than NLSH Lofoten. The physicians at Vesterålen expressed, for instance, concern about the level of expertise at NLSH Bodø after office hours. The stroke unit at NLSH Bodø is organized with a stroke specialist present at the hospital during office hours. After hours, a stroke specialist might not be present at the hospital, but be the second physician on-call, possible located outside the hospital. This is off course a legitimate concern, and something that needs further exploration in the next step of our research.

The next step of our study will therefore focus on the local context for the telestroke service. Few or none studies are found on the significance of the context when implementing a telestroke service. This is unfortunate since the geographical, contextual and organizational environment is known to be significant to other telemedicine services in the region [19, 20]. A telestroke service in North Norway is expected to face other challenges than those reported internationally: In NLSH as in North Norway in general, the number of cases is low, clinicians have high turnover, technical support is not available 24/7 and severe weather conditions and long distances might add to the transport time.

There is long experience with telemedicine in Northern Norway [21-23]. Unfortunately, in Norway as well as internationally, there is also a long track record of telemedicine services terminating after the pilot project is over [24-26]. Therefore it is important to follow the telestroke service by studying the local context and the organizational requirements as well as the clinical outcome of the service. The organization of the health service (work-flow, technical support, maintenance of staff, etc) are important factors to ensure a functional and sustainable telemedicine service.

Another interesting aspect is the expressed concern about the low frequency of use. Low frequency of use may be a threat to the long term success of the telestroke service. This concern came from both the rural hospitals' staff. Compared to the telestroke log data, this concern is particularly interesting, since the log data shows that the recommended testing of the telestroke solution has not been followed. Running tests to maintain users' expertise, in an already stressful work day, may not be prioritized and is easily skipped. On the other hand, not following NST's recommendation may be one of the reasons for the low frequency of use.

VI. CONCLUSION AND FUTURE WORK

The preliminary results indicate that it is possible to implement and organize a telestroke service in rural hospitals in North Norway. So far the usage has been limited to a few cases, but in all these cases, the involved personnel reported beneficial results for the patient, successful online cooperation, and excellent video and sound quality. However, the sparse frequency of use in a North Norwegian context raises important questions. To our knowledge there are few or none studies focusing on the significance of the context when establishing a telestroke service. This will be the next step for our research.

ACKNOWLEDGMENT

We would like to thank the Northern Norway Regional Health Authority (Helse Nord RHF) for funding this research project. Special thanks to Professor Rolf Salvesen and the staff at Nordlandssykehuset, NLSH. We also want to thank Professor Lars Thomassen at the Haukeland University Hospital, for inspiration and guidance.

 ISBN: 978-1-61208-179-3

REFERENCES

[1] Bolle S., Larsen F., Hagen O., and Gilbert M. Video conferencing versus telephone calls for team work across hospitals: a qualitative study on simulated emergencies. BMC Emergency Medicine. 2009; 9 (1): p. 22.

[2] RIS/PACS system. Retrieved: November, 2011; http://en.wikipedia.org/wiki/Picture_archiving_and_communication_system.

[3] Skaset M. Lokalsykehusenes akuttfunksjoner i en samlet behandlingskjede. Oslo 2007. Retrieved: November, 2011; http://www.regjeringen.no/upload/HOD/Vedlegg/Lokalsykehusenes%20akuttfunksjoner%20rapp%20200307.pdf

[4] Helsedirektoratet. Nasjonale retningslinjer for behandling og rehabilitering ved hjerneslag. Oslo2010. Retrieved: November, 2011; http://www.helsedirektoratet.no/publikasjoner/nasjonale_faglige_retningslinjer/nasjonal_retningslinje_for_behandling_og_rehabilitering_ved_hjerneslag___kortversjon_702254

[5] Meschia J. F., Camera in the Emergency Department: The Evolution of Stroke Telemedicine. Mayo Clinic Proceedings. 2009 January 1, 2009; 84(1) pp. 3-4.

[6] Audebert H., Telestroke: effective networking. Lancet Neurol. 2006 Mar;5(3): pp. 279-282.

[7] Audebert H. J. and Schwamm L., Telestroke: scientific results. Cerebrovasc Dis. 2009; 27 Suppl 4: pp. 15-20.

[8] Johansson T. and Wild C., Telemedicine in acute stroke management: systematic review. Int J Technol Assess Health Care. 2010 Apr;26(2): pp. 149-155.

[9] LaMonte M. P., Bahouth M. N., Hu P., Pathan M. Y., Yarbrough K. L., Gunawardane R., et al., Telemedicine for acute stroke: triumphs and pitfalls. Stroke. 2003 Mar;34(3): pp. 725-728.

[10] Schwamm, L. H., Holloway, R. G., Amarenco, P., Audebert, H. J., Bakas, T., Chumbler, N. R., et al. (2009). A Review of the Evidence for the Use of Telemedicine Within Stroke Systems of Care. *Stroke, 40*(7), pp. 2616-2634.

[11] Thommasen L. Behandling av akutt hjerneinfarkt. Tidsskr Nor Lægeforen 2007(127): pp. 1060-1063.

[12] Hess D. C., Wang S., Gross H., Nichols F. T., Hall C. E., Adams R. J., Telestroke: extending stroke expertise into underserved areas. Lancet Neurol. 2006 Mar;5(3): pp. 275-278.

[13] Handschu R., Scibor M., Willaczek B., Nuckel M., Heckmann J. G., Asshoff D., et al., Telemedicine in acute stroke: remote video-examination compared to simple telephone consultation. J Neurol. 2008 Nov;255(11): pp. 1792-1797.

[14] Meyer B. C., Raman R., Hemmen T., Obler R., Zivin J. A., Rao R., et al., Efficacy of site-independent telemedicine in the STRokE DOC trial: a randomised, blinded, prospective study. Lancet Neurol. 2008 Sep;7(9): pp. 787-795.

[15] Nordlanssykehuset. Retrieved: November, 2011; http://www.nlsh.no/om-oss/category2791.html.

[16] Norsk Helsenett. Retrieved: November, 2011; http://www.nhn.no/om-oss.

[17] Pettersen S., Uldal S. B., Baardsgard A., Amundsen M., Myrvang R., Nordvag D., Stenmarkl H., The North Norwegian Health Net. J Telemed Telecare. 1999;5 Suppl 1: pp. 34-36.

[18] Fontana A. and Frey J., The interview: from structured questions to negotiated text. In: Denzin NK, Lincoln YA, editors. Collecting and Interpreting Qualitative Materials: Sage; 2003. pp. 61-106.

[19] Andreassen H. K. and Dyb K., Differences and Inequlities in Health. Information, Communication & Society. 2010 2010/10/01;13(7): pp. 956-975.

[20] Dyb K. and Halford S., Placing Globalizing Technologies: Telemedicine and the Making of Difference. Sociology. 2009 April 1, 2009;43(2): pp. 232-249.

[21] Elford D. R. Telemedicine in northern Norway. J Telemed Telecare. 1997;3(1): pp. 1-22.

[22] Gammon D., Bergvik S., Bergmo T., and Pedersen S., Videoconferencing in psychiatry: a survey of use in northern Norway. J Telemed Telecare. 1996;2(4): pp. 192-198.

[23] Johnsen E., Breivik E., Myrvang R., and Olsen F., Gevinster av norsk telemedisin. Tromsø: NST2006.

[24] Andre B., Ringdal G. I., Loge J. H., Rannestad T., and Kaasa S., The importance of key personnel and active management for successful implementation of computer-based technology in palliative care: results from a qualitative study. Comput Inform Nurs. 2008 Jul-Aug;26(4): pp. 183-189.

[25] European-Commission. telemedicine for the benefit of patients, health care system and society 2008. Retrieved: November, 2011; http://ec.europa.eu/information_society/activities/health/docs/policy/telemedicine/telemedecine-swp_sec-2009-943.pdf

[26] Obstfelder A., Engeseth K. H., and Wynn R., Characteristics of successfully implemented telemedical applications. Implement Sci. 2007; pp. 2:25.

 ISBN: 978-1-61208-179-3

A Maturity Model for Telemedicine Implementation

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***Abstract*— The South African National Department of Health (DoH) has, for more than a decade, recognized the potential benefit of information and communication technology (ICT) in the delivery of healthcare to rural areas. However, despite generous funding and proven technology, not many telemedicine systems have lasted beyond the pilot phase. The purpose of this paper is to propose a maturity model, which can be used to measure and manage the capability of a health system. Its aim would be to sustain health care delivery, after the pilot phase of a telemedicine project. This maturity model comprises of five existing frameworks, namely the Health Readiness Instrument for developing countries, the Layered Telemedicine Implementation Model, the PACS Maturity Model, the Telemedicine Process Model and the NHS Maturity model. The validity of this maturity model is tested by means of a focus group discussion that occurred during a workshop for provincial representatives from three South African provincial DoHs.**

Telemedicine; Maturity Model; eReadiness; South Africa

I. INTRODUCTION

The first phase of telemedicine implementation in South Africa began in 1999. This was guided by the National Strategy for Telemedicine. The objectives of the strategy focused on providing high-quality, cost-effective health care and education; improved recruitment and retention of health professionals; delivery of long-distance health care, and improvement in the accessibility of specialist health care.

By definition, telemedicine refers to the delivery of healthcare services ("medicine") where distance ("tele") is involved. For the purposes of this article, the more specific definition, given by Sood et al. is used, since it encapsulates and addresses the issue of the uneven distribution of health resources, specifically in South Africa's public health sector:

"Telemedicine being a subset of telehealth, uses communications networks for delivery of healthcare services and medical education from one geographical location to another, primarily to address challenges like uneven distribution and shortage of infrastructural and human resources."

South Africa has a population of 48 million people, half of whom reside in rural areas. Despite being one of the largest economies in Africa, South Africa has a rural community which is characterized by very high poverty rates [1]. As a result, the first telemedicine strategy, published by the South African government in 1999, was recognized as a strategic tool to overcome the unequal distribution of healthcare resources.

Since then, many telemedicine projects have been launched, of which, few have survived past the pilot phase. Apart from the obvious waste of equipment and human resources, Yellowlees [2] considers the damage to the reputation of telemedicine as an even greater cost. The South African public health sector is already paying this price: in 2010, the Department of Health placed a moratorium on the launching of any new telemedicine projects until a strategy is in place to increase the success rate of such projects.

II. PURPOSE AND METHODOLOGY

In this paper, a telemedicine maturity model is proposed. This model can be used to measure, manage and optimize all the components of a telemedicine system, as well as the health system within which it is implemented. A maturity model enables the capability maturity of a specific domain to be measured. In addition, it facilitates an improvement process that is best suited to an enterprise and which is in accordance with the prescribed best practices of the domain [3].

An overview of the content of this paper is given in Figure 1, where literature, concerning five related theoretical frameworks, is presented. Using these frameworks as a base, a concept maturity model for telemedicine implementation is proposed. This maturity model is then refined and validated during workshops with four provincial departments of health (DoHs). A conclusion follows, which describes firstly, the extent to which this maturity model enables the measurement of

 ISBN: 978-1-61208-179-3

maturity and secondly, its contribution to sustained telemedicine implementation.

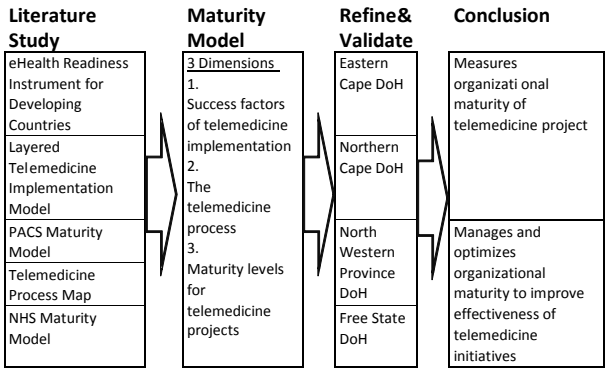

Figure 1: Research Methodology

III. THEORETICAL FRAMEWORK

There are many frameworks, models, checklists, taxonomies, et cetera, that can be useful as input in such a model – all with their own strengths and weaknesses. However, of these, the five frameworks listed in Figure 1, were identified as having the most to contribute to such a maturity model for telemedicine. These are discussed in more detail in the following section.

A. eHealth Readiness Instruments

eHealth readiness is defined as the "degree to which users, healthcare institutions and the healthcare system itself, are prepared to participate and succeed with implementation." Jennett *et al*. [4] specifically refer to eHealth readiness when they argue that time, money and energy, can be saved if the status quo of an eHealth/telemedicine system context is determined before implementation.

Legare *et al.* [5] have identified six different assessment tools, which can be used to measure e-readiness within a health context. However, information concerning the internal validity and reliability of these measuring devices is only available for two of the six tools. Of these, Khoja's E-health Readiness Assessment Tool [6] was selected for the purposes of this paper, because it is specifically directed towards developing countries. This instrument covers five categories:

- Core readiness (planning and integration)
- Technological readiness (availability, reliability, affordability and ICT, and related infrastructure)
- Learning readiness (resources to provide training using the technology)
- Societal readiness (interaction between the institution and other institutions)
- Policy readiness (policies at government and institutional level to address common issues such as licensing, liability and reimbursement)

The first objective of a maturity model is to establish the capability maturity of an organization in terms of a specific domain of practice. The strength of this eHealth readiness instrument lies in the fact that it provides us with a set of statements, which can be used as a yardstick to measure the eHealth readiness of an organization. The validity and reliability of this measuring instrument is determined through various studies [7] and can thus provide us with a set of statements, which can be used with confidence to establish, to a certain extent, the capability maturity.

The drawback of eHealth readiness tools lies in the fact that they do not accommodate the second purpose of a maturity model, namely to describe the best practices of the domain. Nor do they facilitate the process of moving that enterprise towards those best practices [3]. Molla and Licker [8] identified a similar drawback in developing a model and instrument for eCommerce adoption in South Africa, which led to their developing a maturity model for e-commerce.

B. The Layered Telemedicine Implementation Model

This progression towards maturity is recognized by Broens *et al.* [12] who explain that maturity is gained as one moves from one implementation layer to another. South Africa is not the only country where telemedicine projects have a significantly high failure rate. Broens *et al.* [12], in a systematic literature review, confirmed that, after the prototype phase, telemedicine projects are more likely to fail than succeed. They also looked to the literature to answer the question: "why is it so difficult [to implement telemedicine] and what goes wrong?" In this study, the theoretical model of Tanriverdi and Iacono [13] was used as a point of departure in the identification of the so-called *determinants for the successful implementation of telemedicine*.

Broens *et al.* [12] postulate that different *determinants* become applicable as telemedicine implementation maturity is gained. The *Layered Implementation Model* was developed accordingly. The relation between each *implementation layer* (and their associated *determinants* in brackets) are shown in Figure 2.

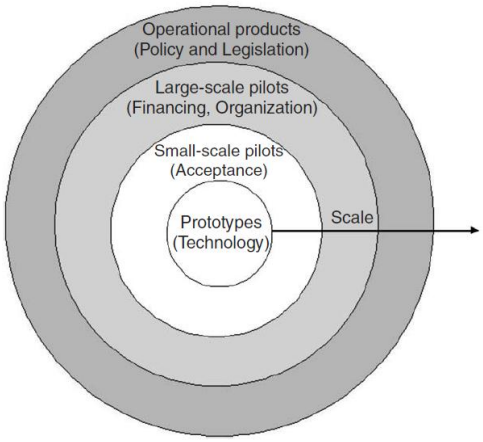

Figure 2: Layered Implementation Model [12]

C. The NHS Infrastructure Maturity Model (NIMM)

NIMM is an IT infrastructure maturity model that was developed by the NHS Technology Office, together with a number of different NHS IT Organizations in the United Kingdom [9]. During its development, the NHS team worked closely with Atos Healthcare, a consultant company, helping to define and develop the NIMM [10].

D. The PACS Maturity Model

Around the time when the NIMM was being developed, Van Wetering *et al.* [11] recognized the potential benefit of maturity models for healthcare services. They specifically considered teleradiology and developed a PACS (Picture Archiving and Communication System) model.

E. The Telemedicine Process Map

Telemedicine, by definition, is the delivery of healthcare services ("medicine") over a distance. For a successful telemedicine process [14] to take place, irrespective of the context or required technology, each step of the Telemedicine Process (Figure 3) needs to be successfully executed.

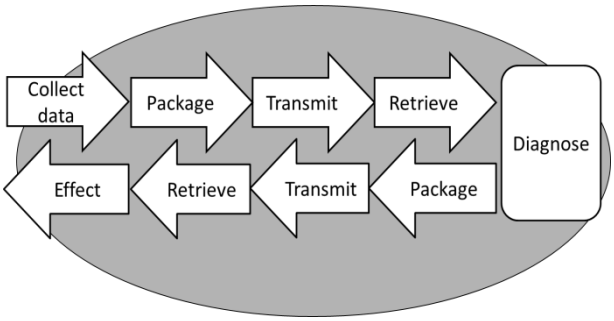

Figure 3: The Telemedicine Process Map [14]

IV. TOWARD A MATURITY MODEL FOR TELEMEDICINE IMPLEMENTATION

These frameworks can be used individually to support telemedicine implementation. However, no one framework offers a comprehensive maturity model for telemedicine implementation.

In the following section, these five frameworks are combined to develop a three dimensional framework (Figure 4). This can be used to measure, manage and optimize all the components of a telemedicine system, as well as the health system within which it is implemented. The three dimensions of this model are:

- eReadiness Categories
- Telemedicine Process Steps
- Maturity Levels

These three dimensions are discussed in the following section.

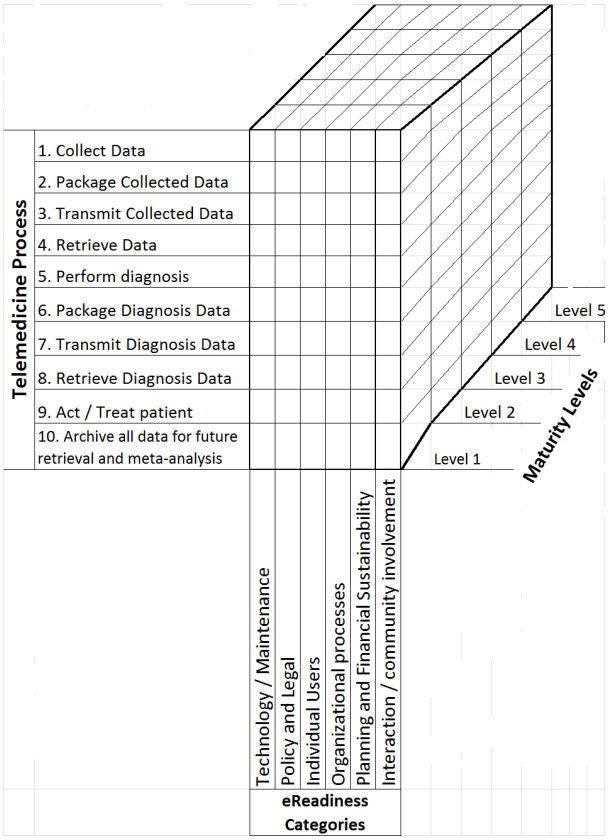

Figure 4: A maturity model for telemedicine implementation

A. eReadiness Categories

Khoja's [6] eHealth readiness categories are aligned with the determinants, proposed by Broens *et al.* [12], for the successful implementation of telemedicine. Both Khoja and Broens *et al.* recognize *technology* and *policy* as determinants for the successful implementation of telemedicine. Technology is also one of the so-called submodels of the NHS Infrastructure Maturity Model [10]. *Governance* – which can be translated here as *policy*, is one of the classes within the business submodel.

Core readiness, *learning readiness* and *societal readiness* are additional eHealth readiness categories and Broens *et al.* have added *user acceptance*, *finance* and *organization (internal and external)* to their determinants. The NHS Infrastructure Maturity Model [10] includes *procurement, financial management, business alignment, people and skills* as well as *standards & procedures*.

Frameworks [6], [10] and [12] are used as a point of departure in order to define, in consultation with representatives from the DoH, the following categories of an axis of the maturity model.

For the purposes of the framework presented in this paper, the success determinants are organized as follows:

- Technology and maintenance: ICT availability, reliability, training, usability
- Policy and legislation: Governmental and institutional policies and procedures, standardization and security
- Individual users: Trust and willingness of users and decision makers, producing evidence, change in way of doing
- Organizational processes: Decision making processes, work procedures
- Planning and financial sustainability: Business models which will ensure continuation of the telemedicine endeavor
- Interaction/involvement with community: Interaction with society and other institutions

B. *Maturity Levels*

In a maturity model, the current maturity level is measured, in the first instance, by how many other levels serve as a guide to system maturity. Most maturity models show five maturity levels [3]. These generic levels correspond with the levels of the NIMM [10], as well as the PACS Maturity Model [11], and were adopted for the purpose of this study. The NIMM level descriptors appear in brackets:

- Level 1: Initial, ad hoc process (Basic)
- Level 2: Managed, stable process (Controlled)
- Level 3: Defined, standard process (Standardised)
- Level 4: Measured process (Optimised)
- Level 5: Optimizing (Innovative)

C. *The telemedicine process*

The steps involved in the telemedicine process can be compared to the links of a chain. If one of these steps is not executed properly, no telemedicine service, of any sort, can be delivered [14]. It is therefore important that the maturity is measured and managed with respect to each of these steps. The telemedicine process is included in its entirety, as the third dimension of the proposed maturity model.

The 10th step was added as a recommendation by representatives from the department of health: "Archive all data for future retrieval and meta-analysis".

D. *Involving the users of the model*

The purpose of this maturity model is to assist those who are responsible for the implementation of telemedicine projects in South Africa. Its aim is to enable them to manage their health system and to ensure the successful and sustained implementation of telemedicine. Although both the public and the private health care sectors are included, for the purposes of this paper, only health care workers from the public health sector, were involved in the refining and validating of this framework.

Three telemedicine training workshops were held on 14 June, 4 August, and 31 August, 2011, respectively. These involved four of the nine provincial Departments of Health (DoHs) in South Africa. Major changes were made to the maturity model based on the conclusions which emanated from the first workshop (14 June, 2011). The most significant of these changes was the inclusion of the telemedicine process. Further proceedings from this workshop are reported on in another paper (15). The descriptors of the framework were refined during the second workshop (4 August, 2011). *Validation?*

The remainder of this paper is devoted to an analysis of the outcomes/results of the third workshop (31 August, 2011) as a means of validating this framework. This workshop involved 25 delegates from two of the largest and most rural provinces. The 25 people who attended this final workshop (31 August, 2011) included:

- 13 medical practitioners,
- 10 ICT Technicians and
- 2 delegates responsible for e-learning and administration.

10 of the delegates (5 from each province) were either radiographers, radiologists or radiographic technicians.

E. *Methodology*

The delegates were briefed about the frameworks presented in this paper and the 25 attendees were purposely allocated to a specific group. Each group was then provided with a 10 x 6 matrix, based on the first two dimensions of the maturity model ("The Telemedicine Process" and "E-Readiness Categories"). Finally, the groups were asked to reach consensus about the level of maturity present in each of the 60 blocks of the matrix.

F. *Results*

The maturity maps from each of the respective groups are shown in Figures 5, 6, 7 and 8 (the colour-coded scale has been converted to gray-scale for the purposes of this paper.)

- Radiology from province A (Figure 5)
- Radiology from province B (Figure 6)
- Doctors (general practitioners) from both provinces (Figure 7)
- ICTechnologists from both provinces (Figure 8)
- The remaining delegates consisted of managers and training co-ordinators.

 ISBN: 978-1-61208-179-3

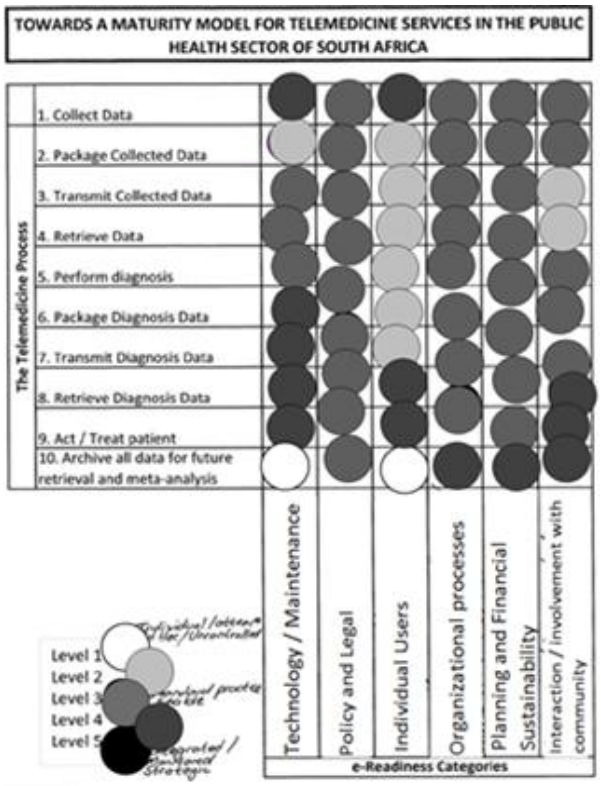

Figure 5: Radiology Maturity of Province A

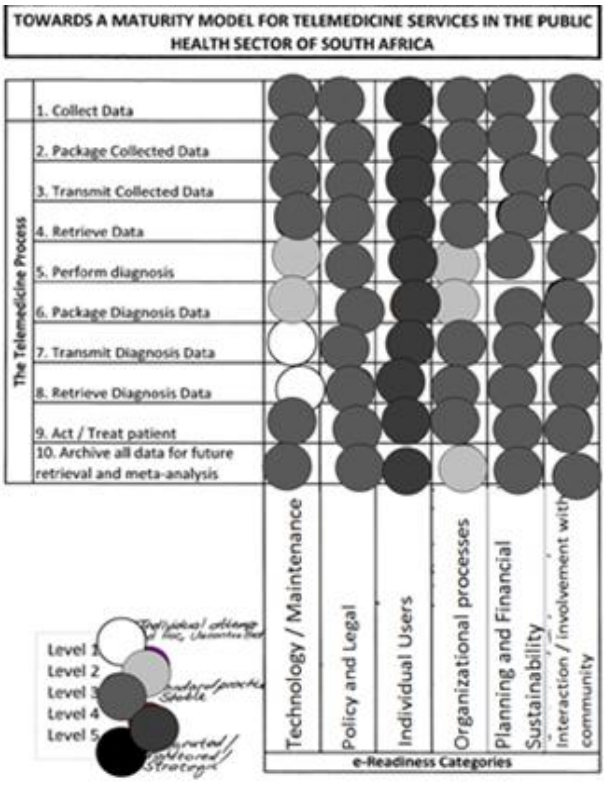

Figure 6: Radiology Maturity of Province B

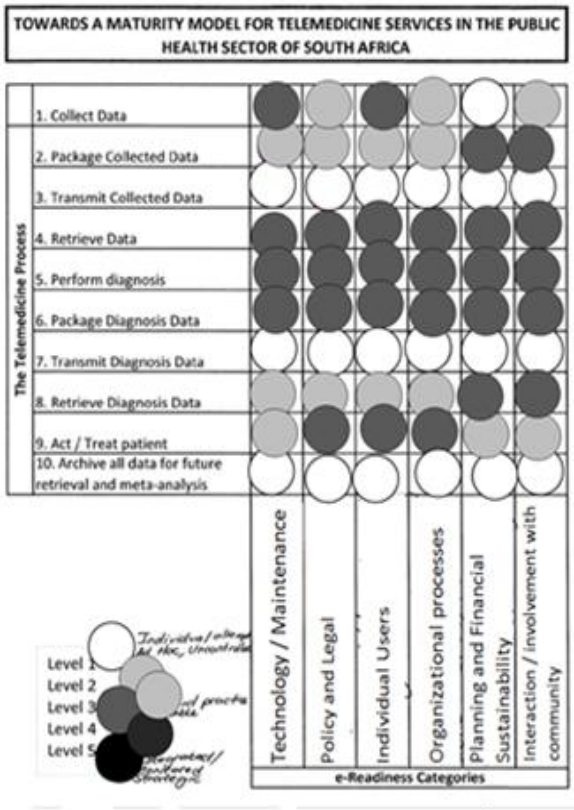

Figure 7: Doctors' perception of telemedicine maturity

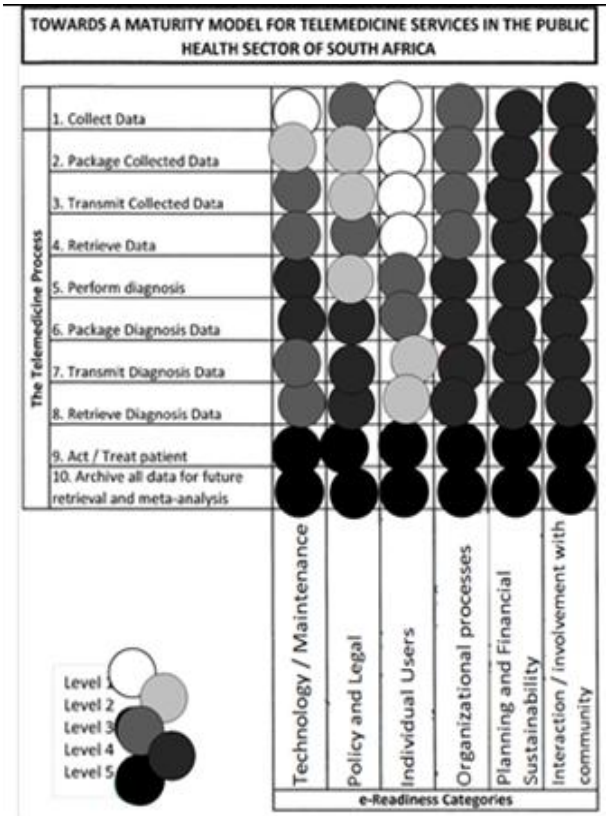

Figure 8: Technologists perception of telemedicine maturity

One of the groups, involved in the workshop, did not reach consensus on the maturity levels of the telemedicine projects involved. Their maturity map is therefore, not included in this paper. This inability to reach consensus can probably be attributed to the diversity within this group, in terms of their exposure to, and perspective on, telemedicine.

G. Discussion

All the delegates participated in a discussion to reflect on the significance of the results of the workshop. These are summarized as follows:

There was a significant difference in the maturity maps provided by the various groups. It is also not surprising that the two maps that showed the greatest degree of similarity, were the two maps produced by the groups who belonged to the same area of telemedicine specialization, namely radiology. (Figures 5 and 6).

Furthermore, the perceived maturity for teleradiology was higher than the perceived maturity for telemedicine, as expressed by the general practitioners (Figure 7), which is in line with a general tendency for teleradiology technology and infrastructure to be more mature than the other telemedicine specializations.

The maturity map, produced by the practicing doctors (Figure 7), clearly shows their frustration with the lack of connectivity, which they felt prevented the telemedicine process from being completed to its full extent.

It is also interesting to note that the doctors (Figure 7) tended to allocate the same maturity level to a certain step of the telemedicine process, irrespective of the eReadiness category under consideration. In contrast, the other groups tended to allocate similar maturity levels to eReadiness categories, irrespective of the telemedicine process. In future, the construct of the framework should be reconsidered to avoid such generalizations across categories.

The maturity map of the ICT Technicians (Figure 8) received much critique from the other delegates. Based on the discussion that followed, the conclusion they arrived at was that there is a distinct difference between ICT Technicians', and health practitioners', perceptions of telemedicine maturity.

General feedback, regarding the use of the model to measure maturity, included a proposal to divide some of the eReadiness categories into more specific categories. For example, there could be different maturity levels associated with "decision making processes" and "work procedures" but in this model they are both grouped under "organizational processes.

Workshop delegates expressed a need for more specific maturity level indicators, both to avoid subjectivity, and as an indication of the direction to take to facilitate improvement.

V. CONCLUSION

Change management was identified, in the literature [2], [16] as well as by the DoH representatives, as the key to the successful implementation of telemedicine. A maturity model for telemedicine implementation could thus be instrumental in managing this change.

Delegates reached consensus that the value of this workshop did not lie in the actual measureable outcomes, but in the fact that different role players, with diverse viewpoints, communicated their opinions based on a common holistic framework. Despite the fact that it is simple and intuitive to use (which is one of the design features of a maturity model [10]), it provides users with a tool to assess the entire context of their telemedicine initiatives.

Initiatives in the future should firstly, focus on the refinement of the construct of this model, in order to avoid ambiguity and subjectivity. Secondly, more research is required to determine if and how this model can be used as a tool to manage and optimize organizational maturity and, in so doing, improve the effectiveness of telemedicine initiatives.

ACKNOWLEDGMENT

Medical Research Council of South Africa (MRC)

REFERENCES

[1] Sorensen T., Rivett U. and Fortuin J. A review of ICT systems for HIV/AIDS and anti-retroviral treatment management in South Africa. J Telemed Telecare 2008;14(1):37.

[2] Yellowlees P.M., Successfully developing a telemedicine system. J Telemed Telecare 2005;11(7):331.

[3] Essmann H.E., Toward innovation capability maturity. 2009.

[4] Jennett P., Yeo M., Pauls M. and Graham J. Organizational readiness for telemedicine: implications for success and failure. J Telemed Telecare 2003;9(2):pp. 27-29.

[5] Legare E., Vincent C., Lehoux P., Anderson D., Kairy D. and Gagnon M.P. et al. Telehealth readiness assessment tools. J Telemed Telecare 2010;16(3):107.

[6] Khoja S., Scott R.E., Casebeer A.L., Mohsin M., Ishaq A. and Gilani S. E-health readiness assessment tools for healthcare institutions in developing countries. Telemedicine and e-Health 2007;13(4): pp. 425-432.

[7] Khoja S., Casebeer A., Scott R. and Gilani S. Validating e-Health readiness assessment tools by using qualitative research methods. eHealth International Journal 2007;3(1).

 ISBN: 978-1-61208-179-3

[8] Molla A. and Licker P.S. eCommerce adoption in developing countries: a model and instrument. Information & Management 2005;42(6):pp. 877-899.

[9] Haris, F. IT Infrastructure Maturity Model (ITI-MM): A Roadmap to Agile IT InfrastructureUniversity of Twente; 2010.

[10] Savvidas A. Your guide to the NHS Infrastructure Maturity Model. 2009.

[11] Van de Wetering R. and Batenburg R. A PACS maturity model: A systematic meta-analytic review on maturation and evolvability of PACS in the hospital enterprise. Int J Med Inf 2009;78(2):pp. 127-140.

[12] Broens T.H.F. Determinants of successful telemedicine implementations: a literature study. J Telemed Telecare 2007;13(6):303.

[13] Tanrevdi, H. and Iacono, I. Knowledge barriers to diffusion of telemedicine. Proceedings of the international conference on Information systems: Association for Information Systems Atlanta, GA, USA; 1998.

[14] Wynchank S. and Van Dyk L., editors. A decision support tool for telemedicine project management. "Prove your Hypothesis": Telemedicine and eHealth in South Africa; 13-15 September 2011; ; 2011.

[15] Van Dyk, L., Schutte, C.S.L. and Fortuin, J., A Systems Engineering Approach to Telemedicine System Implementation in South Africa. ISEM 2011; pp. 107-113.

[16] Bashshur R., Shannon G., Sapci H. Telemedicine evaluation. Telemedicine Journal & e-Health 2005;11(3): pp. 296-316.

 ISBN: 978-1-61208-179-3

Doctors, Patients, and Service Providers:

A cloud-based approach for managing healthcare processes

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***Abstract*—The ability of an eHealth system to empower and support doctors in undertaking healthcare processes and adapting them to the specific needs of their patients is key for its success. In this paper, we present a cloud-based approach for this type of eHealth systems, and consequently encourage their proliferation. First, we discuss a new healthcare business model that emancipates doctors from their reliance on technical assistance, and facilitates their cooperation with healthcare service providers. Then, we introduce a conceptual model of healthcare processes that allows doctors to understand, program, and upkeep them easily. We illustrate how both these components constitute a basis for cloud-based eHealth systems by discussing the development of a prototype implementation. Finally, we show how the prototype can be integrated in existing workflows by discussing a contextual analysis conducted to guide this integration. We conclude by discussing our results.**

Keywords-eHealth; Business Process Management; Cloud Computing

I. INTRODUCTION

Despite the exponential growth in information and communication technologies (ICT) and their pervasive integration in different domains of human enterprises, current ICT solutions do not generally address the needs of today's modern medicine [1]. In particular, in the context of the rise of web-based social networking, Service-Oriented Architectures (SOAs), and cloud computing, little support for translating healthcare processes to the web, and managing remote doctor-patient relations is provided. In order to support this translation, there is a need to develop a new approach for modern healthcare systems that facilitates the sharing of information, modules, and services, as recommended by Valeri et al. in their extensive study conducted for the European Commission for Health [2].

Currently, cloud-based healthcare services made available by third-party providers are growing in number and maturity [10]. These services have an important potential to improve overall healthcare delivery on the web, but they require appropriate Service-Oriented Architectures (SOAs) that stimulate and support their integration into customized healthcare processes. These SOAs enable the creation of cloud-based systems that could empower doctors to create diagnostic, medical, and monitoring processes from third-party services available in the cloud, and publish them on the web for the benefit of their patients without the help or direct intervention of ICT experts. This would allow doctors to exert a more elaborate control over their patients' web experiences, and adjust their processes according to the patients' profiles (e.g. older people, chronically ill, handicapped, or children). As a result, now the patients could execute the personalized processes designed by their doctors more confidently. This direct doctor-patient interaction will allow service providers to study and understand how both doctors and patients use the services they offer. Consequently, service providers could alter, improve, or adjust their services based this essential feedback.

We identify two main requirements for cloud-based eHealth systems: first, they should implement an adequate business model that permits stakeholders (doctors and service providers) to capitalize on their investments, and guarantees a long-term sustainability to build up its success [2]. Second, the systems must support and empower doctors, patients, and service providers, in performing their roles independently. In particular, doctors should easily create healthcare processes and customize them for their patients, patients should use them with confidence and ease, and service providers should create and adjust adequate services relevant to the needs of both doctors and patients.

In this paper we introduce an approach fulfilling these two requirements of cloud-based eHealth systems. It consists of two main components: an eHealth business model designed to emancipate doctors from IT consultants and software developers, and facilitate their collaboration with service providers; and an intuitive conceptual model for healthcare processes that enables doctors, patients, and service providers to understand them easily and evenly. Both components provide a foundation for the development of cloud-based eHealth systems and promise to facilitate more and better ICT integration into healthcare.

In the following section, we discuss some related work before introducing a new cloud-based business model for eHealth that supports doctors in managing their online healthcare processes, and service providers in tapping into the eHealth market. Then, we propose a conceptual model of healthcare processes conceived as a mediation tool for

 ISBN: 978-1-61208-179-3

forging interaction and cooperation between doctors, patients, and service providers. We then present VirtualClinic, a prototypical system designed to illustrate the feasibility of our approach. Finally, we discuss a contextual inquiry conducted at a local clinic to evaluate if VirtualClinic can be integrated in existing workflows and understand how this integration should be effectuated.

II. RELATED WORK

Currently, apart from the challenges discussed earlier, the development of eHealth systems is hindered by several barriers proper to the eHealth sector, such as those stated by Sittig et al. [3].These challenges need to be overcome to develop such architecture and consequently integrate ICT technologies in healthcare successfully. Several cloud-based approaches exist, such as the integrated eHealth Living Labs introduced by Mazurek and Stroinski, which is a platform with application areas from disease research, through treatment organization, to remote consultations, among others [1]; and Rolim et al. for remote monitoring of patients through sensor-based data collection [4]. However, the existing approaches do not provide doctors with the required control over the processes, nor facilitate the incorporation of a wide range of third-party services.

In addition, eHealth business models are still immature and specifically not adapted for cloud computing environments[2]. However, it is possible to formulate new adequate models by relying on the conceptual business architecture proposed by Motahari-Nezhad, Stephenson, and Singhal for cloud computing in [5], which addresses the business context (in this case, eHealth), the support for non-technical profiles, the lifecycle of business processes, and third-party services.

III. A CLOUD-BASED BUSINESS MODEL FOR EHEALTH

In general, business processes should follow an iterative agile lifecycle that permits them to keep evolving and thus adequately answering the changing requirements of their users [6]. In healthcare, doctors can easily devise and personalize the onsite diagnostic, medical, and monitoring processes of their patients, but to the extent of our knowledge, there are no available tools for supporting doctors in developing and maintaining these processes when they are transposed to eHealth systems. Doctors still need external technical support, making difficult to follow the agile lifecycle.

This situation was investigated by conducting a six-month dialogue with three Spanish service providers for eHealth and two leading hospitals in Barcelona. This revealed the characteristics of the classic business model (figure 1) that forms the backbone of current practices in the Spanish sector. Currently, in order to design, develop, and publish online healthcare processes, doctors first need to ask for the help of IT consultants to define these processes in a standardized business process notation (such as BPMN [7]), and later to manage their publication on the web. Then, software developers would implement the processes using their development frameworks. The developers can incorporate third-party services in the processes, but this is usually hindered by the lack of interoperability between the designs of these processes and third-party modules [8].

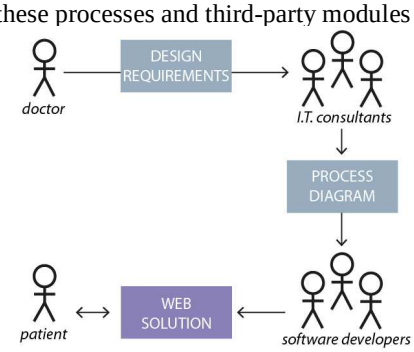

Figure 1. Current business model of the Spanish eHealth sector

The current business model makes doctors heavily dependent on IT consultants and software developers in their quest to provide online healthcare processes for their patients. This requires a hefty dialogue between doctors, IT consultants, and software developers, and therefore increases the risk of losing knowledge during the transition between requirements and design, especially for the design of complex healthcare processes that accommodate various alternatives in the same patients' profile. Similarly, upgrading the resulting healthcare processes to address new requirements (e.g. to cover a new chronic illness, or to introduce a novel memory enhancement service for Alzheimer) also has an important cost. Furthermore, medical knowledge about patients is complex and may be difficult to capture and assimilate by IT professionals.

This complexity leads to centralized solutions (at the level of hospital or larger) that seldom account for interoperability with third-party services and usually do not capture the rich practice of doctors. The maintenance and updating of these centralized solutions is heavy, complex, and very expensive.

The cloud-based model proposed (figure 2) can eliminate dependencies between doctors and technical profiles, improves the doctor's control on the patient's experience, and streamlines the management of healthcare processes. It also provides a platform for service providers to share their services more efficiently. In addition, it creates a more direct and trustworthy relation between patients and their doctors.

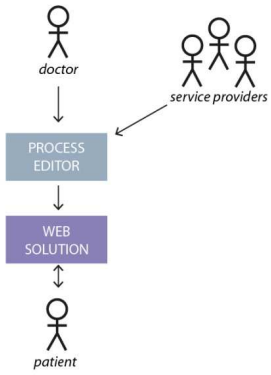

Figure 2. A proposed cloud-based business model

 ISBN: 978-1-61208-179-3

The works of Motahari-Nezhad et al. provide a framework for applying cloud-based business models to eHealth cases by considering the roles of three main actors in healthcare processes: doctors, patients, and service providers. Doctors compose these processes from a pool of available services and customize them in order to address the specific needs of their patients, including personalization. Service providers offer the pool of generic healthcare services that could be configured and personalized to befit different healthcare processes. The services are defined in a generic way that makes the management of healthcare processes more modular and dynamic by enabling the reuse of same services in several distinct processes. This guarantees a larger usage for the services, and therefore increases their economical feasibility and encourages service providers in identifying potential markets for the services they offer. Patients interact with the processes proposed by their doctors through the web without interference from service providers. However, the success of this model rests on having the required services available in the cloud, and on abstracting the technical complexity of process management from doctors in order to allow their intuitive modeling and management. This is addressed in the following section.

IV. A CONCEPTUAL MODEL OF EHEALTH PROCESSES

The functional requirements of cloud-based eHealth systems that empower doctors in managing healthcare processes independently have been defined and studied by Beyer, Kuhn, and Indulskain [9]. They found that the technical and technological complexity associated with business process management represents one of the largest barriers for the direct involvement of non-technical profiles (such as doctors), and therefore should be reduced. Doctors do not have the required knowledge to program processes and therefore can only rely on non-technical paradigms to manage them. Therefore, they cannot utilize the current standardized notations for designing and implementing business processes (such as BPMN). Hence, we propose the following conceptual model to encapsulate the complexity of business process management in order to facilitate the involvement of non-technical profiles, especially doctors, in managing healthcare processes.

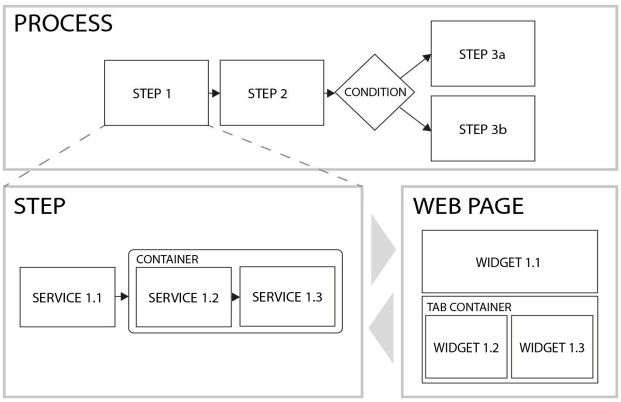

Figure 3. The proposed healthcare process model

This model of healthcare processes has formulated by conducting iterative focus sessions with stakeholders (doctors and service providers), computer scientists, and graphical designers. The objectives of these sessions were to seek a convergence between the different mental models that represent the profiles involved with any cloud-based eHealth system. For this purpose, several different eHealth scenarios were discussed, analyzed, and designed collaboratively (e.g. medical consulting, remote assistance, and follow-up on chronic patients). Figure 3 shows the components (process, step, condition, service, widget, and page) of the resulting model. They are explained in the following.

A. *Process*

The process represents an entire healthcare procedure. Doctors usually manage a variety of processes tailored according to needs of their patients. These needs differ according to the patient's profile and usually evolve in parallel with the evolution of medical practices and treatments. These processes can be published online as a set of linked pages, each hosting one or several components that patients interact with. The process has specific start and end, and several possible routes may exist to execute it from start to end.

B. *Steps and conditions*

A process may be composed of one or several steps. Each step addresses to a specific segment of the healthcare procedure, and groups many atomic actions that correspond to a given objective (e.g. take an appointment, measure and communicate your blood pressure, contact medic and describe symptoms, etc…).

Conditions are logical statements that define bifurcations that processes may have. These conditioned bifurcations allow the process to be flexible and able to respond to several variations of the same patient profile. For example, a condition is used to differentiate between patients with urgent issues that need immediate teleconferencing with their doctor, and those that only require an appointment, allowing the same eHealth process to attend to both cases.

C. *Services*

In essence, a step is an encapsulation of linear sequences of healthcare services connected together to achieve the corresponding segment of healthcare procedure. Services are cloud-based resources offered by service providers. Each represents an indivisible action that users may perform inside a step (e.g. measuring your temperature, selecting an appointment date, etc…). Services are collocated in steps sequentially.

D. *Widgets and web pages*

Services may require user interaction. Widgets are the graphical user interface of these services. Each service may have a single widget, but these widgets may have several interface modes.

In essence, web pages represent the patients' view of the process. They are linked according to the order of the corresponding steps in the process. On the web, each web

 ISBN: 978-1-61208-179-3

page represents a single step of the process. It composed of the widgets that represent the services of the corresponding step. The widgets are collocated vertically on the page in the order of their corresponding services. When services are grouped non-sequentially, the corresponding widgets are presented in a tab-container on the web page.

E. The process dataflow

According to the model, each step in the process requires a set of input data and generates a set of output data that feeds further steps. Similarly, each service requires a set of input data and generates a set of output data as a response. This output data may be used as an input data for further Services inside the same step. In addition, this data is transmitted along the process and can be used as data input for services. This data can be generated by user interaction with widgets and medical sensors, or retrieved from databases connected to the services.

EHealth systems usually have a rich dataflow of medical and personal information of sensitive and private nature. This information should be securely protected to avoid incidences that can affect the public trust in online healthcare systems. This information should only be revealed to people with legitimate access rights, and otherwise encrypted especially when flowing between cloud components.

F. Evaluating the Process Model with Potential Users

The model has been collaboratively developed by a group of nine persons representing the three main profiles (doctors, patients, service providers). In order to evaluate the intuitiveness of this model, a two hours session was organized with sixteen subjects with no experience in business process modeling, but with knowledge about user-oriented design. The process model was briefly introduced to all the participants, then each one was asked to design healthcare processes for a given scenario by using the model. Finally, the participants were asked to fill a questionnaire about their experience, and informal interviews were conducted with each of them.

The results of these activities show subjects easily understand the model (only one participant did not fully grasp the model components). The subjects found the model to be highly intuitive, and used it to design the required healthcare processes accurately (defining different processes and their steps, selecting the proper services, and connecting all components to insure a correct dataflow).

V. VIRTUALCLINIC: A CLOUD-BASED EHEALTH SYSTEM

In order to assess the feasibility of using both cloud-based business model and the healthcare process model introduced in the design of eHealth systems, we have designed and implemented VirtualClinic, a prototype system for remote diagnosis and medical assistance. It consists of a SOA that permits service providers to offer healthcare services in an interoperable manner, allowing their incorporation in customized healthcare processes. The SOA also manages the publication of these processes on the web and the interaction of patients with them. In addition, the system includes a tool that doctors use to compose and manage healthcare processes. The SOA implements the principles of a cloud-based business model for eHealth, and the tool implements the healthcare process model.

A. A Cloud-Based Service Oriented Architecture

The system architecture is designed to automate the composition and publication of online healthcare processes in a cloud environment. It is composed of a core platform hosted on the system server and three different client modules, each hosted on a corresponding client terminal (figure 4). The core platform design is inspired from that of BPEL engines where a server-based platform controls the execution of the processes. This platform incorporates three main modules: the communication module, the workflow engine, and the service repository.

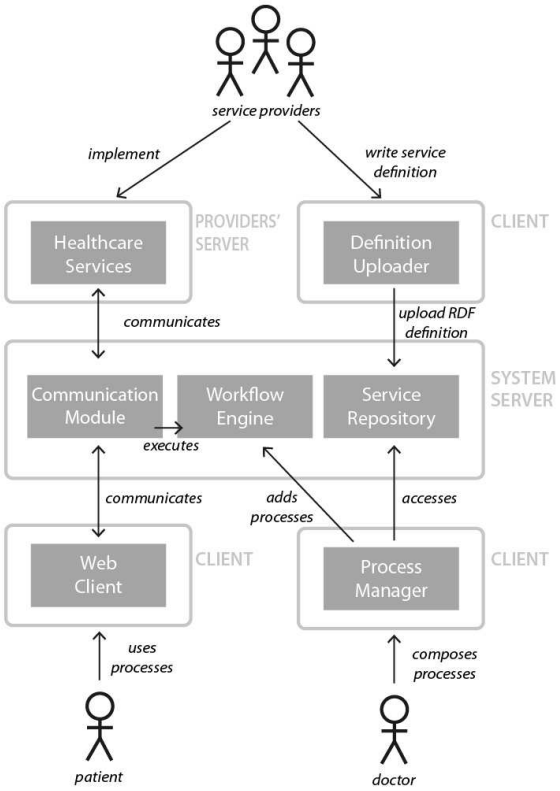

Figure 4. A SOA for eHealth systems

Service providers use their own client on their terminal to add new services to the service repository. The client interface is an online form that generates a standardized RDF definition for each service. Doctors make use of their process manager to compose healthcare processes from these services. The workflow engine compiles and executes the composed processes, and the communication module generates the corresponding web pages, which are accessed by the patient client. The communication module also manages the sending of messages between services, and supports the exchange of information between the process executing on the workflow engine and the patient client,

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enabling patients to interact with the processes a step at a time.

B. A Doctor's Tool for Managing Healthcare Processes

The process manager tool is designed to empower doctors in managing healthcare processes by using the process model to represent them. It addresses the functional requirements as defined by the doctor's role in a cloud-based eHealth system. The tool has two interface modes: one for creating and managing healthcare processes (figure 5), and another for composing the process steps from existing services (figure 6).

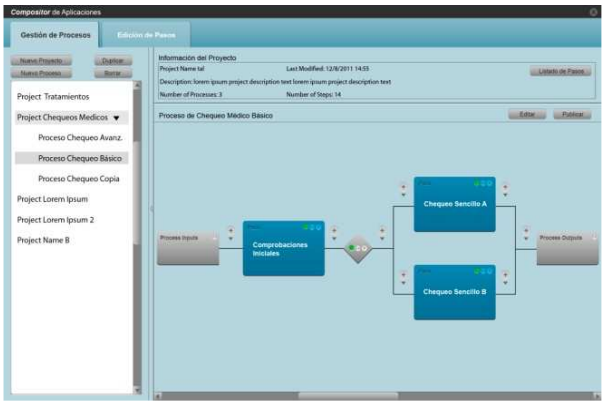

Figure 5. The process manager interface.

Figure 6. The step editor interface.

Doctors can compose a given healthcare process by creating and ordering its steps. In general, the steps are sequentially ordered inside the process, but doctors can define different execution paths by arranging several steps in parallel. This is achieved by introducing a condition in the process that evaluate the output of the previous step in order to decide which of the subsequent parallel steps is the adequate one in the course of the process execution.

The steps are composed from existing services by using the step editor, which is access from the process manager. A browser assists the doctors in searching for and exploring healthcare services available in the repository. Selected services are integrated in the step sequentially, but services can be grouped into service containers. For each integrated service, its data input is automatically connected to the output of its antecedent service, and doctors can edit and modify this linkage. Services are ordered vertically on the corresponding web page, and grouped services are ordered horizontally in tab containers.

C. Executing a remote asistance scenario

VirtualClinic revolves around the scenario where a doctor wishes to remotely provide general medical assistance to two different types of patients: fairly healthy and chronically ill patients. The doctor needs to reduce congestion in the clinic and the patients would like to reduce the travels they effectuate to receive healthcare. Fairly healthy patients only use common eHealth services (e.g. inquiring about their medical history, checking the calendar of consultations, and conferring online with their doctor). Chronically ill patients require a wider more specialized range of services (e.g. checking their vital signs with sensors, sending this data to their doctor, and inquiring about medications and newly developed symptoms). They also might require specific services in accordance with their illness (e.g. Alzheimer patients require memory exercises).

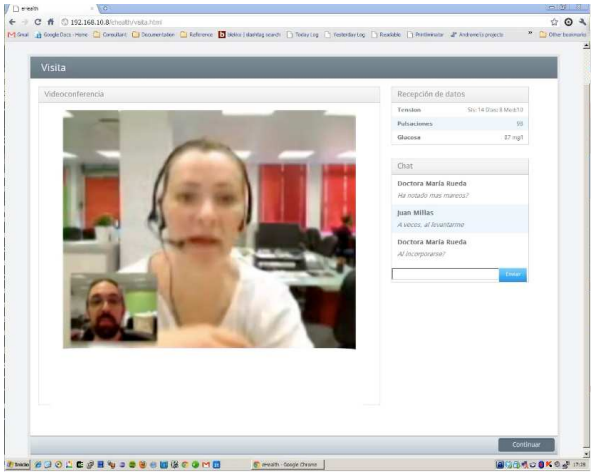

Figure 7. Patient using the remote asistance service

The design and implementation of the VirtualClinic architecture sustain this scenario from a technical stance. The service repository contains a number of general cloud services by default (e.g. registration, billing, calendar, maps, social network services, etc...). In addition, service providers added several healthcare services, including a remote assistance service (figure 7), an electronic prescription service, and a drug delivery service. Given this pool of services, three distinct healthcare processes were created with the process manager and published on the web. One process was dedicated for taking appointments or conferring with a medic for urgent matters; another process allowed chronic patients to renew and update their prescription, and order their medication; the third process centered on the remote diagnosis of older patients. In essence, VirtualClinic provides a proof of concept that illustrates how cloud-based

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systems can be engineered to facilitate both the composition of customized healthcare processes and their execution.

VI. INTEGRATING VIRTUALCLINIC IN REAL SETTINGS

The VirtualClinic as a proof of concept represents a positive assessment of the feasibility of cloud-based eHealth systems. We studied its deployment in a local clinic in order to assess its compatibility and adaptability to real-world settings.

A local clinic (subsidiary of Munich Health, a leading European health insurer) specialized in work-related accidents treatment and prevention was chosen as the test bed for this study. This typical clinic is part of an intricate network of private healthcare services in Spain, which includes private hospitals, laboratories and diagnostic centers. This network represents a prime customer base for commercial healthcare service providers, including the emergent eHealth services.We conducted a contextual inquiry in the local clinic, which included interviewing the different relevant profiles, understanding the workflow among them, and the systems they rely on to manage their work. Its results identify the manner by which VirtualClinic should be integrated.

A. *Identifying the workflow at the local clinic*

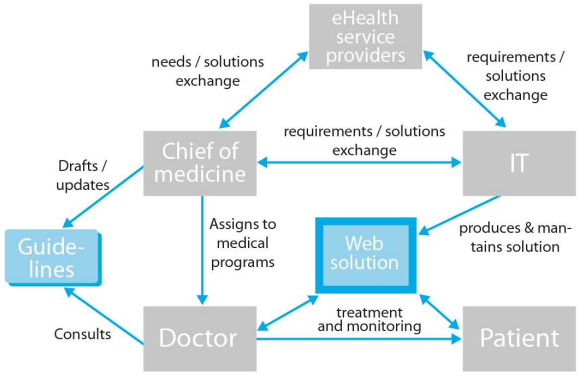

Figure 8. The current workflow in the local clinic

Five main profiles are considered relevant in our context: the *chief of medicine* drafts and updates the clinical guidelines that doctors follow, and assign doctors to specific medical programs (e.g. prevention of aspiratory diseases in the workplace, or treatment of head injury and trauma); the *doctors* (a total of 18) keep a direct and periodic contact with *patients*, and often use the web system to assign them visits, reminders, and exercises. The web system is a doctor/patient interface;*patients*(more than 2,000) use the systemto access relevant information and services from their homes; The*IT department* (5 IT experts) developed the web system and services and upgrades it according to the directions of the chief of medicine; in addition, third-party *eHealth service providers* sell off-the-shelf solutions to the clinic and service them afterwards in collaboration with the IT department, and discuss new products with the chief of medicine.

The workflow associated with these profiles is drawn in figure 8.It isolates the section of the clinic workflow relevant to the deployment of cloud-based eHealth systems. It is typical of contemporary clinical workflows, with a strong initiative in eHealth and telemedicine.

B. *Understanding the views of different profiles*

The interviews with the chief of medicine, a doctor, and two IT experts focused on the potential of adopting a cloud-based model, its advantages and disadvantages from the point of view of each profile.

The chief of medicine requires a more dynamic way to manage the creation and upgrade of clinical guidelines, and include third-party services in them. He views cloud-based systems a necessity as the relation with patients becomes more digitized. The doctor does not wish to rely excessively on remote services nor sees alternatives to meeting regularly with patients, however she recognizes the potential of web-based services in therapy and rehabilitation.The doctor also considers videoconferencing a positive and efficient approach for support and emergencies. The IT experts are capable of building and handling complex systems, they think cloud-based systems are good and advanced solutions but they raise concerns about data security. Adopting a cloud-based infrastructure allows them to expand their system easily by relying on third-party components.

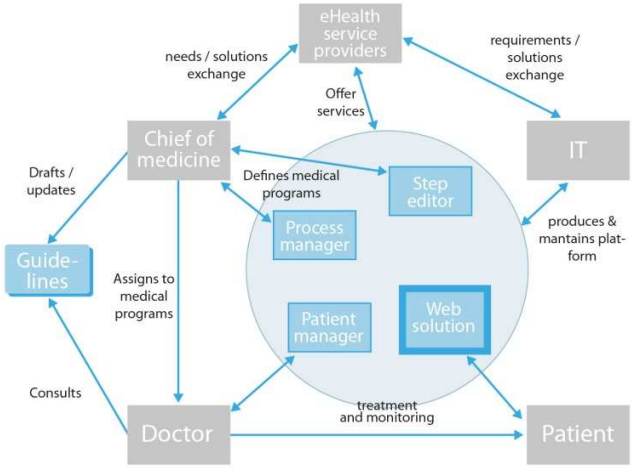

Figure 9. The integration of VirtualClinic in the workflow

C. *Integrating VirtualClinic*

The integration of VirtualClinic in this workflow should preserve the current structure as much as possible and avoid disadvantaging any profile. The system should also be integrated with other existing tools (e.g. the patient manager that doctors use to maintain digital dossiers).

For this purpose an integration proposal has been conceived, discussed with the different profiles and adjusted to provide a good fit. This integration (figure 9) is currently ongoing. According to it, the chief of medicine uses the process manager to draft new processes as clinical guidelines; future upgrades will look into unifying both digital and printed systems. The doctors use an integrated patient manager (currently under development) to assign the processes designed by the chief of medicine to their patients

 ISBN: 978-1-61208-179-3

"step by step". The IT department manages the entire system architecture and mediates the participation of service provides. These can now benefit from a broader opportunity to sell their services. The patient experience also benefits from the new services, as the system is not design to replace any existing procedure.

VII. DISCUSSION

Our experience with VirtualClinic illustrates the viability of cloud-based solutions for eHealth applications. It shows how the technical complexity of these systems can be encapsulated by making the involved profiles more independent and supporting each in performing its role. Doctors assume control over the management of healthcare processes, patients benefit from more personalized and trustworthy procedures, and service providers sell their services in the cloud.

The contextual inquiry conducted at a local clinic and the subsequent integration (undergoing) of the VirtualClinic demonstrate that these systems can be adopted as a major transition step toward a cloud-based business model. They also simplify the workflow by making each profile more independent and empowered: the chief of medicine can manage the guidelines with ease and also integrate services from external providers. Doctors have more access and control over these services. In addition, the IT department no longer needs to maintain direct relation with the chief of medicine.

The approach proposed in this work can be applied in other domains where non-experts require the help of technical profiles in managing their business processes. In particular, it is currently being applied in an eCommerce scenario where a t-shirt manufacturing company wishes to allow customers to design, customize, and order their own t-shirts on the web. In this scenario, one of the interesting challenges is to empower marketing directors to constantly create and publish sales campaigns on the web sites, including social networks.

VIII. CONCLUSION

Current eHealth business models require a constant involvement of IT professionals to create and maintain online healthcare processes. The cost of managing healthcare processes in accordance with these models is elevated, and its efficiency is reduced. In this work, we evaluated the use of a cloud-based business model that simplifies the management of healthcare processes, dispenses this task directly to the doctor, and facilitates the incorporation of third-party healthcare services. Consequently, it allows for a more direct doctor-patient relationship through the web.

A conceptual model of healthcare processes is introduced to address the interaction requirements that the cloud-based business model entails. This process model allows doctors to assume control over the creation and customization of healthcare processes and minimizes their technical complexity. We evaluated the feasibility of our approach by implementing VirtualClinic, an eHealth system design for remote assistance. In addition, a contextual inquiry was conducted at a selected clinic to integrate VirtualClinic. The results illustrate how VirtualClinic is being integrated.

This approach also has its limitations. Several important aspects of eHealth systems were not addressed, including data security and privacy issues, which are important due to existing risks and regulations. The services currently used in VirtualClinic do not raise such concerns; however they should be addressed in the near future to include services (e.g. remote-diagnostics) that raise them. In addition, the cloud-based system requires a largeand diversified pool of services to allow a diversity of processes to be created. The quality of the available services also plays an influential role. Nonetheless, the lucrative opportunities inherent in the eHealth sector act as a sufficient incentive for service providers to refine the services they offer. With the ability to monitor the use of their services, service providers can receive essential feedback to improve them. This constitutes the backbone of our future work.

ACKNOWLEDGMENT

This work has been partially sponsored by the R&D project España Virtual funded by CNIG-Spain under the Ingenio 2010 R&D program. The authors would also like to thank Ernesto Arroyo, Androme IbéricaS.L., DKV Seguros, as well as Mario Quesada and Raúl Vallespín for their contributions.

REFERENCES

[1] C. Mazurek and M. Stroinski, "Innovative ICT Platform for Emerging eHealth Services: Towards Overcoming Technical and Social Barriers and Solving Grand Challenges in Medicine," in proc. eTELEMED 2010, pp. 33-38.

[2] K. K. Lorenzo Valeri, Daan Giesen, Patrick Jansen, Business Models for eHealth Final Report. February. 2010.

[3] D. F. Sittig, A. Wright, J.A. Osheroff, B. Middleton, J.M.Teich, J.S. Ash, E. Campell, and D.W.Bates, "Grand challenges in clinical decision support.," Journal of biomedical informatics, vol. 41, pp. 387-92, Apr. 2008.

[4] C. O. Rolim, F. L. Koch, C. B. Westphall, J. Werner, A. Fracalossi, and G. S. Salvador, "A Cloud Computing Solution for Patient's Data Collection in Health Care Institutions," in proc. eTELEMED 2010, no. i, pp. 95–99.

[5] H. R. Motahari-nezhad, B. Stephenson, and S. Singhal, "Outsourcing Business to Cloud Computing Services: Opportunities and Challenges Outsourcing Business to Cloud Computing Services: Opportunities and Challenges," IEEE Internet computing, 2009.

[6] R. K. L. Ko, "A computer scientist's introductory guide to business process management (BPM)," Crossroads, vol. 15, no. 4, p. 4, 2009.

[7] S. White, "Introduction to BPMN," IBM Cooperation, no. c, pp. 1-11, 2004.

[8] J. Recker and M. Indulska, "How good is BPMN really? Insights from theory and practice," 2006.

[9] M. Beyer, K. Kuhn, and C. Meiler, "Towards a flexible, process-oriented IT architecture for an integrated healthcare network," in proc. Proceedings of SAC 2004, pp. 264-271.

[10] J. D. A. Medinilla Corbellini, S. Giest, J. Artmann, J. Heywood, Country Brief: Spain - eHealth Strategies, no. October. 2010, p. 3

 ISBN: 978-1-61208-179-3

How to Communicate STI and HIV Test Results Online to MSM?

The Barriers and Motives MSM Perceive in the Online Communication of STI and HIV Test Results

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Abstract— **Testlab is an online service for Men who have Sex with Men (MSM) to get tested on STIs and HIV. Testlab is part of the MANtotMAN project. This project aims to improve testing behaviour and increase awareness on STIs and HIV among MSM. Currently, the users of Testlab do not receive specific test result online, because it does not seem appropriate to communicate potentially upsetting news online, without the presence of a health care professional. However, little is known about the barriers and motives MSM perceive in receiving online test results. Forty-four interviews were held with MSM to investigate barriers, motives and the importance of the tone of online communication regarding test results. The main conclusion of this study is that the vast majority of participants would like to have the option to choose whether or not to receive their specific test results online. They perceive little barriers in receiving low impact STIs (Chlamydia, gonorrhoea, syphilis and) test results. More barriers are perceived for HIV online test results.**

Keywords - eHealth; STI, HIV; professional communication; empathic communication

I. INTRODUCTION

Men who have sex with men (MSM) have an increased risk for STIs (Sexually Transmitted Infections) and HIV (Human Immunodeficiency Virus). In the Netherlands, they are therefore advised to be tested on STIs twice a year and to be tested on HIV once a year. There are several options to get tested on STIs and HIV in the Netherlands. One can get tested at the general practitioner, at a STI-clinic of the GGD (Public Health Services), or a STI-clinic at a specialised hospital. Another option to get tested is via Testlab, an online service for MSM to get tested on STIs and HIV. Testlab is a part of the MANtotMAN website, which is part of the MANtotMAN project. This project aims to improve the prevention and treatment of STIs and HIV for MSM.

The MANtotMAN website was developed by the Dutch Aids Fund, Schorer (Dutch institute for homosexuality, health and well-being), the GGD Amsterdam and the GGD Rotterdam (Public Health Services of the municipalities Amsterdam and Rotterdam). The website was launched in the summer of 2008 and has since conducted several theme campaigns aimed to improve test behaviour and to create awareness on STIs and HIV. The website attempts to increase testing and decrease risk behaviour among MSM. The website offers information on safe sex, what to do after having unprotected sex, living with HIV, dating and partners, etc.

The reason Testlab was developed is that a low threshold service to get tested on STIs (Chlamydia, gonorrhoea and syphilis) and HIV was not yet present for MSM. Testlab provides MSM with a new and innovative eHealth application. The difference in the Testlab procedure compared to the other testing alternatives is that the men can fill in the necessary paperwork online; they can choose their date and time to go to a nearest laboratory. Once there, all it takes is a couple of minutes for all the cultures and blood samples are taken. Whereas going to the general practitioner, a hospital or a STI-clinic is far more time consuming and the procedure allows less anonymity than the Testlab procedure. Another major difference of the Testlab procedure is that MSM receive their a-specific test results online. This means that MSM receive an online message either telling them that all tests were negative or that one or more tests were positive. If one or more tests are positive, they are asked to come to the STI-clinic. At the clinic, they receive their specific test results, counselling if needed, treatment and, if necessary, follow-up and confirmation tests.

The 2010 HIV monitor shows that the MANtotMAN project is successful in reaching their target population and that MSM familiar with the website have a higher intention to get tested on STIs and HIV [1]. Not only is their intention to get tested higher, evaluations of the project have indicated that there is a rise in the testing rate among MSM that are familiar with MANtotMAN and Testlab. This shows that there is a need for online interventions on STIs and HIV testing.

When Testlab users were asked about their experiences, some of them indicated that they would have liked to receive specific test results online [2]. However, one can think of several advantages and disadvantages of allowing people to receive online specific test results that can have a large impact. A qualitative study was conducted to answer the following questions:

 ISBN: 978-1-61208-179-3

- What motives and barriers do MSM perceive for receiving specific test results online?
- How important is the tone of voice in the online communication of results?

The theoretical background, the method and results of this study are described in the remainder of this paper. The paper ends with the conclusion of the study.

II. LITERATURE OVERVIEW

The first step in answering the research questions was a literature review about self tests and empathic communication.

A. Advantaged and disadvantages of self tests

Self-tests are becoming increasingly popular and more available to the general public in the Netherlands [3]. Four different types of self-test are indicated: 1) a self-test where the samples are taken at home and results can be viewed immediately; 2) a self-test where the samples are taken at home and then sent to a laboratory, with results received through post or internet; 3) a self-test where people are required to go to a laboratory for collecting of samples and then receive their test results through post or internet; 4) a street-corner test, these are tests offered by organizations in public places such as grocery shops, libraries, etc. Testlab is a type 3 self-test, this type of self-test has the least amount of disadvantages compared to the other types of self-tests.

Critics of self-testing state that self-tests involve high costs and will only increase test results among people at low-risk for disease, and that the high-risk population will not use self-tests. These critics also indicate that testing without supervision of a qualified health professional could lead to adverse medical and psychological outcomes [3-6]. This is one argument for not providing the Testlab users with online test results. A health care professional who tells them personally about the test results, explains these results and who can immediately answer any questions might be better, especially because STIs and HIV are serious diseases that can have a large impact on patients.

On the other hand, self-testing appears to be applicable in the present-day views on consumer autonomy and self-management, and it could also empower consumers to gain control over their personal health [3, 7, 8], which is an argument for providing Testlab users with online results. Protagonists of self-tests believe that the availability of self-tests will lead to increasing test rates as well as earlier diagnosis and treatment. They also indicate that self-tests are more convenient and provide more anonymity than current testing methods, and that it promotes patient empowerment.

B. Empathic Communication in eHealth

Receiving positive test results for an STI or for HIV can have a traumatic impact on a person. More STIs are curable nowadays, but HIV, even though it is a controlled disease, is still incurable. So, it is important to deliver this news tactfully. Bad news in health care can be defined as "any news that drastically and negatively alters the patient's view of her or his future" [9, p.15]. It can be delivered in different ways; there is no standard on how it should be delivered. The literature implies that the communication style is important; the use of an empathic style is best when the diagnosis is of a more serious nature, where a less empathic but objective, professional style is more accepted when the diagnosis is not life altering or life threatening [10, 11]. An empathic style is defined as responding to the receiver's emotions. In this study, we use the term 'informative' for a less empathic, but professional and objective communication style.

A study on how different communication styles can affect risk perception by De Wit, Das and Vet [12] indicates that the use of narratives is more effective in communicating health risk than using objective and statistical communication.

Although a lot of research is done on the use of different communication styles in health communication, little is known about the use of text styles in the communication of online test results [12-16]. Kreps and Neuhauser [17] conclude that if e-health information meets conditions such as tailored messages, interactive, engaging, and can be delivered to mass audiences; it can make a difference in improving the quality of both health care and disease prevention.

This study focuses on informative and empathic text styles for the communication of online test results. Testlab has already shown that is successful in the prevention and early detection of STIs and HIV among MSM. The goal of this study is to find out how this positive trend can be continued in the communication of the test results.

III. METHOD

The method of the qualitative study is described below.

A. Participants

A total number of 44 MSM participated in this study (14 were HIV^+, 30 were HIV^-). Guest et al. indicate that that 12 in depth interviews is sufficient for a fairly homogeneous group [18]. Saunders, Lewis and Thornhill suggest a sample size of 25 to 30 people [19]. Since our target group is heterogeneous, we decided to interview more people than suggested in the literature, to be sure that the results would be relevant.

The participants were between 18 and 64 years of age (mean: 43). The education level varied from vocational education to university education. Some of the men had used Testlab before (N=25) others had no experience with Testlab (N=19). Participants were recruited through the Public Health Services of Amsterdam, Rotterdam-Rijnmond and of the region Twente (municipality: Enschede), and the hospital in Enschede (Medisch Spectrum Twente). STI

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nurses and HIV consultants assisted the researchers with recruiting participants.

B. Sample Selection

The inclusion criteria of this study: participants had to be 18 years or older, they had to be men, they head to be homosexual or bisexual, they had to speak Dutch, and they had to be tested at least once on a STI and/or HIV. These inclusion criteria were communicated to the nurses who recruited the participants and were checked by the researchers when the appointment for the interview with a possible participant was scheduled.

Figure 1. Empathic test result for HIV
Translation:
1. The HIV test result. "Maybe this news upsets you; do realize this is a preliminary test result. You need to come to the STI-clinic for the final test result; there a confirmation test is done"
2. "What to do next?" Also an outline with the next steps, but with empathic additions. "Maybe you are reluctant to go to the STI-clinic, but remember: the sooner you come to the STI-clinic, the sooner you'll have your final results. If you would like you can bring someone to the STI-clinic with you."
3. Advise to come to the STI-clinic as soon as possible, either today or the next working day.
4. The referral letter (download, print, or email)
5. Link with information about HIV and treatment options, empathic addition: "We understand that you might wish more information on HIV, if you do, please click the link below."

C. Materials

Prototypes of web pages with the online test results were constructed. Four screen shots were shown to the participants: positive test results for gonorrhoea presented in an informative style, positive test results for HIV presented in an informative style, positive test results for gonorrhoea presented in an empathic style and positive test results for HIV in an empathic style (see Figure 1). The contents of the test results written in an empathic style were the same as the contents of the test results written in an informative style. However, we added some empathic elements to the text. In the informative text, the men are told "Go to the STI clinic as soon as possible …" while in the empathic version, the men are told "Maybe, you are reluctant to go to the STI clinic …" The informative text states: Below, you can find more information on…" while the empathic versions state "We understand that you might wish more information on …"

The initial interview questions were constructed on the bases of the literature study on informative and empathic texts. These interview questions were formed into a topic list and supported by a PowerPoint presentation that was used during the interviews. This topic list was used to keep a semi-structured nature in the questions and contained questions on motives and barriers the interviewee perceived when receiving online test results. We specifically asked the preferences, motives, and barriers concerning online communication of test results.

D. Procedure

We used semi-structured interviews to gain insight in the motives and barriers that MSM perceive in receiving online STI/HIV specific test results, their needs for specific information when receiving these test results and in which way these results can be best communicated. In Amsterdam the interviews were held at the research department of the GGD Amsterdam, in Rotterdam at the STI clinic of the GGD Rotterdam-Rijnmond and in Enschede at the STI-clinic of the GGD region Twente. The average time for an interview was 45 minutes.

At the beginning of every interview a short introduction about the research was given. Participants who were not familiar with Testlab received an additional explanation about the website MANtotMAN and Testlab (the application, procedures and current communication of test results) to make sure they understood how Testlab works. After the introduction, permission was asked to record the interview and to convert it into text afterwards. Assurance about anonymous collection of the data was given. A PowerPoint presentation was used to show prototypes of web pages with online test results. The participants saw positive test results for gonorrhoea presented in an informative style, positive test results for HIV presented in an informative style, positive test results for gonorrhoea presented in an empathic style and positive test results for HIV presented in an empathic style successively

E. Data Analysis

In this research categorisation of meanings was used to put the data in relevant categories so it could provide insight into the relationships in the collected interview data. Through open coding the general issues with online communication of test results were found and categorized. In all the issues derived from the transcribed interviews we searched for overlapping themes through axial coding. This resulted in the identification of several themes such as the relation between the severity of the test result (e.g. gonorrhoea vs. HIV) and the preference for the type of text (informative or empathic) used in the communication of the test result. All transcripts were imported and analysed with MAXQDA 2010, a software program for the analysis of qualitative data.

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The research team consisted of 3 researchers, all with different backgrounds (psychology, communication sciences and biomedical sciences). The researchers with a background in communication sciences and biomedical sciences performed the interviews. The first 6 interviews were coded by both the researchers and discussed with the supervising researcher to reach consensus about the coding system. This was done to ensure equal coding of the two researchers. After these 6 interviews each researcher coded their own interviews, but discussion took place each time a new code was used. These discussions could lead to an adjustment or addition the initial topic list, or to the rephrasing, combining, or splitting of earlier formulated codes.

IV. RESULTS

The results of this study indicate that more motives than barriers were perceived to receive STI specific test results online. This applies for all participants, although men who had already used Testlab in the past perceived more motives than the men who had never used Testlab. This is why men in Amsterdam and Rotterdam perceived more motives than men in Enschede; Testlab is currently only available in these two cities.

The results showed a difference in the participants' opinions about the STIs (Chlamydia, gonorrhoea and syphilis) on the one hand and HIV on the other. As expected, more barriers were perceived for receiving online test results indicating a positive test result for HIV than receiving results indicating a positive test result for gonorrhoea. Furthermore, the participants had a preference for an empathic style when the results indicated that one was positively tested for HIV and a preference for an informative text style when the results were about gonorrhoea.

A. Motives for online test results

The most important motive mentioned for receiving positive STI and HIV test results online was that one **did not have to wait for appointment at the STI clinic** to get the results. The advantage of not having to wait for an appointment implied that one **could immediately start taking measures to protect themself and his partner(s)** and, more important, it **reduced the anxiety**. When test results are communicated a-specific, the participants indicated they feel a lot of anxiety when they already know that they are tested positively, but have to wait until their appointment at the STI-clinic before they know what they tested positive for.

"A bad feeling, especially since they only say, "you've tested positive on something, but what is it?". This caused stress for a whole week." (Rotterdam; no. 9; Testlab user, HIV-negative)

Another motive for receiving test results online is **patient autonomy**. Some participants mentioned that they found it important to be able to decide for themselves when and where they would get their results and what they would do after getting the results.

"Yes, I would prefer it [online HIV test result], because then I can decide when to see the result, when to process it and what to do next. Whether you want to go to your general practitioner or the STI-clinic […]. Then you have had time to think whether you want to see your general practitioner for additional support or knowledge. And whether you want to talk to someone. But at least you have had time to process it yourself and to come to terms with it." (Amsterdam; no. 4; Testlab user, HIV-negative)

Related to the previous motive, participants also mentioned that they **preferred getting bad news at home**.

"You know what's it about [your online test result], and I was talking about preparation […], and yes I would probably wait until my husband is home. That is much better, in my opinion, than going to the STI-clinic by yourself and to hear it from someone else." (Amsterdam, no. 14; Testlab user, HIV-negative)

Another motive that was mentioned is that the possibility to get online test results simply **fits in the current digital world**.

"Yes, just look at it as demand [online HIV test results], a market condition. If there is demand from the market to give results in this manner, then yes, this might be a good tool to persuade MSM to get tested, as an additional means." (Amsterdam; no. 20; Testlab user, HIV-negative)

B. Barriers for online test results

The barrier that was mentioned most often for both STI test results as HIV test results was **the need for contact with a health professional**. Although most of these men did believe that the option to choose specific online test results should be available.

"Yes, often when you receive something online and you have questions, you don't receive an answer immediately […] I'd rather go to someone who can tell me exactly what I have and what I have to do. I find that much easier." *(Enschede; no. 3; non-user Testlab , HIV-negative)*

The barriers most mentioned for receiving HIV test results online were that **the impact is too large** and **that it can be**

unexpected. Therefore, participants considered it better to receive the test results from a health care professional.

"But I can imagine that you'll freak out [after an online positive HIV test result]. And maybe make some decisions that you wouldn't make when a professional guided you. I think that is a disadvantage of an online test result […] because then you can do it all by yourself, processing it and then thinking "I'll drink that bottle of gin and take those pills." So, no I wouldn't do it [give online test results for HIV]." (Amsterdam; no. 18; Testlab user, HIV-negative)

"Especially for people […] who […] test for prevention […] and I believe that is a large group, who get tested and think, "It'll all be all right". This group, in my opinion, will be even more confronted when you read online "oh, and you have HIV"[…] I believe there is a large group that just [thinks] "I'll get tested every 6 months or each year and I'll test negative for everything" and then you suddenly receive a positive test result for HIV." (Enschede, no. 7; non-user Testlab, HIV-positive).

Another barrier for offering online HIV test results mentioned was "**ostrich policy**". Some participants feared that men who receive a positive HIV test result online would not take the appropriate actions.

"Yes, the biggest problem [with online HIV test results] is that people won't take immediate action, that you won't go to the STI-clinic immediately and that people won't get treatment. And the biggest problem is ostrich policy. That you're going to pretend it didn't happen. That is not only a problem for the person that tested positive, but also for future sex partners." (Amsterdam; no. 16; non-user TestLab, HIV-negative)

C. Empathic versus informative style

Most participants agreed that the informative style was more appropriate for test results for low impact STIs.

"Yes, the shorter and the more factual, the better, I think."(Amsterdam; no. 9; Testlab user; HIV-negative)

Barriers perceived for the empathic test result for low impact STIs included aspects such as **patronizing tone, overbearing and too dramatic**.

"Well, it already starts with, "maybe this news will upset you" that's already a patronizing tone. And then "You must realise" [that it is a preliminary diagnosis]. Then I think to myself, of course you should realise this, but this […] is patronizing, not factual." (Amsterdam; no. 9; Testlab user; HIV-negative).

With regard to online test results for HIV, the participants' opinions differed from each other. There seems to be a slight preference for an empathic style. Some participants perceived the empathic test result to be **more reassuring and personal** than the informative test result.

"This is friendlier. Because it says, "don't be too upset" it gives some empathy that is nice to read, I think. Because that is what happens, it upsets you a bit reading that you've tested positive. And then you explain that it's a preliminary diagnosis. Which comes across better than in the other [informative test result], I believe." (Enschede, no. 9; non-user Testlab, HIV-positive)

V. CONCLUSION

Considering all motives and barriers mentioned by the participants, the first conclusion of this study is that the vast majority of the participants believe that Testlab should offer the possibility to receive specific test results online. Especially Testlab users and participants from Amsterdam and Rotterdam would like this option. A little more resistance was found among MSM from Enschede. The reason for this could lie in the fact that Testlab is not offered in Enschede. It is possible that, even though a general impression of the Testlab website was given, the MSM from Enschede found it difficult to imagine what it would be like to receive test results online.

The answer to our first research question is twofold; the results showed a clear difference between the participants' perceptions of getting online results for gonorrhoea and for HIV. Even though barriers for putting specific test results online have been mentioned for all STIs, all Testlab users in this research thought it would be best if positive test results for gonorrhoea (and other STIs as syphilis and Chlamydia) are given online. For HIV test results both Testlab users and non-Testlab users mentioned more barriers. On the one hand, a large portion of participants believed that people should be given the choice to receive all test results specific, while on the other hand some participants believed people should be protected and therefore positive HIV test results should only be given face-to-face by a health professional. The answer to our first research question

The results also show a difference in preference for a communication style between a diagnosis for gonorrhoea and an HIV diagnosis. The answer to the second research question is that the communication style is important for both diagnoses, but that an empathic style is preferred for an HIV-diagnosis and an informative style for a low impact STI. This is in line with the results from the literature study [10, 11]. Participants felt that a positive HIV test result should be more extensive than the result of a low impact STI. The main motive participants had for preferring

 ISBN: 978-1-61208-179-3

empathic communication is that they found it more personal and reassuring than the informative communication.

Most motives for choosing informative communication of test results involved low impact STI test results. The empathic version was sometimes found overbearing in the case of a low impact STI diagnosis. The main motive for preferring the informative style was that the communication was short and factual. This was highly appreciated for low impact STI test results. The barriers were that the informative communication was less personal and reassuring than the empathic communication.

Based on this study, it seems to be advisable to include the possibility to receive online test results for low impact STIs in self-tests as Testlab. However, providing online specific HIV test results raises several concerns. Since the men that we interviewed mentioned a number of barriers, but also some motives, we recommend doing more research before offering this possibility.

ACKNOWLEDGMENT

We would like to thank the Public Health Services of the municipalities Amsterdam, Rotterdam and Enschede and the outpatient HIV clinic Medisch Spectrum Twente for their help of recruiting seropositive MSM. A special thanks to Livia Kalma for interviewing half of the respondents and analyzing part of the data.

REFERENCES

[1] Stichting HIV Monitoring, "Monitoring of Human Immunodeficiency Virus (HIV) Infection in the Netherlands," Academic Medical Centre of the University of Amsterdam, 2010.

[2] R. Koekebier "Internal evaluation report Testlab - De online soa en hiv test applicatie van MAN tot MAN. Een studie naar gebruik, effectiviteit en usability/acceptability, " Amsterdam: GGD Amsterdam, 2009.

[3] J. Grispen, M. Ickenroth, N. de Vries, G. Dinant, G. Ronda, and T. van der Weijden, "Improving behaviour in self-testing (IBIS): Study on frequency of use,consequences, information needs and use, and quality of currently available consumer information (protocol)," BMC Public Health,10, 2010, pp. 453.

[4] G. N. Colfax, J. S. Lehman, A. B. Bindman, E. Vittinghoff, K. Vrazniza, P. L. Fleming, et al., "What happened to home HIV test collection kits? Intent to use kits, actual use, and barriers to use among persons at riskfor HIV infection," Aids Care, 14, 2002, pp. 675-682.

[5] L. Frith, "HIV self-testing: a time to revise current policy," The Lancet, 369, 2007, pp. 243-245.

[6] A. Ryan, S. Greenfield, R. McManus, and S. Wilson, "Self-care-has DIY gone too far?" British Journal of General Practice, 56, 2006, pp. 907-908.

[7] G. Ronda, P. Portegijs, G. Dinant, F. Buntinx, R. Norg, and T. van der Weijden, "Use of diagnostic self-tests on body materials among Internet users in the Netherlands: prevalence and correlates of use," BMC Public Health, 9 , 2009, pp. 100.

[8] J. Grispen, G. D. Ronda, N. de Vries, and T. van der Weijden, "To test or not to test: A cross-sectional survey of the psychosocial determinants of self-testing forcholesterol, glucose, and HIV," BMC Public Health, 11, 2011, pp. 112.

[9] R. Buckman, "How to break bad news: A guide for health professionals," Baltimore: John Hopkins Press, 1992.

[10] T. Minichiello, D. Ling, and D. Ucci, "Breaking Bad News: A Practical Approach for the Hospitalist," Journal of Hospital Medicine, 2(6), 2007, pp. 415-421.

[11] W. Baile, R. Buckman, R. Lenzi, G. Glober, E. Beale, and A. Kudelka, "SPIKES -A Six-Step Protocol for Delivering Bad News: Application to the Patient with Cancer," The Oncologist, 5, 2000, pp. 302-311.

[12] J. de Wit, E. Das, and R. Vet, "What Works Best: Objective Statistics or a Personal Testimonial? An Assesment of the Persuasive Effects of Different Types of Message Evidence on Risk Perception," Health Psychology, 27(1), 2008, pp. 110-115.

[13] L. Hinyard and M. Kreuter, "Using Narrative Communication as a Tool for Health Behavior Change: A Conceptual, Theoretical, and Empirical Overview. Health Education & Behavior, 34 (5), 2006, pp. 777-792.

[14] E. Peters, I. Lipkus, and M. Diefenbach, "The Functions of Affect in Health Communications and in the Construction of Health Preferences," Journal of Communication, 56, 2006, pp. 140-162.

[15] M. Green, "Narratives and Cancer Communication," Journal of Communication, 56, 2006, pp. 163-183.

[16] L. Block and P. Williams, "Undoing the Effects of Seizing and Freezing: Decreasing Defensive Processing of Personally Relevant Messages," Journal of Applied Social Psychology , 32 (4), 2002, pp. 803-833.

[17] G. Kreps and L. Neuhauser, "New directions in eHealth communication: Opportunities and challenges," Patient Education and Counseling , 78, 2010, pp. 329-336.

[18] G. Guest and A. J. Bunce, "How many interviews are enough? An experiment with data saturation and validity," Field methods, 18(1), 2006, pp. 59-82.

[19] M. Saunders, P. Lewis, and A. Thornhill, "Research methods for business students (5 ed.)," Harlow: Pearson education.

 ISBN: 978-1-61208-179-3

SPoC: Protecting Patient Privacy for e-Health Services in the Cloud

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***Abstract*—The use of digital technologies in providing health care services is in general subsumed under the term e-Health. The Data Capture and Auto Identification Reference (DACAR) project provides an open e-Health service platform that reinforces the integrity, security, confidentiality and auditability of medical data throughout their life-cycle. This paper presents the design and implementation of the core component of this platform, namely the Single Point of Contact (SPoC). A SPoC is essentially a security authority that provides claim-based authentication and authorisation functionalities, and facilitates the development and integration of secure e-Health services hosted within a Cloud Computing environment.**

***Index Terms*—Single Point of Contact, e-Health, Privacy, Security, Cloud Computing**

I. Introduction

The use of modern communication infrastructures in medicine, and the ubiquitous provision of health care services, are collectively known as e-Health [1]. Currently, many countries are keen to shift their traditional health care services to this new paradigm, in order to improve the quality of care and reduce the health care delivery cost [2], [3], [4], [5].

The Cloud Computing technology [6] appears well-suited to meet such demands, as it is able to reduce the capital and operational expenditures for the development and provision of e-Health applications. A Cloud adopts a Service Oriented Architecture (SOA) [7] and supports the functionalities of an integrated e-Health system as a number of coarse-grained and inter-operable software services. These services may exchange and share medical data with each other in order to improve the overall quality of care offered to the patients.

However, confidential health care information is often subject to a variety of risks, and an inconsistency and loss of such information can result in severe consequences [8]. Hence, a *patient-centric* e-Health system must provide the patients with control over the utilisation and dissemination of their own private information [9]. Unfortunately, traditional security mechanisms are insufficient to meet the requirements of patient-centric e-Health services in an open, dynamic Cloud Computing environment, mainly due to:

- **Platform-dependent** – Traditional security mechanisms often rely on specific operating systems or protocols, and thus it is difficult for them to interact and co-operate.
- **Isolated** – It is difficult for service providers to federate across security domains. As a result, users need to manage multiple identifiers for multiple service providers.
- **Cumbersome** – Traditional security mechanisms often rely on firewalls and expect users to access protected network resources over a VPN connection.
- **Inflexible** – A security authority only delegates access rights according to a user's identity and group, without considering other attributes of the user.

The aim of the Data Capture and Auto Identification Reference (DACAR) project [10] is to develop, implement, validate and disseminate a novel, secure, Cloud-based e-Health service platform that reinforces the integrity, security, confidentiality and auditability of sensitive medical data throughout their life-cycle. Our previous work has provided an overview of the DACAR platform [11], and this paper further elaborates on the design and implementation of its core component, namely the ***Single Point of Contact*** (**SPoC**). A SPoC is essentially a security authority, which protects patients' privacy in e-Health applications by providing a claim-based authentication and authorisation functionality [16], and facilitating secure communication between an e-Health service and its clients.

The remainder of this paper is organised as follows. Section II presents the background of this research. Section III discusses the design of the SPoC, including its internal architecture (Section III-A), supports for authentication (Section III-B), authorisation (Section III-C), secure Web Services (Section III-D), and three representative application scenarios (Section III-E). Section IV outlines the implementations of the SPoC and proof-of-concept applications. Finally, Section V draws the conclusions and sketches the future work.

II. Related Work

Benzschawel et al. pointed out that the main expectations of e-Health are to provide better ways to exchange and share medical information and to improve the quality of services offered to patients [9]. A multi-level architecture is proposed to protect patient privacy, which uses: a Central Medical Registry (CMReg) for authentication and authorisation purposes; a Centralised Medical Data Repository for storing anonymised medical documents; and a Document Management System for authorised users to associate medical documents with real patient identities. The design of the SPoC shares many good characteristics with the CMReg, such as the anonymisation of

 ISBN: 978-1-61208-179-3

medical data and the use of pseudonyms to enhance contextual privacy. The main difference between the CMReg and the SPoC is that the CMReg only focuses on people's access to confidential medical data, while the SPoC also facilitates the development and integration of secure e-Health services.

Zhang et al. have identified a set of security requirements for e-Health services hosted by a Cloud computing environment, including authentication, authorisation, ownership of information, and integrity, confidentiality and availability of data [12]. A model is proposed to address the security and privacy issues relating to access to and management of Electronic Health Records (EHRs). The design of the SPoC also takes these requirements into consideration, but in addition it aims to be more generic, and able to support a wider range of application scenarios beyond the sharing of EHRs.

Kilic et al. have proposed the sharing of EHRs among multiple e-Health communities over a peer-to-peer network [13]. A super-peer is used to represent an e-Health community, which is responsible for routing messages and adapting different meta data vocabularies used by different communities. This super-peer design is similar to the design of a SPoC, yet a SPoC provides additional claim-based authentication and authorisation functionalities. Multiple SPoCs may also keep contact with each other in a peer-to-peer fashion to form a *Circle of Trust*.

Claim-based identity management and access control is proposed to overcome the disadvantages of conventional security mechanisms [14]. It thus abstracts from concrete formats and protocols of identity systems and provides a platform-independent way of presenting identity information [15]. Windows Identity Foundation (WIF) [16] is a typical example of this approach, which consists of the following components:

- **User** – A user is a subject of access control, which can either be a human, or a non-human entity.
- **Claim** – A claim is a statement about a subject made by another subject and can relate to any type of identity attribute. A claim is essentially a cryptographically protected security token, and its format is usually standard, e.g., Security Assertion Markup Language (SAML) [17].
- **Security Token Service** (STS) – A STS is an issuer that accepts requests and creates security tokens containing claims. If a STS is used to verify user credentials and certify user identities, the STS is referred to as an Identity Provider. If a STS is used to certify a user's attributes other than identity, the STS is referred to as an Attribute Provider. If a STS accepts a claim and translates it into another application-specific claim, the STS is referred to as a Resource STS (R-STS).
- **Relying Party** (RP) – A RP is a service provider, or an application, which relies on an issuer to provide information about its users' identities and attributes.
- **Client** – A client is a software agent that implements protocols like WS-Trust [18] and WS-Federation [19] to request and pass around claims on behalf of a user.

The SPoC adopts a claim-based approach for both authentication and authorisation. However, its role may change depending on different situations. Firstly, a SPoC is able to issue security tokens by itself. In this sense, a SPoC is a STS. Secondly, a SPoC is able to authenticate internal users, who have accounts in the SPoC's local domain, as well as to certify the attributes that the user has. Therefore, a SPoC can be both an Identity Provider and an Attribute Provider. Thirdly, a SPoC relies on trustworthy issuers to provide information about external users, who do not have accounts in the SPoC's local domain. In this case, the SPoC becomes a RP. Finally, a SPoC is able to translate a claim from another SPoC in the circle of trust, and thus a SPoC can also be a R-STS.

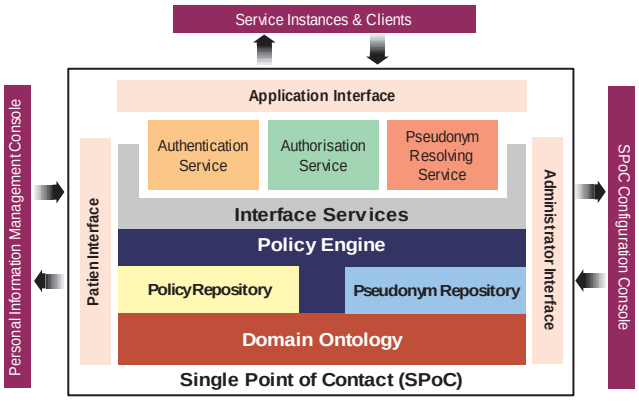

Fig. 1. The internal architecture of a SPoC

Another crucial challenge for a patient-centric e-Health platform is to obtain a variety of patient consents in an electronic way. Coiera et al. have identified four levels of e-consent, including: *general consent*; *general consent with specific exclusions*; *general denial*; and *general denial with specific consents* [20]. The information sharing policy syntax used by the SPoC is able to express all of the above, as well as *service authorisation*, *service subscription* and *investigation*. Furthermore, Pruski has identified the requirements for an e-consent language to capture *specific grantees*, *operations*, *purposes* and *period of validity*, and proposed a novel language called e-CRL [21]. The SPoC's policy syntax is as expressive as e-CRL, and has been successfully applied to other domains beyond health care, such as police and social care [22], [23].

III. Design

A. Internal Architecture

The internal architecture of a SPoC consists of the following modules, as shown in Figure 1:

1) Domain Ontology – A SPoC maintains a dynamic set of domain ontologies using an internal database. This provides the necessary vocabulary for the SPoC to issue various kinds of claims, and for the users and SPoC administrators to create a range of authentication and authorisation policies. Concepts and their relationships can be established and modified conveniently using the *SPoC Configuration Console*. The most notable concepts in the domain ontology include:

- *Domain*: This refers to a distinct business area that is administered by a single organisation. An e-Health

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application may involve multiple domains, such as hospitals, pharmacies, insurance companies, and research institutions. Typically, a domain is represented by one SPoC, and the SPoCs for multiple cooperative domains communicate with each other to form a Circle of Trust (CoT). In a CoT, each SPoC keeps a list of services provided by other SPoCs, as well as a table for translating concepts from foreign domain ontologies to native ones.

- *User*: This refers to a consumer of an e-Health application, which can be a person or an impersonated service. A user must be a member of at least one domain, which is able to certify the user's identity and attributes.
- *Object*: This refers to any entity that is managed by an e-Health application, such as patients and medical devices. An object is identified by a unique identifier (UID) assigned by its owner domain. To withstand contextual privacy attacks [24], opaque pseudonyms are often used in place of transparent UIDs [9].
- *Attribute*: This refers to an atomic unit of information that is used to describe an object. The SPoC supports flexible customisation of application-specific attributes, but it is recommended to use standard medical attributes defined by HL7 [25] or CHH [27] whenever possible. The DACAR e-Health platform stores attributes using Data Buckets [11].
- *Service*: A SPoC maintains the identity, public key, communication end-point and dependent attributes of the e-Health services provided by the local domain. A SPoC also maintains a list of services that are provided by other trustworthy domains in a CoT, as discussed above.

2) Policy Engine – On top of the Domain Ontology module is the Policy Engine, which comprises of a *Policy Repository* and a *Pseudonym Repository*.

The DACAR e-Health platform provides a novel and consistent policy syntax for patients to give explicit consent on the utilisation and dissemination of their own medical data. Considering that patients may have limited IT skills, a friendly user interface, i.e., the Personal Information Management Console, is provided for the patients to give their consents using structured natural language. Then, an interpretor converts these consents into formal policy syntax and uploads them to the Policy Repository. Technical details about the design and implementation of DACAR's policy syntax are provided in [11], [22] and [23]. Briefly, the policy syntax can be used for the following:

- ***Service Authorisation Policy***: This allows or denies an individual with certain identity, roles or application-specific attributes to consume an e-Health service.
- ***Service Subscription Policy***: This represents a patient's subscription to an e-Health service, and allows the service to access or modify a set of the patient's medical data, so that the service is able to perform its functionality. This set of medical data is referred to as the *dependent attributes* of that service.
- ***Specific Consent***: This allows or denies an individual with certain identity, roles or attributes, to access or modify a patient's medical data in a fine-grained manner.
- ***General Consent***: Sometimes it could be difficult for a patient to name the grantees of a specific consent, because they are unclear, unknown, or difficult to describe. In this case, a general consent is used to express the patient's willingness to share his/her medical data with e-Health services, from a certain domain, for a certain purpose, or in a certain application context.
- ***Audit***: This obligates information sharing in exceptional situations, such as a medical incident investigation.

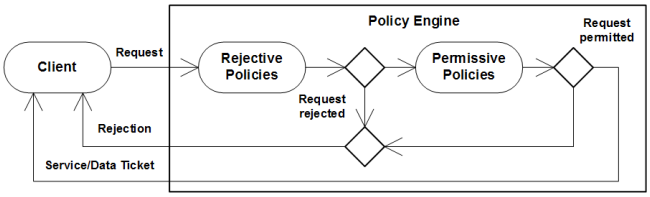

Fig. 2. Decision-making process of the Policy Engine

Figure 2 depicts the decision-making process of a Policy Engine. When it receives a request for an e-Health service or medical data, it firstly checks existing rejective policy rules in the Policy Repository. If an explicit rejection is found, the Policy Engine rejects the request immediately. Otherwise, it continues to check existing permissive policy rules. Unless an explicit permission is found, the request would still be rejected. This decision-making process allows a rejective rule to override a permissive rule, when both conflicting rules coexist in a Policy Repository. Furthermore, because a decision is made when the Policy Engine identifies an explicit rejective or permissive policy rule, the total number of relevant rules to analyse and the way they are ranked may have an impact on the average time that the Policy Engine takes to make a decision. Alternative decision-making strategies and performance improving methods will be investigated in future work.

3) Interface Services – The SPoC offers three interface services to e-Health applications and their clients, including:

- *Authentication Service*: This service verifies users' identities using flexible methods and issues claims about users' identities and attributes.
- *Authorisation Service*: This service accepts requests for e-Health services or medical data, analyses the requests using the Policy Engine and issues security tokens such as *Service Tickets* and *Data Tickets*.
- *Pseudonym Resolving Service*: This service uses the Pseudonym Repository to resolve opaque pseudonyms into transparent UIDs, so that privileged users or applications can associate anonymised medical data with real patient identities.

B. Authentication

An authentication mechanism enables an entity to prove to a remote end its identity using a cryptographic protocol.

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It is a fundamental building block for service oriented e-Health systems. A SPoC thus provides flexible methods for authenticating internal and external users.

Internal users refer to the members of a SPoC's local domain. Usually, a security infrastructure is already set up to manage internal user accounts and attributes. In this circumstance, a SPoC can be integrated to this existing infrastructure. For example, a SPoC may authenticate internal users of a Windows domain using Active Directory, and look up their attributes using LDAP. If such a security infrastructure did not exist, a SPoC would manage user accounts and attributes using its Domain Ontology database, and employ *Federated Identity Providers* for authentication purposes. Currently, multiple technologies are available for federated identity management, such as U-Prove [28] and OpenID [29]. The SPoC adopts U-Prove, because it separates the retrieval of identity information from the release of this information to destination sites, prevents the issuing organisations from tracking and linking user actions, and thus protects patients' privacy better.

When an internal user requests an e-Health service that is provided by the same domain, the SPoC supports a single sign-on and does not ask for the user's credentials repeatedly. In the case that the service is provided by a different domain, the SPoC issues a claim about the user's identity and attributes, and forwards it to the SPoC in charge of the foreign domain.

External users refer to people who do not have an account in a SPoC's local domain. In this circumstance, the users should firstly log on to the local SPoC to obtain a claim about their identity and attributes. This claim, together with a service request, is forwarded to the foreign SPoC in charge of the target service. The foreign SPoC translates the external user's attributes into its local domain ontology, and then proceeds to the authorisation process.

C. Authorisation

An authorisation mechanism endows different entities in a system with different access rights to sensitive information and resources. A SPoC uses its Policy Engine to match a request for an e-Health service or medical data to existing security policies, and determines whether the request should be permitted or not. If the request is permitted, the SPoC shall issue a security token, which entitles the requester to consume the service, or to Create, Read, Delete, and Update (CRUD) corresponding medical data as appropriate.

1) Service Authorisation: The Policy Engine requires a service request and a claim regarding the requester in order to make an authorisation for service access. The service request provides information about the target e-Health service, including its qualified name and favourite locations where the requester prefers a service instance to be created in the Cloud. The claim provides information about the requester's identity, role and other application-specific attributes. The Policy Engine analyses existing ***Service Authorisation Policies*** in the Policy Repository, as discussed in Section III-A. If the request is permitted, the SPoC issues the requester a *Service Ticket*, which is essentially a security token signed by the SPoC and encrypted by the requester's public key, and the target service's public key, respectively.

The contents of a service ticket include:

- The communication end-point of the e-Health service instance that the SPoC has initialised in the Cloud.
- Opaque pseudonyms of the requester's identity and attributes. The reason for including these in a service ticket will be explained in the following paragraphs.
- A symmetric session key for the service instance and its client to encrypt subsequent application-level messages.
- A time stamp and period of validity of the service ticket.

2) Data Authorisation: The DACAR platform uses Data Buckets [11] to provide long-term persistence of atomic medical data and associated meta-data. Each Data Bucket provides a CRUD service as an interface for e-Health services to access and modify medical data being stored in that bucket.

The Policy Engine requires a data request and a claim regarding the application service and its consumer in order to make an authorisation for CRUD operations on data. The data request provides information about the target Data Bucket, including the qualified name of the medical attribute, a query string that narrows down the result set, and the intended CRUD operations to be carried out on the results. The claim provides the identity of the application service, and the identity and attributes of the service consumer. In practice, a *Service Ticket* is reused for this purpose. This is why a service ticket contains opaque pseudonyms of a service consumer's identity and attributes. On the one hand, this facilitates an application service to impersonate its consumer while requesting medical data. On the other hand, the service consumer's privacy is also protected, as the service cannot reveal its consumer's real identity and attributes from the opaque pseudonyms.

A data authorisation process involves two steps. Firstly, the Policy Engine analyses existing ***Service Subscription Policies*** and ***General Consents*** in the Policy Repository to find out whether a patient has subscribed to this service, and whether the service is trusted in general. If so, the service identity would be sufficient for data access rights to be granted. Otherwise, the Policy Engine resolves the service consumer's identity and attribute pseudonyms and analyses existing ***Specific Consents*** to find out whether this particular service consumer is trusted by the patient. If so, the data access rights should be granted. Access rights to medical data is represented by a *Data Ticket*, which is essentially a security token signed by the SPoC and encrypted by the public keys of the application service and the target CRUD service respectively. The contents of a data ticket include:

- The communication end-point of the CRUD service.
- The approved operations over the result set.
- A symmetric session key for the application service and the CRUD service to encrypt application-level messages.
- A time stamp and period of validity of the data ticket.

D. Secure Web Service

The DACAR platform provides a software toolkit for programmers to develop Web services with message-level secu-

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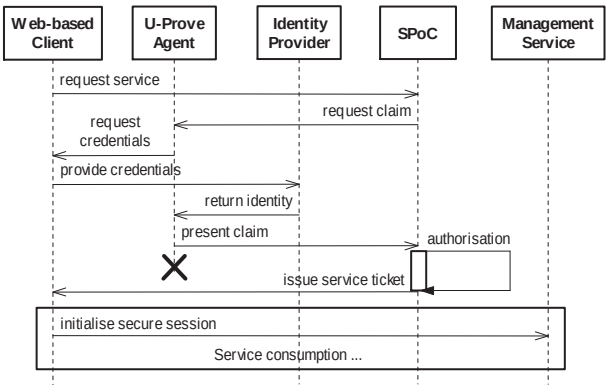

Fig. 3. Application scenario 1: A SPoC authenticates & authorises an internal user to consume an e-Health service

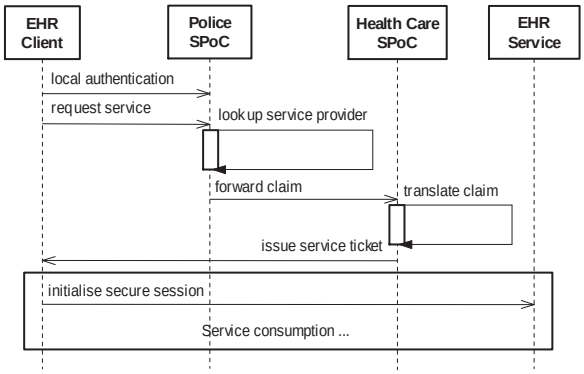

Fig. 4. Application scenario 2: A SPoC authorises an external user to consume an e-Health service

rity. As discussed in previous sections, both the *Service Ticket* and the *Data Ticket* carry a symmetric session key, which can be used by an e-Health service, its clients and the CRUD service of a Data Bucket to encrypt confidential application messages with a strong, yet efficient, algorithm, such as the Advanced Encryption Standard (AES) [30].

This security mechanism is designed to be a platform-independent solution for application developers to establish a secure communication model conveniently. It can be applied alone, or on top of any existing transport-level or message-level security mechanisms as a reinforcement.

E. Application Scenarios

This section provides a comprehensive view of the SPoC's work flow by presenting three concrete application scenarios:

Scenario 1: In this scenario, Deirdre, a patient of Chelsea & Westminster Hospital (C&W), wants to update her home address registered with the C&W SPoC using the Personal Information Management Console (PIMC), i.e., a Web-based front-end of the SPoC management service. The work flow of this application scenario is depicted by Figure 3.

Firstly, Deirdre opens the PIMC website in a browser. Because only C&W's internal users are allowed to consume this service, the SPoC needs to authenticate the user's identity. Instead of using a local identity management infrastructure, in this scenario the SPoC uses Federated Identity Providers and redirects Deirdre to a U-Prove Agent.

Secondly, the U-Prove Agent displays a list of trustworthy Identity Providers and Deirdre chooses to log on from one of them, e.g., Windows Live ID. Deirdre enters her credentials on the log on page, and the Identity Provider issues a claim about Deirdre's identity, e.g., "Deirdre@hotmail.com", to the U-Prove Agent. However, it should be noted that the Identity Provider cannot find out that Deirdre is using this identity to mange her health care information through the C&W SPoC, so Deirdre's privacy is protected.

Thirdly, the U-Prove Agent forwards the claim to the SPoC, which in turn starts the authorisation process. The SPoC works out that "Deirdre@hotmail.com" has a patient account with the hospital, and a ***Service Authorisation Policy*** permits the *Patient* role to consume the SPoC management service. Hence, the SPoC issues a *Service Ticket* to the PIMC client, which contains the communication end-point of the SPoC management service in the Cloud and a valid session key.

Fourthly, the PIMC client establishes a secure session with the SPoC management service, and Deirdre uses the Web-based user interface to update her home address.

Scenario 2: In this scenario, David, a police officer of Lothian & Borders Police, wants to view the Electronic Health Record (EHR) of a victim in a traffic accident investigation. The EHR service is managed by the C&W SPoC, which has a trust relationship with the Police SPoC. The work flow of this application scenario is depicted by Figure 4.

Firstly, David logs on from his local SPoC for the police domain and requests the EHR service. The Police SPoC realises that the service being requested is not provided by the local domain, and looks it up in the list of services provided by other SPoCs in the circle of trust. It turns out that the EHR service is offered by the C&W SPoC, so the Police SPoC issues a claim about the requester's identity and attributes, e.g., "**Name**:*David*; **Role**:*Police Officer*". This claim is encrypted, so that only the C&W SPoC is able to view its contents.

Secondly, the Police SPoC forwards the claim, together with an EHR service request, to the C&W SPoC, which translates the claim into local domain ontology, e.g., "**Name**:*David*; **Role**:*Data Viewer*; **Level**:*6*". A ***Service Authorisation Policy*** permits the *Data Viewer* role to consume the EHR service, so the C&W SPoC issues the requester a *Service Ticket* containing the communication end-point of an EHR service instance in the Cloud and a valid session key.

Finally, the EHR client establishes a secure session with the EHR service instance, and David obtains part of the victim's health care information that is classified at or below *Level 6*.

Scenario 3: In this scenario, Kate, a nurse of Chelsea & Westminster Hospital (C&W), wants to set up a number of medical sensors controlled by a handheld device to upload Deirdre's six physiological vital signs to the Early Warning Score (EWS) service. The work flow of this application scenario is depicted by Figure 5.

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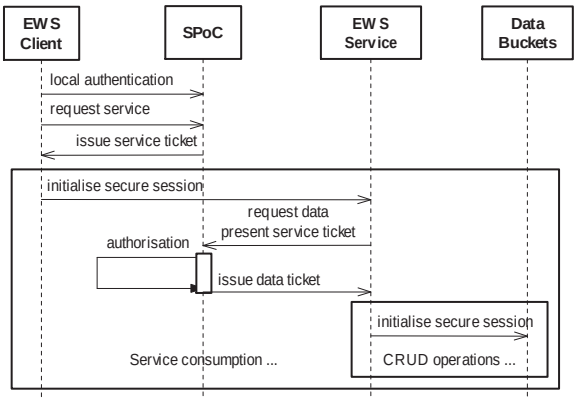

Fig. 5. Application scenario 3: A SPoC authorises an application service to access medical data

EWS is a clinical service widely used in UK hospitals. Traditionally, EWS requires medical staff to record a patient's blood pressure, heart rate, body temperature, respiration rate, Oxygen saturation and pain level on a paper-based observation chart periodically, and to calculate a risk score according to predefined equations. In the case that a patient is evaluated to be *at risk*, the medical staff should take appropriate actions immediately. This traditional approach is prone to mistakes, as the measurement, recording and calculation work all need to be done manually. DACAR's EWS e-Health service fully automates this process by capturing vital signs using medical sensors, transmitting the values to data buckets using smart hand-held devices, monitoring patient status constantly in real-time, and pushing alerts to medical staffs' mobile phones.

Firstly, Kate starts the EWS client running on a smart handheld device, logs on to the local SPoC and requests the EWS service. A ***Service Authorisation Policy*** permits the *Nurse* role to consume the EWS service, and thus the SPoC issues a *Service Ticket* containing the communication end-point of an EWS service instance in the Cloud, a valid session key and pseudonyms of Kate's identity and role.

Secondly, Kate sets up the application context by scanning her RFID staff card, the RFID label of the ward, and Deirdre's RFID wristband. The EWS client submits the *Service Ticket* to the EWS service instance, and establishes a secure session, captures vital sign values using medical sensors, marks each value with a set of meta-data, such as who captured the measurement for which patient using which device, and at what location and time, and then uploads the data samples to the EWS service.

Thirdly, the EWS service monitors Deirdre's status constantly by analysing the vital sign values it has received. The service also stores these data samples into corresponding Data Buckets, so that other e-Health services, such as Audit Trail, Electronic Health Records and Evidence-based Medicine, may reuse this data. To store data, the EWS service requires access rights to the CRUD services of the Data Buckets. Hence, it sends a data request and the original *Service Ticket* to the SPoC. The SPoC analyses existing ***Specific Consents***, ***Generic Consents*** and ***Service Subscription Policies*** to find out whether Deirdre allows Kate, the *Nurse* role, or the EWS service in general to upload her vital sign data. If so, the SPoC issues a *Data Ticket*, which contains the communication end-points of corresponding CRUD services in the Cloud, the permitted operations and valid session keys.

Finally, the EWS service instance establishes secure sessions with the CRUD services and starts to upload data samples to the Data Buckets.

IV. Implementation

Currently, a prototype of the SPoC has been implemented using Microsoft .NET Framework 4.0, Windows Communication Foundation (WCF) and Windows Identity Foundation (WIF). The *Authentication*, *Authorisation* and *Pseudonym Resolving* services are deployed as self-hosting network services running in Windows Server 2008. The SPoC is integrated with a Windows security domain, authenticates internal users with Kerberos and X.509 certificates, and issues claims about user identities and attributes with Active Directory Federation Service (ADFS) 2.0. The SPoC can also authenticate external users with Federated Identity Providers using U-Prove, but this feature is not mature, as the U-Prove technology is still under development. The SPoC's Domain Ontology database is implemented using SQL Server 2008, and the information sharing policy syntax and the Policy Engine are implemented in Java.

Furthermore, a number of client software and demonstration applications have also been implemented. The SPoC administrator's Configuration Console is implemented with Windows Presentation Foundation (WPF) as both a standalone application and a XAML Browser Application (XBAP). The patient's Personal Information Management Console is implemented with ASP.net. The Early Warning Score (EWS) service is implemented as a WCF service hosted by IIS 7 Web server, and a variety of EWS clients are developed on computer, iPhone and Windows mobile platforms.

The DACAR platform and its proof-of-concept e-Health services have been deployed on the Flexiscale public Cloud [26] for testing and demonstration purposes. Preliminary experimental results about system performance have been published in [11]. In the mean time, a private Cloud infrastructure is being built at Chelsea & Westminster Hospital in London. The stability and scalability of the system and selected e-Health services will be evaluated in a real-life clinical environment.

V. Conclusion and Future Work

The main expectations of e-Health are to provide better ways to exchange and share medical information, and to improve the quality of services offered to the patients. However, a significant challenge is to protect patients' privacy and ensure that sensitive medical data is never lost or misused. The Data Capture and Auto Identification Reference (DACAR) project aims to provide a Cloud-based secure e-Health service platform, of which the core component is the **Single Point of Contact** (SPoC). A SPoC facilitates the development

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and integration of e-Health services by addressing the most fundamental security requirements, including authentication, authorisation, secure data transmission and persistence.

A SPoC authenticates the users of an e-Health system in many flexible ways. Firstly, it can be integrated with an existing security infrastructure to authenticate internal users, who have accounts in the SPoC's local domain. Secondly, it can manage user identities with Federated Identity Providers using the U-Prove protocol. Last but not least, multiple SPoCs can form a circle of trust and authenticate external users from other trustworthy domains in a claim-based fashion.

A SPoC supports dynamic creation of domain ontologies, which provide a necessary vocabulary for medical information management and access control. Furthermore, a SPoC supports a patient-centric health care model and provides user friendly interfaces for patients to create security policies to govern the utilisation and dissemination of their own medical data. As a security authority, a SPoC issues *Service Tickets* for privileged users to consume various kinds of e-Health services, and *Data Tickets* for privileged e-Health services to create, read, update and delete (CRUD) patients' medical data in Data Buckets. Both the service and data tickets contain symmetric session keys for e-Health services, their clients and CRUD services of Data Buckets to encrypt application-level messages. Hence, the integrity and confidentiality of sensitive medical data are guaranteed in transmission. This security mechanism is platform-independent, and thus can be used alone, or on top of any existing transport-level or message-level security mechanisms as a reinforcement.

Currently, a prototype of the DACAR platform and its demonstration applications have been implemented and deployed on the Flexiscale public Cloud. A more comprehensive evaluation of the platform in a real life clinical environment will be carried out at Chelsea & Westminster Hospital in London. In future work, the design and implementation of the SPoC's policy engine and the U-Prove authentication module will be improved. Another avenue of future work is to build bridges between DACAR and other e-Health service platforms, e.g., Microsoft Health Vault, to enable secure sharing of health care information on a larger scale, and ultimately to integrate primary, secondary and home care.

ACKNOWLEDGEMENT

This research is partially supported by grant from UK's Technical Strategy Board and EPSRC. Also, we acknowledge the hard work of our research partners, including Microsoft Corp., HoIP CIC, Flexiant Ltd., Chelsea & Westminster NHS Foundation Trust, Imperial College London, Kodit Database Ltd., GS1 UK Ltd. and CipherLab UK Ltd.

REFERENCES

[1] D. Slamanig and C. Stingl, "Privacy Aspects of eHealth," in *Proc. of ARES'08*. IEEE, March 2008, pp. 1226–1233.

[2] H. J. Cheong, N. Y. Shin, and Y. B. Joeng, "Improving Korean Service Delivery System in Health Care: Focusing on National E-health System," in *Proc. of eTELEMED'09*. IEEE, 2009, pp. 263–268.

[3] "Federal Health IT Initiatives," [Online] http://www.hhs.gov/healthit

[4] "Canada Health Infoway," [Online] http://www.infoway-inforoute.ca

[5] J. Dzenowagis and G. Kernen, "Global vision, local insight," World Health Organization Press, Report for the World Summit on the Information Society, 2005.

[6] R. B. Prasad, C. Eunmi, and L. Ian, "A Taxonomy and Survey of Cloud Computing Systems," in *Proc. of NCM'09*. IEEE, 2009, pp. 44–51.

[7] M. Endrei, J. Ang, A. Arsanjani, S. Chua, P. Comte, P. Krogdahl, M. Luo, and T. Newling, *Patterns: Service-Oriented Architecture and Web Services*. IBM Redbooks, July 2004.

[8] M. Smith, W. Buchanan, C. Thuemmler, D. Bell, and R. Hazelhoff, "Analysis of Information Governance and Patient Data Protection within Primary Health Care," Int. Journal for Quality in Health Care, 2010.

[9] S. Benzschawel and M. D. Silveira, "Protecting Patient Privacy when Sharing Medical Data," in *Proc of eTELEMED'11*. IEEE, 2011.

[10] DACAR. Data capture and auto identification reference project. TSB/EPSRC project No. 400092. [Online] www.dacar.org.uk

[11] L. Fan, W. Buchanan, C. Thuemmler, O. Lo, A. S. Khedim, O. Uthmani, A. Lawson, and D. Bell, "DACAR Platform for e-Health Services Cloud," in *Proc of CLOUD'11*. IEEE, July 2011, pp. 1–8.

[12] R. Zhang and L. Liu, "Security Models and Requirements for Healthcare Application Clouds," in *Proc. of CLOUD'10*. IEEE, 2010, pp. 268–275.

[13] O. Kilic, A. Dogac, and M. Eichelberg, "Providing Interoperability of eHealth Communities Through Peer-to-Peer Networks," *IEEE TITB*, vol. 14, Issue 3, pp. 846–853, 2010.

[14] W. A. Alrodhan and C. J. Mitchell, "Enhancing User Authentication in Claim-based Identity Management," in *Proc. of CTS'10*. IEEE, 2010, pp. 75–83.

[15] I. Thomas and C. Meinel, "Enhancing Claim-Based Identity Management by Adding a Credibility Level to the Notion of Claims," in *Proc. of SCC'09*. IEEE, 2009, pp. 243–250.

[16] D. Baier, V. Bertocci, K. Brown, E. Pace, and M. Woloski, *A Guide to Claims-based Identity and Access Control*, Patterns & Practices. ISBN: 9780735640597, Microsoft Corp., Jan. 2010.

[17] N. Ragouzis, J. Hughes, R. Philpott, and E. Maler, "Security Assertion Markup Language (SAML) V2.0 Technical Overview," OASIS, Tech. Rep., Oct. 2006.

[18] A. Nadalin, M. Goodner, M. Gudgin, A. Barbir, and H. Granqvist, "WS-Trust Specification v1.4," OASIS Standard, Tech. Rep., Feb. 2009.

[19] "Web Services Federation Language (WS-Federation) v1.1," BEA, BMC, IBM, Layer 7 Technologies, Microsoft, Novell and VeriSign, Tech. Rep., Dec. 2006.

[20] E. Coiera and R. Clarke, "e-Consent: the Design and Implementation of Consumer Consent Mechanism in an Electronic Environment," *JAMIA*, vol. 11, no. 2, pp. 129–140, 2004.

[21] C. Pruski, "e-CRL: A Rule-Based Language for Expressing Patient Electronic Consent," in *Proc. of eTELEMED*. IEEE, 2010, pp. 141–146.

[22] O. Uthmani, W. Buchanan, A. Lawson, C. Thuemmler, and L. Fan, "Novel Information Sharing Syntax for Data Sharing Between Police and Community Partners, Using Role-Based Security," in *Proc. of ECIW'10*. IEEE, 2010, pp. 394–402.

[23] B. Buchanan, L. Fan, A. Lawson, R. Scott, B. Schafer, C. Tuemmler, and O. Uthmani, "Interagency Data Exchange Protocols as Computational Data Protection Law," *JURIX*, vol. 223, pp. 243–147, Dec. 2010.

[24] X. Lin, R. Lu, X. Shen, Y. Nemoto, and N. Kato, "Sage: a Strong Privacy-preserving Scheme Against Global Eavesdropping for eHealth Systems," *IEEE J-SAC*, vol. 27, Issue 4, pp. 365–378, May 2009.

[25] "Health Level Seven," [Online] www.hl7.org

[26] "Flexiscale public Cloud," [Online] http://www.flexiant.com/products/flexiscale/

[27] "The Compound Healthcare Headings Model - What Is It and How to Use It," Clinical Data Structures & Implementation Support, NHS Scotland Data Recording Advisory Service, Tech. Rep., June 2011.

[28] C. Paquin and G. Thompson, "U-Prove CTP White Paper," Microsoft, Tech. Rep., March 2010.

[29] "OpenID Authentication 2.0," OpenID Foundation, [Online] http://openid.net/specs/openid-authentication-2_0.html

[30] J. Daemen and V. Rijmen, *The Design of Rijndael: AES - The Advanced Encryption Standard*. ISBN:3-540-42580-2, Springer, 2002.

 ISBN: 978-1-61208-179-3

Creation of OAIS-Compliant Archival Packages for Long-Term Preservation of Regulatory Metadata, Records and Dossiers

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Abstract – **The authors continue their previous research on the long-term preservation solution for complex digital objects preserved as archival information packages in the domain of pharmaceutical records by evolving the proof of concept application "ArchiMed" to the level of the prototype. The research is put in the context of the responsibility of Marketing Authorisation Holders for submitting medicinal products' dossiers to the National Competent Authorities, i.e., regulatory institutions, and the problems of long-term preservation of such records. The authors explain the problems those institutions are facing, the theory behind the long-term preservation concept and the requirements that digital preservation systems are facing with. The authors also explain the regulatory business process for better understanding of the organisational differences and technical issues on the European level. The differences between four formats of dossiers, NtA, CTD, NeeS and eCTD, are indicated. Based on the detected problems and previous proof of concept, the ArchiMed module was developed in order to further test its functionalities required by the digital preservation theory and to prove its conformance with the most important international standards like ISO 15489-1, ISO 14721: 2003 and others. The authors conclude that the proposed solution contributes to the regulation of archival procedures in the area of long-term preservation of regulatory records in the digital form. The paper shows how to regulate the regulatory process in the domain of control of medicines from the archival point of view with the aim of long-term preservation of important electronic records.**

Keywords – digital preservation, medicinal products, dossiers, OAIS, ArchiMed, regulatory business, Europe, eCTD.

I. INTRODUCTION

Marketing Authorisation Holders (MAHs) are responsible for submitting medicinal products' dossiers and National Competent Authorities (NCAs) as regulatory institutions are responsible for granting marketing authorisation for their medicinal products. Marketing authorisation is issued by NCA after the positive assessment of submitted dossiers. The EU Member States' NCAs started to receive electronic medicinal product dossiers published according to the electronic Common Technical Document standard (eCTD) [1][2]. An eCTD dossier consists of sequence(s), modules and sections of administrative records, summaries, quality records, non-clinical and clinical records, and XML backbone. It is recommended that a MAH organises the eCTD dossier for the same medicine always in the same root folder, but this requirement is not obligatory. Beside eCTD, there are several other standards for pharmaceutical records in circulation, and NCAs often have additional national requirements concerning records, which are not included in international standards and have to be submitted separately, usually in the *working-documents* folder.

MAHs and NCAs have difficulties with managing dossiers and other records and with preparing them for the long-term preservation. MAHs should be able to preserve their records in order to meet regulatory and legal requirements, to provide support for everyday business processes, to provide business continuity and legal evidence when needed. NCAs should prepare for digital archiving in order to react on time in case of any public safety incident. Additionally, they are often under supervision of national archival authorities. Difficulties in managing and preserving electronic dossiers and other records, in a MAH organisation, can result with failure when their headquarters or NCA asks them to show medicinal product records that were valid for the specific product in the specific period, when they are asked to show records that were submitted for particular market, or to show the latest state of the dossier. NCAs have similar difficulties and more serious obligations regarding demands of the public health. That is why we are proposing a better solution in managing and archiving regulatory dossiers and records. The proposed solution is a result of extension of our previous research [3] and integration with the newly developed application for managing regulatory processes. The concept that lies beneath the solution is strongly process-oriented and based on ISO 14721:2003 – Open Archival Information System Reference Model.

Next, the research that preceded the development of the proposed solution is presented followed by the detailed description of the regulatory business processes. Then, the proof of concept and integration into the prototype application is explained followed by the conclusion and information on the future research.

 ISBN: 978-1-61208-179-3

II. RESEARCH

Archival materials, in this case dossiers and other records created in the process of controlling medicines, are easily created by the use of information technology. The same technology also enables those materials to be easily changed or modified. For various usages in the everyday workflow this is an advantage but in the context of the preservation it should be looked upon as a disadvantage. Archived materials, once they become records, should not be changed in any way that affects their authenticity, integrity, reliability or usability, as defined by ISO 15489-1 [4]. This could be solved by storing those records in a safe place, only if the technology would not change substantially in the matter of few years. Kuny [5] is consenting with the Moore's law when stating: "Organizations are being asked to make fiscal commitments to creating complex technical infrastructures that change every 3-5 years and which require increasingly expensive technical expertise to keep functioning." Nevertheless, when the electronic records need to be preserved in the long-term it is not only the problem that the infrastructure, i.e., computer architecture, is changing quickly, but the software applications and file formats change as well. Therefore, to be able to read an old e-record it is necessary either to keep the original hardware/software solutions, which is highly unlikely and very expensive, or to use one of the other techniques, migration most likely, as in Thibodeau [6]. This means changing the records in order for them to function and be readable using the latest technology. How to do this without endangering authenticity?

The Authenticity Task Force [7] differentiates two kinds of establishing the notion of authenticity – the presumption and the verification of authenticity.

- *A presumption of authenticity* is an inference that is drawn from known facts about the manner in which a record has been created and maintained. The evidence that supports the presumption that the record creator created and maintained them authentic are enumerated in the Benchmark Requirements Supporting the Presumption of Authenticity of Electronic Records. A presumption of authenticity will be based upon the number of requirements that have been met and the degree to which each has been met. The requirements are, therefore, cumulative: the higher the number of satisfied requirements, and the greater the degree to which an individual requirement has been satisfied, the stronger the presumption of authenticity.
- In any given case, there may be an insufficient basis for a presumption of authenticity, or the presumption may be extremely weak. In such cases, further analysis may be necessary to verify the authenticity of the records. *A verification of authenticity* is the act or process of establishing a correspondence between known facts about the record and the various contexts in which it has been created and maintained, and the proposed fact of the record's authenticity.

In any case, it is best if it could be proved that the records are not changed in the way that their authenticity is questioned, or, when the migration is needed, that the authenticity was not compromised during that process. Both requirements could be answered by the properly established preservation environment with properly implemented and documented preservation processes and procedures. OAIS reference model [8] could be used to build such a system environment. Although it does not suggest the concrete technology to be used it presents a model to be built using the latest technology. By creating all the functional entities and their interrelated connections, a trusted digital preservation environment could be established. OAIS information model comprises of three types of information packages – submission information package (SIP), archival information package (AIP), and dissemination information package (DIP). It is important to understand that if both Marketing Authorisation Holder and National competent authority have implemented the digital archive according to the OAIS reference model than what MAH creates is a DIP from their standpoint while the same package is a SIP from the NCA's standpoint it is a SIP. We will refer to this notion later on in the explanation of the functions of the proposed solution for long-term preservation of authentic medicinal records.

In the process of long-term preservation the metadata are of the utmost importance. Dobreva and Ikonomov [9] state that "there are two key issues which need to be considered *vis-à-vis* metadata and preservation:

1. What metadata are needed for preservation purposes (...) (besides assuring a reliable preservation process, they should help the designated communities to understand the resources), and
2. How to preserve the metadata accompanying existing digital objects.

Having all these in mind, preservation metadata area provides many challenges. What preservation metadata to use? What minimum set needs to be supplied in order to guarantee a reliable preservation process? How to automate the creation of preservation metadata? How to guarantee that the digital resources developed within a particular project are accompanied by sufficient preservation quality metadata? And how to guarantee interoperability between multiple existing schemes? It is not easy for any organisation or project to make decisions regarding the metadata in this situation." Having acknowledged these problems and the fact that there are several main metadata standards, in our previous work [3] we have suggested the minimum set of metadata to be preserved mapped them across the different standards (METS, ISO 23081, ISO 14721:2003) for ease of the future preservation actions. Also, in our previous research we have developed a model for the long-term preservation of pharmaceutical records in the eCTD file format, determined the functionalities that an application intended for the creation of a complex electronic object record of a medicine, intended for the long-term preservation in a digital archive, should have, and created a proof of concept – ArchiMed – the application for archiving and long-term preservation of eCTD records. Upon the latest research we have determined the improvement possibilities and developed the application further, from the proof of concept to the prototype level, in order to be able to advance managing the regulatory processes.

 ISBN: 978-1-61208-179-3

III. REGULATORY BUSINESS PROCESSES

Regulatory processes in the domain of control of medicines are very complex in Europe [16]. There are a lot of stakeholders involved and collaboration between them is difficult due to their organisational differences and technical issues. MAHs could submit dossier and other records for marketing authorisation, renewal of that authorisation or variation of authorisation for medicines placed on one particular national market, several European Member States' markets or for a single European Community market. If MAH sends application for more than one market, it has to opt between tree different procedures – centralised procedure, decentralised procedure or mutual recognition procedure. Selection of marketing authorisation procedure depends on the legal basis, type of application and MAH's sales strategy. As we will see later, this will be an important factor in the creation of digital archival records.

The *centralised procedure (CP)* is set aside for medicines applied to the single market of the Community. Marketing authorisation granted under this procedure is suitable for all Member States markets and this procedure is led by the European Medicines Agency. It is mandatory for innovative or biosimillar medicines developed by biotechnological manufacturing processes such as "recombinant DNA technology, controlled expression of genes coding for biologically active proteins (…), hybridoma and monoclonal antibody methods (…), medicinal products (…) containing a new active substance which (…) was not authorised in the Community" (for AIDS, cancer, neurodegenerative disorder, diabetes), and for orphan medicines [11]. Medicinal products with a new, unauthorised active substance for other treatments and medicines that significantly improve therapies or represent improvements in scientific or technological sense, and generic or hybrid medicines, which have reference medicinal product authorised by European Medicines Agency can also be authorised via the centralised procedure.

The *decentralised procedure (DCP)* is a marketing authorisation procedure that starts at the same time in a referent Member State and all other involved Member States. The referent member state is represented by NCA in the particular Member State that leads the process by producing assessment report. Assessment report is the basis for granting approvals in other NCAs.

The *mutual recognition procedure (MRP)* is a procedure of granting marketing authorisation in which applicant sends its application to other Member States after the medicine has been approved for market in the referent Member State.

The *national procedure (NP)* is reserved for one national market only.

Majority of NCAs have their own particular requirements regarding the dossiers and this makes submitting of application even more complex. That is the main reason why we have decided to shift back to business processes instead of focusing to the business process resources or dossiers. The main problem lies in usage of different formats of business process resources (dossiers). Although some of them have become obsolete on the conceptual level [12], some medicines, which are important for different markets do not have new documentation, some applicants are incapable of publishing technically valid electronic dossiers, and for stated reasons even now applicants submit dossiers in four different formats – NtA (Notice To Applicants), CTD (Common Technical Document), NeeS (Non-eCTD electronic Submission) and eCTD. NtA consists of four parts (administrative, pharmacological-biological, nonclinical and clinical part) and it is considered to be obsolete on the conceptual level. CTD, NeeS and eCTD share the same structure and granulation (administrative module, module of summaries, quality module, module for nonclinical data and module for clinical data), but CTD is a paper dossier, and NeeS and eCTD are e-dossiers. The difference between NeeS and eCTD is that NeeS does not contain XML backbone and thus does not enable the review software to monitor the lifecycle of contained files automatically. However, it is easier for MAHs to produce NeeS dossier because they do not have to invest in specialised publishing tools. Because of that majority of smaller generic pharmaceutical companies and MAHs prefer to use NeeS. Bigger companies work with eCTDs, but staff of their local MAHs subsidiaries lack the technological knowledge sufficient for producing technically valid dossiers. eCTD dossiers are a novelty even for NCAs' staff, despite the Heads of medicines agencies meeting in Reykjavik in 2005 during which the shift to eCTD was agreed.

Because of situation described above the dossier-centric approach has resulted in the operational problems for MAHs and NCAs and in insufficiencies of records management technologies so far. Typical large IT vendors usually do not have enough know-how for regulatory affairs' processes, especially for NCAs' processes. MAHs and NCAs respond to these difficulties by avoiding the use of the eCTD dossiers, because, for using electronic dossiers in-house, processes and organisation of work should be carefully designed and heavy, non-scalable, partially operational and very expensive typical IT solutions should be invested into [13]. That is the very reason why we are suggesting turning back to the root problem. It means satisfying the requirement for managing regulatory processes and regulatory affairs first, and then managing dossiers and documents.

Our first goal is to focus on the regulatory business processes. They are supported by carefully designed metadata and by a process of metadata inheritance starting from the regulatory processes themselves and going all the way to the related archival packages with their components and files. Metadata can be colected even reversibly, from XML of the eCTD dossier back to the process.

Our second goal is to automate the creation of archival information packages (AIPs) and dissemination information packages (DIPs). Dissemination information packages are packages of content prepared for dissemination to NCAs or to other stakeholders from MAHs' perspective. For NCAs they will be considered as submission information packages. AIPs should enable long-term preservation of content with pertaining metadata in a manner that they logically encapsulate content and enable reporting about the content. Reports can provide information necessary for long-term preservation activities, i.e., information about the containing filetypes that might become obsolete and need to be migrated.

 ISBN: 978-1-61208-179-3

IV. PROOF OF CONCEPT AND INTEGRATION INTO THE PROTOTYPE APPLICATION

Previously developed proof of concept application "ArchiMed"[3] was improved and is being integrated with the newly developed application for managing regulatory affairs' processes called "READY", produced by Nanokinetik. ArchiMed is being integrated into READY on the module level. The newly created prototype made of READY and ArchiMed has functionalities for managing regulatory processes and managing dossiers as well as other documents and metadata as the OAIS-compliant information packages.

Information packages, in the previous, self-standing, ArchiMed application were divided into SIPs (1 and 2) and AIPs. SIP 1 represented the package for eCTD or NeeS dossiers, and SIP 2 represented the package for *workingdocuments*. AIPs were used for archived content in the external repository.

In the new prototype the information model was redesigned (compare with [3]) and now it additionally encompasses flexible AIPs and DIPs – as a category reserved for content prepared for MAH–NCA communication. DIP prepared as described is a SIP from NCAs' perspective and the basis for creation of NCAs' AIPs (see Figure 1). The main difference between AIPs and the other packages prepared by the new prototype is that AIPs can be versioned, which means that new components and files can be added, while DIPs/SIPs cannot be modified or deleted at all. This restriction is introduced because the content sent or received by NCA should have quality of non-repudiation. Each version of AIPs can be tracked reversibly so AIPs have broad long-term preservation prospect and quality of authenticity at the same time. Authenticity is supported by versioning, tracking and protection of each version, and every part of its content, by the MD5 checksum. For the purpose of the development of the new prototype, content of packages was redesigned and a new category of component was added into the prototype data model. It is positioned on a level between package and file, introduced for enabling adding, editing or deleting large "chunks" of information previously prepared by the READY application or other external system. Files and components are categorized. In this sense stand-alone files also pertain to one category. Non-file components are *eSubmissions* (category which describes structure of root folders, sequences, modules, sections, and files), *workingdocuments* (category with possibility to pre-define or import directory structure for files required by a particular NCA) and other categories created according to the business needs. The new prototype also introduced changes related to metadata describing packages and functions.

The main objects of ArchiMed module are:

- package (AIP in OAIS context),
- disseminated package (DIP/SIP in OAIS context, depending on the standpoint),
- component, and
- file.

The metadata was coded according to the international standards ISO 14721:2003 Open Archival Information System – Reference Model [8], ISO 23081 Metadata for records [14][15], and METS scheme [16]. Different metadata groups from the stated standards and scheme were reduced to a common denominator. The intention was to have possibility of mapping ArchiMed metadata to OAIS, ISO 23081 and METS metadata groups. Even external metadata, which are extracted from the content or READY application, can be mapped to the standards, i.e., metadata on an eCTD document type definition version belongs to OAIS provenance preservation description information, ISO 23081 use metadata group and to METS techMD class of descriptive metadata section [3]. Some metadata describing packages are also functioning as identifiers – hash strings and metadata related to the validity of package and validity check intervals.

Disseminated package contains similar metadata and it could be created out of one or more components form one or more packages because it represents what is going to be sent from MAH to NCA. Component related metadata include identifier, hash strings and relation metadata for connection component with a particular package. File metadata additionally take account of file types, extensions and version of file formats, because ArchiMed enables content analysis and reporting for preservation purposes. This is the realisation of the *Preservation planning* function of OAIS functional model. Other component metadata are inherited from the READY application and the content. The content related metadata is metadata about applicant, agency, invented name, active substance etc.

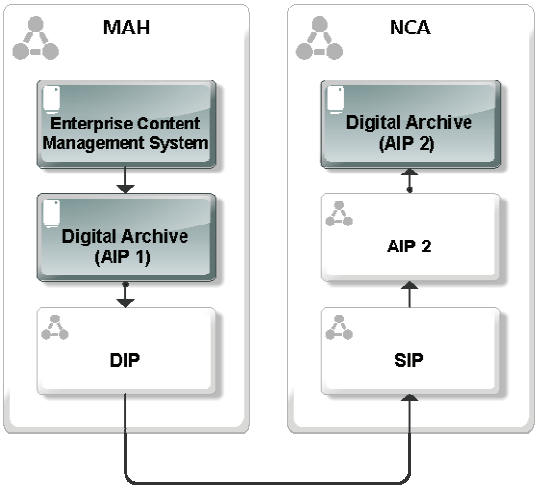

Figure 1. Conversion from the MAHs' Archival Information Package (AIP 1) to the Dissemination Information Package (DIP) intended for the National Competent Authorities (NCAs) where they receive it as the Submission Information Package (SIP) and preserve as AIP 2.

Functions of ArchiMed module prototype are divided to package functions, component and file functions, and reporting functions.

1. *Package functions*

1.1. *Create package* – function inserts new AIP to database and creates basic information from input para-

meters. Function also adds version number of AIP and generates MD5 hash for every file in the component, every component of the package and for the whole AIP package. XML file with metadata is created and value of MD5 hash function is added into the XML metadata file. If the hash check interval is set, function *check package* will be called on particular date and time.

1.2. *Edit package* – function updates package information in database and raises the version of the package. All package attributes can be edited by using this function (i.e., components and files can be added into package). The new XML metadata file is created, MD5 check is recalculated and its new value is embedded into the XML file.
1.3. *Delete package* – deletes package from the database.
1.4. *Create dissemination package* – creates package that will be delivered to NCA, local MAH, or other regulatory affairs' stakeholder.
1.5. *Get package* – function returns package or packages information from the database. Packages are retrieved according to the selected descriptors, i.e., function gets all packages for a particular medicinal product that was valid for particular period.
1.6. *Get all packages* – function returns all packages' information from the database.
1.7. *Check package* – function performs MD5 hash check on a specified package.
1.8. *Check all packages* – function performs MD5 hash check on all packages and finds invalid ones.

2. *Component and file functions*

2.1. *Select component type* – function categorizes components. Files and components are categorized (they have a value of component type attribute; in this sense stand-alone files also pertain to one category). All additional components except *eSubmission* and *workingdocument* should be defined with *Add component type* function. Function *Select component type* is called after *Create package*, *Add component/file* or *Edit package*.
2.2. *Add component type* – each structure should be defined as a component of the package.
2.3. *Delete component type* – function deletes unnecessary component type if there is no package containing component of such type in the database.
2.4. *Add component/file* – function inserts new component into a package. Function is also called when creating a package. It generates MD5 hash for the created component(s) and file(s). *Valid-until* metadata can be used for adding information about validity of the component (i.e., when MAH receives license that is valid until a defined date). This information can be imported and mapped from the READY application's metadata.
2.5. *Edit component/file* – function updates component in a package, i.e., edits component for new version of the package.
2.6. *Delete component/file* – function deletes component and/or files from a package in order to prepare new version of the package.
2.7. *Check component/file* – function performs MD5 hash check on a specified component in a package (component could be a file).

3. *Report functions*

3.1. *Check expiration* – function returns all packages that expire before the defined date.
3.2. *Filetype report* – function returns statistical data for every file type in repository per package and per component in the package. Function should be used for preparation of the migration of independent files and files in components (all components in a package) into new version of the package.
3.3. *Sent to partners report* – function returns all disseminated packages that have been sent to the selected partner (MAH should be able to prove which package was sent to which NCA).

For the example of proof of concept and integration into the prototype application see Figure 2.

V. CONCLUSION AND FUTURE RESEARCH

We have put this research in the context of the regulatory processes in the domain of control of medicines. We have described the difficulties the Marketing Authorisation Holders have with managing dossiers and other records and with preparing them for the long-term preservation. Upon researching the relevant resources and clarifying the digital preservation requirements, we have explained the regulatory business process and possible marketing authorisation procedures, as well as the types of records created and used. In this research we have argued not only the importance of long-term preservation of digital records created in the process of controlling medicines but the importance of their preservation of the authentic records too. In any legal dispute involving digital medicinal products' dossiers it is very important that it is possible to prove their authenticity, integrity, reliability and usability. In that sense the records should be preserved in the way that any change, intentional or unintentional, is detected. It is also important that the system is capable of automatic records' validation possibilities, background or initiated at any time. The system we have proposed is having these characteristics and is also capable of checking the expiration state of the records, of reporting the file types in the archive thus facilitating the migration procedures etc. We have developed the prototype application READY. Previously developed ArchiMed proof of concept has been developed as READY's module. We have also presented the ArchiMed module's package functions, component and file functions, and report functions.

It is important to point out that the prototype application is fully consistent with the OAIS's functional model's Preservation planning function. It preserves records' authenticity,

 ISBN: 978-1-61208-179-3

integrity and reliability by calculating the hash values both for individual files and packages. It enables and facilitates preservation of usability by detecting file format types and format versions, which is very usable for the long-term preservation planning. Therefore, in our opinion, it presents a valuable contribution to the regulation of archival procedures and long-term preservation of regulatory metadata, records and dossiers. We are expecting that stakeholders and end-users will be using READY application since it is going to be consistent with the Best archiving practice (guidance) that are just being put together at the EU level. Also, the new pharmacovigilance legislation will require, starting from 1 July 2012 at the EU level, that all documentation changes are to be tracked. READY application could improve intra-EU collaboration in the area of DCP and MRP procedures since the national agencies should work together on the preservation of regulatory records.

The future research will be focused on the development of the fully functional application from the prototype described here. It will be necessary to study the additional functionalities that the application intended for the long-term preservation of the regulatory digital records and dossiers should have in order to make Marketing Authorisation Holders, National Competent Authorities and in the end – patients certain that the sensitive and important records will be properly preserved for the needed period of time.

REFERENCES

[1] EU Module 1 specification v.1.4, August 2009, http://esubmission.emea.europa.eu/eumodule1/docs/EU%20M1%201.4/EU%20M1%20Specifications%20v1.4%20FINAL.pdf (23/12/2010).

[2] ICH M2 EWG electronic common technical document specification, July 2008, http://estri.ich.org/ectd/eCTD_Specification_v3_2_2.pdf (23/12/2010).

[3] H. Stančić, A. Rajh, and K. Pavlina, "Long-term Preservation Solution for Complex Digital Objects Preserved as Archival Information Packages in the Domain of Pharmaceutical Records," Digital World 2011, IARIA, Gossier, Guadeloupe.

[4] ISO 15489-1 Information and documentation – Records management.

[5] T. Kuny, "A Digital Dark Ages? Challenges in the Preservation of Electronic Information," 63rd IFLA Council and General Conference, 4 September, 1997, http://archive.ifla.org/IV/ifla63/63kuny1.pdf (27/08/2011).

[6] K. Thibodeau, "Overview of Technological Approaches to Digital Preservation and Challenges in Coming Years," The State of Digital Preservation: An International Perspective, CLIR, Washington, D.C., July 2002, pp. 4-31, http://www.clir.org/pubs/reports/pub107/pub107.pdf (27/08/2011).

[7] The Long-term Preservation of Authentic Electronic Records: Findings of the InterPARES Project – Authenticity Task Force Report, March 2002, http://www.interpares.org/book/interpares_book_k_app02.pdf (27/08/2011).

[8] ISO 14721:2003 Space data and information transfer systems – Open archival information system – Reference model.

[9] M. Dobreva and N. Ikonomov, "The Role of Metadata in the Longevity of Cultural Heritage Resources," Proc. EACL 2009 Workshop on Language Technology and Resources for Cultural Heritage, Social Sciences, Humanities, and Education –LaTeCH – SHELT&R 2009, Athens, Greece, 30 March 2009. Association for Computational Linguistics, 2009, pp. 69-76.

[10] H. Dureja and R. Dulichand, "New Drug Approval Process: Regulatory View," Pharmaceutical Reviews journal, 2010, 8/4, http://www.pharmainfo.net/reviews/new-drug-approval-process-regulatory-view (23/11/2011).

[11] European Medicines Agency pre-submission procedural advice for users of the centralised procedure, May 2011, http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004069.pdf, (10/08/2011).

[12] H. Stančić, Teorijski model postojanog očuvanja autentičnosti elektroničkih informacijskih objekata (dissertation). Zagreb, Faculty of Humanities and Social Sciences University of Zagreb, 2005.

[13] A. Rajh and N. Zorić, "Prva regionalna radionica o elektroničkoj dokumentaciji o lijeku," Farmaceutski glasnik, Hrvatsko farmaceutsko društvo, Zagreb, 2011, 67/5.

[14] ISO 23081-1 Information and documentation – Records management processes – Metadata for records – Part 1: Principles (ISO 23081-1:2006).

[15] ISO 23081-1 Information and documentation – Records management processes – Metadata for records – Part 2: Conceptual and implementation issues (ISO/TS 23081-2:2007).

[16] METS – Metadata Encoding and Transmission Standard: Primer and Reference Manual, Version 1.6 Revised, Digital Library Federation, 2010, http://www.loc.gov/standards/mets/METSPrimerRevised.pdf (01/09/2011).

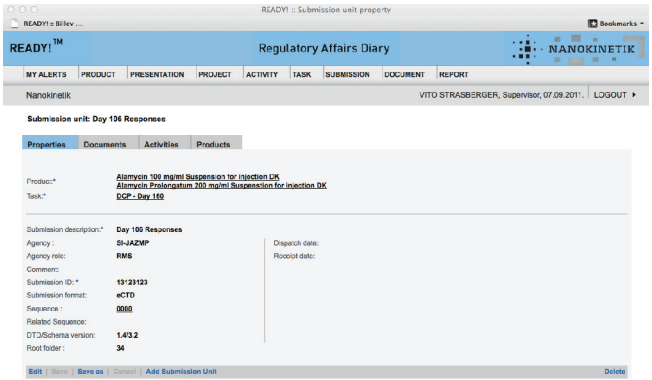

Figure 2. READY Application

Patient Privacy Preservation: P-RBAC vs OrBAC in Patient Controlled Records Type of Centralized Healthcare Information System. Case study of Walloon Healthcare Network, Belgium

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***Abstract*—This paper addresses the issue of access control to sensitive data in the health sector. Our work aims to identify a suitable access control model based on specific access requirements and constraints for Patient Controlled Records type of Centralized Healthcare Information System, particularly, Walloon Healthcare Network. Two prominent access control models are considered, Privacy-aware Role Based Access Control and Organization-based Access Control. In this paper, we outline the access control requirements and based on those requirements, we apply, compare, and point out the advantages and disadvantages of the two models.**

***Keywords*-Access Control; Privacy Preservation; e-health; P-RBAC; OrBAC; Patient controlled record.**

I. INTRODUCTION

E-Health provides significant opportunities for healthcare institutions to deliver technologically effective services to their patients. With the online availability of health record, healthcare professionals can make use of it in health service, for instance, an emergency situation where health record history is required in order to provide a safe and effective treatment. However, the major concern in e-health is security; as data is available online, it is vulnerable to attacks. Failing to secure this type of information can lead to huge fines, lawsuits, or long-term loss of patients' trust. Yet to provide adequate security, in a manner that is not burdensome to patient can be a major challenge.

Many researches [1][4][5][6][7][9][12] have been conducted in the aspect of privacy preservation in e-health, particularly, access and usage control. In general, access control refers to the cautious actions/measures that need to be taken before data is liberated while usage control refers to the actions/measures taken after data is granted access. In the data protection point of view, specially, privacy-related environment, the enforcement of the two controlling steps is necessary. Concerning to access control, many models are available [3][13], however only a few of them are proposed so far in e-health literatures such as RBAC [3], P-RBAC (Privacy-aware Role-based Access Control) [7], OrBAC [2] and the workflow-based [4]. Every model has its own strengths and weaknesses and it suits to different access requirements and constraints. Thus, it is important, when building an e-health system, to identify and study different access control models before adopting it.

This paper provides a study of two prominent access control models P-RBAC and OrBAC. Our main goal is to identify an appropriate access control model that can be adopted to preserve and protect patient's health record in patient controlled health records type of centralized healthcare information system(PCRCHIS), particularly, Walloon Healthcare Network(WHN) [1][10]. The complexity of policy expression, evaluation, and the ability to fulfill the system requirements are our main comparison parameters. The rest of this paper is organized as following.

Section II is an introduction to Walloon Healthcare Network and its access requirements and constraints. Section III talks about some standard access control models. Section IV introduces the P-RBAC and OrBAC models. Section V is about applying P-RBAC and OrBAC in WHN. Section VI talks about the advantages and disadvantages of the two models, and Section VII is the conclusion and future work.

II. WALLOON HEALTHCARE NETWORK

Walloon refers to the French speaking region in Belgium. Walloon Healthcare Network (WHN) [1] is a project aiming to provide an electronic healthcare facility to patients in Walloon region by joining together all healthcare institutions, clinics, and also physicians and allow exchanging patient's record when needed.

A. System Architecture

As illustrated in Figure 1, WHN is a network of health institutions such as hospitals, and clinics, but also of physicians that aims at supporting the exchange of patient's data between healthcare professionals, in a timely and secure way. WHN is organized as a hub that interconnects all entities, and provides central storage. Two types of data are actually stored centrally:

- pointers to EHR(Electronic Health Record) stored in institutions.
- SumEHR(Summarized Electronic Health Record) which is a summary record maintained by the

 ISBN: 978-1-61208-179-3

physicians.

Thus, WHN provides indexes to data that resides in network nodes (healthcare institutions), but does not store that data itself. In addition, WHN also manages in a central way the access permissions that apply to various pieces of data it manages (indexed data as well as SumEHR). WHN central server is in charge of the overall authorization process; it receives requests from the nodes, checks them against the applicable access policy, and returns the requested information. For more details, refer to [1].

WHN adopts the PCRCHIS like architecture, which refers to a system where management and control of access rights are performed by patient or trusted person. It has two important aspects. First, patient controlled record [8] refers to a system where management and control of access are performed by patient or patient's trusted-person. In this system, patient can grant access to anyone they wish and role of healthcare institution in controlling patient's record is minor and their responsibility is only to secure the storage of patient's health record. Second, centralized system [8] refers to a large network of healthcare institutions such as hospitals or clinics join together locally or regionally with one central point of access control. Thus, the access requirements in PCRCHIS are not as simple as that of the standalone system(system used particularly in a specific healthcare institution). The main issues in this system are:

1) Interoperability: How to ensure that the policies/rules defined in one healthcare institution are understood by other in the network.
2) Access and Usage: How to protect patient's record when it is shared across different healthcare institutions. In this system, data is exchangeable between different institutions. Thus, we need a proper mechanism to ensure that the same level of protection is assured while it is at the destination or moved out.
3) Patient's knowledge and policy management: In this system, patient has the pivotal rights to grant access and manage the access policies over their health records. It is understood that, not all users have the required computer skills, it is really hard to assume that user has the sufficient knowledge to administrate the access policy by themselves. In this case, the careful design of policy administration point is an important task in order to response to or cope with the errors made by patient. In addition, the rule validation and conflict resolution should be also carefully addressed.

B. Access Requirements and Constraints

This section presents the requirements and constraints needed to access patient record in WHN. Through WHN's specification [1], we can identify the requirements as following:

1) In this system, patient's record can be accessible by five types of user:s Users in role generalist-doctor, specialist-doctor, emergency-doctor, guardian, and trusted-person. Guardian, a person closed to patient who can represents patient in case he/she can not exercise his/her rights, for instance, parents can be a child's guardian if child's age is below 18. Trusted-person is a user or group of users, assigned by patient, who can decide instead of patient when patient is in situation where he/she can not exercise his/her rights physically or morally. In general, trusted-person can be patient's wife, husband, or parents.
2) Requester has the therapeutic relationship with patient. This relationship is defined by patient. Therapeutic relationship is an indication of the relation between requester and patient.
3) Accessing patient's record is subjected to patient's consent. And consent can be revoked any time.
4) Patient can grant access to his/her record and the rights assignment can be done by patient or through the support of the guardian, trusted-person, or healthcare professional. In any case, the assignment requires patient's consent. It is important to note that patient can also transfer the rights to guardian or trusted-person in case patient can not exercise his/her rights. For example, in case patient becomes mentally disable.
5) Every access to patient's record, requester needs to notify, this is considered as an obligation.
6) Access to patient's record is allowed for a specific purpose. There are three types of purpose. **Personal archive**: It is generally related to patient. It is allowed in case he/she wants to consult his/her health record. **Normal**: it is granted to doctor for normal health examination. **Emergency**: It is granted only to doctor in emergency situation. It is important to note that patient needs to define in advance the access policy in case of emergency situation. Patient can allow the selected groups of doctor or all doctors to access his/her health record.

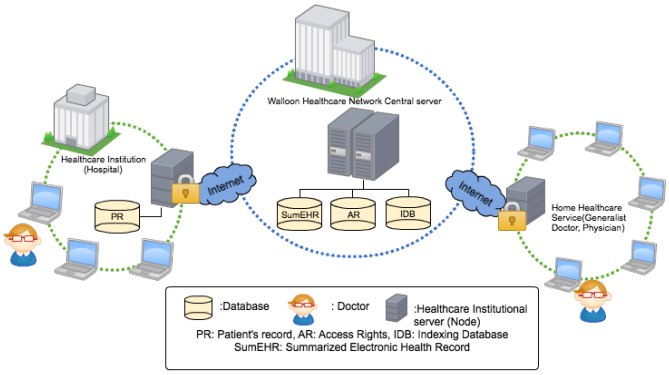

Figure 1. Simplified Schema of Walloon Healthcare Network

With the above requirements, we can identify the general rules to access patient's record as following. Requester is

granted access to patient's record if:

- **Rule-1:** Requester is in one of the five user groups as mentioned above.
- **Rule-2:** Requester has therapeutic relationship with patient and patient's consent .
- **Rule-3:** Requester fulfilled their duty or obligation such as notifying system for traceability.
- **Rule-4:** Access purpose falls into three types of purpose mentioned above.

III. Standard Access Control Models

In this section, we outline some standard access control models such as DAC, MAC, and RBAC. And based on the requirements in Section II, we point out why they are not suitable for the proposed system.

Discretionary Access Control (DAC) [3][13] is an access control model where restriction of access to objects is done based on the identity of subjects. The controls are discretionary in the sense that a subject with certain access permission is capable of passing that permission on to any other subjects. For example, an access control to files and folders in Unix system where user can define permission for other users to access their file or folder is a clear example of DAC. One implementation of DAC is the access control list that has been used widely in operating, networking, and database management system.

Although the ability of passing access permission on to any other subjects seems to match with the requirements in PCRCHIS, DAC fails to fulfill other important requirements such as the ability to express complex permission assignment that involves purposes, obligations and conditions, which are the most important elements for expressing the privacy-related policy. Moreover, DAC can not support data and role hierarchy expression which is required in PCRCHIS for data as well as user management. For example, the classification of generalist-doctor to many sub-groups according to their speciality/skill such as a doctor specializing in liver, nose, heart, and so on. This proves the necessity of role hierarchy. In addition, DAC has the problem of controlling the permission transfer and policy change, which are required in the proposed system (Section II(B) requirement 4), for instance in case of guardian or trusted-person. In order for the guardian or trusted-person to be able to represent a patient, a patient needs to define the permission transfer, which is considered as the legal binding document. Another draw back of DAC is the ability to express the separation of duties.

Mandatory Access Control(MAC) [3][13] is used widely in the operating system, databases, and networking system. MAC refers to a type of access control model by which the system constrains the ability of a subject or requester to access or perform some sort of operation or action to an object or resource. In practice, the subject refers to an entity that can be a user or application; object refers to the files, directories, ports (in networking), or databases (tables or attributes in database management system). In MAC, subjects and objects each have a set of security attributes and when a subject makes an attempt to access an object, an authorization rule enforced by the system examines these security attributes and then the decision can be made whether the access can take place. To determine if the operation on the object by a subject is allowed or not, those parameters will be tested against the set of the authorization rules made by the policy maker or administrator of the system. MAC provides the central control of the security. User or subject does not have the rights to assign or override the policy unlike ACL, which allows subject to make decision or override the access policy. MAC provides more control level compared to ACL as both subject and object carry the secured attributes that need to be checked or tested by system for every access attempt.

The disadvantage of MAC lies in the complexity of the configuration, since for each resource (application, data) and subjects (user) must be determined, which access authorizations are necessary. This tends to be very difficult for the system that works with the large number of users and resources, particularly, in system like PCRCHIS(refer to its definition in Section II). Another down part is that MAC is not designed to enforce privacy policies and barely meet privacy protection requirements, particularly, purpose binding (i.e. data collected for one purpose should not be used for another purpose without user consent), conditions and obligations. The purposes and obligations are a part of the requirements in PCRCHIS. Purposes are not only used to sharpen the access control but also to enforce the security protection in case of emergency situation. Additionally, MAC can unnecessarily over-classify data through the high-water mark principle and hurt productivity by limiting the ability to transfer labeled information between systems. This would be a great disadvantage for PCRCHIS.

Role-Based Access Control(RBAC) has been introduced in many research literatures [3][5][7][8]. The authors address the issue of protecting patient record by restricting access based on user's role and in this model, users who are in the same role can exercise the same level of rights. With this classification, access control on patient's record can be realized only with the simple access policy as access permission depends strongly on the role. However, it is hard to realize a complex and fine-grain access policy, particularly, in the contextual environment. For example, system that needs to differentiate access levels in the same role (requirement number 2 in Section II(B)), and most importantly, system that needs to express obligations or purposes (the requirements number 5 and 6 in Section II(B)). To complement this weakness, a context-awareness and privacy-awareness have been proposed [7]. In accordance with the spirit of the RBAC model, context-awareness or privacy-awareness RBAC(P-RBAC), access permission is granted to

 ISBN: 978-1-61208-179-3

user based not only on user role but also on the result of the occurrence events in the system or purpose of access. The context can be anything ranging from spatial, temporal to user pre-defined context. This new approach offers rich, fine-grain and flexible way to express the privacy-related policies, particularly, in the proposed system.

The authors realize the privacy-awareness by adding other entities to the core RBAC model such as conditions, obligations, and purposes of access. It is important to note that although standard RBAC can not express the obligations, purposes, and conditions, it has the ability to provide many features that are necessary for expressing access policy in WHN such as the ability to express data and role hierarchy, permission transfer as well as separation of duties. More details can be found in Section IV.

In June 2003, Abou and Baida proposed OrBAC [2] for healthcare application domain. With OrBAC, the access permission is granted to user under a specific role in particular organization and contexts. A user in one healthcare institution can access data to another institution if and only if the permission is granted by those institutions. This provides data integrity and confidentiality. OrBAC supports the control of data as well as user in system like organization structure and access permission is granted based on user role in an organization. In addition, it can also express the access permission in contextual environment, role and data hierarchy, separation of duties as well as permission transfer, which perfectly matches in WHN's requirements. Based on the requirements in Section II. We find that among the five models, OrBAC and P-RBAC are the most appropriate models. More discussion can be found in Section VI.

IV. P-RBAC AND ORBAC

This section presents a brief introduction to P-RBAC and OrBAC to provide the fundamental knowledge for model expression that is required in the next section.

A. Privacy-Aware Role-Based Access Control Model

P-RBAC [7] is an extension of the model RBAC [3], which provides complete support for expressing highly complex privacy-related policies. Its focus is to protect personally identifiable information and as such privacy-sensitive, taking into account characteristics such as goals (purposes), conditions, and obligations. P-RBAC extends the classical RBAC by adding three more privacy-related entities such as purposes, conditions, and obligations.

As shown in Figure 2, P-RBAC consists of the following entities: **Users** represent human or the interactive entity. **Roles** represent a function or job title within the organization with some associated semantics regarding the authority and responsibility conferred on a member's role. **Data** refers to all resources related to an organization or individual identified or identifiable. **Actions** are the operations on resources; action varies depending on the content and format. **Purposes**, in P-RBAC, permissions are assigned to roles and users for a specific purpose. **Conditions** are the mechanisms to precisely define the authority over resources to a specific role; using condition, we can express different access rights for user in the same role. **Obligations** are the necessary actions to be made before the actions on content can be exercised.

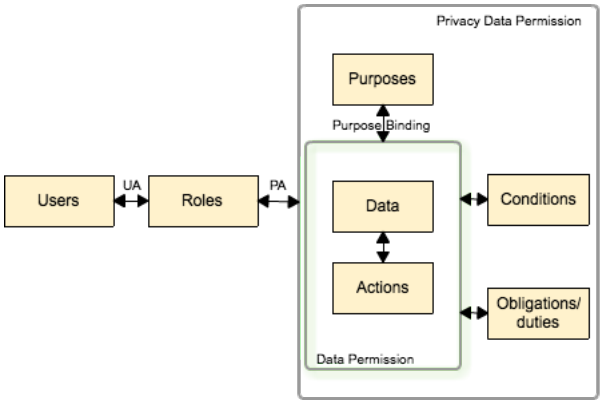

Figure 2. P-RBAC Entities Model

1) P-RBAC definition and rule formulation

- U is a set of users (u); D is a set of data (d); A is a set of actions (a); Pu is a set of purposes (pu); Ob is a set of obligations (ob); R is a set of roles (r)
- LC: condition language; PA: permission assignment
- Data Permission (DP): DP = $\{(a,d) \mid a \in A, d \in D\}$
- Privacy-sensitive Data Permission (PDP): PDP = $\{(dp, pu, c, ob) \mid dp \in DP, pu \in Pu, c$ is a expression of LC, $ob \in Ob\}$.
- PA on a role is defined as: **PA: (r, ((a,d), pu, c, ob)))**
- User Assignment UA $\subseteq U \times R$ (many to many relations)
- Privacy-sensitive Data Permission Assignment PDPA $\subseteq R \times PDP$

2) The Basic Condition Language

Core P-RBAC [7] includes a simple language for expressing conditions; they are expressed using contextual variables. Such variables record privacy-related information that is to be taken into account when enforcing privacy permissions. Contexts range from temporal, spatial to the pre-defined context by user. It is important to note that the condition expression here is defined in such a way so that it can be served to model several conditions usually found in privacy permission. The conditions that can be expressed by LC are defined in what follows.

Definition: Let X be a set of contextual variables(CV); each variable $x \in X$ has a finite domain of possible values, denoted as Dx; every domain is equipped with a pair of corresponding relational operators $\{=, \leq, \geq, \neq, \ni\}$. An atomic condition ac defined over X has the form (x opr v) where $x \in X$, $v \in Dx$, opr $\in \{=, \leq, \geq, \neq, \ni\}$. The

conditions of LC (over X) are defined as follows:

- An atomic condition is a condition of LC.
- Let ci and cj be conditions of LC; then ci ∧ cj is a condition of LC.

3) The Basic Obligation Model

An obligation is the duty for subject to fulfill before access is granted. An obligation may be different depending on context and system environment. For example, a system that serves online song or music, obligation may be a payment while in healthcare information system, obligation can be a notification of access to patient for traceability purpose. To simplify the problem we focus on one typical example of obligation, which is notification to data owner after each access to his/her sensitive data. we formalize our obligation as a ”notify” function . The function takes an email address of content owner and acknowledgement message as the inputs and returns ”yes or no” statement as an output in case of success to notify and fail to notify respectively. Thus, our obligation function can be written: **notify(patient's email, notified_message)**.

B. Organization-Based Access Control Model (OrBAC)

OrBAC [2] allows expressing a variety of security policies based on the concept of organization. The main goal of OrBAC is to allow the policy designer to define a security policy independently from the deployment. The chosen method to fulfill this goal is the introduction of an abstract level in the model. OrBAC model is based on three principles: organization, concrete and abstract level, and context. Organization is an entity that each security policy is defined for. Like other models, concrete authorization in OrBAC relies on three entities, which are subject, action, and object. Subject is an interactive entity, user or application that requests access on the organization's object. Action is an operation on object. Object is a resource requested by subject. In OrBAC, a concrete authorization is derived from abstract permission, which consists of three entities such as role, activity, and view. Role represents a function or job title within the organization with some associated semantics regarding the authority and responsibility conferred on a member's role. Activity groups actions into an abstract set and view is a set of abstract objects.

Typically, as presented in Figure 3, a subject in concrete level is mapped to a role in abstract level where an action is mapped to an activity and an object is mapped to a view. OrBAC has many advantages, in addition to its ability to express the permission; it can also express a mixed policy with permissions, prohibitions, and obligations. With OrBAC, security policies could take into account delegation, hierarchy, and context [11]. There are five categories of context: **temporal**, **spacial**, **context declared by the user**, **prerequisite Context**, and **provisional context**.

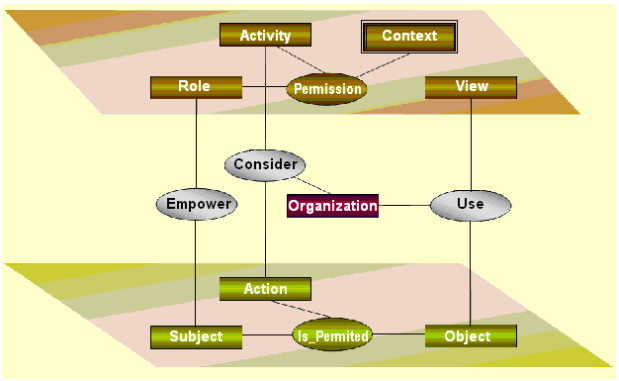

Figure 3. OrBAC Entities Relationship Schema

1) OrBAC definition and rule formulation

In this section, we present a mean of representation and reasoning about the permission, prohibition, and obligation in given of the entities, Subject, Action, Object, Role, Activity, and View.

1. Abstract expression (Permission, Prohibition, or Obligation) indicates an authorization, prohibition, or obligation of an organization allowing user under a specific role to perform an activity on a view that is considered by and used in an organization. This authorization is constraint with a specific contextual attributes if presented . They are expressed as following:

- Permission(Organization,Role,Activity,View,context)
- Prohibition(Organization,Role,Activity,View,context)
- Obligation(Organization,Role,Activity,View,context)

2. Concrete expression (Permission, Prohibition, or Obligation) indicates an authorization, prohibition, or obligation of an organization for a specific user to perform a requested action on requested object. It is important to note that concrete permission, prohibition, or obligation is derived from the abstract level expression and can be expressed as following:

- Is_permitted(Subject, Action, Object)
- Is_prohibited(Subject, Action, Object)
- Is_obliged(Subject, Action, Object)

3. Deriving concrete permission: It is important to note that in order to get the concrete permission from abstract level, we have to pass a few verification processes such as to verify if subject is in role, action is in activity, and object is in view, which are allowed in abstract permission. The expressions can be written as following.

- Empower (Organization, Subject, Role): Organization assigns a role to subject(user).
- Use (Organization, Object, View): Organization uses an object in a view.
- Consider(Organization, Action, Activity): Organization considers an action in an activity.

In case contexts are represented, the concrete permission can be achieved if and only if all contextual attributes are

 ISBN: 978-1-61208-179-3

checked and they hold together subject, action and object.

- Hold(Organization, Subject, Action, Object, Context)

V. APPLYING P-RBAC AND ORBAC

In this section, we express the access rules applied in WHN by using P-RBAC and OrBAC based on an access scenario below. It is important to note that in order to avoid confusion when comparing the policies expression of the two models. We term them as following: $Rule1_{P-RBAC}$ is used for P-RBAC to express the access rule "1" in P-RBAC and $Rule1_{OrBAC}$ is used for OrBAC to express the access rule 1 in OrBAC. We define variables, values, and functions used in P-RBAC and OrBAC as following:

1) P-RBAC: Roles (R)= { Specialist-Doctor}; Objets (O) = {Liver_report}; Actions (a)= {read}; Purposes (PU)= { Norma, Emergency}; OB={Notity}; N/A= not available;
2) OrBAC: Orgs = { CSL, CHN } Where CSL= Clinic Saint Luc, CHN = Central Hospital of Namur; Users(U)(Subjects) = {Alice, Charlie, Pierre}; Roles (R)= {Specialist-Doctor}; Objets (O) = {Liver_report}; Activities (av)= {Consult, Notify}; Actions (a)= {read, send}; Views = {Health records}; Purposes (PU)= { Normal, Emergency}; OB={Notity}; ANY_org= represents any organization.

Supposing that an object as data and object as person are merged into a single entity called "object". Then we are able to refer object.role to identify the role of data owner in this case patient; object.ehr for health record; object.consent refers to a list of consented users; object.email refers to email address of patient; object.therapeutic_ relationship refers to list of users who have the relationship with patient; object.ar refers to access record. Supposing that subject is a user who initiates request then subject.id is user identification; subject.role is role of requester(subject); subject.pu refers to purpose of access; subject.in refers to institution that subject belongs to.

A. Scenarios Description

Supposing that there are two institutions joining WHN, one is CSL and other is CHN. Charlie is a specialist doctor at CSL and CHN while Pierre is a specialist doctor at CHN only. Alice has registered as a patient in WHN. Alice has declared her Liver_report in WHN. Alice assigned Charlie and Pierre as her "Specialist-Doctor". Alice would like to set the access rights on her dossier as following:

- Rule 1: User in role Specialist-Doctor can read Alice's Liver_report if: Data being requested is belong to Alice; and user has therapeutic relationship with Alice; and user has Alice's consent; and purpose of access is for emergency situation; and the notification of access is fulfilled.
- Rule 2: Alice would like to give consultation(read) permission to Specialist-Doctor on her Liver_report only when requester is working under institution different from CSL for the purpose of normal treatment, but every accesses, he/she has to notify system. It is important to note that Rule 1 is included in Rule 2. The differences between rule 1 and 2 are purpose and the introduction of another access requirement which is the location(institution) from which the request is initiated.

B. Apply P-RBAC

$Rule1_{P-RBAC}$: (Specialist-Doctor,((Read, object.Liver_ report), subject.pu=Emergency, object.role=patient $\wedge$ object. therapeutic_relationship $\ni$ subject.id $\wedge$ object.consent $\ni$ subject.id, notify(object.email, notify_message)=yes))

$Rule2_{P-RBAC}$: (Specialist-Doctor,((Read, object.Liver_ report), subject.pu= Normal, object.role = patient $\wedge$ object.therapeutic_relationship $\ni$subject.id $\wedge$ object.consent $\ni$ subject.id $\wedge$ subject.in$\neq$"CSL", notify(object.email, notify_message)=yes)))

C. Apply OrBAC

$Rule1_{OrBAC}$**: abstract permission and obligation**
Permission(ANY_org,Specialist-Doctor,Consult,object. Liver_report,object.role=patient $\wedge$ object. therapeutic_relationship $\ni$ subject.id $\wedge$ object.consent $\ni$ subject.id $\wedge$ subject.pu = Emergency).
Obligation(ANY_org, Specialist-Doctor, Notify, object.ar, object.role = patient $\wedge$ object.therapeutic_relationship $\ni$subject.id $\wedge$ object.consent$\ni$subject.id $\wedge$ subject.pu = Emergency).

$Rule2_{OrBAC}$**: abstract permission, obligation, and prohibition**
Permission(ANY_org,Specialist-Doctor,Consult,object. Liver_report, object.role=patient $\wedge$ object.therapeutic _relationship$\ni$ subject.id $\wedge$ object.consent$\ni$ subject.id $\wedge$ subject.pu= Normal)
Obligation(ANY_org, Specialist Doctor, Notify, object.ar, object.role=patient $\wedge$ object.therapeutic_relationship$\ni$ subject.id $\wedge$ object.consent$\ni$ subject.id $\wedge$ subject.pu= Normal)
Prohibition(CSL,Specialist-Doctor,Consult,object. Liver_report, object.role=patient $\wedge$ object.therapeutic _relationship$\ni$ subject.id $\wedge$ object.consent$\ni$ subject.id $\wedge$ subject.pu= Normal)

VI. DISCUSSION

In WHN, access permission to medical record is based on requester role, relationship between requester and patient, patient's consent, purpose of access, and obligation. In addition, patient can also restrict access by using spatial or temporal context such what has been illustrated in rule 2 Section V (B,C). Based on the illustration in Section V, we

 ISBN: 978-1-61208-179-3

find that OrBAC can be used but not really appropriate for this system.

First, in WHN, the entity organization(institution) does not play an important role in access policy, it is required only in the indexing process and later it is considered as the link to content. The impertinent role of entity organization can be seen clearly in the scenario where patient grants access to guardian or trusted-person(they, as presented in Section II, are not necessary the users under any institutions). This access scenario shows that the organization entity does not play an important role at all in access policy. The organization may be of course used to restrict access, but in this case it can be considered as a conditional attribute as illustrated in P-RBAC (Section V(B), $Rule2_{P-RBAC}$).

Second, as illustrated in Section V, we found that using OrBAC in the scope of WHN is more complex than using P-RBAC. Let compare rule $Rule2_{P-RBAC}$ and $Rule2_{OrBAC}$ in Section V(B) and V(C) respectively: Using P-RBAC, as illustrated in rule $Rule2_{P-RBAC}$, we can express the access rights in a single rule where the organization entity (considered in OrBAC) becomes simply as a conditional attribute (subject.in). $Rule2_{P-RBAC}$ expresses the rights for all users in role Specialist-Doctor, but it restricts access from a particular IN (Institution), CSL as an example. in OrBAC with the same scenario, we need to have three rules. One applied to permission while other applied to obligation and prohibition. In the data processing point of view, time required to process or evaluate $Rule2_{OrBAC}$ is more than that of Rule2$_{P-RBAC}$.

To make it clear for the second remark, let us take a scenario (rule 2) where Alice sets a new policy in which she prohibits users from two particular institutions, this time CSL and CHN, to access her Liver_report. In this case, if we express it by using P-RBAC, we still use one rule by having one more condition on institution (subject.in$\neq$"CSL" $\wedge$ subject.in$\neq$"CSL") while with OrBAC we need four rules, one for permission, one for obligation and other two for prohibition(CSL and CHN). Although concept of grouping for organization entity can be used in OrBAC, in case of prohibition, it consumes time in policy evaluation process.

In WHN, obligation and purpose of access are required, both models can provide these features. In P-RBAC, both obligation and purpose can be expressed in the permission assignment. In OrBAC, obligation is expressed in the separate rule(Section V (C)) while purpose can be considered as the contextual attribute as illustrated in Section V(C) (rule $Rule1_{OrBAC}$). For prohibition, in OrBAC, it can be expressed by using a separate rule($Rule2_{OrBAC}$) while in P-RBAC it can be expressed in condition or using a negative permission expression [7].

In either way, expressing access policy by using OrBAC in the scope of WHN is seen as less suitable and more time-consuming in policy evaluation process as compared with P-RBAC, especially when obligation and prohibition are involved. Based on above explanation, we can say that the two models can be adopted in WHN but the most appropriate one is P-RBAC. This conclusion is done based on four important points:

- In WHN or patient controlled records healthcare information system, in general, the entity organization does not play a significant role in the access policy, in some access scenarios(guardian and trusted-person), patient can grant access to anyone he/she wishes regardless of the institution they belong to. This proves the impertinent of entity organization in access policy.
- OrBAC is an organization based access control model where user must be strictly attached to organization. This does not fit well for the roles legal representative(guardian) and trusted-person(refer to Section II) because the two roles can be an independent role in the system and not under any institution where patient's record is stored.
- OrBAC is not specifically designed for privacy-aware. It is created for expressing access policy to control the resource in the system that adopts user management pattern like organization structure while P-RBAC is proposed for privacy-aware that fits well with the requirements in healthcare information system such as the WHN.
- Referring to the examples in Section V(B) and V(C), we found that expressing access policy by using P-RBAC can have a better response time(the proof of policy complexity can be seen by the number of attributes and operations in rules and the rules in policy) as compared with OrBAC, in other words, less time-consuming in evaluation process. This is because P-RBAC's policy contents less rules as compared with that of OrBAC.

VII. Discussion on some security issues

In this section, we discus about three security issues: rule validation, rule conflict detection and resolution, and security in case of emergency situation(breakglass).

A. Rule validation

In system where access control is based on rule, it is required for rule(access rule or policy) administrator to have the knowledge on how rule works and to be beware of what they are doing and the consequence of doing it. Under the scope of WHN or PCRCHIS in general, it is understood that it is not possible to make an assumption that all patients have sufficient computer skill or knowledge and can operate or set rule by themselves. Thus, to solve this problem, under the scope of WHN, the rule validation can be done by three groups of user:

1) Patient(record owner): Patient can set up the rule through policy administration point by themself without the support from healthcare professional or other

people such as their trusted-person or guardian(refer to its definition in Section II(B)), but if the problem occurs, for instance, patient mistakenly defines a rule that is not like what he/she wishes, it is the responsibility of patient themself.

2) Patient's trusted-person and guardian: In WHN, it is required for a patient to assign her trusted-person and/or guardian to represent them in case patient can not exercise his/her rights. Those person can help patient in setting up and validating the rule if patient wishes to do so.
3) Healthcare professional: In WHN, healthcare professional can also help patient to set the rule on their behalf, but patient's consent written in paper is required in this case.

B. Rule conflict detection and resolution

In P-RBAC, conflicting rules can be detected automatically by using conflict detection algorithms proposed by Qun Ni and Bertino in [7]. The conflict detection algorithms allows user to detect the conflict between rules(P-RBAC rules) and provides an alert to user for correction.

C. The security issue in case of emergency situation

In e-health, emergency access to patient's record in case of critical event such as emergency treatment is a major concern. The trade off between security and safety of patient must be carefully balanced. In WHN, we use a predefined rule in case of emergency situation. Patient needs to decide by themself about the access rights in case of emergency. He/she can allow user in role "emergency-doctor"(refer to Section II) to access their record for the fixed purpose(emergency). However, every access user needs to notify patient for traceability purpose. Note that in emergency situation, normal rules applied to required patient record are revoked and rule in case of emergency is applied.

VIII. Conclusion and future work

In this paper, we identified the access constraints and requirements for WHN based on the specification and privacy regulation of WHN. We also present two prominent access control models, P-RBAC and OrBAC. An access scenario with multiple rules is used to illustrate the performance of both models. Based on the discussion in Section VI, we conclude that in e-health system where role of organization is less important, for example, PCRCHIS. P-RBAC is the best candidate to be used if the complexity of policy expression and evaluation are the major concerns. It is important to note that although this paper is primarily the result from the study of WHN, we can also apply it in other systems having similar requirements and system architecture to WHN. Our future work includes the design of a platform based on P-RBAC allowing to create and to evaluate the rules/policies in PCRCHIS by taking WHN as the real case study. ODRL will be used as the default rights expression language.

References

[1] Espace dévelopeur de RSW (Development of WHN): https://www.reseausantewallon.be/developpement/default.aspx, latest access: July 2011.

[2] A.Bou, R. Baida, P.Balbiani, S.Benferhat, F.cuppens, and Y.Deswarte. Organization Based Access Control Model. 4th IEEE International Workshop on Policies for Distributed Systems and Networks, June, 2003.

[3] D.F.Ferraiolo, R.Sandhu, S.Gavrila, D.R.Kuhn, and R.Chandramouli. Proposed NIST Standard for Role-Based Access Control. ACM Transactions on Information and System Security, August 2001, pp.4(3):222-274.

[4] Giovanni Russello, Changyu Dong, and Naranker Dulay. A Workflow-Based Access Control Framework for e-Health Applications. Advanced Information Networking and Applications Workshops, 2008, pp.111-120.

[5] Hung, Patrick C. K, and Zheng Yi. Privacy Access Control Model for Aggregated e-Health Services. Proceedings of the 2007 Eleventh International IEEE EDOC Conference Workshop. IEEE Computer Society, pp.12-19.

[6] Lorenzo D. Martin, Qun Ni, Dan Lin, and Elisa Bertin. Multidomain and Privacy-aware Role Based Access Control in e-Health. Second IEEE International Conference on Pervasive Computing Technologies for Healthcare, Jan-Feb 2008, pp. 131-134.

[7] Qun Ni, Bertino, Elisa, Lobo, Jorge, Brodie, Carolyn, Karat, Clare-Marie, Karat, John, Trombeta, and Alberto. Privacy-aware Role-Based Access Control. ACM Transaction Information and System Security, July, 2010, pp.24-3.

[8] Rostad and Lillian. An Initial Model and a Discussion of Access Control in Patient Controlled Health Records. Proceedings of the 2008 Third International Conference on Availability, Reliability and Security, IEEE Computer Society, pp. 935-942.

[9] Al-Neyadi, Fahed, Abawajy, and Jemal H. Context-Based E-Health System Access Control Mechanism. Advances Information Security and Its Application, Communications in Computer and Information Science, Springer Berlin Heidelberg, 2009, pp.68-77.

[10] Règlement relatif à la protection de la vie privée (Regulations for the Protection of User Privacy), Version 06h100809. https://www.reseausantewallon.be/Documents%20partages/R%C3%A8glement%20Vie%20Priv %C3%A9e.pdf, 2009, latest access: July 2011.

[11] Frédéric C and Nora.C. Modeling Contextual Security Policies in OrBAC. International Journal of Information Security (IJIS), August, 2008, pp. 285-305.

[12] Suzanne Gonzales-Webb and Craig M. Winter. HL7 Role-Based Access Control (RBAC) Role Engineering Process. HL7 Security Technical Committee, September 2007.

[13] Vincent C. Hu, David F. Ferraiolo, and D. Rick Kuhn. Assessment of Access Control System. National Institute of Standards and Technology, September 2006.

 ISBN: 978-1-61208-179-3

Clinical Wall applied for Polypathological Patient Care

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***Abstract*—Polypathological patients have a complex health scenario that is not generally well addressed by traditional Electronic Health Record systems. In order to treat chronic diseases that these patients have, there is a need for coordination and communication among health personnel of different levels of care (primary care, specialty care, home care) and distinct profiles. Also these healthcare professionals will require to do complex interactions such make shared decisions within their collaborative work. To enhance this coordination among healthcare professionals, we propose the idea of "Clinical Wall" as a 2.0 tool that allows professionals to debate, share knowledge and make decisions based on the clinical patient information.**

Keywords-Polypathological Patient; Continuity of Care; Web 2.0; Shared clinical decision; eHealth; Clinical Wall.

I. INTRODUCTION

One of the implications of aging, from the clinical viewpoint, is the fact that is increasing the number people with two or more chronic diseases. Likewise there are studies that affirm that number of diseases per patient has incremented in the last two decades [1]. The World Health Organisation calculates that 60% percent of global deaths are caused by chronic diseases [2]. As a result, there is a growing concern within the Public Health Services in developed countries about polypathological patients. For instance in Australia people with multiple chronic diseases represent 50% or more of the population with chronic diseases [3]. These patients are characterized by their high complexity and vulnerability with a large number of symptoms and high prevalence of functional impairment. As a result, these patients are likely to be dependent on caregivers who support them in their daily routine [4].

Within the Andalusian region the fragility of the polypathological patients has been shown in fulfilled studies, verifying that in primary care up to 40% of polypathological patients have three or more chronic diseases, 94% are polymedicated [5], 34% have a Barthel under 60, 37% have cognitive impairment [6], over 60% need caregiver, and 40% of these have overload signs [7]. Most of these variables are related to the insufficient sociofamiliar [8], so it still tends to be a comprehensive assessment that includes clinical areas, functional, and sociofamiliar.

A. Integrated healthcare process

Integrated Healthcare Processes (IHP) Management is a central strategy for improving the quality of the Andalusian Health Service. These Healthcare Processes are based on the development of flexible organizational models and an appropriate management of the processes according to the integration of scientific knowledge and evaluation of their performance in healthcare environment. The IHPs are based on increasing the involvement of professionals in a patient centered assistance, ensuring clinical practice according to the available scientific knowledge, facilitating continuity of care, and evaluating the clinical results.

The IHP for polypathological patient care specifies the professionals who will take part in healthcare, as well as, their role in this process [9]. The polypathological patient, more than any other patient, requires sustained assistance in shared care between primary and hospital for presenting special complexity that often requires quick access to interconsultation, complex diagnostics and hospital

 ISBN: 978-1-61208-179-3

admissions . The answer to these needs has been the incorporation of a model of continuity of care based on collaboration programs between internists and general practitioners with the defence of the figure of the internist of reference for each healthcare centre. During the last years different practical experiences have shown that is possible to consolidate this model both at large and small hospitals. The following professionals are described in the IHP:

- General Practitioner participates on the identification of the polypathological patient in order to be included in this IHP, the Comprehensive Assessment, in the Continuing Assistance Plan (CAP), home care, and attention to the caregiver.
- Internist of reference on the identification of the polypathological patient in order to be included in this IHP, in the CAP, home care, and attention to the caregiver.
- Family Nurse. Participates in the Comprehensive Assessment, in the CAP, in home care, and in attention to the caregiver.
- Hospital Nurse. Participates in the CAP, in home care, and in attention to the caregiver.
- Community Liaison Nurse. Participates in home care, and in attention to the caregiver.

The following figure shows a summary of process architecture that takes place in the care of polypathological patients, extracted from the IHP:

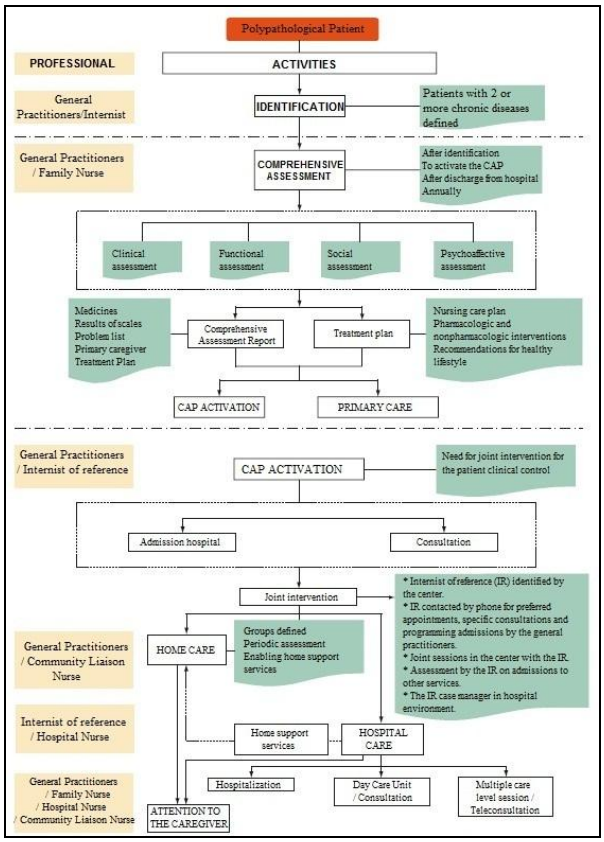

Figure 1. Process architecture: The care of polypathological patients

Just as is shown in the IHP, polypathological patient care involves many professionals with different roles and responsibilities. They must complement each other to obtain continuity of patient care across the different health centers of the region.

II. METHODS

"Virgen del Rocío" University Hospital (VRUH) is currently developing the *eHealth Platform*, a system able to deploy new services and pilots projects within the hospital environment. Within the project called *PITeS: Methods and Tools for Design and Implementation of Telemedicine and eHealth for the care of Chronic Patient*, a system called Polypathological Patient Module (PPM) is being developed to allow communication and coordination between the healthcare professionals involved in the polypathological patients care.

The platform is a complement to the Electronic Health Record (EHR) systems in use at patient care. The infrastructure currently deployed is composed by one EHR system in Primary Care and another different in Specialized Care.

Although there are some interoperability capabilities between these EHR systems, it is not possible to share all the patient information between the healthcare centers involved. For this reason, the PPM aims to facilitate the continuity of care accessing through Web Services the relevant patient information contained within the different EHR systems.

A. *Clinical Wall*

From the VRUH, we are working in order to enhance the EHR with tools that assist clinicians in their work in day by day.

The PPM includes the possibility to generate records that contain what we have called Clinical Wall. When two or more professionals have the need to exchange opinions about the patient care, they can start a conversation in the Clinical Wall. The Clinical Wall allows to exchange messages between healthcare professionals who participate on the patient care, until agree on conclusions or final decisions. If any of these healthcare professionals who participates in the Clinical Wall decides that is required the opinion of another colleague, they can invite these experts to the conversation to incorporate their clinical expertise.

The clinical dialogue hosted in the Clinical Wall is not for urgent communications. The platform will not be used in emergencies because there are other established protocols within the hospital to meet these events. In order to minimize the impact on the daily routine of healthcare professionals this system doesn't require real-time communication. The Clinical Wall dialogue allows sharing information between healthcare professionals to help them in the definition of coordinated therapies and prescriptions.

If the clinician who starts the conversation wishes to receive a response within the next 24 hours, he/she can activate an alert to notify via SMS to the healthcare professional who must answer this consulting.

 ISBN: 978-1-61208-179-3

Below, the figure shows a business process diagram designed to record information in the Clinical Wall report:

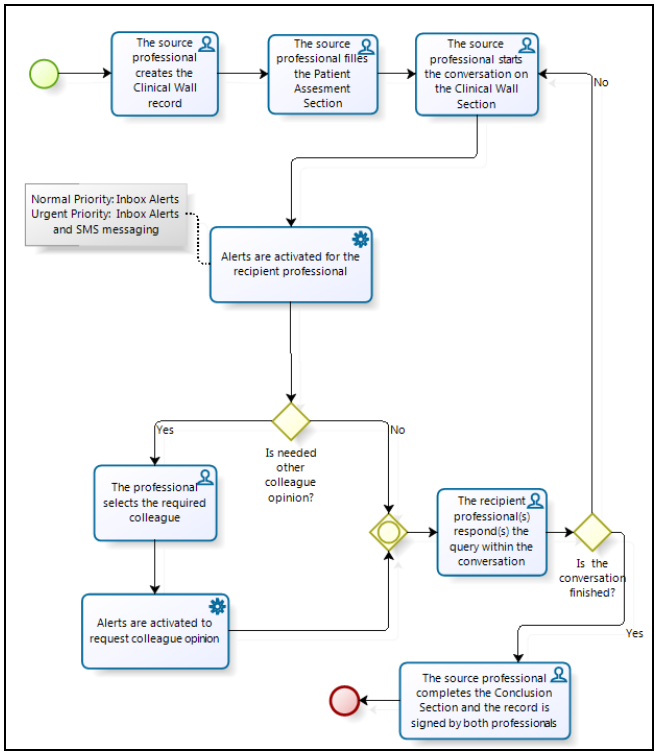

Figure 2. Business process diagram

The principal users of the platform will be the professionals described in the IHP as responsible for polypathological patient care. These professionals will use the platform within their daily routine so they should not receive SMS notifications.

Additionally, the platform will also give users access to specialists from various ailments common to these types of patients. For example, to questions related to cardiology and respiratory medicine will exist user within the respective departments of the hospital to evaluate and establish their clinical assessment. Because it is expected that these specialists don't have a volume of consultations as high as those included in the IHP , will receive an SMS alert showing them that have a new message in your inbox if someone have made them a consultation for them.

Furthermore, we defined interesting alerts that appear in a pending tasks box when the professional access to the platform. If you have urgent alerts will be sent an SMS to the mobile professional or professionals who are involved in the care of the patient.

B. ISO 13606 Standard

The platform has a relational database designed based on the specifications of the ISO 13606 reference model [10]. In this database are modelled all properties of the components of this model, establishing the corresponding relationships of the components from the archetypes repository. The ISO 13606 Standard defines a reference model defined for the message exchange containing clinical information. In this model the clinical information to be transmitted is structured into extracts, which contain folders, which brings together documents, which are composed of headers and entries, and these entries may contain elements or groups of elements.

C. Arquetypes

The definition of the Clinical Wall record is based on logical structures called archetypes. Archetypes are formal definition of semantic relationships between concepts defined as a set of constraints within an underlying reference model. [11]. Archetypes are able to define the relationships between the clinical concepts as a new layer that allows the management of clinical knowledge evolution.

A very important feature of the archetypes is their reusability. Archetypes define specific concepts such as blood pressure, body weight or body temperature. These concepts are useful in different health areas. Likewise, the archetypes of blood pressure or other concepts can also be reused in a multitude of health services and greatly reduce the costs associated with the implementation of this architecture [12]. Its application allows the development of easily-scalable systems and with semantic interoperability, designed to adapt to changing clinical needs of health professionals.

A set of archetypes have been defined in order to create a composition with 3 sections to record the dialogue between the clinicians.

Patient Assessment Section. This section is going to be filled by the healthcare professional that starts the dialogue with a clinical question. In order to provide patient clinical context for the colleagues this section includes patient evolution, examination, complementary tests, treatment plan and current clinical assessment.

Clinical Wall Section the name of this section is to illustrate the similarities with conversations in the wall of a social network websites where people exchange messages on a topic. The dialogue starts when the first healthcare professional wants to share or ask for additional information to other professionals who provide care to one specific patient. Other professionals can provide additional inputs and they will be stored as a conversation.

Conclusions section, participants can agree and sign their conclusions and future actions for patient care. Some possible outcomes from the conversation are changes in treatment plan, new appointment for hospital or GP encounter, schedule for additional tests.

III. IMPLEMENTATION

In order to separate information and knowledge the system architecture design has been based on the ISO-13606 standard. The system DataBase includes all the classes detailed in the ISO 13606 Reference Model and store archetypes that model the relationship between the information stored with the clinical knowledge. In this process we have applied LinkEHR for archetype edition

Our system also incorporates the ICEfaces framework based on JavaServer Faces (JSF) standard to create a separation between presentation and behavior. JSF provides

 ISBN: 978-1-61208-179-3

rich architecture for component state management, data processing event management and user login validation.

In addition, the system includes a productive persistence layer based on Hibernate tools. These opensource tools optimize the maintenance, performance and flexibility of databases.

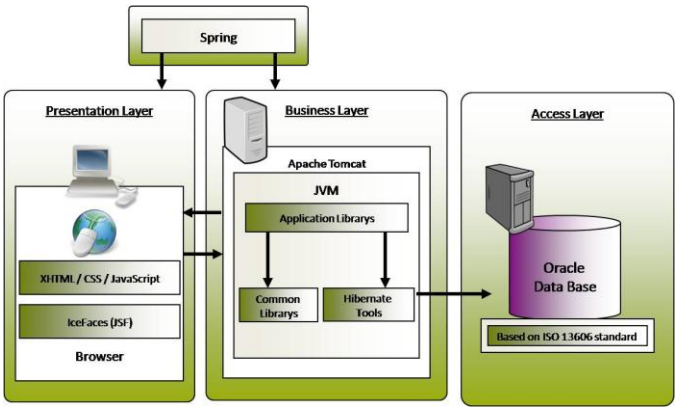

Figure 3. Platform architecture

IV. DISCUSSION

The platform expects to help in the complexity of polypathological patient care workflows allowing communication between the healthcare professionals involved and supporting interactions between the group actors that treat the set of diseases that affect every patient

This tool aims to support professional interactions that are not well handled by the traditional EHR systems because based on web 2.0 tools enables decision sharing among a group of professionals. The following complex interactions required in collaborative work [13] are able to be performed within the Clinical Wall:

- Confer: Healthcare professionals are able to discuss the patient situation with others colleagues before they make a decision
- Inform: Healthcare Professionals are able to notify others actors involved why they made a specific decision.
- Validate: Healthcare Professionals often require reviewing additional information to validate and support the decision they make.
- Assimilate or Share: Healthcare Professionals are able to share the decisions they are making or the information they have obtained, with the professionals involved in one specific patient care and the large community of professionals distributed to IHP professionals of the Primary Care and Specialized Care Centers.

On the other hand, given that polypathological patients suffer two or more chronic diseases, frequently is needed the participation of experts from different healthcare specialties.

It requires a fluent communication between all the professionals that are in charge of the patient care in order to provide coordinated care.

By being patients with chronic diseases, must take into account that polypathological patients will need a monitoring of disease throughout his life. Then, it's possible that the patient be seen by various professionals in the same specialty. An important aspect is to leave reflected the decisions taken on assistance in any record of the health record.

The platform and specially the Clinical Wall are going to increment the communication and coordination of the clinical staff. As a consequence it could be inferred that the security and quality of patient care will be improved.

Currently we are finalizing the development of the Clinical Wall. Next stage will be pilot the system in the VRUH environment. From the results of this pilot, the impact of the Clinical Wall on the patient care will be evaluated.

V. CONCLUSION

Traditional EHR systems don't provide enough support for clinical workflow needs. In the case of Polypathological Patients these needs increase because their treatment requires strong collaboration among different healthcare levels and specialties.

Our proposed Clinical Wall enables asynchronous communication among healthcare professionals within a collaborative work environment. This will improve the current clinical protocol based on phone communication for both urgent and non urgent information. The system will support the communication among healthcare professionals as a team and allow them a better workload administration because many interruptions by non-urgent calls will be avoided. Furthermore, the Clinical Wall will improve patient safety because it avoids interpretation errors caused by misunderstanding in phone communications.

We expect that evaluation of the pilot in our clinical environment could demonstrate the system benefits and extend the service to all the clinical specialties included in our hospital and a network of 36 primary care centres in our region.

ACKNOWLEDGMENT

This project has been funded by the Instituto de Salud Carlos III within the call Strategic Help in Health (code PI09/90518) and RETICS Innovation in Healthcare Tecnology call (code RD09/0077/00025)

REFERENCES

[1] A.A. Uijen and E.H. van de Lisdonk, "Multimorbidity in primary care: Prevalence and trend over the last 20 years," European Journal of General Practice, 2008, Vol. 14, No. s1 , Pages 28-32, doi:10.1080/13814780802436093.

[2] World Health Organisation, Preventing chronic disease: a vital investment, World Health Organisation: Geneva, WHO global report, 2005.

[3] G.E. Caughey, A.I. Vitry, A.L. Gilbert, and E.E. Roughead, "Prevalence of comorbidity of chronic diseases in Australia," BMC Public Health 2008, Vol. 8, doi:10.1186/1471-2458-8-221.

[4] M. Bernabeu-Wittel, B. Barón-Franco, J. Murcia-Zaragoza, A. Fuertes-Martín, C. Ramos-Cantos, et al., "A multi-

 ISBN: 978-1-61208-179-3

institutional, hospital-based assessment of clinical, functional, sociofamilial and health-care characteristics of polypathological patients (PP)," Archives of Gerontology and Geriatrics, Volume 53, Issue 3, November-December 2011, Pages 284-291.

[5] J. Galindo-Ocaña, M. Bernabeu-Wittel, F. Formiga, A. Fuertes-Martín, B. Barón-Franco, JM. Murcia-Zaragoza, et al. "Effects of renin–angiotensin blockers/inhibitors and statins on mortality and functional impairment in polypathological patients" European Journal of Internal Medicine, in press. doi:10.1016/j.ejim.2011.06.004 .

[6] M. Bernabeu-Wittel, M. Ollero-Baturone, L. Moreno-Gaviño ,B Barón-Franco,A. Fuertes, J. Murcia-Zaragoza, et al. "Development of a new predictive model for polypathological patients. The PROFUND index" European Journal of Internal Medicine, Volume 22, Issue 3, June 2011, Pages 311-317

[7] L. Moreno-Gaviño, M. Bernabéu Wittel, M. Álvarez Tello, M. Rincón Gómez, S. García-Morillo, et al., "Overload felt by the figure of the main caregiver in a cohort of patients with multiple pathologies," "Sobrecarga sentida por la figura del cuidador principal en una cohorte de pacientes pluripatológicos," Abril 2008, Aten Primaria, Vol. 40, Núm. 04.

[8] M. Rincón-Gómez, M. Bernabeu Wittel, P. Bohórquez-Colombo, L. Moreno-Gaviño, M. Cassani-Garza, MA. Ortiz.Camúñez et al." Perceived quality of healthcare in a multicenter, community-based population of polypathological patients" Archives of Gerontology and Geriatrics, Volume 52, Issue 2, March-April 2011, Pages 142-146.

[9] M. Ollero-Baturone, M. Alvarez, B. Barón-Franco, M. Bernabéu-Wittel, A. Codina, et al., Integrated care process for polypathological patient care, Atención al paciente pluripatológico. Proceso Asistencial Integrado, 2007, Public Health Direction of Andalusian Autonomus Government: Sevilla, second edition, available from: http://www.juntadeandalucia.es/salud/servicios/contenidos/procesos/docs/pluri.pdf.

[10] ISO13606, "Health Informatics - Electronic Health Record Communication," 2008-2010, Technical Committee 215.

[11] T. Beale, "Archetypes constraint-based domain models for futureproof information systems," In: In Workshop on Behavioural Semantics, 25 November 2009, 2000 OOPSLA'02, OpenEHR.

[12] D. Kalra, G. Mennerat, F. Devlies, J. Tapuria, and A. Thienpont G, "Management and maintenance policies for EHR interoperability resources, EuroRec Institute," 2008, Q-Rec.

[13] R. Khan, "BPM and Web 2.0," A BPTrands Column. BPTrends. 2008.

 ISBN: 978-1-61208-179-3

Integrated Vocabulary Service for Health Data Interoperability

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***Abstract*— The paper addresses the problem of interoperation when searching across patient data represented in several medical vocabularies. This is an important issue of relevance to eHealth integration that will allow clinical information to be used in clinical research. We propose a novel way to semantically integrate a number of vocabularies for reference using a vocabulary service.**

Keywords–interoperability, controlled vocabularies, electronic health record.

I. INTRODUCTION

The increasing amount of health-related data available calls for new ways of analysing them together as a unified set, despite their heterogeneity. The interoperability of healthcare data is an active research topic, especially with the investigation of the reuse of routine clinical data for clinical research. In many instances, users of healthcare data are familiar with only one medical vocabulary. For instance, in the English primary care, Read Codes Version 2 (RCV2) is still widely used. However, activities, such as patient cohort identification and recruitment, often need to query heterogeneous patient data repositories that use different coding systems. In this paper, we describe our approach to integrating medical vocabularies semantically by providing a vocabulary service for vocabularies commonly used in Europe. The remainder of the paper is organised as follows. Section II gives an overview of the medical vocabularies, existing work on vocabulary collections, their features and limitations. We then introduce our approach to an integrated vocabulary service in Section III, followed by details of the application architecture and web service implementation in Sections IV and V. Finally, we give our conclusions and future work.

II. MEDICAL VOCABULARIES

Medical vocabularies have been in use since patient information needed to be coded for statistical reporting, long before computers started being used in health care [1]. Different vocabularies have been created for various purposes and there is currently no single agreed vocabulary in use. The two main uses for medical vocabularies are for classification of diseases for statistics and reporting, and for the coding of clinical data for patient care. Reviews of the common medical terminology include the works of [2, 3]. The first category of vocabularies includes classifications, such as ICD-10 [4] and the OPCS Classification of Interventions and Procedures (OPCS-4) [5]. They are mainly used to simplify data and create abstractions for statistical reporting and for reimbursements [1]. The second category includes those that can represent detailed information as part of a patient's electronic healthcare record (EHR). Examples include SNOMED CT [6], Read Codes [7], ICPC-2 [8]. As noted by Cimino [1], As a number of vocabularies are used to represent healthcare data, a large amount of data can potentially be used to support clinical research, provided there is an effective means to semantically integrate them.

The Unified Medical Language System (UMLS) [9] is a collection of many controlled vocabularies in the biomedical sciences, developed in an attempt to unify disparate vocabularies and to facilitate the sharing of medical knowledge [1, 3]. UMLS consists of three Knowledge Sources (Metathesaurus, Semantic Network and SPECIALIST Lexicon) and also provides a set of software tools to provide a mapping structure among the different vocabularies. The UMLS Metathesaurus is a large, multi-purpose and multi-lingual vocabulary database, containing information about biomedical and health related concepts, synonyms and relationships among them [10]. The Semantic Network defines how the concepts in the Metathesaurus are assigned semantic types, which are broad subject categories, such as Disease, Finding and Clinical Drug, which are linked to one another through semantic relationships [11]. Despite the UMLS including a number of commonly used vocabularies, it does not support RCV2 and other widely used mappings and languages used in Europe.

III. INTEGRATED VOCABULARY SERVICE

Our approach to resolve some of the limitations of the UMLS is to develop an integrated vocabulary service, which will enable the support of more European terminologies and languages. It follows the lessons learnt and therefore extends on the work achieved in the ePCRN project [12], a US National Institute of Health project investigating an electronic infrastructure to support the design and implementation of randomised clinical trials, while facilitating translational research in primary care in the United States.

A. Background: ePCRN

In the ePCRN project, the National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS) provided the

 ISBN: 978-1-61208-179-3

controlled terminology and ontology. The EVS is a project of the US National Cancer Institute Center for Biomedical Informatics and Information Technology (NCI CBIIT) and forms the semantic base for the Cancer Common Ontologic Representation Environment (caCORE), the NCI cancer Biomedical Informatics Grid (caBIG®), and the new NCI CBIIT semantic infrastructure [13], for supporting interoperability in translational research. As the NCI Metathesaurus is more US-oriented, it has fewer European coding systems and only supports vocabularies in the English language. The NCI EVS develops and supports the NCI Metathesaurus vocabulary source (NCIm), which is based on the UMLS Metathesaurus and thus provides a mapping of concepts to terms within multiple vocabularies. With the aim to include more European terminologies and support other European languages, we have developed an integrated vocabulary service (as part of the TRANSFoRm project [14]), using LexEVS. LexEVS is the open-source software package, on which the NCI EVS is built. LexEVS provides a comprehensive set of software and services to load, publish and access controlled terminologies. It supports a wide variety of ontology formats including UMLS RRF, OWL, OBO, HL7 RIM, and LexGrid XML. Other related works include i2b2 SHRINE [15] and the Ontology Lookup Service [16].

B. *Extending UMLS with Read Codes V2*

The first version of the integrated vocabulary service (VS) allows RCV2 to be semantically interoperable with the UMLS. A customised database of RCV2 has been created to cater for the English primary care domain. The UK Terminology Centre (UKTC) [17] provides the mapping from RCV2 to SNOMED CT and the integrated VS is based on this mapping, such that RCV2 concepts can be linked to search on the UMLS. A subset of the UMLS Metathesaurus 2010AA release is hosted by the integrated VS. It includes the NCI Thesaurus and vocabularies such as SNOMED, ICD10, and ICPC2, in different languages.

IV. APPLICATION ARCHITECTURE

Following a standard tiered architecture, the VS server is divided into three logical tiers: presentation, service and database tiers as depicted in Figure 1.

A. *Presentation Tier*

The presentation tier provides both a Web interface for web client access and a Web service interface for programmatic access. The web interface is designed as an Ajax application using Google Web Toolkit (GWT) technology. The Ajax web client renders the web page on the user's web browser and calls a GWT Remote Procedure Call (RPC) servlet, on the server side, when the user initiates a search. The web services interface is implemented using Metro; the web service stack was originally developed by Sun Microsystems. Both the GWT RPC servlet and the web service component, in turn, invoke the query service, the entry point of the service tier, to execute a search.

B. *Service Tier*

At the service tier, the query service component coordinates access to different vocabulary databases and combines the search results together. The UMLS vocabulary database is accessed through LexEVS, but additional vocabulary databases are accessed through direct JDBC calls. The LexEVS runtime is a Java class library, which provides various APIs to access vocabulary contents in the LexEVS format.

C. *Database Tier*

LexEVS builds an index on the vocabulary databases using Lucene technology, when the vocabulary data are imported into the LexEVS database. During query execution, the LexEVS runtime consults the Lucene index [18], in order to speed up the data search.

V. WEB SERVICE IMPLEMENTATION

The TRANSFoRm Integrated VS provides a Web service API for remote programmatic access via Web Services Description Language (WSDL) and XML schema files. WSDL is an XML-based language for describing Web services and how to access them. It specifies the location of a service and the operations the service exposes. A client can therefore communicate with the service through the WSDL-provided interfaces, regardless of programming language.

A. *Data Model*

Figure 2 shows the data model used in the integrated VS. LexEVS allows meta concepts, such as UMLS concepts

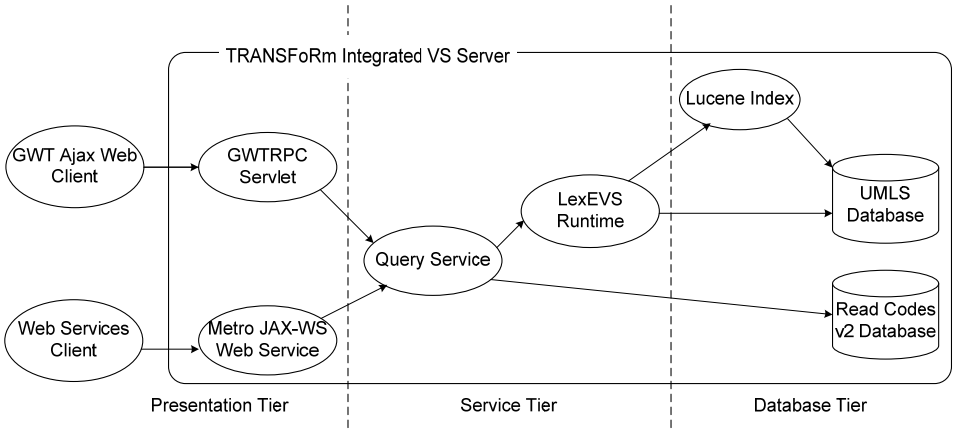

Figure 1. TRANSFoRm VS Server Architecture

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to be represented using different formats. UMLS concepts have equivalent concepts in different source vocabularies, such as SNOMED CT, ICD-10. The integrated VS uses the RCV2-to-SNOMED CT map to link the Read Codes V2 to the UMLS concepts. The user is presented with only the mapping from meta concept to source vocabulary concept,

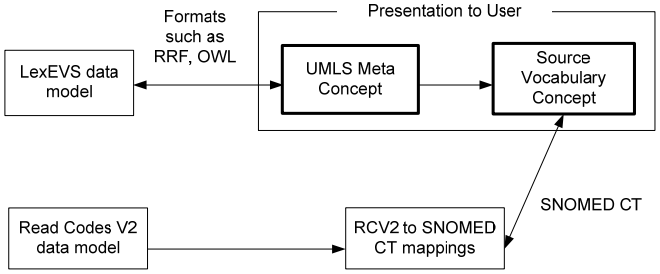

Figure 2. Integrated Vocabulary Service Data Model

depending on the functions requested.

B. Services

Three basic operations are provided as a basic service:

- Search for a term – searches a medical term and returns a list of matching concepts, sorted by relevance.
- Search for a code – searches for a specific code and the function returns the meta concept matching the source vocabulary code searched.
- Return the semantic type for a specific code – the coding system may be specified.

C. Web Interface

The aim for using the vocabulary service is to enable searching by concept, which is a key feature of the eligibility criteria and query formulation that can support researchers to identify eligible patients for their studies. Through an example search, we demonstrate how the vocabulary service Web interface works in helping to map concepts to a wide range of medical terminologies, hence enabling searches across heterogeneous healthcare data. Figure 3 shows a screenshot of the results for an example search for a clinical term ("Type II Diabetes") on the web-based interface of the TRANSFoRm integrated vocabulary service. In this scenario, the user wants to know the RCV2 for Type II diabetes. The term is entered in the search box and the ReadCodes2 option is ticked to include the terminology as it is not provided within UMLS. The elements of the result are described as in Figure 3:

1. UMLS concepts matching the search term are shown in the top left box. The search term "Type II Diabetes" is matched to all the available terminologies (from UMLS and RCV2), and 25 concepts were returned.
2. Each UMLS concept has a unique UMLS code, semantic type, and definition. For instance, the selected concept is "Diabetes Mellitus, Non-Insulin-Dependent", for which further information is displayed on the top right of Figure 3. The UMLS Code "C0011860" provides the unique UMLS identifier for that concept, while the Semantic Type "Disease or Syndrome" indicates the subject category within the categories of UMLS concepts.
3. For the selected concept, its super and sub concepts are rendered on the display, describing the important relationships with other concepts. For instance, a super concept for "Diabetes Mellitus, Non-Insulin-Dependent" is "Diabetes Mellitus", while the sub concept "Diabetes mellitus type 2 in obese" is a more specific concept.
4. Codes from hosted vocabularies (including language and textual description) are also provided for the selected concept. In Figure 3, only the vocabularies in English have been selected. For instance, in RCV2, three terms have been matched to "Type II Diabetes".

VI. CONCLUSION AND FUTURE WORK

We have developed an integrated vocabulary service in response to the need for interoperability among medical terminologies used more commonly in Europe. Based on our previous work in the ePCRN project, we have extended the UMLS to support Read Codes Version 2, which are still commonly used in primary care EHR systems in England. The current vocabulary service implementation is based on LexEVS 5.1. A newer version of LexEVS, namely LexEVS 6 has been released, which adds comprehensive support of emerging HL7 terminology service standards [19]. We plan to investigate and migrate to LexEVS 6 to align with the emerging standard. With a vision to support clinical research across Europe in the longer term, we plan to investigate and add more European focused. Additionally, vocabularies related to medication present a big challenge, which definitely needs significant future work.

ACKNOWLEDGMENT

This work was supported in part by the European Commission – DG INFSO (FP7 247787) for the TRANSFoRm project, and the National Institute for Health Research Birmingham and Black Country Comprehensive Local Research Network (NIHR BBC CLRN).

REFERENCES

[1] J. J. Cimino, "Review paper: coding systems in health care," *Methods of Information in Medicine*, vol. 35, no. 4-5, pp. 273-284, 1996.

 ISBN: 978-1-61208-179-3

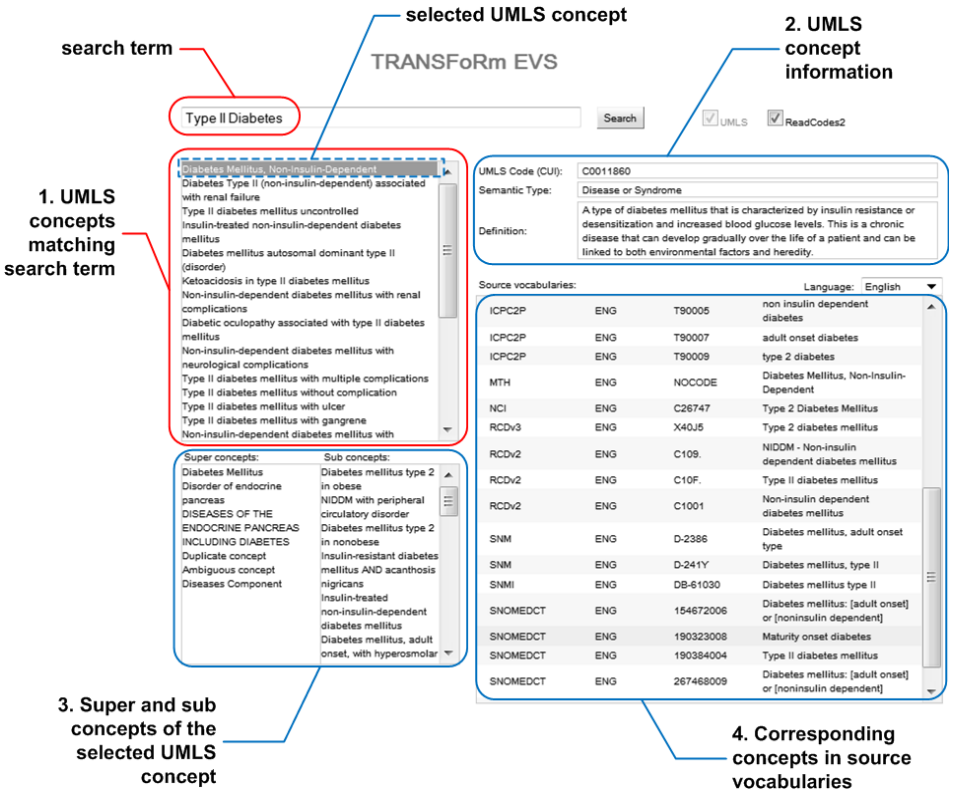

Figure 3. Annotated Screenshot of the Web-based Interface of the TRANSFoRm Integrated Vocabulary Service.

[2] J. S. Rose et al., “Common medical terminology comes of age, Part One: Standard language improves healthcare quality,” *Journal of Healthcare Information Management: JHIM*, vol. 15, no. 3, pp. 307-318, 2001.

[3] J. S. Rose et al., “Common medical terminology comes of age, Part Two: Current code and terminology sets--strengths and weaknesses,” *Journal of Healthcare Information Management: JHIM*, vol. 15, no. 3, pp. 319-330, 2001.

[4] World Health Organization, “International Classification of Diseases (ICD).” [Online]. Available: http://www.who.int/classifications/icd/en/. [Accessed: 19-Sep-2011].

[5] NHS Connecting for Health, “OPCS-4 Classification.” [Online]. Available: http://www.connectingforhealth.nhs.uk/systemsandservices/data/clinicalcoding/codingstandards/opcs4. [Accessed: 19-Sep-2011].

[6] NHS Connecting for Health, “SNOMED CT.” [Online]. Available: http://www.connectingforhealth.nhs.uk/systemsandservices/data/uktc/snomed. [Accessed: 15-Aug-2011].

[7] NHS Connecting for Health, “Read Codes,” *NHS Connecting for Health*, 10-Aug-2011. [Online]. Available: http://www.connectingforhealth.nhs.uk/systemsandservices/data/uktc/readcodes. [Accessed: 10-Aug-2011].

[8] Wonca International Classification Committee, “ICPC-2.” [Online]. Available: http://www.globalfamilydoctor.com/wicc/sensi.html. [Accessed: 19-Sep-2011].

[9] US National Library of Medicine, “Unified Medical Language System (UMLS),” 29-Jul-2009. [Online]. Available: http://www.nlm.nih.gov/research/umls/. [Accessed: 15-Aug-2011].

[10] US National Library of Medicine, “Chapter 2: Metathesaurus,” in *UMLS Reference Manual*, 2009.

[11] US National Library of Medicine, “Chapter 5: Semantic Network,” in *UMLS Reference Manual*, 2009.

[12] ePCRN, “The electronic Patient Care Research Network.” [Online]. Available: http://www.epcrn.org/.

[13] National Cancer Institute, “Enterprise Vocabulary Services (EVS).” [Online]. Available: https://cabig.nci.nih.gov/concepts/EVS/. [Accessed: 15-Aug-2011].

[14] “TRANSFoRm.” [Online]. Available: http://www.transformproject.eu/. [Accessed: 16-Aug-2011].

[15] G. M. Weber et al., “The Shared Health Research Information Network (SHRINE): A Prototype Federated Query Tool for Clinical Data Repositories,” *Journal of the American Medical Informatics Association : JAMIA*, vol. 16, no. 5, pp. 624-630, 2009.

[16] R. G. Côté, P. Jones, R. Apweiler, and H. Hermjakob, “The Ontology Lookup Service, a lightweight cross-platform tool for controlled vocabulary queries,” *BMC Informatics*, vol. 7, p. 97.

[17] NHS Connecting for Health, “UK Terminology Centre.” [Online]. Available: http://www.connectingforhealth.nhs.uk/systemsandservices/data/uktc. [Accessed: 15-Aug-2011].

[18] Apache, “Apache Lucene Project.” [Online]. Available: http://lucene.apache.org/. [Accessed: 19-Sep-2011].

[19] Healthcare Services Specification Project (HSSP), “Common Terminology Services 2.” [Online]. Available: http://hssp.wikispaces.com/cts2. [Accessed: 19-Sep-2011].

 ISBN: 978-1-61208-179-3

Personas: The Linking Pin in Holistic Design for eHealth

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***Abstract*— Personas, lively descriptions of distinctive user groups for a technology, have the potential to be a useful tool for designing useful and usable eHealth services. In this paper we discuss the role of personas in a holistic design approach for eHealth: the CeHRes roadmap. We show, using the case of a mobile tick and Lyme tool, how one can develop personas and how one can use these personas in future design efforts. We argue that they can be useful for creating requirements and eHealth design, can be the basis for the development of scenarios that guide problem analysis with stakeholders, and finally, can inform both formative and summative evaluations.**

Keywords-Personas; Holistic Design; Human-Centered Design; Business Modeling

I. INTRODUCTION

Since their introduction, personas have rapidly gained popularity as an important tool for inspiring technology design. Originally, personas have been defined as "*hypothetical archetypes* of actual users" [1]. They are a set of fictitious persons, each one typical for a group of people, who will, potentially, use a new technology. Traditionally, personas are presented by means of a short biography with a photo and the goals they hope to achieve by means of the technology. Such descriptions can be quite detailed, including, for example, hobbies and the breed and name of the dog that the persona has for a pet. They are used by a technology development team to get a good grasp of the different user groups (in a way they are a short summarization of a user group's distinctive characteristics), as inspiration for design and, finally, to engage the design team members [2].

Within the context of electronic health (eHealth) design, personas have been used in several projects, including the development of electronic patient records [3], a public website with cancer-related information [4], a digital assistant for nurses [5], and a handheld device to monitor chronic heart failure [6]. These publications, however, do not provide detailed, hands-on guidance for developing and utilizing personas for eHealth. An important step forward in systematic use of personas in eHealth was made by LeRouge and colleagues [7]. Illustrated by the design process of a mobile self-management tool for diabetes patients, they document the development, use and usefulness of personas for eHealth in detail. However, all the aforementioned studies focus only on the use of personas in a human-centered approach towards design, thereby ignoring the business model that needs to be created if one wants an eHealth technology to be sustainable as well. In this paper, we discuss the development, use and usefulness of personas in a holistic design approach towards eHealth, which incorporates both human-centered design and business modeling. We illustrate this discussion using the development of a mobile tool for preventing and treating tick bites, in order to prevent Lyme disease.

The rest of this paper is organized as follows. In Section 2, we discuss the CeHRes (center for eHealth research) roadmap, a holistic design approach for eHealth, which will form the basis of the mobile 'tick tool' development, and in which we embed the use of personas. In Section 3 we introduce the design case used to illustrate our use of personas, followed by the procedure we applied to determine and understand the most prominent user groups, and to create personas. To conclude this section, we outline how we have used these personas and will use them in future design activities. We complete this paper with a reflection on the use of personas in the development process and an outline of future work.

II. HOLISTIC DESIGN FOR EHEALTH

A. CeHRes Roadmap

The development of technology (be it in the context of health, government, or somewhere else) can be guided by means of several design approaches. Human-centered design, which advocates the systematic, continuous consultation of potential users, from as early in the design process on [8], is one such approach. It has been found to have positive effects on the final system; for example, it prevents the inclusion of superfluous features and increases user acceptance [9]. Another approach, business modeling, focuses on generating a good fit between the technology in development on the one side, and organizational resources and capabilities on the other side, in order to create a viable technology [10].

The CeHRes roadmap is a framework that guides the design of eHealth applications [11]. It incorporates both a human-centered design, and a business modeling approach.

 ISBN: 978-1-61208-179-3

Figure 1 displays the roadmap and shows the five main phases in the development process:

1. **Contextual inquiry**. In the first phase, the design team must get an understanding of prospective users and their context, and analyze the strong and weak points of the current provision of care.
2. **Value specification**. Next, it is determined which values the different stakeholders deem important. These values and prospective users' needs and wishes need to be translated into functional, organizational and technical requirements
3. **Design**. Based on the requirements, (a prototypical version of) the technology is developed. The framework advocates the application of cooperative design in which the design team creates the technology with prospective users and stakeholders together.
4. **Operationalization**. At this moment the technology is launched, marketing plans are set into motion, and organizational working procedures are put into practice.
5. **Summative evaluation**. Finally, the eHealth technology is evaluated: How is it being used and what is its effect on patients and healthcare?

The CeHRes roadmap should not be seen as a waterfall process, but is iterative in nature: formative evaluations should be conducted continuously. Each phase comes with a set of design and evaluation tools that can be deployed, but their suitability depends on the situation at hand. A complete overview of these tools and their uses can be found at [12].

B. Personas as Linking Pin in the CeHRes roadmap

Within the holistic approach to eHealth design that the

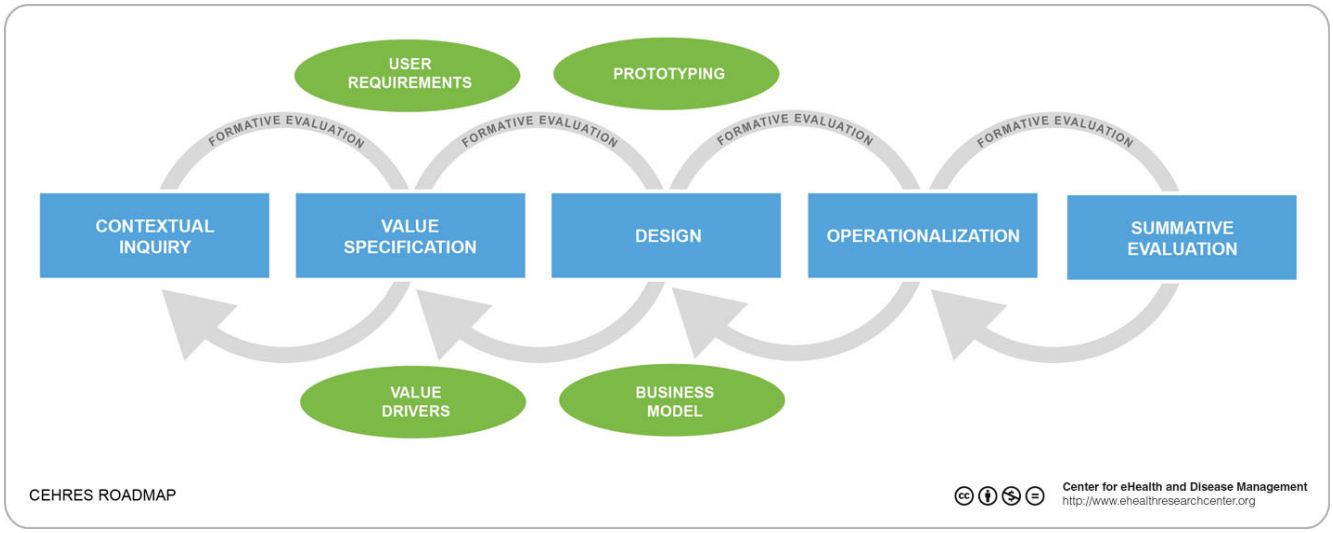

Figure 2. CeHRes roadmap

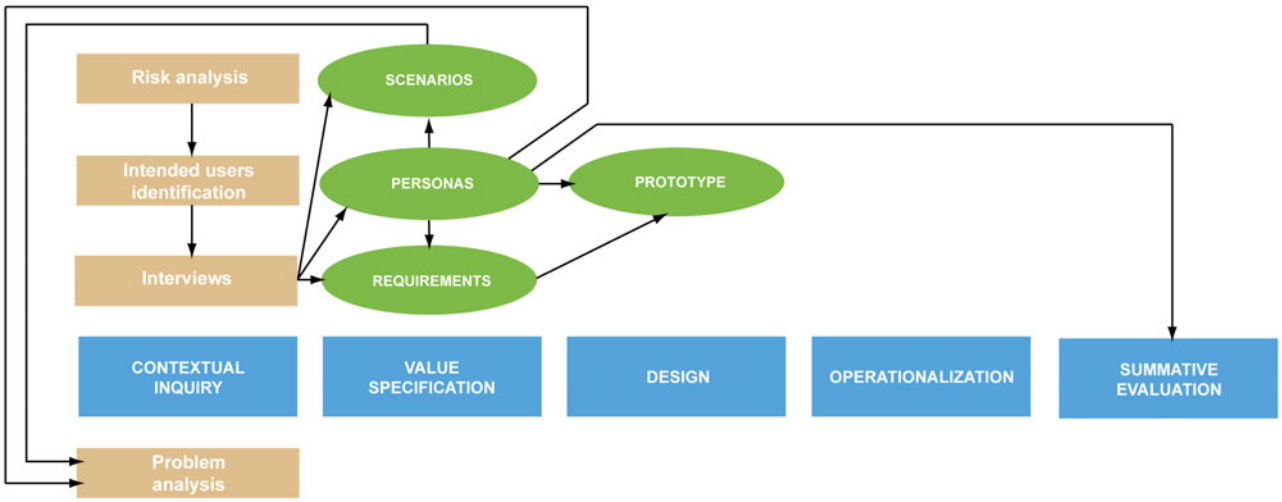

Figure 1. Personas in the CeHRes roadmap

TABLE I. EXCERPTS OF TABLE DESCRIBING INTERVIEW RESULTS AND TRANSLATION TO PERSONA: THE ONE THAT DOESN'T CARE

Interview segment	The one that doesn't care	Sample quote	Translation to persona
Knowledge of ticks and Lyme disease	Widespread: some people know nothing, some people know a lot. For persona 'medium knowledge' is used.	Woman: "yes, a bug that sucks blood out of you. It will get stuck to your skin and then it will suck your blood I believe." Daughter: "And then it squirts something back and then you become ill from that. Then you get Crohn's disease? [interviewee thinks] No, Lyme disease." Woman: "It will probably have something like clawlike teeth. And I think something's in there. […] It's about the head, that should come out. Because there's something in it. And when you've done that, you have to see whether you get this little circle. You have to keep an eye on it. And when this little circle turns up you have to go your GP immediately."	But he does know some things about the bug. He knows that it's an insect that bites and sucks your blood. He also knows it can give you Lyme disease. Finally, he thinks that ticks fall down on you from trees
Dealing with tick bites	Have different strategies for dealing with tick bites: ▪ Removing themselves with (tick)pliers ▪ Visiting a doctor	Man: "Well, we have these tick pliers, so I think I'd give it a shot. To get it out." Interviewer: "Do you have these?" [shows tick pliers] Man: "Yes. Although I'd need the description to find out what is the best way to do that." Man: "yes, I've understood that you need to visit your GP then." Interviewer: "So you'd call your GP?" Man: "Yes. Not at first of course. When you're bitten you're not sure. It could of course also be a mosquito bite."	and that if you're bitten you should visit your GP to get the tick removed.

CeHRes roadmap is, personas can play an important role. They can serve as inspiration for functional design and interface & interaction design, but they can also be used to reflect on the existing organizational structures behind care (e.g., by letting stakeholders discuss a persona's journey through healthcare for a given situation, thereby identifying weak and strong points). As such, the use of personas and the CeHRes roadmap to develop eHealth technology serve as a catalyst for change in health care: New care through new technology.

Figure 2 shows how we have embedded personas within the CeHRes roadmap. We would like to stress that this is not the only possible strategy for using personas, nor is it necessarily the best way for doing so. Whether and how one should use or develop personas depends on the design context and the means available to the design team. That being said, we think that the role we have assigned to personas, both in the roadmap and the case study, ensures that the resulting personas are valid and that their usefulness is maximized.

The development of the personas is based upon a risk analysis to determine the most important user groups for the new eHealth technology, and interviews with members from these user groups. These personas, combined with scenarios (fictitious anecdotes of a persona experiencing an illness and the associated healthcare) will then be used as input during a stakeholder session that has the goal to reflect on the existing care delivery process and to eventually alter this practice. They also serve as input for the requirements engineering and actual design of the new eHealth technology and the evaluation thereof.

III. FROM THEORY TO PRACTICE: THE CASE OF DESIGNING A MOBILE TICK TOOL

Lyme Borreliosis is an infectious disease caused by Borrelia spp. and transmitted to humans by a bite from an infected tick. In 2006-2007, 1.1 million citizens (out of a population of 16 million) in the Netherlands were bitten at least once by a tick [13]. This number is in line with a trend that shows that the number of tick bites and infections with tick-borne diseases is increasing in the last decades.

In order to end this trend and to prevent the contraction of Lyme disease, a novel approach to alerting citizens to the dangers of tick bites, and how to deal with these insects was needed. It was decided to create a new intervention by following the CeHRes roadmap. The use of mobile technology was introduced as a technology push. As people are mostly confronted with ticks on locations away from home (e.g., forests or dunes), it was posited that people would benefit from information and instructions provided on site.

The design team consisted of two experts on eHealth development and two experts in the field of infectious disease control. Furthermore, four local health authorities (in Dutch: GGD) were committed to the project and invested time and effort in the recruitment of participants and contributed their thoughts during the development process.

 ISBN: 978-1-61208-179-3

TABLE II. EXCERPTS OF TABLE DESCRIBING INTERVIEW RESULTS AND TRANSLATION TO PERSONA: THE ONE THAT CHECKS

Interview segment	The one that checks	Sample quote	Translation to persona
Knowledge of ticks and Lyme disease	Medium to high knowledge of ticks and Lyme disease	Woman: "They are these little bugs. You don't see them very well. You have a chance of being bitten by one when you go walking in the forest. I don't know whether there are any other places […] but for sure where there are trees. So you can be bitten by one. Not only humans, animals as well. And if it stays stuck for too long, then there's a chance you become ill. Then you get Lyme disease and that's a big drama. So you have make sure you get it out on time."	By now, Anouk also knows some things about ticks. She knows that you can get a tick bite when walking in the forest and that it can make you very ill. So she thinks it's very important to find a tick bite as soon as possible.
Dealing with tick bites	Will remove the tick themselves with (tick)pliers	Woman: "Remove them myself" Interviewer: "And how would you do that?" Man: "You have these special devices you can put on them." Interviewer: "Do you have one of those at home?" Man: "My parents used to have one. But since I live together we don't have those. Maybe a good idea to get one of those sometime."	Should she find a tick that has bitten, then she would remove it herself using tick pliers.

At the moment of writing, the development process for the mobile tick tool has not been completed. We have completed the development of the personas and are preparing the stakeholder meeting which will use the personas as input for rethinking the prevention and care activities for Lyme disease. We will discuss this in more detail in Section III D.

A. Determining user groups

The first step in the development of our personas was to determine the primary user groups for the mobile tick tool. Therefore, the four Local Health Authorities conducted a risk analysis: they identified the groups of people that were most at risk of contracting Lyme disease as a result of a tick bite and that would be most susceptible towards persuasive efforts. The risk analysis was based upon a systematic procedure for risk determination for infection prevention [14]. This procedure, on its turn, was developed using a literature review, Dutch national infection prevention guidelines, practical experience, and previously published procedures for risk determination.

The risk analysis identified three primary user groups: Recreationists, children, and green professionals (e.g., gardeners and foresters). We decided to create one mobile application for recreationists and children, as these groups partly overlap (people that spend a lot of time outdoors may do this with their children). For green professionals we will develop a separate specific mobile tick application in collaboration with occupational health experts. In this paper, we will now focus on the development of the personas for the primary user group 'recreationists' only.

B. Interviewing the primary user group

In order to understand our primary user group 'recreationists,' and the designated context of use, we conducted 15 semi-structured interviews. The interview protocol was based upon the overview of persona attributes by [7]. It consisted of three main parts. The first part, **demographics** focused on interviewee characteristics, such as age, family situation, etc. The second part, **healthcare specifics**, zoomed in on the interviewee's knowledge of ticks and Lyme disease, how they deal with ticks and tick bites (including checking for tick bites), their attitudes towards possible information sources for tick- and Lyme related information, their stance towards preventive measures, and finally, the frequency with which they visit risk areas. The last issue was questioned by asking interviewees to state how often they visited risk areas, identified in [15, 16]. In the last part of the interview, **technical specifics** were discussed. Interviewees were asked about their skills, possession of mobile technology, wishes and expectations regarding a mobile tick tool and a web-based variant, and finally, in which situation they would use these technologies. As the interviews were semi-structured, the interviewer was allowed to discuss interesting issues that came up during the interview.

The interview participants were recruited by two Local Health Authorities (one in a high endemic, and one in a low endemic area) and consisted of persons receiving vaccinations for international travel. This group of people can be assumed to be frequent recreationists. All interviews took place at the Local Health Authority office; right before or after the interviewees received their vaccinations. Some interviews were conducted with individuals, some with pairs of people (e.g., husband and wife). Each interviewee received a gift voucher for their participation. Prior to the interview, the interviewer explained the goal of the interview, explained that the interviewee would remain anonymous, and obtained permission for making an audio recording. Each interviewee then signed an informed consent form. An average interview lasted 30 minutes.

 ISBN: 978-1-61208-179-3

There is no set procedure for translating interview data into personas. We transcribed the interviews and then analyzed using Atlas.ti 6.2 by classifying each comment under the applicable category in the persona attributes overview, as suggested by [7]. Then, we created an overview, displaying each interviewee's response to the most important attributes.

C. *Personas for a public mobile Lyme tool*

From the overview with interviewees' responses it became clear that there were two distinctive groups of people and that we should create two personas. The first persona we called **the one that doesn't care**. This persona corresponded with the answers of 12 interviewees, making it our primary persona. In short, this persona is not really concerned about ticks or Lyme disease, does not visit risk areas often, does not check for ticks, and intends to use technology only when being confronted with a tick bite. Our second persona, **the one that checks**, was represented by 3 interviewees, making it our secondary persona. This person has experience with being bitten by a tick, often visits risk areas, (almost) always checks for ticks, and will use technology to read about ticks out of curiosity.

In order to create the persona biographies, we created two tables (one for each persona) in which we listed relevant interview segments, how the group of interviewees representing a persona responded, typical quotes, and finally, the section of the persona biography that represents this interview result. In Table 1 and 2 we provide excerpts from these tables for the two different personas.

Figure 3 shows our persona for the one that doesn't care. We have given this persona a name, Mark, and added a picture to the biography to make it livelier. Each sentence in the persona description corresponds to a finding from the interviews.

Mark is 54 years old and planning engineer for a construction company. He lives together with his wife. Together, they have two children (21 and 19 years old) that live on their own by now. They don't live completely alone though, together they take care for their dog: Tommy

Fortunately, Mark has never been bitten by tick. But he does know some things about the bug. He knows that it's an insect that bites and sucks your blood. He also knows it can give you Lyme disease. Finally, he thinks that ticks fall down on you from trees, and that if you're bitten you should visit your GP to get the tick removed. Mark has seen ticks before, Tommy takes them home now and again. Then, Mark or his wife remove them with tick pliers.

Mark does not visit nature very often. In the summer he likes to sit in his backyard, and when they go on vacation he and his wife like to make long walks through the forests or the mountains. He does not take preventive measures to prevent a tick bite then. He also doesn't check for tick bites afterwards. It simply does not cross his mind.

His digital skills are perfectly fine, Mark thinks. After all, he thinks it's fun to try out new technology and he has numerous apps on his iPhone 4g. He takes his phone everywhere and never turns it off. Mark will only start to search for information about ticks on the Internet or on his iPhone when he notices he's been bitten by a tick. In that case, he will Google first, but will also check out the website of his Local Health Authority.

Photo: ChrisGoldNY, used under creative commons license

Figure 3. Persona Mark

D. *Using personas in the development process*

Writing the biographies of our personas marked the end of persona development. At the moment of writing, we now enter the stage of utilizing personas in our holistic design process. There are, in our view, a variety of ways for benefiting from these user representations which we will use in the design of our mobile tick tool.

First, personas will be used to inspire the creation of requirements, as well as functional and interface & interaction design of prototypical versions of the mobile tick tool. The design team must question the usefulness and appearance of the design with the different personas in mind. Is this function one Mark or Anouk (the secondary persona) would use? Will Mark and Anouk understand the explanations about Lyme disease that are published on this website? Furthermore, the personas, and especially their disposition towards preventing tick bites and checking for tick bites, will be used as a basis for persuasive design. It is towards these attitudes that

 ISBN: 978-1-61208-179-3

persuasive strategies, as implemented in the mobile tick tool need to be geared [17].

Second, personas will serve as the basis for the creation of scenarios describing a typical case of getting a tick bite and consequently, contracting an Erythema Migrans (a frequent first, innocent sign of Lyme disease). These scenarios will also be inspired by interviews we held with people that contracted Lyme disease, and their stories. These scenarios will be presented to stakeholders (identified on the basis of the prevention and care protocol for Lyme disease in the Netherlands) such as GPs, Local Health Authorities and tourist services in high endemic areas. By means of these scenarios we wish to stimulate a discussion about the strong and weak points of the current prevention and care path for tick bites and an Erythema Migrans (problem analysis in Figure 2). The identified problems can then be tackled through the design of the mobile tick tool and the business model that accompanies it. As a result, personas will also serve a role in the business modeling track of the design process.

Third and finally, personas will influence the design of the evaluations that will be conducted throughout the design process. During formative evaluations (conducted in order to receive redesign input), personas will be used when recruiting evaluation participants, as suggested by [2]. It is also possible to use personas for cognitive walkthroughs. In this case, experts can be asked to look at a prototype and to determine whether they can find redesign issues, asking themselves questions like: Would Mark understand what he is looking at? Could Anouk use this function successfully and satisfactorily? With regard to the summative evaluation of the mobile Lyme tool, the personas will be used to select the proper evaluation criteria, especially when it comes to the persuasive effect of the mobile tick tool. Persuasive goals and strategies need to be set according to each persona and need to be evaluated accordingly.

IV. CONCLUSION AND FUTURE WORK

In this paper we have discussed how one can develop and utilize personas for eHealth within the context of an holistic design approach. Personas can be the linking pin in the development process of eHealth. They serve as lively summarizations of user groups, can inform design, and finally, inspire problem analysis activities with stakeholders. Therefore, we can only encourage eHealth developers to look seriously into the possibilities for utilizing personas in their development processes. In the future, we will complete the design of the mobile Lyme tool, following the CeHRes roadmap and utilizing the personas where applicable.

ACKNOWLEDGMENT

We would like to thank the local health authorities of West-Brabant and Zeeland for their cooperation. We especially want to thank Angelique Maat for her enthusiasm and great help during the recruitment of participants.

REFERENCES

[1] A. Cooper, The inmates are running the asylum. Why high-tech products drive us crazy and how to restore the sanity. Indianapolis: SAMS, 1999.

[2] J. Pruitt and T. Adlin, The persona lifecycle. Keeping people in mind throughout product design. Amsterdam: Morgan Kaufmann Publishers, 2006.

[3] K. Bredies, "Using system analysis and personas for e-Health interaction design," presented at the Design research society conference, Sheffield, UK, 2008.

[4] L. Goldberg, et al., "Usability and accessibility in consumer health informatics," American Journal of Preventive Medicine, vol. 40, pp. 187-197, 2011.

[5] L. Spinhof and L. Calvi, "User and task analysis in a home care environment," presented at the 20th international symposium on human factors in telecommunication, Sofia Antipolis, France, 2006.

[6] E. Villalba, et al., "User interaction design for a wearable and IT based heart failure system," presented at the 12th international conference on human-computer interaction, Beijing, China, 2007.

[7] C. LeRouge, et al., "User profiles and personas in the design and development of consumer health technologies," International Journal of Medical Informatics, in press.

[8] J. D. Gould and C. Lewis, "Designing for usability: key principles and what designers think," Communications of the ACM, vol. 28, pp. 300-311, 1985.

[9] S. Kujala, "User involvement: a review of the benefits and challenges," Behaviour & information technology, vol. 22, pp. 1-16, 2003.

[10] T. Spil and B. Kijl, "E-health business models: From pilot project to successful deployment," IBIMA business review, vol. 1, pp. 55-66, 2009.

[11] N. Nijland, "Grounding eHealth: Towards a holistic framework for sustainable eHealth technologies," Dept. of Psychology, Health and Technology, University of Twente, Enschede, the Netherlands, 2011.

[12] Center for eHealth research and disease management. (2011). eHealtwiki. Available: http://www.ehealthwiki.org

[13] A. Hofhuis, et al., "Ziekte van Lyme in Nederland 1994-2009 [Lyme disease in the Netherlands 1994-2009]," Infectieziekten bulletin, vol. 21, pp. 84-87, 2010.

[14] F. Konings, "Risico-inventarisatie bruikbaar instrument voor infectiepreventie [Risk inventory useful instrument for infection prevention]," Infectieziekten bulletin, vol. 21, pp. 124-127, 2010.

[15] P. R. Wielinga, et al., "Longitudinal Analysis of Tick Densities and Borrelia, Anaplasma, and Ehrlichia Infections of Ixodes ricinus Ticks in Different Habitat Areas in The Netherlands," Applied environmental Microbiology, vol. 72, pp. 7594-7601, 2006.

[16] F. Konings, et al., "Effectieve preventie van tekenbeten [Effective prevention of tick bites]," GGD West-Brabant, Breda2009.

[17] H. Oinas-Kukkonen, "Behavior change support systems: The next frontier for web science," presented at WebSci10: Extending the frontiers of society on-line, Raleigh, NC, USA, 2010.

 ISBN: 978-1-61208-179-3

Health Technology Trust: Undeserved or Justified?

A review of technological risks in eHealth

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***Abstract* - Challenges for global health care are considerable. Increasing healthcare expenditures, ageing, the rise of chronic diseases and the public health threat of infectious diseases give reason to worldwide concern. Many believe eHealth technologies to contribute to the solution of these issues and to the necessary innovation of healthcare systems. Is the widespread trust among public administrations, care professionals, researchers and the general public justified? The present paper aims to assess the risks of eHealth technologies for both patient safety and quality of care. A quick-scan of scientific literature was performed to collect publications on risks associated with the use of eHealth applications in cure and care. Only random clinical trials (RCTs) were included. Data-management issues were excluded. Of 340 identified publications, 17 met the inclusion criteria. Human, technological or organizational risks appear to be no subject of RCTs. But they come into view *en marge* implementations. As such, the selected studies suggest there is evidence for risks caused by the use of eHealth in healthcare which can negatively affect the quality of care and the safety of patients. A realistic reconsideration of the implementation of eHealth interventions is recommended. The ceHRes roadmap is an evidence-based guideline to systematically avoid or minimize these risks.**

Keywords - risks; eHealth technology; patient safety; quality of care; trust

I. INTRODUCTION

Challenges for global health care have been documented extensively. Most countries face a serious increase in healthcare expenditures that corresponds to ageing, a growth in multi-morbid chronic illnesses, the menace of infectious diseases, consumerism or other dynamics [1, 2]. eHealth technologies have frequently been hailed as a panacea for these challenges. These technologies have proven their potential to contribute to the increase of (cost-) effectiveness and efficiency of care, the improvement of the quality of care, the empowerment of consumers, system transparency, and eventually to the reduction of health care costs [3-7]. But expectations have recently been mitigated due to the publication of studies that emphasize the complex nature of innovation in healthcare and the lack of rigid evidence for impact of eHealth technologies on health care outcomes thus far [8, 9]. Moreover, the application of eHealth technologies in healthcare may introduce risks for patient safety and quality of care [10-12]. Nonetheless, trust in information and communication technologies (ICT) seems to remain unaffected by these moderating results. This is remarkable against a backdrop of widespread declining trust in the legal system, in politics, finance, science and other public domains [13, 14]. Public administrations, care professionals, researchers and the general public are generally trustful and overly optimistic about the 'a-political' power of digital technology in virtually all public and personal domains [15, 16]. Investments in ICT are rarely withdrawn because of identified or alleged risks for patient safety or for the quality of care. Where interpersonal trust is an attitude towards others whom we hope will be trustworthy, institutional trust refers to institutions or systems (i.e. the government or the administration of justice) and their trustworthiness [17]. The value of institutional trust lies in its opportunities for cooperation, knowledge, autonomy and other 'social goods' that contribute to the foundations of society [18]. In the case of eHealth technology the question if trust is warranted is socially important as well. Is it plausible, justified and well-grounded to trust technologies that are designed to advance health, safety and care? Are these systems trustworthy themselves? Is adherence related to trust? Trust in and trustworthiness of eHealth interventions are obviously affected by (perceived) risks and lack of knowledge in the long run. Over the last decades studies of risk (and technology) have grown into a major interdisciplinary field of research. Risk researcher Hansson states "When there is a risk, there must be something that is unknown or has an unknown outcome. Therefore, knowledge about risk is knowledge about lack of knowledge. This combination of knowledge and lack thereof contributes to making issues of risk complicated from an epistemological point of view" [19]. Since epistemology is not our focus here we will apply a an internationally accepted definition for risk i.e. "the combination of the probability of occurrence of harm and the severity of that harm" [20]. This definition is also used

 ISBN: 978-1-61208-179-3

in the international standard for risk management of medical devices [21] which is the regulatory sector in which part of the eHealth technologies can be classified.

In a recently published study we have reported on flaws and drawbacks of eHealth technologies [22]. This study was based on a comprehensive analysis of eventually sixteen frameworks regarding the development and implementation of eHealth interventions over the last decade (2000-2010). The reported drawbacks may legitimately be conceived as risks since they imply equivalent and immediate hazards for the patient's safety or the quality of care. Therefore we think it relevant for the present study to provide a short summary of these findings. Table I shows a summary of these risks phrased in conceptual terms.

TABLE I. RISKS DERIVED FROM PREVIOUS RESEARCH*

Conceptual risk	Description
eHealth technology development as an expert-driven process	If project management fails to arrange stakeholder participation in the full development process risks for rejection by (end-)users increase.
eHealth technology development ignores evaluation	If the development is viewed as a linear, fixed and static process instead of a iterative, longitudinal research activity risks of suboptimal outcomes increase.
Implementation of eHealth technology as a post-design activity	If conditions for implementation are not properly accounted for right from the start in all subsequent stages stakeholders may drop out.
eHt development does not affect organization of healthcare	If it is ignored that eHealth technologies intervene with traditional care characteristics and infrastructure unexpected effects cause stakeholders to abandon.
eH technologies as instrumental, determinist applications	If eH interventions ignore users' needs for affective, persuasive communication and information technologies for motivation, self management and support, they drop-out..
eH research fails to integrate mixed-methods and data triangulation	If conventional research methods keep falling short of assessing the added value for healthcare in terms of process (usage, adherence) and outcome variables (behavioral, clinical outcomes; costs) societal and scientific refutation follows.

* Van Gemert-Pijnen et al., 2011 [22]

Precisely the opposites of factors that improve the uptake and impact of eHealth technologies constitute risk for both patient safety and quality of care; they increase the probability of occurrence of harm and the severity of that harm. For further reading we refer to the abovementioned review.

In the present study we seek to validate these outcomes by assessing the nature and prevalence of any risk to patients´ safety and quality of care that may be associated with eHealth applications, as established in randomized controlled trials. These interventions include web-based and mobile applications for caregivers, patients and their relatives within a treatment relationship as well as technology regarding quality in healthcare. This provides an inventory of documented risks that impact on quality of care and the patients' well-being. Increasing use of eHealth technology is one of the major developments in today's healthcare [23]. The opportunities of web-based and mobile eHealth technologies should therefore remain central to the global health discourse. At the same time it is required to explore the risks of these technological advancements.

II. LITERATURE SCAN

The present desk research involves a literature scan to exploratory assess only those risks that are reliably documented in the scientific literature. The scan is restricted to publications regarding risks that affect the quality of healthcare and the patients' safety. The public health domain is excluded. Issues concerning security of data-transmission, storage, encryption, standardization, data-management and privacy are not included to avoid overlap and redundancy [24]. The search is limited to randomized controlled trials (RCT) to allow for comparisons. No systematic review was performed.

The bibliographic database SciVerse Scopus was searched because of its broad content coverage including 100% coverage of Medline titles and over 16.000 peer-reviewed academic journals. The used search query combined the topic 'eHealth' with search terms regarding risk, healthcare-setting and study design. The complete query can be found in Appendix I. One author reviewed the titles and abstracts of the identified publications to decide whether they should be examined in full detail. Inclusion criteria are: (1) the article deals with an eHealth application and/or (2) deals with risks for (3) quality of care in general and/or patients´ safety resulting from the use of the application. Articles describing such risks merely as unintended outcomes were included as long as these risks affect quality of care and/or patients´ safety. Articles whose titles contained outcome-measures or evaluation criteria of an eHealth program were included as well. If risks or limitations where explicitly mentioned in the abstract, the article was included. Furthermore (4) articles had to be RCTs published (5) between 2000-2011. Finally (6) only articles written in the German and English language were scanned. An overview of the inclusion criteria is presented in Table II. The study selection process is included in Appendix II.

 ISBN: 978-1-61208-179-3

TABLE II. INCLUSION CRITERIA FOR THE STUDY SELECTION PROCESS

Inclusion criteria
1. eHealth application
2a. in Title: outcome-measure and/or evaluation and/or risk
2b.in Abstract: risk and/or limitation found
3. Quality of care and/or patients´ safety/well being
4. Design: Randomized controlled trial
5. Publication year: between 2000 – 2011
6. Language: German or English

Identified risks were structured according to a multi-level approach covering risks dealing with either human factors (patient), technology factors or organizational factors, referring to the framework for health information systems evaluation as proposed by Yusof et al. [25].

III. OUTCOMES

A. Study characteristics

The search was performed in SciVerse Scopus in July 2011 delivering initially 340 potentially relevant publications. Of these, 17 were eventually included after the selection procedure described sub II.

B. Multi-level risks assessment

Human, technological or organizational risks appear to be no primary subject of the RCTs identified in the search. However they emerge as secondary effects or unintended outcomes of eHealth technology implementations. Identified risks have been structured with regard to their primary occurrence at a human level, a technological level and organizational level.

1) Risks concerning Human factors

Masa et al. [26] compared conventional spirometry to online spirometry with regard to outcome measures like forced vital capacity, quality criteria (acceptability, repeatability) and the number of maneuvers and time spent on both of the two procedures. They found that the number of spirometric maneuvers needed to meet quality criteria was somewhat higher in the online mode as compared to conventional spirometry. Online spirometry also took more time for patients (mean differences of 0.5 additional maneuvers and 0.7 minutes more). Higher time-consumption may also negatively affect the remote technician instructing the patient while the latter uses the spirometer. The spirometric values achieved online were very similar to the values achieved by conventional spirometry.

Some eHealth applications appear to be more beneficial for specific patient groups. Bujnowska-Fedak et al. [27] tested a tele-homecare application for monitoring diabetes. Older and higher educated patients, spending a lot of the time at home and having acquired diabetes recently, benefited most from the application. A positive association was found between educational level and ability to use the tele-monitoring system without assistance. Spijkerman et al. [28] evaluated a web-based alcohol-intervention without (group 1) and with (group 2) feedback compared to a control group in order to reduce drinking behavior in 15-20yrs. old Dutch binge-drinkers. They found that the intervention may be effective in reducing weekly alcohol use and may also encourage moderate drinking behavior in male participants over a period of 1-3 months. The intervention seemed mainly effective in males while for females a small adverse effect was found. Women following intervention group 1 were less likely to engage in moderate drinking and had increased weekly drinking a little, although significantly (p=.06; 1.6 more drinks/week), at one month follow-up. Zimmerman et al. [29] performed a secondary analysis on data from an RCT on a symptom-management intervention for elderly patients during recovery after coronary artery bypass surgery. They found that the intervention had more impact on women than on men for symptoms such as fatigue, depression, sleeping problems and pain. Regarding measures of physical functioning no gender differences were found. Cruz-Correira et al. [30] tested adherence to a web-based asthma self-management tool in comparison to a paper-based diary. The tool was designed to collect and store patient data and provide feedback to both patient and doctor about the former's condition in order to support medical decision making. Patients' adherence to the web-based application was lower than in the control group. Willems et al. [31] tested a home monitor self-management program for patients with asthma where data such as spirometry results, medication use or symptoms were recorded. They found a low compliance of participants with the intervention protocol. Participants in the intervention group recorded in average less PEF tests (peak expiratory flow; lung function data): 1.5 per day versus the required number in the protocol of 2 tests per day. Verheijden et al [32] tested a web-based tool for nutrition counseling and social support for patients with increased cardiovascular risk in comparison to a control group receiving conventional care. The authors found that the uptake of the application in the intervention group was low (33%) with most participants using the tool only once during the 8 months study period. Patients properly using the intervention were significantly younger than those who did not. Morland et al. [33] compared an anger management group therapy for veterans delivered face-to-face versus via videoconferencing. Group therapy via videoconferencing teleconferencing seemed effective to treat anger symptoms in veterans. While no differences could be found between the two groups regarding attendance or homework completion, the control group reported a significant higher overall group therapeutic alliance than the intervention group. Postel et al. [34] evaluated an eTherapy program for problem drinkers, where therapist and patient communicated online to reach a reduction of alcohol use, as compared to a control group receiving regular information by email. While effective for complying participants, they found high drop-out rates in the eTherapy group though quitting the program

 ISBN: 978-1-61208-179-3

did not automatically mean that the participant had also relapsed or increased alcohol consumption. Ruffin et al. [35] tested a web-based application where participants received tailored health messages after giving information about family history of six common diseases. In the intervention group the authors found modest improvements in self-reported physical activity and fruit and vegetable intake. But participants also showed a decreased cholesterol-screening intention as compared to the control group who received standard health messaging.

In summary, higher time consumption, unintended adverse effects, and selective benefits differing for sex, education, age and other variables are the risks observed on the side of the human (end-)user. Frequently adherence (or compliance, drop-out, alliance, up-take) is mentioned and associated with a negative impact on the intended effect of an intervention.

2) Risks concerning Technology

Evaluating a tele-homecare application for monitoring diabetes Bujnowska-Fedak et al. [27] observe usability problems among participants; 41% of them (patients with type 2 diabetes) were unable to use the system for glucose-monitoring needing permanent assistance. Patients who could easily use the application derived a greater impact from its use. Nguyen et al. [36] evaluated an internet-based self-management program for COPD patients but discontinued before the sample target was reached due to technical and usability problems with the application. Participants stated at the exit interview that decreased accessibility, slow loading of the application, and security concerns prevented them from using the website more frequently. Participants reporting usability problems had to complete (too) many actions on a PDA-device before being able to submit an exercise or symptom entry. Other problems dealt with limited wireless coverage of the PDA. The technical problems decreased participants´ engagement with the tools. Decreased engagement was associated with the number of web log-ins and the exercise and symptom entered via the website and/or the PDA. While evaluating a web-based asthma self-management tool Cruz-Correira et al. [30] found nine patients reporting problems (19 in total) related to the use of a web-based self-management tool. Most problems concerned the internet connection and the graphical user interface. Two of the patients could not even use the application because of technical problems. Demaerschalk et al. [37] tested the efficacy of a telemedicine application (vs. telephone-only consultation) for the quality of decision making regarding acute stroke. They found technical issues in 74% of telemedicine consultations versus none in telephone consultations. The observed technical problems did not prevent the determination of treatment decision but some did influence the time necessary to treatment decision-making. Jansà et al. [38] used a telecare-application for type 1 diabetes patients having poor metabolic control to send glycaemia values to the diabetes team. They found that 30% of team-patient appointments were longer than expected (1h vs. 0.5h) due to technical problems with the application. Technical problems concerned the inability to send results of counseling caused by problems with the application itself, the server or internet-access. Using a telemanagement application for diabetes patients Biermann et al. [39] found that 15% of the participants had difficulties in handling the application, the consequences of which were not elaborated. In a study of an asthma self-management telemonitoring program by Willems et al. [31] 1/3 of participants experienced technical problems, mostly with malfunctioning devices. Practitioners had to contact patients e.g., regarding a missed data transfer leading to logistical problems.

In summary, a variety of issues have been reported at the technology level affecting patient safety or quality of care. They range from usability problems and security issues to problem with accessing the server or malfunctioning devices.

3) Risks concerning Organization

Copeland et al. [40] tested whether a telemedicine self-management intervention for congestive heart failure (CHF) patients could be effective in terms of improving physical and mental health-related quality of life and cost-effectiveness as compared to a control group receiving usual care. They could not find substantial differences between groups, but overall costs related to CHF were higher for the intervention group. The authors state that this might be related to the intervention encouraging medical service utilization by facilitating access to care.

One tele-management application for diabetics allows patients to measure their blood-glucose values and send it to their care provider [39]. Though time-saving for patients, use of the application lead to 20% more time investment (50 vs. 43 min. per month over a 4-month period, and 43 vs. 34 min. per month over an 8-month period) on the side of the care provider compared to conventional care. The higher time expenditure did not reflect time necessary to manage the application itself: it was due to more access to the provider, so that patients tended to call more often. Montori et al. [41] also found a comparable risk concerning time-consumption. They tested a telecare-application for data-transmission for type 1 diabetes patients. The nurses needed more time reviewing glucometer data (76 min. vs. 12 min.) and giving the patient feedback (68 minutes vs. 18 minutes) in the telecare condition as compared to the control group. The authors found more nurse feedback time to be significantly associated with more changes in insulin doses; more changes of doses thus appeared in the telecare group.

Strayer et al. [42] tested a personal digital assistant (PDA) as a tool for improving Smoking Cessation Counseling (SCC) against a paper-based reminder tool. In semi-structured interviews medical students providing SCC

 ISBN: 978-1-61208-179-3

reported that they felt barriers for using the PDA in practice such as a lack of time or a lack of training. Also they felt uncomfortable to use the PDA in the presence of patients. The PDA tool did not increase key SCC behaviors of the participants of the intervention group as compared with the paper-based reminder.

In summary, increased time consumption, barriers for proper use and financial issues are the risks observed at the organizational level.

IV. CONCLUSION

RCTs of the immediate risk of eHealth technology for patients' safety or quality of care have not been found. Risks emerge as unintended, secondary outcomes in the margin of studies aiming to evaluate the effectiveness of eHealth interventions. The selected studies suggest nonetheless evidence for risks at all three levels of the multi-level approach applied. Ten studies mention risks concerning the patient at the human level, especially where adherence issues lead to suboptimal use of an intervention and corresponding low effectiveness. But also adverse effects were reported, as well as the fact that not all patient groups can equally benefit from an eHealth intervention. Issues at a technological level were found in seven studies, revealing considerable rates of usability problems, limited access or other technical problems. Organizational issues were found with regard to higher use of resources (time, money, staff) affecting quality of care in two studies. Table III shows the level and nature of the risks observed in our study.

TABLE III. OBSERVED RISKS

Risk level	**Description**
Human level	Adherence (or compliance, drop-out, alliance, up-take)
	Unintended adverse effects
	Selective patient benefits (sex, education, age and other variables)
Technology level	Usability problems
	Access
	Security issues
	Malfunctioning devices
Organizational level	Higher time consumption
	Barriers for proper use
	Higher costs

In some cases the causes of the risks were qualified as study (design) artifacts. In many instances the consequences have not been elaborated.

V. DISCUSSION

Risk is a complicated epistemological issue that refers to a lack of knowledge along subjective and objective dimensions. Trust is an important social good. But trust is risky. The observed lack of academic interest for risk assessment in eHealth technology should be a matter of concern. Patient safety and quality of care deserve a high level of risk awareness when it comes to new technologies. At present risks emerge in the margin of RCTs in eHealth. They are conceived as problems, issues, disadvantages, costs or other designations that one way or another affect human, technological or organizational functioning in a detrimental manner.

Though both quantity and quality of the reported issues do not seem disturbing at first glance, a wider search would almost certainly deliver a more disquieting range and diversity of risks. Given the outcome of our study that none of the RCTs were designed to study risks, we must conclude that they do in fact not represent the studies with the highest evidence level related to our research question. Therefore, a follow-up search, including review articles, controlled clinical trials, and perhaps also observational studies should be performed. Furthermore, in databases such as MAUDE (Manufacturer and User Facility Device) of the U.S. Food and Drug Administration, in grey literature, articles in professional magazines and other (online) sources of different organizational, consumer and academic nature a variety of incidents involving risks have been recorded[1]. While often viewed as avoidable or improvable intervention flaws or explained as study (design) artifacts they should not be played down. Their presumed prevalence and incidence give rise to reconsideration when it comes to exploring the opportunities of web-based and mobile eHealth technologies for global healthcare innovation.

This reconsideration implies the need for extensive research that explicitly focuses on establishing the volume and nature of such risks. It also implies an improved way of monitoring to advance transparency in the reporting of risk prevalence and safety incidents. Finally it implies a higher level of healthcare risk management, continuity of care and understanding of how risks affect patients through risk identification, operating ways to avoid or moderate risks and developing contingency plans when risks cannot be prevented or avoided.

The results of the present scan are in accordance with outcomes from the ceHRes study that covers over a decade of eHealth technological development [22]. The 'conceptual' risks (Table I) represent the same categories of risks that result from the literature study. For instance expert-driven eHealth interventions that neglect the essential role of patients lead to adherence issues mentioned sub B1). Or disregarding conditions for implementation imply underestimating issues such as time-consumption mentioned sub B3). To minimize and avoid such risks a 'Roadmap' has been developed to design, develop, implement and evaluate eHealth interventions (see Appendix III). It uses concepts and techniques from business modeling and human centered design [43]. The roadmap serves as a guideline to

[1] Risk analyses of these and other sources will be published in 2012.

 ISBN: 978-1-61208-179-3

collaboratively improve the impact and uptake of eHealth technologies. For this purpose it is published as a wiki (ehealthresearchcenter.org/wiki/).

For now the ubiquitous trust in technology seems unjustified and needs to be put in perspective to be deserved. We have the instruments and the knowledge to reconsider the implementation of eHealth to achieve this. Until then present stakeholders should be aware to minimize such risks ex ante. But at the end of the day it is the acceptability of a risk that determines the necessary course of action.

ACKNOWLEDGMENTS

Under its 2011 Work plan (Domain Drugs and Medical technology; theme: information- and communication technology), the Dutch Health Care Inspectorate commissioned the National Institute for Public Health and the Environment (RIVM) to conduct this study of which we here present the first outcomes. It was carried out in collaboration between the Centre for Biological Medicines and Medical Technology and the Centre for Public Health Forecasting (RIVM), the Center for eHealth Research (IBR Institute for Social sciences and Technology, University of Twente). We thank ms. Fabiola Mueller for her work in data collection and mr. Adrie de Bruijn for his input in discussions about the subject of this study.

REFERENCES

[1] WHO 2003. The world health report 2003 – Shaping the future. Geneva: World Health Organization.

[2] WHO 2010. Global Status Report on Noncommunicable Diseases 2010. Geneva: World Health Organization.

[3] Nijland N., van Gemert-Pijnen J.E.W.C., Kelders S.M., Brandenburg B.J., Seydel E.R. Factors Influencing the Use of a Web-Based Application for Supporting the Self-Care of Patients with Type 2 Diabetes: A Longitudinal Study J Med Internet Res 2011;13(3):e71.

[4] Kelders S.M., Van Gemert-Pijnen J.E.W.C., Werkman A., Nijland N., Seydel E.R. Effectiveness of a Web-based intervention aimed at healthy dietary and physical activity behavior: a randomized controlled trial about users and usage. J Med Internet Res. 2011 Apr 14;13(2):e32.

[5] Verhoeven F., Tanja-Dijkstra K., Nijland N., Eysenbach G., J.E.W.C. van Gemert-Pijnen, Asynchronous and Synchronous Teleconsultation for Diabetes Care: A Systematic Literature Review J Diabetes Sci Technol. 2010 May; 4(3): 666–684.

[6] Resolution WHA58-28. eHealth. In: Fifty-eighth World Health Assembly, Geneva, 16-25 May 2005. Resolutions and decisions. 2005. Geneva: World Health Organization. http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf [accessed 9 May 2011].

[7] Glasgow, R.R., eHealth Evaluation and Dissemination (2007) *Research American Journal of Preventive Medicine 32*(5) , 119-126.

[8] Black A.D., Car J., Pagliari C., Anandan C., Cresswell K., Bokun T., et al., The impact of eHealth on the quality and safety of health care: a systematic overview. *PLoS Med* 2011; 8: e1000387- doi: 10.1371/journal.pmed.1000387

[9] Atienza A.A., Hesse B.W., Baker T.B., et al. Critical issues in eHealth research. Am J Prev Med 2007;32(5):S71-S74.

[10] Geertsma R.E., De Bruijn A.C.P., Hilbers, E.S.M., Hollestelle M.L., Bakker G., and B. Roszek. New and Emerging Medical Technologies - A horizon scan of opportunities and risks. RIVM report 360020002, 2007. Bilthoven: RIVM.

[11] IGZ (Dutch Healthcare Inspectorate). State of Health Care. 2008 Medical technological risks underestimated [Staat van de gezondheidszorg 2008. Risico's van medische technologie onderschat]. Den Haag: IGZ.

[12] National Academy of Sciences (Nov. 2011) *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington: Institute of Medicine.

[13] Barben D. Analyzing acceptance politics: Towards an epistemological shift in the public understanding of science and technology. *Public Understanding of Science* May 2010 vol. 19 (3) 274-292.

[14] Dierkes M. & Von Grote, C (Eds.) *Between understanding and trust: the public, science and technology*. Harwood Academic, 2000

[15] WRR [Dutch Scientific Council for Government Policy] *iOverheid* [*iGovernment*]. Amsterdam: Amsterdam University Press.

[16] Beeuwkes Buntin M., Burke MF, Hoaglin MC and D. Blumenthal (2011) The Benefits of Health Information Technology. *Health Affairs* (30)3, 464-471

[17] Hardin, R. (2002). *Trust and Trustworthiness*, New York, NY: Russell Sage Foundation.

[18] McLeod, C, Trust, *The Stanford Encyclopedia of Philosophy (Spring 2011 Edition)*, Edward N. Zalta (ed.) http://plato.stanford.edu/archives/spr2011/entries/trust/ [accessed 9 Oct. 2011].

[19] Hansson, SO, Risk, *The Stanford Encyclopedia of Philosophy (Fall 2011 Edition)*, E. N. Zalta (ed.) http://plato.stanford.edu/archives/fall2011/entries/risk/ [accessed 9 Oct. 2011].

[20] ISO/IEC Guide 51:1999. Safety aspects - Guidelines for the inclusion in standards. ISO, Geneva, Switzerland, 1999.

[21] EN ISO 14971:2009. Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01). CEN/CENELEC, Brussels, Belgium, 2009.

[22] Van Gemert-Pijnen J.E.W.C., Nijland N., Ossebaard H.C., Van Limburg A.H.M., Kelders S.M., Eysenbach G., Seydel E.R. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. *J Med Internet Research*.. In press. doi:10.2196/jmir.1672

[23] Duchatteau D.C. and M.D.H. Vink (2011). Medical-technological developments care. Background study. [Medisch-technologische ontwikkelingen zorg 20/20. Achtergrondstudie]. Den Haag: Council for Public Health and Health Care [Raad voor de Volksgezondheid en Zorg].

[24] IGZ (Dutch Healthcare Inspectorate). State of Health Care. 2011. In health care, patient information exchange challenges not resolved with ICT without standardization of processes [Staat van de gezondheidszorg 2011. Informatie-uitwisseling in de zorg: ICT lost knelpunten zonder standaardisatie van de informatie-uitwisseling niet op]. Utrecht: IGZ

[25] Yusof M.M., Kuljis J., Papazafeiropoulou, A. and L.K. Stergioulas (2008). An evaluation framework for health information systems: human, organization and technology-fit factors (HOT-fit). *Int. J. Med. Inform.* 77(6):386-398. PMID:17964851

[26] Masa, J. F., González, M. T., Pereira, R., Mota, M., Riesco, J. A., Corral, J., Farré, R. (2011). Validity of spirometry performed online. *European Respiratory Journal*, *37*(4), 911-918. doi: 10.1183/09031936.00011510

 ISBN: 978-1-61208-179-3

[27] Bujnowska-Fedak, M. M., Puchała, E., & Steciwko, A. (2011). The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in Poland. *Telemedicine and e-Health, 17*(3), 153-163. doi: 10.1089/tmj.2010.0113

[28] Spijkerman, R., Roek, M. A. E., Vermulst, A., Lemmers, L., Huiberts, A., & Engels, R. C. M. E. (2010). Effectiveness of a Web-based brief alcohol intervention and added value of normative feedback in reducing underage drinking: A randomized controlled trial. *Journal of Medical Internet Research, 12*(5), e65p.61-e65p.14. doi: 10.2196/jmir.1465

[29] Zimmerman, L., Barnason, S., Hertzog, M., Young, L., Nieveen, J., Schulz, P., & Tu, C. (2011). Gender differences in recovery outcomes after an early recovery symptom management intervention. *Heart and Lung: Journal of Acute and Critical Care*. doi: 10.1016/j.hrtlng.2010.07.018

[30] Cruz-Correia, R., Fonseca, J., Lima, L., Araújo, L., Delgado, L., Castel-Branco, M. G., & Costa-Pereira, A. (2007). Web-based or paper-based self-management tools for asthma--patients' opinions and quality of data in a randomized crossover study. *Studies in health technology and informatics, 127*, 178-189.

[31] Willems, D. C. M., Joore, M. A., Hendriks, J. J. E., van Duurling, R. A. H., Wouters, E. F. M., & Severens, J. L. (2007). Process evaluation of a nurse-led telemonitoring programme for patients with asthma. *Journal of Telemedicine and Telecare, 13*(6), 310-317. doi: 10.1258/135763307781644898

[32] Verheijden, M., Bakx, J. C., Akkermans, R., Van Den Hoogen, H., Godwin, N. M., Rosser, W., . . . Van Weel, C. (2004). Web-based targeted nutrition counselling and social support for patients at increased cardiovascular risk in general practice: Randomized controlled trial. *Journal of Medical Internet Research, 6*(4).

[33] Morland, L. A., Greene, C. J., Rosen, C. S., Foy, D., Reilly, P., Shore, J., Frueh, B. C. (2010). Telemedicine for anger management therapy in a rural population of combat veterans with posttraumatic stress disorder: A randomized noninferiority trial. *Journal of Clinical Psychiatry, 71*(7), 855-863. doi: 10.4088/JCP.09m05604blu

[34] Postel, M. G., De Haan, H. A., Ter Huurne, E. D., Becker, E. S., & De Jong, C. A. J. (2010). Effectiveness of a web-based intervention for problem drinkers and reasons for dropout: Randomized controlled trial. *Journal of Medical Internet Research, 12*(4), e68p.61-e68p.12. doi: 10.2196/jmir.1642

[35] Ruffin, M. T., Nease, D. E., Sen, A., Pace, W. D., Wang, C., Acheson, L. S., Gramling, R. (2011). Effect of preventive messages tailored to family history on health behaviors: The family healthware impact trial. *Annals of Family Medicine, 9*(1), 3-11. doi: 10.1370/afm.1197.

[36] Nguyen, H. Q., Donesky-Cuenco, D., Wolpin, S., Reinke, L. F., Benditt, J. O., Paul, S. M., & Carrieri-Kohlman, V. (2008). Randomized controlled trial of an internet-based versus face-to-face dyspnea self-management program for patients with chronic obstructive pulmonary disease: Pilot study. *Journal of Medical Internet Research, 10*(2). doi: 10.2196/jmir.990

[37] Demaerschalk, B. M., Bobrow, B. J., Raman, R., Kiernan, T. E. J., Aguilar, M. I., Ingall, T. J., .Meyer, B. C. (2010). Stroke team remote evaluation using a digital observation camera in arizona: The initial mayo clinic experience trial. *Stroke, 41*(6), 1251-1258. doi: 10.1161/strokeaha.109.574509

[38] Jansà, M., Vidal, M., Viaplana, J., Levy, I., Conget, I., Gomis, R., & Esmatjes, E. (2006). Telecare in a structured therapeutic education programme addressed to patients with type 1 diabetes and poor metabolic control. *Diabetes Research and Clinical Practice, 74*(1), 26-32. doi: 10.1016/j.diabres.2006.03.005

[39] Biermann, E., Dietrich, W., Rihl, J., & Standl, E. (2002). Are there time and cost savings by using telemanagement for patients on intensified insulin therapy?: A randomised, controlled trial. *Computer Methods and Programs in Biomedicine, 69*(2), 137-146. doi: 10.1016/s0169-2607(02)00037-8

[40] Copeland, L. A., Berg, G. D., Johnson, D. M., & Bauer, R. L. (2010). An intervention for VA patients with congestive heart failure. *American Journal of Managed Care, 16*(3), 158-165.

[41] Montori, V. M., Helgemoe, P. K., Guyatt, G. H., Dean, D. S., Leung, T. W., Smith, S. A., & Kudva, Y. C. (2004). Telecare for Patients with Type 1 Diabetes and Inadequate Glycemic Control: A randomized controlled trial and meta-analysis. *Diabetes Care, 27*(5), 1088-1094. doi: 10.2337/diacare.27.5.1088

[42] Strayer, S. M., Pelletier, S. L., Martindale, J. R., Rais, S., Powell, J., & Schorling, J. B. (2010). A PDA-based counseling tool for improving medical student smoking cessation counseling. *Family Medicine, 42*(5), 350-357.

[43] Van Limburg A.H.M., Hendrix R.M.G., Ossebaard H.C., Seydel E.R. and J.E.W.C. van Gemert-Pijnen. (2011). Business modelling to advance the development and implementation of eHealth technologies. *J Med Internet Res.*, in press.

Appendix I

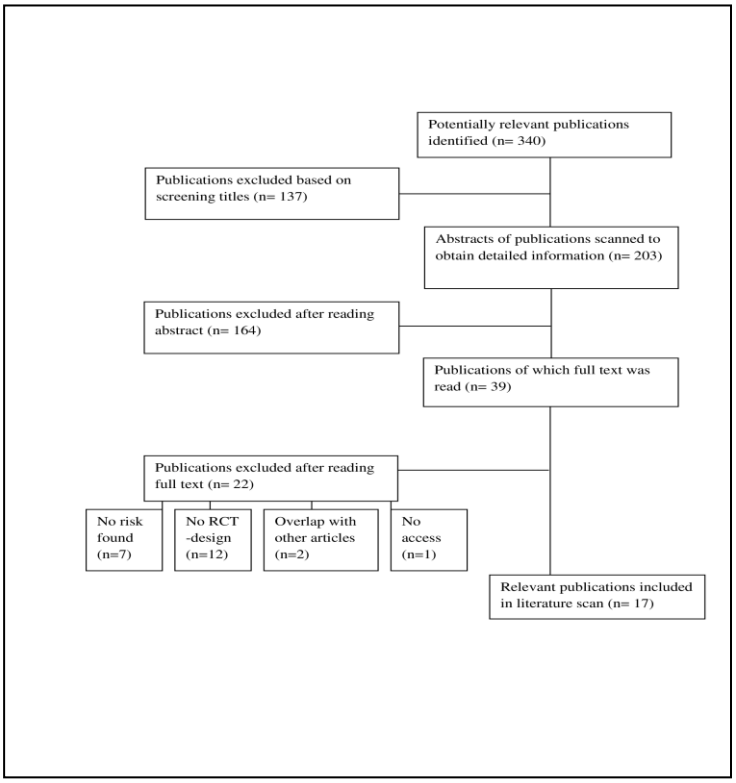
Search query used in SciVerse Scopus

(TITLE-ABS-KEY(ehealth OR e-health OR "e health" OR etherapy OR e-therapy OR "e therapy" OR emental OR e-mental OR "e mental" OR telemedicine OR telecare OR teleconsult OR telemonitoring OR telehealth OR teleconference OR "health information technology" OR "web based") OR TITLE-ABS-KEY("internet based" OR "web application" OR domotica OR “personal digital assistant” OR “pda”) AND TITLE-ABS-KEY(risk OR risks OR danger* OR threat OR threats OR limitation* OR barrier* OR problem* OR concern* OR challenge OR challenges OR “adverse effect*” OR quality OR drawback OR drawbacks) AND TITLE-ABS-KEY(health OR care OR “healthcare” OR healthcare) AND TITLE-ABS-KEY("randomized clinical trial*" OR "randomised clinical trial*" OR "randomized controlled trial*" OR "randomised controlled trial*" OR rct OR "RCTs" OR experimental)) AND PUBYEAR AFT 1999 AND PUBYEAR BEF 2012 AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German"))

 ISBN: 978-1-61208-179-3

Appendix II

Study selection process



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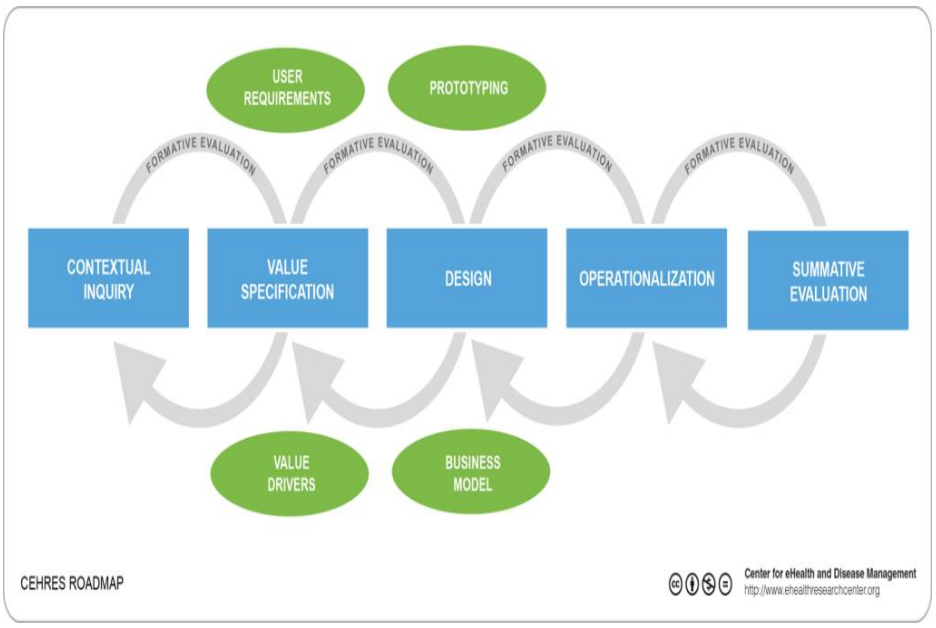
Appendix III

ceHRes Roadmap to improve the impact of eHealth interventions



 ISBN: 978-1-61208-179-3

Improved Surveillance of Haemophilia Home Treatment Using Mobile Phones

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Abstract—**Haemophilia is an inherited blood coagulation disorder which results in permanent disability due to repeated bleeding and early death. The availability of plasma derived or recombinant coagulation concentrates reduces the symptoms of this disease and allows the patient to live an almost normal life. The missing coagulation factor is administered intravenously on demand in case of bleeding symptoms or as prophylactic regimen mostly three times per week. The German law and also the law of many other countries require thorough documentation of inhospital and patient home treatment. The common way of documentation is by paper diary. Professional control of home treatment is delayed until presentation at the haemophilia center and does not allow immediate monitoring of bleeding and treatment measures. Only the use of telemetric systems may provide possibilities for online documentation and therefore early recognition of critical bleeding episodes or concentrate use. In collaboration with medical experts on haemophilia treatment and on the basis of experiences with the electronic diary system "Haemoassist™" as well as the use of the modern smartphones technology, a new telemetric system was developed at the Philipps-University in Marburg (Germany). This paper provides an overview of the new concept named "smart medication".**

Keywords-Telemedicine; mobile phones; mobile application development; home treatment; chronic disease; Haemohilia.

I. INTRODUCTION

Haemophilia is a rare x-chromosomal inherited disease with a prevalence of 1 in 20,000 males worldwide. The disease is characterized by the missing coagulation factor VIII (Haemophilia A) or IX (Haemophilia B) which untreated leads to spontaneous bleeding in major joints or soft tissue. Prior to the availability of factor VIII or IX concentrates the average life expectance was below 20 years of age. Repeated bleeding episodes led to progressive hemarthrosis and finally to often lethal cerebral hemorrhage. Since factor VIII and IX concentrates were available, life expectance and quality increased dramatically. Unfortunately transmission of HIV and Hepatitis C virus by plasma derived factor treatment in the early 80th led to a dramatic drawback. As the coagulation factor has to be administered on a regular base (prophylactic treatment) mostly three times per week or immediately in case of suspected bleeding (on demand) the patients are trained for self home treatment from early childhood on. However, haemophilia treaters need to monitor home treatment according to German law, to assure cost effective treatment. In spite of the small number of patients haemophilia treatment required nearly 1.5 % of the overall German health care budget in 2010 [1]. Documentation and monitoring of self home treatment is done by paper based protocols presented during consultation in the haemophilia center. They don't allow immediate surveillance at the time of bleeding or treatment. Analyses of bleeding and treatment regimens are difficult and time consuming to obtain. Electronic devices have shown to be useful for online surveillance and further documentation [2]. Our aim was to improve and facilitate the use these devices.

At first this abstract gives a short overview about the current situation in haemophilia home treatment. The second section explains the need of treatment documentation, its requirements and specifics. The third section describes the platform "smart medication", with its three applications, security issues in handling patient data, and planed future extensions. Finally a conclusion is given in section four.

 ISBN: 978-1-61208-179-3

II. HAEMOPHILIA HOME TREATMENT

Because of the contamination of the concentrates with blood-borne viruses (e.g., hepatitis viruses and HIV) in the past, every injection with human blood, plasma, and plasma-derived products must be recorded [3]. In Germany, the Transfusion Act ("Transfusionsgesetz") regulates the documentation and requires the following data:

- Identification number of the patient, full name, date of birth, and address;
- Batch number;
- Date and time of the injection.

"The responsible haemophilia care center has to ensure that the data of the documentation can be used product- and patient-related" and that it can find and trace back any potential contaminated product [4]. The common way of documentation by the patient is to use a paper diary. Because of only occasional consultation (2-3 times per year) at the haemophilia center, bleeding and treatment problems are identified much later than they occur and are difficult and time consuming to analyze. As patients often live far away from the treatment center a higher frequency of consultation is not feasible. Patient hand written entries into the paper diary are often difficult to read and incomplete [5].

In contrast, entries into electronic devices allows the doctor to monitor the patients bleeding episodes and self-treatment regimen from everywhere at any time. The recorded data could help the doctor to find abnormal bleeding pattern on a regular base. All data are saved and backed up central in server rooms to avoid the risk of loss [8]. Smart electronic algorithms allow early identification of bleeding and treatment problems (alert) or incomplete documentation.

III. "SMART MEDICATION" – ASSISTANCE OF HOME TREATMENT

An electronic diary for the documentation of the haemophilia home treatment named "Haemoassist™" system was developed by Wyeth-Pharma GmbH. The electronic handheld was tested in the last 5 years with more than 100 patients and the gained experience represent the basis for the development of the new system "smart medication" [6].

A. The System "smart medication"

"Smart medication" was solely developed as a scientific project in collaboration between the Philipps-University in Marburg, Germany, and Haemophilia treaters in Frankfurt and Münster, Germany. The established prototype is now in the process of presentation to industry for funding of the following pilot and outline process. Long term collaboration with insurance companies and federal institutions are in discussion (Figure 1). Google's operating system Android for smartphones is currently the market leader worldwide and serves as initial basis for the following developments. "Smart medication" consists of the following components:

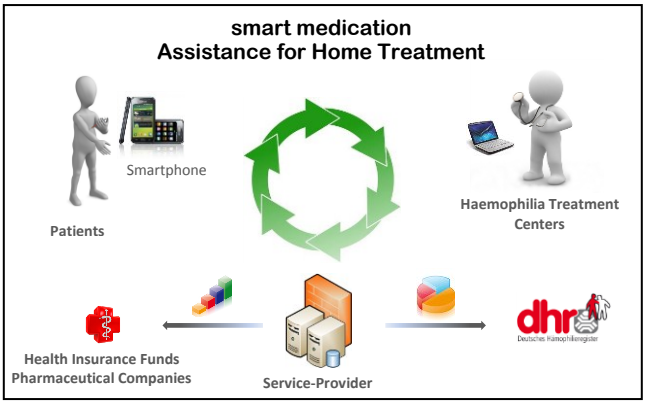


Figure 1. The concept of "smart medication" [10]

- Patients enter all bleeding and treatment data into a mobile device, which are then transmitted to the treatment center. The device can also be used as an emergency tool for direct contact (Phone call), transmission of text (SMS) or even photographs (e.g., swelling of joint) (Figure 3).
- Haemophilia treatment centers document any to a particular patient prescribed and dispensed concentrate batch by a mobile device allowing barcode scanning of the batch. The dispensed concentrate is electronically assigned to the patient stock and by this allows complete backtracking. Patients may find the available concentrate at their storage place but also as virtual storage on their mobile device. Treatment centers can early identify if the patient runs out of stock (low level) or does not document properly (higher than expected home stock). One of the main goals was easy and rapid application by the patient (Figure 2).
- A web-based monitoring tool allows the doctor an online overview of all treatment and bleeding data and simultaneous analysis of all treated patients (Figure 4). Emergency cases are presented as priority message. Defined electronic algorithms (alerts) allow rapid identification of bleeding and treatment problems as well as inappropriate documentation by the patient. Follow-Up data allow early identification of target joints (joints with repeated bleeding and progressive arthrosis).

 ISBN: 978-1-61208-179-3

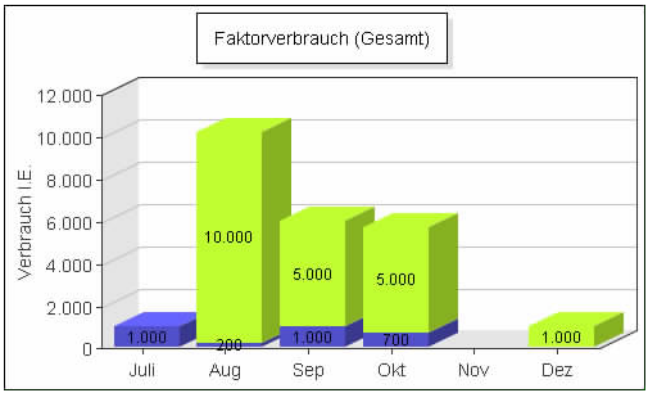


Figure 2. Factor consumption statistics

Analysis of the aggregated data also allow comparison between patient files within one center as well as comparison to pooled data of the other participating centers (benchmarking).

- For the Health Insurance companies, Pharmaceutical Companies and the federal organizations (e.g., German Haemophilia Register) the system could provide anonymized and aggregated analyses and statistics.

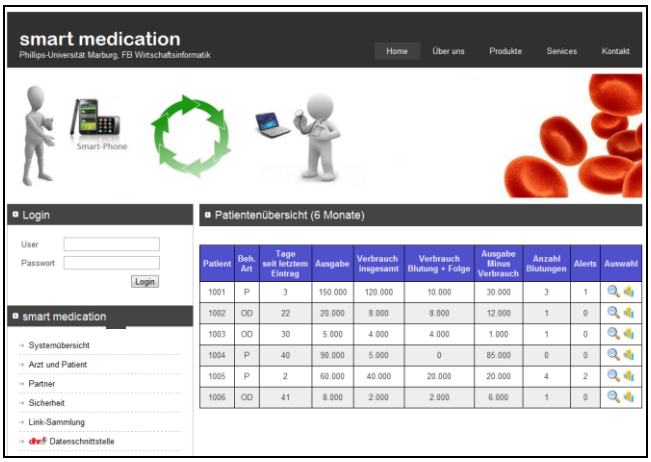
Figure 3. Screenshots of the applications.

B. *Security*

Especially the use of personal patient data requires a high standard of data security. During the development several safety functions were implemented in the system. Some of the most important are:

- A login per PIN/PUK.
- Encoded storage of the password per hash function (SHA-512).
- Encoded data communication per TLS/SSL-protocol
- Centralized data storage.
- A link between the application and the smartphone used.
- Validation of the entries on the phone and on the server.
- Consequent use of the recommendations of the German Federal Office for Information Security (see [11]).

Patient overview



Factor consumption

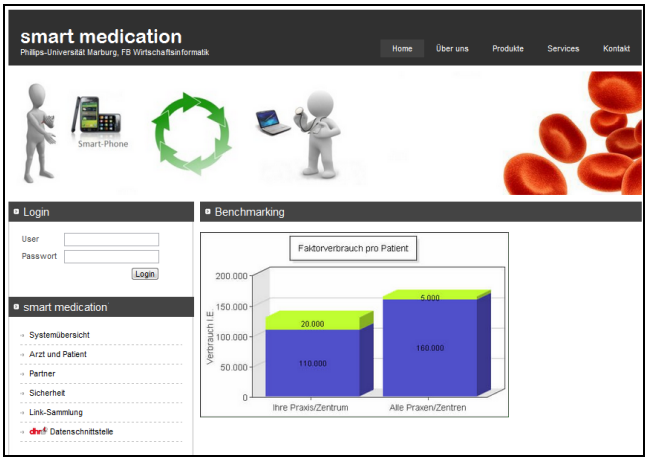


Figure 4. The website [9].

C. *Future extensions*

For developing these applications we used the experience of the former system "Haemoassist™" and worked together with several medical experts to enhance the benefit for the patient and medical attendance to a maximum. We used as a basis Google's operating system Android. The next steps will be the adjustment and enhancement of the system by working together with some patients with severe haemophilia as test users, the preparation of the upcoming roll out in Germany and the hosting of the platform. The aim is also to migrate the application from Android to other operating systems like Apple's iOS or RIM's BlackBerry OS. Therefore the idea is to use HTML 5 and a cross-platform like PhoneGap (see [12]) or Titanium (see [13]) to gain productivity and lower maintenance costs when implementing on multiple platforms.

Besides the positive effects on the patient's life and the advantage for the therapy we will analyze the monetary aspects of the employment of this electronic assistant system. We plan to work together with health insurance companies to explore the common costs of a patient with severe haemophilia in detail (e.g., the medicine consumption, the necessity of further treatments, and the need of visiting a haemophilia treatment center). The factor concentrates are some of the most expensive drugs. An unnecessary overuse induces high costs with no improvement for the patients' health. In contrast a critical shortage can lead to an inability to work and thereby to even higher costs for the society. Therefore an optimized therapy can not only enhance the safety for the patient, but could also reduce the costs for the health care system.

IV. CONCLUSIONS

The genetic disease haemophilia needs life-long medical attendance and treatment. Appropriate use of the required concentrate by self-home treatment improves life expectance and quality of life dramatically. However, close monitoring of home treatment by the haemophilia center is still mandatory. The still common use of paper based diaries doesn't allow early identification of bleeding or treatment problems and are difficult to read and time consuming for further analyses. Modern mobile devices offer a simple and sustainable solution and can reduce the time and effort for patients own documentation but also for documentation by haemophilia treatment centers.

The intention of the system "smart medication" is to provide a full managed service platform for the patient and the responsible doctors. It provides an application for the patient to record all necessary information easily, fast, and secure, and offers emergency functions like sending messages and photographs, contacting the doctor directly, and initiating alerts autonomously. The recorded information fulfills the legal requirements in Germany and allows a location-independent monitoring at any time.

Medication management allows a complete trace back of any concentrate given to the patient for self-treatment. Every data is consolidated, saved in an electronic file, and can be monitored online with the web application. By real-time data processing bleeding and therapy is analyzed at an early stage and may prevent the development of possible target joints in future [7].

In conclusion, the electronic documentation system "smart medication" can improve the quality of bleeding and treatment documentation. Early analysis of treatment problems has a high potential to improve self-home treatment and prevent subsequent health problems such as progressive joint damage and disabling hemorrhage. This may also lead to reduced treatment costs in future [4].

REFERENCES

[1] F. Osterloh, „Gesundheitshaushalt 2010: Das bisschen Haushalt", available at: http://www.aerzteblatt.de/v4/archiv/artikel.asp?id=73234, last accessed: Aug. 2011.

[2] W. Mondorf, B. Siegmund, R. Mahnel, H. Richter, M. Westfeld, A. aller, H. Pollmann, "Haemoassist™- a hand-held electronic patient diary for haemophilia home care" in Haemophilia, 15(2), 2009, pp. 464-472.

[3] Jeanne M. Lusher, "Hemophilia: From Plasma to Recombinant Factors", in 50 Years in Hematology: Research That Revolutionized Patient Care, Washington, DC, Dec. 2008, pp. 25-27.

[4] Bundesministerium der Justiz, "Transfusionsgesetz: §14 Dokumentation, Datenschutz, § 19 Verfahren", availavle at: http://www.gesetze-im-internet.de/tfg/index.html, last accessed: Aug. 2011.

[5] D. Schmoldt, B. Siegmund, H. Pollmann, W. Mondorf, A. Rösch, „smart medication – Eine telemetrische Smartphone-Applikation für die ärztlich kontrollierte Heimselbstbehandlung in der Hämophilietherapie" in e-Health 2012, Solingen, Germany, in press.

[6] B. Siegmund, W. Mondorf, R. Klamroth, M. Westfeld, J. Tuischer, H. Pollmann, „Das Heamoassist®-System" in e-Health 2010, Solingen, Germany, 2009, pp. 134 – 137.

[7] K.-H. Beck, J. Holzschuh, A. Klein, „Qualitätssicherung in der Hämophiliebehandlung aus Sicht des MDK", in: Hämostaseologie Supplement 2010 (41), Stuttgart, Germany, 2010, pp. 76 – 80.

[8] A. Rösch, D. Schmoldt, W. Mondorf, H. Pollmann, „Implementation of a telemetric smartphone application for improved surveillance of hemophilia home treatment", available at: http://www.isth2011.com/prgrm-common/abstracts/html/01130.html, last accessed: Aug: 2011 [XXIII Congress of the International Society on Thrombosis and Heamostasis, Kyoto, Japan, July 23-28, 2011].

[9] "Deutsches Hämophilieregister (DHR) - Was ist das DHR?", available at: http://www.pei.de/DE/infos/fachkreise/dhr/dhrnode.html, last accessed: Aug. 2011.

[10] D. Schmoldt. „Prototypische Entwicklung einer telemetrischen Smartphone Applikation für die ärztlich kontrollierte Heimselbstbehandlung am Beispiel der Hämophilie", diploma thesis, Philipps-Universität, Marburg Jan. 2011.

[11] "Federal Office for Information Security", available at: https://www.bsi.bund.de/EN/TheBSI/thebsi_node.html, last accessed: Nov. 2011.

[12] "PhoneGap", available at: http://www.phonegap.com/, last accessed: Nov. 2011.

[13] "Titanium Mobile", available at: http://www.appcelerator.com/products/titanium-mobile-application-development/, last accessed: Nov. 2011.

[14] Myung-kyung Suh,Chien-An Chen, Jonathan Woodbridge, Michael Kai Tu, Jung In Kim, Lorraine S. Evangelista, Majid Sarrafzadeh. A Remote Patient Monitoring System for Congestive Heart Failure . Journal of Medical Systems (JOMS), June 2011.

[15] Marilyn J. Field, Jim Grigsby. Telemedicine and Remote Patient Monitoring. JAMA, October 2011.

 ISBN: 978-1-61208-179-3

A Monitoring and Feedback Tool to Support Patients in Achieving a more Active Lifestyle

The development of portable technology embedded in primary care

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***Abstract*—The paper describes the process of development of an innovative monitoring and feedback tool to improve the level of physical activity of chronically ill patients. The tool aims to support chronic obstructive pulmonary disease and diabetic patients' self-management in achieving an active lifestyle. The tool consists of a sensor that transfers data to a Smartphone; subsequently the Smartphone is connected to a server. Patients wearing the sensors will receive feedback on their Smartphones based on pre-set activity goals. Use of the tool will be embedded in a healthcare model to be executed by practice nurses in primary care. Both the tool and the healthcare model are developed in an iterative way based on user requirements research. An intensive cooperation has been set up between the research team, two enterprises that produce the technology, healthcare professionals, and patient representatives. From the very first phase onwards, patients, professionals, and technology developers are actively involved in the project in order to increase the probability of effective use of the tool in practice. The tool will be validated and tested in pilot studies. Eventually a randomized controlled trial will be set up to measure the effects of embedding the tool in primary care.**

Keywords—physical activity; accelerometer; persuasive technology; self-management support; primary care.

I. INTRODUCTION

A quarter of all people in the Netherlands suffer from a chronic disease such as chronic obstructive pulmonary disease (COPD) or diabetes. The number of people with diabetes is increasing most of all. It is estimated that in 2025, seven percent of the total Dutch population will have a diagnosis of diabetes [1]. For a lot of people with COPD or diabetes it is very hard to be sufficiently active. People with COPD suffer from shortness of breath and people with diabetes are often overweight. This makes exercise more difficult. Nevertheless, physical activity is very important for COPD and diabetic patients because it improves their quality of life and long term prognosis.

Most patients with COPD or diabetes are treated in primary care by general practitioners and practice nurses. According to guidelines and care standards, stimulating physical activity should be a central element in the treatment of people with COPD or diabetes [2][3]. The level of success regarding this element of the care process depends for the greater part on the degree to which patients succeed in executing their self-management role. Therefore, healthcare providers should involve the patient in decisions on self-management, and together with the patient should seek lifestyle interventions that fit with the motivation, needs, and capabilities of the patient [4][5].

An example of a lifestyle intervention is self-monitoring of physical activity using a pedometer or an accelerometer. This is often identified as an effective approach towards behaviour change [6][7]. Use of technology for long term monitoring and feedback could support patients in achieving a more active lifestyle and could also help care providers to coach patients in establishing this behavioural change more easily. In the project **It's LiFe!** (an acronym for **I**nteractive **T**ool for **S**elf-management through **Li**festyle **Fe**edback**!**) an innovative monitoring and personalized feedback tool will be developed and tested. The tool aims to support COPD and diabetic patients in achieving an active lifestyle as part of their self-management. The project started in September 2010 and will last four years.

Nowadays there are tools on the market that try to improve people's level of activity, such as the Fitbit®, but those tools do not give continuous feedback on people's mobile phones [8]. In 2009 Klasnja et al. reported on the UbiFit. This tool (the flower phone) does contain similar features [9]. In this project we analyse such exercise tools with the aim of identifying the underlying principles of persuasive technology [10]. During the development, as far as possible, effective principles will be merged into the It's LiFe! tool. Furthermore, one of the most basic assumptions about the combination of technology and lifestyle interventions is that it will only succeed when the technology is actually part of care services in which healthcare professionals see patients' levels of activity as a "vital sign" and are aware of the need to promote exercise [11]. This is the reason why a healthcare model (HCM) will be developed on the basis of which practice nurses will simultaneously support patients' self-management to achieve a more active lifestyle.

During the first stage of the project the following research questions were answered:

 ISBN: 978-1-61208-179-3

- What feedback and information do patients need to optimally support them in their self-management role and how should the feedback to the patient be presented in order to promote optimal use of the tool and optimal patient compliance?
- What information do professional caregivers need to optimally support patients in their self-management role and how should the information generated by the system be presented in order to stimulate use of the tool and patient compliance?
- How can the use of the monitoring and feedback tool to support patients in maintaining a healthy lifestyle be integrated in an HCM that is based on the principles of patient involvement, shared decision making, and current insights into disease management and the chronic care model?

In this work-in-progress paper the methods and some preliminary results of the first year will be described and plans for the upcoming years will be explained.

II. METHODS

To design useful technology that meets the needs of patients and healthcare professionals, it is important to involve both parties in a very early stage of the development process. A user centred design strategy was used during the first phase of the project in which the tool and an HCM were developed. Several strategies for designing medical devices were combined into a specific model tailored to this project [12]. This model is depicted in Figure 1. The model was used to specify the steps to be taken to define the user requirements.

Defining the user requirements was an iterative process that started with identifying the users and their context. The general project idea was developed together with several experts and business partners. Subsequently general use cases were written from the perspectives of a COPD patient, a diabetic patient, and a practice nurse. They were narrative stories of the use of the tool embedded in daily living and in daily practice. During interviews with patients and healthcare professionals, end users were asked to give their opinions about the use cases.

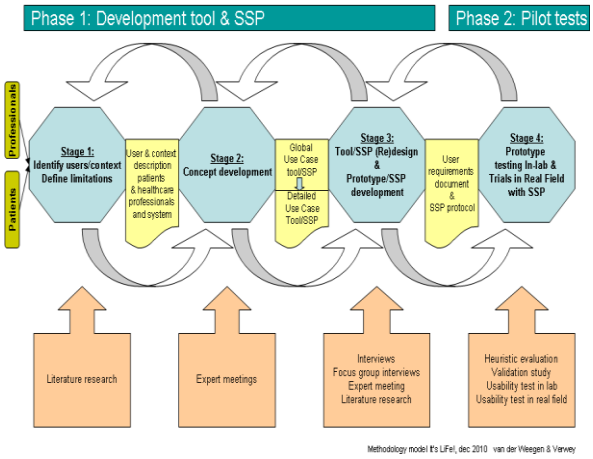

Figure 1. User requirements model.

Semi-structured interviews were conducted with 15 people with COPD or diabetes. After analysing the interviews the use cases were modified and specified. The results of all interviews were verified and explored in two focus groups, in which the interviewees participated. The data were supplemented by interviews with 15 healthcare professionals. After analysing the data using NVivo and open coding, general themes emerged and these results were input for the user requirements document.

Furthermore, two members of the research team are patient representatives who gave feedback on every step in the process. In addition two expert meetings took place, in which project plans and progress were presented to people with a broad range of expertise in COPD and diabetes care, sensor technology, general practice, human movement, and health promotion and implementation science. All experts provided their feedback on the course of the project.

The technological development of the tool is an ongoing process taking place in collaboration with two companies: Maastricht Instruments BV and Sananet Care BV. There are in fact two parallel paths in the project: the research team of Maastricht University conducts research and "feeds" the technical team with information about user requirements for the tool so that gradually the elements of the technology evolve. This continuous interaction between the two teams is a unique aspect of this project.

Simultaneously with the technological development, the HCM is being developed (the Self-management Support Programme). This was done by conducting a literature study and furthermore through 15 semi-structured interviews with general practitioners, physiotherapists, nurse specialists in diabetic and pulmonary care, and practice nurses.

III. PRELIMINARY RESULTS

A. *Technology*

The original project idea was that the tool should consist of three parts: a sensor with a 3D accelerometer, a mobile phone, and a server/website for both patients and care providers. The patient would receive three types of feedback on the mobile phone concerning:

1. the amount of activity;
2. the amount of activity in relation to an activity goal;
3. the response of a practice nurse based on the measured activity.

The user requirements study provided the details for this framework.

Patients have indicated that the sensor should be small, discreet, and shockproof and that it should measure accurately. The mobile phone should have a large screen so that patients can read information easily. Furthermore patients opted for a mobile phone with a touch screen. Personal activity goals will be set in minutes per day in consultation with the practice nurse. Patients would like to set goals that are achievable and adapted to their abilities. The immediate feedback patients want to see is the percentage of minutes that they have been active during the day compared to their activity goal, presented as an image and in colour. In their opinion it is not necessary to see the

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data on the level of intensity and history of activities directly. They appreciated an option in the system in which they can fill in details themselves so that they can give reasons why they did not succeed in achieving their goals. They preferred to receive mostly positive feedback and limited negative feedback. Patients said that they want to receive a neutral response from the system when they achieve their goals. Negative feedback is not necessary; when negative results occur, they said they would probably already feel guilty and would not want to be further stressed by the system.

Based on the requirements the following tool was developed. The sensor has the same dimensions as a match-box and contains a 3D accelerometer. The patient wears the sensor somewhere around the hip (clipped on a belt or in the pocket). The sensor is wirelessly connected to an Android Smartphone with a touch screen. An application called It's LiFe! will be installed on the Smartphone. The application consists of a widget which fills the home screen of the Smartphone. The widget shows a bar that continually fills as the participant moves closer to his or her activity goal of that particular day.

In the first fortnight of use, a baseline measurement will take place to give insight into the "normal activity pattern" of the patient. Based on this insight the patient will set an activity goal in minutes per day during a face to face consultation with the practice nurse.

While using the tool the patient gets feedback messages via the application. On the phone the patient can get more information about his or her activity level such as the degree of intensity during a day, a week, and a month. At some specific moments, for example, during the baseline measurement or when goals are reached, the patient can start dialogue sessions on the application to give more information about how activities are experienced. Based on this information the patient gets "intelligent" answers, tips, feedback, and reminders on the phone. The results of participating patients will be sent to the general practice so that practice nurses can respond to this information. The different types of feedback are depicted in Figure 2.

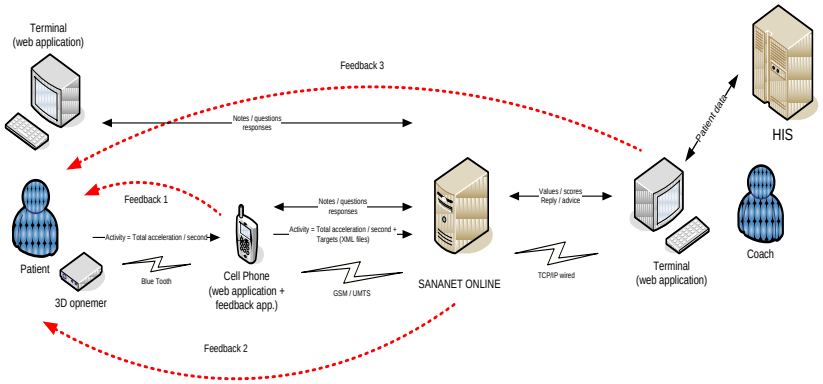

Figure 2. It's LiFe! tool feedback types.

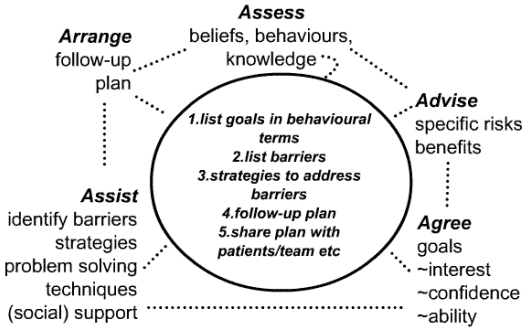

Figure 3. Self-Management Support Model with five A's (Glasgow et al., 2002; Whitlock et al., 2002).

B. *Self-management Support Programme*

Based on a literature study a model was proposed (see Figure 3). The model gives an outline of how the contact between patient and practice nurse proceeds. Practice nurses will use a consultation approach to coach patients in their self-management regarding physical activity based on a "five A's cycle" counselling technique (assess–advise–agree–assist–arrange) [13]–[15]. During the interviews, healthcare professionals were asked to give their opinions about specific aspects of this approach such as using motivational interviewing, risk assessment, and goal setting.

The interviews with professionals gave insight into "care as usual" for COPD and diabetic patients, the opinions of professionals about the Self-management Support Programme (SSP), and their attitudes regarding the use of technology and anticipated barriers and facilitators when implementing the technology in primary care. Most practice nurses reacted positively: "With this tool I can give these patients something tangible to help them improve their daily activity levels."

Both patients and professionals agreed that the sensor should measure accurately. Professionals often stated that patients tend to overestimate their normal physical activity. A remarkable difference between the results of the patients and those of professionals was that, in the opinion of most professionals, elderly patients find it very difficult to use technology, whereas the patients did not mention this

difficulty in such a way. The opinions of the professionals about the potential of the system to give a personal response to patients between consultations varied.

At the time of writing, the latest draft of the Self-management Support Programme has now been presented to a panel of experts.

IV. Conclusion and Future Work

Supporting self-management regarding physical activity is part of the healthcare services of general practices. Both the technology and an HCM are being developed in an iterative way based on user requirements research. Intensive cooperation between the research team, technical team, and patient representatives increases the probability of successful use of the technology. The development is an ongoing process; in the upcoming years the technology will be validated and tested and a randomised controlled trial (RCT) will be set up to measure the effects of embedding the tool in primary care.

During the second year of the project the usability and validity of the prototype will be tested in a lab environment. In addition, the tool and the SSP will be tested in a pilot study of 20 patients from two general practices. At the time of writing, this part of the project is in preparation.

In the last two years of the project an RTC will be set up to measure the effects of embedding the tool in primary care. There will be three branches in the trial, each with 80 patients from eight different general practices: one group will receive "care as usual", one group will receive only the care described in the SSP, and one group will receive the complete intervention with both the SSP and the tool. The primary outcome measures will be physical activity and goal attainment. The secondary outcome measures will be quality of life and self-efficacy. Physical activity will be measured objectively by an accelerometer differing from the one developed in this project. Additionally, physical activity will be measured subjectively by a questionnaire as part of the SSP.

This project focuses on patients with COPD or diabetes who are treated in primary care, but if their effectiveness is proven, the tool and the model could also be used by patients with other chronic conditions. Furthermore the tool sensor could be extended by measuring other parameters.

Acknowledgements

The project is funded by Zon MW in the programme "New Instruments for Healthcare". The two companies involved in the development are:

- Maastricht Instruments BV

Oxfordlaan 70, 6229 EV Maastricht, the Netherlands
www.maastrichtinstruments.nl

- Sananet Care BV

Rijksweg Zuid 22A, 6131 AP Sittard, the Netherlands
www.sananet.nl

References

[1] Hoeymans N. and Melse J.M., Rijksinstituut voor Volksgezondheid en Milieu, Ministerie van Volksgezondheid Welzijn en Sport. "Gezondheid en determinanten: deelrapport van de VTV 2010 van gezond naar beter," ("Health and determinants: report section VTV 2010 from healthy to better,") Houten: Bohn Stafleu Van Loghum, 2010. Retrieved from <http://www.vtv2010.nl/deelrapporten/gezondheid--determinanten/ >23.11.2011.

[2] Long Alliantie, "Zorgstandaard COPD," ("Care standard COPD,") Amersfoort: Long Alliantie Nederland, 2010. Retrieved from < http://www.longalliantie.nl/zorgstandaard-copd >23.11.2011.

[3] "NDF care standard: transparancy and quality of diabetic care for people with diabetes type 2," Amersfoort: Nederlandse Diabetes Federatie, 2007. Retrieved from < http://www.diabetesfederatie.nl/start/zorgstandaard/diabetes-care-standard/download.html > 23.11.2011.

[4] Bodenheimer T., Lorig K., Holman H., and Grumbach K., "Patient self-management of chronic disease in primary care," JAMA, vol. 288, no. 19, 20 Nov. 2002, pp. 2469–2475.

[5] CBO, "Zelfmanagement, samen werken aan zorg die bij de patient past," ("Self-management, working together towards patient centred care,") 2011. Retrieved from <http://www.zelfmanagement.com/ >23.11.2011.

[6] van Achterberg T., Huisman-de Waal G. G., Ketelaar N. A., Oostendorp R. A., Jacobs J. E., and Wollersheim H. C., "How to promote healthy behaviours in patients? An overview of evidence for behaviour change techniques," Health Promot. Int., vol. 26, no. 2, Jun.2010, pp. 148–162.

[7] Tudor-Locke C. and Lutes L., "Why do pedometers work?: a reflection upon the factors related to successfully increasing physical activity," Sports Med., vol. 39, no. 12, 2009, pp. 981–993.

[8] Khan K. M., Weiler R., and Blair S. N., "Prescribing exercise in primary care," BMJ 2011;343:d4141.

[9] "Introducing the new fitbit ultra." Retrieved from <http://www.fitbit.com/product >23.11.2011.

[10] Klasnja P., Consolvo S., McDonald D. W., Landay J. A., and Pratt W., "Using mobile & personal sensing technologies to support health behavior change in everyday life: lessons learned," AMIA Annu. Symp. Proc., 2009, pp. 338–342.

[11] Fogg B. J., Persuasive Technology: Using Computers to Change What We Think and Do. Amsterdam; Boston: Morgan Kaufmann Publishers, 2003.

[12] Shah S. G. and Robinson I. "User involvement in healthcare technology development and assessment: structured literature review," Int. J. Health. Care. Qual. Assur. Inc. Leadersh. Health Serv., vol. 19, no. 6/7, 2006, pp. 500–515.

[13] Whitlock E. P., Orleans C. T., Pender N., and Allan J., "Evaluating primary care behavioral counseling interventions: an evidence-based approach," Am. J. Prev. Med., vol. 22, no. 4, May 2002, pp. 267–284.

[14] Glasgow R. E., Funnell M. M., Bonomi A. E., Davis C., Beckham V., and Wagner E. H., "Self-management aspects of the improving chronic illness care breakthrough series: implementation with diabetes and heart failure teams," Ann. Behav. Med., vol. 24, no. 2, Spring 2002, pp. 80–87.

[15] Glasgow R. E., Emont S., and Miller D. C., "Assessing delivery of the five 'As' for patient-centred counselling," Health Promot. Int., vol. 21, no. 3, 2006, pp. 245–255.

 ISBN: 978-1-61208-179-3

eHealth Traffic Detection and Classification Using Machine Learning Techniques

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***Abstract*—With the growing number of available eHealth applications, the amount of eHealth traffic transmitted through communication networks increases significantly. This implies that network mechanisms must provide Quality of Service (QoS) assurances to support these new applications. In order to improve network performance, there is a need to develop new QoS methods that would properly detect and classify eHealth traffic. In this paper we present a selection of machine learning - based traffic classification methods in the context of eHealth services provisioning. We also present a mapping of eHealth application classes to appropriate QoS classes. Finally we propose an eHealth-aware approach, which can perform real-time traffic classification. In this technique the packet content is not inspected and at the same time the privacy of transmitted information is preserved.**

***Index Terms*—eHealth applications, traffic classification, flow analysis, machine learning;**

I. Introduction

High capacity and throughput of current telecommunication networks make it possible to provide remote eHealth services to users, no matter if they are at home or on the move. Telemedicine applications are gaining popularity and the amount of eHealth traffic transmitted through communication networks increases significantly. At the same time, network mechanisms must provide Quality of Service (QoS) assurances to a whole range of different eHealth applications. Appropriate service levels should be guaranteed for simple consulting services as well as life-critical clinical telemedicine applications.

The increasing demand to ensure appropriate bandwidth, maximum delay and jitter for telemedicine applications is very challenging for current network QoS mechanisms. eHealth services have diversified demands and each application type requires different treatment [1]. Existing QoS solutions [2], [3] were designed to support generic types of applications and have not been tuned to address e-Health needs. Current methods have difficulties in detecting eHealth traffic and cannot provide proper classification of medical applications. All these problems have a significant impact on the reliability of eHealth services. In order to improve network performance there is a need to develop new QoS methods that would properly detect and classify eHealth applications at the edge of the network.

We can identify several challenges in the design of QoS classification mechanisms for eHealth traffic. This kind of traffic is very often related to time-critical applications, where delays should be kept to minimum. Such behaviour requires real-time operation of QoS classification algorithms. Moreover, early detection of traffic type is necessary to allow proper handling by the network nodes. Since new eHealth applications are constantly emerging, the classifier should also have the ability to recognise previously unknown traffic. Finally the classification is usually performed on an encrypted traffic, which makes it difficult to asses the packet content. An ideal method for eHealth traffic classification should address all the above design challenges.

In this paper, we review different traffic classification techniques in the context of eHealth services provisioning. We propose the mapping of eHealth application classes to QoS classes and point out which e-Health traffic characteristics are the best metrics for the classification algorithms. We also propose an eHealth-aware classification approach, which is based on Machine Learning (ML) techniques. It takes advantage of IP traffic classification based on statistical properties of a flow. It applies complex classification techniques, where decision is made through the multi-criteria reasoning without looking deep into the packet content. By employing this approach the privacy of the data is intact and classification can be performed at the edge of the network in real time to guarantee proper handling of eHealth traffic by each network node.

II. Related work

Traffic classification is an important aspect of every QoS solution and is usually performed at the edge of the network, where the application traffic originates. In the literature on QoS solutions for eHealth traffic, we can find QoS mechanisms that investigate priority assignment and scheduling techniques for eHealth applications [4]. However, these techniques cannot distinguish medical applications and take an assumption that eHealth traffic can be easily detected. Such an approach may lead to incorrect classification of eHealth data and decreased quality of service. Therefore ehealth tarffic classification is a subject to our research.

In general, there are several methods, which address the traffic classification problem in the communication networks

 ISBN: 978-1-61208-179-3

[2], [3]. The basic and most common methods are focused on the evaluation of the QoS related fields in the IP packet header. They look at the so called "5 tuple" - a set of packet's source IP address, destination IP address, source and destination TCP/UDP port number and layer 4 protocol type [2]. Although such classification is simple, fast and differentiates basic networking services (e.g., voice service from data service), it very often mis-classifies the traffic or puts traffic from diversified applications into one category. Therefore it was argued that such a simple method is not enough to perform complex classification tasks [2], [3], [5].

Additional information about a network flow can be obtained by analyzing the information contained in the packet payload. This approach, denoted as Deep Packet Inspection (DPI) [2], investigates application-specific packet metrics, which can significantly increase classification success rate. The main drawbacks of this approach are problems with accessing encrypted messages and high computational complexity of payload analyzing algorithms (hardware implementations needed). Moreover DPI techniques require previous knowledge about application-specific parameters, which have to be updated for every new application. Since medical data is usually encrypted and requires real-time packet processing the applicability of DPI methods to classify this type of traffic is rather limited.

The techniques described above (port numbers, DPI) have limited practical relevance in case of eHealth applications, but they can still serve as a reference (ground-truth) for more advanced methods. New solutions might be based on machine learning classifiers, which are capable of making decisions based on the observation of the traffic flow features like packet lengths and packet inter-arrival times. This makes them particularly suitable for the classification of e-Health traffic.

Previous works on ML traffic classification [3], consider both supervised and unsupervised learning approaches. Both techniques usually require a training phase to precede the classification phase. Supervised learning techniques are particularly suitable to solve classification problems, whereas unsupervised learning techniques enable clustering of traffic flows into groups sharing common features. As such, they must be accompanied by the labelling algorithm that would assign particular applications to the identified clusters, which is challenging. The additional benefit of these methods is the ability to classify applications which are unknown. The examples of ML classifiers that can be used for QoS mechanisms are: J48 Decision Tree, K-Nearest Neighbourhood, Random Tree, Naive Bayes and the Neural Networks method [3], [5]. Although ML-based techniques have several features making them suitable to e-Health traffic classification, not all of them are applicable to this particular problem. It has been also presented that the accuracy of a single classifier is not good enough to classify different types of applications when early classification is required [5].

A selection of ML techniques and classifiers suitable to e-Health traffic is presented in Section IV. Based on this methods, we propose a solution, which combines different classifiers in order to maximize the performance and accuracy of eHealth applications classification.

TABLE I
EHEALTH APPLICATIONS CLASSIFICATION BASED ON THE REQUIRED QOS PARAMETERS

Service type	Bandwidth	Delay	Packet loss	Class
Teleconsultation	High	Low	Low	1
HPC services	High	Low	Min	1
HD video	Max	Low	Low	1
HD images	High	Medium	Min	2
Sensor data	Medium	Low	Min	3
Patient data	Medium	Medium	Low	4
e-learning	High	Medium	Low	4
Voice	Medium	Low	Medium	5

III. EHEALTH TRAFFIC CHARACTERISTIC

There are various types of medical applications and each of them has different requirements when it comes to quality of service parameters. The QoS measures have been well defined in the domain of communication services; however, they have not been well defined in the eHealth domain. eHealth service category introduces a more diversified set of traffic patterns with bandwidth, delay and reliability requirements very different from typical network flows. They also introduce some of the highest QoS requirements among all services provided over IP networks. Real-time teleconsulation services require high throughput and are susceptible to packet delays (speech and HD video transmission). Video streaming from endoscopes and other medical devices has similar requirements. Medical images transmission needs high bandwidth and a very low packet loss ratio. This is especially important in case of high resolution images (X-ray, MRI, USG), because distorted images may lead to a wrong diagnosis. Clinical telemedicine applications, medical simulation tools and image reconstruction programs require guaranteed data delivery and minimal packet loss. Data transmission from medical sensors is not delay tolerant and even minimal packet loss is unacceptable (e.g., heart rate monitoring sensors).

Before an appropriate traffic classification technique can be designed, there is a need to characterize different types of eHealth traffic and identify all its distinctive features. Based on this information applications can be grouped together into classes, which require similar service parameters and forwarding priorities. This is necessary to properly mark classified packets and introduce further QoS mechanisms in the network (e.g., scheduling).

In Table I, we present the result of our analysis of eHealth application types in the context of the required QoS parameters. The above classification distinguishes five basic classes of eHealth applications. The first class contains highest priority services, which have strict requirements regarding bandwidth and maximum packet delay (e.g. High Perfomance Computing - HPC services). The second class contains data transmission services, which need guranteed packet loss rates. The third

 ISBN: 978-1-61208-179-3

group of applications gathers services which have low packet loss and delay. The next class aims at high bandwidth provisioning and has some tolerance against packet delay. The last class targets VoIP connections in eHealth networks, which require low packet delay and jitter.

IV. Classification algorithms and traffic classifiers

Having in mind the requirements towards classification of e-health traffic, we have identified several ML-based techniques as particularly suitable to the analysis of e-Health traffic. As a general rule ML classifiers investigate multiple flow descriptors - called *features* - simultaneously and provide learning capabilities, which introduce adaptive behaviours. They need to be trained on the examples of traffic flows from different applications, and the proper learning process is crucial to the final performance of the classifier. Moreover, the performance is very often dependent on the type of the data and on the set of features selected for observation, which describe characteristics of given application. Therefore, not all well performing classifiers would be valuable during the analysis of e-Health traffic.

In order to identify ML classifiers, which are the most suitable for our research subject, we have defined a set of criteria that are driven by e-Health traffic characteristics:

- Real time operation – most techniques require the observation of a full traffic flow to provide good classification results. This approach imposes significant delay, which is not tolerable in our case. Therefore in our solution we need methods where the observation of a whole flow is not required.
- Low number of necessary packets – a decision regarding classification needs to be made on the shortest possible part of the flow.
- Ability to perform classification based on a randomly selected part of the flow – in many cases the beginning of a flow cannot be observed, and the classifier should still make an accurate decision.
- Small processing overhead – a lightweight solution is required, but higher overhead is acceptable in the learning phase, which is performed offline.
- Ability to classify currently unknown application types.
- Small number of required features.
- Ability to work with encrypted traffic.

Below, we present an overview of the ML methods which were selected based on the evaluation of the above criteria:

1) Simple K-Means method: This method, proposed in [6], is the unsupervised learning approach based on the Simple-K-Means algorithm. The main advantage of this method is that it only needs the first few packets of the traffic flow, which depict application's negotiation phase [6]. It is thus assumed that unique negotiation phase is the differentiator between applications. This method has also very small set of features limited to the investigation of packet lengths. As an unsupervised learning method, Simple-K-Means divides observed traffic flows into clusters. During the learning phase each cluster is associated with a set of related applications. The particular flow in the cluster is classified as belonging to the most prevalent application from this set. The most challenging aspect of this approach is to properly assign different applications to clusters, so that given application is dominating in at least one of them and thus can be selected as a result of the classification. Although real-time classification is possible with this approach, difficulties might occur when the beginning of the flow is lost.

2) Multiple Sub-Flows method: The authors in [7] propose a supervised learning solution, which allows classification a flows based on the observation of N consecutive packets from any part of the flow. This feature is an important asset of the method. During the training process sub-flows of length N are extracted from the original flow, which represent parts with diversified characteristics. The classifier is trained on the sub-flows instead of the original flow. Therefore, the number of packets required for actual classification is relatively small (around 25), likewise is the number of necessary features. Capturing the start of the flow is not required. This method fulfils many of the identified criteria. Its disadvantage is however the inability to identify new application types.

3) Statictical protocol fingerprint method: This approach, presented in [8], analyses the flow and extracts its statistical properties, called protocol fingerprints, that would correspond to the behaviour of given protocols. This is performed in a training phase. Supervised learning - based classification is then performed by comparing those fingerprints to the statistical behaviour of the observed flow. On this basis particular protocols are identified. The method requires evaluation of only 3 features and enables real-time processing by observing first few packets of the flow. This approach is a promising technique with good performance. However when applied to e-Health traffic it may not always be possible to identify the application types correctly. This is because many applications would use several protocols in parallel, e.g. to transmit voice and data information separately.

4) Semisupervised classification method: Erman et al. [9] proposed a hybrid approach that takes advantage from both supervised and unsupervised ML techniques. The aim was to minimize the problem with proper labeling of clusters, which are the result of unsupervised techniques. Although this method requires the observation of full flows, it can be still valid in our case since it provides a unique ability to classify unknown application types. In this approach, both labeled and unlabeled flows are used in the training phase. Unsupervised method is exploited to form clusters whereas labeled flows in the cluster provide a way to map the cluster to the particular application type. The classifier, i.e., supervised technique, is then used to map unlabeled flows to one of the clusters/applications. An advantage of this method is reduced processing overhead in the learning phase.

5) Multi-classification: The authors in [5] observed that a significant number of network traffic classifiers performs well when applied to full flows. In order to work with parts of the flows, more sophisticated classification methods

 ISBN: 978-1-61208-179-3

TABLE II
SELECTION OF TRAFFIC CLASSIFICATION METHODS VS. CRITERIA IDENTIFIED FOR E-HEALTH TRAFFIC

	Real time operation	Number of packets	Flow beginning can be skipped	Processing overhead	Unknown applications	Small number of features	Encrypted traffic
5-tuple (Ports)	Yes	Low	Yes	Low	No	N/A	No
DPI	No	Low	Yes	Very High	No	N/A	No
Simple K-Means	Yes	Low	No	Low	No	Yes	Yes
Multiple Sub-Flows	Yes	Low	Yes	Average	No	Yes	Yes
Protocol fingerprint	Yes	Low	No	Average	No	Yes	Yes
Semisupervised	No	High	No	Average	Yes	Yes	Yes
Multi-classification	Yes	Very low	No	Moderate-High	No	Not clear	Yes

are required. Based on these observations they proposed a multi-classifier approach. In this method several classification techniques are combined to work in parallel. Classification is made based on the observation of a very short fragment of the flow ($<$10 packets). Although each classifier alone would perform rather poorly under such conditions, the appropriate combination of outputs from standalone classifiers can significantly increase the performance. However, this fast traffic classification method is performed at a cost of increased processing overhead.

V. OUR APPROACH

Table II presents the comparison of different QoS classification techniques based on the criteria specified for e-Health traffic. It can be observed that none of the standalone classifiers would be able to fulfil all the requirements that we have identified for eHealth traffic. Moreover, the performance of these methods, when applied to classification of eHealth traffic, should be verified through experimental results on real-life traffic streams. Therefore, in our future research we will focus on implementing different multi-classification methods that would take advantage of the standalone classifiers described in the previous chapter. We will investigate different combination techniques to achieve the optimal set of features and the best classification accuracy for any type of eHealth traffic.

The eHealth application classes proposed in Section III will be used by the ML-based classification techniques as the base for assigning clusters into appropriate flow groups. Such an approach will allow straightforward mapping of eHealth application classes into the appropriate QoS classes. In this way, the results of eHealth traffic classification could be directly used by the packet scheduling mechanisms used in existing QoS architectures (e.g., Diffserv, Interserv).

VI. CONCLUSIONS

The main difficulties in eHealth services provisioning are connected with the reliability and privacy issues of personal data transmissions over public networks. Ubiquitous eHealth service category poses the most stringent performance requirements to Internet technology and network systems in terms of quality of service due to its nature of life and liability. Current methods for QoS provisioning over IP networks were not designed to guarantee reliable transfer of data for eHealth applications. The main problems lay in proper eHealth traffic detection and classification in order to assign packets to appropriate QoS classes.

This paper presented an overview of traffic classification methods, which might be applicable to different eHealth applications. It proposed a basic mapping of eHealth application classes to appropriate QoS classes and also proposed machine learning - based traffic classification techniques for real-time packet flows. The proposed methods are able to address most of the challenges of eHealth traffic classification and does not require any packet payload inspections. In this way the privacy of the transmitted information can be preserved.

ACKNOWLEDGMENT

This work is partially supported by the Polish Ministry of Science and Higher Education under the grant agreement no. 543/N-COST/2010/0 ”Traffic analysis in eHealth networks”.

REFERENCES

[1] L. Skorin-Kapov and M. Matijasevic, “Analysis of qos requirements for e-health services and mapping to evolved packet system qos classes,” *International Journal of Telemedicine and Applications*, vol. 2010.

[2] J. Evans and C. Filsfils, *Deploying IP and MPLS QoS for multiservice networks: theory and practice*, ser. The Morgan Kaufmann Series in Networking, R. Adams, Ed. Morgan Kaufmann Publishers is an imprint of Elsevier, 2007.

[3] T. Nguyen and G. Armitage, “A survey of techniques for internet traffic classification using machine learning,” *Communications Surveys & Tutorials, IEEE*, vol. 10, no. 4, pp. 56–76, 2008.

[4] P. Koutsakis, “Guaranteed bandwidth allocation and qos support for mobile telemedicine traffic,” *2008 IEEE Sarnoff Symposium*, pp. 1–5, 2008. [Online]. Available: http://ieeexplore.ieee.org/lpdocs/epic03/wrapper.htm?arnumber=4520075

[5] A. Dainotti, A. Pescap, and C. Sansone, “Early classification of network traffic through multi-classification,” in *Traffic Monitoring and Analysis*, ser. Lecture Notes in Computer Science, J. Domingo-Pascual, Y. Shavitt, and S. Uhlig, Eds. Springer Berlin / Heidelberg, 2011, vol. 6613.

[6] L. Bernaille, R. Teixeira, I. Akodkenou, A. Soule, and K. Salamatian, “Traffic classification on the fly,” *ACM SIGCOMM Computer Communication Review*, vol. 36, no. 2, pp. 23–26, 2006.

[7] T. Nguyen and G. Armitage, “Training on multiple sub-flows to optimise the use of machine learning classifiers in real-world ip networks,” in *Proceedings. 2006 31st IEEE Conference on Local Computer Networks*. IEEE, 2006, pp. 369–376.

[8] M. Crotti, M. Dusi, F. Gringoli, and L. Salgarelli, “Traffic classification through simple statistical fingerprinting,” *ACM SIGCOMM Computer Communication Review*, vol. 37, no. 1, pp. 5–16, 2007.

[9] J. Erman, A. Mahanti, M. Arlitt, I. Cohen, and C. Williamson, “Semi-supervised network traffic classification,” in *Proceedings of the 2007 ACM SIGMETRICS International Conference on Measurement and Modeling of Computer Systems*. ACM, 2007, pp. 369–370.

 ISBN: 978-1-61208-179-3

A Systematic Review of Trust in Automation and Assistance Systems for Older Persons' Overall Requirements

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Abstract - The objective of the study was the numeric investigation of the existing literature containing the factor trust in automation as well as assistance systems for overall requirements for older people. Therefore, a systematic literature review with a total of 150 dissimilar keyword-combinations based on three different descriptors in three bibliographic online databases was performed. The study revealed that 18 articles deal with trust in healthcare or assistance systems but several of them only superficially. None of the identified studies focused explicitly on trust in Ambient Assisted Living despite of the increasing market relevance in the last decade. Older people as target group for qualitative and quantitative research in this field are detected and partially examined. Obtaining access to older persons' trust in automation in general and Ambient Assisted Living work systems need further research.

Keywords-Ambient Assisted Living; Assistive Technology; Automation; Elderly People; Trust.

I. INTRODUCTION

As a result of demographic change, the number of people in advanced age, who want to spend a self-determined, independent life at home, is growing. Unfortunately, not all elderly people are able to reach this goal without assistance. This often leads to conflicting goals. An age-related decline in physical fitness as well as physical limitations in consequence of diseases or accidents mean that elderly need support in realizing their desire for living in their familiar surroundings. This results in a tension between traditional personal care, new technical support and also affordability of individual support.

On the one hand, personal care can be provided by the family or human caregivers. Human assistance in activities of daily living (ADL) like taking a bath, preparing meal or going for a walk is a great relief for people with health restrictions. On the other hand, science deals for several decades with the research of new technologies to support people in their own home [56]. Meanwhile, innovations in the home environment offer numerous opportunities for technology-supported systems. Researchers have developed a plurality of services combined with technical support for elderly people. Terms as 'Smart House' [35], 'Smart Home' [69], 'Assistive Technology (AT)' [57] or 'Ambient Assisted Living (AAL)' [16] are just a few of the frequently used terms in this context.

In this article, the importance of trust in assistance technology for elderly people is in the center of interest. For using AAL, technology which assists an impaired person in everyday life [4], the user needs trust in this assistance system. Since in case of emergency the assistance can save lives, it can be quickly realized that trust has fundamental meaning in the consideration of development, purchase and use of AAL. The fact that older people, who are typically not grown up with technologies like personal computer, smart phone or Internet, which are often integrated in AAL [15], implies special demands towards the design of these devices.

The present study is structured as follows: The background section contains the development of AAL as effect to the demographic change and the importance of trust as influence factor in this research context. In the third section the literature review as research framework is described in detail. Following, the acquired data are analysed in its entirety and moreover, studies regarding trust in healthcare and assistance systems are considered separately. Finally, a discussion of the received results and an overview about further research activities is demonstrated.

II. BACKGROUND

This section contains the background information about the development of AAL as reaction to the demographic change as well as trust as influence factor for AAL.

A. Development of AAL as Reaction to the Demographic Change

According to the United Nations Department of Economic and Social Affairs (UNDESA) in the total population the proportion of people over the age of 60 years is constantly increasing [75]. Compared to more than 700 million in 2009 the number of people over the age of 60 is predicted to grow to 2 billion in the year 2050. Worldwide this would correspond to a tripling in a period of 40 years. The annual growth rate of the 'generation 60plus' amounts 2.6 per cent. This enlargement surpasses the overall population's growth rate of 1.2 per cent per annum. At the present time, over a fifth of the population in the more developed regions is 60 years of age or over. Prediction for the year 2050 show that nearly one third of the total population will belong to that age group [75]. These facts underline the economic significance of this age group.

Moreover, technological progress and a high degree of information technology are factors that gain more and more relevance in everyday life. The beginning of research in the field of Assistive Technology (AT) can be followed to the early 1970's. The so called phone chains used the standard

 ISBN: 978-1-61208-179-3

telephone system and were organized by a network of elderly and professionals [56]. Mutual telephone calls were used for regular control and once a member of the group did not respond, the doctor or relatives were notified. This can be regarded as the first working electronically emergency system for elderly persons.

The next step was the development of home emergency call systems. One of the most famous was the HTS831, which had two different buttons: A red one and a green one. Moreover, the system implied a wireless transmitter, which the user can wear around the neck. In case of emergency the user can either push the button at the transmitter or the red button at the station to contact the emergency center. As a security and monitoring function, the user had to press the green button once a day [56]. In the middle of the 1990's, the first video conference system for private homes was offered. Installed TV-top boxes or a separate video telephone functioned as a user interface. Additionally, this system contains functions for personal discussions and organization of, e.g., nursing, medical or entertainment services [20]. To sum up, the effort to develop useful and coherent life assistance services which aid older persons to live longer in their home existed for several decades.

In the last few years, due to the knowledge about the growing distribution of older people and the technological progress, the construction of AAL has significantly increased in their importance. A lot of national and international Non-Governmental Organizations (NGOs) and research projects were focusing on this topic. As a result, different concepts have entered the market [7, 15, 19, 68]. For instance, by sensory floor mats which register movements in the living ambiance and react by automatically turning the lights on the risk of falling can be reduced [64]. Another example of AAL can be found in the combination of personal and technological support offered by the Fraunhofer Institute. By means of summarizing and demand-oriented analyzing of sensor data, an individualization of care as well as nursing services is possible [15]. These two examples belong to the concept of AAL (Ambient Assisted Living). Reference [16] as first defined AAL "as the use of AmI [Ambient Intelligence] in everyday live. Assisted means assistance, by technical devices as well as by technical or human services" [16]. In 2007, a more elaborate definition of AAL traces back to [4]. Hereafter, AAL delineates "living in a smart technology supported environment that reacts sensitive and adaptive to the presence of people and objects and thus provides various services to the human. The aim is to preserve, enlarge and extend the personal freedom and autonomy, by promoting and supporting the personal independence" [4; translated by the authors].

In contrast to home automation [40], AAL limited not only to life in relation to housing, but extends to all areas of life. AAL focuses on the assistance functions of an adaptive overall system while home automation deals mainly with automation and networking of devices. AAL has set itself the objective of maintaining, increasing and extending the user's personal freedom and autonomy. Summarizing, AAL systems are intended for people with health impairments which have need for security and furthermore communication requirements to prevent loneliness. The present European research focuses on these overall requirements of elderly persons. Since the concept of AAL regards on these holistic requirements, the importance of trust in AAL needs a more profound understanding.

B. Trust as Influence Factor for AAL

As seen in [47], trust in medical technology is empirically different from trust in other technology. Moreover, trust plays an important role in multiple user groups as patients and physicians [46]. These research findings imply that the factor trust has to be considered in the development of medical and healthcare products and has effects in the usage of AAL systems by older people. To emphasize the diversity of the construct trust there are added numerous 'trust relationships'. Inter-personal trust, social trust and trust in automation can be mentioned. Inter-personal trust comprises a human's trust with another human whereas social trust characterizes trust with a system or an institution [6]. The so called trust in automation designates a human's trust with a technology or a device [46].

It can be found that trust is an attitude toward technology that affects reliance and which can be gauged. Moreover, people have the tendency to rely on technology they have trust in and to reject technology they do not trust [33]. When people trust automation, the usage is often influenced positively [31, 32]. But also negative examples exist due to inappropriate calibration of user trust [53]. It can be mentioned that, if trust is not calibrated to the true capacity of the system, users may over rely (misuse) or under rely/ reject (disuse) on the automation [54]. Based on [46] which deal with patients and healthcare providers in obstetric work systems, important implications for trust in healthcare systems and AAL-Technology emerge. The study demonstrates that trust building in medical technology transpires - not only in a relationship between doctor and patient or patient and technology. There is a complex network of relationships, which ultimately forms a 'network of trust' in technology use.

Already [50] observed a network of trust in supervisory control systems. In addition to the system she included system designer, operators, management and society as other actors. Trust as factor given to AAL systems, is also affected by a large proportion of implicit trust in the network around the use of the actual technology. Following the 'Actor Network Theory' [8, 30], the reliance on the network located around the AAL system, is equally important for the usage of assistive technology. As an example, for [73] the use of a defibrillator implies not only trust in the product and its functions but also in the network around this product. This network includes product designer, the organization which implements the product and the coaches, explaining the technology to the inexperienced users [73]. As it were, distrust in health care provider can also lead to patients' distrust in medical technology or the hospital per

 ISBN: 978-1-61208-179-3

se [45]. Therefore, consideration of the social system or work system [18], which wrapped technology, is necessary for an understanding of trust. Reference [46] clarified that in case of complex medical or assistance technology, building trust in automation is more precisely building trust in a work system. Furthermore, during the use of the same system the perspectives of multiple user groups (end user, relatives, and health care provider) are various [46]. Summarizing, it can be seen that there are a lot of factors which differ in the formation of trust and which have to be considered in the development and application of AAL.

The objective of the present study was the numeric investigation of trust in automation and home assistance systems in the existing literature.

III. RESEARCH FRAMEWORK

A literature review was executed to reveal the relevant scientific approaches in the context of trust in AAL, healthcare assistance systems and other automation. By means of this research method, information about how extensively the issue is previously addressed in the research can be demonstrated. To increase the precision of the literature review in this innovative and fast-moving research field, relevant articles were identified by means of computerized search in the online bibliographic databases 'Web of Science' [72] 'PubMed' [59] and 'PsycINFO' [58] starting in November 2010 up to a publication date of January 2011. The three database searches are carried out with filter. In 'Web of Science' key search terms are filtered by topic, in 'PubMed' by MeSH Terms and in 'PsycINFO' by keywords. These three different terminologies represent the generic terms for the search algorithm in the respective database.

TABLE I. KEY SEARCH TERMS

Attributes	Auxiliaries	Population
Reliance	Ambient Assisted Living/ AAL	Adult
Trust	Assist* System/ Technology	Age*
	Assistive Technology Service/ ATS	Elder*
	Automation	Old*
	Healthcare	
	Intelligent/ Interactive Home	
	Medical Technology	
	Smart Home/ House/ Living	
	Technology	

*Search included stated terms and derivates (e.g., age, aging, aged).

For investigation in the three databases, 150 dissimilar search term combinations are performed in each setting. The used key search terms are presented in Table I. The first search requests always contain a term of the categories 'Attributes' and 'Auxiliaries'. At first, the term trust has been set and was queried alternately with the keywords of the descriptor 'Auxiliaries'. After carrying out these searches, the term reliance was set and also requested with those from the second category. Then, the already carried out 30 search combinations have been linked sequentially to the concepts of the third descriptor 'Population'. By extending the research with these four search terms and consideration of the abbreviations AAL and ATS, ultimately 150 searches per database were performed.

Due to the large number of search combinations and potentially relevant studies, the search results are already reviewed to further availability during the database search. For this, both title and abstract are considered. Afterwards, to identify the relevant full text articles a set of exclusion criteria are selected. For inclusion in the literature review articles had to fulfil the following criteria:

(1) The study described explicitly the connection between trust and automation or assistive technology, whereby trust is seen as an influence factor for the interaction with the system

(2) The article was published in a journal or presented on an international conference

(3) Studies which were first presented on a conference and afterwards published with identical findings as a journal article were only taken into consideration with the journal release

(4) The publication was written in English

(5) Due to the database research date, studies are included until January 2011.

A data form was used to remove the important information for each relevant article. After structuring the articles and integrating the data in the fact sheet, a detailed data analysis was undertaken.

IV. DATA ANALYSIS

The previously described 150 search term combinations in each database identified in a first step 8.498 potentially relevant articles for the literature review. By means of the structural query, the database 'Web of Science' has offered 4.401 publications. The database 'PubMed' yielded 3.855 results and the search requests in 'PsycINFO' could emerge 242 studies. Owing to the consideration of the above described five exclusion criteria, after analyzing titles and abstracts of the 8.498 studies, 164 publications are factored in the next part of the review. In this step, the full-text of these 164 articles was reviewed. After analysis of the full text versions, 92 articles were included for the further literature analysis. With regard to the exclusion criteria, totally 72 of the revealed studies were excluded. Thus, 56 per cent remains of the original 164 articles. Fig. 1 gives a numerical overview about the structural sequence of the literature research.

Because of the five exclusion criteria shown above, 72 articles (44 per cent) were excluded after the full-text review. Most of the studies (48 articles) are not relevant due to the wrong topic focus. These 48 articles, among 15 studies which had focused on trust in websites or online platforms as well as trust in e-commerce applications are not followed up owing that exclusion criterion. Further 17 studies are eliminated since they were not published on a conference or in a journal. The last seven excluded articles are

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published once in a journal and additionally published on a conference with almost identical results. These studies are only considered one time with the more actual journal article in our results. Thus, in the end, 92 articles were analyzed in detail in the literature review.

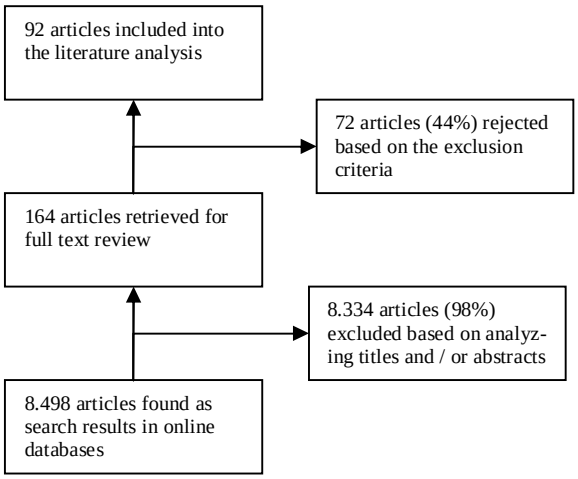

Figure 1. Literature research sequence diagram (authors design)

These articles comprise the topics trust in **automotive** [1, 10, 28, 34, 60, 70], **aviation** [2, 5, 23, 29, 37, 38, 53, 63, 78], **combat identification** [13, 61, 62, 77, 80], **general design advancement** [25, 33, 36, 49, 55], **supervisory control systems** [3, 31, 32, 39, 48, 79], **healthcare and assistance systems** [21, 22, 42, 43, 44, 66] and **others** [14, 41].

A. Data analyses of overall results

In the next step, the data sheet with the overall studies has been analyzed (A) and compared with the results from the topic trust in healthcare and assistance systems (B).

(1) **Publication date**

Between 1987 and 1991 only two studies are published in this context [49, 67] The first experiment of trust in a human-machine supervisory control system was realized by [31]. Whereas, until 1999, 15 studies are published in total, from 2000 to 2010, 77 articles with regard to trust in technology and assistance systems can be found. Since 2003, every year six studies or more are indicated. In 2008, a maximum of 11 relevant articles can be revealed.

(2) **Type of study**

In a next step, the distinction between conceptual and empirical/experimental articles can be examined. From the overall 92 reviewed studies, 22 consider conceptual and 70 empirical methods for their research. These conceptual articles comprise former summaries and literature reviews (12 articles) as well as articles with the focus on framework, model or questionnaire development (10 articles). The 70 empirical articles can be differentiated into quantitative and qualitative research methods. Since 1987, viewed overall 62 quantitative studies (including experiments, online, postal or paper standardized questionings or a combination of experiment and questioning) were identified. It can be observed, that solely five studies include questionings only. In contrast, 57 studies used experiments or a combination of experiments and questionnaires for measuring trust. By comparison, eight articles with qualitative methods as qualitative interviews, workshops and focus group interviews were considered.

(3) **Participants characteristics**

In a next step, the participants' age distribution should be considered. In order to receive a better understanding of the participants in experiments or surveys, a clustering in five age groups was conducted. These groups were subdivided into 'participants younger than 30 years' 'participants from 30 to 60 years', as well as 'participants older than 60 years'. Moreover, one age group comprised a combination of younger (< 30 years) as well as older (> 60 years) participants. Further studies performed experiments or interviews without age differentiation.

Regarding the 70 empirical studies, in 22 of the studies and hence 31 per cent, there was no age differentiation declared. In 35 surveys participants were younger than 30 years and in five surveys between the age of 30 and 60 years. Only in eight surveys (16 per cent of overall) participants were older than 60 years. In five articles the participants exclusively belong to the age group over 60 years. In three further studies both, younger participants (< 30 years) and people over the age of 60 were examined.

Participation rates range from an experiment with six [26] or a qualitative interview with nine participants [76] to a postal survey with 1187 participants [9]. In total, in 43 of the articles (61 per cent) less than 50 participants have taken part in the surveys to trust in automation or assistance systems. In eight studies between 51 and 100 and in 16 studies between 101 and 500 participants were involved. Reference [9] was the only study with more than 500 participants. In two articles there was no participant number specified. Moreover, only three out of the surveys contained a limitation with regard to the gender. One study by [43] questioned 24 women, or rather 24 mothers who have recently given birth. In two other articles, only male participants, once pilots [71] and one time male students [51] were regarded. In 38 surveys both gender were examined and 29 surveys had not make an explicit distinction.

(4) **Publication type**

Another study detail can be carried out by the differentiation between 'conference vs. journal publication'. Among the 92 examined articles, 18 articles (20 per cent) were presented at a corresponding conference and 74 articles published in a journal. The journal with the most publications and major interest in the research of trust and automation was 'Human Factors' with a total of 21 articles (23 per cent). By far, the journal 'Ergonomic' with eight relevant articles, the 'International Journal of Industrial Ergonomics' with four and several journals with three studies are following.

 ISBN: 978-1-61208-179-3

B. Data analysis of studies regarding trust in healthcare and assistance systems'

This rising relevance of the concept trust which can be found in the different research topics can also be supported through the numbers of relevant articles in trust and 'healthcare and assistance systems'. In this field of research the interest is growing in the last decade.

(1) **Publication date**

The first published paper related to trust in healthcare automation was presented in 2002. The conference paper by [42] was the first article that emphasizes the factor trust. From this point on until January 2011, 18 articles can be found. These articles deal with reliance on healthcare, medical or household assistance systems. In the years 2003, 2004 and 2006 no publications within this context can be found, whereas since 2007, every year articles are considered. In 2010, the largest number with five studies in this context can be found. Fig. 2 gives a detailed overview about the annual distribution of the found studies in the cluster 'healthcare and assistance systems' in comparison to the other topics. As can be seen, the importance of a conscious handling and perception of the concept trust in combination with automation and particularly healthcare and assistance systems is increasing in the last years. The first study with regard to trust in automation and human-machine interaction was published in 1987 [49]. In contrast, the first publication regarding trust as variable for developing healthcare systems for older persons was presented in 2002 [42].

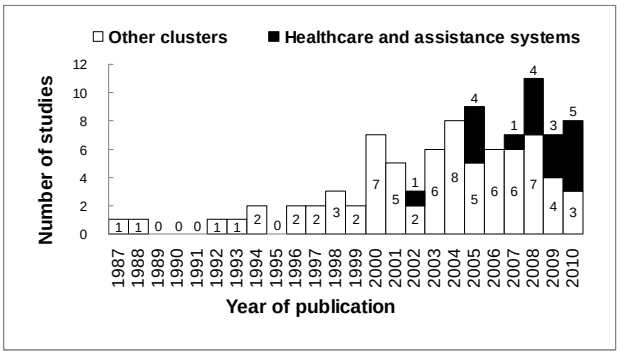

Figure 2. Year distribution of studies in 'healthcare and assistance systems' vs. other topics (authors design)

(2) **Type of study**

Four of the 18 articles in this cluster used conceptual methodologies. Three articles focused on framework or model development [21, 42, 44] and one study summarized the relevance of training in technology used by tele-home care nurses [66]. Moreover, 14 articles included empirical research– seven used quantitative and seven qualitative methods. The publications with quantitative methodologies are divided into three studies with a combination of questionnaire and experimental design, two studies with exclusive questionnaire surveys and two experiments. The qualitative research exclusively consists of articles with qualitative interviews.

In comparison, within the other topics quantitative studies with a number of 55 studies predominate. In particular, in new research areas qualitative surveys are utilized to get a detailed understanding of the topic. For this comprehension, the focus is set on qualitative interviews as occurred in the research area of trust in healthcare and assistance systems. Seven of the overall 18 studies (39 per cent) included qualitative interviews with individuals or workshop and focus group discussions. In 2010, four studies used qualitative interviews which show that researchers are still in the process of developing a detailed understanding. Given, that general research on trust in human-machine interaction has started in 1987 [49] and to this day ambiguities in this context exist [23, 29, 52] it is understandable that qualitative interviews are still used in the present research area.

(3) **Participants characteristics**

For the 14 empirical articles an age group differentiation was performed. In three of the studies, participants are younger than 30 years and in one study they are between 30 and 60 years. Moreover, five of the articles consider participants over the age of 60 years. Further two studies consider a combination of younger and older participants and three surveys give no information about age differentiation. In case of the work system in healthcare and assistance systems as AAL, the end user most time is over the age of 60. Therefore, it is of immense relevance that this target group will be considered in the research. Fig. 3 displays the previous study numbers in which participants over 60 years were involved.

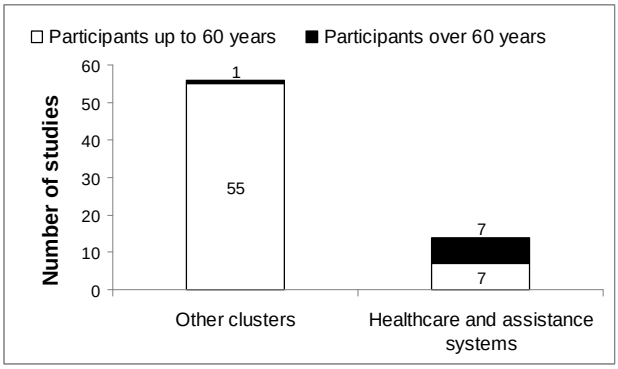

Figure 3. Age differences of study participants in the different clusters (authors design)

As can be seen, in the other clusters the target group of people over the age of 60 plays only a subordinate role. Only one author has considered elderly persons' trust in a human-decision aid system and compared the results to people younger than 30 years [14].

In contrast, in the healthcare sector researchers have focused more on the age group over 60 years. Of the total

of eight studies that have dealt with participants over 60 years, seven studies (88 per cent) are located in this cluster. Two studies have taken a differentiation of younger and elderly persons into account [22, 65]. Moreover, five articles have exclusively focused on people over 60 years [11, 17, 24, 27, 76]. With a percentage rate of 50 per cent of the overall studies which are analyzing the factor trust in healthcare and assistance systems by experiments or surveys, the age group over 60 years is strongly represented.

Concerning the number of participants in the topic 'healthcare and assistance systems', in nine of the studies the participant rate has amounted less than 50 participants. In two studies the participant rate ranged from 51 to 100 persons and three articles take more than 100 participants into account. These articles also include the reference [9] with a postal questionnaire of 1187 people. With reference to the participant rate it can be highlighted that the study with the most participants [9] as well as one of the studies with the less participants (n=9) [76] belong to the topic trust in healthcare and assistance systems.

Regarding the gender distinction within the different methodological designs, 12 articles have regarded both sexes; one article made no differentiation and one study [43] viewed only female participants. This study with solely female participants interviewed 24 women who recently have given birth. They were questioned in a qualitative interview to analyze trust in medical technology and obstetrics work system [43]. For the observation of this complex work system additionally interviews with care providers were conducted [46]. Furthermore, it can be said that healthcare and technical support for elderly persons are themes which concern men and women equally. Therefore, it seems logical that most of the studies deal with both genders.

(4) **Publication type**

Moreover, among the 18 studies, six articles (33 per cent) are presented as conference papers and 12 articles (67 per cent) were published in journals. The journal 'Ergonomics' with two publications was the only one which was represented several times. The author Enid Montague with four research studies since 2009 has taken a pioneering role in context of trust and healthcare technology [43, 44, 46, 47]. Additionally, Coughlin et al. [11, 12] and Ho et al. [21, 22] are listed with two articles.

Due to the actuality of the research field, the distribution of articles presented on conferences and published in journals can be explained. From the overall 18 studies in the healthcare cluster, 12 were published in journals and six studies were presented on conferences. By comparison, from 74 articles within the other topics, 62 were published in journals and 12 studies, thus 16 per cent, were presented on conferences.

V. DISCUSSION

The significant increase of elderly persons due to the demographic change and the resulting rise in purchasing power affects the development of reliable AAL systems [74]. Since 2005 the European and national sponsoring programs for AAL steadily increase and the relevance of supported living in home environment which enlarges and promotes the personal independence growth up. Moreover, it is difficult to understand that AAL has absolutely no consideration in connection with measuring trust so far. The search combinations 'reliance or trust' and 'Ambient Assisted Living/ AAL' yielded none results in the current literature study. Until January 2011, there was no study explicitly examining trust in AAL systems. Moreover, the relevance of measuring trust in healthcare technology and assistance systems is not prominent within the research results. It can be seen that the consideration of trust in connection with healthcare, medical technology or assistance systems is still in an initial stage. A few studies considered trust in intelligent home systems [12], smart home [11], telemedicine systems [24], as well as automation [65] or technology [76] at home. Furthermore, it must be noticed, that there is no consistent terminology for assistance systems for elderly persons. None systematic approach and documentation as well as a uniform technology and understanding exist in research, which complicated measuring trust.

One the one hand, these results could imply that the topic is not relevant for the scholarship. On the other hand, due to the increasing number of studies in the last decade this statement can be disproved. Analyzing the publication date shows that all relevant articles are composed in this period. It can be seen that the research focus has gained in importance in the last decade.

Another interesting fact can be found in the different frequency distribution of quantitative and qualitative studies. In the analysis of the type of study it can be highlighted that researchers who are regarding trust in healthcare and assistance systems use qualitative as well as quantitative methodologies. The fact that trust in 'healthcare and assistance systems depends not only on the single technology but furthermore on a complex work system [46, 73], underlines the relevance of more research in this topic.

Moreover, researchers have recognized that participants' characteristics of elderly have been taken into account. An analysis of trust in this sector can only be realized with the integration of people over the age of 60. Seven articles in the last decade consider older participants' trust in healthcare and home assistance systems. The increasing demand and importance of AAL due to the higher life expectancy and demographic shift clarify a considerable backlog demand in measuring elderly persons' trust in AAL. Moreover, it requires more research in this age group to close the gap of the few studies and less quantitative results.

Finally, it can be summarized that by reason of the novelty of the research of measuring trust as influence factor for using healthcare and assistance systems the exact influence of trust cannot be quantified. Only 18 articles which cover that topic were found owing to the literature

 ISBN: 978-1-61208-179-3

review. Initial developments reveal that trust in healthcare and medical technology differs from reliance on other technologies [47] Reference [44] examined a tool to measure patients' trust in medical technology, which may be useful for further quantitative research. Actually, a small number of studies had examined the complex network of trust in the equally complex subject AAL for elderly persons. Both, qualitative and quantitative research is required to meet the high demand of the next years. Furthermore, elderly persons as participants must take more into account for measuring and understanding trust in an AAL work system. For obtaining access to elderly persons' trust in an AAL work system a deeper understanding of their needs as well as fears and worries is essential. Additionally, trust of reference persons may have influence in using AAL. For researchers and designers of AAL recognizing the influence factor trust will support the development of marketable solutions.

The knowledge gained by the literature review provides potential for further research. In the following, a multidimensional model of trust in AAL will underline the significance of this research area. Based on different types of trust interacting in an AAL service network, a generally accepted model due to the existing literature and a requirement analysis with older people and service provider will be developed. Furthermore, a questionnaire distributed with the support of a healthcare service provider will be performed to validate the theoretical trust model. Experiments in different surroundings and various AAL test designs will be implemented afterwards to evaluate the influence factor trust in AAL.

LIMITATIONS

The systematic review had to fight some limitations in the research process. First, the selection of online databases should be considered. Literature for trust in automation and healthcare can be seen as an interdisciplinary field. Therefore three bibliographic databases were used. 'Web of Science' comprised interdisciplinary content across 256 disciplines the database 'PubMed', focuses on healthcare content and 'PsycINFO', psychological literature. Due to this selection, articles which are not integrated in these databases are excluded for the review. Second, the information provided in the articles is very heterogenic. Some include a specific description about the experimental design, while other studies fail to provide detailed information. Third, due to the fact, that only English language articles were included into the review, a distorted picture is drawn, because the studies found and included focus on English-speaking authors. Fourth and finally, the studies included in the literature review were screened until January 2011. Thus, articles which were published afterwards are not considered for this systematic review.

FUNDING

This research was supported by grants from the German Federal Ministry of Education and Research (BMBF). It is part of the project SMILEY (Smart and Independent Living for the Elderly) supported by BMBF under contract 01FC10004.

REFERENCES

[1] G. Abe and J. Richardson, "Alarm timing, trust and driver expectation for forward collision warning systems," Applied Ergonomics, vol. 37, 2006, pp. 577-586.

[2] N. Bagheri and G. Jamieson, "The impact of context-related reliability on automation failure detection and scanning behavior systems," Proc. 2004 IEEE International Conference, Man and Cybernetics, vol. 1 (10–13), 2004, pp. 212-217.

[3] J. E. Bahner, A.-D. Hueper and D. Manzey, „Misuse of automated decision aids: Complacency, automation bias and the impact of training experience," International Journal of Human-Computer Studies, vol. 66, 2008, pp. 688–699.

[4] T. Becks, J. Dehm and B. Eberhardt, "Ambient Assisted Living. Neue "intelligente" Assistenzsysteme für Prävention, Homecare und Pflege," Frankfurt am Main, 2007.

[5] J. P. Bliss and M. C. Dunn, "Behavioural implications of alarm mistrust as a function of task workload," Ergonomics, vol. 43(9), 2000, pp. 1283-1300.

[6] K. Blomqvist, "The many faces of trust," in Scandinavian Journal of Management, vol. 13(3), 1997, pp. 271-286.

[7] BMBF, "Assistenzsysteme im Dienste des älteren Menschen. Steckbriefe der ausgewählten Projekte in der BMBF-Fördermaßnahme „Altersgerechte Assistenzsysteme für ein gesundes und unabhängiges Leben – AAL"," 2010, doi:http://www.aal-deutschland.de/deutschland/dokumente/projektportrats-aal.pdf.

[8] M. Callon, "Some elements of a sociology of translation: Domestication of the scallops and the fishermen of St Brieuc Bay," in "Power, Action and Belief: a new Sociology of Knowledge? Sociological Review Monograph," J. Law, Ed., London, 1986, pp. 196-233.

[9] M. Calnan, D. Montaner and R. Horne, "How acceptable are innovative health-care technologies? A survey of public beliefs and attitudes in England and Wales," Social Science & Medicine, vol. 60, 2005, pp. 1937–1948.

[10] J. S. Chugh and J. K. Caird, "In-Vehicle Train Warnings (ITW): The Effect of Reliability and Failure Type on Driver Perception Response Time and Trust," in Human Factors and Ergonomics Society 43rd Annual Meeting, Houston, TX, 1999.

[11] J. F. Coughlin, L. A. D'Ambrosio, B. Reimer and M. R. Pratt, "Older Adult Perceptions of Smart Home Technologies: Implications for Research, Policy & Market Innovations in Healthcare," Proc. IEEE Proceedings of the Engineering in Medicine & Biology Annual Conference, Lyon, 2007.

[12] J. F. Coughlin, J. Lau, L. Ambrosio and B. Reimer, "Adult children's perceptions of intelligent home systems in the care of elderly parents," Proc. Proceedings of the 3rd International Convention on Rehabilitation Engineering & Assistive Technology, 2009.

[13] M. T. Dzindolet, L. G. Pierce, H. P. Beck and L. A. Dawe, "The perceived utility of human and automated aids in a visual detection task," Human Factors, vol. 44, 2002, pp. 79–94.

[14] N. Ezer, A. D. Fisk and W. A. Rogers, "Age-Related Differ-

 ISBN: 978-1-61208-179-3

ences in Reliance Behavior Attributable to Costs Within a Human-Decision Aid System," Human Factors, vol. 50(6), 2008, pp. 853-863.

[15] Fraunhofer, „Zuhause Daheim: Das Projekt JUTTA," 2011, doi:http://www.inhaus.fraunhofer.de/Geschaeftsfelder/Health-und-Care/jutta.jsp.

[16] S. Giesecke et al., "Ambient Assisted Living. Country Report Germany. 2005.

[17] C. Harrefors, K. Axelsson and S. Sävenstedt, "Using assistive technology services at differing levels of care: healthy older couples' perceptions," Journal of Advanced Nursing, vol. 66(7), 2010, pp. 1523–1532.

[18] H. W. Hendrick and B. M. Kleiner, „Macroergonomics: An introduction to work system design," Santa Monica, CA: Human Factors and Ergonomics Society, 2001.

[19] W. Heusinger, „Das intelligente Haus- Entwicklung und Bedeutung für die Lebensqualität," Frankfurt am Main, 2005.

[20] J. Hilbert, K. Scharfenorth and J. Haberle, „Vom Virtuellen Altenheim zu TESS inkontakt. Erfahrungen aus einem Entwicklungs- und Erprobungsprojekt für mehr Lebensqualität im Alter," IAT, Ed., Jahrbuch 1998/1999, 1999, pp. 132-143.

[21] G. Ho, L. M. Kiff, T. Plocher and K. Z. Haigh, "A model of trust and reliance of automation technology for older users," Papers of the AAAI Fall Symposium "Caring Machines: AI in Eldercare", Menlo Park, CA, 2005a, pp. 45-50.

[22] G. Ho, D. Wheatley and C. T. Scialfa, "Age differences in trust and reliance of a medication management system," in Interacting with Computers, vol. 17, 2005b, pp. 690–710.

[23] J. S. Hughes, S. Rice, D. Trafimow and K. D. Clayton, "The automated cockpit: A comparison of attitudes towards human and automated pilots," in Transportation Research, vol. F12(5), 2009, pp. 428-439.

[24] Y. Jasemian, "Elderly comfort and compliance to modern telemedicine system at home," Proc. of Second International Conference on Pervasive Computing Technologies for Healthcare, PervasiveHealth 2008, Tampere, 2008.

[25] J. Y. Jian, A. M. Bisantz and C. G. Drury, "Foundations for an empirically determined scale of trust in automated systems," in International Journal of Cognitive Ergonomics, vol. 1(4), 2000, pp. 53-71.

[26] X. Jiang et al., "Measurement of human trust in a hybrid inspection system based on signal detection theory measures," in International Journal of Industrial Ergonomics, vol. 34, 2004, pp. 407-419.

[27] M.-L. Jung and K. Loria, "Acceptance of Swedish e-health services," in Journal of Multidisciplinary Healthcare, vol. 3, 2010, pp. 55–63.

[28] B. H. Kantowitz, R. J. Hanowski and S. C. Kantowitz, "Driver acceptance of unreliable traffic information in familiar and unfamiliar settings," Human Factors, vol. 39, 1997, pp. 164–176.

[29] A. Keller and S. Rice, "System-Wide versus Component-Specific Trust Using Multiple Aids," The Journal of General Psychology, vol. 137(1), 2010, pp. 114–128.

[30] B. Latour, "Science in Action: How to Follow Scientists and Engineers Through Society," Milton Keynes, 1987.

[31] J. Lee and N. Moray, "Trust, control strategies and allocation of function in human-machine systems," Ergonomics, vol. 35, 1992, pp. 1243–1270.

[32] J. D. Lee and N. Moray, "Trust, self-confidence, and operators' adaptation to automation," International Journal of Human-Computer Studies, vol. 40, 1994, pp. 153–184.

[33] J. D. Lee and K. A. See, "Trust in automation: Designing for appropriate reliance," Human Factors, vol. 46(1), 2004, pp. 50–80.

[34] M. N. Lees and J. D. Lee, "The influence of distraction and driving context on driver response to imperfect collision warning systems," Ergonomics, vol. 50(8), 2007, pp. 1264–1286.

[35] G. Leopold, "Will 'Smart House' Provide Shelter for High-Tech Firms?," Electronics, vol. 58(26), 1985, pp. 45-46.

[36] P. Madhavan and D. A. Wiegmann, "Similarities and differences between human–human and human–automation trust: an integrative review," Theoretical Issues in Ergonomics Science, vol. 8(4), 2007, pp. 277–301.

[37] A. J. Masalonis, J. A. Duley, S. M. Galster, D. J. Castano, U. Metzger and R. Parasuraman, "Air traffic controller trust in a conflict probe during Free Flights," Paper presented at the 42nd Annual Meeting of the Human Factors and Ergonomics Society, Santa Monica, CA, 1998.

[38] J. M. McGuirl and N. B. Sarter, "Supporting trust calibration and the effective use of decision aids by presenting dynamic system confidence information," Human Factors, vol. 48(4), 2006, pp. 656–665.

[39] S. M. Merritt and D. R. Ilgen, "Not all trust is created equal: dispositional and history-based trust in human-automation interactions," Human Factors, vol. 50(2), 2008, pp. 194-210.

[40] I. Miles, "<Shift> <Control>,...<Home>? A Response to Robins and Cornford," Futures, vol. 22(8), 1990, pp. 880-885.

[41] C. A. Miller, "Trust in adaptive automation: the role of etiquette in tuning trust via analogic and affective methods," Proc. First International Conference on Augmented Cognition, Las Vegas, NV, 2005.

[42] C. A. Miller, K. Haigh and W. Dewing, "First, cause no harm: Issues in building safe, reliable and trustworthy elder care systems," Proc. Proceedings of the AAAI-02 Workshop "Automation as Caregiver", 2002.

[43] E. N. H. Montague, "Patient source of learning about health technologies and ratings of trust in technologies used in their care," Ergonomics, vol. 53(11), 2010a, pp. 1302–1310.

[44] E. N. H. Montague, "Validation of a trust in medical technology instrument," Applied Ergonomics (2010), 2010b, doi:10.1016/j.apergo.2010.01.009

[45] E. N. H. Montague and B. M. Kleiner, "Using variance analysis to detect mismatches in role expectations in patient physician interactions in obstetric work systems," Paper presented at the 2009 International Ergonomics Association, Beijing, China, 2009.

[46] E. N. H. Montague, W. W. Winchester III and B. M. Kleiner, "Trust in medical technology by patients and healthcare providers in obstetric work systems," Behaviour & Information Technology, vol. 29(5), 2010, pp. 541-554.

[47] E. N. H. Montague, B. M. Kleiner and W. W. Winchester III,

 ISBN: 978-1-61208-179-3

"Empirically understanding trust in medical technology," International Journal of Industrial Ergonomics, 2009, doi:10.1016/j.ergon.2009.01.004.

[48] N. Moray, T. Inagaki and M. Itoh, "Adaptive automation, trust, and self-confidence in fault management of time-critical tasks," Journal of experimental psychology, vol. 6(1), 2000, pp. 44-58.

[49] B. M. Muir, "Trust between humans and machines, and the design of decision aids," International Journal of Man Machine Studies, vol. 27, 1987, pp. 527–539.

[50] B. M. Muir, "Trust in automation: I. Theoretical issues in the study of trust and human intervention in automated systems," Ergonomics, vol. 37(11), 1994, pp. 1905–1922.

[51] B. M. Muir and N. Moray, "Trust in automation. Part II. Experimental studies of trust and human intervention in a process control simulation," Ergonomics, vol. 39(3), 1996, pp. 429-460.

[52] R. Parasuraman and D. Manzey, "Complacency and bias in human use of automation: An attentional integration," Human Factors, vol. 52(3), 2010, pp. 381-410.

[53] R. Parasuraman and C. Miller, "Trust and etiquette in high-criticality automated systems," Communications of the Association for Computing Machinery, vol. 47(4), 2004, pp. 51–55.

[54] R. Parasuraman and V. Riley, "Humans and automation: use, misuse, disuse, abuse," Human Factors, vol. 39(2), 1997, pp. 230–253.

[55] R. Parasuraman and C. D. Wickens, "Humans: Still Vital After All These Years of Automation," Human Factors, vol. 50(3), 2008, pp. 511–520.

[56] W. Paulus, J. Hilbert and W. Potratz, "ICT for Housing," in Information and Communication Technologies for Active Ageing. Opportunities and Challenges for the European Union, N. Malanowski and M. Cabrera, Eds., Amsterdam, 2009.

[57] B. Philips and H. Zhao, "Predictors of assistive technology abandonment," in Assistive Technology, vol. 5, 1993, pp. 36-45.

[58] PsycINFO, 2011, poi:http://www.apa.org/pubs/databases/psycinfo/index.aspx (last checked 27.06.2011).

[59] PubMed, 2011, poi:http://www.ncbi.nlm.nih.gov/pubmed (last checked 27.06.2011).

[60] B. Rajaonah, F. Anceaux and F. Vienne, "Trust and the use of adaptive cruise control: a study of a cut-in situation," Cognition, Technology & Work, vol. 8(2), 2006, pp. 146-155.

[61] S. Rice, "Examining single- and multiple-process theories of trust in automation," The Journal of general psychology, vol. 136(3), 2009, pp. 303-319.

[62] S. Rice, K. D. Clayton, A. Wells and D. Keller, "Manipulating Trust Behaviors in a Combat Identification Task," Workshop Human Factors Issues in Combat Identification, 2008.

[63] S. Rice and K. Geels, "Using System-Wide Trust Theory to Make Predictions About Dependence on Four Diagnostic Aids," The Journal of General Psychology, vol. 137(4), 2010, pp. 362-375.

[64] C. Sälzer, "Besser wohnen mit Technik?," Das AALmagazin, vol. 2, 2010, pp. 12-16, poi:http://www.aal-magazin.de/uploads/media/AALmagazin_Ausgabe_02.2010.pdf

[65] J. Sanchez, G. Calcaterra and Q. Q. Tran, "Automation in the home: The development of an appropriate system representation and its effects on reliance," Proc. Proceedings of the Human Factors and Ergonomics Society 49th annual meeting, 2005.

[66] K. Shea and J. A. Effken, "Enhancing Patients' Trust in the Virtual Home Healthcare Nurse," Computers, Informatics, Nursing, vol. 26(3), 2008, pp. 135–141.

[67] T. B. Sheridan, "Trustworthiness of command and control systems," in 3. IFAC/IFIP/IEA/IFORS Conference on Analysis; Design and Evaluation of Man-Machine Systems, Oulu, Finland, 1988, pp. 14-16.

[68] S. Solaimani, H. Bouwman and M. de Reuver, "Smart Home: Aligning Business Models and Providers Processes; A case survey," Proc. 21st Australian Conference on Information Systems Aligning Business Models and Providers Processes, Brisbane, 2010.

[69] M. Spring; "Home smart home," Building, vol. 30, 1986.

[70] N. A. Stanton and M. S. Young, "Driver behaviour with adaptive cruise control," Ergonomics, vol. 48(10), 2005, pp. 1294- 1313.

[71] Y. J. Tenney, W. H. Rogers and R. W. Pew, "Pilot opinions on cockpit automation issues," International Journal of Aviation Psychology, vol. 8, 1998, pp. 103–120.

[72] ThomsonReuters, Web of Science, 2011, poi:http://thomsonreuters.com/products_services/science/science_products/a-z/web_of_science/ (last checked 27.06.2011).

[73] S. Timmons, R. Harrison-Paul and B. Crosbie, "How do lay people come to trust the Automatic External Defibrillator?," Health, Risk & Society, vol. 10(3), 2008, pp. 207-220.

[74] tns emnid, "Wohnwünsche im Alter," Grafikreport, Januar 2011, poi:http://www.dgfm.de/pdf-datei-en/pressemeldungen/2011/bau2011/Emnid_Wohnwuensche.pdf (last checked 06.07.2011)

[75] UNDESA;, "World Population Ageing 2009," Department of Economic and Social Affairs: Population Division, New York, 2010.

[76] B.-M. Wälivaara, S. Andersson and K. Axelsson, "Views on technology among people in need of health care at home," International Journal of Circumpolar Health, vol. 68(2), 2009, pp. 158-169.

[77] L. Wang, G. A. Jamieson and J. G. Hollands, "Trust and Reliance on an Automated Combat Identification System," Human Factors, vol. 51(3), 2009, pp. 281-291.

[78] C. D. Wickens et al., "False alerts in air traffic control conflict alerting system: Is there a "cry wolf" effect?," Human Factors, vol. 51(4), 2009, pp. 446-462.

[79] D. A. Wiegmann, A. Rich and H. Zhang, "Automated diagnostic aids: The effects of aid reliability on users' trust and reliance," Theoretical Issues in Ergonomics Science, vol. 2(4), 2001, pp. 352–367.

[80] M. Yeh and C. Wickens, „Display signaling in augmented reality: Effects of cue reliability and image realism on attention allocation and trust calibration," Human Factors, vol. 43(3), 2001, pp. 355-365.

 ISBN: 978-1-61208-179-3

Barriers to Cost and Clinical Efficiency with Telehomecare and Proposed Solutions

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Abstract— **Efficiency gains are often promoted as a benefit of using technology. In home care, telehealth technology provides an opportunity for cost and clinical efficiency gains through the efficient use of monitoring technology in conjunction with in-person contact. However, most telehomecare programs use the technology in addition to the in-person visits. This study was a randomised controlled field study comparing the effects of a telehomecare intervention that substitutes for some standard home care services for patients following hospital discharge for heart failure with the effects of standard home care services alone. Contrary to study goals, findings revealed the patients in the technology group received more visits and a longer period in home care than the usual care group. As requested in the conference call for papers, the purpose of this paper is to describe the issues and barriers the team faced in implementing a substitution protocol and to propose solutions that may promote cost and clinical efficiency in future work.**

*Keywords-**telehealth; telehomecare; visit pattern; efficiency.***

I. INTRODUCTION

The emergence of telehomecare in the United States coincided with several important concerns: a growing population of people over age 65, an increasing incidence of chronic illness, a national nursing shortage, and dramatic changes in the financial structure in home care [1]. The enactment of the Balanced Budget Act of 1997 resulted in a major restructuring of how agencies are reimbursed for home care. Prior to this legislation the home care agency was reimbursed for each in-person home visit made to a patient's home. Since October 2000, Medicare, the major insurer for older adults and disabled persons, has reimbursed home care agencies through a prospective payment system (PPS), replacing the fee-for-service method. Depending on the medical diagnosis and other established characteristics, agencies receive a set amount of reimbursement per 60 day home care episode. Patients must receive at least five in-person nursing or physical therapy visits to receive the full amount of reimbursement, but, beyond that the agency is free to use other strategies to meet the care needs.

Given these changes, agencies now face the challenge of managing increasingly complex older adults in a highly constrained fiscal environment where patterns of care and reimbursement are based on client need and agency efficiency. Although challenging, this change has promoted new "freedoms." Home health providers and patients may collaborate to design a 60-day episode of care based on patients' needs, preferences, and mutually derived goals. This "freedom" provides the opportunity to adopt innovative ways, including the use of telehealth, to improve quality of care, enhance patient participation in their care, and promote efficiencies. If telehealth is a viable substitute to home visits and costs less on a per visit basis, then more care can be delivered, as needed, under the current PPS reimbursement mechanism. Under this system, telehealth becomes attractive as a substitute, as well as an addition to home health visits, rather than just being an added expense. Our study revealed several barriers to achieving efficiency. Published results from previous studies are reviewed, and then our study design; protocol; data collection and data analysis; and results are described, followed by a discussion of the barriers and proposed solutions.

II. STATE OF THE SCIENCE

The prospective payment system provides the impetus for home health agencies to explore substitution of in-person home visits with telehomecare visits. The potential for cost-savings makes the use of this technology an attractive strategy for health care insurers and home health providers. Several studies suggest that telehomecare visits will cost less per-visit than home visits based on tasks completed and projected savings in travel costs. On average, it takes clinicians 30 - 60 minutes to travel to patients' homes [2] and longer times are common in rural areas. This amount of travel is not only inefficient but it is also associated with an element of risk [3]. One rural telehomecare program reported $14,810 savings in drive time over 14 months [4]. Dansky, Palmer, Shea and Bowles [5] used data from their clinical trial to project potential savings if telehomecare was substituted for some in-person visits. They proposed that a substitution rate of 33% would

 ISBN: 978-1-61208-179-3

save $318.00 per patient and a rate of 50% would save $700.00 per patient.

Despite its potential, few studies have evaluated the cost or clinical efficiency of telehomecare. No reported studies involved patients in determining the pattern of use of the technology in their plan of care and non have attempted to force a substitution pattern. Cost analyses have varied in quality with most being limited to reporting of anecdotal [4] [6][7] or projected data [5][8]. Available data from systematic reviews [9][10] provide mixed conclusions about whether telehomecare is a clinically and cost effective method for delivering health care services, and, major gaps in knowledge exist regarding the clinical and cost effectiveness of telehomecare when it is employed under the constraints of PPS, substitutes for some in-person nurse visits, and involves patients in decisions regarding its use.

III. STUDY DESIGN AND PURPOSE

The study was a randomised controlled field study comparing the effects of a telehomecare intervention that substitutes for some standard home care services for patients following hospital discharge for heart failure with the effects of standard home care services alone. The purpose of this paper is to describe the barriers the team faced in implementing a substitution protocol and to propose solutions that may promote cost and clinical efficiency.

IV. SAMPLE AND SETTING

Eligibility criteria included hospitalization within two weeks for heart failure exacerbation, age 55 and older, receiving home care services, and able to see, hear, and stand on a scale. Patients were not eligible if they were on a heart transplant list, receiving hemodialysis, or in another disease management study. Eligible patients were provided with Institutional Review Board approved informed consent and enrolled by trained research assistants from an academic health system with three hospitals and received home care and the telehealth intervention at a Medicare certified not-for-profit home care agency. The agency provides approximately 140,000 nursing and therapy visits annually. Services include physical, occupational and speech therapies, social services, home health aide services and nursing care. The agency serves a five county, urban and suburban area and admits on average 200 Medicare patients per month, 20% of them are heart failure patients.

V. PROTOCOL AND TELEHEALTH EQUIPMENT

The study protocol directed specially trained home care nurses to install the telehomecare machine in the homes of consenting patients within two days of hospital discharge and to teach the patients and caregivers (if present and interested) how to operate the equipment. The telehealth equipment, manufactured by Carematix, included wireless blood pressure monitoring, pulse oximetry readings, blood sugar levels as needed, and body weight. In addition, videophones were installed to provide visual interaction between the nurse and patient. The patient and telehealth nurse were linked over ordinary telephone lines via a standard modem, the data was available via a website. The devices allowed a patient to take his or her own measurements. The measurements were visible to the patient and transmitted directly to the home health nurse. Readings that appeared outside of pre-set parameters were highlighted in color to alert the nurse for review. The nurse advised the patient to transmit their data by 11am each day. The nurse was also able to take the readings live during a video visit and interact face-to-face with the patient to answer questions and provide information about his or her medical condition. With the video interaction and daily monitoring, we felt confident we could use the technology in place of some of the in-person visits and based on previous studies where it was proposed that 45% of in-person visits could be achieved with technology [6], we proposed the following visit pattern.

VISIT PATTERNS FOR TELEHEALTH PATIENTS

Week 1: 2 in-home visits
Week 2: 1 in-home; 1 video visit
Week 3: 1 in-home; 1 video visit
Week 4: 2 video visits
Week 5: 2 video visits
Week 6: 1 video visit; decision point

Nurses determine if it is time to discharge the patient or whether the patient could benefit from two more weeks of telehealth monitoring and teaching. If discharged the nurse goes to the home (visit 5) to make the discharge visit and packs the telehealth equipment for return. If not discharged at week 6, the video nurse continues one video visit per week for weeks 7 and 8 then goes into the home for the final visit to either close the case or recertify.

VI. FIDELITY MEASURES

To assure fidelity to the telehealth substitution pattern a rigorous process was followed including initial education, six refresher classes, monitoring by the project manager, and one-on-one communication with the nurses. Upon admission the visit protocol was provided in writing to every nurse caring for a telehealth patient. The project manager monitored the visit pattern and was in telephone or email contact with the nurses throughout the home health episode encouraging that the visit protocol be followed. If the suggested visit pattern was not being followed, the project manager contacted the nurse directly to discuss why and reviewed the study protocol as well as notified the nurse's manager. In addition, the principal investigator and agency executive administration met regularly in an attempt to obtain the support needed for protocol adherence. The use of the equipment by the patients was also monitored and

 ISBN: 978-1-61208-179-3

patients were called by the telehealth nurse to reinforce teaching and encourage patients to transmit their data.

VII. DATA COLLECTION

In addition to patient outcomes such as hospital readmission, emergency department use, self care and functional status [11], the cost and clinical efficiency of the telehealth intervention was measured by the number of nurse visits in each group, the mileage driven, and the percentage of patients re-certified for a second episode of home care versus being discharged to self care. The data was obtained from the home care agency records as recorded by the nurses on their billing and patient records.

VIII. DATA ANALYSIS

The total number of home visits was calculated from index home care admission to discharge. Patients kept on service for another episode of home care were counted as recertified and their visits and days were included in the total visit count and length of stay. Chi square was used to compare the groups on categorical characteristics and the independent sample Mann Whitney U test was used to compare numbers of visits, mean number of visits over the study period, and length of stay in home care. The two-sided Fishers Exact test was used to assess the association between group and recertification.

IX. RESULTS

Two hundred and seventeen patients enrolled in the study with 116 in usual care and 101 in the telehealth group. The average age was 71.3 (SD=10.2) in the telehealth group versus 73.5 (SD=9.6) for control patients, p=.092. Overall, study patients had high risk characteristics such as 69% rated their health as fair or poor, 32% had less than a high school education, 65% were African American, 39% had an annual income <$20,000/year, 69% were hospitalized at least twice in the 12 months prior to enrollment, 34% lived alone, and had an average of 6.4 co-morbid conditions.

On average, the telehomecare patients received 5 (SD 1.8) nursing visits during the initial home care episode (including recertification) and the usual care patients received 4.2 (SD 1.1), p = .013. Over the entire six month study period, telehomecare patients received on average 11 home visits (SD 8.9) and usual care patients received on average 8 home nursing visits (SD 4.6). Contrary to the study protocol goals, this was significantly more in person contact for the telehomecare patients than the usual care patients (p = <.001). Further, the telehomecare patients were recertified for an additional episode of home care significantly more often than usual care patients (24% compared to 9%, p = .003) and the length of the initial home care episode for telehomecare patients was significantly longer at 54 days (SD 41) compared to usual care patients at 35 days (SD 23), p=<.001.

X. DISCUSSION

A. *Barriers to Cost and Clinical Efficiency*

Although the study protocol called for a substitution pattern that should have resulted in the telehomecare patients receiving fewer in-person visits due to use of the technology that is not what happened. Several barriers prevented the nurses from using the technology efficiently including staffing levels, incentives and already low visit numbers; personal interest; and technology issues.

1) Staffing levels and incentives: The nurses' schedule is based on the expectation that they complete in-person visits for six patients per day. Productivity standards are measured against the number of in-person visits completed. The nursing shortage contributes to the problem because there are more patients than nurses to care for them. One might expect this would increase the impetus to turn to technology, but we are not yet seeing that. One possible reason why this technology was not adopted was the nurse's potential motivation to keep revisits on their schedules rather than defer to video visits. Video visits were meant to substitute for in-person visits but were not conducted by the field nurses. Substituting in-home visits with video visits could potentially reduce a field-nurse's caseload for the day. This in turn, could impact their productivity, but would more likely lead to the assignment of a new start of care for the nurse and potentially an additional patient to manage. Agency nurse-manager support of the technology implementation was low, which in turn, led to slow adoption by the field nurses for this project. Finally, timely delivery of telehealth equipment was problematic at times adding to the nurse's lack of ownership and interest in the technology. In addition, the numbers of in-person visits are already quite low leaving little room for substitution since Medicare rules require only five in-person visits by either nursing or physical therapy to qualify for full payment.

2) Personal Reasons: When this project began, the home health agency was using paper documentation and had not implemented an electronic medical record. This in turn, may have contributed the nursing staff's discomfort with technology – including telehealth equipment. This discomfort could have triggered the nurse's mistrust of the telehealth equipment readings and further distanced them from accepting and adopting the technology into their nursing practice. In addition, agency field nurses were asked to install the equipment, which could prove challenging at times due the unavailability of electrical outlets and phone jacks if large heavy furniture were blocking them. These experiences led many nurses to view telehealth as 'one more thing to do' despite its potential benefit to home health patients. Finally, the model of telehealth required the field

 ISBN: 978-1-61208-179-3

nurse to share the patient with a telehealth nurse. Collaborating about the case took extra time and was not valued.

3) Technology Issues: The nurses did not have Internet access from the patients' home so it was not convenient to use the telehealth equipment while in the community. This required a telehealth nurse to operate back at the agency office for video visits and monitoring the biometric data. In addition alarms from the telehealth equipment were often false alarms yet caused time spent on phone calls or visiting to make sure all was well. Occasionally the equipment would not transmit the readings due to technical or connection problems and a visit was spent to fix the equipment. This was also a source of frustration and was time consuming for the nurses.

B. Proposed Solutions

Technology applications, like any new innovation, must fit into the workflow and benefit the user in order for adoption to be favored. Several proposed solutions may help overcome some of the barriers to cost and clinical efficiency.

1) Restructuring productivity and creating financial incentives: When telehomecare is introduced to a homecare agency management should consider redefining the productivity standards to include the use of technology. If management recognized the time and effort it takes to install, teach, and maintain telehomecare equipment as part of the nurse's workload adoption might improve. However, the financial incentives are not in place within home care to support such change. The benefit of telehomecare is reduced readmissions but currently the home care agency is not penalized financially for readmissions. They do run the risk of losing the patient to another agency once they come out of the hospital, but beyond that telehealth is currently an expense and return on investment has been difficult to achieve. Other third party payers than Medicare may reward the home care agency for improved outcomes, but the majority of home care patients are covered by Medicare.

2) Training and support: To overcome the personal barriers to technology adoption the agency must provide adequate training and ongoing technical support. Nurses want to care for their patients and when technology issues pull them away from patient care they become frustrated. It is important to choose the right team to conduct telehomecare. Identify the early adopters and enlist their help as champions, project leaders, and resource persons. Share data that demonstrates the patient benefit of telehealth. Nurses are motivated by achieving good outcomes of care, helping them see how technology can assist them with their goal may help. Finally, provide access to the technology from the field. Without Internet access the nurses are unable to monitor the patient's readings and feel disconnected from the telehealth program. In this situation a second nurse is needed to monitor and coordinate the telehealth data into the plan of care. This requires time and effort for communication, which could slow the response time, and trust between providers may take time to develop. If the field nurse could monitor the telehealth themselves via the web or smart phone alerts the responsibility and continuity of care would certainly increase.

3) Technology issues: The equipment must be reliable, simple, and easy to install and use. Care must be taken to screen patients carefully to provide the technology with those who are motivated to use it, need it, and are able to operate it. Delivery, set-up, pick-up, cleaning, and storage of the equipment are not tasks nurses are interested in. Consider methods to support nurses in their role of patient care such as shipping the equipment directly to the home, hiring technicians for installation and removal, and choosing equipment that is user friendly and wireless. Improvements in technology will hopefully lead to smart systems that recognize trends in patient data, decrease the number of false alarms, and provide decision support to improve care.

XI. CONCLUSION

Telehomecare is a common and growing technology used in community based settings. Several studies have demonstrated its usefulness for monitoring chronic conditions, teaching and promoting self care, and preventing hospital readmissions. The program requires an investment in equipment and personnel and most agencies use the technology in addition to usual in-person visits. Our attempt to push for a substitution pattern using technology to replace up to 45% of in-person visits was not successful. In spite of close monitoring and encouragement, many barriers and a lack of incentives prevented successful implementation of this strategy to promote cost and clinical efficiency. Issues related to staffing, technology, and incentives were barriers. Several solutions are proposed that require changes in policy and agency operations. Further research is needed to test these solutions for their impact on cost and clinical efficiency.

ACKNOWLEDGMENT

The study was funded by the National Institute of Nursing Research, National Institutes of Health. USA RO1-NR008923

REFERENCES

[1] Medicare Program. (2000, July 3). Prospective Payment System for Home Health Agencies. Federal Register, 65 (128), 41128-41214.

[2] Burdick, A.E., Mahmud, K., and Jenkins, J.P. (1996). Telemedicine: Caring for patients across boundaries. Ostomy Wound Management, 42 (9), 26-37.

 ISBN: 978-1-61208-179-3

[3] Denton, M.A., Zeytinoglu, I.U., Webb, S., and Lion, J. (1999). Occupational health issues among employees in home care agencies. Canadian Journal of Aging, 18 (2), 154-181.
[4] Dimmick, S. L., Mustaleski, C., Burgiss, S., and Welsh,T. (2000). A case study of benefits and potential savings in rural home telemedicine. Home Healthcare Nurse,18 (2), 125-135.
[5] Dansky, K.H., Palmer, L., Shea, D., and Bowles, K .H. (2001). Cost analysis of telehomecare. Telemedicine Journal and e-Health, 7 (3), 225-232.
[6] Wootton, R., Loane, M., Mair, F., Allen, A., Doolittle, G., Begley, M., et al. (1998). A joint US–UK study of home telenursing. Journal of Telemedicine and Telecare, 4 (Suppl. 1), 83–85.
[7] Whitten, P., Mair, F., and Collins, B. (1997). Home telenursing in Kansas: Patients' perceptions of uses and benefits. Journal of Telemedicine and Telecare, 3 (Supplement 1), 67–69.
[8] Pringle-Specht, J. K., Wakefield, B., and Flanegan, J. (2001, January). Evaluating the cost of one telehealth application connecting an acute and long-term care setting. Journal of Gerontological Nursing, 34-39.
[9] Inglis, S.C., Clark, R.A., McAlister, F.A., Ball, J., Lewinter, D., Cullington, S., Stewart, S., and Cleland, J.G. "Structured telephone support or telemonitoring programmes for patients with chronic heart failure," Cochrane Database of Systematic Reviews, vol. (8), pp. CD007228, Aug 4. 2010.
[10] Pare', G., Mirou, J., and Sicotte, C. (2007). Systematic review of home telemonitoring for chronic diseases: The evidence base. Journal of the American Medical Informatics Association. 14 (3), 269-277.
[11] Bowles, K.H., Hanlon, A.L., Glick, H.A., Naylor, M.D., O'Connor, M., Riegel, B.J., Shih, N.W., and Weiner, M.G. Clinical effectiveness, access to and satisfaction with care using a telehomecare substitution intervention: A randomized controlled trial. International Journal of Telemedicine and Applications. 2011 (in press).

 ISBN: 978-1-61208-179-3

Toward a Business Continuity Plan for Home-Care Systems

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***Abstract*—Demographic changes in recent years have contributed to a shift in care models, with the development of home-care as a new alternative to traditional hospitalization. On the other hand, our society is increasingly influenced by modern Information and Communication Technology (ICT). The health care has greatly benefited from these technological advances. However, the use of these technologies for real life application may pose problems resulting in system failure, which might have significant impacts on patient safety and on the ability to deliver high-quality care services. Thus, continuity of service remains a critical area of concern for home-care. Appropriate means must then be taken to ensure an efficient, robust and advanced home-care system. In this context, we propose an approach based on Business Continuity Management (BCM) to ensure the ability to operate in spite of unforeseen events and to quickly recover from any type of business interruption. This paper provides a framework for BCM and its key concepts. Then, we describe a generic methodological approach for introducing BCM to home-care; outlining key issues to be considered.**

Keywords-Continuity in eHealth Care; Safety; Detection emergency situations

I. INTRODUCTION

Demographic changes, especially a rapid ageing of the population and a growing segment of people with chronic illnesses and physical disabilities [1][2], in addition to the increasing costs in the healthcare sector [3][4], are having a growing and profound impact on the health care system [5]. These changes lead to a need for new care delivery mechanisms and structures [5][6].

As a result, many countries tried different alternatives. One of these new initiatives is the home-care [8]. In the recent years, we are noting an increasing demand for home-care services; in France, as it mentioned in [9], between 2005 and 2009, the number of persons under home-care increased by 120%, the number of hospitalization days in home-care raised by 119% and the number of patients increased 148%.

In Canada too, home-care organizations are growing rapidly. It is even the most rapidly expanding sector of the Canadian health care delivery system [8]. Indeed, finding ways to deliver high quality health care adapted to the needs of these patients is a major challenge for health care system [9]. In response to this challenge, there is a considerable international interest in exploiting the Information and Communication Technology (ICT) solutions to enhance the quality and safety of Health Care, in general, and home-care in particular [10].

These trends are strong incentives for e-Health research. The European Union has undertaken a number of research projects to assist the elderly [1], proposing solutions to the issues of mobility (I2HOME), communication (SHARE-it), remote monitoring (CAALYX, eCAALYX), timely access to patient specific information (COGKNOW, EasyLine+) [1], and involving patients more actively in their own care process (Coplintho).

Nowadays, the introduction of new technology in practice is confronted with some problems resulting in system failure [4][7], which lead to unexpected and possibly harmful effects [11], such as delay in appointments, problems with data transmission of patients' records, etc.

The projects we have mentioned, and even others using information and communication technologies in the health sector, have largely dealt with the benefits of their solutions to enhance the delivery of health care services. However, they did not consider constraints and challenges faced in using ICT effectively in the health sector. No plans were proposed in case of failure of their solution, such as solutions to face a power outage, a unavailability of the system or even when the patient does not know how to use the device, etc.

As ICT becomes more integrated with health programs and activities, the impact of ICT outage on the system remains a critical area of concern. This should be taken into consideration when designing the system in order to ensure business continuity. Appropriate recommendations must then be taken to ensure an efficient, robust and advanced health care system.

However, while there is a growing focus in literature to discuss telemedicine applications for home-care [4][7][10] [11][12][13], less attention has been paid to take into consideration organizational business interruptions, and issues involved in the use of telemedicine applications for daily delivery of home-care services.

 ISBN: 978-1-61208-179-3

We propose the development of a Business Continuity Management methodology (BCM) for home-care organizations to ensure the ability to operate in spite of unforeseen events and quickly recovering from any type of business interruption.

It's is the purpose of the BCM, which is supposed to investigate actions to put in place in case of unavailability of the system. The BCM is then an appropriate approach for such critical need for these new systems based on the use of new technologies.

The present work carried out in the framework of a regional research project "SySO", supported by the French region Midi-Pyrénées, aiming at supporting continuity of home-care under technical or organizational failure; this project is linked to a national project "Plas'O'Soins"[30], funded by the French Agency for Research (ANR) intending to develop a software platform to improve coordination between different care providers in home-care.

This paper is organized into three main sections. First, we review relevant concepts related to Business Continuity Management (BCM). Second, we outline the characteristics of home-care processes. We present then a methodology to introduce BCM to home-care field. Finally, we offer conclusions and future research.

II. BUSINESS CONTINUITY MANAGEMENT

It is vital to accept that disruptive events will continue to happen despite our best efforts to mitigate risks. Organizations are increasingly concerned with their ability to continue serving their customers in spite of those incidents [14].

The present section carries out a brief review of literature on Business Continuity Management key concepts.

A. Business Continuity Management concepts

The British Standard BS25999, published by the British Standard Institute (BSI) [15], defines BCM as a "holistic process that identifies potential threats to an organization and the impacts to business operations,…, it provides a framework for building organizational resilience with the capability for an effective response that safeguards the interests of key stakeholders, and value-creating activities,..."

Most of the relevant literature advocates that BCM is a decision-making process [14]; it includes the concepts of business resilience, long term performance, and value preservation [15][16].

BCM aims to offer an "uninterrupted availability" of all key activities and resources [17]. It incorporates treatments and controls to continue essential business processes, once an outage event has occurred [18].

Zambon [19] and Cerullo [20] articulate that the purpose of BCM is also to recover operations within a "predefined time", and to reduce the "time required" to restore conditions to a state of business as usual.

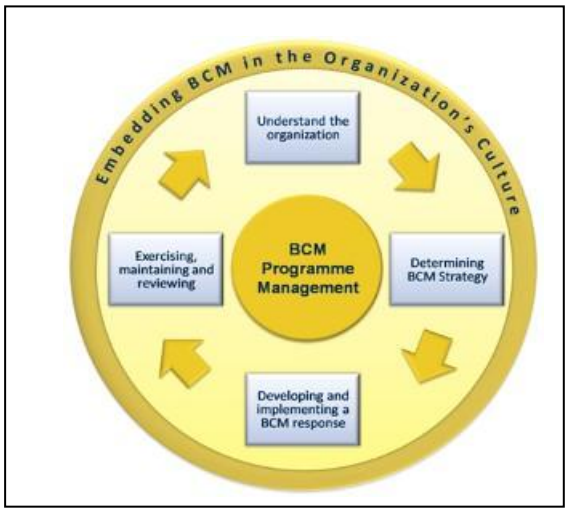

Figure 1. Business Continuity Management Lifecycle (BS25999-1:2006).

B. BCM Lifecycle

Until recently, no widely agreed methodology was available to implement BCM. The standard BS25999 has changed this situation providing guidelines to understand, develop and implement a BCM: The Business Continuity Institute's Good Practice Guidelines [21].

The BCM life-cycle as it is proposed in BS25999 [21], Figure 1, integrates a four-stage process. It takes an organization through:

- An initial understanding of the organization by the identification of activities and resources supporting key processes of the organization,
- Determining BCM strategy, a description of what the plan is trying to achieve and how to make it work;
- Developing and implementing a BCM response: based on a Business Impact Analysis, to evaluate the impact of the disruption of the core processes previously identified; and determining the incident response structure, preparing and agreeing the content of the contingency plans, and developing the plans,
- Exercising and testing of the plans, the management of the plan through training, rehearsals, and reviews, to ensure the plan stays effective and up to date.

A further review of the literature provides us with some common inclusions compliant with the BS25999 BCM life-cycle. Some researchers [18][20][22] suggest that BCM should address three interdependent objectives:

- Business impact analysis (BIA): Identify major risks and impacts of business interruption,
- Business continuity plan development: Develop a plan to mitigate or reduce the impact of the identified risks,
- Exercising, testing and updating of the plan.

 ISBN: 978-1-61208-179-3

They also state that the primary output from the BCM process is a Business Continuity Plan (BCP), which is a set of procedures and documents describing a sequence of actions, and people responsible for carrying them out, to resume business processes following a disruption [23][24].

However, as we noted, as it is also mentioned in different guides and papers [18][19][21], there is no standard format for BCP; therefore each organization needs to assess its own requirements.

C. BCM in Health Care

1) Traditional Hospitalization

BCM within the health care context is in its infancy [14], but, today, most health care administrators recognize that BCP is not solely about planning for a sudden influx of patients, but also about planning for disasters that harm their IT systems and physical facilities [25].

As the Health Care system employs more digital technology to improve the quality of care, organizations are becoming increasingly concerned with their ability to continue serving their patients in spite of unforeseen events [14][20].

However, managing business continuity in health care environment is more sensitive [26], since Health sector is very sensitive to any kind of interruption that would impact their operations, their ability to help people and the vast amounts of data they require.

2) Home-care

Home-care is increasingly common in care delivery systems; it plays an important role as a mechanism for integration and coordination between health care actors [5]. Like other organizations, home-care organizations are vulnerable to internal and external events and risks that can interrupt their business operations and ability to accomplish their primary and critical missions.

The home-care process is a collaborative process [13][27] connecting an important number of technical and human resources, that involve multidisciplinary care providers [28] (doctors, nurses, case managers, physiotherapists, occupational therapists, dieticians, social workers, physicians, etc.) and personnel who provide a range of basic activities to support daily living for patients (home health aide, personal care worker, home health attendant, and home support worker), regional public units for funding, patients and their relatives [8].

This multidisciplinary collaboration is both indispensable and complicated [26]. In addition, the deployment of such a process takes place in a specific context: a very dynamic and uncertain environment [27].

In order to coordinate this complex cooperative process, it is crucial for it to be supported by telemedicine applications, as shown in Figure 2. The platform that we propose to develop in the Plas'O'Soins project offers a package of services such as coordinating the activities of home-care caregivers, facilitating communication between them, managing activities schedule, etc.

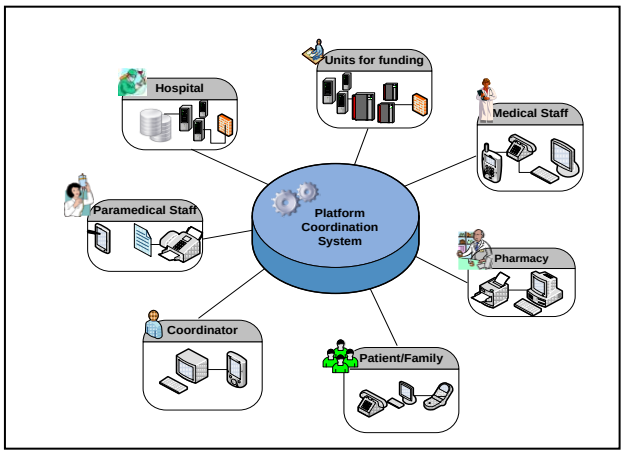

Figure 2. Home-care ecosystem.

This imposes that home-care organizations should adapt their business to include a response to both organizational and technical dysfunctions. Then, home-care organizations need not only to be able to manage the disruption caused by such incidents, but also to have plans to deliver their care services to patients 24/7.

Our aim is to define a BCM methodology and adapt it to the particularities of the Home care processes.

III. PROPOSED BCM APPROACH IN HOME-CARE

The proposed Business Continuity Plans that we found in literature are a set of procedures and documents in a text format, determining how the organization will keep functioning after a disruptive event until the restoration of interrupted activities within a predetermined time. That means, for example, that solutions and a list of people who need to be informed as a priority are all part of the plan.

Our aim is to formalize a Business Continuity Plan (BCP), following a model-centered approach, in order to provide a BCP model for home-care.

In this section, we present steps and considerations to model and formalize a BCP for home-care organizations, which will improve their chances of continuing operations during or after disruptive events.

1) The method

We stay compliant with the BCM lifecycle proposed by the BS25999 standard, and we model each of the different steps:

1. Organization Modeling: to describe how the home-care is organized, to represent process related concepts, actors and their roles, and data flows, so that the current processes may be analyzed. For this we choose a process oriented modeling approach to design and model home-care existing processes and the exchanged data. So to be able to analyze the processes, different views are required: organizational view, data view, and business process view. For these reasons ARIS software (Architecture of Integrated Information System) [31] was retained.

 ISBN: 978-1-61208-179-3

2. Business Continuity Plan Modeling: to develop a BCP model we will start by developing a BCP meta-model, defining BCP main related concepts, and BCP elements.
Then, to support continuity of care under technical and organizational failure, and to ensure the resilience and robustness the system and keep it operational 24/7; the BCP model that we propose will be defined based on the organizational and technical models of home-care organizations.

The home-care sector depends on an important number of regulatory requirements and crucial business processes have time constraints, since we can't represent everything with events, to generate an appropriate response to anomalies based on organizations' business policies, best practices and regulatory requirements, we have to elicit business rules adequately. The anomaly detection process, could then be modeled using Complex Event Processing (CEP) concepts [29].

The CEP is a strategic technology especially effective in situations involving numerous factors that interact in variable ways [29]. It allows applications to identify complex sequences of events, events that are an abstraction of two or more events, like event A is followed by B, then by C. These complex patterns of events can have temporal constraints (within 5 hours) or spatial constraints (within 5 miles).

3. Exercising: Anomaly Treatment Process

BCP shows how to continue doing business until recovery is accomplished. Thus, we need to analyze the anomalies. Based on the organizational model, and the BCP model, we will define how these models evolve in response to anomalies. The principle phases of the anomaly treatment process that we propose are depicted in Figure 3.

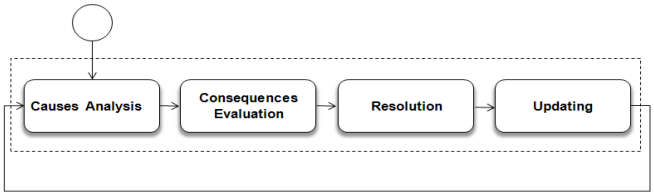

Figure 3. Anomaly Treatment Process.

- Phase 1: 'Cause Analysis" holds identifying the failure and analyzing its potential causes. The sources of anomalies may be hardware or software failure, technical problems or organizational dysfunctions, due to a drift of a business rule, a processes that has failed to complete or disruptive events occurring on devices.
- Phase 2: "Consequence Evaluation" focuses on the impact of the outage including both the likelihood and consequence; it involves also assessing the severity of impacts that are likely to occur from the failure. For this we need firstly to identify relevant impact criticality criteria to set the priorities. This impact evaluation defines the maximum acceptable outage for each key business process and sets the recovery priorities for the activities and resources underpinning them.
- Phase 3: "Resolution" In this phase, we propose a number of treatments form the BCP to ensure the business continuity after the outage has occurred.
- Phase 4: Finally, the BCP should be dynamic, evolving as the business environment changes and its dependency on advanced technology changes, thus a BCP "update" phase after an interruption is imperative, we may add new solutions , new consequences, new causes, or new anomalies …

IV. CONCLUSIONS AND PERSPECTIVES

Discontinuities are inevitable in complex systems such as our home-care system. If they are not identified and treated, they contribute to decreases in patient safety.

Ensuring business resilience has proven to be increasingly challenging as the home-care field employs more ICT applications and all signs for the future point to even more reliance on digital data.

In this position paper, we presented a framework for a Business Continuity Management approach to ensure the permanence of key processes in home-care system supported by an e-platform.

To provide a level of preparedness in order to respond, manage and recover from disruptive events so that a return to 'business as usual' status is achieved in the shortest possible timeframe; the Business Continuity Plan for home-care organizations that we propose helps detecting the outage and restoring operations as soon as possible.

Our ongoing work is to achieve a formal description of the BCP, following an approach grounded in Model-Driven Engineering (MDE). This formal description will be based on a combination of several models, e.g., Complex Event Processing rules, Business Rules, Temporal Logics, as well as organizational models, such as Role maps or Business Process models. These complementary approaches will provide the ability to react to event as they occur, and will offer an effective decision management solution.

ACKNOWLEDGMENT

The work presented here, as well as the PhD of Olfa Rejeb, is mainly funded by French Region Midi-Pyrénées, with support from Ecole des Mines d'Albi Carmaux.

REFERENCES

[1] M. N. Kamel Boulos et al., "Connectivity for Healthcare and Well-Being Management: Examples from Six European Projects," International Journal of Environmental Research and Public Health, vol. 6, no. 7, pp. 1947-1971, Jul. 2009.

[2] I. Robert-Bobée, Projections de population pour la France métropolitaine à l'horizon 2050 : la population continue de croître et le vieillissement se poursuit, Division Enquêtes et études démographiques, INSEE, pp. 1-2, 2006.

 ISBN: 978-1-61208-179-3

[3] R. Haux, E. Ammenwerth, W. Herzog, and P. Knaup, "Health care in the information society. A prognosis for the year 2013," International Journal of Medical Informatics, vol. 66, no. 1-3, pp. 3-21, Nov. 2002.

[4] A. Essén and M. Conrick, "New e-service development in the homecare sector: Beyond implementing a radical technology," International Journal of Medical Informatics, vol. 77, no. 10, pp. 679-688, Oct. 2008.

[5] R. M. M. Cotta, M. Morales Suárez-Varela, J. S. Cotta Filho, A. Llopis González, J. A. Días Ricós, and E. R. Real, "Home hospitalization in light of demographic changes and new health challenges," Revista Panamericana De Salud Pública = Pan American Journal of Public Health, vol. 11, no. 4, pp. 253-261, Apr. 2002.

[6] P. van Bilsen, J. Hamers, W. Groot, and C. Spreeuwenberg, "Demand of elderly people for residential care: an exploratory study," BMC Health Services Research, vol. 6, pp. 39-39, Mar. 2006.

[7] A. Jacobs, M. Leys, and S. De Rouck, "A methodology for shifting the focus of e-health support design onto user needs: a case in the homecare field.," International Journal of Medical Informatics, vol. 77, no. 9, pp. 589-601, 2008.

[8] A. Côté, G. Fox, The future of home-care in Canada: roundtable outcomes and recommendations for the future, Public Policy Forum, pp. 4-5, 2007. (www.ppforum.ca)

[9] FNEHAD, Livre blanc des systèmes d'information en hospitalisation à domicile, white paper (in French), pp. 15-19, 2009.

[10] A. D. Black et al., "The impact of eHealth on the quality and safety of health care: a systematic overview," PLoS Medicine, vol. 8, no. 1, pp. e1000387, 2011

[11] R. Haux, "Aims and tasks of medical informatics," International Journal of Medical Informatics, vol. 44, no. 1, pp. 9-20; discussion 39-44, 45-52, 61-66, Mar. 1997.

[12] M. Duke and A. Street, "Hospital in the home: constructions of the nursing role - a literature review," Journal of Clinical Nursing, vol. 12, no. 6, pp. 852-859, Nov. 2003.

[13] R. Bastide, S. Zefouni, and E. Lamine, "The homecare digital ecosystem: An information system support architecture," 4th IEEE International Conference on Digital Ecosystems and Technologies, pp. 475-480, 2010.

[14] B. N. L. Geelen-Baass and J. M. K. Johnstone, "Building resiliency: ensuring business continuity is on the health care agenda," Australian Health Review: A Publication of the Australian Hospital Association, vol. 32, no. 1, pp. 161-173, Feb. 2008.

[15] BSI, British Standard Institute, BS25999 Business Continuity Management. Code of Practice, pp. 3-3, 2006.

[16] B. Herbane, D. Elliott, and E. M. Swartz, "Business Continuity Management: time for a strategic role?," Long Range Planning, vol. 37, no. 5, pp. 435-457, Oct. 2004.

[17] M. Devargas, "Survival is not compulsory: an introduction to business continuity planning," Computers & Security, vol. 18, no. 1, pp. 35-46, 1999.

[18] ANAO, Australian National Audit Office, Better practice guide: Business Continuity Management, keeping the wheels in motion, pp. 27-50, 2000.

[19] E. Zambon, D. Bolzoni, S. Etalle, and M. Salvato, "A Model Supporting Business Continuity Auditing and Planning in Information Systems," Second International Conference on Internet Monitoring and Protection (ICIMP 2007), pp. 33-33, 2007.

[20] V. Cerullo and M. Cerullo, "Business Continuity Planning: A Comprehensive Approach," Information Systems Management, vol. 21, no. 3, pp. 70-78, Jun. 2004.

[21] BSI, British Standard Institute, Business Continuity Institute's Good Practice Guidelines (GPG), pp. 3-14, 2010.

[22] S. Buchanan and Gibb, "A framework for business continuity management," International Journal of Information Management, vol. 26, no. 2, pp. 128-141, 2006.

[23] C. Frost, "Effective Responses for Proactive Enterprises: Business Continuity Planning," Disaster Prevention and Management, vol. 3, no. 1, pp. 7-15, 1994

[24] R. Stanton, "Beyond disaster recovery: the benefits of business continuity," Computer Fraud & Security, vol, no. 7, pp. 18-19, July 2005.

[25] Paul Rozek, Don Groth, "Business Continuity Planning," Technology health management, pp. 1-1, 2008

[26] C. A. Woodward, J. Abelson, S. Tedford, and B. Hutchison, "What is important to continuity in home care?. Perspectives of key stakeholders," Social Science & Medicine (1982), vol. 58, no. 1, pp. 177-192, Jan. 2004.

[27] E. Lamine, S. Zefouni, R. Bastide, and H. Pingaud, "A System Architecture Supporting the Agile Coordination of Homecare Services," Collaborative Networks for a Sustainable World, vol. 336, pp. 227-234, 2010.

[28] A. van Wersch, J. Bonnema, B. Prinsen, J. Pruyn, T. Wiggers, and A. N. van Geel, "Continuity of information for breast cancer patients: the development, use and evaluation of a multidisciplinary care-protocol," Patient Education and Counseling, vol. 30, no. 2, pp. 175-186, Feb. 1997.

[29] D. Luckham, "The Power of Events: An Introduction to Complex Event Processing in Distributed Enterprise Systems," Computer Science, vol. 5321, pp. 3-3, 2008.

[30] Project "Plas'O'Soins", funded by the French Agency for Research (ANR), http://plasosoins.org/

[31] A.W. Scheer, ARIS-Business Process Modeling, 3rd ed., Springer-Verlag, pp. 21-102, 2000.

 ISBN: 978-1-61208-179-3

 ISBN: 978-1-61208-179-3

Addressing Barriers to Wider Adoption of Telehealth in the Homes of Older People: An Exploratory Study in the Irish Context

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***Abstract*—Understanding barriers to wider Telehealth adoption is vital to enable its embracement by those who could greatly benefit from the technology. The aim of this exploratory study was to identify barriers to wider Telehealth adoption in the homes of older people, particularly in the Irish context. Objectives included identifying barriers from the perspective of five groups of stakeholders, determining the most pressing barriers and suggesting possible approaches to addressing such issues. Fifteen semi-structured interviews were conducted. Findings were analysed against existing literature, current technology adoption trends and successful initiatives implemented in different countries. This study suggests that technology usability issues, implementation costs, lack of organisational willingness to change and the lack of incentive to healthcare professionals to embrace Telehealth are the most pressing barriers to wider adoption. Suggestions to address these issues are discussed.**

Keywords-Telehealth; barriers to adoption; older people; chronic condition management.

I. INTRODUCTION

In line with European demographic trends, the proportion of older people in the Republic of Ireland is expected to double in the coming decades [1, 2]. As a consequence of population ageing, Ireland is expected to experience a significant increase in the prevalence of chronic conditions. By 2020 the number of people experiencing cardiovascular disease (CVD) events is expected to rise by 50%, while the number of those diagnosed with diabetes and hypertension is likely to increase by 62% and 40%, respectively [3]. At present, chronic conditions account for three quarters of the total healthcare expenditure in Ireland [4]. Projections indicate that the demand for such healthcare services will continue to grow as a consequence of population ageing, representing a significant burden to the Irish public finances [5].

The importance of shifting the focus of healthcare services from curative to preventative strategies, where patients are empowered to take active control over their health, is being recognised as the key to control costs and increase efficiency in healthcare [4]. It is amid this context that Telehealth technologies emerge as a relevant alternative to address these issues. Telehealth is here defined as the use of information and communication technology (ICT) based systems to assist the diagnosis, monitoring, management and empowerment of patients with chronic conditions [6]. Remote vital signs monitoring systems are a common example described in the literature [6]. Emerging evidence has demonstrated the potential for Telehealth systems to reduce unnecessary hospital admission [7, 8], decrease mortality rates [6, 9], lower costs of care per patient and increase satisfaction among users [10].

Despite all such positive factors, Telehealth has not yet been widely adopted in any country [8, 11]. A complex interplay of barriers has been identified in the literature and some of those have so far proven difficult to overcome [8, 11]. Poor ICT skills [8, 11], confidentiality concerns [7, 8, 12] and lack of awareness of the available technology and its potential benefits [6, 8, 11, 13, 14] were associated with lower Telehealth acceptability among both older people and healthcare professionals. Technology issues involving usability problems [6, 14], poor system stability and reliability [8, 11] have been associated with low Telehealth up-take post pilot programmes. Moreover, limited access to broadband connections [7, 8] and lack of interoperability between various Telehealth solutions have been highlighted as significant barriers to effective information sharing amongst patients and healthcare professionals [6, 8, 12, 14, 15].

The fragmentation within the healthcare sector [6, 8, 16], absence of service 'champions' capable of promoting the recognition of Telehealth as part of core healthcare services [7, 11] and overall lack of willingness to innovate [6-8, 11] have been pointed as organisational obstacles to the embracement of Telehealth in the healthcare sector. The absence of clear guidelines defining roles and responsibilities of the different stakeholders involved [7, 8, 11, 17], lack of technical quality standards [7, 11] and unclear data protection legislation are also believed to hamper Telehealth adoption amid healthcare professionals. Additionally, the lack of robust evidence supporting the role of Telehealth in chronic condition management and unclear evidence for return on investment are perceived as significant barriers to its wider adoption among the medical community [7, 8, 14].

The absence of reimbursement arrangements to incentivise healthcare providers to embrace Telehealth is perceived as a fundamental barrier to its mainstream adoption [6, 11, 13, 14, 16]. Additionally, it has been pointed that existent payment systems in fact discourage healthcare providers to embrace Telehealth [8, 13, 14, 18-20]. This is because most systems remunerate professionals per in-

 ISBN: 978-1-61208-179-3

person contact with patients and remote contact supported by Telehealth (e.g., remote vital signs monitoring, e-mails, video-consultation) is not currently covered under most reimbursement systems.

Although much has been debated about the barriers to Telehealth adoption, little research has been done to investigate the extent to which such obstacles apply to the Irish context [8]. Moreover, few studies have attempted to explore barriers to Telehealth adoption from the perspectives of different stakeholders [17]. Therefore, the aim of the present exploratory study was to answer the following question: "what are the main barriers to the wider adoption of Telehealth in the homes of older people, in the Irish context?" Research objectives included: 1) to identify barriers to wider Telehealth adoption from the perspective of five groups of stakeholders: Potential Consumers, Healthcare Professionals, Service Providers, Technology Providers and Irish Context Experts; 2) to determine the most pressing barriers; and 3) to suggest possible approaches to address such issues.

The remainder of this paper is structured as follows: Section II explores the study methods, while Section III presents a summary of the main barriers to Telehealth adoption indentified by interviewees. Potential solutions suggested by participants are also described in this section. In Section IV findings are critically analysed against the literature, the most pressing barriers are identified and potential solutions are discussed. Conclusions are presented in Section V along with a reflection upon study limitations and opportunities for further research.

II. METHODOLOGY

After obtaining final approval from the King's College London Ethics Committee (ref KCL/10-11_379), fifteen semi-structured interviews were conducted between February and May 2011. Potential participants were approached through convenience sampling strategy and interviewees were selected based on the assumption that they had the necessary experience to help investigating the research question.

A. Sampling and Recruitment

To verify barriers to Telehealth adoption from the Potential Consumer (PC) point of view, relatives (sons, daughters, nephews or nieces) of older people currently receiving long-term care were approached. The rationale for selecting this group was that 1) their generations are more likely to benefit from the use of Telehealth by the time they reach old age, in comparison with their older relatives and 2) they were expected to have reasonable understanding of older peoples' needs due to their experience with relatives who require long-term care. It was assumed that this group could shed light on the research topic both from a potential user point of view and a family member / caregiver perspective. Two nursing homes in Dublin, Ireland were approached and invitation letters were made available at the reception desk. To maximise response rate, invitation was extended to visitors and staff members who met the main inclusion criteria (sons, daughters, nephews or nieces of older people who require long-term care or suffer from chronic conditions). In total, five (n=5) PCs were recruited. Face-to-face interviews were conducted in a suitable area (e.g., visitors' room) in the nursing homes.

To explore the views of Healthcare Professionals (HCPs), GPs who regularly visit residents in the same nursing homes above mentioned were approached. An invitation letter was made available to potential participants in one of their visits to the nursing homes. In total four (n=4) HCPs were recruited. Face-to-face interviews were conducted in a suitable area in the nursing home or, alternatively, in the participant's private practice facility.

Service Providers (SPs) were defined in this study, as organisations concerned with the supply of Telecare / Telehealth products and services. Two SPs have been identified in Ireland. An invitation email introducing the study was sent to both companies. One of them (n=1) agreed to take part and a telephone interview was arranged.

Technology Providers (TPs) were defined as companies that develop Telehealth systems and have headquarters in Ireland. Five organisations have been identified and contacted through the same approach used with SPs. Three subjects (n=3) agreed to participate. Although in the case of two companies the appointed interviewee was not based in Ireland, this was considered acceptable since both individuals had the desired experience to contribute to the study. Depending on interviewees' location a face-to-face or telephone interview was arranged. Face-to-face interviews took place in a suitable area of the respondents' workplace.

Finally, Irish Context Experts (ICEs) were defined in this study as individuals who have significant knowledge of the Irish health and social care systems and are familiar with Telehealth systems. Two potential interviewees with this profile were identified through snowballing strategy (i.e., through the indication of other interviewees) and were approached via email, as described above. Both agreed to take part (n=2) and face-to-face interviews took place in a suitable area of their workplaces.

B. Data Collection and Analysis

All participants received a study information sheet and gave informed consent prior to interview. Topic guides have been used to support the semi-structured interviews and different questions have been included to suit the different stakeholders' background. A diagram illustrating possible Telehealth configurations has been used to frame discussions about barriers to Telehealth adoption (Fig. 1). The diagram displayed technologies commonly described in the literature including remote vital signs monitors, video-consultation and electronic health record (EHR) systems. Considering the likelihood that most PCs and HCPs would not be familiar with Telehealth technologies, two videos were shown to further support the interviews. Video 1 [21] described the use of a Telehealth remote monitoring system to support patients with chronic pulmonary disease. Video 2 [22] explained the functions of a personal EHR that allows patients to organize, store, and share health information online. Both videos are freely accessible on the Internet and have been used for illustration purposes only. Moreover, an Apple iPad device

 ISBN: 978-1-61208-179-3

was used to display the videos. This was considered beneficial should interviewees not be familiar with touch screen interfaces, a common feature in Telehealth devices.

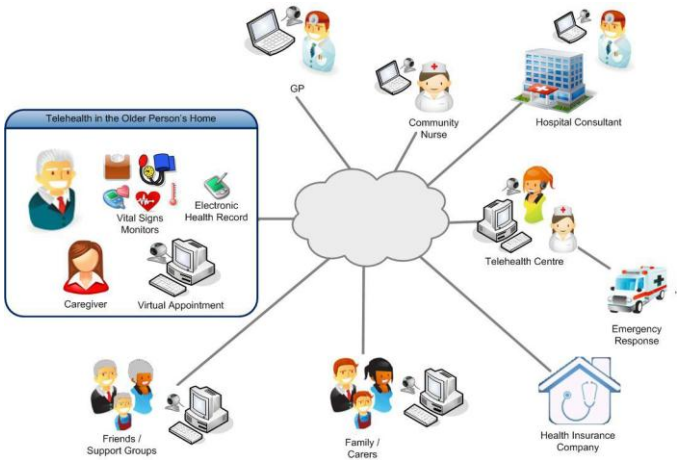

Figure 1. Diagram representing possible Telehealth configurations (source: self)

Interviews were audio recorded and manually transcribed. Based on interview transcripts, a thematic content analysis was carried out. The use of the qualitative analysis software NVivo 9 (www.qsrinternational.com/products_nvivo.aspx) greatly facilitated this process. In order to determine the most pressing barriers to Telehealth adoption in the Irish context, findings were critically analysed and compared to the literature. Current technology adoption trends and successful initiatives implemented in different countries have been also considered in this analysis.

III. RESEARCH FINDINGS

The most significant barriers identified by interviewees are explored below. Participants also suggested possible strategies to promote Telehealth adoption, and these can be found at the end of this section.

A. Acceptance Barriers

1) Poor ICT skills: PCs, SP1, TPs and ICEs suggested that at present the lack of technology skills is a barrier to Telehealth adoption among older people. Nevertheless, these participants acknowledged that this should not be a barrier to Telehealth adoption in the near future. PCs believed that their generations will be more familiar with electronic devices by the time they reach old age and will have greater understanding of the advantages the technology can offer.

"My aunt had a panic button but she never wore it. I think she was afraid of the technology. I don't think older people adapt well to change. (...) I would think now we are more open, I'm only 70, I would be more open than she was. She was probably 90 when she got it. I think as the time goes on people will be more receptive to these things." (PC5)

HCPs were less optimistic about this matter. The group pointed that older patients often demonstrate decreased ability to learn new skills, posing an important barrier to wider Telehealth adoption. Two HCPs also believed that this will continue to be an issue for future generations of older people.

2) Lack of face-to-face contact: HCPs suggested that the lack of face-to-face contact with patients may represent an important barrier to Telehealth adoption among medical professionals. It was pointed that remote contact could negatively impact doctors' decision making capacity, since relying on hard data, without clinical observation, could potentially increase the risk of medical errors.

"I think baseline details like blood pressure, fine, but when you go into more details like breathlessness, wheeze, chest tightness, you can't actually see "are they cyanosed?", "what is their chest actually like?". You know, would you be able to rely on the data that much?"(HCP2)

TPs agreed that the lack of face-to-face contact may increase liability concerns among medical professionals. SP1 added that remote contact with patients may also raise fears of decreased business among physicians.

"[Doctors'] biggest drive for business is the repeated visits they receive from this demographic. So I find they are absolutely reluctant to engage with anything that may possibly reduce the amount of visits, which will happen, in their practice. That is a huge obstacle to overcome." (SP1)

Lack of face-to-face contact has not been seen as an issue to any PCs interviewed in this study.

3) Confidentiality concerns: Two PCs demonstrated apprehension about their health information travelling online. This was not a concern for the remainder PCs who acknowledged that, at some extent, most people already share sensitive information electronically (e.g., bank transactions).

"I know there would be people that wouldn't like to put their information in like that. (...) I wouldn't see a problem with that. I presume that would all be securely done, like bank accounts would be the same." (PC5)

Confidentiality concerns were perceived as a barrier to Telehealth implementation among HCPs. Interviewees were suspicious about how to ensure that only authorized professionals have access to EHRs and who would be ultimately liable for maintaining patient data protection.

"There are huge safety issues with having all that information accessible, and who will have access to it. Because it could just get into the wrong hands, and suddenly you are in major trouble for not protecting your patient's information. (...) At present GPs own the information to a certain extent, so if you share that with the community nurse, who owns that? And who is ultimately responsible for that if it is used inappropriately?" (HCP3)

SP1, TPs and ICEs did not believe confidentiality concerns are a significant barrier to Telehealth adoption. These groups shared the perception that this issue may be

easily solved through adequate regulation and awareness raising.

4) Lack of familiarity with Telehealth and its benefits: SP1, TP1, TP2 and ICE1 agreed that the overall lack of awareness among healthcare professionals and patients about Telehealth existence and benefits is an important barrier to its wider adoption in Ireland.

"The big difficulty here in Ireland (...) in terms of the healthcare professionals is (...) the ignorance of what is the actual equipment that is out there. (...) Predominantly, they will go with what they know works, and it can be a real challenge to break that down sometimes." (SP1)

B. Technology Barriers

1) Technology usability: When asked if they would like to have a device to cater specifically for their health needs most PCs expressed that they would prefer if this could be done through the devices they already have at home, such as laptops and mobile phones. The reasons supporting these views included privacy concerns and practical issues such appliance size, mobility, ease to use and level of disruption to users' lifestyle.

"I wouldn't like to have a specific health device at home. (...) I think it is the whole thing about privacy, you know, you can have as many people on the computer and they've got their own password so it remains private." (PC2)

"I would rather have something small like that (pointing to an iPhone). Something like that would be easier to use, that you could have beside the bed, rather than sitting up (...) People don't have space for all these stuff, do they?" (PC5)

"I would like to have something in my pocket which could do it more or less automatically. Personally I don't think people are prepared to sit down, well, I wouldn't do that. People get tired; you don't have the same drive all the time. I think if it was automatic, that would be better." (PC3)

SP1, TPs and ICEs acknowledged that existent Telehealth systems are still in early stages of development and many issues around technology usability must be further explored. ICEs added that the frequent lack of gerontological expertise among Telehealth designers is an issue that must be addressed.

"Design challenges are huge because you are dealing with unwell people and older people. So it is much easier to get a bunch of young engineers to go crazy over the iPhone and do all kinds of this jazzy stuff (...). Somebody who is sick with COPD just needs to press the button and make it work. That is all they want to know. (...) But yet, there are innovative ways of doing that. (...) And fit with life style is a big factor. So if the system is not in tune with the person's daily rhythm, they will not use it." (ICE1)

Usability issues have also been identified as a barrier to Telehealth embracement by healthcare professionals. TPs suggested that the views of healthcare providers may not be sufficiently considered by technology designers, resulting in systems that are not in tune with providers' workflow. HCPs also demonstrated concerns about how realistic it would be to incorporate Telehealth into their usual practice, as they may not have time to interpret the additional information generated.

"I had a patient today who brought me a reading of his diabetes in a graph, so it makes it much easier to review. (...) But it can be quite time consuming, that consultation took over 30mins (...) sometimes it is just too much information, you know?"(HCP4)

PCs also expressed disbelief that doctors would have the time to analyse large amounts of data generated by Telehealth and suggested that many doctors may choose not to consider it when making patient-related decisions.

2) Other technology barriers: SP1, TPs and ICEs agreed that lack of access to broadband is an important obstacle to reach older people in Ireland. Incompatibility among Telehealth devices and lack of interoperability amongst EHR systems were also identified as important barriers to wider implementation. Nevertheless, the role of organisations such as the Continua Health Alliance (http://www.continuaalliance.org/) has been acknowledged as a significant movement pushing towards system compatibility.

C. Organisational Barriers

1) Low levels of trust among stakeholders: PC4, SP1 and TPs suggested that low levels of trust from medical professionals in their patient's ability to measure their readings appropriately, as well as in the accuracy of devices and security of connections used may pose obstacles to wider Telehealth implementation. TP3 challenged this argument since data collected by patients should be considered as trustworthy as the subjective information reported by them during medical appointments.

"What you see a lot is that the professionals can't really trust the data that is coming from the patient. I don't think that sort of barrier holds much weight. Because ultimately, when the patient walks into a doctor's office and tells them about their condition, that is no more or less trustworthy than the patient recording it and sending. (...) I think [this attitude] is making it harder for this type of data emigration to penetrate in the industry, but I think it will go away at some point." (TP3)

2) Increased professional responsibility and lack of organisational willingness to change: SP1, TPs and ICEs acknowledged that wider adoption of Telehealth requires healthcare professionals to significantly adapt their professional practice. Interviewees explained that, for example, Telehealth enables professionals to look after a much larger number of patients and to provide more continuous care than they would through traditional methods. It was suggested that an overall lack of willingness to embrace such changes may be a significant barrier to Telehealth implementation.

 ISBN: 978-1-61208-179-3

Among HCPs, one interviewee clearly expressed he would not be willing to change his usual practice in order to adopt Telehealth.

"This my own perspective, I've studied medicine to deal with people, I didn't study medicine to look at their computer printouts, or blood pressure going up and down. (...) that might work, but that wouldn't be for me. I mean, it would wreck my head now if I would spend half of my day looking at printouts, or people emailing me stuff about it, I just don't do that, you know?" (HCP1)

3) Lack of 'champions' in the healthcare system: SP1, TPs and ICEs suggest that the lack of strong 'champions' in the healthcare system may be one of the reasons for the virtually inexistent movement towards Telehealth adoption in the Irish context.

"We still need a champion here in Ireland. It needs a good reference site, a strong pilot in order to achieve what it can achieve." (SP1)

D. Policy and Legislation Barriers

SP1 and ICEs argued that it is still largely unclear how data protection legislation applies to Telehealth. They suggested that this issue is an obstacle to different stakeholders to become involved with Telehealth.

Most HCPs suggested that Telehealth would not achieve wider adoption in Ireland without a clear Government led strategy. They believed that this would be necessary to address data protection concerns.

"I think [data protection legislation] would have to be determined by the government, there would have to be policies in place in terms of safety, informed consent (...) because if it is just done through the private companies I think it will be perceived as too ad-hoc or that there is something in it for the individual company." (HCP3)

E. Evidence Base Barriers

TPs and ICE1 acknowledged that despite a significant number of successful pilots, Telehealth still lacks robust studies, such as large randomized controlled trials (RCTs), to support its efficacy and cost-efficiency. Nevertheless, they pointed that the lack of RCTs may be also used as an excuse for non adoption among medical professionals. It was suggested that Telehealth may instead require different scientific evaluation methods to demonstrate its value.

"(...) you can argue that [careful patient selection] is exactly what you have to do with Telehealth, that there is no point in randomly selecting people in the same way that you won't randomly give people drugs to treat their conditions. (...) I think quite often, evidence is used as an excuse for inaction rather than being the real reason why they won't invest. There are lots of other things happening in medicine that doesn't have evidence base." (TP2)

F. Financial Barriers

SP1, TPs and ICEs acknowledged that the high costs of establishing the necessary infrastructure, staff training, processes reconfiguration, etc., may be a major barrier to the adoption of Telehealth by healthcare systems that are already under economy strain (which is the case of the HSE, the national healthcare agency in Ireland). It was pointed, however, that this would largely depend on the level of government involvement in the implementation process.

"High costs of establishing infrastructure [is a barrier] only if the Government decides to do it. There is already lots of infrastructure out there for other reasons, we can piggyback on existing mobile networks or smart meters, and other things that are happening around us." (TP2)

HCPs also pointed that the costs of system implementation could prevent small GP practices to engage in Telehealth. Interviewees demonstrated disbelief that wider adoption would be achieved without government financial incentive.

ICE1, HCPs and two PCs also expressed that many older people may not have the resources to afford Telehealth if this is provided through out of pocket purchasing, therefore, hindering wider adoption.

"I just don't see it becoming a big thing if it is done privately (...) it wouldn't be standardised enough. There would be only certain people that would be able to avail of that service then." (HCP2)

G. Lack of Incentive to Healthcare Professional

According to SP1, TPs and ICEs the lack of clear incentives to healthcare professionals to embrace Telehealth may be one of the most significant barriers to its uptake. Interviewees suggested that, even if other obstacles are addressed, Telehealth will struggle to be widely adopted if healthcare professionals do not perceive clear advantages over traditional practice.

1) Absence of reimbursement arrangements: The fact that Telehealth is not currently covered by reimbursement arrangements was seen by HCPs, SP1, TPs and ICEs as a significant disincentive to the involvement of healthcare professionals. They argued that even though Telehealth may represent cost-savings to the wider healthcare system, healthcare professionals will be reluctant to engage unless reimbursement systems are created.

"You have to look at what incentives does a GP have to offer vital signs to his or her patients? Not much, because they are not under reimbursement systems, it doesn't exist in the HSE so it would be up to the GPs to do it privately. So they don't really have a huge incentive to do it."(ICE1)

2) Disincentives caused by existent payment system: TPs and ICEs pointed that, different than other technologies that have successfully penetrated in the healthcare industry, Telehealth does not fit into the existent procedure-driven model. Interviewees argued that technology diagnostic solutions, for example, clearly allowed professionals to increase their income streams, what is not the case of Telehealth. There was a common perception that unless the focus of reimbursement arrangements shifts from procedures to health outcomes, Telehealth will hardly penetrate in the healthcare system.

 ISBN: 978-1-61208-179-3

"The reasons why radiology was adopted so fast are quite simple. On the one hand it allowed you to generate more income, because you could get more patients through the radiology department more quickly. It also didn't interfere with the status quo and the workflow in the hospital in a fundamental way (...). So if the doctor gets paid to see you, but doesn't get paid to look after you when you are out of the room, why would they invest in it and pay attention to it? (...) I guess a lot of doctors will not like this because they prefer the system whereby you are paid by the appointment, because they can see an obvious way to increase their income, by increasing number of appointments." (TP2)

"*The answer to that is really simple. Our healthcare system is based on a model that incentivises poor health. (...) Nothing will change until we change that model." (TP3)*

H. Suggested Actions for Wider Adoption of Telehealth

PCs suggested that in order to achieve wider adoption, Telehealth technologies must be flexible enough to match different user's lifestyles and preferences. Participants added that devices should be small, portable and easy to use, what could be more easily addressed if Telehealth systems could run in devices people already own, such as mobile phones.

TPs and ICEs agreed that in the future technology developers should focus on the design of Telehealth software applications, as oppose to hardware. Overall, they highlighted that the input of gerontologists and healthcare professionals is critical to successful Telehealth technology design.

PCs suggested different strategies to promote awareness among older people and family members. This included mass media advertisement (television, newspapers, Internet), availability of information leaflets in medical practices and the creation of a government approved website, with "neutral" and up-to-date information that could facilitate informed consumers' choice.

Most interviewees indicated that government-led Telehealth implementation could address several of the barriers discussed. Government legislation could, for example, address data protection and medical liability issues. National policies were seen as necessary to endorse a standardised adoption of Telehealth across the country and to promote educational support through undergraduate training and continuous professional development. Interviewees in all groups indicated that State provision would be important to ensure that older people with lower incomes have access to Telehealth. TPs also pointed that government initiatives could stimulate the establishment of the required infrastructure to allow Telehealth data sharing. This could include the subsidy of broadband for older people and financial incentives for the adoption of interoperable EHR systems by healthcare providers and organisations.

Considering the current Irish system configuration, ICE1 suggested that it may be easier to start the implementation of Telehealth through the secondary sector. She explained that chronic disease support teams are currently based in hospitals and Telehealth could offer cost-saving advantages for such departments.

The establishment of reimbursement schemes has been the most suggested measure to incentivise Telehealth adoption among healthcare professionals. Considering the fact that Ireland has a public health system in place, reimbursement policies were also expected to be determined by government policies.

Finally, in order to avoid barriers associated with healthcare professional reluctance to embrace Telehealth, TPs and ICEs suggested that a possible strategy to achieve wider adoption of Telehealth in the homes of older people would be focusing on the development of Telehealth solutions that do not necessarily require healthcare professional involvement. Interviewees indicated that the platform created by Telehealth devices could be used to promote education, motivation and social support to patients and caregivers. As well as being a channel for accurate information and advice, Telehealth systems could promote treatment compliance among users through clear goal setting and feedback tools. Moreover, interviewees suggested that future developments should explore the capacity of Telehealth technologies to connect older people in equivalent disease stages and caregivers in similar situations. Participants argued that this approach could promote knowledge sharing and tackle social isolation, a frequent problem among chronic disease patients and caregivers. Additionally, this could address some of the business model and reimbursement issues previously mentioned, since Telehealth would be no longer seen as a medical device that is prescribed by a doctor, but a consumer device, which older people and family members could be interested in purchasing privately.

IV. DISCUSSION

In line with international literature, interviewees in this study suggested that the lack of clear incentives for healthcare professionals to engage in Telehealth is one of the most pressing barriers to its wider adoption [8, 14, 20, 23]. It has been acknowledged that the absence of reimbursement arrangements significantly discourages healthcare professionals to offer this service [6, 11, 13, 14, 16]. Moreover, the fact that Telehealth does not fit into the existent procedure-driven healthcare model was seen as another barrier to its penetration in the healthcare sector [8, 13, 14, 18-20]. Past experiences in healthcare show that the introduction of new technologies is not an issue when its adoption model is aligned with existing incentive schemes. The rapid adoption of computed tomography and magnetic resonance imaging scanners in the healthcare sector in many countries is an example [24].

Although these barriers have so far proven more difficult to overcome, several countries have been successfully employing strategies to stimulate Telehealth adoption amongst healthcare professionals. Many countries use government mandates to achieve broad ICT adoption in the health sector. In Denmark and Norway, for example, high rates of electronic prescriptions have been achieved since the

 ISBN: 978-1-61208-179-3

Governments made this practice mandatory for primary care providers [25].

The establishment of reimbursement structures is also considered vital to incentivise Telehealth adoption among healthcare professionals. Studies show that the reimbursement structure adopted will vary depending on the country's healthcare financing model and governments play a key role in defining this [8, 25]. In Sweden and the UK the existing (small scale) provision of Telehealth has been publicly funded. In Germany, regulatory changes have enabled Telehealth reimbursement through health insurers. In the Netherlands phone and e-mail consultations are reimbursed via fixed prices by the health insurance companies [8].

Innovative reimbursement frameworks, such as pay-for-performance schemes, are also being introduced in different countries in an attempt to shift away from procedure-driven models. In the UK around 15% of GPs' salaries is based on their performance against a set of quality measures [26].

Finally, government financial incentives have been used in Australia, Denmark, the Netherlands and the UK as effective policy tools to incentivise technology adoption among healthcare professionals [8, 25]. In the US the Medicare and Medicaid EHR Incentive Program offers financial stimulus of up to $44,000 / $63,750 to physicians and hospitals that demonstrate meaningful use of EHR systems certified by the Government. The scheme has registered over 77,000 professionals and hospitals in only seven months since its implementation [27]. This is particularly significant considering that the fragmentation of the US American health sector is usually pointed as a barrier to the implementation of any measures in large scale [12].

Technology usability issues have been highlighted by virtually all interviewees, in agreement with several studies [6, 11, 14, 16]. It has been pointed by interviewees that devices specifically designed to cater for healthcare needs may not be well accepted by users. Leveraging devices that people already have, such as mobile phones or laptops, was pointed as a better strategy for Telehealth adoption, since people are already familiar with such devices and these fit more readily into their lifestyles. Participants added that this could make Telehealth more affordable and readily accessible to the public. This perception is in large agreement with trends towards the use of mobile platforms for Telehealth provision (e.g., smartphones, computer tablets). Projections indicate that smartphone applications will enable the mobile health industry to reach 500 million users in 2015 [28].

The lack of organisational willingness to conform to changes is considered a pressing barrier to wider Telehealth implementation [6-8, 11]. While the role of 'champions' in promoting change in the healthcare system has been acknowledged by interviewees and the literature [7, 11] achieving wider adoption of Telehealth will require more than individual leadership. May et al. [17] argue that in order to overcome intra-organisational inertia, coherent policies promoting an organisational vision are needed. According to Castro [25] strong national-level leadership has been essential to countries like Denmark, Finland, and Sweden to successfully drive and coordinate wider adoption of ICT in the health sector. Comprehensive national strategies, as suggested by several interviewees, are required to address this and other pressing barriers to wider adoption of Telehealth as discussed below.

The strategies above explored indicate that a high level of government involvement may be necessary to transform healthcare provision and allow wider adoption of Telehealth. Interviewees in this study point, however, that the high initial costs of establishing the infrastructure and incentivising healthcare professionals is an important barrier to government led Telehealth implementation in Ireland. Financial challenges have also been acknowledged by different studies [11, 12, 14, 15, 25].

Issues involving poor ICT literacy among older people pointed by other studies [8, 11] were perceived by most interviewees as a trivial barrier. Recent evidence show that the interest of older people in technology has grown at a fast pace in the last decade [29, 30]. In Ireland, the percentage of people aged between 65 and 74 years accessing the Internet at least once a week has increased more than five times between 2003 and 2010 [31]. The use of the Internet for health purposes has also increased among the older population [29] indicating that this barrier may gradually become insignificant.

Other acceptance barriers mentioned in the literature such as lack of face-to-face contact [7] and confidentiality concerns [7, 8, 12] have also been cited by interviewees. However, it is possible to suggest that these issues are not significant barriers to Telehealth adoption for several reasons. According to Darkins et al. [10] patient satisfaction was significantly high among older participants in the VHA Telehealth programme and lack of face-to-face contact with healthcare professionals has not been observed as a barrier to Telehealth adoption. This may indicate that the benefits offered by the technology may outweigh such concerns. Similarly, Castro [25] suggests that confidentiality concerns should not be a barrier to ICT penetration in the healthcare industry, considering that technical controls (e.g., encryption, electronic identification, audit logs) are available to ensure personal health data security. In Denmark, for example, health data is securely shared through an official e-health portal. In this context patients have access to this website and can easily control privacy functions, including monitoring who has accessed or modified their personal medical records. In Ireland the recently implemented National HealthLink Project (http://www.healthlink.ie/) is another example of how patient data (e.g., laboratory results) can be securely shared over the Internet.

Interviewees in this study challenged several authors [7, 8, 14] suggesting that lack of RCTs is not a significant barrier to Telehealth adoption. Participants argued that careful patient selection is desired to achieve Telehealth benefits, thus alternative study designs should be used to evaluate Telehealth value. This has been previously observed by other authors [11, 13]. The MAST is an example of a new model for Telehealth evaluation which has been developed to support decision making in European countries [32].

 ISBN: 978-1-61208-179-3

There are indications, therefore, that evidence base barriers should not be of major significance.

The interviews supported the main findings of the literature in relation to certain technology barriers including limited access to broadband connections by older people [7, 8] and lack of integration between various Telehealth technological solutions [6, 8, 12, 14, 15]. It is important to acknowledge, however, that several initiatives are being undertaken and such barriers may not be significant in the long-term. The Irish government has recently implemented a national scheme which aims to achieve extensive broadband coverage by 2012 [33]. Moreover, with the increasingly fast adoption of smartphones, the native broadband Internet connection capabilities of those devices may in practice address the connectivity infrastructure requirements for Telehealth, as opposed to government-led, residence-based broadband connection programmes [34]. Similarly, interoperability issues are being tackled by both private and public sectors. Through the Continua Health Alliance, over 240 healthcare and technology companies worldwide are working together to set quality and interoperability standards for Telehealth solutions [35]. Studies by Anderson [12] and Castro [25] indicate that in the UK and Denmark government agencies are setting such standards.

V. CONCLUSION

The research findings point to a number of direct and indirect obstacles, which largely correspond to those discussed in the international literature. Issues involving evidence base, technology interoperability and broadband access were not considered to be of major significance, given that important initiatives are already addressing these barriers. Similarly, based on interviewees' perceptions and technology adoption trends, older people's acceptance is not believed to be a pressing barrier to wider Telehealth implementation in the medium term.

The findings indicate that technology usability issues may significantly hinder Telehealth adoption. The use of devices that people are familiar with such as mobile phones, laptops and computer tablets is supported by this study as a strategy to promote Telehealth use. Another important barrier is the lack of organisational willingness to change, currently perceived in the healthcare sector. While implementation costs were seen as a challenge to government action in Ireland, strong national-level leadership is considered essential.

Finally, the lack of incentive to healthcare professionals to embrace Telehealth is considered a pressing barrier to its wider adoption. The absence of arrangements to reimburse healthcare providers and the incongruence with the present procedure-driven healthcare model are believed to significantly discourage professionals to offer this service. Possible approaches to address healthcare professional incentive barriers have been suggested and include government mandates, the establishment of reimbursement schemes and the use of government financial incentives.

The imminent population ageing and epidemiologic trends indicate that new forms of healthcare provision are urgently needed. Shifting away from the current disease-centric healthcare model towards a health-centric system is not only an economic necessity but also a moral obligation. The adoption of Telehealth technologies is believed to contribute towards these issues by allowing more efficient service provision in a patient-driven model. However, the disruption to traditional healthcare practices caused by the introduction of Telehealth represents a major challenge, one that requires the support from all stakeholders involved. Governments around the world are gradually implementing strategies to promote a new vision in the healthcare sector and significant changes are envisaged in the long-term.

Even though interview findings indicate large agreement with the literature, the small scope of this study does not allow for the generalisation of these results. Also, this research project would have greatly benefited from the participation of representatives of the Irish Government, what was initially intended. The fact that Potential Consumers and Healthcare Professionals interviewed in this study did not have personal experience with Telehealth technologies indicate that one has to cautiously consider their contributions.

While identifying barriers to wider Telehealth adoption is an important starting point to promote its implementation, it seems possible to suggest that future research should focus on clear and practical strategies to increase Telehealth adoption in the homes of older people. Investigating innovative ways of incentivising healthcare professionals and organisations to embrace Telehealth in their usual practices seems to be one of the most needed areas for research.

ACKNOWLEDGMENT

The author would like to thank Professor Anthea Tinker from the Institute of Gerontology, King's College London, for her support and supervision.

REFERENCES

[1] M.C.K.Gaßner and M. Conrad, "ICT enabled independent living for elderly – A status-quo analysis on products and the research landscape in the field of Ambient Assisted Living (AAL) in EU-27," Berlin: Institute for Innovation and Technology as part of VDI/VDE Innovation + Technik GmbH, 2010.

[2] P. McGill, "Illustrating Ageing in Ireland North and South: Key Facts and Figures," Belfast: Centre for Ageing Research and Development in Ireland, 2010.

[3] K.P. Balanda, S. Barron, L. Fahy and A. Mclaughlin, "Making chronic conditions count: hypertension, stroke, coronary heart disease, diabetes. A systematic approach to estimating and forecasting population prevalence on the island of Ireland," Dublin: Institute of Public Health in Ireland, 2010.

[4] DoHC, "Tackling chronic disease - a policy framework for the management of chronic diseases," Dublin: Department of Health and Children, 2008.

[5] R. Layte, "Projecting the Impact of Demographic Change on the Demand for and Delivery of Healthcare in Ireland," Dublin: ESRI, 2009.

[6] COCIR, "COCIR Telemedecine toolkit. For a better deployment and use of Telehealth," Brussels: European

 ISBN: 978-1-61208-179-3

Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, 2010.

[7] N. Goodwin, "The State of Telehealth and Telecare in the UK: Prospects for Integrated Care," Journal of Integrated Care, 2010. 18(6): pp. 3-10.

[8] L. Kubitschke and K. Cullen, "ICT & ageing–European study on users, market and technologies. Final report," Brussels: Commission of the European Communities, 2010.

[9] J. Barlow, D. Singh, S. Bayer and R. Curry, "A systematic review of the benefits of home telecare for frail elderly people and those with long-term conditions," Journal of telemedicine and telecare, 2007. 13(4): pp. 172.

[10] A. Darkins, P. Ryan, R. Kobb, L. Foster, E. Edmonson, B. Wakefield and A. E. Lancaster, "Care coordination/home telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of Veteran patients with chronic conditions," Telemedicine and e-Health, 2008. 14(10): pp. 1118-1126.

[11] T.H.F. Broens, R. M. H. A. H. I. T. Veldw, M. M. R. Vollenbroek-Huttenw, A. T. V. Hermenswz, H. J., Halteren and L. J. M. Nieuwenhuis, "Determinants of successful telemedicine implementations: a literature study," Journal of telemedicine and telecare, 2007. 13(6): pp. 303.

[12] J.G. Anderson, "Social, ethical and legal barriers to e-health," International journal of medical informatics, 2007. 76(5-6): pp. 480-483.

[13] A. Runge and F. Feliciani, "Telemedicine: from technology demostrations to sustainable services," in The European Files: The Telemedicine challenge in Europe. Brussels: European Commission, 2010.

[14] M. Alwan and J. Nobel, "State of Technology in Aging Services According to Field Experts and Thought Leaders," Washington: American Association of Homes and Services for the Aging (AAHSA), 2008.

[15] S. Koch, "Home telehealth--current state and future trends," International journal of medical informatics, 2006. 75(8): pp. 565-576.

[16] J.-M. Pique, "Impact on the restructuring of healthcare," in The European Files: The Telemedicine challenge in Europe. Brussels: European Commission, 2010.

[17] C. May, T. Finch, J. Cornford, C. Exley, C. Gately, S. Kirk, et al., "Integrating telecare for chronic disease management in the community: What needs to be done?" BMC Health Services Research, 2011. 11(1): pp. 131.

[18] J. Bonfini and C. Parker, "Telehealth: Making House Calls Count," in The European Files: The Telemedicine Challenge in Europe. Brussels: European Comission, 2010.

[19] J. Cruickshank, "Healthcare without Walls: A Framework for Delivering Telehealth at Scale," London: 2020health.org, 2010.

[20] L.L. Barrett, "Healthy@ Home," Washington: AARP Foundation, 2008.

[21] Intel, "NHS Lothian Pilot," [Online]. Available: http://www.intel.com/corporate/healthcare/emea/eng/videos/video.htm [Accessed 22 February 2011].

[22] Microsoft, "Microsoft HealthVault - Interesting New Platform," [Online]. Available: http://www.youtube.com/watch?v=g9hLT2bMfbY [Accessed 22 February 2011].

[23] D.W. Bates, "Physicians and ambulatory electronic health records," Health Affairs, 2005. 24(5): pp. 1180.

[24] E.H. Oh, Y. Imanaka and E. Evans, "Determinants of the diffusion of computed tomography and magnetic resonance imaging," International journal of technology assessment in health care, 2005. 21(1): pp. 73-80.

[25] D. Castro, "Explaining International IT Application Leadership: Health IT," Washington: The Information Technology and Innovation Foundation, 2009.

[26] NHS, "GP Payments Calculation Service Memorandum of Information (MOI)," 2010 [Online]. Available from: http://www.connectingforhealth.nhs.uk/systemsandservices/gpsupport/gppcs/gppcsmoi.pdf. [Accessed 15 August 2011].

[27] CMS, "Centers for Medicare & Medicaid Services," 2011 [Online]. Available from: https://www.cms.gov/EHRIncentivePrograms/50_Spotlight.asp#TopOfPage. [Accessed 14 August 2011].

[28] E. Mikalajunaite, "500m people will be using healthcare mobile applications in 2015," 2010 [Online]. Available from: http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/. [Accessed 16 August 2011].

[29] K. Cullen, C. Dolphin, S. Delaney and M. Fitzpatrick, "Survey of Older People and ICTs in Ireland (2008)," Dublin: Work Research Centre (WRC) & Age Action Ireland, 2009.

[30] H. Seybert and A. Loof "Internet usage in 2010 – Households and Individuals," Eurostat, European Commission, 2010.

[31] Eurostat, "Individuals regularly using the Internet," 2011 [Online]. Available from: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=isoc_pibi_use&lang=en. [Accessed 01 August 2011].

[32] K. Kidholm, C.D. Pedersen, J. Rasmussen, L.K. Jensen, A.G. Ekeland, A. Bowes, et al., "A new model for assessment of telemedicine—MAST," International Journal of Integrated Care, 2011. 11(6).

[33] DCENR, "Rural Broadband Scheme Announced by Minister Rabbitte," 2011 [Online]. Available from: http://www.dcenr.gov.ie/Press+Releases/Rural+Broadband+Scheme+Announced+by+Minister+Rabbitte.htm. [Accessed 14 August 2011].

[34] Miscrosoft Tag, "The Growth of Mobile Marketing and Tagging," 2011. [Online]. Available from: http://tag.microsoft.com/community/blog/t/The_Growth_of_Mobile_Marketing_and_Tagging.aspx [Accessed 07 August 2011].

[35] Continua Health Alliance, "About the Alliance," 2010 [Online]. Available from: http://www.continuaalliance.org/about-the-alliance.html. [Accessed 18 February 2011].

 ISBN: 978-1-61208-179-3

eHealth Wikiplatform to Increase the Uptake and Impact of eHealth Technologies

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***Abstract* - We have constructed an evidence-based holistic guideline to develop technologies in order to improve the measurable impact of eHealth. It accounts for most observed deficiencies and comprises human-centred, context-sensitive and practical principles that are effective and useful for all stakeholders. These principles are: multidisciplinary in action, development as co-creation, the social nature of technology, integration of development, implementation and evaluation. The guideline is published as an on line eHealth wiki in order to share knowledge and information on how to improve the uptake and impact of eHealth technologies in a collaborative effort of researchers, developers, policymakers, and healthcare professionals. In the panel presentation we will elaborate and discuss the possibilities of the wiki to contribute to better outcomes in eHealth. We will show cases in which the eHealth wiki has been applied, and we'll show the benefits of this holistic approach. We invite participants to discuss the use of a virtual knowledge platform to increase the quality of eHealth technologies and to foster the implementation of eHealth technologies in practice.**

Keywords - eHealth; design; implementation; holistic; health 2.0; wiki

I. INTRODUCTION

eHealth technologies may contribute to solve some serious challenges to global health and health care. The impact of eHealth technologies on healthcare practice is below professional expectation, which is widely discussed in scientific literature [1-7]. In our research [8-18] we have identified four clusters of major causes: a) inadequate research methods, b) lack of knowledge about the process of technological innovation, c) a skewed medical expert-driven approach to eHealth technologies, and d) the use of inapplicable old world theories on human behavior. These causes often lead to the development of high-tech solutions that are unsuitable for use in complex healthcare environments or in patients' social situations.

The development of eHealth technologies involves a lot more than simply designing a product or a service, and includes more than merely procuring stand-alone medical devices. We recognize the social dynamics and the significance of eHealth technologies and its potential for improving healthcare. Creating a new technology works as a catalyst for innovation. It induces clarification of how the process of healthcare delivery actually runs; who are the key stakeholders; how is payment organized et cetera. It also illustrates the interdependencies between technology, healthcare providers, their social-cultural setting, and the infrastructural organization of healthcare. Ideally, all stakeholders should be aware of these complex relationships. In the wake of Health 2.0 and Medicine 2.0 initiatives, a growing number of studies have emphasized the importance of a *participatory development* process involving (end-)users, and other stakeholders such as payers, decision-makers, insurers, government officials to increase the uptake of eHealth-interventions. To support a participative development process we have introduced a holistic research and development guideline; the CeHReS roadmap [19].

A. CeHRes Roadmap

A holistic approach accounts for the major issues of finance, management and the biased technology-driven approach. It constructs a productive fit through the integration of social sciences, engineering and business modelling. In the international arena (EU-eHealth, European Centre for Public Policy [20]) the need for a holistic eHealth approach towards durable technological interventions and sustainable innovations in healthcare has been explicitly emphasized. The roadmap (Fig. 1) serves as a practical guideline to help plan, coordinate and execute a participatory development process of eHealth technologies. The guideline is meant for developers (e.g., technicians, designers, health care professionals), researchers and policy-makers. It also serves as a tool for educational purposes (e.g., students, healthcare providers) and as an analytical instrument to support decision-making in eHealth.

 ISBN: 978-1-61208-179-3

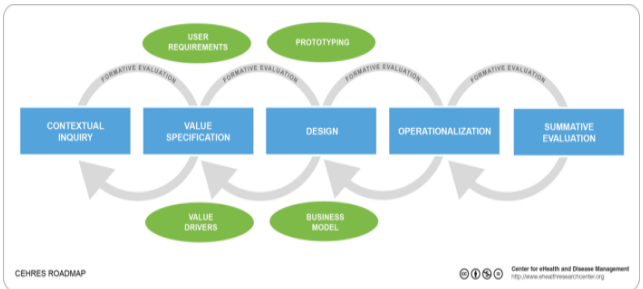


Figure 1. CeHRres roadmap

The guideline is based on reviews in the field of eHealth and progressive insights from current research projects using the guideline. Multidisciplinary theories and methods from psychology, communication, and human-computer interaction design are used to study the capacities of technology for behavior change.

The model integrates *persuasive technology* and *business modelling*. Persuasive technology is used to make technologies human-centered, tailored to stakeholders' needs, capacities and capabilities to change their (professional) behavior. Business modelling is interwoven with the development of eHealth technologies to foster ownership by co-creation and to construct business cases to successfully implement eHealth technologies. The roadmap consist of five cycles (see Fig. 1).

1. **Contextual inquiry**. To understand the problem and needs of various stakeholders, the contextual environment should be analyzed (field observations, focus groups, literature reviews etc). This results in an overview of problems and needs that are prioritized into a strategy for possible solutions by stakeholders.
2. **Value-specification**. Next, the stakeholders determine who the key-stakeholders are involved with the innovation in healthcare. These key-stakeholders determine the critical vales (socio-economic, cultural, clinical) based on the problem and needs inventory, using software for critical decision making to prioritize these values, important for the next step.
3. **Design.** The value specification will be translated into functional requirements and technical requirements via experts (for example hygiene experts) and technical design experts. These requirements will be evaluated by the other stakeholders (end-users).
4. **Operationalization**. A business case and implement-tation plan will be developed by stakeholders (management, payers, providers et al.) based on the Contextual inquiry and value specifications and design requirements.
5. **Evaluation cycles**. These formative and summative evaluations cycles consist of research activities to test whether the technology fits with needs and contexts; and what the effects are (clinical, behavioral, organizational).

B. eHealthwiki-toolkit

The eHealthwiki toolkit is based on web 2.0 technology to share health research information. This is why the Dutch National Institute for Public Health and the Environment (RIVM) invests in its development. Thus a narrative literature review on current eHealth frameworks for development, implementation and evaluation was conducted to obtain insight in the quality criteria for development and implementation of eHealth technologies [19].

The eHealthwiki toolkit will be used as a virtual knowledge network for sharing information to enhance the quality of the development and implementation of eHealth technologies. The objective of the eHealthwiki is to foster collaboration between research, business and healthcare practice (supply and demand). It communicates and generates evidence of best-practices to enhance the social impact of research. The wiki is demand driven and functions as a virtual knowledge platform providing methods, tools and key features for successful eHealth technologies.

The wiki represents the CeHRes Roadmap (see Appendix I) and its corresponding tools for eHealth development and implementation (via a clickable image, tools are linked to the roadmap). The wiki supports participatory development via the collaborative effort of researchers, developers and healthcare professionals. The eHealth wiki *structure* captures the several cycles of the roadmap. The cycles, like contextual inquiry (see Appendix II) and the corresponding methods and tools are depicted and explained for usage in practice.

C. The panel discussion

To discover the values of the eHealthwiki we will organize several panel discussions among stakeholders during the autumn of 2011 (researchers, developers, engineers, policymakers, insurers, healthcare providers et al.).

The proposed eTelemed-panel consists of researchers and developers in the field of social sciences, medicine, engineering and business modeling. Conform the holistic guideline (Fig. 1), we are carrying out the contextual inquiry and value specification among key-stakeholders to adjust the design (content &structure) to stakeholders' needs. Several workshops have been carried out to show how the wiki can enhance the quality of eHealth technologies demonstrating the use of the methods and tools in our research & development projects (teledermatology; Infection control, etc). The eTelemed-panel discussion will address several generic, controversial issues to discuss the challenges of health 2.0 platforms , virtual collaboration and

 ISBN: 978-1-61208-179-3

the credibility of eHealth platforms in general. We will elaborate on issues such as:

- How would a 2.0 knowledge platform for eHealth be useful for several stakeholders?
- How to use it as a virtual tool for collaboration?
- How to manage an eHealth wiki and to deal with credibility and to avoid 'vandalism'?
- Will it work in diverse settings; What are the challenges in other fields using an ehealthwiki (semantic-wiki for ehealth education) for collaborative development of guidelines for medical practice, sharing knowledge of best-practices (research-wiki), for education, disruptive wiki's (ebuss-wiki) to create innovative structures for healthcare (based on business models)?
- How to inspire collaborative use of the wiki and convey it to a variety of research areas in eHealth?
- How to use an eHealthwiki as an instrument to enhance the social impact of research? (putting evidence into practice)?
- How to solve implementation issues in various contexts?

We will ask the panelists to *prepare statements* for the discussion; the presentation will be moderated by Lisette van Gemert-Pijnen (first author).

The outcomes will be used to contribute to general academic debate with regard to the usefulness of a wiki for improving collaboration in eHealth. The outcomes will also be used to upgrade the eHealthwiki and to finalize its' design. The eHealthwiki will ultimately be disseminated via web2.0 communities for eHealth research and development and via other virtual knowledge networks for eHealth development.

II. CONCLUSION

In this paper we have introduced a holistic guideline for the development of eHealth technologies and the connected eHealth toolkit for research and development. At the moment we are discussing the value of such an approach for the quality of eHealth technologies (design and implementation)

Outcomes are used to upgrade the design of the eHealthwiki and to develop an infrastructure for implementation. Furthermore we will work to make the broader case on how wiki-development facilitates scientific collaboration and the social impact of science.

REFERENCES

[1] Black AD, Car J, Pagliari C, et al. The impact of eHealth on the quality and safety of health care: a systematic overview. PLoS Med 2011;8(1):e1000387. PMID:21267058

[2] WorldHealthOrganization. Medical devices: managing the mismatch: an outcome of the priority medical devices project. Geneva, Switserland: WHO Press, 2010. ISBN:9789241564045

[3] Arnrich B, Mayora O, Bardram J, Tröster G. Pervasive healthcare: paving the way for a pervasive, user-centered and preventive healthcare model. Methods Inf Med 2010;49(1):67-73. PMID:20011810

[4] Atienza AA, Hesse BW, Gustafson DH, Croyle RT. E-health research and patient-centered care examining theory, methods, and application. Am J Prev Med Jan 2010;38(1):85-88. PMID:20117562

[5] Chaudhry B, Wang J, Wu S, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med 2006;144(10):742-752. PMID:16702590

[6] Chaudhry SI, Phillips CO, Stewart SS, et al. Telemonitoring for patients with chronic heart failure: a systematic review. J Card Fail Feb 2007;13(1):56-62. PMID:21080835

[7] Ammenwerth E, Brender J, Nykanen P, Prokosch HU, Rigby M, Talmon J. Visions and strategies to improve evaluation of health information systems. Reflections and lessons based on the HIS-EVAL workshop in Innsbruck. Int J Med Inform Jun 30 2004;73(6):479-491. DOI:10.1016/j.ijmedinf.2004.04.004

[8] Kelders SM, Van Gemert-Pijnen JE, Werkman A, Nijland N, Seydel ER. Effectiveness of a Web-based intervention aimed at healthy dietary and physical activity behavior: a randomized controlled trial about users and usage. J Med Internet Res 2011;13(2):e32. PMID:21493191

[9] Kelders SM, van Gemert-Pijnen JE, Werkman A, Seydel ER. Usage and effect of a web-based intervention for the prevention of overweight; a RCT. Stud Health Technol Inform 2010;160(Pt 1):28-32. PMID:20841644

[10] Kelders SM, van Gemert-Pijnen JE, Werkman A, Seydel ER. Evaluation of a web-based lifestyle coach designed to maintain a healthy bodyweight. J Telemed Telecare 2010;16(1):3-7. PMID:20086259

[11] Nijland N. Grounding eHealth: towards a holistic framework for sustainable eHealth technologies. Enschede: University of Twente, 2011. ISBN:9789036531337

[12] Nijland N, Cranen K, Boer H, van Gemert-Pijnen JE, Seydel ER. Patient use and compliance with medical advice delivered by a web-based triage system in primary care. J Telemed Telecare 2010;16(1):8-11. PMID:20086260

[13] Nijland N, van Gemert-Pijnen J, Boer H, Steehouder MF, Seydel ER. Evaluation of internet-based technology for supporting self-care: problems encountered by patients and caregivers when using self-care applications. J Med Internet Res 2008;10(2):e13. PMID:18487137

[14] Nijland N, van Gemert-Pijnen JE, Boer H, Steehouder MF, Seydel ER. Increasing the use of e-consultation in primary care: results of an online survey among non-users of e-consultation. Int J Med Inform Oct 2009;78(10):688-703. PMID:19625210

[15] Nijland N, Van Gemert-Pijnen JEWC, Kelders SM, Brandenburg BJ, Seydel ER. Factors influencing the use of a web application for supporting the self-care of patients with type 2 diabetes type II: a longitudinal study. J Med Internet Res 2011;In press. DOI:10.2196/jmir.1603

[16] Verhoeven F. When staff handle staph: user-driven versus expert-driven communication of infection control guidelines. Enschede: University of Twente, 2009. ISBN:9789036528689

[17] Verhoeven F, Tanja-Dijkstra K, Nijland N, Eysenbach G, van Gemert-Pijnen L. Asynchronous and synchronous teleconsultation for diabetes care: a systematic literature review. J Diabetes Sci Technol May 2010;4(3):666-684. PMID:20513335

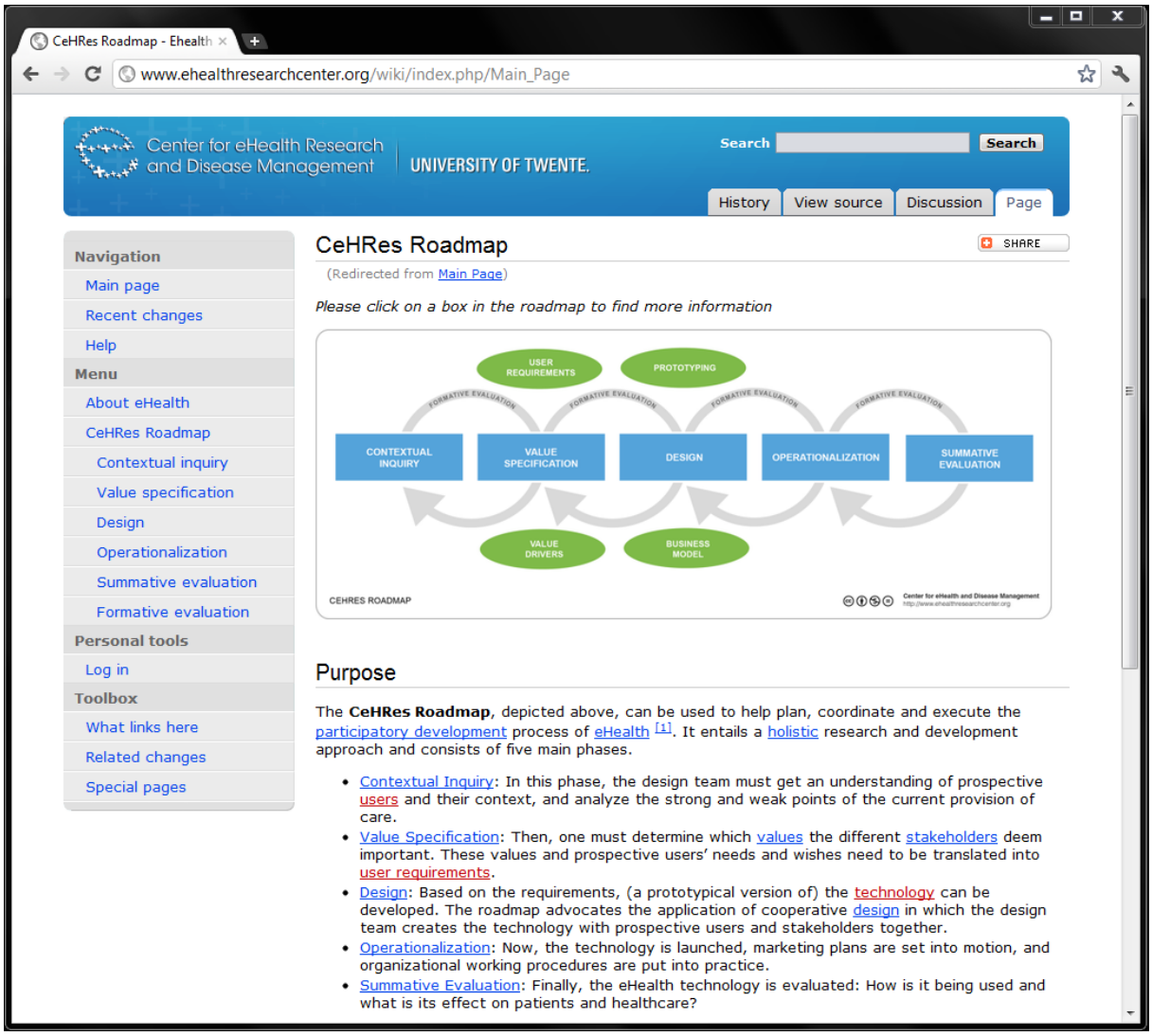
[18] Verhoeven F, van Gemert-Pijnen L, Dijkstra K, Nijland N, Seydel E, Steehouder M. The contribution of teleconsultation and videoconferencing to diabetes care: a systematic literature review. J Med Internet Res 2007;9(5):e37. PMID:18093904

[19] Van Gemert-Pijnen JEWC, Nijland N, Ossebaard HC, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011; In press. DOI:10.2196/jmir.1672

[20] European Centre for Public Policy. URL: http://health.parlicentre.eu/

 ISBN: 978-1-61208-179-3

Appendix I: Screenshot of Homepage eHealthwiki



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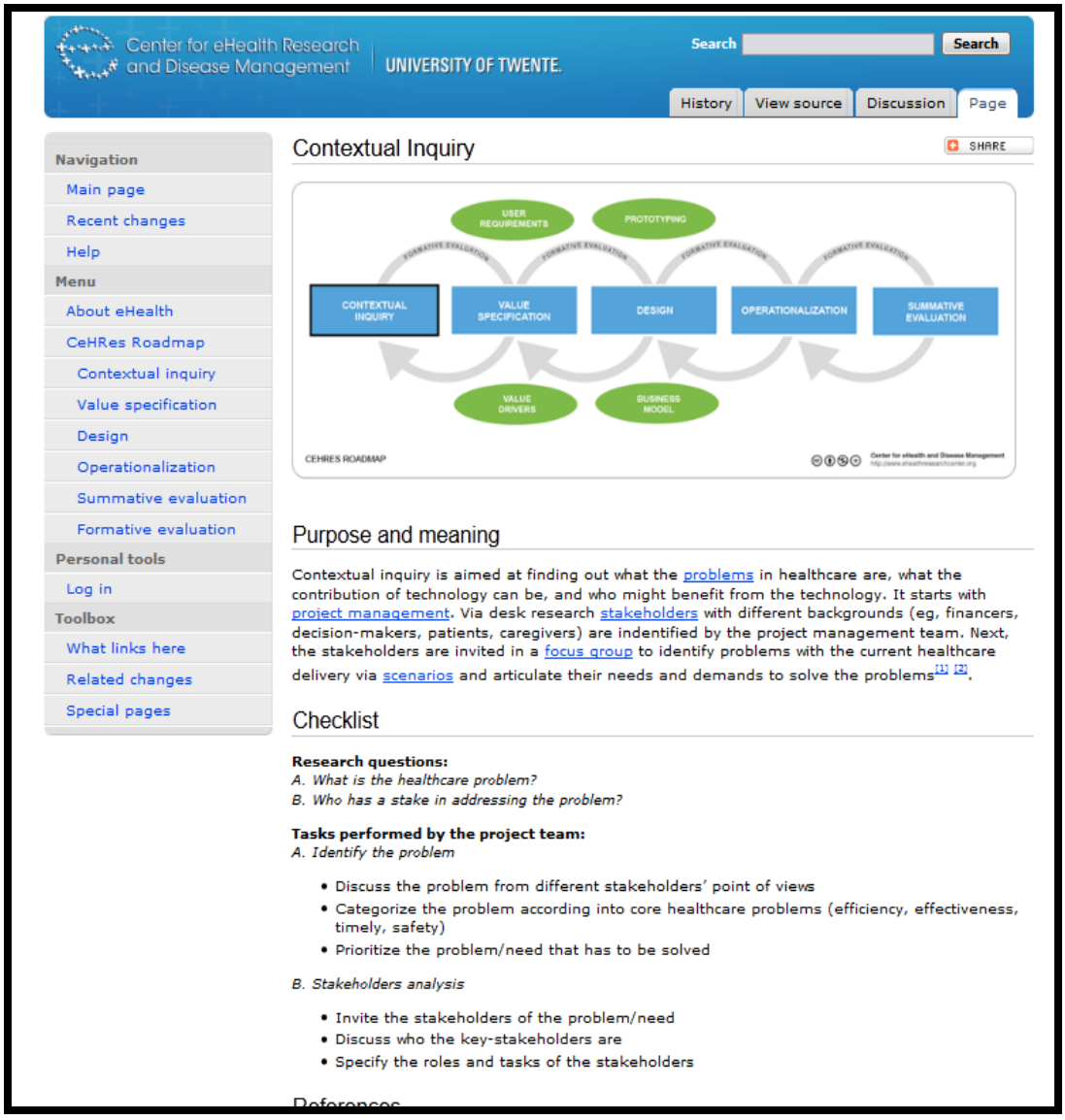
Appendix II: Screenshot of eHealth wiki depicting the Roadmap and its cycles



 ISBN: 978-1-61208-179-3

Technological Changes in High Reliability Organization: Implementation of a Telematic Rescue Assistance System into German Emergency Medical Services

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Abstract- **The introduction of a Telematic Rescue Assistance System into the German Emergency Medical Services aims at the enhancement of treatment quality and efficiency of rescue operations. Rescue teams are supported on site by a specialized emergency physician in a remote Competence Centre. Using mobile radio networks the Telematic Rescue Assistance System enables real time transmission of voice communication, vital parameters, pictures and videos from any emergency site. The successful and sustainable operation of a Telematic Rescue Assistance System in German Emergency Medical Services organizations requires the elaboration of a context and object adjusted implementation strategy. Dealing with technology change in a so called High Reliability Organization, organizational culture and structure affect primarily the design of available implementation instruments. Further requirements to the arrangement of an implementation process result from the sociotechnical specificities of the Telematic Rescue Assistance System. The present work presents the methodology used within the research project to develop an adequate implementation strategy, pointing out the relevant requirements and the chosen instruments to implement the system within five different Emergency Medical Services departments in 2012.**

Keywords - Telematic Rescue Assistance System; German Emergency Medical Services; High Reliabilty Organizations; Technology Implementation; Implementation Management

I. INTRODUCTION

Within the German research project Med-on-@ix (2007-2010) engineers, researchers and physicians from Aachen developed a preliminary model of the *Telematic Rescue Assistance Systems* (TRAS) and evaluated the prototype for 10 months within a trial run in the *Emergency Medical Services* (EMS) of the city of Aachen. The evaluation of the system revealed the potential of telemedical support during EMS missions regarding high quality treatment of emergency patients and the enhancement of information and time management.

The TRAS allows the immediate support by EMS teams during an emergency operation by a tele-EMS physician in a remote *Competence Center* (CompC). Not only the real-time transmission of vital data and pictures from the emergency site but also the video footage out of the *Mobile Intensive Care Unit* (MICU) via 3G mobile radio networks, provide the necessary information basis for the qualified telemedical support. Via mobile communication the tele-EMS physician is connected with the team on site and provides the necessary medical know-how and decision authority in terms of adequate diagnosis and treatment. The CompC serves as an information crosspoint between prehospital, clinical and related health care facilities along the medical supply chain [1].

The project work pursued a joint organizational and technical development approach [2] to guarantee a user-centered requirement management and a continuous process improvement in line with the development. The constant involvement of EMS physicians and paramedics into the design and development process as well as trials at different levels of development (simulation studies in 2008 and 2009) and the final trial run in regular operations of the fire department in Aachen aimed at a wide scope of requirements regarding the implementation of the TRAS in German EMS organizations.

The follow-up project "TemRas – Telemedical Rescue Assistance System" started in 2010 faces the challenge to establish the TRAS at a broader level to be used in five different EMS departments in Western Germany. The research action is funded by the Ministry of Innovation, Science and Research of the state of North-Rhine Westphalia (MIWF) and the European Union for three years. At a technical level the roll-out of the TRAS requires the adaption of the software architecture to enable simultaneous support of multiple MICUs. The adapted software architecture overcomes the absence of standards for data exchange, integrates the existing devices used by MICUs and manages the communication for different applications [3]. The telematic network connects the MICU, the EMS team on site and the CompC. The long

 ISBN: 978-1-61208-179-3

distance communication is based on 3G mobile networks. Bluetooth and wireless transmission both enable the real time data transmission in the near area from the monitor/defibrillator unit, a Bluetooth stethoscope and a digital camera as well as a video life stream from a network camera in the MICU to the CompC (Figure 1.).

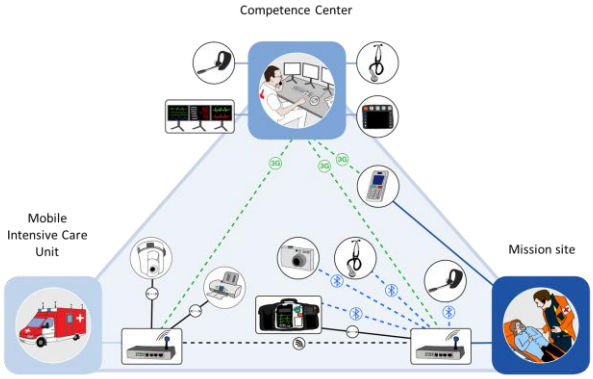

Figure 1. The optimised Telematic Rescue Assistance System

Besides the technical optimization of the TRAS, the main challenge is the implementation of the system in rural and urban areas with heterogeneous initial conditions in terms of resources, operating standards as well as user groups with different level of qualification and motivation.

The use of the TRAS implies a perceptible impact on communication structures and team processes [2]. Therefore the introduction into EMS organizations requires an implementation strategy considering system-related requirements as modified working processes, new working environments and new equipment. Furthermore organization-related requirements have to be considered to design the necessary actions. The implementation context is characterized by existing working conditions, cultural specification of the organization and structural conditions of the EMS department.

This paper offers an insight into the design of the implementation strategy pursued in the project TemRas. Starting with a literature review on the state of the art (section II), section III offers an insight into the characteristics of EMS as target organization of technology change. The methodology presented in section IV is partly borrowed from sociological and management theories. Whether sociological technology acceptance models underline the necessity of participatory implementation approaches, economical and marketing methods turn the gaze on the possibilities to bring about the organizational adoption and the long-term use of new technologies. Based on empirical values from the final evaluation results of the former project and scientific findings about EMS as a High Reliability Organization (HRO), an implementation strategy is developed relying on organization-related and object-related requirements (section V). The paper finally concludes with the idea how to learn from high reliability theory to design successful implementation processes.

II. STATE OF THE ART

To achieve the intended results by introducing new technologies a careful design of the implementation process is almost as relevant as the system design itself [4]. Since the decision to adopt a new technology does not online depend on the character of the product but goes in line with the first impression of its usefulness and the measures aiming at familiarizing the user with the changed working processes. The proper use of telemedical applications and the embedment into approved working routines affect the dissemination of the innovation through the healthcare sector. The aim of implementing telemedicine into healthcare organizations is to generate improved working processes with recourse to telemedical assistance. Care organizations develop routines around the use of new technologies and thereby create a selfreinforcing cycle of stability [4].

Following Gersick and Hackman routines are “functionally similar pattern of behavior in a given stimulus situation without explicitly selecting it over alternative ways of behaving” [5] . Current organizational routines can therefore be a source of organizational resistance against implementation of new technology combined with unknown working procedures.

Although past research has discovered that the decision to adopt a new technology does not guarantee its successful implementation [6] there has been only a few empirical studies on how to manage the group and interpersonal process to make implementation happen [7]. The organization’s willingness to adopt a new technology is a basic condition for successful implementation depending besides the user acceptance on the attitudes of managers towards technological change [8]. Research on technology acceptance revealed the necessity to consider not only the decision to adopt as a punctual event but to make a distinction between the classical terms of attitude, adoption or diffusion. Kollmann [9] recommends a gradual construct of acceptance considering user attitudes in a first phase, the willingness to try out a technology and in the end the long-term incorporation of a technology into organizational routines. Implementation measures aim at the creation of new organizational routines around the technology use, requiring a positive attitude and the readiness to try out something new. The success of the implementation process thus depends on the creating positive acceptance from the first user contact on. The closeness to the organizational environment encourages the consideration of cultural and structural particularities of the target organization.

Studies on adoption of new technologies in healthcare organizations underpin that technology implementation is a process during which new beliefs, new skills, and new collaborative routines are simultaneously developed [7]. Edmonson et al. [7] found out that “organizational differences in size, resources, academic status, innovation history, and senior management support were not primarily associated with implementation success” but ascribe these results to the unusual degree of homogeneity

 ISBN: 978-1-61208-179-3

across the observed cardiac surgery departments, introducing minimal invasive cardiac surgery. The authors point out the importance of collective learning processes and the role of team leaders as innovation drivers. It is decisive to foster open communication and mutual trust within the teams, "reinforcing a particular technological frame, which affects how others think about a new technology and the nature of the challenge it presents" [7]. Edmonson et al. [7] suggest a four-step process to establish new working routines: enrollment, preparation, trials, and reflection. The process model that emerged from these data is mundane: (1) carefully select a team, (2) practice and communicate, (3) work to encourage communication while experimenting with new behaviors in trials, and (4) take time to reflect collectively on how trials are going so that appropriate changes can be made [7].

Similar studies and observations in EMS organizations have not yet been carried out. The remarks made so far show the necessity to take a closer look at the organizational culture to design an implementation strategy, along with stimulating of positive technology acceptance as a prerequisite for organizational adoption.

III. TECHNOLOGY CHANGE IN HIGH RELIABILITY ORGANIZATIONS

As EMS teams are able to balance effectiveness and safety despite the complexities of the environment regarding uncertainty of the situation, time pressure and restricted available resources, EMS organizations are considered High Reliability Organizations (HRO). Risky environment and the fact of facing partly insoluble tasks make human errors practically inevitable in these organizations; nevertheless fewer mistakes are made than expected, as problems are identified at an early stage. These organizations do this by consistently noticing the unexpected and reacting in a very flexible way.

Following the HRO model by Weick and Sutcliffe [10] these organizations have a collective state of *mindfulness* in common. Five principles of acting and organizing create a mindful way of behaving:

1. preoccupation with failures rather than successes,
2. reluctance to simplify interpretations,
3. sensitivity to operations,
4. commitment to resilience and
5. deference to expertise.

Members of mindful organizations pay attention to small deviations from regular operations and consider even small failures as a potential cause for bigger problems. They do not try to overlook mistakes to focus on successes but take failures as learning moments. HRO avoid the human tendency to oversimplify the world around us. In order to create more varied and differentiated expectations of what could happen HRO build diverse teams and welcome a wide variety of perspectives that challenge the conventional wisdom.

The concentration on things that disconfirm, are uncertain or implicit creates a so called "mindful culture" [11] that Weick describes as an informed culture creating and sustaining continuously intelligent wariness. A mindful organization culture provides a basic framework for the capability to discover and to manage unexpected events, to create high reliability.

Paulina and Callois [12] showed by analyzing reliability strategies in the military, space and semiconductor industries that HRO tend to limit their speed of technological innovation in order to preserve their level of reliability. LaPorte [13] explains this phenomena with the risky environment in which HRO operate "in wich any change in circumstances, internal processes or technical innovation is more likely to degrade than to improve existing operations". These assumptions have so far not been transferred to the analysis of EMS organizations; however no successfully realized widespread innovations in EMS are observable within the last decades.

IV. METHODOLOGY - DEVELOPMENT OF A IMPLEMENTATION CONCEPT

Contrary to the traditionally interpretation of the implementation as a closed stage of development within a engineering process, current approaches dealing most with strategy implementation processes foster a new point of view. Instead of splitting the development process into a planning, an implementation and an evaluation phase, implementation activities refer to change tasks realized at different stages of development. Daniel [14] defines implementation as all activities that ensure the future success of the application deployment object in the implementation context, regardless in which phase of the development the corresponding activities take place. Those activities target both person- and object-related objectives concerning then the two reference planes 'result-related objectives' and 'process objectives'. Figure 2. shows the defined objectives in line with the implementation of the TRAS.

	person-related objectives	object-related objectives		
	user-acceptance	quality	cost	time
result-oriented	high acceptance for the TRAS	compatibility between the TRAS and the EMS organization	low follow-up costs	early introduction
process-oriented	high acceptance for the implementation process of the TRAS	fault-free approach, little impairment of day-to-day business	Low implementation costs	short duration of implementation

Figure 2. Objectives of the implementation activities

Beside the positive user acceptance in view of an organizational adoption of the system, best quality of the TRAS and the implementation process as well as an early and brief introduction of the TRAS is intended.

To achieve the defined context- and object-objectives (Figure 2.) requirements towards a successful

 ISBN: 978-1-61208-179-3

implementation strategy were identified on both sides by referring scientific findings from the project itself and external theoretical and empirical research work.

Context-oriented implementation is focusing primarily on overcoming personnel and organizational barriers of implementation. Approved instruments originate from the categories information, qualification, motivation and organization [15]. Applied measures concerning these categories can have cross-sectional effects such as informational and qualifying measures can have motivational impact on the target group. The success of all implementation measures depends on the acceptance by the affected persons and their willingness to take part in the change process. In this regard information and communication actions have a direct link to technology acceptance.

As Chau and Hu [16] showed in their study upon telemedicine acceptance by physicians the main task of management in technology change process consists in demonstrating and communicating the technology's usefulness to the routine tasks and services [16]. To avoid the so called "Not invented here" syndrome [17] the design of the TRAS has to fully recognize the needs of the user groups. The early involvement of paramedics and physician into the development process had the most important impact on the user acceptance. The consequent dialog and the constructive way of dealing with feedbacks, fears and inhibitions paved the way to a user-centered technology creation.

Object-related requirements were derived from several evaluations of the previous project Med-on@ix. The use of the TRAS was evaluated during a one-year trail from different perspectives. Besides the quality of treatment, focusing on time management and the appropriateness of the treatment process, the user acceptance of the TRAS was evaluated to gather potential for improvement of the system. By analyzing the impact of the TRAS on working routines of EMS teams several requirements were identified aiming at the elaboration of working and communication rules to be considered in telemedically supported missions [18]. Change tasks where identified concerning the use of checklists to guarantee a necessary level of standardized working procedures and the training of users in using the TRAS properly.

Bergrath et al. [19] evaluated the technical and organizational feasibility of the pilot TRAS based on 157 EMS missions in the city of Aachen, concluding that the use of the TRAS is feasible even if technical reliability and availability has to be improved in the future. The authors reported technical problems caused by network disconnections especially inside buildings. Evaluation of organizational implementation revealed successful cooperation between the EMS team on site and the tele-EMS physician in terms of ECG interpretation, diagnosis and treatment decisions.

To achieve the implementation objectives (Figure 2.) context and technology related requirements are describe in the following section and the implementation strategy is drawn to meet cultural and structural particularities of the implementation project. The morphological box in Figure 3. modeled after Baumgartner and Schneeberger [20] offers an insight into the range of strategic design parameters.

dimensions of the implementation strategy			design options			
culture	behavioural style		top-down		bottom-up	
	managerial style		directive		participatory	
structure	object	Extent of implementation	Complete object		Gradual introduction of object modules	
		Stage of development	Ideal solution		Approximate solution with rework option	
	context	context definition	overall context		successive introduction into context areas	
		transition between context areas	coupled	overlapping	parallel	decoupled
	time	Point in time	Considering the relevant maturity level		Considering favorable opportunities	

Figure 3. Development of an implementation strategy

The implementation of the chosen strategy is finally realized through different implementation measures. As mentioned above implementation instruments belong to the categories information, qualification, motivation and organization.

V. RESULTS – THE IMPLEMENTATION STARTEGY

A. *Organization-related requirements*

The implementation of new technologies into German EMS organizations underlies the barriers of the federal healthcare system. State specific EMS legislations bring about different structures of service, working practices, level of qualification and various allocations of rights and duties. The introduction of technological assisted working procedures has therefore to meet shared needs of EMS organizations, avoiding conflicts with structural conditions by adapting the TRAS at the prevailing conditions. As for example the training of paramedics is integrated into weekly standard on-the-job training. For same reasons the application of the TRAS does not explicitly interfere in the handling of emergency calls and the working processes of the dispatch center for rescue services.

As the impact of the TRAS is particularly connected to the performance of teams on site, the implementation efforts focused the operational capability. The TRAS has to be easily integrated as an add-on solution to regular operational processes. The evaluation of the Med-on-@ix System by paramedics showed the necessity to accompany the introduction of the TRAS by intensive training to generate qualified working routines in view of failure-free communication and teamwork processes. Users pointed out the importance of open communication and feedback possibilities. Regular debriefings and feedback between the users on site and the tele-EMS physicians constitute further important implementation measures.

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Besides the importance of teamwork and open discussions for HRO [21][22], strong internal leadership is accounted within the implementation process by an elaborated role concept regarding both the operation of the TRAS during emergency missions and the implementation process itself realized by the project team. The implementation of the TRAS requires the support by authorities to foster the dissemination and consequent use of the new technology by the whole organization. Therefore the pre-information of authorities and the participatory design of the organizational implementation are decisive.

Research findings about HRO [23] bring about further requirements to be considered:

- well-defined project objectives
- target-orientation within the project
- team-orientation
- definition of roles

B. *Object-related requirements*

The development of the TRAS as a sociotechnical system faces beside technological challenges particularly many organizational challenges, critical in view of a successful implementation of the TRAS into daily work of EMS. The implementation builds on a joint technical and organizational development [2] aiming at an optimized user-centered design of the technical system as well as the organizational concept enabling the operation of the TRAS. The design of the TRAS requires the consequent adaption of the system upon the organizational conditions of use. The modular architecture of the system offers the possibility to implement different functionalities and various complexity levels, enabling an organization specific implementation effort.

The scope of the implementation constitutes a more challenging characteristique of the implementation object. On the one hand various divisions of the EMS department as well as the dispatch center, municipal administration and clinic workers are involved into the change project. On the other hand the involved paramedics and physicians have different needs, qualifications and levels of technical affinity.

The use of the TRAS implies beside specific organizational procedures, legal regulations concerning the delegation of medical treatment and technical complexity. In the consequence the implementation of the TRAS is confronted with a difficult communicability. In combination with the necessity of training mentioned above the implementation requires extensive measures of preparation.

Bergrath et al. [19] showed the failure-free use of the TRAS depends on the reliability of mobile radio networks. As these technologies remain instable inside buildings and in rural areas and as the context of use requires high reliability the implementation of such a system has to be realized as an add-on to traditional EMS working procedures.

C. *Implementation strategy*

Analyzing the described requirements success criteria for the adoption of a TRAS can be derived. Information and communication instruments avoid misunderstanding and miscommunication about the implementation project. It is therefore decisive to look for an early opportunity to inform the members of the organization. Starting with a roadshow in every EMS department with possibilities for an open discussion, regular meetings in line with training units and feedback meetings scheduled along with the TRAS operation.

By identifying promoters of the implementation project at various hierarchy levels and within the different involved divisions of the EMS organization the information flow and the diffusion of the TRAS within the implementation context is raised. To gather current moods or hidden rumors internal contact persons act as mediators and opinion-formers to intensify the harmonization between user needs and system design. Thereby the designated mediators play an important role in fostering positive user acceptance, reporting everyday experiences with the system to the system developers.

Referring to Figure 3. the main design elements of the developed implementation strategy are showed in Figure 4.

dimensions of the implementation strategy			design options			
culture	behavioural style		top-down ⟷		bottom-up	
	managerial style		directive ⟷		participatory	
structure	object	Extent of implementation	Complete object		Gradual introduction of object modules	
		Stage of development	Ideal solution		Approximate solution with rework option	
	context	context definition	overall context		successive introduction into context areas	
		transition between context areas	coupled	overlapping	parallel	decoupled
	time	Point in time	Considering the relevant maturity level		Considering favorable opportunities	

Figure 4. Implementation strategy for the introduction of a TRAS

The chosen strategy to implement a TRAS into a German EMS organization is characterized primarily on a cultural level by a top down strategy concerning the initialization of the implementation project. Authorities of the EMS department and municipal administration have to drive the adoption by legitimating the use of the TRAS in regular operations.

As the decision to adopt the technology is first of all taken on a team level several measures have to be taken to encourage the involvement of paramedics and physicians as primary user groups. The participatory approach is realized through feedback and communicative instruments. By the involvement of users into the development of technical and organizational system components user acceptance is achieved and a common goal comprehension is generated through consequent dialogue. The latter

 ISBN: 978-1-61208-179-3

fosters in combination with extensive training on the job the mindful culture needed to achieve high reliability.

The extent of implementation is defined by the modular character of the TRAS. The gradual introduction of system components reduces the complexity of the implementation. To foster the user involvement regarding the adjustment of the system the TRAS is initially operated within a small team of users or rather by running only one equipped MICU.

As the TRAS is used within a heterogenic flied of applications facing different infrastructural conditions the system is based on a modular architecture facilitating the implementation of approximate solution with rework options.

Furthermore the implementation is relieved by the stepwise extension of the user group. The involvement of selected EMS teams at a first level of the roll-out stimulates the organizational adoption.

The TRAS is implemented as an add-on solution for EMS missions. The parallel running of the traditional and the innovative way of treatment underpin the fall-back character of the tele-EMS physician. The implementation of the TRAS aims at reducing the time period when no EMS physician is available on site.

To reduce the procurement costs the implementation date is matched with the tendering of new MICU by the EMS departments. Considering these favorable opportunities the necessary conversion work is combined with the regular construction of the MICU.

VI. CONCLUSION AND OUTLOOK

The successful use of a TRAS in EMS missions requires an elaborated implementation approach starting already in the first development phase. Implementation research offers several starting point to successful technology introduction, lacking at the same time of practicable models to elaborate an implementation project.

The present paper suggests a methodology to design a context and object oriented implementation strategy. We pointed out the importance of user involvement within the design of organizational and technical aspects of the TRAS to gain the necessary acceptance and finally to reach the organizational adoption. Regarding the here considered use case, the characteristics of an EMS organization as a HRO play a significant role in the choice of implementation instruments. Learning from HRO theories we considered organizational conditions producing high reliability into the technology change strategy.

As information technology is more and more adopted within the healthcare sector research on best practice implementation projects are needed to foster the capacity for innovation also in prehospital healthcare organizations. Current research activities might take into account the importance of planned implementation to achieve marketable technical innovations. Furthermore the scientific discourse on learning from high reliability organizations to design efficient and well-accepted technology changes might radiate on various interdisciplinary research areas.

VII. ACKNOWLEDGMENT

This work was funded by the Ministry of Innovation, Science and Research of the state of North-Rhine Westphalia (NRW). The project TemRas is realized in cooperation with the University Hospital Aachen, Philips HealthCare, P3 communications GmbH, 3M GmbH.
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REFERENCES

[1] M. Protogerakis, A. Gramatke, and K. Henning, "A System Architecture for a Telematic Support System in Emergency Medical Services.", IEEE, Proceedings of The 3rd International Conference on Bioinformatics and Biomedical Engineering, 2009, pp. 1–4.

[2] M. Schneiders, D. Schilberg, and S. Jeschke, A Joint Organizational and Technical Development of a Telematic Rescue Assistance System for German Emergency Medical Services. In: Proceedings of eTELEMED 2011, The Third International Conference on eHealth, Telemedicine, and Social Medicine 2011/ DigitalWorld 2011. Hrsg. v. (c) IARIA: Gosier, Guadeloupe, France, 2011, pp. 150-155.

[3] S. Thelen, M. Schneiders, D. Schilberg, and S. Jeschke, "Modular Software Architecture Approach for a Telematic Rescue Assistance System". In: Proceedings of the IADIS International Conference E-Health 2011. Hrsg. v. Macedo, Mário: Rom, 2011, pp. 201-204.

[4] B. T. Karsh, „Beyond usability: designing effective technology implementation systems to promote patient safety", Quality and Safety in Health Care, vol. 13(5), 2004, pp. 388-94.

[5] C. J. G. Gersick and J. R. Hackman, „Habitual routines in task-performing groups* 1", Organizational behavior and human decision processes, vol. 47(1), 1990, pp. 65-97.

[6] W. J. Orlikowski, „Using technology and constituting structures: A practice lens for studying technology in organizations", Resources, Co-Evolution and Artifacts, 2008, pp. 255-305.

[7] A. C. Edmondson, R. M. Bohmer, and G. P. Pisano, „Disrupted routines: Team learning and new technology implementation in hospitals", Administrative Science Quarterly, 2001, pp. 685-716.

[8] D. Leonard-Barton and I. Deschamps, „Managerial influence in the implementation of new technology", Management Science, 1988, pp. 1252-1265.

[9] T. Kollmann, „Attitude, adoption or acceptance? Measuring the market success of telecommunication and multimedia technology", International Journal of Business Performance Management, vol. 6(2), 2004, pp. 133-152.

[10] K. E. Weick and K. M. Sutcliffe, Managing the unexpected: Assuring high performance in an age of complexity. Jossey-Bass, 2001.

[11] K. E. Weick and T. Putnam, „Organizing for mindfulness", Journal of Management Inquiry, vol. 15(3), 2006, pp. 275-287.

[12] V. D. S. Paulino and M. Callois, „Innovation and reliability strategies in the military, space and semiconductor industries: a comparative analysis". International Journal of Innovation Management (ijim), World Scientific Publishing Co. Pte. Ltd., vol. 14(05), 2010, pp. 795-821.

[13] T. R. La Porte, „High reliability organizations: unlikely, demanding and at risk", Journal of Contingencies and Crisis Management, vol. 4(2), 1996, pp. 60-71.

[14] A. Daniel, „Implementierungsmanagement", Ein anwendungs-orienterter Gestaltungsansatz, Wiesbaden, 2001.

[15] U. Zeyer, Implementierungsmanagement: ein konzeptioneller Ansatz am Beispiel der Implementierung von Lean Management. Hampp, 1996.

[16] P. Y. K. Chau and P. J. H. Hu, „Investigating healthcare professionals' decisions to accept telemedicine technology: an empirical test of competing theories", Information & management, vol 39(4), 2002, pp. 297-311.

[17] R. Katz and T. J. Allen, „Investigating the Not Invented Here (NIH) syndrome: A look at the performance, tenure, and communication patterns of 50 R & D Project Groups", R&D Management, vol. 12(1), 1982, pp. 7-20.

[18] M. Schneiders, M. Protogerakis, and I. Isenhardt, „User acceptance as a key to success for the implementation of a Telematic Support System in German Emergency Medical Services", Automation, Communication and Cybernetics in Science and Engineering 2009/2010, 2011, pp. 563-568.

[19] S. Bergrath, D. Rörtgen, R. Rossaint, S. Beckers, H. Fischermann, J. Brokmann, M. Czaplik, M. Felzen, M. Schneiders, and M. Skorning, „Technical and organisational feasibility of a multifunctional telemedicine system in an emergency medical service – an observational study ", Journal of Telemedicine and Telecare, 2011, in press.

[20] R. Baumgartner and T. Schneeberger, „Generic Management: Unternehmensführung in einem komplexen und dynamischen Umfeld", Duv, 2006.

[21] D. P. Baker, R. Day, and E. Salas, „Teamwork as an Essential Component of High Reliability Organizations", Health Services Research, vol. 41(4) , 2006, pp. 1576-1598.

[22] A. S. Frankel, M. W. Leonard, and C. R. Denham, „Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability", Health Services Research, vol. 41(4), 2006, pp. 1690-1709.

[23] Shortell, S. M, J. Schmittdiel, M. C Wang, R. Li, R. R Gillies, and L. P Casalino „An empirical assessment of high-performing medical groups: results from a national study", Medical care research and Review, vol. 62(4), 2005, pp. 407.

 ISBN: 978-1-61208-179-3

Co-creation with Stakeholders: A Web 2.0 Antibiotic Stewardship Program

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Abstract - **Patient Safety needs a rethinking about medicine due to the aging society, increase in chronic diseases and infections and a decrease in available budget for healthcare. Besides, patients are the driving force behind transparency of healthcare decisions. Participative Medicine supported by technology is promising to innovate medical thinking and workflows. In this paper we discuss a holistic eHealth development approach for participative medicine. We show, using the case of antibiotic stewardship, how participation of stakeholders can be used to co-create a digital platform with applications to support decision–making and collaboration. We demonstrate that participation of stakeholders (healthcare workers, providers, policymakers, management, patients) is needed to co-create eHealth technologies that make sense by being accessible, affordable, applicable, manageable and enjoyable.**

Keywords–eHealth; Antibiotic Stewardship; Holistic Development.

I. INTRODUCTION

Most eHealth interventions are designed and implemented without taking the exact needs of the end-users and other stakeholders into account. This leads to a suboptimal adoption of the interventions and therefore sorts less favorable effects. In the wake of Health 2.0 and Medicine 2.0 initiatives, a growing number of studies have emphasized the importance of a *participatory development* process involving (end-) users, and other stakeholders like payers, decision-makers, insurers, and government officials to increase the uptake of eHealth interventions [1]. To support a participative development process, we introduced a Holistic development guideline, the CeHReS (Centre for eHealth Research and disease management) roadmap [1].

Using this roadmap, we describe the development process of an Antibiotic Stewardship Program (ASP), that is part of Infection Manager, a cross-border Web-based platform for infection management [2]. The platform is available in Dutch, German, English and soon also in French.

The goal of ASPs is to improve antibiotic prescribing and utilization in institutional care settings worldwide. This is an urgent need; it is estimated that around 30%–50% of the antibiotic use in hospitals is unnecessary or inappropriate [3, 4]. A dramatic increase in antibiotic utilization is observed in several studies, resulting in multi-drug resistance among microorganisms and causing treatment complications [5, 6]. At the same time, no new pharmaceutical agents for effective antibiotic therapies are developed (due to high investments costs and long development time). So, antibiotic resistance is a growing threat for patients. This threat increases even more due to the aging society and increase in chronic diseases and infections [7]. Additionally, antibiotic resistance has a substantial economic impact as a consequence of the need for more expensive drugs and longer hospital stays associated with therapy failure [8, 9].

ASPs have been introduced as a solution to overcome the overuse and misuse of antibiotics in hospitals [10]. The focus of these ASPs is to support the prescribing behavior of healthcare workers (HCWs) via diverse interventions aimed at 1) prescribing narrow-spectrum antibiotics instead of broad-spectrum [11], 2) optimizing dose, type, and duration of therapy, 3) education of HCWs to change their behaviour regarding prescribing antibiotics, and 4) guidelines to support decisions.

Some promising results are known of such ASPs, for example, reduction in costs (shorter hospital stays, shorter courses of drugs/therapies) and a decrease in antimicrobial resistance, such as MRSA [12-14]. However, several barriers hinder the effective implementation of ASP-interventions such as a lack of resources knowledge, poor adherence, and lack of management support [12, 15-17].

Academic literature suggests to increase the adoption and implementation of ASP-interventions via a stakeholder-driven development approach and the use of innovative technologies to support decision making (providing support at the right moment, right place, and in the right format) [10]. Like with other eHealth interventions, most of the ASP-interventions are expert-driven rather than taking HCWs' and patients' needs and demands into account [1, 6]. Contrary to what, for example the Centers for Disease Control and Prevention (CDC) recommend, most ASP-interventions are still developed by infection control experts. Stakeholders from various disciplines (pharmacists, physicians, nurses, patients, payers, and government agencies) are scarcely involved and often eHealth specialists are not consulted. We know from prior research that socio-cultural and socio-economic factors and management support are important determinants for successful implementation of medical interventions [18]. By applying the CeHReS roadmap, we show how ASP-interventions can be developed that make sense to all stakeholders and that can overcome the aforementioned barriers.

The aim of the Infection Manager platform is to provide applications for HCWs, managers and other stakeholders to

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improve decision-making and to facilitate knowledge sharing and collaboration. The Infection Manager is a Web-based platform in which we can offer applications for communication, information, and coordination of infection control. The Joomla architecture supports flexible and dynamic development of applications by means of templates and modular expandability.

Based on prior research about the development of a web-based application called MRSA-net [18, 19], we know that HCWs need a layered structure for infection control: *Communication* to consult medical experts and each other, to discuss interventions (forums), and to contact the research and development team of the portal. Modules for *coordination* are used to support the (care) process, for example by offering an infrastructure for information sharing or communication, or by offering tools for monitoring resources and benefits. *Documentation* or information modules refer to the guidelines and protocols that ground the applications and are made available on the platform. Besides we learned from prior research that stakeholders should be involved to create ownership and commitment for adherence to infection control interventions [18, 20]. In this paper we discuss the participatory development with stakeholders, focusing on the development of a Web-based ASP as one of the applications of the Infection Manager by involving stakeholders.

The next section includes a short explanation of the CeHReS roadmap that we have developed [1, 21]. This roadmap was used as a guideline for the development process. In Section III, the research methods that we used for the development of the Infection Manager and the ASP-interventions are described. After that, in Section IV, the research results are described. In the last sections, the results are discussed, and our plans for the operationalization and evaluation of the ASP-interventions are explained.

II. HOLISTIC DEVELOPMENT FOR EHEALTH; THE CEHRES ROADMAP

Internationally, (EU eHealth, European Center for Public Policy) the need has been explicitly emphasized for a holistic and interdisciplinary eHealth approach for durable technological interventions and sustainable innovations in healthcare [22]. A holistic approach would account precisely for the issues of finance, management and the one-sided technology-driven approaches. It constructs a productive fit through the integration of social sciences, engineering and business modelling.

The CeHRes roadmap [1, 21] is developed as an answer to the need for a holistic and interdisciplinary approach. The foundation for the roadmap is based on reviews in the field of eHealth, multidisciplinary theories from social sciences and engineering, business model theories, and empirical research applying the framework [1, 23, 24].

The roadmap serves as a practical guideline to plan, coordinate and execute the participatory development of eHealth technologies. It is meant for developers (for example, technicians, designers, or healthcare professionals), researchers and policy-makers, and also for educational purposes (for example, students and healthcare providers). It also serves as an analytical instrument for decision-making about the use of eHealth technologies.

The roadmap integrates *persuasive technology design*, *Human-Centered Design* and *Business Modelling*. Persuasive and Human-Centered Design are applied to make technologies tailored to stakeholders needs, capacities and capabilities so that behavior change is enhanced. Business Modelling is interwoven with the development of eHealth technologies to foster dialogue and ownership by co-creation and to construct business cases to implement eHealth technologies. We use Business Modelling to assess the needs of all stakeholders and transform these needs into a value-driven implementation by making a business model [25]. The Business Model Canvas, introduced by Osterwalder, acts as a blueprint and can be used to compose a business model [26]. The business model has to ascertain that the technology sustainably reaches its intended goals and effects.

The roadmap consist of 5 cycles; contextual inquiry, value-specification, design, operationalization and evaluation. These cycles are explained in depth elsewhere [1, 21], in this paper we will describe the methods we applied in the first cycles of the roadmap.

III. METHODS

Different methods are used for the development of the infection manager and ASP-interventions.

A. Development of the Infection Manager

To create a starting-point and explore the possibilities of eHealth technology to support infection management, the CeHReS roadmap was applied in a lean and mean way. Hereto, first ideas were researched and explored roughly while creating modules that can be adjusted with iterations later on in the development. The contextual inquiry, value specification and design phase are completed and described below. In the discussion, in Section A, future research activities (operationalization and evaluation phase) are described. Figure 1 shows how the Infection Manager research activities fit into the CeHReS roadmap; the roadmap phases are shown in the blue blocks, and the methods that were applied in each phase are shown below each phase, in orange blocks (Figure 1).

For the contextual inquiry, a quick scan of the literature on antibiotic stewardship was performed. The stakeholders (HCWs, consultant clinical microbiology, hygienists) were selected based on the literature scan and expert validation. The contextual inquiry phase was further combined with the value specification and design phase via interviews. To optimize the understanding of the context and needs as identified in the literature scan, interviews were held with

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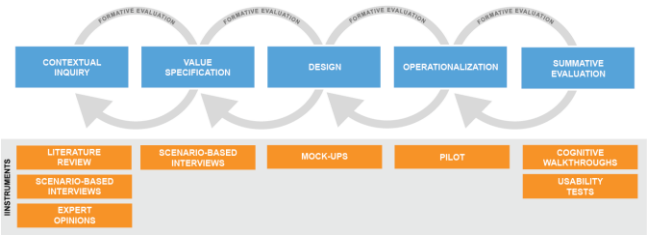

Figure 1. First development process: The Infection Manager

stakeholders (HCWs; physicians, consultants clinical microbiology, hygienists). During these interviews the value specification was performed by inquiring about the need for a layered infection management platform (communication, coordination, documentation). Three different mock-ups, that gave an impression of the possible lay-out and functionalities of the Infection Manager, and a number of scenarios, description of situations in which the Infection Manager could be useful, served as input for the semi-structured interviews. The comments made about the mock-ups served as input for the design process.

B. *Development of the ASP-applications*

The CeHReS roadmap was applied for a second iteration for the development of the ASP applications in the Infection Manager. For the ASP applications, we completed the contextual inquiry and value specification. Figure 2 shows the applied methods in orange blocks below each phase. The remaining roadmap phases (design, operationalization and evaluation) are described in the discussion, in Section A: Future research activities.

In a local hospital three sites were selected, based on the urgency for patient safety and ASP: pulmonary diseases, surgical sites, and urology. In this paper we focus on the research activities carried out at the pulmonary ward. During the contextual inquiry, a literature scan identified the cornerstones for ASP as mentioned in the introduction of this paper. After that, the stakeholders of the ward to be included in the focus group were defined, based on a more in-depth literature scan [27]. The following stakeholders participated in the focus group:

- HCWs (consultants clinical microbiology, pharmacists, chest physicians, residents, nurses)
- Management (nurse manager, general manager, staff member of management)

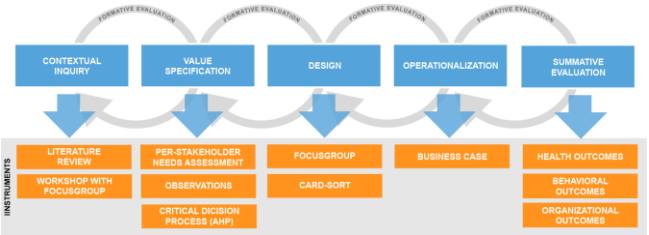

Figure 2. Second development process: ASP applications

In the focus group, the contextual inquiry was completed and value specification was performed. Via assignments and discussion the current workflow and work practices regarding antibiotics and the roles and tasks of the involved stakeholders came to surface. A number of other topics were discussed: the coordination flows and communication involved in the care process regarding antibiotics, problems that are encountered, and potential solutions.

IV. RESULTS

The results of the contextual inquiry, value specification and design phase of the Infection Manager, and the results of the contextual inquiry and value specification of the ASP application are described in the following paragraphs.

A. *Infection Manager Results*

In the interviews, the stakeholders expressed specific needs for communication, coordination and documentation regarding infection management in their work practice. Their preferences indicated a platform with applications, featuring at least functionalities such as document sharing, a forum for collaboration, and useful links to information resources. Also, the three different mock-ups were evaluated and criticized regarding their design. This resulted in a stakeholder preference for a dashboard-style design, with textual and pictorial operating buttons. The results were summarized and were incorporated in the (working) prototype design. Figure 3 shows the current prototype of the Infection Manager. The three rows represent the applications for communication, coordination and documentation. Each button represents a specific application. For example, MRSA-net informs and educates the general public and HCWs about the prevention of MRSA.

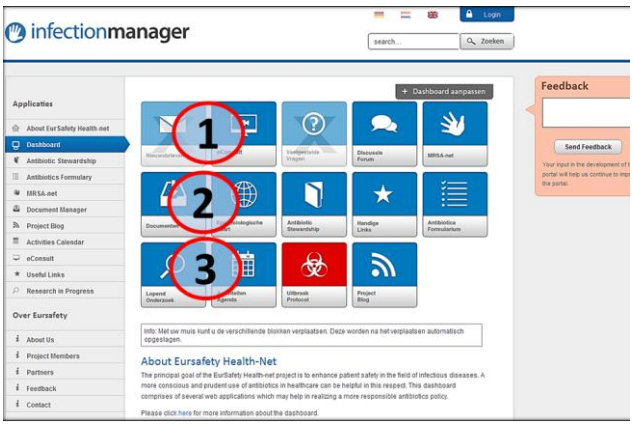

Figure 3. Screenshot of the Infection Manager website
1: applications for communication (e.g., forum); 2: applications for documentation (e.g., document manager); 3: applications for coordination (e.g., calendar)

B. ASP contextual inquiry results

The literature scan suggests that ASPs that are supported by technology, consist of either a single or multiple strategies and can have positive effects, especially on the costs level and appropriate antibiotic use [27-30]. Especially for the hospital management these are interesting effects. Other effects that are also beneficial for the patient are shorter Length-of-Stay or a quicker shift from intravenous to oral antibiotics [30, 31].

The focus group with the stakeholders resulted in more insight into the roles of the different stakeholders, and in an overview of their problems and needs.

1) Defining key-stakeholders

During the focus group, the stakeholders were asked to define their role and tasks in the care process regarding antibiotics. Together, they defined the key-stakeholders as the chest physician, resident, and nurse. On a secondary level, consultants clinical microbiology, pharmacists, infectiologists and other consultants need to be involved. Lastly, management and support staff are not directly involved, but have support and managing roles. According to the participants in the focus group, missing stakeholders in the focus group were an infectiologist, and a dietician. Since they are not the key-stakeholders in antibiotic stewardship, their absence was not considered problematic.

2) Problems with the current use of antibiotics

During the focus group, the stakeholders mentioned several problems regarding their work practice with antibiotics that may threaten patient safety, see Table 1.

Problems refer to the lack of access to information regarding the treatment or the patient status (including test results), or in other words, problems with the patient information flow. Another problem that was mentioned, was insufficient cooperation and consultation between the physician and pharmacists, microbiologists or other consultants, due to insufficient information sharing and unstructured procedures for consultation. Further, insufficient knowledge of (new) procedures or medication application poses a problem.

TABLE I. WORKSHOP RESULTS: PROBLEMS

Problem Category	Problems
Knowledge & Skills	1. Unfamiliarity with guidelines and (new) procedures 2. Inexperienced nurses and residents
Documentation	1. ICT systems for protocols, 2. Reference books are inaccessible and not user-friendly
Patient-information flow	1. Uncertainly regarding prescribed medication (due to prescribing program and transfer of information) 2. Test results are unclear or not findable in the information system 3. Patient data or status inaccessible to consultants 4. Insufficient or no feedback to consultants about the effects of treatment 5. Swabs or screening materials are lost during logistics
Communication, consultation	1. Consultation about patients over the phone is inadequate 2. Consultants lack necessary patient information to give accurate consults
Resources, personnel	1. There is no 24/7 consultant occupation or service 2. Lack of resources and personnel for asp
Coordination, responsibility	1. Overview/coordination of patient care process is sometimes unclear
Commitment, adherence to treatment plans	1. Treatment plans are not always as timely executed as was decided 2. New programs or ICT systems do not receive hospital-wide commitment

3) Stakeholders' Needs

As demonstrated in Table 2, most urgent needs include the key-stakeholders' (chest physician, resident and nurse) wish for more structured cooperation and consultation about antibiotic use in patient care. All stakeholders expressed a need for quick, easily accessible information regarding the patients' former and most recent status, including test results and treatment plans, in other words, better patient-information flows. This way, HCWs are able to act, decide, or give consultations based on complete, up-to-date information. Importantly, the physician and residents are considered to be the main 'hub' in patient-information flows, because they need a good overview and they carry end responsibility. Usability and compatibility of ICT systems with work practice, and better accessible protocols, guidelines or other procedural information are also highly needed by all stakeholders even though they are most relevant to the key-stakeholders.

TABLE II. WORKSHOP RESULTS: NEEDS

Need category	Needs
Knowledge & Skills	1. Increased knowledge exchange among HCWs 2. Adequate instruction & education
Documentation	1. Accessible information regarding medication, guidelines or procedures 2. User-friendly documentation
Patient-information flow	1. Well-arranged patient information sharing and accessibility 2. Structured consultation and feedback 3. Well-organized screening/swab logistics and feedback
Communication, consultation	1. Face-to-face (bed side) microbiology consults 2. Adequate patient information sharing 3. Feedback on treatment effects to consultants
Resources, personnel	1. Nightly and weekend availability of consultants to make policy 2. Management commitment to provide resources
Coordination, responsibility	1. Chest physician has overview of patient care process 2. Need to know who principal consultant is.
Commitment, adherence to treatment plans	1. Hospital wide commitment to new programs 2. Clarity about treatment plans and insight in status of its execution

4) ASP Value Specification

During the workshop, the added values of an ASP were discussed. The stakeholders discussed and agreed on several values that were categorized as follows:

- ASP that is compatible with current ICT systems and work flow and practices (one login with access to all types of information/communication).
- ASP that saves time and procedures that correspond with medical practices (no extra system; no extra work).

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- ASP that is flexible and dynamic, tailored to HCWs and management needs and preferences.
- ASP that is available for HCWs, regardless of time and place, to support decision making (critical points of care).
  - Quality of Care; treatment decisions based on evidence/data.
  - Timeliness; patient receives timely and accurate care.
- ASP that supports cooperation and consultation among HCWs (physician, nurse, consultants).

V. DISCUSSION

The results of the applied methods show that including stakeholders in the development process, renders a holistic view on problems and the accompanying values that need to be taken into account during development. Especially the stakeholder focus group resulted in a holistic view, for both researchers and stakeholders. By discussing stakeholder roles and values in an ASP, a broad understanding among the participants was created and solutions that have a reach beyond their own tasks were discussed. In addition, early in the development process it became clear that a one-fits-all solution in this case (to support infection control and ASP) is almost impossible. However, tailoring and designing with and for specific user-groups can help to fulfill specific needs. Applications should be adjusted for user groups to fit their specific needs and fit in their context. Thus, the technology that is used needs to be modular, because formative evaluations and adjustments to accommodate other user groups (other care facilities or types of HCWs) require easily adaptable applications. We have experienced that the roadmap offers the tools to involve stakeholders in different phases of the design process. The per-application development ensures that different needs can be met. By bundling the applications in the Infection Manager, overview is created and the stakeholders are able to see how the (different) applications could be helpful to them. So in this sense, a one-fits-all solution might still be possible.

A. *Future research activities*

Since the Infection Manager and its applications (including the ASP application) are still under development, the last roadmap cycles need to be completed, future research focuses on the application of these remaining cycles to the Infection Manager and the ASP applications.

1) *Infection Manager Operationalization*

For the Infection manager, a selected user group (project members of EurSafety Health-net) is approached to try-out the Infection Manager. Based on the feedback of these first users, the system will be evaluated formatively and upgraded, so that it better fits the needs of the users. At the same time, the Infection Manager needs to be filled with applications for communication, coordination and documentation. Based on research, applications (such as the ASP applications), will be developed.

2) *Design and operationalization of ASP applications*

The ASP applications will be designed according to the identified problems, needs and values. To accommodate stakeholder needs for education, an ASP education application will be developed. During the literature scan, essential content of such an application was identified, validated by infection control experts and summarized in an ASP guideline (handbook). This ASP education document is currently available in PDF format in the Infection Manager. However, to fit HCW needs regarding structure and content, the guideline will be translated into a web-based, more interactive version via a *card sort* study.

Further, an application will be designed to support prescribing behavior through information sharing and consultation regarding *dose*, *duration* and *type* of antibiotics. This application is an important start in view of the stakeholders (experts, management) to support HCWs and show the potentials of ASPs in order to increase commitment of HCWs to an ASP, to foster ownership and to clarify responsibilities. Thus, this application supports the coordination of care. The content of the application will be expert-driven, and via interviews and/or a focus group functional requirements for the design will be determined with the key-stakeholders. After field-testing and final adjustments the application will be ready for use.

Besides education about ASP, HCWs expressed a need for *interactive information or communication* about procedures or specific cases regarding ASP. An application will be designed together with HCWs to increase the access and usability of information. The precise content and functionalities will be determined by studying current work-processes via a focus group and field observations. The resulting topics (of ASP related information) will be prioritized by HCWs via a critical decision system, the Analytic Hierarchy Process [32]. Lastly, the application's content will be organized using methods such as card sorts, as this approach has proven to be useful in the development of MRSA-net; a web-tool for practical information based on medical protocols [18]. The design is further established by using mock-ups and usability tests.

To facilitate decision making, the effects of the ASP applications are evaluated and will be made available to the necessary stakeholders via a *communication* system to enable discussion among key-stakeholders and to support decision making.

3) *Infection Manager Business Model*

Meanwhile, a business model will be developed for the implementation of the Infection Manager and its applications. Preparing the implementation of an eHealth intervention such as the Infection Manager should start as early as possible in the development. Many eHealth interventions fall short as the attention for the implementation starts too late, usually ex post development [24]. Therefore, already in the contextual inquiry the problems are defined and the stakeholder network is made. In the value specification the values are determined, and in the design phase, implementation scenarios are developed with stakeholders. In the operationalization phase, the business model is really put to effect. In this stage, the

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business model and technology have become concrete enough to detail out the implementation and introduce the technology into practice. Currently, we are forming business models on a per-application basis to find sustainability for these applications, as well as a business model for the Infection Manager as a whole. Thus, we investigate how we can offer the Infection Manager to various stakeholders in a cross-border setting.

4) Evaluation

To assess the benefits of the ASP we will measure the effects using a combination of qualitative and quantitative instruments. Which effects are to be measured will be determined by the results of a systematic review that is currently being carried out to find all clinical and financial effects of ASP, and the methods used to measure this. The review outcomes will be used for the evaluations of the Infection Manager and ASP. A formative evaluation will be carried out continuously to get insights in the accessibility, applicability, and usefulness of the Infection Manager and its applications. We will use standard usability methods for prototyping and evaluations [33].

VI. CONCLUSION

In this paper, we have discussed how an eHealth technology can be developed with involvement of various stakeholders using a holistic approach. The first two ASP-applications (for guideline communication and prescribing behavior) will be available in December 2011. Future research involves the development of the applications for education and evaluation. The development procedure will be carried out simultaneously in other wards (urology, surgery) of Dutch and German border region hospitals.

ACKNOWLEDGMENT

We would like to thank the pilot hospital for supporting and cooperating in our research. Especially we want to thank the stakeholders for their engagement.

REFERENCES

[1] Gemert-Pijnen, J.v., N. Nijland, H. Ossebaard, A. Limburg, S. Kelders, G. Eysenbach, et al., "A holistic framework to improve the uptake and impact of eHealth technologies," Journal of Medical Internet Research, In Press. DOI:10.2196/jmir.1672,

[2] Infection Manager. www.infectionmanager.com, accessed on 22 November 2011.

[3] Hecker, M.T., D.C. Aron, N.P. Patel, M.K. Lehmann, and C.J. Donskey, "Unnecessary Use of Antimicrobials in Hospitalized Patients: Current Patterns of Misuse With an Emphasis on the Antianaerobic Spectrum of Activity," Archives of Internal Medicine, 163(8), 2003, pp. 972-978.

[4] Owens Jr, R.C. and P.G. Ambrose, "Antimicrobial stewardship and the role of pharmacokinetics–pharmacodynamics in the modern antibiotic era," Diagnostic Microbiology and Infectious Disease, 57(3), 2007, pp. S77-S83.

[5] Kaki, R., M. Elligsen, S. Walker, A. Simor, L. Palmay, and N. Daneman, "Impact of antimicrobial stewardship in critical care: a systematic review," Journal of Antimicrobial Chemotherapy, 66(6), 2011, pp. 1223-1230.

[6] Hulscher, M.E.J.L., R.P.T.M. Grol, and J.W.M. van der Meer, "Antibiotic prescribing in hospitals: a social and behavioural scientific approach," The Lancet Infectious Diseases, 10(3), 2010, pp. 167-175.

[7] Yoshikawa, T.T., "Antimicrobial Resistance and Aging: Beginning of the End of the Antibiotic Era?," Journal of the American Geriatrics Society, 50, 2002. pp. 226-229.

[8] Lesprit, P., L. Merabet, J. Fernandez, P. Legrand, and C. Brun-Buisson, "Improving antibiotic use in the hospital: Focusing on positive blood cultures is an effective option," La Presse Médicale, 40(6), 2011, pp. e297-e303.

[9] McGowan Jr, J.E., "Economic impact of antimicrobial resistance,' Emerging Infectious Diseases, 7(2), 2001, pp. 286-292.

[10] MacDougall, C. and R. Polk, "Antimicrobial stewardship programs in health care systems," Clinical Microbiology Reviews, 18(4), 2005, pp. 638.

[11] Frank, U., "Antibiotika am Krankenbett," 15th ed., 2010, Berlin Heidelberg: Springer Verlag.

[12] Hersh, A., S. Beekmann, P. Polgreen, T. Zaoutis, and J. Newland, "Antimicrobial Stewardship Programs in Pediatrics," Infection Control and Hospital Epidemiology, 30(12), 2009, pp. 1211-1217.

[13] Liebowitz, L. and M. Blunt, "Modification in prescribing practices for third-generation cephalosporins and ciprofloxacin is associated with a reduction in meticillin-resistant Staphylococcus aureus bacteraemia rate," Journal of Hospital Infection, 69(4), 2008, pp. 328-336.

[14] Nicastri, E., S. Leone, N. Petrosillo, M. Ballardini, C. Pisanelli, P. Magrini, et al., "Decrease of methicillin resistant Staphylococcus aureus prevalence after introduction of a surgical antibiotic prophylaxis protocol in an Italian hospital," New Microbiologica, 2008. 31(4), pp. 519-525.

[15] Hersh, A.L., M.D. Cabana, R. Gonzales, B.N. Shenkin, and C.S. Cho, "Pediatricians' perspectives on the impact of MRSA in primary care: A qualitative study," BMC Pediatrics, 9(1), 2009, doi:10.1186/1471-2431-9-27.

[16] Gurses, A., J. Marsteller, A. Ozok, Y. Xiao, S. Owens, and P. Pronovost, "Using an interdisciplinary approach to identify factors that affect clinicians' compliance with evidence-based guidelines," Critical Care Medicine, 38(8), 2010, pp. S282-S291.

[17] Grimshaw, J., R. Thomas, G. MacLennan, C. Fraser, C. Ramsay, L. Vale, et al., "Effectiveness and efficiency of guideline dissemination and implementation strategies," International Journal of Technology Assessment in Health Care, 21(01), 2005, pp. 149-149.

[18] Verhoeven, F., "When staff handle staph: user-driven versus expert-driven communication of infection control guidelines," dissertation, 2009, Enschede: University of Twente.

[19] Wentzel, J., J. Karreman, and J.v. Gemert-Pijnen, "Towards an Internet-based Infectious Disease Management Platform to Increase Patient Safety," proc. eTELEMED conference, 2011, IARIA: Gosier, Guadeloupe, France. pp. 47-50.

[20] Van Gemert-Pijnen, J, J. Karreman, S. Vonderhorst, F. Verhoeven, and J. Wentzel, "Participatory development via user-involvement: A case study about the development of a web-based patient-communication system about Methicillin-resistant Staphylococcus aureus," Electronic Journal of Health Informatics, In Press.

[21] Van Limburg, A.H.M and Van Gemert-Pijnen, J., "Introducing eHealth business modelling instruments for implementing eHealth technologies based on an integrated approach with human-centered design," proc. eTELEMED conference, 2011, IARIA: Gosier, Guadeloupe, France, pp.134 -139.

 ISBN: 978-1-61208-179-3

[22] European Health Telematics Association, "Sustainable Telemedicine: paradigms for future-proof healthcare," 2008, EHTEL: Brussels.

[23] Black, A.D., J. Car, C. Pagliari, C. Anandan, K. Cresswell, T. Bokun, et al., "The Impact of eHealth on the Quality and Safety of Health Care: A Systematic Overview," PLoS Med, 8(1), 2011, pp. e1000387.

[24] Nijland, N., "Grounding eHealth: towards a holistic framework for sustainable eHealth technologies," dissertation, 2011, University of Twente: Enschede.

[25] Van Limburg M., van Gemert-Pijnen J.E., Nijland N., Ossebaard H.C., Hendrix R.M.G., and Seydel E.R., "Why Business Modelling is crucial in the development of eHealth technologies," Journal of Medical Internet Researdh, Accepted Pending Revision.

[26] Osterwalder, A., Y. Pigneur, and C. Tucci, "Clarifying business models: origins, present, and future of the concept," Communications of the Association for Information Systems, 16(1), 2005, pp. 1-25.

[27] Ewering, S., "Integrating stakeholders in the development of an Antibiotic Stewardship Program," Bachelor Thesis. Faculty of Behavioural Sciences, 2011, University of Twente: Enschede.

[28] Agwu, A.L., C.K.K. Lee, S.K. Jain, K.L. Murray, J. Topolski, R.E. Miller, et al., "A world wide web-based antimicrobial stewardship program improves efficiency, communication, and user satisfaction and reduces cost in a tertiary care pediatric medical center," Clinical Infectious Diseases, 47(6), 2008, pp. 747-753.

[29] Bassetti, M., A. Di Biagio, B. Rebesco, G. Cenderello, M.E. Amalfitano, and D. Bassetti, "Impact of an antimicrobial formulary and restriction policy in the largest hospital in Italy," International Journal of Antimicrobial Agents, 16(3), 2000, pp. 295-299.

[30] Fine, M.J., R.A. Stone, J.R. Lave, L.J. Hough, D.S. Obrosky, M.K. Mor, et al., "Implementation of an evidence-based guideline to reduce duration of intravenous antibiotic therapy and length of stay for patients hospitalized with community-acquired pneumonia: a randomized controlled trial," American Journal of Medicine, 115(5), 2003, pp. 343-351.

[31] Camins, B., M. King, J. Wells, H. Googe, M. Patel, E. Kourbatova, et al., "The Impact of an Antimicrobial Utilization Program on Antimicrobial Use at a Large Teaching Hospital: A Randomized Controlled Trial," Infection Control and Hospital Epidemiology, 30(10), 2009, pp. 931-938.

[32] Saaty, T., "How to make a decision: The Analytic Hierarchy Process," European Journal of Operational Research, 48(1), 1990, pp. 9-26.

[33] Nielsen, J., "Usability Engineering," 1993, San Francisco: Morgan Kaufmann.

 ISBN: 978-1-61208-179-3

Personalized Motivation in Dementia Management through Detection of Behavior Patterns

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***Abstract*— Dementia is one of the most common diseases in elderly people. Many people with dementia eventually become totally dependent on others for their care. With proper treatment, symptoms of dementia can be significantly reduced and stabilized. A successful treatment depends on recognizing which symptoms person experiences, making a careful evaluation, and identifying possible causes and methods to treat. Nursing Homes usually host a considerable number of people with dementia. To detect the disease in early stages may allow work on the development of mechanisms to reduce the cognitive impairment. The personalized motivation may help to adapt the patient environment, allowing adequate stimulating events, providing an opportunity for physical and psychosocial activity. The requirement is to study the behavior of patients in order to detect conduct disorders in their routines. This study presents a behavior pattern detection architecture based on the Ambient Assisted Living paradigm, and Process Mining technology allowing re-learning mechanisms in dementia disorders.**

Keywords-Dementia; eHealth; Monitoring; Motivation; Cognitive enhancement.

I. INTRODUCTION

Nowadays, dementia is one of the most devastating diseases of the elderly, causing a progressive decline of physical and mental functioning. International official organisms estimate that there are currently 30 million people with dementia in the world, adding about 5 million new cases annually. Detailed population-based studies of prevalence of dementia estimate that number of people affected will be over 100 million by year 2050, in different world regions [1]. People with dementia experience forgetfulness, depression, disorientation and confusion, becoming unable to plan and organize activities, even simple everyday tasks. Dementia is a loss of brain function [2]. The decline of memory, as well as other problems with language, decision-making ability, the capacity to discern and personality are necessary aspects for diagnosis. Symptoms of dementia include difficulty with many areas of mental function, such as language, memory, perception, emotional behavior, and cognitive skills [2].

It is estimated that 30-40% of people with dementia living alone at the time of diagnosis [2]. From that moment there is an increase in dependency, an increase in the risk of serious accidents, and difficulties to follow a proper treatment for the disease. To stop the advance of the dementia in elderly people it is needed to perform an individual comprehensive monitoring of the person. On one hand this allows detecting the dementia presence in early stages, and on the other hand, permits the evaluation of the state of the patient illness. Early identification of motor and cognitive changes, characterizing the beginning of this disease, may improve the therapeutic treatment and planning changes in lifestyle resulting [3].

The deployment of this kind of individual monitoring of patients is very demanding and requires the use of intelligent environments based in paradigms like Ambient Assisted Living (AAL) [4]. The use of advanced sensors, capable of detecting and monitoring the movement in people with cognitive impairment, allows collecting relevant data on the overall activity of the person. The results of studies show that the time a patient with Mild Cognitive Impairment spent to travel a given distance is greater than that used by healthy people. In addition, elder patients with cognitive impairment have a greater variation in the proper conduct of their daily activities [3].

There are multiple techniques for unobtrusively monitoring naturally occurring computer interactions to detect sustained changes in cognitive performance. Researchers have shown the importance of the early detection of cognitive decline. That detection is associated to a gently behavior change on the user. In this way subtle changes on the patient's behavior might suppose the presence of dementia illness in an early stage. The detection of these kinds of behavior changes has been approached using Process Mining techniques [5]. This approach is based on the inference of a basic workflow based model of the user behavior, and to compare that model with posterior behavior models of the same user. Differences among models show the behavior changes and, finally, will help the detection of dementia. An early detection allows for more effective clinical intervention, working on algorithms for inferring a user's cognitive performance using monitoring data from computer games and psychomotor measurements [6]. The research methodology of eMotiva Project is being tested into a Nursing Home, primarily focuses on detection of behavior patterns in dementia patients, besides engage in a cognitive, physical and language rehabilitation. The integrated cognitive stimulation program is a treatment of cognitive impairment aimed at maintaining and enhancing several cognitive processes affected by dementia [5] [7].

 ISBN: 978-1-61208-179-3

Current best practices in care of elderly are based on comprehensive approaches that include actions, such as the stimulation and maintenance of cognitive processes. It has been shown that stimulation of ongoing cognitive activity can decelerate the degenerative process involving the diseases associated with dementia [8]. The modern society has experienced a rapid growth in the use of computers by elders. E-mail, Web browsing, computer games etc. are among the most common routine activities for this group of users. This work is developed in the framework of the National Spanish Project eMotiva. A pilot study is being carried out, relating the National Association of Physicians in Nursing Homes (SEMER).

The paper presents the implementation of an active integral system of monitoring and motivation for dementia patients. The execution of the monitoring subsystem is based on recognizing patterns in time series, while the personalized motivation is based on computer technologies motivation.

The research objective is to promote social inclusion as a therapeutic method, using digital content in response to behavior disorders. The purpose is the integration and deployment of the infrastructure for monitoring and encouraging people with dementia in a nursing home environment. The aim is the stimulation, reinforcement and maintenance of those cognitive processes affected by dementia.

Evaluation results regarding usability and improvement on the dementia management are being gathered by pilots in focus group in a Nursing Home in Valencia (Spain).

The following sections explain, in the first instance, the main objects that the project aims to obtain with their execution, as well as the methodology employed to the investigation development. In the following section, the eMotiva platform is explained, including a succinct description of the ongoing technology being used for detecting behavior patterns of patients. After that, the ongoing work in Nursing Home environment is explained, detailing the progress and achievements with the intervention, in the sense of utility and functionality of the platform. Finally, a discussion about main contributions of the project is presented, enclosed to outcomes.

II. MOTIVATION AND OBJECTIVES

There is no known cure for dementia. It is a disease that reveals how language skills disorders deprive people of their basic skills to be beings with feelings, thoughts and expression. Dementia patients require constant attention, because there is a serious loss of cognitive function, and gradually worsen over time, affecting memory, thinking and behavior [9].

Each incidence of the Dementia has two victims: the person with the disease and the caregiver. Caregivers are faced with the meaning of mind and dependence on the Dementia patient [10].

The main objective of the research is to create a tool that facilitates the association between health-care professionals and elder people with cognitive impairment caused by diseases associated with dementia, to provide them with personal and social benefits, encouraging inclusion social and therapeutic method through the use of digital content. The purpose of the research presented is to improve the daily environment of people with dementia, those who come daily or live permanently in residential institutions. The implementation of system has represented the creation of smart spaces based on the paradigm of Ambient Intelligence.

The research team work on spaces with wireless sensors and pattern recognition algorithms, also computational tools of motivation with multimedia content, which make possible the detection of patterns and the generation of integrated actions based on motivation for a correct treatment. This system supports residencies for physicians can design their own models of motivation, and to provide new models to detect behavior patterns. In this sense, the physician becomes self-sufficient in configuring the system, improving sustainability. Wireless sensor infrastructure is done through advanced radio interfaces and high energy efficiency, based on the wireless communications network *Zigbee* [11], providing complex network connectivity (scalable and configurable).

The applied methodology that is being used is goal-oriented and carried out in different stages described below:

- Development and application of intelligent tools for analyzing, designing and detect patterns in people with dementia.
- Creation of innovative multimedia motivational tools, a set of serious games, which make possible influencing attitudes and subsequent behavior of people with dementia, in order to improve or alleviate their degenerative process.
- Creation of a network infrastructure of sensors and actuators, radio interfaces using low energy to facilitate the interconnection of monitoring and motivation devices.
- Creation of a Smart Environment to monitor people with dementia in institutional residence. Implementation of the system with the tools developed in several pilots in a residence associated to the Spanish Association of Physicians in Nursing Homes (SEMER).

The interesting aspect about this platform is the motivation that occurs in people who are indisposed to move and train. Each physical and cognitive game presents a challenge and an attempt to improve day by day. It is important to focus on those games where people interact with self movement, recreations where the user moves and works against sedentary activity. The wireless controller that is used in games is able to detect motion and rotation in three-dimensional space. There is a significant increase in physical activity and, as a therapeutic tool, games help improving motor skills. The wireless controllers stimulate different motor skills and likewise help improving coordination and reflex.

From the psychosocial point of view, there is the conviction that human factors (attitudes, attention, motivation, memory, etc.) affect the interaction with computers. Regarding to social interaction, the use of this type of technologies promotes learning process, reflection

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and cognitive changes [12]. Moreover, video games are presented as elements that promote motivation, being playful. Video games generate emotions and cause effects on emotional interaction of people. The general atmosphere of the games developed (nice and visually pleasing relaxing landscapes) creates a climate of tranquility and animosity. The purpose is to manage in a properly way the cognitive impairment, to maintain or enhance cognitive aspects such as orientation, memory, different visual-spatial and executive abilities, or language.

The emotional aspects become central, considering the first-person games have the potential to induce emotions in the players. People may be emotionally involved with what happens on the screen, which increases their motivation to perform the task, developing a sense of immersion, in other words, a direct participation in a world of objects. Emotions represent an important part of motor learning, a way of reinforcement or avoidance certain behaviors [13]. They produce a significant motivation, helping prevent apathy, inactivity or passivity.

The games aim to raise enough motivation so users feel connected to their internal dynamic, which includes a playful and entertaining feature, besides a high value of perceptual stimulation and the incorporation of progressive and gradual levels of difficulty, encouraging the motivation.

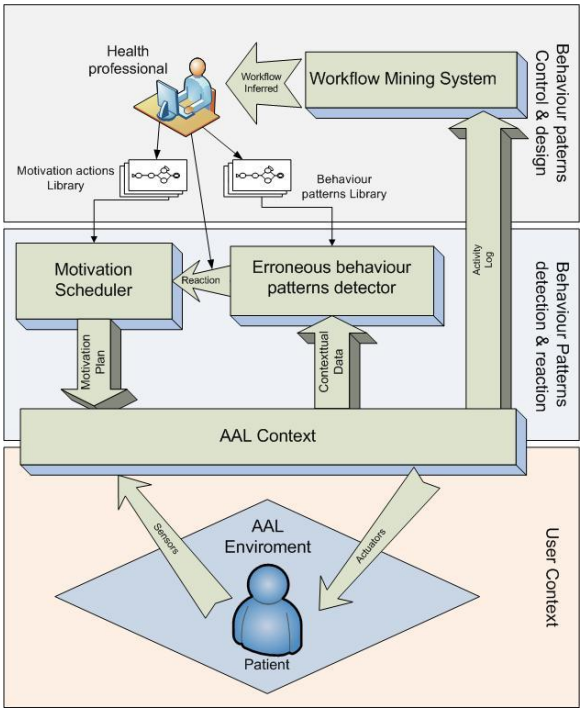

Figure 1. eMotiva Architecture

III. EMOTIVA PLATFORM

The project presented aims to create an intelligent environment to monitor people in nursing homes. The aim is to help staff Nursing Homes through the use of serious games to alleviate the cognitive decline in dementia patients, a sensing system to monitor the activity of residents, and a support system to detect anomalous behavior in patients (events), providing reasons and solutions to help to correct those behaviors.

Figure1 shows the eMotiva architecture. This architecture is mainly composed by three layers: the user context layer, the behavior patterns detection and reaction layer, and the behavior patterns design and control layer.

- The user context layer is in charge of keeping a continuously actualized picture of the user data. This layer has the similar function that the AAL context. This layer is composed by the sensors, and the actuators that are in touch with the users. The sensors gather the raw information of the user, which is stored in the context layer. The data gathered by that layer is used by the rest of modules to perform intelligent individualized user behavior detection. The monitoring and motivation platform is deployed by using a choreography paradigm [14]. All the sensors and actuators are connected as services to a choreographer, and the choreographer allows the communication among the services installed. In that architecture is possible to make service composition using workflow technology. Thanks to that, it is possible to preprogrammed motivation workflows that can be described by the professionals. Professionals can use workflow technology to predefine motivation sessions. In eMotiva, a workflow engine based on Timed Parallel Automatons (TPA) [15] was created in order to allow professionals the composition of services to perform the convenient games according to the individual used needs.

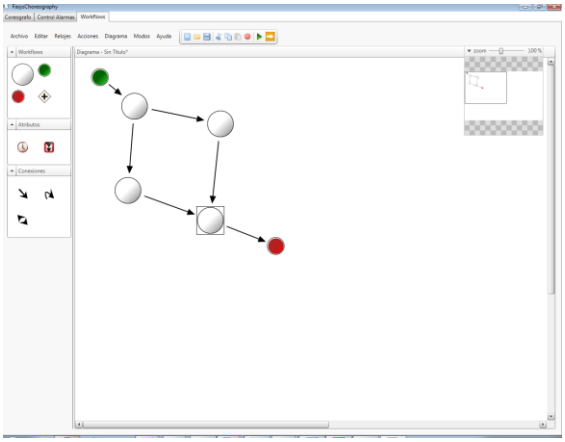

Figure 2. Screen capture of the workflow design tool is shown

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- The behavior patterns detection and reaction layer is able to react to anomalous behavior patterns to individuals. This layer is compounded by the erroneous behavior patterns detector and the motivation scheduler modules. The erroneous behavior patterns detector module is able to detect anomalous behaviors of individuals that must be corrected. This module is based on Artificial Intelligence technologies to allow the detection of those patterns. This quick reaction layer uses a rule engine to detect specific situations preprogrammed by health professionals, to detect specific situations. For example, that module is able to detect the presence of patient in prohibited spaces like the kitchen, or patient that is too much time in bathroom. In addition to this, an algorithm that allows comparison of workflows describing behavior patterns with the real actions performed by patients was implemented. This algorithm, called WIAA (Workflow Instance Aceptor Algorithm), shows how the flow of the current actions of the subject fits with the expected flow. In case of differences, these are highlighted. The result of the algorithm can be shown to health professional in a graphical way.

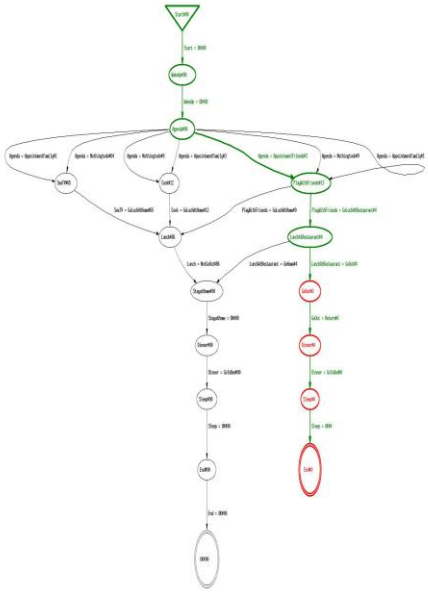

Figure 3. Screen capture of the Comparison of a workflow inferred by PALIA and compared with an execution instance Using WIAA

- The behavior patterns design and control layer is in charge of providing knowledge about how the plans are executed in the Nursing Homes, helping health professionals to evaluate the behavior evolution of patients. This layer is compounded by Workflow Mining System that is able to present graphically the activities flow of the user actions to health professional. The core of the Workflow Mining System is based on PALIA Algorithm [16]. This algorithm is able to infer workflows from the user activity logs and present it to health professionals. Using this graphical information, the health professionals could individually detect erroneous behavior patterns of the user and provide corrective motivation protocols.

  The wide variety in human behavior makes difficult to detect dementia symptoms with a static view of the subject flow. In this way, a workflow representing the usual flow of the user behavior is not conclusive. Hence, the Workflow Mining System is able to provide a comparative view of the user activities at different stages.

  Figure 3 shows an example of workflow inferred by PALIA Algorithm compared with an execution instance using WIAA algorithm. The green states represent the states that the instance has visited. And the red ones are those that are not foreseen by the original workflow.

As it was mentioned previously, the eMotiva Choreographer is in charge to allow the interconnection of the different services installed in the system. The choreographer dispatches the messages among the modules using a specific XML message protocol called XMSG, based on the combination of FIPA [19] and SOAP [20] protocols. There are Java, DotNet and Android choreographer versions that can interchange messages, to allow the interconnection among services programmed in different platforms. In figure 4, a graphical view of the choreographer is shown

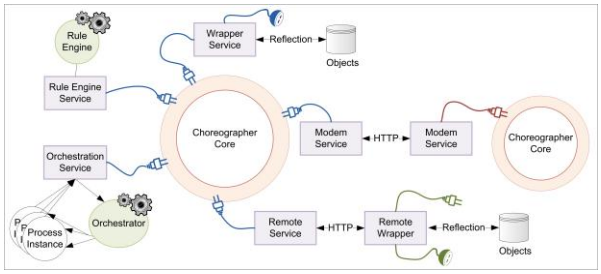

Figure 4. Choreographer Architecture

The choreographer has some facilities to allow a better communication of services. There are TCP and Message Queue Connectors that allow interconnect different choreographers among themselves, rule Engine Services and configuration services that allows starting

and stopping individually services without to re-start the choreographer.

IV. MOTIVATION RESULTS

The introduction of new techniques for detection of particular behaviors in patients with cognitive impairment, and the introduction of a system to propose appropriate activities to correct the behavior or detect the cause of its origin are useful for professionals in Nursing Homes. To measure the eMotiva system acceptance by professionals of the Nursing Home, a methodology based on TAM (Technology Acceptance Model) [17], it is completing a questionnaire to gather opinions about the usefulness and simplicity of use perceived by users. At this stage of research, according to the initial proposal, it has achieved the integration and deployment of the necessary infrastructure for monitoring and motivation of patients in Nursing Home. The current infrastructure is detecting behavior patterns, and providing mechanisms for personal motivation. The research team is working on stimulation, reinforcement and maintenance of cognitive processes.

Motivational tools are being implemented in order to influence the attitude or behavior of people with dementia, to mitigate and slow the degenerative process. According to this, it has been crucial to find out what would be more interesting activities to reinforce certain conditions. A series of in-depth interviews [18] with medical and health professionals in Nursing Homes were done. They had asked about the admission procedures of patients, a description of their routine activities, interaction with caregivers, the main symptoms and behaviors found in a state of mild dementia, the methods developed by physicians to detect anomalous behavior in patients, types of intervention, the perceived relevance, as professionals, towards motivation, and the physical and psychological benefits the games can report. Interviews results contributed to the proper planning of the technical and psycho-sociological intervention.

In-depth interviews were accompanied by other qualitative research technique, participant observation, the basic method by which the social scientist obtains information about some aspect of the world. It allows finding and studying certain behaviors described in the exact moment they are happening [18]. Participant observation was done at Nursing Home, allowing the patients to share their background, experience and everyday life, meet directly with all information apprehended by patients about their own reality. It was important to get people their definitions of reality and the contacts with which they organize their world. Dementia patients were observed during the sessions, interacting with them and participating in their activities, in order to they were comfortable and relaxed, without changes in their routine and common behavior.

A network of sensors and actuators has been installed, using low power radio interfaces, which facilitate the interconnection of monitoring devices and motivation. It is interesting to contribute ideas to develop with location sensors, and to study their utilities.

Regarding the serious games developed, there is a brief description of them, aiming their main benefits. The first game is based on a graphical model as realistic as possible to allow the user to immerse themselves in a delightful environment, interacting with it. The user moves and works against a sedentary lifestyle. Wireless controllers detect motion in a space of three dimensions. There is an increase in physical activity, enabling improved motor skills. The wireless controllers stimulate different motor skills.

In the following package of games, patients work with touch screen, allowing interaction between the user and screen in a simple way. The games enhance the psycho-motor capabilities and several cognitive processes. They aim to raise enough motivation so that users feel connected to their internal dynamics, which includes a playful and entertaining feature, with a high value of auditory and visual stimulation, incorporating difficulty levels that encourage the patient to improve and keep learning.

Finally, a set of games have been developed to enhance cognitive processes such as perception, memory, attention, language and emotions. Players must answer a series of general knowledge questions, adapted to their particular condition, and also to associate a set of images and sounds to known events of their lives. These serious games are also played with touch screen, encouraging the patient to interact with user-friendly new elements, as the touch technologies are. The newness represent a relevant element of motivation for people, although in the case of patients with dementia may become an obstacle, due to fear of the unknown, not understanding things correctly, the incomprehension of a new task. The eMotiva Project has the challenge of overcoming these obstacles, showing high profits and earnings of ICT in all social groups, in this concrete case study, in people with dementia, helping to improve their treatment and quality of life.

V. CONCLUSIONS AND DISCUSSION

Dementia is the most destructive disease of the elderly. It leads to a progressive decline of mental functioning, experiencing lack of memory, depression, confusion, or inability to plan and organize activities, even simple everyday tasks. Dementia illness can be detected and treated in early stages finding behavior disorders in people. This requires an individualized and appropriate human behavior modeling. The eMotiva Project is designed at motivating and monitoring of Dementia patients in Nursing Homes. The aim is to promote social inclusion as a therapeutic method by the use of digital content in response to behavior disorders.

Mild Cognitive Impairment (MCI) is the stage between normal forgetfulness due to aging and the development of some type of dementia. People with cognitive impairment have mild problems with thinking and memory that does not interfere with daily activities. The purpose of eMotiva Project is to provide tools for the detection and study of patterns of behavior associated with the disease, as well as a

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set of tools to help alleviate the degenerative process, reinforcing the fundamental cognitive aspects.

Symptoms of Mild Cognitive Impairment include, for example, forgetting recent events or conversations, difficulty performs more than one task at a time, difficulty solving problems, or take longer to perform more difficult mental activities. The monitoring and motivation strategies developed are currently working on these points, and waiting for complete data collection, there is significant progress in meeting the objectives. The psychosocial intervention, the methods of motivation and reinforcement of physical and cognitive processes damaged by dementia are intended to provide benefits, such as the following: Speech problems such as difficulty finding the name of familiar objects, misplaced items, lost on familiar routes, changes in personality and loss of social skills, to lose interest in things previously enjoyed, flat mood, learning new information or routines, forgetting events in their life, difficulty reading or writing, wrong use of words, deficient understanding of language, withdrawing from social contact, difficulty in performing basic tasks and recognizing family members. This platform is being tested in the National eMotiva Project, aiming to reveal the validity and acceptance of a personalized computerized support system for treatment of dementia disease.

ACKNOWLEDGMENT

The authors want to acknowledge Spanish Government, eMotiva Project (TSI-020110-2009-219) partners, Health Institute Carlos III through the retics combiomed (RD07/0067/2001), and Programa Torres Quevedo from Ministerio de Educación y Ciencia, co-founded by the European Social Fundation (PTQ05-02-03386) for their support.

REFERENCES

[1] Alzheimer´s Disease International www.alz.co.uk/adi/pdf/prevalence.pdf Retrieved: september, 2011

[2] E. Krishnamoorthy, M. Prince, and J. Cummings (Ed.) 2010, Dementia: A global approach. New York: Cambridge University Press

[3] T. Hayes, F. Abendroth, A. Adami, M. Pavel, T.A. Zitzelberger, and J.A. Kaye, 2008. Unobtrusive assessment of activity patterns associated with Mild Cognitive Impairment. Alzheimer's and Dementia 4(6): 395–405

[4] H. Steg, H. Strese, J. Hull, and S. Schmidt, 2005. Europe is facing a demographic challenge. Ambient assisted living offers solutions. Technical report, European Commission (Contract No. 004217)

[5] C. Fernández-Llatas, J.M. Garcia-Gomez, J. Vicente, J.C. Naranjo, M. Robles, J.M. Benedí, and V. Traver, 2011. Behaviour patterns detection for persuasive design in Nursing Homes to help dementia patients. 33nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society 2011. Forthcoming

[6] H. Jimison, M. Pavel, J. McKanna, and J. Pavel, 2004. Unobtrusive monitoring of computer interactions to detect cognitive status in elders. IEEE Transactions on Information Technology in Biomedicine 8(3): 248–252

[7] S. Chatterjee, and A. Price, 2009. Healthy living with persuasive technologies: framework, issues and challenges. Journal of American. Medical Informatics Assocciation, 16(2):171-178, 2009

[8] L. Clare, and R.T. Woods, 2004. Cognitive training and cognitive rehabilitation for people with early-stage Alzheimer's disease: a review. Neuropsychological Rehabilitation, 14, 385–401.

[9] N. Aggarwal, A.A. Vass, H.A. Minardi et al., 2003. People with dementia and their relatives: personal experiences of Alzheimer's and of the provision of care. Journal of Psychiatric and Mental Health Nursing, 10, 187–197.

[10] A. Rosen, and E.K. Proctor (eds.) 2003. Developing Practice Guidelines for Social Work Interventions: Issues, Methods and Research Agenda. New York: Columbia. University Press

[11] A. Elahi, and A. Gschwender, 2009. ZigBee Wireless Sensor and Control Network. New York: Prentice Hall

[12] J. Rosen, B.H. Mulsant, M. Kollar et al., 2002. Mental health training for nursing home staff using computer-based interactive video: a 6-month randomized trial. Journal of the American Medical Directors Association, 3,291-296

[13] M. Knapp, L. Thorgrimsen, A. Patel et al., 2006. Cognitive stimulation therapy for people with dementia: cost-effective analysis. The British Journal of Psychiatry, 188, 574-580

[14] C. Fernández-Llatas, J.B. Mocholí, P. Sala, J.C. Naranjo, S.F. Pileggi, S. Guillén, and V. Traver, 2011. Ambient Assisted Living Spaces Validation by Services and Devices Simulation 33nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBC2011. Forthcoming

[15] C. Fernández-Llatas, S.F. Pileggi, V. Traver, and J.M. Benedí, 2011. Timed Parallel Automaton: a Mathematical Tool for Defining Highly Expressive Formal Workflows Asia Modelling Symposium AMS 2011. Forthcoming

[16] C. Fernández-Llatas, T. Meneu, J.M. Benedí, and V. Traver, 2010. Activity-Based Process Mining for Clinical Pathways Computer Aided Design 32nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society 2010. Forthcoming

[17] A.K. Yarbrough, and T.B. Smith, 2007. Technology Acceptance among Physicians: A New Take on TAM. Medical Care Research and Review , 64(6), 650-672

[18] A.J. Gordo López, and A. Serrano Pascual (coord.), 2008. Estrategias y prácticas cualitativas de investigación social. Madrid: Pearson Educación

[19] P. D. O'Brien and R. C. Nicol. Fipa towards a standard for software agents. BT Technology Journal, 3:51{59, 1998.

[20] Henrik F. Nielsen, Noah Mendelsohn, Jean J. Moreau, Martin Gudgin, and Marc Hadley. SOAP version 1.2 part 1: Messaging framework. W3C recommendation,W3C, June 2003.

 ISBN: 978-1-61208-179-3

MIRAGE: An E-repository of Medical Images for Learning Biomedical Informatics

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***Abstract*— Although around 5 billion medical image studies were carried out in 2010, there is still a shortage of medical image databases that are available for students due to well-know reasons. To this end, an online image repository, MIRAGE, has been developed for teaching and learning biomedical informatics, which accommodates collections of published medical images of both 2D and 3D. The facilities of domain-based, atlas-based, and content-based retrieval (CBIR) are implemented to proffer the search in the repository. The novelty of the system is that not only a collection of 3D brain images is warehoused, but also CBIR for 3D is developed coupled with 3D visualization, leading to a versatile educational material, leading to future tele-education. The initial evaluation of the repository by users of both research students and lecturers has proven its positive impact.**

Keywords - medical image data base; image retrieval; CBIB; image labeling.

I. INTRODUCTION

With the advances of Internet technology, e-learning and e-teaching have flourished and borne fruits in a number of applications. In recent years, many online learning systems are available to students and have played an important part in assisting them learning. These systems usually tend to be in general purpose in order to meet majority students' need, e.g., institutional e-print repositories providing published materials of papers, reports, etc.. However, sometimes, subject-based databases are in demand by a number of groups, leading to the development of discipline-based systems. For example, an online system, ENDOCAS [1], has implemented imaging assisted surgery (IAS) systems to provide *information help*, *action help* and *training help* by offering assistance on planning surgical intervention, integrating mechanic components of the robots, and simulating complex environment for surgical training respectively. Whereas in [2], a medical image repository has been integrated with a web-based learning system, providing web-based tools to assign and assemble the contents of medical images.

E-learning has not only offered a new way of learning, but also brings all the advantages that an internet can offer to the learning and teaching process, such as flexibility, accessibility and straightforwardness. On the other hand, however, although medical imaging has revolutionized health care delivery in the last 30 years, and around 5 billion medical imaging studies were conducted worldwide [3] in 2010 alone, there are very limited numbers of online databases available, due to the well known reasons of patients' privacy and security, prompting the development of purpose-built repository for the benefit of both students and lecturers.

At Middlesex University in the UK, a new MSc programme was introduced in 2007 on BioMedical Modelling and Informatics (BMI) that has been attracting an increasing number of students. During the course of studying and conducting final projects, a large number of medical images had been employed in addition to many other forms of data. Following a successful bid to JISC [4] at the UK in 2009, an attempt to establish a subject-based repository started. The main aim of the online repository, MIRAGE, is to develop a subject-based repository of medical images, in the immediate term, benefiting MSc students who are on the programme of Biomedical Modelling and Informatics (BMI) at Middlesex University at the UK. It is anticipated the repository will be adopted by and serve the community in the middle term. As a result, MIRAGE, acronym of Middlesex Image Repository with a CBIR Archiving Environment, has been up and running and is available at [5].

The structure of the paper is organized as follows. Methodology is detailed in Section II, which is followed by Evaluation of Section III. Proceeding Conclusions and Discussion, the Section of Results is given in Section IV.

II. METHODLOGY

Figure 1 demonstrates the interface of the system.

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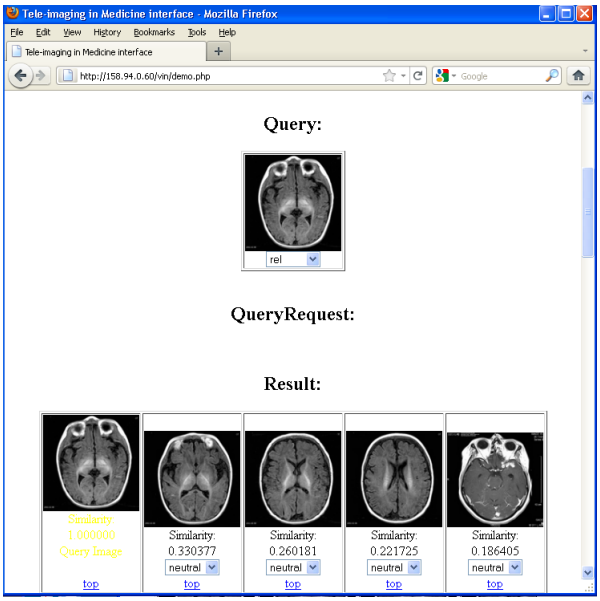

Figure 1. The interface of MIRAGE system at http://image.mdx.ac.uk/vin/demo.php . Top: menu interface; bottom: retrieval results for a query.

The repository began with the ingestion of a large collection of medical images into the existing server that then had only archived a few hundreds of images of limited domains. Since many image data are without any textual labeling, archiving image data is different from that to textual files that can be indexed using a few key words embedded in the files. This deposition stage hence included the establishment of both feature and image databases. A number of approaches in extracting features had been applied in pre-processing images. By building on from an open source software GNU GIFT (GNU Image-Finding Tool [6], the online system currently not only facilitates a means to search images by their contents, notably content-based image retrieval (CBIR), but also interfaces with OASIS+, the online teaching system at Middlesex University to ensure it can be accessed easily.

The system at present accommodates over 100,000 images. All the collected images in the server comply with the informed consent requirement and consist of 2D medical images, 3D brain images (CT, MR and PET) and 4D cardiovascular ultrasound images. MIRAGE adapts an open framework of GIFT for the retrieving of 2D medical images. By introducing the automatic image annotation, MIRAGE offers the possibility of combining visual content with keywords to achieve the higher level of semantic search. In addition, MIRAGE has developed its own method for 3D brain images retrieval to complement to the existing 2D medical image repositoryCBIR for 3D Brain Images.

A. *The System*

Figure 2 illustrates the infrastructure of MIRAGE. To address the problems that current text-based image retrieval systems suffer, MIRAGE integrated the methods of both content-based image retrieval (CBIR) for 2D and 3D collections and automatic image annotation to label the images with its keywords, leading to a higher level of semantic search. It therefore consists of three modules as shown in Figure 2, with components of image annotation, 2D image retrieval and 3D image retrieval.

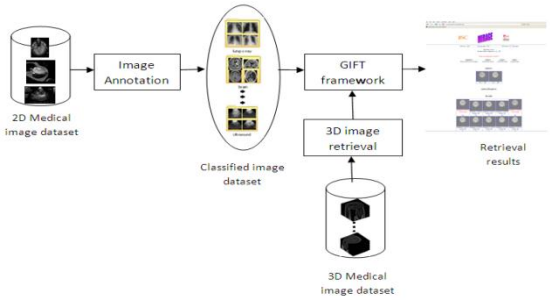

Figure 2. The Framework for MIRAGE.

Built on the open source GNU Image Finding Tool (GIFT), the online database is based on the Query-by-Example (QBE) paradigm coupled with user-relevance feedback facility whereby retrievd images most closely resemble a query image in appearance (i.e., the content that an image is carrying). Two algorithms have been implemented for indexing image collections, which are IDF (Inverse Document Frequency) and Separate Normalisation. IDF is a classical method and is based on counting the number of documents in the collection being searched, which contain (or are indexed by) the terms in question [3]. The inverted-file database system has been applied in text retrieval systems, giving rise to the efficiency when

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employed in an image system. The weighting features are calculated as in Eq. (1) [7].

$$feature\_relevance_{qj} = \frac{1}{N}\sum_{i=1}^{N}(tf_{ij}R_i)log^2(\frac{1}{cf_i})$$
$$image\_score_{kq} = \sum_j tf_{kj}feature\_relevance_{qj} \quad (1)$$

where tf_{ij} is the term frequency of a feature in either a query or a resultant image, cf_i the collection frequency of a feature, whereas q is a query containing N images ($i = 1,2...N$) with relevance R_i = 1(relevant) or -1(irrelevant). In addition, k is a retrieved image, j the index of a feature, and R the user-relevance of a query image with value between [-1,1].

On the other hand, feature normalisation is required to compensate the scale disparity between the feature components that are defined in different domains. On the client side, a web page based interface is given. Whist the client-server communication is achieved using the XML-based Multimedia Retrieval Markup Language (MRML). All client-server communication, including queries from the client or results returned by the server, is realised using message passing. Consequently, the client can be implemented in any programming language. The current MIRAGE client is implemented using PHP (Personal Home Programming) language to generate dynamic web pages for the client web browser.

B. Image Annotation based on Domains

One feature that the MIRAGE has is its ability of image annotation fully automatic, in order to achieve a higher level of semantic search, and to organize and categorize images of interests. Automatic image annotation is the process by which a computer system automatically assigns metadata in the form of captioning or keywords to a digital image. At present, the Bag-of-visual-Words (BoW) [8] paradigm becomes very popular and has been successfully applied for image categorization. By transforming images into a set of 'visual vocabulary', images are represented using the statistics of the appearance of each word as feature vectors, upon which the learning of an image classification rule could be achieved as a classifier. This idea has been adopted in the MIRAGE system coupled with SIFT sparse coding approach [9], which is achieved in the following four steps that is also illustrated in Figure 3.

- Step 1 -- the visual features are extracted from local patches of each image in the training dataset , leading to the construction of a visual dictionary of *codebook*;
- Step 2 -- to quantize the visual features of the image dataset into discrete *'visual words'*.;
- Step 3 -- an image is represented as a unique distribution (e.g. a histogram) over the generated dictionary of words; and
- Step 4 -- image representations of the training dataset obtained in Step 3 are applied to train the classifiers using supervised machine learning methods. Finally, the trained classifier automatically allocates new images into corresponding categories and hence labels them.

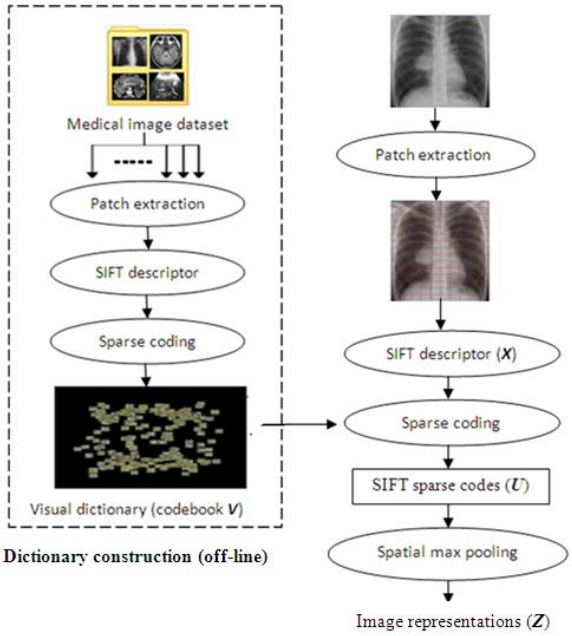

Figure 3. Dictionary construction and image representations.

Unlike traditional BoW paradigm, sparse coding is employed in the MIRAGE instead of vector quantization (VQ) to extract the SIFT descriptors of local image patches. Furthermore, instead of using histograms, multiple scales of max pooling are employed as an image representation by the use of simple linear support vector machines (SVMs). In comparison with the SVMs using nonlinear kernels, e.g. histogram intersection kernels, linear SVMs can dramatically reduce the training complexity while maintaining a good performance.

C. CBIR for 3D Brain Images

For 3D brain images, four texture based methods are implemented as shown in Figure 4, including , 3D Local Binary Pattern (LBP), 3D Grey Level Co-occurrence Matrices (GLCM), 3D Wavelet Transforms (WT) and 3D Gabor Transforms (GT) as detailed in [10, 11]. Figure 5 depicts the flowchart of CBIR for 3D images.

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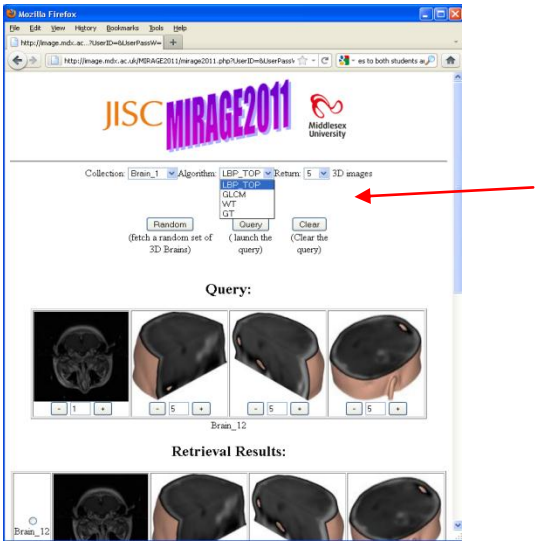

Figure 4. The interface of 3D images retrieval with four texture-based methods (arrowed) and visualization.

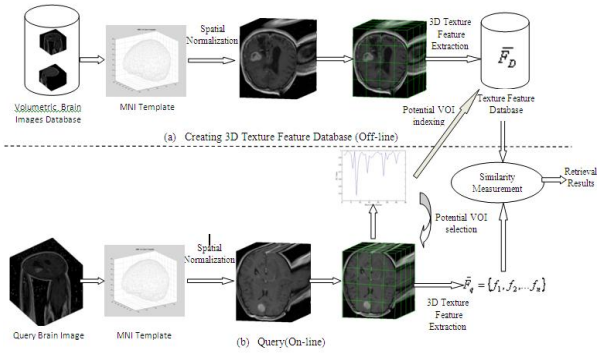

Figure 5. Framework for Content-based 3D Brain Image Retrieval

As shown in Figure 5, the collection of 3D brain images firstly underwent a pre-processing stage to normalize them into the same resolution before the indexing stage. After spatial normalization of volumetric brain data into a standard template, the data are then divided into 64 non-overlapping equally sized blocks, from which, 3D texture features are extracted to create a feature database. On the query side, a pre-processing stage is introduced to detect the potential VOI of lesions after spatial normalization from a query image. Subsequently, the extraction of 3D texture features from a query only takes place from these potential sub-blocks that, in the retrieval stage, are in turn compared with the corresponding features in the feature database to obtain retrieval results. Figure 6 demonstrates an example retrieved using different texture approaches [12].

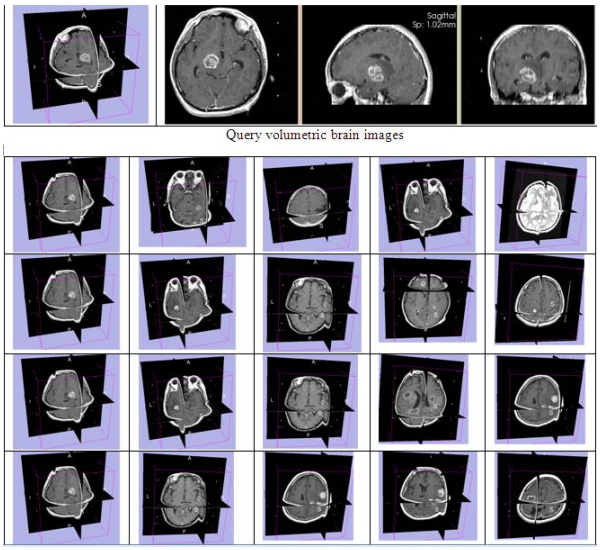

Figure 6. Retrieved results in top 5 ranking from 3D GLCM (row 1), 3D WT(row 2), 3D GT (row 3), and 3D LBP (row 4).

The judgement of each approach is subject to the applications of the retrieval task as to which of the measures of size, location or shape plays more important role than the others.

III. EVALUATION

The system evaluation is carried out from both objective and subjective prospects. As an objective evaluation, a number of statistic measures are applied to evaluate the research methods, such as Average Accuracy Rate (AAR) for image classification and Mean Average Precision (MAP) for image retrieval. On the other hand, the subjective evaluation is accomplished by using a survey questionnaire conducted by the students and researchers/lecturers at MU who have employed the medical image repository MIRAGE in their teaching and research.

To assess the effectiveness of image classification, a confusion matrix is firstly created as explained at [13]. Then with regard to the performance of image retrieval, traditional measures of Precision (P) and Recall (R) are worked out. By representing P-R graph using one value, MAP value is applied to measure overall performance for all queries and is calculated as Eq. (2).

$$\text{Mean Average Precision (MAP)} = \frac{1}{M}\sum_{i=1}^{M} AP_i \qquad (2)$$

where M is the total number of the queries, AP_i is the AP value for the i^{th} query, which is formulated as Eq. (3).

$$\text{Average Precision (AP)} = \frac{1}{N_r}\sum_{j=1}^{N_r} P_j \qquad (3)$$

Upon which N_r is the total number of relevant images in a dataset for a query, and p_j is the precision when retrieving

the j^{th} relevant image. A P-R graph together with a MAP value is therefore applied to evaluate the performance of CBIR for 2D and 3D images in this project.

In addition, an on-line questionnaire as given on the interface (e.g., the bottom line at Figure 1) is designed in the hope to subjectively evaluate and further improve the system. The questionnaire consisted of 15 questions organized in three categories on i) the general information on the use of MIRAGE; ii) the evaluation of system usability; and iii) the comments/recommendations in regarding to the features of MIRAGE.

IV. RESULTS

A. Results on Image Annotation

In order to train a codebook for image annotation, a training dataset is firstly selected containing 1000 images that are randomly chosen from our medical image repository. Then 200,000 random patches are collected from these images. Subsequently, from each patch, SIFT descriptors are extracted, yielding a feature database that has the size of 200,000*128 elements, which are finally applied to train the codebook with the size of 1024*128 in terms of feature vectors.

With respect to ground truth for image annotation, six domain names are defined at the highest level, including brain, lung (x-ray), microscopy, abdomen, ultrasound and graph respectively. Each category is allocated 100 images as ground truth with each half as being training and testing sets respectively. The classification results for the six categories are visualized in a confusion matrix in Table 1.

TABLE 1: CONFUSION MATRIX FOR THE SIX MEDICAL IMAGE CATEGORIES, WHERE B, L, M, A, U, G REPRESENT CATEGORIES OF BRAIN, LUNG, MICORSCOPY, ABDOMEN, ULTRASOUND, AND GRAPH

		Classification Results						AR (%)
		B	L	M	A	U	G	
Ground Truth	Brain	48	0	2	0	0	0	96
	Lung (x-ray)	0	50	0	0	0	0	100
	Microscopy	0	0	49	0	1	0	98
	Abdomen	0	0	0	50	0	0	100
	Ultrasound	0	0	0	0	50	0	100
	Graph	0	0	0	0	0	50	100
ER(%)		0	0	3.92	0	1.96	0	

The values in the last column of Table 2 are the Accuracy Rate(AR) values for each class, whereas the values in the last row are the Error Rate(ER) for each class. The Average Accuracy Rate (AAR) for all classes is 99% (297/300), and Average Error Rate (AER) is 1% (3/300), demonstrating the approach of annotation being very efficient.

B. Results for 3D image retrieval with CBIR

Figure 7 plots the average Precision Recall Graph for ten queries across the whole datasets (around 100 of 3D MR brain images). The MAP and average query time by using the approaches of 3D GLCM, 3D WT, 3D GT and 3D LBP are given in Table 3. The query time amounts to the time spending on both feature extraction and retrieval, the results based on the programs that are written in MATLAB R2009a running on a computer with specifications of Intel P8600 CPU of 1.58GHz with 3.45GB RAM.

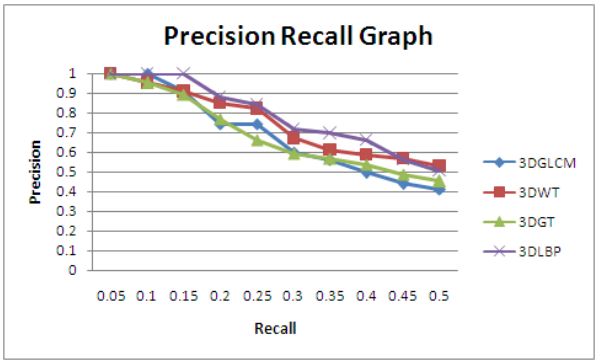

Figure 8. Average precision recall graph for ten queries.

TABLE 2. MAP AND QUERY TIME FOR 4 TEXTURE REPRESENTATION METHODS.

Methods	Mean Average Precision (MAP)	Query time
3D GLCM	0.690	10.96s
3D WT	0.749	1.22s
3D GT	0.691	10.77m
3D LBP	0.786	0.21s

The above results show the approach of LBP not only can achieve precision rate by up to 78% but also can perform retrieval in real time with sub-second speed. All these four methods are implemented in the system giving users the choices.

C. Results on Subjective Evaluation

An on-line questionnaire is applied to subjectively evaluate and thereafter further improve the system. This questionnaire comprises three parts covering the general impression of the repository, system evaluation and comments on the system respectively. This survey has been carried out by MSc students and researchers at MU, by which a total of 15 people participated.

 ISBN: 978-1-61208-179-3

In terms of expectations, all respondents 'agreed' (80%) or 'strongly agreed' (20%) with the retrieved results, suggesting that the system meets users' expectations. They all 'agreed' (30%) or 'strongly agreed' (70%) that the system was fast and easy to use, and was useful to teaching and learning. On the other hand, users of 60% and 40% strongly agree or agree that the system is useful for teaching and learning.

V. CONCLUSION AND DISCUSSION

This project integrates the existing technologies to implement a versatile, useful and easy to operate system for teaching and learning, The techniques include GIFT framework for CBIR and image annotation using SIFT sparse codes while developing its own re-useable module retrieval and visualization of 3D brain images.

Works on 4D ultrasound images with CBIR facility currently is underway with future working including visualization of 3D video images (=4D) while performing the retrieval.

With respect to the issue of security, the system is controlled via password. Because it is not connected to any clinical systems and the images are without any identifications, the risk to patients' privacy is very limited. Furthermore, all collections are from published work on the search of implying information in images, i.e., data mining. With this in mind, the developed system MIRAGE is wide open to the communities of research, learning and teaching, especially when remote teaching and leaning prevail.

On the other hand, the source code for 3D image retrieval and visualization are to be realised to the public to benefit the community that are carrying out similar work.

ACKNOWLEDGEMENT

This work is financially funded by the research council JISC at the UK, their support is gratefully acknowledged. The authors would also like to thanks all those MSc students and staff at Middlesex University who took part in the evaluation survey.

REFERENCES

[1] www.endocas.org. 01.12.2011.

[2] C.H. Hsiao, T.C. Hsu, J.N. Chang, S.J.H. Yang, S.T. Young and W.C. Chu, Developing a medical image content repository for E-Learning, Journal of Digital Imaging, Vol. 19 (3), pp. 207-215, 2006.

[3] www.jisc.ac.uk. 01.12.2011.

[4] C.A. Roobottom., G. Mitchell and G. Morgan-Hughes, Radiation-reduction strategies in cardiac computed tomographic angiography. Clin Radiol 65 (11), pp. 859–67, 2010.

[5] http://image.mdx.ac.uk. 01.12.2011

[6] http://www.gnu.org/software/gift/gift.html. 01.12.2011.

[7] S. Robertson, Understanding Inverse Document Frequency: On theoretical arguments for IDF, Journal of Documentation, 60 (5), pp. 503–520, 2004.

[8] H. Müller, W. Müller, D.M. Squire, Z. Pecenovic, S. Marchand-Maillet and T. Pun, An open framework for distributed multimedia retrieval. Technical Report 00.03, Computer Vision Group, Computing Group, University of Geneva, rue Gnral Dufour, 24, CH-1211 Geneva, Switzerland, 502, 503, 2000.

[9] V. Viitaniemi and J. Laaksonen, Spatial Extensions to Bag of Visual Words, VIVR'09, 2009, Santorini, Greece.

[10] J. Yang, K. Yu, Y. Gong and T. Huang, Linear Spatial Pyramid Matching Using Sparse Coding for Image Classification, 2009 IEEE Conference on Computer Vision and Pattern Recognition, 2009, Miami, USA.

[11] X.W. Gao, Y. Qian, M. Loomes, R. Comley, B. Barn, A. Chapman, and J. Rix, Texture-based 3D image retrieval for medical applications, IADIS e-Health2010, 2010.

[12] Y. Qian, X.W. Gao , M. Loomes, R. Comley, B. Barn, R. Hui, and Z. Tian, The Third International Conference on eHealth, Telemedicine, and Social Medicine, eTELEMED 2011, 2011.

[13] R. Kohavi and F. Provost, , Editorial for the Special Issue on application of machine learning and the knowledge of discovery process, Machine Learning 30, pp. 271, 1998.

 ISBN: 978-1-61208-179-3

Can an Ad-hoc ontology Beat a Medical Search Engine? The Chronious Search Engine case.

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***Abstract*—Chronious is an Open, Ubiquitous and Adaptive Chronic Disease Management Platform for Chronic Obstructive Pulmonary Disease(COPD) Chronic Kidney Disease (CKD) and Renal Insufficiency. It consists of several modules: an ontology based literature search engine, a rule based decision support system, remote sensors interacting with lifestyle interfaces (PDA, monitor touch-screen) and a machine learning module. All these modules interact each other to allow the monitoring of two types of chronic diseases and to help clinician in taking decision for care purpose. This paper illustrates how the ontology search engine was created and fed and how some comparative test indicated that the ontology based approach give better results, on some estimation parameters, than the main reference web search engine.**

Keywords- Telemedicine; chronic disease management; ontology search engine.

I. INTRODUCTION

Scientific advances over the past 150 years, particularly in the medical field, have allowed the extension of life expectancy in western countries and this trend seems to increase in future years. Conservative estimates suggest that by 2030 in EU countries the proportion of people over 60 years regard the entire population will be around 50%; this means that we will see a gradual increase in the number of those subjects with chronic diseases (i.e., diseases not involving healing), that will therefore increase the cost and effort over health care facilities [1].

Chronic diseases are slowing but constantly replacing malnutrition and infection as primary causes of mortality in the population [2]. The World Health Organization (WHO) has recently emphasized that chronic diseases are a global priority [3].It was calculated that, if governments are able to put in place public health policies that produce a 2% yearly reduction in mortality rates for chronic diseases, 36 million deaths would be prevented worldwide between 2005 and 2015 [4].

Chronic diseases are difficult to treat and, apart from deaths, have collateral social impact that are becoming an economic emergency both in western and developing countries. As the number of patient with chronic diseases is rising there will be an increasing cost for hospitalization structure both public and private. Considering some specific diseases like Chronic Kidney Disease (CKD), sometimes there is, during the medical treatment, a non-return point from where the hospitalization is continuous as for dialysed people. The traditional approach consisting in periodic check-ups and periodic lab exams seems a model that won't be sustainable as the population gets older and the total number of patients with chronic diseases rises. At present the physician deals with an increasing number of chronic patients that are lowering the periodic check-ups and so reducing the ability to prevent, if not death, worsening in patient's quality of life.

In the latest years, we have seen a tremendous growth in IT infrastructure, both from the hardware and communication capacity. Nowadays a common mobile phone is much more powerful in terms of hardware and software capacity than the first calculating machine that allowed the man to land on the moon forty years ago. The continuous growth of the World Wide Web (WWW) and, linked to this, the continuous growth in bandwidth capacity for data transmission allows to have cheaper and more widely available bandwidth, for larger portions of the population.

As consequence of the exponential growth of hardware and software infrastructure it is possible to rethink the whole approach to the treatment of complex chronic diseases by limiting the hospitalization only to situations of severe worsening of patient condition. This was the original idea behind the EU funded Chronious project [5]: constructing a generic platform to monitor, in an unobtrusive way, patient with chronic disease in two goals [6]:

- Improve the patients quality of life, by reducing as much as possible the hospitalizations.
- Allow the clinician a continuous monitoring of the patients, both in standard and potential risk situations.

To gain this two goals, the Chronious platform has to integrate different technologies such as hardware and software modules that need to interact among themselves. This paper is focused on the ontology search engine module: we will illustrate what are the aims of this module and what are the main components. The storage system for the documents is an ontology, developed specifically for the CODP and CKD diseases. We will illustrate how this ontology was created and enriched, from medical literature

 ISBN: 978-1-61208-179-3

sources. Finally we will illustrate our tests conducted against the principal medical search engine and how the preliminary results seem to indicate that such approach can outperform the results of a web search engine. The paper is organized in the following sections. We will first describe the Ontology Chronious Search Module and what were the needs and how we solved them. Chapter three fully illustrate the whole process of document uploading and processing of the text to gain the enrichment of the ontology. Finally we will illustrate our tests results and suggest some future improvements.

II. CHRONIOUS SEARCH MODULE

Chronious is an hardware/software platform devoted to monitor in a remote way COPD and CKD patients. In Figure 1, a schema of the whole system is presented:

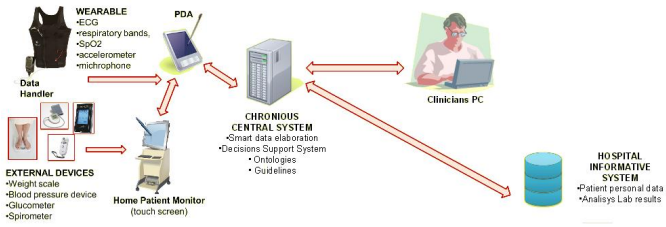

Figure 1. Chronious modules

The chronic patient is equipped at home with the following devices:

- a Personal Digital Assistant (PDA) that contains machine learning algorithms, acting as a first alerting system and that is used to transmit data to a central system through GPRS technology.
- A Home Patient Monitor (HPM) that is used to allow patients to insert qualitative information on diet, activity and drugs intake.
- Bluetooth medical devices: weight scale, blood pressure intake device, glucometer, air quality monitoring tool. Coupled with these devices a sensorized t-shirt for vital parameters recording like cardiac and respiratory signals.

For the two pathologies, different sets of equipments are given to the patient according to the clinician. For example the glucometer is usually assigned to CKD patient affected by diabetes comorbidity .

The data collected are automatically transmitted via GPRS to a Central System that, using a web interface, and a rule-based Central Decision Support System (CDSS), allows clinician to monitor patient and to receive suggestions on how to act in case of a worsening trend or a potentially life risk situation.

The CDSS uses JENA [7] framework and a set of rules codified in OWL [8] format to display suggestions to the clinician. An example of such a rule is displayed in table II.

Table I
EXAMPLE OF A SUGGESTION GIVEN BY THE CDSS

patientID	1
AlertType	White
Date	01/02/2011
Description	body temperature up to 38
Suggested action	hospitalization of the patient
Guideline Text	text from literature

For CKD we used the KDOQI Guidelines [9], for COPD we create a set of rules based on clinician experience. The suggestions are portion of text extracted from literature reference or documents provided by the experts. Managing documents and information , and organising concepts, such as comorbidities, and relations between them is a central task, for having a correct outcome to the CDSS calling.

Searching literature reference, we find that latest information retrieval/storage systems studies, seem to indicate that ontology structure are a better way details concepts and the relations between them [10]. Ontologies have been used successfully on medical [11], genetic [12] and surgery [13] fields. The document repository for storing informations on the COPD and CKD diseases, was chooses as an ontology. This lead us to other issues: how to build the ontology and how to enrich it with new concepts and to validate it.

Agreeing with doctors , the main reference on the medical field is the PubMed[14] site. PubMed is a free database accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics. As of 1 July 2011, PubMed has over 21 million records going back to 1966, selectively to the year 1865, and very selectively to 1809. About 500,000 new records are added each year. As of 1 July 2011, 11.9 million articles are listed with their abstracts and 3.3 million articles are available full-text for free. The problem was how to integrate all this huge among of information in the PubMed site with the Chronious Ontology. Apart from the integration the main problem was how to connect all sparse information about COPD and CKD pathologies in a way to produce a real value information to the clinician. Querying Pubmed for generic COPD (at 1th September 2011), we have as outcome 33319 documents.

We coupled the Chronious Documents repository with a Search Module for having an interface that clinician can use to fast access literature specific information on the two diseases treated by Chronious.

Using these intuitions, the whole Chronious Search Module of the Chronious System is composed of four main parts:

- Upload tool: a web interface that is able to upload files to the repository.
- The repository itself and the ontology used to underline concepts and relation extracted from the raw text.
- Enrichment tool: a tool that after the text information extraction is able to say which new concepts and relations should be accepted.

 ISBN: 978-1-61208-179-3

- A search tool. This is the final web interface for the clinician that using the concepts and terms provided in a free text search or more structured way is able to query the repository and give documents as feedback.

Being that the Chronious Search Tool was the entry point for the CDSS, the clinician feedbacks about the whole architecture underlined potential issues. The main issue, was that it is useless to use a personalized search engine while going via web to PubMed was so fast and so accessible. Another issue was that the clinician should upload manually the document into the repository. We will describe the processing of a single document to demonstrate how we solve these issues.

III. The Chronious upload/processing system

The Chronious ontology have been developed using the DOLCE ontology [15], however to enrich the relation between the nodes of the ontology graph, a functionality for transforming text into concept were needed. The upload functionality is based on a web interface that is able to upload a pdf file and associating it with some general information like author, journal, year, volume. Due to the fact that the more documents are uploaded the better the ontology can be enriched, we code a web spider that is able to use Pubmed site structure to download automatically.

Even if the final step of the process, the Enrichment Tool validation, needs a human approval of the concept chosen, this automated download tool helps the boring part of downloading a document from PubMed and uploading to the Chronious system.

The automated download tools is basically a web crawler that periodically use a query string over the Pubmed search functionality, do the HTTP request, parse the html pages and find html tag for having information about the pdf file to download. The code was developed using .NET framework 3.5 being that the CLR provide a library that is able to interact directly with an html page using the DOM (Document Object Model) system.

This allows easily to mimic nearly every interaction that the human user can have with the page like: entering text in the input fields and clicking on a link to simulate the ”save as” functionality.

After the downloading finished successfully the information are stored on a RDBMS database so that only new papers are downloaded and parsed.

One of the problem faced with this approach is the copyright issues that affects the contents of the PubMed database. The greatest part of the articles indexed by PUBMed are protected by copyright, as they come from journals that have copyright agreements, so in most of the case the content of the document cannot be viewed for a user that have no subscription. The problem is not present if we use the upload tool is used inside an institution that have a subscription with PubMed based on the ip address.

However if the Automated Upload Tool is installed on a normal pc downloading document provide an infringement of the PubMed copyright.

To avoid this we decide to use a lower set of documents that are provided by Pubmed for free until the document is published on the journal, for having a first test on the system and to see if the concepts extracted were in line with the ontology we build. To prevent any possible copyright issue, we decide to show to the final user only the DOI of the document so in case the user would like to see the whole document he must open a browser window. This action will shift the copyright from the Chronious system to the final user of the search tools. At the end of the enrichment process the module removes the physical pdf. Once the document is uploaded into the repository a Natural Language Processing (NLP) is used to for Information Extraction (IE). For implementing the NLP algorithms the GATE [16] framework will be used. GATE is a leading infrastructure for developing and deploying software components, that process human language. Among others it provides a framework, based on JAVA, that implements the architecture and can be used to embed language processing capabilities in different applications.

GATE supports many document formats like: Plain Text, HTML, SGML, XML, RTF, Email, PDF and Microsoft Word.

Every text is splitted into sentences and words and and every concept extracted is then indexed and associated with a weight that evaluate the correspondence with the other concepts already present into the Chronious ontology.

Once this evaluation is done the concept extracted are presented to the human user using a web interface, where the new concepts are shown with their evaluation indexes see Figure 2.

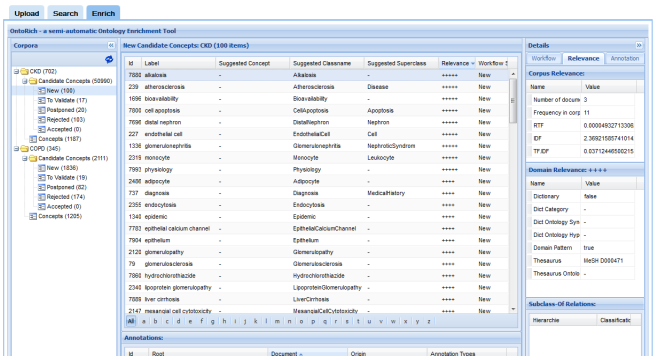

Figure 2. Enrichment Tool

After the whole process finished, a web interface that able to query the ontology for terms evaluation in a structured or free text search form (see Figure 3) is the last interface. So a clinician is able to use it for fast finding literature reference. In addition, the search functionality, uses also the concepts

in the ontology so it is possible to have fast reply to query like ”abnormal coughing toxicity”.

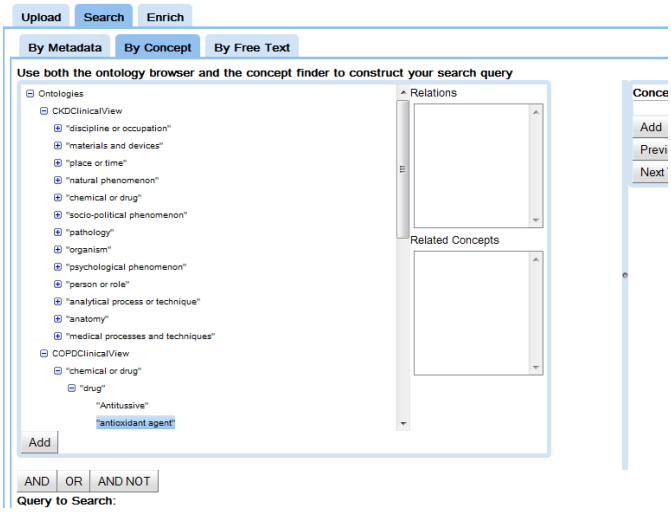

Figure 3. Search Tool

The goodness of the query results should finally be evaluate. Next chapter will detail the criteria used.

IV. Evaluation

As we said having another search functionality apart from PubMed raised some murmurs from clinicians, so we need to show that from the perspective of information retrieved, the Chronious Search Tool has some advantages over PubMed.

For doing this, various classifications and criteria for ontology evaluation have been considered in the literatures [17]. However, no standard evaluation criteria have been defined so far. Reference literature proposed [18] a ”three dimensions” classification to evaluate ontology in three categories: Structural Dimension, Functional Dimension and Usability-Profiling Dimension. Considering that Structural Dimension and Usability-Profiling Dimension where validated by ontology experts we focused on Functional Dimension with three different tests see Table II:

Table II
Features to be tested in Chronious ontology testing

Test Identifier	Description
TF-B-1	Agreement Among Experts
TF-B-2	User-Satisfaction
TF-B-3	User-Satisfaction and Completeness of Search Result

The questionnaire interview approach can be applied in TF-B-1 to conclude the agreement among medical experts to evaluate the correctness of the developed Chronious ontologies. Test participants for this test were medical experts, especially in CKD and/or COPD area.

The black-box test TF-B-2 utilizes the same approach as TF-B-1, the questionnaire interview approach, to measure the overall satisfaction of the end-user. Because there are three different search options in the Search Module (Search by Metadata, Search by Concept, and Search by Free Text), the questionnaire should take all these options into account and compare their search result quality with each other. The people involved for this interview were the end-user of Chronious Healthcare Professional GUI, i.e., the medical experts.

In black-box test TF-B-3, Precision P is defined as the number of relevant documents retrieved by a search $g(r)$ divided by the total number of documents retrieved by that search N.

$$P = \frac{g(r)}{N}$$

while Recall R is defined as the number of relevant documents retrieved by a search $g(r)$ divided by the total number of existing relevant documents G (which should have been retrieved).

$$R = \frac{g(r)}{G}$$

Precision and Recall are two widely used statistical classifications, especially in information retrieval domain. Precision can be seen as a measure of exactness or fidelity, whereas Recall is a measure of completeness.

Usually, Precision and Recall scores are not discussed in isolation. Instead, either value for one measure are compared for a fixed level at the other measure (e.g., Precision at a Recall level of 0.75), or both are combined into a single measure, such as the F-measure [19], which is the weighted harmonic mean of Precision and Recall:

$$F = \frac{(\beta^2 + 1) \cdot P \cdot R}{(\beta^2 \cdot P) + R}$$

Whereby β is a value between 0 and 1 reflecting the weighting of Precision vs. Recall.

Before doing an evaluation we uploaded into the repository 1000 free access documents grabbed by the Automatic Upload Tool from Pubmed using two different query strings

- CKD treatment for CKD ontology part.
- COPD treatment limited to year 2008 for COPD ontology part.

Because the document repository of Chronious Search Module and of the PubMed Central system is artificially identical (constrained with some specific limitations), for same search query, the two systems should contain the same number of relevant documents to this query, i.e., G for that query in both systems should be equal. It follows that, no matter which value the variable G has, the comparison of F-measure between these two search systems will only be influenced by $g(r)$ and N of the search result. Hence, if the value of $g(r)$ and N are available for a search both with Chronious Conceptual Search option and with PubMed Central system, the F-measure of the search results with

 ISBN: 978-1-61208-179-3

both systems can be compared with each other with the help of their function diagrams (the search query used in both systems must be identical).

Some outputs of our tests can be seen in Table III

Table III
FEATURES TO BE TESTED IN CHRONIOUS ONTOLOGY TESTING

G	F-measure Chronious	F-measure Pubmed
500	0.724637681	0.595238095
1000	0.531914894	0.426136364
2000	0.347222222	0.27173913

The table shows that, the Chronious Conceptual Search option performs better than the PubMed Central system with the search query, no matter how many relevant documents existed in the repository to this query. With this approach, although the F-measure value of a search result cannot be estimated for every type of query, the search performance of the Chronious Search Module, however, can be compared with the search performance of the PubMed Central system, using the F-measure.

V. CONCLUSION AD FURTHER IMPROVEMENTS

Even if the test results seem promising, it is not possible to say that in general the ontology search approach can outperform a search functionality like PubMed one. However the good news, is that such kind of approach on storing information, is promising for developing future artificial intelligence systems for application in telemedicine. Linking concepts like symptoms to drug or caring procedures with relations underline by literature studies can greatly help clinician during their daily routines. It would be interesting to evaluate the Conceptual Search on the whole corpus of the Pubmed database even if this would be impossible due to copyright restriction and infrastructure storage possibilities. For sure PubMed will remain the main reference literature search engine, however it is our opinion that having structures information like the one in Chronious ontology, will for sure be an added value.

Another interesting task would be the evaluation of a complex free text query search over the two systems. Free text search remains the first approach for searching information. Reflection on how to benefit from ontology structured data in improving outcome for free text search seems is a research problem that require a deeper evaluation.

Last we point out that Chronious Enrichment Tool still need to have a human interaction. A still open research task, is the one of having some kinds of automation in inserting the new concepts and relations in the existing ontology, in way to have a sort of unsupervised concepts enrichment that mimics the rule extraction in transaction datasets. We leave these suggestions hoping that the reader will be interested to think about them.

REFERENCES

[1] C. Zoccali, A. Kramer, and K. Jager, "Chronic kidney disease and end-stage renal disease a review produced to contribute to the report the status of health in the european union: towards a healthier europe," *NDT Plus*, vol. 3, no. 2, pp. 213–224, 2010.

[2] A. R. OMRAN, "The epidemiologic transition: A theory of the epidemiology of population change," *Milbank Quarterly*, vol. 83, no. 4, pp. 731–757, 2005.

[3] W. H. Organization, "Preventing chronic diseases: a vital investment," 2005.

[4] K. Strong, C. Mathers, S. Leeder, and R. Beaglehole, "Preventing chronic diseases: how many lives can we save?" *Lancet*, vol. 366, no. 9496, pp. 1578–1582, 2005.

[5] TeSAN. (2008, Jun.) Chronoius official site. [Online]. Available: http://www.chronious.eu

[6] M. Vitacca, L. Bianchi, A. Guerra, C. Fracchia, A. Spanevello, B. Balbi, and S. Scalvini, "Tele-assistance in chronic respiratory failure patients: a randomised clinical trial," *European Respiratory Journal*, vol. 33, no. 2, pp. 411–418, 2009.

[7] Jena official web site. [Online]. Available: http://jena.sourceforge.net

[8] W3C. (2009, Nov.) Owl specifications. [Online]. Available: http://www.w3.org/TR/owl-features/

[9] KDOQI, "KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease." *American journal of kidney diseases : the official journal of the National Kidney Foundation*, vol. 49, no. 2 Suppl 2, Feb. 2007.

[10] K. M. S.C. Punitha and M. Punithavalli, "Article: Impact of ontology based approach on document clustering," *International Journal of Computer Applications*, vol. 22, no. 2, pp. 22–26, May 2011.

[11] J. M. Abasolo and M. Gomez, "Melisa. an ontology-based agent for information retrieval in medicine." in *In: Proceedings of the First International Workshop on the Semantic Web (SemWeb2000*, 2000, pp. 73–82.

[12] M. Ashburner, C. A. Ball, J. A. Blake, D. Botstein, H. Butler, J. M. Cherry, A. P. Davis, K. Dolinski, S. S. Dwight, J. T. Eppig, M. A. Harris, D. P. Hill, L. Issel-Tarver, A. Kasarskis, S. Lewis, J. C. Matese, J. E. Richardson, M. Ringwald, G. M. Rubin, and G. Sherlock, "Gene ontology: tool for the unification of biology. The Gene Ontology Consortium." *Nature genetics*, vol. 25, no. 1, pp. 25–29, May 2000.

[13] O. B. R. Mudunuri and T. Neumuth, in *GI Jahrestagung*, S. Fischer, E. Maehle, and R. Reischuk, Eds., vol. 154. GI, 2009, pp. 1044–1054.

[14] Pubmed official site. [Online]. Available: http://www.pubmed.org

 ISBN: 978-1-61208-179-3

[15] M. B. L. Schneider and D. Koepsell, "Article: Impact of ontology based approach on document clustering," *Frontiers in Artificial Intelligence and Applications*, vol. 229, no. 2, pp. 28–38, May 2011.

[16] GATE. (2008, Jun.) Gate official site. [Online]. Available: http://www.chronious.eu

[17] M. G. J. Brank and D. Mladenic, "A survey of ontology evaluation techniques," in *In In Proceedings of the Conference on Data Mining and Data Warehouses (SiKDD 2005*, 2005.

[18] M. C. A. Gangemi, C. Catenacci and J. Lehmann, "Modelling ontology evaluation and validation," in *Proceedings of the 3rd European Semantic Web Conference (ESWC2006), number 4011 in LNCS, Budva*. Springer, 2006.

[19] C. J. van Rijsbergen, *Information retrieval*. Butterworths, 1979.

 ISBN: 978-1-61208-179-3

Enforcing Security in Pervasive Healthcare Monitoring Gestational Diabetes Mellitus

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***Abstract*—Life expectancy is rising world wide thanks to the current advancement of medicine. Due to the fact that the population is growing old, also the incidence of chronic illnesses in the population is rising. For this reason, new paradigms of healthcare are being developed to achieve a better medical follow-up and also handle the rising costs. One approach that is proving successful is telemedicine, which focuses on decentralising the delivery of healthcare by means of new technologies based on network connectivity. One problem that rises in the definition of telemedicine systems is the one of security of medical data. In this paper we present our telemedicine system for monitoring Gestational Diabetes Mellitus (GDM). We addressed the problem of securing the communication between the patients and the doctors. The result is a fully implemented telemedicine system for GDM that mitigates the risks associated with the most common malicious attacks directed to a distributed system.**

Keywords-Telemedicine; Gestational Diabetes; Security; Personal Health System.

I. INTRODUCTION

The life expectancy is rising world wide thanks to the availability of new and higher standards for healthcare, but to this improvement a decrease in the incidence of chronic or permanent health conditions [1] did not follow. The world expenditure in healthcare is surging due to the wide spread availability of high standard care. This creates new challenges for healthcare professionals. Also new trends in technical development enable new services that allow to improve care even more.

In particular, we are addressing the issue of collecting and evaluating medical data by means of telemedicine. This allow healthcare professionals to have more accurate data. By pro-actively notifying medical experts they can react faster to a changes in the condition of a patient. Further more patients can benefit as well, because they can live their file with more freedom, following their daily activities.

Healthcare activities can be grouped into three categories: measuring physical values, diagnosing and administering therapies. These activities can be described more technically as monitoring, recognizing, and decision making. In our research we are going to set up a common pervasive healthcare infrastructure that aims to support all these activities. Here we report on the architecture for the pervasive healthcare monitoring framework, that addresses the first category of activities. Therefore we are going to set up a personal health system (PHS) that integrates the patients as actors into the monitoring process. We are doing so to obtain more accurate data, which in consequence allows medical services to provide better services to the patients.

Patients collect their physiological data either on their own or by using smart devices, e.g. in form of wearable computing devices forming a body area network that collects physiological data autonomously. The physiological data needs to be collected and eventually augmented with metadata, like the data origin, although it is not enough to simply store this data. The monitoring process covers a first data processing step, which is a filtering to identify abnormal conditions. If such a condition has been identified a medical expert has to be notified. By this notification, the medical expert gets supported, because a) more data is available and b) his attention is drawn to the cases where the data indicate an abnormal condition, and an action from him might be required. This supervision of incoming data is the core of the monitoring activity. Monitoring can use a reasoning component that evaluates the incoming data and checks it, respecting the context and the history of the patient.

It goes without saying that the design of a pervasive healthcare monitoring framework, as well as the entire pervasive healthcare infrastructure, has high requirements towards the security of those system, as they deal with highly confidential personal data.

In our current study, we are addressing patients suffering from Gestational Diabetes Mellitus (GDM). GDM occurs during pregnancy due to increased resistance to insulin. GDM is a type of diabetes which temporarily affects 4% of otherwise healthy pregnant women, and typically disappears after delivery. As relatively milder hyperglycemia can cause adverse effects in the baby and in the mother, then cases of glucose intolerance in pregnancy are also considered to represent GDM. Current GDM care consists in a routine check once per week, meaning that in between these checks, the woman can develop poor glycemic control and further adverse effects. GDM is not a typical chronic disease, where patients diverge from the healthcare plan over time. In contrary women suffering from GDM are typically very engaged

 ISBN: 978-1-61208-179-3

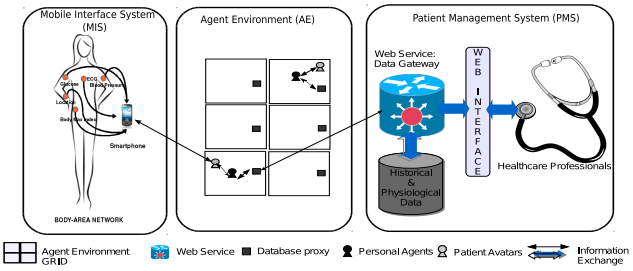

Figure 1. Components of the GDMM system

in their course, as their health, as well as the health of their child is effected. Also it is desired to let the women live their normal day-to-day activities, therefore a telemedicine system is preferred. Thus women suffering from GDM have a high motivation to participate in a monitoring of their condition. In fact, the women collect their physiological data, like weight, blood sugar, blood pressure, with conventional measuring devices and the data is transfered to the pervasive healthcare monitoring system using a special application on a smart phone. On the server side the data is stored and a reasoning component scans for anomalies or threats based on the data collected so far, and additional information given by the doctors in charge. If this component detects a possible threatening condition it notifies a medical expert. Caretakers can interact with the system with a web front-end. They can analyse the entire data collected from a particular patient, can see and react on notifications, and can update the current treatments of the patient. The main tasks of this monitoring system is to collect and provide data and to hint medical experts to possible interesting data. The medical activities of recognition and acting upon it, i.e. naming a therapy, are not addressed by this system, as these activities are reserved to medical experts. The overall process and main components are shown in Figure 1. We refer to the overall system developed in our project as the Gestational Diabetes Mellitus Monitoring (GDMM) system.

In this paper we will present the architecture of the GDMM system (Section II) and discuss how security has been addressed (Section II-B. Then we highlight related work and compare our approach to existing ones concerning the implementation of security issues in Section III. Finally we conclude our paper and give an outline to future work.

II. Architecture of a Pervasive Healthcare Monitoring System

Here we describe the components of a pervasive healthcare monitoring system and its security mechanisms.

A. Components of a pervasive healthcare monitoring system

In the previous section we have outlined the intended usage of a the GDMM system and the requirements towards the system. Here we propose the architecture for a system that will satisfy these needs. Despite the fact that it has to cope with different devices used by different groups of users, from a broad perspective such a system is a web-based application and it has to be able to manage different devices and roles users can have. Currently the medical staff, like doctors and nurses, will use a web-based interface to interact with the system. The patients will send their physiological data via smart phones. Nevertheless, the communication devices are not strictly bound to user groups. So a mobile application for doctors can be considered, as well.

Figure 1 shows that our system is composed of three main components, which are the *Mobile Interface System* (MIS), the *Agent Environment* (AE) and the *Patient Management System* (PMS). Furthermore, these components are interfaced between each others by means of a mediator component, realised as a Web service Data Gateway connector that accepts HTTPS requests. The MIS component collects the physiological data of the patient and delivers such data to the AE component and to the PMS component. The AE component utilises logic programming to model intelligent agents that filter the data submitted to the PMS and rise alerts in case of significant events, such as a possibility of preeclampsia in the patient or a high level of blood sugar that requires a treatment adjustment. Depending on the dynamic load, the AE system is subdivided into multiple instances where the patients connect with their smart phones to transmit their physiological data, that are then evaluated by intelligent agents. The patients are represented in the AE as *avatars* that can communicate to a personal intelligent agent, embodied in the AE. A personal intelligent agent exists for each patient. This agent is responsible to monitor her condition. This allows us in future extensions to specify individual strategies about when to notify a medical expert. Furthermore, it enables us to respect general medical guidelines but also to handle individual deviations from the standard procedures for each patients. Finally, the PMS allows the doctors to visualise the patient's data, and to visualise the alerts produced by the AE. The three tier logic architecture shown in Figure 1 translates then to a four tier architecture as shown in Figure 2.

We use a design pattern described by Meier et al. [2] for the design of the monitoring system. This patterns extends the well-established 3-tier architecture for web applications in two ways. First, it advocates for a fourth layer, taking the client device into account. It proposes to distribute the overall system into specific clients, web servers, application servers and databases. Secondly, it suggests for an additional layering within the application server.

The web interface for the medical staff can be accessed by a current standard web-browser. In contrast we need to create a specific application for the Android smart phones to allow patients to send their physiological data to the system. These components form the first layer in the *client*. More details about these user interfaces can be found in [3], [4].

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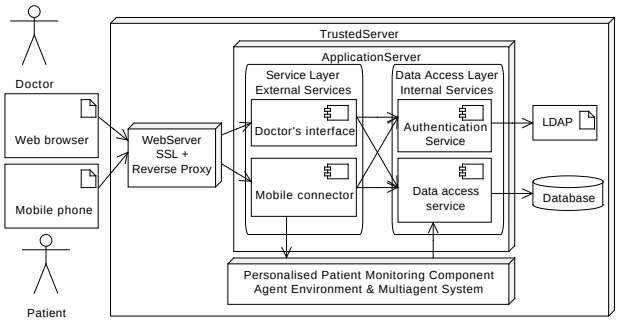

Figure 2. Architecture of the GDMM system

For the interaction with the backend system we use a REST architecture style [5], which forms the second layer. In the layering of the *application server* we have deviated form the 4-tier pattern by externalizing the business logic into the AE. The agents subscribe to the information produced by the patients and then the agent stores the incoming data (glucose, blood pressure, pulse, weight and symptoms) in the database. The rules for monitoring the patient are encoded as logic rules that produce alerts according to the physiological values of the patient. To define such rules we use two approaches, one based on deductive reasoning, specifying that if a set of glucose events are out of the boundaries, then an alert for treatment adjustment has to be risen, and one based on abductive reasoning, where, given a set of observations related to the symptoms of the patients the agent sends an alert with an explanation on the current status of the patient. The details of the rules used and the application of abductive logic is explained in more detail in [4]. Furthermore, to handle resources efficiently the agent itself can be serialized and stored in the database.

Finally, in the fourth layer the data is stored in a database to allow for efficient and persistent storage. Here we use a Postgres database. For authentication we can either use a database or an existing LDAP service.

The entire GDMM system has been fully implemented and first scalability analysis have been performed. According to our tests the system performs well. With a single instance of the system on a single machine we would be able to monitor up to several hundreds women suffering GDM [3].

B. Enforcing Security in the pervasive healthcare monitoring framework

Security is a central aspect when dealing with personal and medical data. We want to ensure confidentiality, which means that no one but the caretaker of a patient and the patient itself should be able to access the medical data. To create a secure system, extra effort has to go into modelling the interaction amongst the different components, securing the stream and storing of the data. To build our system, we followed the following security principles as defined by the Open Web Application Security Project (OWASP) [6]:

- We keep security simple, preferring simple security solutions over complex ones to reduce the potential for errors.
- We minimise the attack surface area, giving to an attacker as few attack opportunities as possible.
- We follow a *positive security model*, or white listing, which restricts values or actions to pre-defined elements. This is contrary to black listing, which allows all values or actions except those which are forbidden.

Generally speaking, a doctor is only allowed to access patient data if there exists a treating relationship between them. User's permissions are determined by their group membership and treatment relationships. Direct outside access to the server is restricted to secure HTTP. There is no mail server or other service running on the machine which could be vulnerable and lead to outside intrusion.

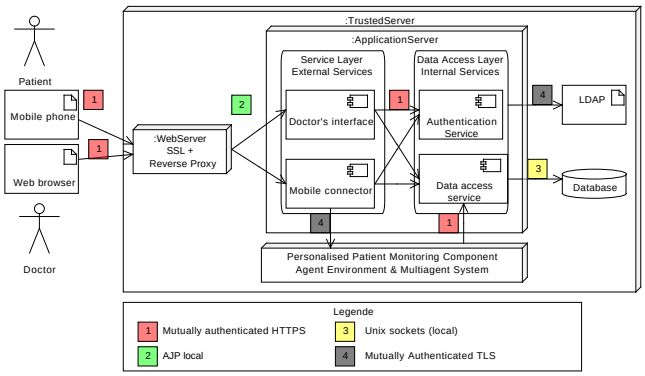

Figure 3. Security of the GDMM system

Figure 3 illustrates the details about how security is defined in the GDMM system, that we will explain in details later. To define this architecture we took into consideration the top ten list of security risks [7] for Web applications. Then we will show the proposed security interfaces to tackle these risks and we will describe their functionalities. This approach of validating a security of the architecture has also been used by Maji et al. [8].

- **Injections** can lead to unwanted code execution by insufficient input validation and escaping when creating commands between layers of a system.
- **Cross site scripting (XSS)** is a special case of code injection where an attacker can input HTML code which will be directly included when generating a page.
- **Broken Authentication and Session Management** refers to vulnerabilities related to authentication and session management.
- **Insecure Direct Object References** are requests using a user changeable object identifier which is not verified.

- **Cross-Site Request Forgery (CSRF)** denote malicious requests, which make use of an existing authentication token to perform requests on the user's behalf.
- **Security Misconfiguration** results in security problems due to outdated or wrongly configured software.
- **Insecure Cryptographic Storage** refers to breakable or circumventable cryptographic data protection.
- **Failure to Restrict URL Access** is a missing access control for restricted pages, which allows users without permission to access the pages.
- **Insufficient Transport Layer Protection** can cause an attacker to read passwords or sensitive data by monitoring traffic.
- **Unvalidated Redirects and Forwards** can be manipulated by an attacker to redirect to a malicious page while originating from a trusted page.

To avoid the security issue listed above, we defined a security layer at every interface of the system.

1) Security in the Mobile Phone and in the Web Interface: We have developed a mobile client as an App for the Android OS, we require at least version 2.3.3. In this App we have to make sure that the patient and the smart phone are authenticated with the system. For this purpose we use a double mean of authentication. To authenticate the phone, we store an encrypted certificate within the smart phone in binary format. Then, we provide our patients with a QR code, containing the keys for the certificate store and for encryption on the phone. This is described in Figure 4.

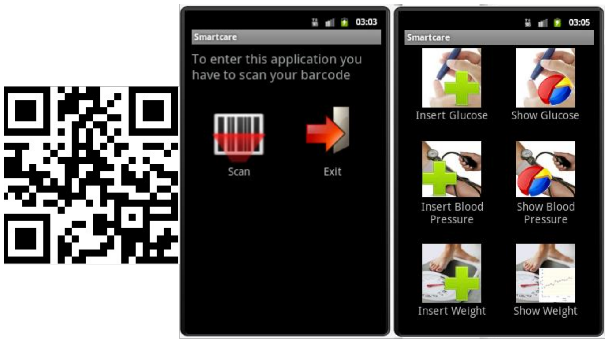

Figure 4. Bar Code Scanning in the Mobile Phone Client.

Consequently, in order to steal the identity of a patient, it is not enough to have the handheld device, it is also necessary to have the barcode. Through this double mean of authentication we aim at minimizing the risks of *Insufficient Transport Layer Protection*, *Unvalidated Redirect and Forwards* and *Insecure Cryptographic Storage* with respect to the smart phone client. In particular, the protection on the transportation layer is achieved using a mutually authenticated HTTPS connection between the smart phone and the system that makes use of signed certificates, this also minimize the risk of unvalidated redirect and forwards weaknesses. The storage within the smart phone again depends on the key stored in the QR code, consequently if the smart phone is stolen, without the QR code it is not possible to access the data of the user.

To authenticate the caregivers when accessing our GDMM system, we utilize user name, password and a certificate as the two authentication means. The certificate is stored on a smart card. Such a certificate is used to open a mutually authenticated HTTPS connection with the PHS. A limitation of our approach occurs when *CSRF* attacks have to be handled. Currently we cannot completely handle those attacks. One way to mitigate this could be the usage of a one time password, including the current time into the computation of the password. This will limit the validity of authentication tokens that can be used to produce data in the system from both of the patient and caregiver sides. Finally, *XSS* attacks are handled by sanitising the input that caregivers and patients can introduce in the system.

2) Security in the Server side: Figure 5 shows how we secured the distributed agent platform by means of a TLS transportation layer and HTTPS connections.

To secure the agent environment, we need to secure all the interfaces with the external world. As far as it concerns the *Data Layer*, this resides on an encrypted partition, consequently if access on the Data Layer is gained maliciously, to access the data it would be necessary to know the key for the encryption. This ensures that we can minimise the risks of attacks performed by *injection* or *insecure cryptographic storage*. Furthermore, every node of the agent environment, where the personal agents of the patient are deployed, contains a keystore and a truststore. The keystore contains a certification for the node of the agent environment which is used to open TSL connections to the other agent environment nodes. Similarly, when a mobile client connects to our GDMM system, it first opens a secure HTTPS connection with the mobile connector of the GDMM system, exchanging certificates with it. When the mobile client is authenticated, the mobile connector opens a TSL connection to the agent environment, by exchanging certificates, which minimises the risk that attacks based on *broken authentication and session management* are successful with respect to the communication performed by the smart phone client and the agent environment. Also, the use of certificates, minimises the risk that an attacker can exploit *insecure direct object references* as the connections between the different entities in the system are all authenticated, mitigating the risk of a middle-man attack. Additionally the right management system ensures that clients can only see data they are entitled to see, mitigating the risk of URL manipulation. Using truststores and keystores improves the security of the system also with respect to *security misconfiguration* issues as the certificates have to be properly set up in order to have a meaningful communication amongst the components of the system. Finally, *injection* attacks by injecting agents into the agent environment are particularly

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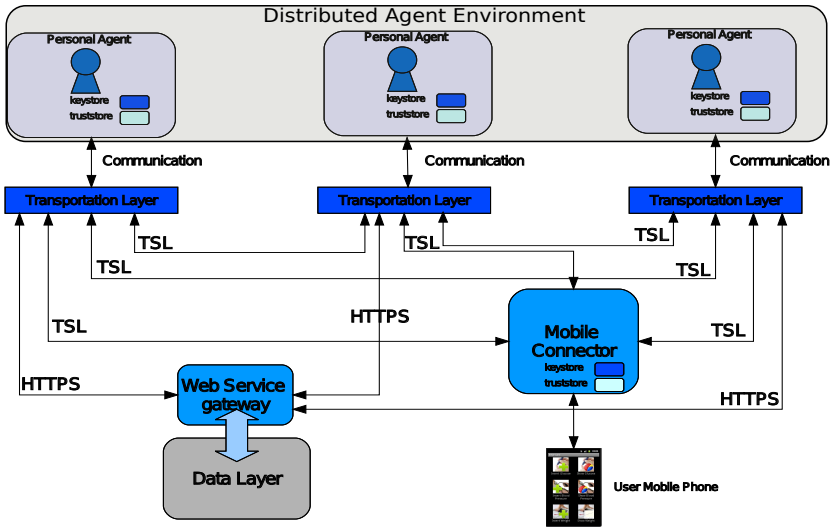

Figure 5. Security in the Agent Environment APIs

difficult as the only mean of communication with a node is the transportation layer, meaning that to inject an agent, the attacker should have a legitimate certificate and know the private key of one of the internal components of our framework. Other injection attacks, like SQL injections, are not possible, because we apply the white listing security approach, allowing only pre-defined types of data as inputs.

III. Related Work

Orwat et al. [9] have presented an extensive survey about research performed in pervasive healthcare. They have in total reviewed publications from 67 different projects worldwide. According to their survey the monitoring of patients is a heavily addressed field (in 63% of the projects surveyed). Also the usage of common mobile devices is recognised as a common way (51% of all projects). Automated monitoring and alerting experts is addressed by 46% of the projects. So the functionality described here are in the core of pervasive healthcare systems research. Even though the potential values of such applications is widely recognised it is quite surprising that the issue how to design those system in a secure way, has not been adequately addressed. This impression is supported by the review from Isern et al. [10]. They describe several agent-based monitoring projects aiming to monitor the state of patients with different degrees of centralisation. One problem of those projects is that they did not focus on security aspects. The pervasive healthcare monitoring framework, presented in this paper, tries to narrow this gap, by embedding concepts needed for an individual monitoring of patients into a framework for secured web-based applications.

As pointed out before the body of work using pervasive healthcare to monitor patients is considerable large. Even though two aspects are interesting. First, to the best of our knowledge the GDMM system is the first one that addesses GDM. So far only diabetes type I and II have been addressed, in particular type I, e.g. by Farmer et al. [11] or in the DiaBetNet project [12]. Second, the aspect of securing such PHS is not broadly addressed, so far. For instance Orwat et al. [9] found only in 11 publication references to the problems induced by privacy and security concerns to PHS. And only few of them discuss how to address those issues. We will focus here on these and more recent work, addressing the security issue in PHS.

A number of researchers used mobile phones to implement pervasive healthcare systems. Therefore securing GSM and WAP connections has been focused e.g. by [13], [14].

Systems, like ours, which taking advantage of the IP based communication use well-established approaches, based on encrypted communications via HTTPS, e.g. [15].

Toledo et al. [15] have presented a platform for chronic care for patients suffering from chronic obstructive pulmonary disease (COPD). The authors performed a field test with 157 patients, connecting the patients to medical experts in a call centre. Therefore they use an electronic chronic patient record that can be accessed by the persons in the call centres but also by the caretakers while they visit the patients. So different devices needed to connect to a centralized server. The authors presents an extended security concept. Different devices had to be integrated. For all devices connection are SSL encrypted, e.g. using the HTTPS protocol. Specific services can only be accessed from the Intranet or via a VPN access. Also token and certificates are used to secure the connection between mobile services. Also user have to identify themselves, using login and password information.

Salvador et al. [13] aim to monitor cardiac patients. Patients interact with a mobile phone with a centralised

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service. Consequently considerable efforts have been but into securing the mobile connection based on GSM build in security and WAP sessions. Patients are served by personal healthcare agents (note here these are real medical experts). These experts need access to the patients data. They are connected via a secured internet connection. Also medical data is transmitted in an anonymous way, where the id of the patient is a shared secret between sender and receiver, to foster privacy aspects. Of course also an authorisation and right management has been implemented to control the access of the healthcare agents. Both user groups has to identify them to the system using a login/ password pair.

Maji et al. [8] have presented a four tier architecture for web-based telemedicine applications, too. Instead of adding specific client components, they have added a web proxy layer in front of a firewall. This proxy separates the server side application from the internet. From a functional point of view the web proxy layer allows to separate the session handling from the generation of the device depended presentation of the content. While this is an interesting idea for separating the different tasks located in the presentation layer of a conventional three-tier web architecture, this is quite similar from the security perspective to what we can achieve by using a reverse proxy in the web server.

IV. Conclusion and Future Works

In this paper we have presented the Gestational Diabetes Mellitus Monitoring system. In particular, we have highlighted the components of this PHS and how these are interconnected. We have also explain in details how these interconnections are secured and how these security means can protect the GDMM system from the most widely spread and serious security threats.

The GDMM system is currently prepared to test it in the field. Another aspect we are currently work on, is to generalise the architectural concepts of the GDMM system into a more general pervasive healthcare monitoring framework. Other aspects that we plan to implement is to allow for personalised monitoring rules.

Acknowledgment

We would like to thank Dr. Juan Ruiz and his team for sharing their insights in GDM, and their support of our research. This work has been partially funded by the Hasler Stiftung and by the Nano-Tera grant 10020.

References

[1] J. Epping-Jordan, "Innovative care for chronic condition," World Health Organization, Tech. Rep., 2001.

[2] J. Meier, A. Homer, D. Hill, J. Taylor, P. Bansode, L. Wall, R. B. Jr, and A. Bogawat, "App Pattern: Four-Tier Web Application Scenario," 2009, https://apparch.codeplex.com/wikipage?title=AppPattern-Four-TierWebApplicationScenario(TableModule, accessed 02.09.2011.

[3] J. Krampf, S. Bromuri, M. Schumacher, and J. Ruiz, "An agent based pervasive healthcare system: a first scalability study," in *Proceedings of the 4th ICST International Conference on eHealth (eHealth 2011)*. Springer, 2011, (to appear).

[4] S. Bromuri, M. Schumacher, K. Stathis, and J. Ruiz, "Monitoring gestational diabetes mellitus with cognitive agents and agent environments," in *Proceedings of the 2011th IEEE/WIC/ACM International Conference on Intelligent Agent Technology (IAT 2011)*, Aug. 2011.

[5] R. T. Fielding, "Architectural styles and the design of network-based software architectures," Ph.D. dissertation, 2000, chair-Richard N. Taylor.

[6] OWASP, "The Open Web Application Security Project: Category:Principle," 2011, https://www.owasp.org/index.php/Category:Principle, accessed 15.06.2011.

[7] ——, "The Open Web Application Security Project: Top 10 2010-Main," 2010, https://www.owasp.org/index.php/Top_10_2010-Main, accessed 14.09.2011.

[8] A. K. Maji, A. Mukhoty, A. K. Majumdar, J. Mukhopadhyay, S. Sural, S. Paul, and B. Majumdar, "Security analysis and implementation of web-based telemedicine services with a four-tier architecture," in *Proc. 1. Int. ICST Workshop on Connectivity, Mobility and Patients' Comfort*. IEEE, 2008.

[9] C. Orwat, A. Graefe, and T. Faulwasser, "Towards pervasive computing in health care a literature review," *BMC Medical Informatics and Decision Making*, vol. 8, no. 26, 2008.

[10] D. Isern, D. Sanchez, and A. Moreno, "Agents applied in health care: A review," *international journal of medical informatics*, vol. 79, pp. 145 – 166, 2010.

[11] A. Farmer, O. Gibson, P. Hayton, K. Bryden, C. Dudley, A. Neil, and L. Tarassenko, "A real-time, mobile phone-based telemedicine system to support young adults with type 1 diabetes," *Informatics in Primary Care*, vol. 13, pp. 171 – 177, 2005.

[12] V. Kumar and S. Lie, "DiaBetNet project page," 2010, http://slie.dyndns.org/projects/DiaBetNet/webpage/, accessed 07.09.2011.

[13] C. H. Salvador, M. P. Carrasco, M. A. G. d. Mingo, A. M. Carrero, J. M. Montes, L. S. Martin, M. A. Cavero, I. F. Lozano, and J. L. Monteagudo, "2005," *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE*, vol. 9, no. 1, pp. 73 – 85, 2005.

[14] G. Ghinea, S. Asgari, A. Moradi, and T. Serif, "A jini-based solution for electronic prescriptions," *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE*, vol. 10, no. 4, pp. 794 – 802, 2006.

[15] P. d. Toledo, S. Jimnez, F. d. Pozo, J. Roca, A. Alonso, and C. Hernandez, "Telemedicine experience for chronic care in copd," *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE*, vol. 10, no. 3, pp. 567 – 573, 2006.

 ISBN: 978-1-61208-179-3

Towards Object-aware Process Support in Healthcare Information Systems

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***Abstract*—The processes to be supported by healthcare information systems are highly complex, and they produce and consume a large amount of data. Besides, they require a high degree of flexibility. Despite their widespread adoption in industry, however, traditional process management systems (PrMS) have not been broadly used in healthcare environments so far. One major reason for this is the missing integration of processes with business data; i.e., business objects (e.g., medical orders or reports) are usually outside the control of a PrMS. By contrast, our PHILharmonicFlows framework offers an object-aware process management approach, which tightly integrates business objects and processes. In this paper, we use this framework to support a breast cancer diagnosis scenario. We discuss the lessons learned from this case study as well as requirements from the healthcare domain that can be effectively met by an object-aware process management system.**

***Keywords*-Process Management, Object-aware Process Management, Data-driven Process Execution.**

I. INTRODUCTION

Healthcare processes are characterized by their high complexity and the large amount of data they have to manage [1], [2]. The latter is usually represented through business objects like medical orders, medical reports, laboratory reports, and discharge letters. Since healthcare processes require the cooperation among different organizational units and medical disciplines [3], adequate process support is crucial. In this context, process management systems (PrMS) are typically the first choice for implementing process-aware information systems. However, despite their widespread adoption in industry, existing PrMS are not broadly used in healthcare environments [4]. One major reason for this deficiency is that contemporary PrMS are *activity-driven*. The processes are modeled in terms of "black-box" activities and their control-flow defines the order and constraints for executing these activities. However, activity-centric process modeling approaches like BPMN [5] or BPEL [6] present numerous limitations [29]: business data is typically treated as second-class citizen [7], [11]. For example, most PrMS only cover atomic data elements, which are needed for control flow routing and for supplying the input parameters of activities [8]. Business objects, in turn, are usually stored in external databases and are outside the control of the PrMS. Hence, integrated access to data and processes as crucial in the healthcare domain is missing; i.e., PrMS are unable to provide immediate access to important process information in case of unexpected events [26].

Regarding the execution of activity-driven PrMS, a process requires a number of activities to be completed in order to terminate successfully. Healthcare processes and their steps, in turn, depend on the availability of certain information [3]. For example, if a patient has a temperature of above 38,5°C, the doctor may have to prescribe a medicine to contain the fever. Consequently, the activation of an activity does not directly depend on the completion of other activities, but rather on the changes of business object attributes.

Typically, it is also not possible to squeeze processes from the healthcare domain into one monolithic process model [1]. In healthcare environments, there exists numerous processes depending on each other. For example, the distribution of a medicine in the hospital pharmacy may depend on the patient's treatment process which, in turn, may depend on his diagnosis process. The latter comprises diagnostic processes like blood tests and image examinations (or imaging encounters). To be applicable in a healthcare context, therefore, a PrMS must provide mechanisms for coordinating the interactions between interdependent processes.

Another challenge arises from the fact that activities are not only executed in the context of single process instances. Instead, they may be invoked at different levels of granularity comprising several process instances (of the same and of different type). A medical doctor, for instance, may examine one patient at a time, while a nurse prepares medications for several patients in one go. Finally, healthcare processes are highly dependent on medical knowledge as well as on specific case decisions [3], [25]. Thus, the type and order of invoked activities may vary from process instance to process instance. For this reason, healthcare processes cannot be "straight-jacketed" into a set of pre-defined activities [11], [24].

Generally, the described limitations of existing PrMS can be traced back to the missing integration of processes and data [28], [29]. To overcome these limitations, several approaches have already pioneered concepts for enabling data-driven process execution [11]–[13], [16], [17], [20], data-driven exception handling and process adaptation [17], [18], process coordination [9], [16], integrated access to data [11],

 ISBN: 978-1-61208-179-3

and process definition based on data behavior [14], [20]. However, none of them considers all identified limitations in a comprehensive and integrated way. In addition, some of these approaches do not make a difference between the modeling and execution of a process; i.e., they provide rich capabilities for process modeling, but do not explicitly take runtime issues into account.

Opposed to these approaches, PHILharmonicFlows targets at a comprehensive framework addressing the described limitations [28]. In addition, PHILharmonicFlows enforces a well-defined modeling methodology governing the object-centric specification of processes and being based on a formal operational semantics [30]. In this paper, we evaluate the applicability of PHILharmonicFlows framework to healthcare processes. To limit the scope, we focus on modeling issues in this paper. For this purpose, we present a breast cancer diagnosis procedure as performed at a Women's hospital.

Section II describes the medical scenario considered as well as the list of requirements to be supported by any PrMS in order to be applicable in a healthcare environment. In Section III, we model this scenario using the components provided by PHILharmonicFlows. Following this, in Section IV, we discuss how the requirements listed in Section II are met by the framework. Related work is discussed in Section V. Finally, Section VI concludes with a summary and an outlook.

II. Description of Healthcare Scenario

The healthcare scenario we consider is a breast cancer diagnosis process we obtained from a process handbook of a Women's hospital. As illustrated in Figure 1, this process comprises anamnesis, a physical examination (including the collection and confirmation of symptoms), a set of medical examinations (e.g., MRI, mammography, blood analysis), and a tumor biopsy. Some of these procedures are illustrated in Figure 2. We describe the different procedures using state charts. The latter are typically considered as intuitive modeling paradigm providing a natural view for end users [15].

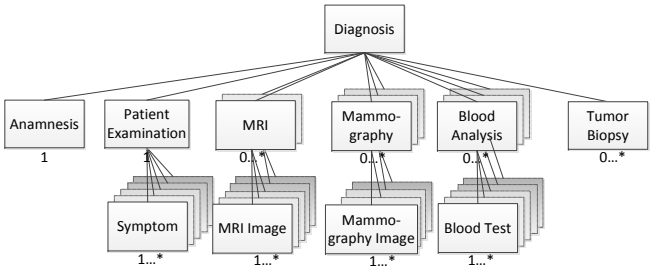

Figure 1. Objects involved in the breast cancer diagnosis process

During anamnesis (cf. Fig. 2b) the physician asks the patient specific questions (e.g., about her history of diseases, family diseases, or current medication). In the meanwhile, the doctor examines the patient and interviews her about the presence of any symptom (cf. Fig. 2d). The physician also asks the patient about breast nodules and he performs a physical examination in order to confirm or exclude the symptoms (cf. Fig. 2c). If the symptoms brought up by the patient are not confirmed during the physical examination, the presence of the tumor will be denied (cf. Fig. 2a). In this case the diagnosis process is finished. Otherwise, the doctor decides about a battery of examinations based on the symptoms confirmed.

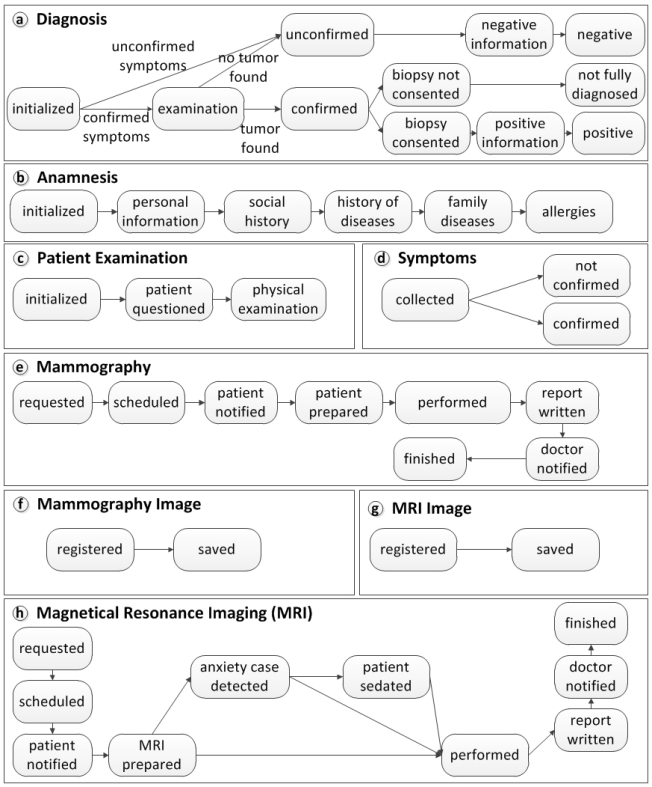

Figure 2. State diagrams for diagnosis, anamnesis, patient examination, symptom, mammography, and breast MRI examinations

One of the examinations required to detect the presence of a breast tumor or to exclude it is mammography (cf. Figure 2e). To perform this examination, the secretary of the radiology department must schedule it. At the day of the appointment the procedure is performed and the resulting images are stored in a database (cf. Figure 2f). The MRI examination comprises a similar process shown in Figure 2g. The images from both examinations are then analyzed by a specialized physician of the radiology department and are added to the respective medical reports. As opposed to the mammography examination, for which the equipment does not cause claustrophobia, during the MRI examination (cf. in Fig. 2h) the patient may have a case of elevated anxiety due to the enclosure of the MRI equipment. In such cases, the

radiology specialist being responsible for the examination must decide whether or not the patient shall be sedated before continuing with the procedure.

In the meanwhile, the doctor may request further examinations as, for example, another MRI examination or additional blood tests. Otherwise, if the existence of a tumor is confirmed, the doctor may want to biopsy this mass in order to confirm the malignancy of the tumor (cf. Fig. 2a). In this case, however, the consent of the patient is required. The biopsy report is returned to the physician who will inform the patient about the malignancy status of the tumor. Finally, the diagnosis process is finished as positive, confirming the presence of a breast tumor.

Though this diagnosis scenario seems to be rather simple, it indicates a number of requirements to be supported by the PrMS in order to be applicable to this healthcare environment:

Req. 1 - Data and process integration: Our scenario is composed of many procedures (e.g., anamnesis, searching symptoms, mammography, and MRI). The product of each of these procedures is data related to the patient's diagnosis; e.g., the data obtained when interviewing the patient in the context of the anamnesis. Respective data is not only important for keeping the patient's history updated or for registering all events for the purpose of auditing, they are also vital for process execution. Milestones reached during process execution do less depend on the execution of certain activities, but more on the availability of certain data. For example, a mammography medical report may only be written after having captured and stored the respective images. In addition, user decisions (typically based on available data) are fundamental for process execution. A radiology specialist, for example, may decide whether or not to sedate a patient during an MRI examination.

Req. 2 - Intense use of forms: Like most healthcare processes, the sketched scenario is characterized by a large number of medical forms to be filled by authorized medical staff (e.g., doctors, nurses, laboratory staff) with information being relevant to patient treatment. As example consider the information obtained when interviewing the patient about her anamnesis.

Req. 3 - Interacting processes: The breast cancer diagnosis process needs to interact with other processes (e.g., MRI); i.e., there are points in the diagnosis process where data from the MRI process is needed. In particular, these processes have *synchronization points*, where the further execution of a particular process instance depends on the data produced during the execution of one or several related instances. Respective synchronization points do not only correspond to one-to-one relationships; i.e., the execution of a particular process instance may also depend on multiple instances of another process type. In our example, the execution of the diagnosis process depends on the results of various examinations.

Req. 4 - Flexibility regarding process instantiation: Figure 1 also shows different cardinalities for the different procedures of the diagnosis process. These indicate whether or not the execution of the respective procedures is mandatory and whether they may be executed more than once. Mandatory procedures (e.g., *Anamnesis*, *Patient Examination*) have cardinality *1*, while optional ones (e.g., *MRI*, *Mammography*, *Blood Analysis*, *Tumor Biopsy*) have cardinality *0...**. The latter indicates that there are no restrictions regarding the number of instances of respective optional procedures. Based on the patient's case, doctors may decide which of these optional procedures shall be ordered and which not. Moreover, it is possible to request them more than once.

Req. 5 - Authorized user access: To ensure privacy, it is necessary that only authorized users may access patient data. In our scenario, for example, the secretary of the radiology department must not access information about the patient obtained during the anamnesis and she must not register symptoms of the patient. However, she may access the data related to the request and the scheduling of a mammography or an MRI examination. Besides, the permission to access data often depends on the progress of the process, which means that certain data should be only accessible at certain points during process execution. For example, the medical report of a mammography is accessible for the ordering doctor only when the procedure is completed and the report has been approved by the radiologist.

Req. 6 - Flexible data access: The system must provide the flexibility to users to access and modify data at arbitrary points during process execution. This is very important in order to be able to react to unexpected events. For example, in case of an emergency, the system must allow the doctor to access examination data before the medical report becomes available.

III. Case Study: Modeling with PHILharmonicFlows

In the previous section, we introduced fundamental requirements for adequately supporting healthcare processes. These indicate that healthcare processes fulfill the major characteristics of *object-aware processes* [31]:

1) *Object behavior:* The processing of individual object instances must be coordinated between different users, and valid attribute settings must be specified.
2) *Object interactions:* The behavior of individual objects must be coordinated with the one of related objects.
3) *Data-driven execution:* The progress of a process instance depends on business objects and their attribute values.
4) *Integrated access:* Authorized users should be able to access and manage process-related data objects at any point in time.
5) *Flexible activity execution:* Activities should be executable at different levels of granularity; e.g., it should

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be possible that an activity may relate to one or to multiple process instances.

PHILharmonicFlows has recognized the need to offer flexible support for this kind of processes [28]. More precisely, it provides a comprehensive framework with components for both modeling and executing object-aware processes. To be able to define these processes in tight integration with data, the framework enforces a well-defined modeling methodology that governs the definition of processes at different levels of granularity. In this context, PHILharmonicFlows differentiates between *micro processes* and *macro processes* capturing either the *behavior* of single objects or the *interactions* among multiple objects.

The behavior of an object can be expressed by a number of possible *states*. Whether or not a particular state is reached depends on the values of object attributes. The interactions among objects, in turn, are enabled when involved objects reach certain states. Hence, object states serve as interface between micro and macro processes.

As prerequisite for integrated access to data and processes, a *data model* has to be defined. The latter enables the definition of object types as well as their attributes and relationships (including cardinalities) [30]. The data model depicted in Figure 1, for example, gives an overview of the object types being relevant in the context of our diagnosis process; i.e., there is one object type for each of the phases of the diagnosis process. Furthermore, Figure 5 illustrates the attributes of object type *Mammography*.

In PHILharmonicFlows, for each *object type* defined by the data model, one specific *micro process type* has to be defined. At runtime, object instances of the same and of different object types can be created at different points in time. In this context, the creation of a new object instance is directly coupled with the creation of a corresponding micro process instance. A *micro process type* expresses the behavior of the respective object type; i.e., it coordinates the processing of an object among different users and specifies what valid attribute settings are. Additionally, the cardinality of an object type in relation to other object types defines restrictions regarding the instantiation of micro process types and object types respectively. For example, in our case the cardinality of object type *Anamnesis* in relation to object type *Diagnosis* is *1*; i.e., there must be exactly one instance of object type *Anamnesis* for each *Diagnosis* instance. By contrast, it is not mandatory that there exists an instance of object type *Mammography* for each *Diagnosis* instance. However, it is up to the respective physician to initiate a specific number of instances of this examination as long as cardinality constraints are fulfilled. To meet Requirement 4 (cf. Section II), PHILharmonicFlows provides the flexibility to handle a varying number of instances of interrelated examinations. More precisely, it is up to the user to decide when and which examinations are required. We will see in the following, that using macro processes it becomes possible to define sophisticated execution and instantiation constraints in this context.

At micro process level, each micro process type comprises a number of *micro step types*, which describe elementary actions for reading and writing object attribute values. More precisely, each micro step type is associated with one particular attribute of the respective object type. Micro step types, in turn, may be connected with each other using *micro transition types*. To coordinate the processing of individual object instances among different users, several micro step types can be grouped into *state types*. The latter are then associated with one or more user roles being responsible to assign values to the required attributes. At runtime, a micro step can be reached if for the corresponding attribute a value is set. A state, in turn, can only be left if values for all attributes associated with the micro steps of this state are set. Whether or not the subsequent state in the micro process is immediately activated then may also depend on user decisions. For this purpose, micro transition types connecting micro step types belonging to different state types can either be categorized as *implicit* or *explicit*. Using *implicit micro transitions*, the target state is automatically activated as soon as all attribute values required by the previous state become available. *Explicit micro transitions*, in turn, additionally require a user commitment; i.e., users may decide whether or not the subsequent state should be activated. This way, users are enabled to still change corresponding attribute values even if all attribute values required to leave the state have been already set.

An example of a micro process type is illustrated in Figure 4. Object type *Mammography* and its respective micro process type are instantiated when the doctor orders a new *Mammography* examination. In order to *request* a *Mammography*, the (authorized) user must set the *order date*; i.e., to complete micro step *order_date* a value needs to be assigned to the corresponding attribute. In our example, the micro transition type between state types *requested* and *scheduled* is explicit (dotted line). This ensures that the doctor may still review the examination request before sending it to the secretary of the radiology department. In state *scheduled*, in turn, the *Secretary* must fill attributes *scheduled_date*, *scheduled_doctor* and *scheduled_room*. She further has to decide when to notify the patient about the scheduled appointment; i.e., the next state *patient notified* will only be activated when explicitly being confirmed by the *Secretary*.

A user decision, in turn, is required if a micro step type has more than one outgoing micro transition types. In this case, the responsible user has to decide which subsequent state shall be activated. Figure 3 shows a fragment of the *MRI* micro process type, where the radiology specialist must decide, in case of a patient's anxiety scenario, whether or not to sedate the patient. As we can observe in this example, the dotted lines indicate explicit micro transitions.

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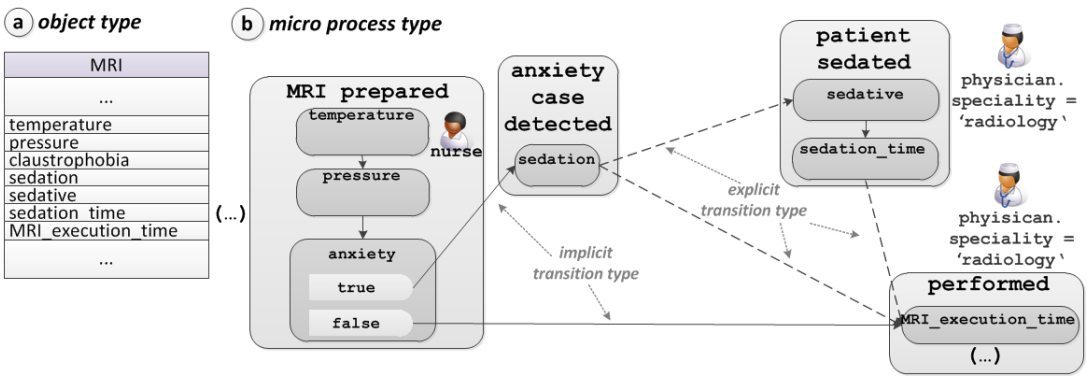

Figure 3. Partial view of the MRI micro process type

To enable coordination, user roles have to be assigned to the different states of a micro process type. Based on these role assignments, a corresponding *authorization table* is automatically generated for each object type. More precisely, PHILharmonicFlows grants different permissions for reading and writing attribute values as well as for creating and deleting object instances to different user roles. In this context, the different states are considered as well; i.e., users may have different permissions in different states. The right to write an attribute can either be *mandatory* or *optional*. When initially generating the authorization table, the user role associated to a state type automatically receives mandatory write authorization for all attributes related to any micro step type of the respective state type. Optional data access may be additionally granted to user roles not being associated to the state type. This way, users currently not being involved in process execution are enabled to access process relevant data if desired.

Based on the authorization table, PHILharmonicFlows also automatically generates user forms. Which input fields are displayed to the respective user depends on the permissions he has in the currently activated state. If he only has the permission to read an attribute in a particular state, the form field will not be editable and be marked as read-only. A mandatory or optional attribute, in turn, is associated with an editable field. In particular, mandatory fields are highlighted in the respective form.

The concepts provided by PHILharmonicFlows to enable data authorization for micro process types are exemplified in Figure 5. It illustrates the authorization table of micro process type *Mammography*. In this example, state type *requested* has only one mandatory attribute *order_date* (marked as *MW* in the authorization table). This attribute has to be set by the physician requesting the examination. In addition, attributes *order_desired_date* and *order_observations* are optional (marked as *OW*). In state *scheduled*, the same physician may change the values of the aforementioned optional attributes, as opposed to the secretary of the radiology department. The latter may only read the values of these attributes (marked as *R*). However, she is allowed to write attributes *scheduled_date*, *scheduled_doctor* and *scheduled_room*, which, in turn, may only be read by the doctor.

Whether or not subsequent object states can be reached may not only depend on object attributes, but also on the states of other micro process instances. At runtime, for each object instance one corresponding micro process instance exists. As a consequence, a healthcare scenario may comprise dozens up to hundreds of micro process instances. Taking their various interdependencies into account, we obtain a complex *process structure*. In order to enable the interaction between these micro process instances, a *coordination mechanism* is required to specify the interaction points of the processes involved. For this purpose, PHILharmonicFlows automatically derives a state-based view for each micro process type. This view is then used for modeling macro process types. A *macro process type* refers to parts of the data structure and consists of both *macro step types* and *macro transitions types* between the latter. As opposed to traditional process modeling approaches, where process steps are defined in terms of black-box activities, a macro step type always refers to an object type together with a corresponding state type. The macro process type resulting for our example from Figure 6 illustrates this. The process begins with the instantiation of object type *Diagnosis*, which triggers the initiation of its micro process. Then, object type *Anamnesis* is instantiated (i.e., the responsible doctor receives a corresponding item in his worklist) and its micro process instance is initialized. During *Patient Examination*, it is possible to have the *symptoms* collected, which are then confirmed after the *physical examination* has taken place. If the symptoms are not confirmed, the diagnosis will be finished as negative, indicating that no tumor was found. Otherwise, the diagnosis process continues with requesting imaging encounters. It is important to note that for one primary examination, there may be more than one symptom collected.

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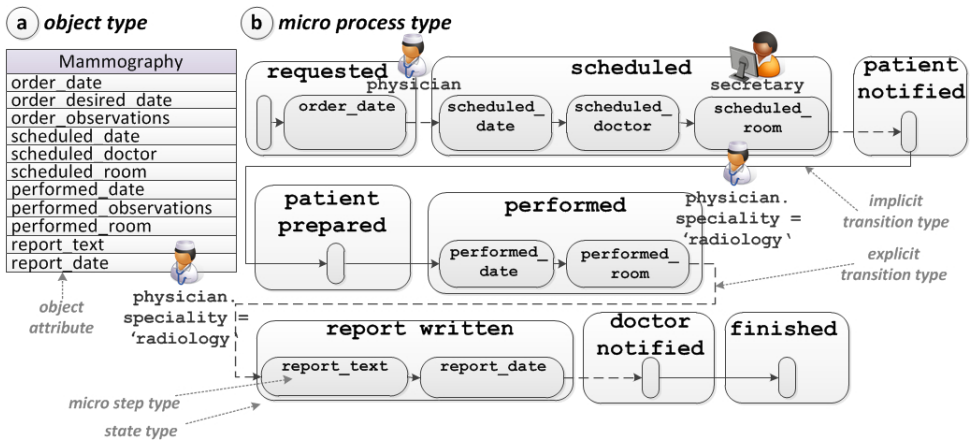

Figure 4. Mammography micro process type

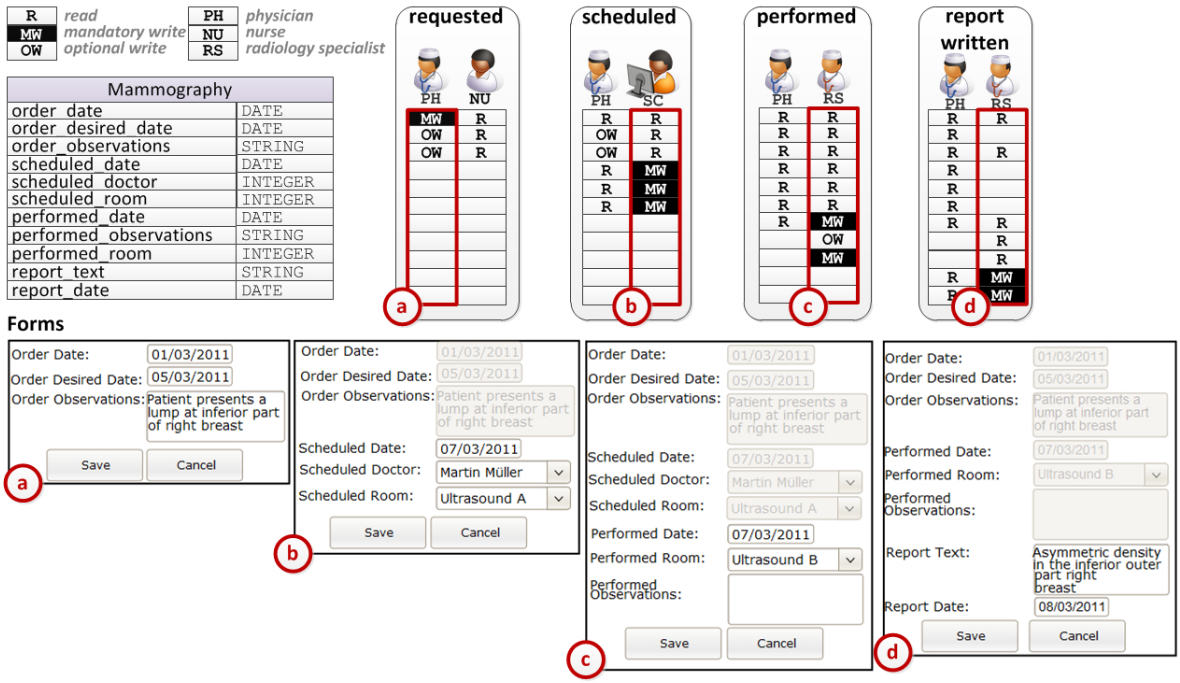

Figure 5. Authorization table and forms of the Mammography micro process type

Since the activation of a particular state may depend on instances of different micro process types, macro input types are assigned to macro step types. The latter can then be associated with several macro transitions. To differentiate between AND and OR semantics in this context, it is additionally possible to model more than one macro input for each macro step type. At runtime, a macro step is enabled if at least one of its macro inputs becomes activated. A macro input, in turn, is enabled if all incoming macro transitions are triggered.

To take the dynamically evolving number of object instances as well as the asynchronous execution of corresponding micro process instances into account, for each macro transition a corresponding *coordination component* needs to be defined. For this purpose, PHILharmonicFlows takes the relationship between the object type of the source macro step type and the one of the target macro step type into account. To cover this, the framework automatically structures the data model into different *data levels*. All object types not referring to any other object type are placed on the top level (Level #1). Generally, any other object type is always assigned to a lower data level as the object types it references. As illustrated in Figure 7, in our case study, object type *Diagnosis* is at the top level, while all the examinations are placed at a lower level. For example, images refer to respective examinations (i.e., imaging encounters). Hence,

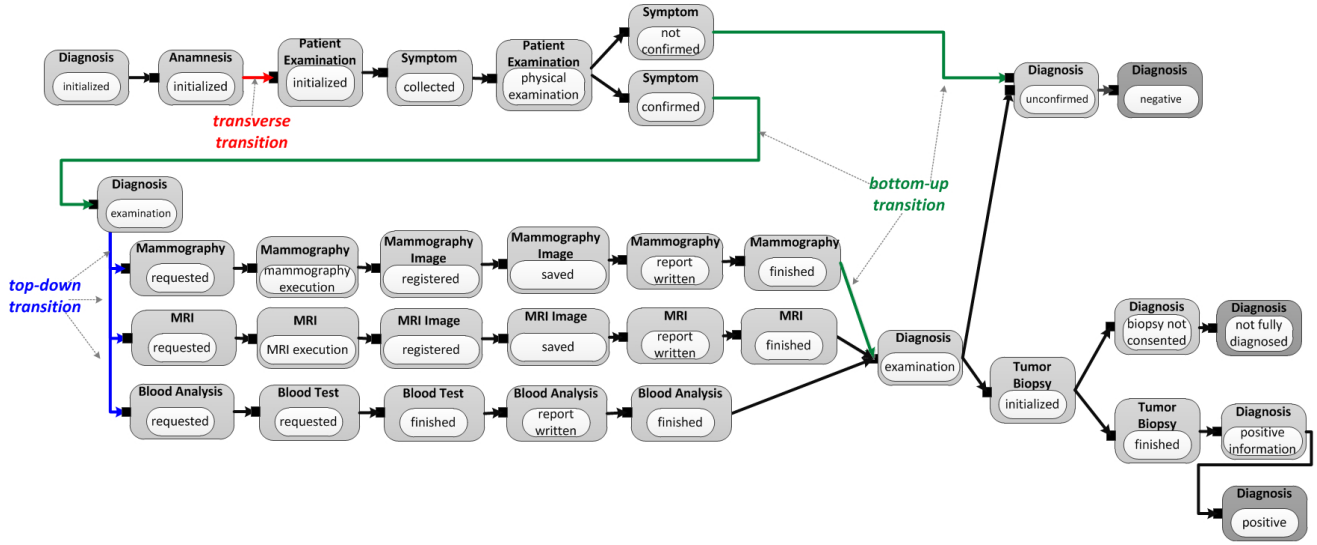

Figure 6. A macro process type coordinating the interactions among the different micro process types

they are placed at Level #3. In this paper, we do not discuss self-references and cyclic relations, but they are considered by PHILharmonicFlows framework.

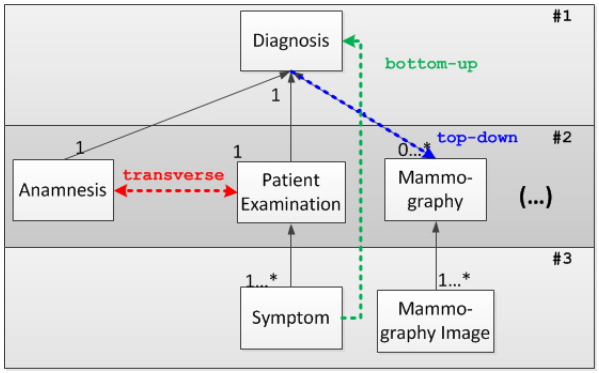

Figure 7. Different kinds of relationships between object types

By organizing the object types of the data model into different levels, PHILharmonicFlows automatically categorizes macro transitions either as *top-down* or as *bottom-up* (cf. Figure 7). Furthermore, if the object types of the source and sink macro state refer to a common higher-level object type, the macro transition is categorized as *transverse*. For macro transitions types connecting macro step types that refer to the same object type no coordination component is needed. These transitions are denoted as *self-transitions*. For all other ones, the coordination component required depends on the type of the respective macro transition. A *top-down transition* characterizes the interaction from an upper-level object type to a lower-level one. Here, the execution of a varying number of micro process instances depends on one higher-level micro process instance. In this context, a so called *process context type* must be assigned to the respective macro transition type. Due to lack of space, we do not go into details. We also do not discuss transverse macro transition types here. A *bottom-up transition*, in turn, characterizes an interaction from a lower-level object type to an upper-level one. In this case, the execution of one higher-level micro process instance depends on the execution of several lower-level micro process instances of the same type. For this reason, each bottom-up transition requires an *aggregation component* for coordination. For this purpose, PHILharmonicFlows provides *counters* managing the total number of lower-level micro process instances and the number of micro process instances for which the state corresponding to the source macro step type is currently activated. To enable asynchronous execution, additional counters for reflecting the number of micro process instances currently being before or after the respective state or being skipped are provided. These counters can be used for defining aggregation conditions enabling the higher-level micro process instance to activate the state. As illustrated in Figure 8, the *Diagnosis* process is finished in state *negative* if no *Symptoms* is confirmed. The aggregation condition for this case (`#IN=#ALL`) indicates that all micro process instances of object type *Symptom* must reach state *not confirmed* in order to activate the state *unconfirmed* from the respective instance of micro process type *Diagnosis*. In this example, we illustrate how such counters work. As illustrated in Figure 8, there are three micro process instances of *Symptom* related to one micro process instance of *Diagnosis*. In this example, the counter indicates that two of the running instances of *symptom* have already reached state *not confirmed* (`#IN=2`), while instance has not yet reached this state (`#BEFORE=1`). When all three instances reach this state (i.e., the condition

defined in the aggregation is met), state *unconfirmed* is activated at the respective *Diagnosis* instance.

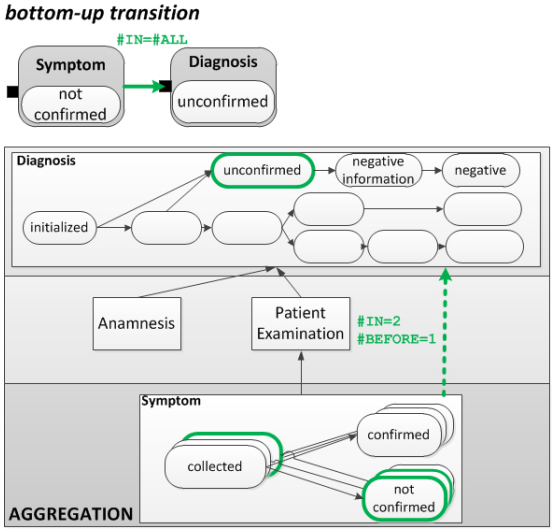

Figure 8. Aggregation example

The *runtime environment* provides data- as well as process-oriented views to end-users. In particular, authorized users may invoke activities for accessing data at any point in time as well as activities needed in order to proceed with the execution of micro process instances. In this context, the formal operational semantics of PHILharmonicFlows enables a well-defined execution logic and additionally enables us to automatically generate most end-user components of the runtime environment (e.g., tables giving an overview on object instances, user worklists, and form-based activities).

Insights into the operational semantics provided by PHILharmonicFlows can be found in [30].

IV. Discussion

In Section II, we have introduced a healthcare scenario, which we have then modeled in Section III using the PHILharmonicFlows framework. In this section, we discuss how the requirements posed by the healthcare scenario are covered.

Req. 1 - Data and process integration: The well defined modeling methodology of PHILharmonicFlows ensures that each procedure (e.g., anamnesis, primary examination, mammography, etc.) is modeled from a data-oriented perspective (i.e., by using object types) as well as from a process-oriented one (i.e., by using micro process types). Hence, all the data produced by such procedures is stored and managed without need to access external databases during the execution of black-box activities. This also enables users to access and manage process-related object instances at any point in time (assuming proper authorization) and not only in the context of upcoming mandatory activities.

Req. 2 - Intense use of forms: Based on authorization tables, PHILharmonicFlows automatically generates user forms. For this purpose, it takes the currently activated state of a micro process instance as well as the user and his data access permissions into account. Each form comprises fields corresponding to read and write permissions of respective attributes. Moreover, in PHILharmonicFlows, object instances and activities are not strictly linked with each other. For example, it is also possible to execute a particular form in relation to a collection of object instances of the same object type. Here, entered attribute values are assigned to all selected object instances in one go. In addition, a user may invoke additional object instances of different (related) types. When generating corresponding forms, the currently activated states of these instances as well as the permissions assigned to the respective user in these states are taken into account.

Req. 3 - Interacting processes: As discussed in Section III, this requirement is met by PHILharmonicFlows using the macro process component. Using macro step types it becomes possible to define the required synchronization points. At runtime, it is possible to execute the individual micro process instances asynchronously to each other as well as asynchronously to the micro process instances of other types. In addition, it is possible to instantiate them at different points in time. Consequently, the resulting process structure comprises a varying number of interrelated micro process instances being in different execution states. For this reason, each macro transition type can be further specialized using different coordination components. The choice of the latter depends on the relation between the corresponding object types within the overall data structure. This way, not only the asynchronous execution but also the different cardinalities between different sets of dependent micro process instances are considered.

Req. 4 - Flexibility regarding process instantiation: Using PHILharmonicFlows it becomes possible to consider a dynamic number of inter-related micro process instances. Taking the defined cardinality constraints into account, users can freely decide which and how many micro process instances shall be created. If the minimum cardinality is not met, PHILharmonicFlows automatically assigns a corresponding mandatory activity to the worklists of responsible users demanding the creation of new instances of the respective micro process type. Opposed to this, if the maximum cardinality is reached, PHILharmonicFlows prohibits the creation of additional micro process instances. By specifying the cardinality of each object type, it is possible to define which of them must be instantiated (cardinality *1*) and which ones are optional (cardinality *0...*). This enables qualified staff members to request examinations at arbitrary points of the diagnosis process and to react on unexpected events (e.g., drug prescription in case of intense fever).

Req. 5 - Authorized user access: The *authorization table*

 ISBN: 978-1-61208-179-3

enables the level of data privacy required by healthcare processes. For each micro process type, it is possible to define which attributes can be written or read by a particular user (role) according to the currently activated micro process state. PHILharmonicFlows ensures that no data is written or read by unauthorized users. Since each state type has one user role associated to it, the authorization table automatically ensures that this same role owns the corresponding data permissions; i.e., the role has mandatory write permission to the attributes associated with the micro step types, which belong, in turn, to the state type.

Req. 6 - Flexible data access: As opposed to traditional PrMS, PHILharmonicFlows presents two different views to the end-users: a process-oriented (i.e., worklists) and a data-oriented (i.e., overview tables listing individual object instances together with their attribute values). The latter enables the access to data at any point in time by authorized users. Thus, data access does not depend on the activation of an upcoming activity; i.e., the data can be accessed beyond the context of a particular mandatory activity.

V. Related Work

Healthcare is a challenging domain for process support, since it comprises structured and unstructured processes whose support requires a high degree of flexibility. There are many researchers showing interest in this area [11], [23]. The case-handling paradigm focuses on administrative processes and, like PHILharmonicFlows, aims at data and process integration by managing the data inside the "case" scope and by enabling form-based activities. It also intends to increase the degree of flexibility by providing access to information outside the context of an activity. However, data is only provided in terms of atomic elements and can be read by all users involved in the case. Furthermore, there is no full support regarding interactions among different cases.

Interactions among process fragments, in turn, are supported by the Proclets approach [1], [9]. However, data is managed outside the scope of the process management system and can only be accessed when an activity is being executed.

The document-based workflow approach α-flow [21], [22] incorporates workflow semantics into the documents involved. Such documents are edited and viewed taking the separation of responsibilities and inter-institutional collaboration into account.

For more details about existing data-aware process management approaches, we refer readers to [31].

VI. Summary & Outlook

We analyzed a breast cancer diagnosis scenario. By modeling it with PHILharmonicFlows we studied how effectively this framework covers the semantics of healthcare processes. First, we elicited a list of requirements not adequately met by traditional process management systems in this context. Following this, we modeled the considered scenario by using components of the PHILharmonicFlows framework. Finally, we discussed the effectiveness of this approach and showed how it covers the requirements of healthcare processes.

Healthcare processes are knowledge-intensive and need a high level of flexibility in order to allow qualified staff members to flexibly react to unexpected events. Compared to other data-oriented approaches, in a very effective way PHILharmonicFlows covers the requirements posed by healthcare processes. By tightly integrating data and processes, our approach enables an environment where data drives the process and permits a higher degree of flexibility allowing data access outside the context of black-box activities as well. Furthermore, the distinction between two levels of granularity permits the interaction of processes being executed independently. It further enables flexibility by allowing users to decide which processes to instantiate when.

Like in activity-centered approaches [32], schema evolution is a complex and error-prone task to be accomplished for object-aware processes as well. We are working on an extension of the framework to support it; i.e., a mechanism to manage and to apply changes in object-aware processes as well as their running instances. Since all components of the framework are tightly integrated, the mechanism must take into account that each change operation may affect more than one component, causing a cascading effect. Thus, the mechanism must be able to detect such interdependencies between components and to assist the user to apply the changes in the process without affecting correctness and compliance.

Acknowledgment

The authors would like to acknowledge financial support provided by the *Deutscher Akademischer Austausch Dienst (DAAD)*.

References

[1] R. S. Mans, N. C. Russell, W. M. P. van der Aalst, A. J. Moleman, and P. J. M. Bakker, *Proclets in Healthcare*, Eindhoven: BPM Center, 36, 2009.

[2] M. Reichert, *What BPM Technology Can Do for Healthcare Process Support*, Proc. 13th Conf. on Artificial Intelligence in Medicine (AIME'11), LNAI 6747, 2–13, 2011.

[3] R. Lenz and M. Reichert, *IT Support for Healthcare Processes – Premises, Challenges, Perspectives*, Data & Knowledge Engineering, 61(1), 39–58, 2007.

[4] P. Dadam, M. Reichert, and K. Klaus, *Clinical Workflows - The Killer Application for Process-oriented Information Systems?*, Proc. 4th Int'l Conf. on Business Information Systems (BIS'00), 36–59, 2000.

[5] Object Management Group, *Business Process Model and Notation (BPMN)*, version 2.0, January 2011, http://www.omg.org/spec/BPMN/2.0, 2011.

[6] M. Juric, *Business Process Execution Language for Web Services BPEL and BPEL4WS 2nd Edition*, Packt Publishing, 2006.

[7] D. Cohn and R. Hull, *Business Artifacts: A Data-centric Approach to Modeling Business Operations and Processes*, IEEE Data Engineering Bull., 32(3), 3–9, 2009.

[8] M. Reichert and P. Dadam, *A Framework for Dynamic Changes in Workflow Management Systems*, Proc. 8th Int'l Workshop on Database and Expert Systems Applications (DEXA'97), 42–48, 1997.

[9] W. M. P. van der Aalst, P. Barthelmess, C. Ellis, and J. Wainer, *Workflow Modeling Using Proclets*, Proc. 5th Int'l Conf. on Cooperative Information Systems (CoopIS'00), LNCS 1901, 198–209, 2000.

[10] W. M. P. van der Aalst and K. van Hee, *Workflow Management: Models, Methods, and Systems*, MIT Press, 2004.

[11] W. M. P. van der Aalst, M. Weske, and D. Grünbauer, *Case Handling: A New Paradigm for Business Process Support*, Data & Knowledge Engineering, 53(2), 129–162, 2005.

[12] B. Mutschler, B. Weber, and M. Reichert, *Workflow Management versus Case Handling: Results from a Controlled Software Experiment*, Proc. 23rd Annual ACM Symposium on Applied Computing (SAC'08), 82–89, 2008.

[13] C. Guenther, M. Reichert, and W. M. P. van der Aalst, *Supporting Flexible Processes with Adaptive Workflow and Case Handling*, Proc. 3rd. IEEE Workshop on Agile Cooperative Process-aware Information Systems (ProGility'08), IEEE Computer Society Press, 229–234, 2008.

[14] K. Bhattacharya, R. Hull, and J. Su, *A Data-Centric Design Methodology for Business Processes*, Handbook of Research on Business Process Management, 503–531, 2009.

[15] R. Liu, K. Bhattacharya, and F. Y. Wu, *Modeling Business Contexture and Behavior Using Business Artifact*, Proc. 19th Int'l Conf. on Advanced Information Systems Engineering (CAiSE'07), LNCS 4495, 324-339, 2007.

[16] D. Müller, M. Reichert, and J. Herbst, *Data-Driven Modeling and Coordination of Large Process Structures*, Proc. 19th Int'l. Conf. on Cooperative Information Systems (CoopIS'07), LNCS 4803, 131–149, 2007.

[17] D. Müller, M. Reichert, and J. Herbst, *A New Paradigm for the Enactment and Dynamic Adaptation of Data-driven Process Structures*, Proc. 20th Int'l Conf. on Advanced Information Systems Engineering (CAiSE'08), LNCS 5074, 48–63, 2008.

[18] S. Rinderle and M. Reichert, *Data-Driven Process Control and Exception Handling in Process Management Systems*, Proc. 18th Int'l Conf. on Advanced Information Systems Engineering (CAiSE'06), LNCS 4001, 273–287, 2006.

[19] G. M. Redding, M. Dumas, A. Hofstede, and A. Iordachescu, *A Flexible, Object-centric Approach for Business Process Modeling*, Proc. IEEE Int'l Conf. on Service-Oriented Computing and Applications (SOCA), 1–11, 2009.

[20] I. Vanderfeesten, H. A. Reijers, and W. M. P. van der Aalst, *Product-Based Workflow Support: Dynamic Workflow Execution*, Proc. Int'l Conf. on Advanced Information Systems Engineering (CAiSE'08), LNCS 5074, pp. 571–574, 2008.

[21] C. P. Neumann and R. Lenz, *alpha-Flow: A Document-based Approach to Inter-Institutional Process Support in Healthcare*, Proc. 3rd. Int'l Workshop on Process-oriented Information Systems in Healthcare (ProHealth 2009), LNBIP 43, 569–580, 2009.

[22] C. P. Neumann and R. Lenz, *The alpha-Flow Use-Case of Breast Cancer Treatment – Modeling Inter-Institutional Healthcare Workflows by Active Documents*, Proc. IEEE Int'l Workshops on Enabling Technologies: Infrastructures for Collaborative Enterprises (WETICE-2010), 17–22, 2010.

[23] N. Mulyar, M. Pesic, W. M. P. van der Aalst, and M. Peleg, *Declarative and Procedural Approaches for Modelling Clinical Guidelines: Addressing Flexibility Issues*, Proc. 1st Int'l Workshop on Process-oriented Information Systems in Healthcare (ProHealth 2007), LNCS 4928, 335–346, 2007.

[24] B. Silver, *Case Management: Addressing Unique BPM Requirements*, BPMS Watch, 1–12, 2009.

[25] N. Gronau and E. Weber, *Management of Knowledge Intensive Business Processes*, Proc. 2nd Int'l Conf. on Business Process Management (BPM'04), LNCS 3080, 163–178, 2004.

[26] V. Künzle and M. Reichert, *Towards Object-aware Process Management Systems: Issues, Challenges and Benefits*, Proc. 10th Int'l Workshop on Business Process Modeling, Development, and Support (BPMDS'09), LNBIP 29, 197–210, 2009.

[27] V. Künzle and M. Reichert, *Integrating Users in Object-aware Process Management Systems: Issues and Challenges*, Proc. 5th Int'l Workshop on Business Process Design (BDP'09), LNBIP 43, 29–41, 2009.

[28] V. Künzle and M. Reichert, *PHILharmonicFlows: Towards a Framework for Object-aware Process Management*, Journal of Software Maintenance and Evolution: Research and Practice, 23(4), 205–244, 2011.

[29] V. Künzle, B. Weber, and M. Reichert, *Object-aware Business Processes: Fundamental Requirements and their Support in Existing Approaches*, Int'l Journal of Information System Modeling and Design, 2(2), 19–46, 2011.

[30] V. Künzle and M. Reichert, *A Modeling Paradigm for Integrating Processes and Data at the Micro Level*, Proc. 12th Int'l Working Conf. on Business Process Modeling, Development and Support (BPMDS'11), LNBIP 81, 201–215, 2011.

[31] V. Künzle and M. Reichert, *Striving for Object-aware Process Support: How Existing Approaches Fit Together*, Proc. 1st Int'l Symposium on Data-driven Process Discovery and Analysis (SIMPDA'11), 2011.

[32] M. Reichert, S. Rinderle-Ma, and P. Dadam, *Flexibility in Process-aware Information Systems*, LNCS Transactions on Petri Nets and Other Models of Concurrency (ToPNoC) 2, LNCS 5460, 115–135.

 ISBN: 978-1-61208-179-3

RFID-based Body Sensors for e-Health Systems and Communications

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Abstract— Body sensors for e-health applications are involved in patients' health monitoring and risk prediction systems. They can be used with RFID tags in some e-health applications which may be either internal or external. Body sensors are implantable and easy to fit around the particular organ in the human body. Long term diseases such as cancer, diabetic etc. need permanent body sensor. In this paper, RFID based body sensors are considered for e-health system and communications. This paper proposes a theoretical model of e-health system for people with diabetic and other long term diseases. In the theoretical model of risk prediction system, biosensor (glucose sensor) is considered as a body sensor. Quick care and resolution may be considered with latest technologies such as wireless networks, sensors and 2G-RFID system. Through this model, patients will be able to manage their life as normal because it is simple to use.

Keywords-Body sensors; e-health system; RFID; risk prediction.

I. INTRODUCTION

In e-health systems and communications, RFID-based body sensors can be used in many e-health applications not only for risk prediction. This device based on risk prediction system can be used easily with low-cost, and handy because this new system can be integrated within mobile phones. It means that the additional feature will be added to the mobile phone. Body sensors observe all behavior of the body conditions whenever we need. If any abnormal condition is diagnosed, body sensor reports to patient through the mobile phone. If patient's condition gets serious or risk factor is higher than normal conditions, message will be reported to risk monitoring staff who works close to area. Here, patient's location at the time may be different from his normal registered residence, but patient's current location can be identified using latest communication technology.

The body sensor, e-health system and communications, are mainly depending on the e-health applications, which show quick risk predictions. This system is not only for patients but also it fits to others who really want to monitor their body conditions and fitness daily. In addition to these benefits, it could be used anywhere and during the travelling or on the move. Some risks are age dependent, but this paper focuses on common risks predictions for all ages. In the human body, palms and feet have sensible area where prediction system can be used to monitor some risks through the e-health systems and communication.

The proposed theoretical model of e-health system can be applied to people with diabetic and other long term diseases. In this model, communication aspect of risk prediction system is designed with RFID-based body sensor. Through this model, patients' quick care and possible resolutions during the emergency situations can be delivered quickly and accurately. This model is targeted to patients with incurable long term disease such as diabetic and cancer because the risk factor of damaging other organs in the body is very high.

Wireless body sensor network (WBSN) is widely used in patient's monitoring, and risk prediction of e-health system [4]. When patients use WBSN nodes around the body randomly, constraint communication channel (CCC) is considered with transmission latency. In order to provide efficient e-health system, the improvement of CCC depended on resources and delays are necessary in terms of quality and quantity. Wearable sensors are introduced that RFID tags embedded with sensor are allocated to each position where risk is predictable.

Active RFID tags integrated with sensors use battery during the communication. Passive RFID tags integrated with sensor don't use battery because they receive necessary operating power from the RFID reader. In most of the e-health systems, passive RFID tags with sensors are used to implement the wireless environment around the patient. Further, advantages of passive RFID tags such as lower cost, smaller size, longer life time etc. are useful.

The remainder of this paper is organized as follows. Section II explains the RFID-based e-health systems and overall tasks of body sensors. Section III introduces the theoretical model for monitoring and risk prediction system with ADCA techniques. In Section IV, wireless networks for e-health systems are given with general discussions and recommendations. Overall conclusions will be in Section V.

 ISBN: 978-1-61208-179-3

II. RFID BASED E-HEALTH SYSTEM

The complete e-health systems and communications are divided into few tasks they are body sensors functions, e-health system interfaced with RFID tags, RFID readers and microprocessor, e-health data and signals from e-health applications and relevant communication system which control the emergency and priority situations. To design and develop such communications system, the Adaptive Dynamic Channel Allocation (ADCA) technique for patients' monitoring and risk predicting data transmission is briefly mentioned.

A. Body sensors and functions

Body sensors have many types, which work according to the internal, abnormal and physical conditions of the body. Internal nerves system may affect the body; therefore, body sensor should be able to observe the nerve system. If particular organ is damaged and started to function strangely, it needs to be monitored with a special type of body sensor [13]. Some time same body sensor may be used, but it must be located to near that particular organ. Physical conditions such as weight, height, temperature etc. are observed by basic body sensors. They are easy to use, but functions are changed according to the e-health applications. If it is normal fever, it will monitor the temperature and display the results through the e-health system [2]. If it is high temperature monitored from the body sensor, the e-health systems and communications act quickly to solve the problem straightaway. Here, the priority of the communication is very important rather than the other actions.

B. RFID reader and e-health system

Communication between the RFID reader and dedicated microprocessor is interfaced by few data and control signals. Here, e-health system consists of RFID reader, which connects the external systems, RFID tags embedded with body sensor [15] and microprocessor, which handles relevant signal processing for efficient communication. In e-health system, internal and external communications including interfacing must be efficient and reliable, but their signal properties such as rate, bandwidth etc. are varied according to the requirements. Data and control signals are very useful to make a quick connection or link for emergency e-health applications. RFID tags receive all pulses from the body sensors and pass all information to RFID reader.

C. Data from e-health applications

Data varied with e-health applications [16] need to be analyzed for risk predictions. Analyzed data can be used as reference data or signal which could be even different to individual patient. Communications between the e-health system and e-health application must be accurate. Data can be corrupted between these because many devices may be involved around there without any protections. Same equipment may have more than two features, which may be interfered each other. It is called feature interaction, which is one of the serious issues addressed in e-health systems. However, data must be cleaned and secured throughout the analysis otherwise risk prediction will be wrong. Data and relevant signals used in RFID reader and microprocessor are obtained carefully from the body sensors through the RFID tags.

D. Communications for e-health applications

Reliable and secure communication should be allocated for e-health applications because risk prediction should be able to handle within the fraction of the second. Is it possible? Heart attack needs to be responded within fixed minutes otherwise all communication systems are useless. Responding time for individual prediction depends on the e-health applications. In the next section, channel selection and priority procedures are considered for a theoretical model. As soon as I complete the practical model for the future risk prediction system, I can provide all the limitations and conditions in the next paper.

III. MODEL OF RISK PREDICTION SYSTEM

The theoretical model of risk prediction system can be applied as a general platform to all e-health applications which are either implemented with existing systems or new. This theoretical model should be able to use for multi e-health applications simultaneously.

As shown in Figure 1, patient monitoring and risk prediction are combined with relevant communication schemes.

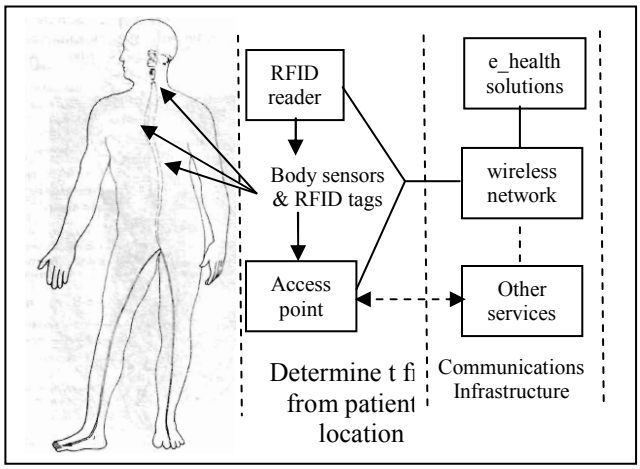

Figure 1. Patient monitoring and e-health system

In addition to this, communication is divided according to the priority. For instance, if patient needs immediate action within fixed time, RFID tag displays necessary procedures as a First Aid steps. Anyone around may provide First Aid before the e-health solution is executed. Through the other services, doctor, ambulance, and solution providers of e-health deliver the practical solution as soon as

possible. Doctors don't need to read all the history after he reaches the patient's home. While he is travelling on the way, he must be informed what to do to save the life. Multiple solutions are considered simultaneously within limited time. In order to do such actions, constraint communication should be established.

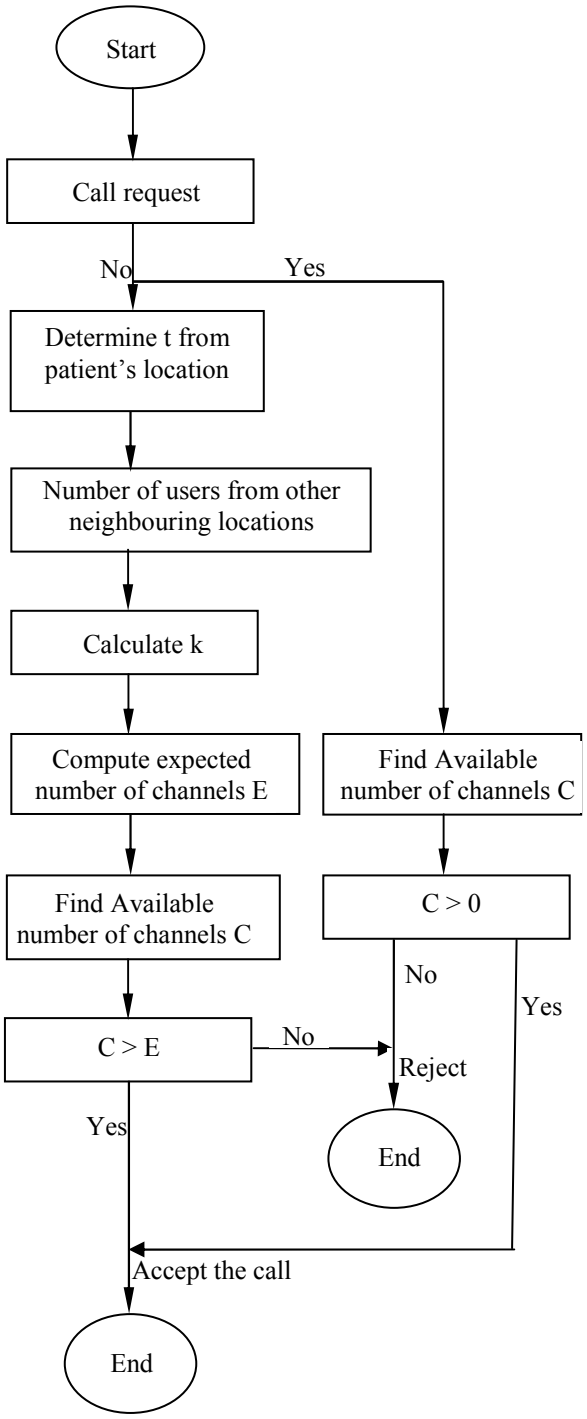

Figure 2. ADCA technique for patient monitoring

A. Sensors for risk prediction system

Sensors are widely used in e-health systems, which monitor and record all necessary information from allocated sensors. In this paper, glucose sensor monitors all the abnormal behavior of blood circulations in the vassal. If the concentration of glucose level is increased in the blood vassal, diabetic patient may take self decision for quick care [1]. If patients are unable to do certain precautions, automatic care will be considered according to the priority.

In this technique, patient's emergency or priority calls are considered for quick decisions. In order to allocate the channel, flow chart depicted in Figure 2, will provide necessary steps [3].

Time t can be calculated from patient's location information where patient requests the call. It is the time interval between the acceptance and departure of the new call.

$$k_i = \frac{v^i}{e^v i!} \quad (1)$$

Equation (1) represents Poisson distribution, which can be used for recording the arrival calls [7].

$$k = \frac{1}{e^{\mu t}} \quad (2)$$

From the equation (2), k is calculated as the probability of calls. Here, μ is the mean value of calls. When patient's call is active during the interval t the probability k, is calculated to compute the expected number of channels.

B. ADCA technique

The ADAC algorithm is used to borrow available bandwidth from neighbours' base stations when they are free to lend for emergency cases [5]. Wireless networks allow patients to use more than base station, but they are within the coverage area. If some base stations get busy than other base stations, channels should be transferred to other available base stations. During the channel allocation, delay is very important and it should be reduced. This situation should be identified and solved with where ADCA algorithm should have appropriate modifications. Hybrid multichannel multi-radio [6] is introduced to enhance the performance which is better than pure ADCA. Moreover, in order to decrease the blocking call probabilities bandwidth and to increase the system's overall performance, degradation and upgrade policies have been considered [14]. Through dynamic channel selection, devices can adaptively move to a clean channel as needed to avoid interference.

 ISBN: 978-1-61208-179-3

C. *Palm-based risk prediction with sensors*

According to the [9], palms are considered as risk prediction area where we can use our new prediction system. Main sensible area of risks indicated by numbers is clearly shown on each part of the palms given in Figure 3. These areas are represented as risk monitoring points because most of the symptoms linked with particular organ can be identified through these points. Nerve between the particular point and organ is very important. If it is damaged, risk predictions through these points will fail straightaway. In that case, body sensor should be used directly from that particular organ. All points indicated by numbers are linked with each part of the human organ. For instance, assume a human organ is in trouble for some reason and nerve is not damaged. In this case, risk prediction is possible through that point, but efficient body sensor must be used. Generally, if any of an organ in the human body is started with minor problems, sensible areas or points indicated in the palm will be affected with some kind of pain. Sensors will identify the pain including pulses which behave abnormal during the risk time. Pain may be continued for several days or months in regular interval. Risk prediction cannot be confirmed without proper monitoring. It means that each e-health application has certain properties, characteristics and definitions. According to the e-health application, patient's monitoring pattern will change.

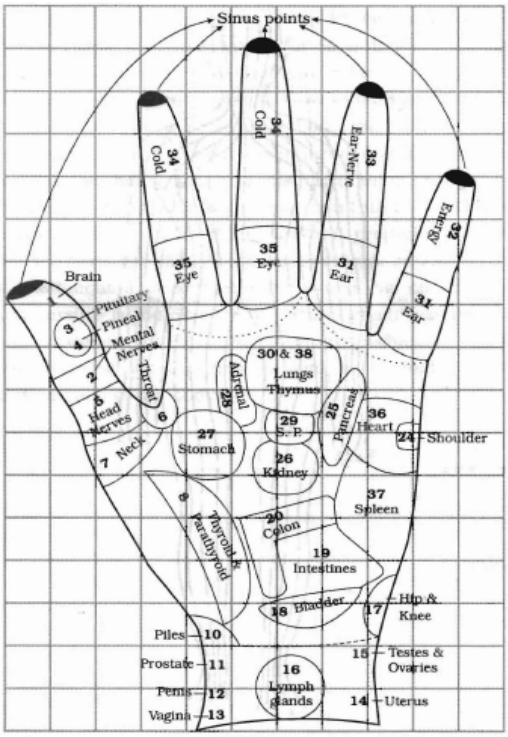

Figure 3. Risk monitoring points for prediction

These body sensors (biosensors) will predict the risks and abnormal behaviour in the particular organ. In order to identify these risks, proper risk prediction system for all ages is considered in the next section.

Wearable gloves can be designed with RFID tags, which contain correct sensor and necessary facilities to monitor the risk area indicated in Figure 3. They are linked with high speed wireless technology, so monitored data and patient's information are analyzed quickly. In order to finalize the results, efficient sensors must be used.

Figure 3 provides specific numbers, which are called risk indicating area. If body sensor is used in number 25, the basic history of the diabetic patient can be identified. It depends on the body sensor and abnormal pulses created from that specific number. If body sensor is slightly moved, correct signal would not be recorded therefore, correct decision may not be possible.

IV. WIRELESS NETWORKS

Wireless networks, such as WLAN, WiFi, WiMax, etc., are considered in the E-health implementations. The 2.4 GHz ISM band is allocated in many wireless network and technologies (examples: Wi-Fi, Bluetooth, ZigBee/802.15.4, DECT, etc.) in hospitals and homes. In ten years, wireless network will be everywhere because RFID sensors and wireless sensors network (WSN) have been applied most of the applications in profit and nonprofit organisations.

In E-health, WSNs have been deployed in where individual E-health application is monitored. In this paper, RFID sensors are incorporated with WSN which consists of a group of RFID tags integrated with RFID sensor. These RFID sensors are supplied by low energy batteries and having very limited sensing, signal processing, and wireless communication capabilities. All RFID sensors transmit data to the same collector node, known as base station (BS). Such networks have been deployed in a wide range of monitoring in E-health applications.

Wireless sensors networks in E-health applications are increased with significant traffic loads during the busy period. In order to simplify this problem, MAC protocols based on deterministic scheduling algorithms can be used [8]. In this research, optimized version of this algorithm will be consensually considered. In order to control the delay and save the power, TDMA-based MAC protocols can be used, but it needs superframe time-slot to transmit data. The proposed algorithm for our research should help to improve this time-slot and reduce energy consumption in E-health applications.

 ISBN: 978-1-61208-179-3

A. Discussion and recommendations

Communication is established through many ways, which increases the efficiency of e-health systems they are such as e-health via high speed satellite and mobile network communications. In order to increase the quality of service in the e-health system, the digital video broadcasting through satellite version 2 (DVB-S2) can be applied [10]. Through this version, variable rates can be applied to individual e-health application.

In order to improve the e-health systems' communication, maximum lifetime of WBSN and WBAN, minimum energy route and efficient way of using constraint are challenging issues.

The e-health systems and communications prefer to allocate bandwidth efficiently when integrating heterogeneous wireless networks is obviously a challenge. "Consistency medical QoS providing over integrated WiFi/WiMax wireless networks" is challengeable research. Efficient radio resource management, scheduling and connection admission control, are still open issues in WiMax networks they are also crucial in integrated WiFi/Wimax wireless networks for E-Healths services.

Some risks may be unbelievable, but they need to be monitored at least 24 hours continuously. Some risks may be monitored more than 24 hours, but not continuously. Some cases are different it means that monitoring should be done over a fixed period of time in daily or monthly basis. In order to monitor such a risk prediction data, programmable e-health system will be recommended.

According to [12], traffic-awareness is most helpful when traffic demands are concentrated at a small number of heavily-loaded access points located close to each other.

V. CONCLUSIONS

Body sensors are very useful in patients' health monitoring and risk prediction systems. When they are used with RFID tags, e-health systems and communications are processed easily, accurately and quickly. Body sensors are implantable for long term diseases such as cancer, diabetic etc. without major surgery.

In the theoretical model of prediction system, channel selections and priorities are very important. Existing dynamic channel allocation algorithms are investigated and compared with modified algorithm, which should be less complex than the existing one. Quick responding and complexities are traded off; therefore, channel selection algorithms must be considered carefully.

RFID and wireless based e-health system are investigated with body sensors. Although there are few disadvantages when they are used individually, multiple actions and solutions can be performed simultaneously.

Communication for e-health system should be efficient reliable and secure for multiple e-health applications. In order to improve such an e-health systems and communication, ADCA technique should be modified to multiple rate e-health applications with latest high speed network and communication technology.

Diabetic patient may have a lot of other symptoms because it will easily damage most of the human organs very quickly. Risk prediction system will help to find all risks in a daily basis without pricking pain. In order to improve the risk prediction methodology in the e-health system, risk prediction and patient monitoring should be integrated with WBSN or RFID technology. In the future e-health system, immediate resolutions techniques are also added. It means that efficient ADCA technique should be used to implement the priority channel for a particular patient.

ACKNOWLEDGMENT

I would like to give my particular thanks to my collaborator Prof. G. Markarian for his insightful comments and constructive suggestions.

REFERENCES

[1] Allen, N. A., Fain, J. A., Braun, B., and Chipkin, S. R. (2009). *Continuous Glucose Monitoring in Non–Insulin-Using Individuals with Type 2 Diabetes: Acceptability Feasibility, and Teaching Opportunities.* DIABETES TECHNOLOGY & THERAPEUTICS, Volume 11, Number 3, pp.151-158.

[2] Bielskis, A. A., Denisovas, V., Drungilas, D., and Gricius, G. (2010). *Multi-Agent-Based Human Computer Interaction of E-Health Care System for People with Movement Disabilities.* ISSN 1392 – 1215, Italy.

[3] Papazoglou, P. M., Karras, D. A., and Papademetriou, R. C. (2005). A dynamic channel assignment simulation system for large scale cellularTelecommunications, ECE Dept., University of Portsmouth, UK.

[4] Challa, N., Cam, H., and Sikri, M. (2008). *Secure and Efficient Data Transmission over Body Sensor andWireless Networks.* Computer Science and Engineering Department, Arizona State University, Tempe, Az 85287, USA: Hindawi Publishing Corporation EURASIP Journal onWireless Communications and Networking.

[5] Dagtas, S., Pekhteryev, G., Sahinoglu, Z., Cam, H., and Challa, N. (2008). *Real-Time and SecureWireless HealthMonitoring.* USA: Hindawi Publishing Corporation, International Journal of Telemedicine and Applications.

[6] Ding, Y., Pongaliur, K., and Xiao, L. (2008). *Hybrid Multi-Channel Multi-Radio Wireless Mesh Networks.* Michigan State University, USA: Department of Computer Science and Engineering.

[7] Varpe1, D., and Mundada, G. (2011). A Distributed Dynamic Channel Allocation In Cellular Communication, Department of Electronics and Telecommunication, PICT, Pune University, Pune, Maharashtra,India

[8] Gama, Ó., and Carvalho, P. (2007). *A Time-slot Scheduling Algorithm for e-Health Wireless Sensor Networks.*

Department of Informatics, University of Minho Braga, Portugal.

[9] Devendra, V. (1997). Health in your hands, Navneet publication (India) Ltd, Thirty-fifth edition, pp. 65-70.

[10] Panayides, A., Pattichis, M., Pattichis, C., and Pitsillides, A. (2011). *A Tutorial for Emerging Wireless Medical Video Transmission Systems.* Department of Computer Science, University of Cyprus, Cyprus: Ieee Antennas & Propagation Magazine, Accepted For Publication.

[11] Park, C., and Chou, P. H. (2010). *An Ultra-Wearable, Wireless, Low Power, ECG Monitoring System.* University of California.

[12] Rozner, E., Mehta, Y., and Akella, A. (2007). *Traffic-Aware Channel Assignment in Enterprise Wireless LANs.* University of Texas at Austin.

[13] Sullivan, T. J., Deiss, S. R., and Cauwenberghs, G. (2007). *A Low-Noise, Non-Contact EEG/ECG Sensor.* Division of Biological Sciences, University of California, San Diego: IEEE.

[14] Vergados, D. D. (2008). *Simulation and Modeling Bandwidth Control in Wireless Healthcare Information Systems.* Department of Information and Communication Systems Engineering, Greece: SIMULATION, Vol. 83, Issue 4, pp. 347–364

[15] Yang, L., Vyas, R., Rida, A., Pan, J., and Tentzeris, M. M. (2008). *Wearable RFID-Enabled Sensor Nodes for Biomedical Applications.* Georgia Electronic Design Center, School of Electrical and Computer Engineering, USA: Electronic Components and Technology Conference, EEE, pp 2156-2159.

[16] Zeeb, E. (2010) *Generic Platform forAdvanced E-Health Applications.* University of Rostock, 18057 Rostock, Germany: Institute of Applied Microelectronics and Computer Engineering.

 ISBN: 978-1-61208-179-3

Design of a Mobile Phone App Prototype for Reflections on Perceived Stress

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***Abstract*— In working life today, people often experience high levels of stress and display strong reactions to different stressors. Those who are exposed to high levels of stress for a long time face an increased risk for deterioration in physical and mental health often leading to sick leave and high consumption of healthcare. To prevent this, continuous support is needed. Development of IT-tools for continuous stress management is, however, in its early stages. We present a prototype of a mobile phone app for self-reflection, a tool that is also integrated in a larger web based stress management system built on research of social networks for increased well-being. The mobile phone app aims at helping people become more aware of patterns of stressful events. It logs and displays basic information about self-perceived stress situations, such as location and time, and the user can add information about the situations and perceived stress levels. As the app constitutes a part of the web based stress management system, not only self-reflection but also reflection together with peers and stress experts is possible. The prototype of the mobile phone app has been qualitatively evaluated using stress management criteria, and the paper also exemplifies its utility in the context of the larger system.**

Keywords-mobile phone app; stress management; self-reflection; stress situation; web based stress management

I. INTRODUCTION

Stress and stress management have become important issues in today's society. High demands from work life constitute one of the factors that can make people experience unhealthy levels of stress. Also, it is difficult for many to achieve a balance between work and family. As for other health problems, the Internet offers various solutions for people who want to improve their situation and cope with stress exposure. Different kinds of applications for self-help are available on the Internet. There are health information resources of various kinds, intervention programs and forums for peers. More recently, a number of mobile tools have also emerged in the field of stress management, both to measure stress levels and to support people in stressful situations. However, there is still no system that takes a holistic approach, combining various forms of support, from different sources and stakeholders, and that links mobile apps with web based stress management systems. In this paper, we present the design of a newly developed mobile phone app that aims at supporting self-reflection on stressful everyday situations. The app is also prepared to become a complementary part of a holistic stress management system (see e.g., [1]-[2]). With this extension, the overall system integrates self-documentation, self-reflection, information sharing, communication and support among different actors to a working whole. It allows for both individual learning and group supported learning among different actors who contribute with knowledge and experiences about stress and how to cope with stress.

Next section presents theories of stress and stress management that have had implications for the design of the mobile phone app and the overall stress management system. Thereafter, the basic design of the web based part of the stress management system will be presented briefly. The sections that follow introduce the prototype of the mobile phone app for self-reflection and the way it is integrated in the overall stress management system. At the end, we reflect upon our results and present some future actions.

II. STRESS AND STRESS MANAGEMENT

A. Stress

Stress involves both physiological and psychological components, and is about how we perceive the demands placed on us as well as our ability to manage them. The term "stress" can either be used to relate to the cause and act as a stressor on the human body and mind, or be seen as an effect, a stress-reaction, of an event or thought [3]. Those who are exposed to high stress for a prolonged period of time are at increased risk for physical and mental health problems which can lead to sickness and high consumption of healthcare [4]-[5]. Stress factors related to the profession, such as a frustrating work situation, or imbalance in work-life, are important causes of psychological and physiological stress, mental illness and psychosomatic conditions [6]-[7]. Also high levels of engagement at work can lead to increased stress levels [8]-[9]; overcommitted employees tend to suffer from perceptual distortion of demands that prevent them from assessing cost-gain relations and to set limits [8].

B. Coping Strategies

Coping ability can help to manage a stressful situation. Work control, such as flexibility at work and control over

 ISBN: 978-1-61208-179-3

work tasks can help people to cope with high levels of work stress. Coping strategies can be effective in helping people in stressful conditions, such as poor sleep quality and work-related stress experiences. Coping is classified as either problem-focused, which is when the individual confronts the problem directly, or emotion-focused, meaning that the individual focuses on controlling emotional reactions. The concept of coping has also been classified in terms of active coping, such as planning and pacing activities, and passive coping, which is resting and taking medications [10].

C. Self-Reflection

Aukes et al. (2007) declare that personal reflection is the examination of one's experiences to help clarify and create meaning of the experiences, and to promote learning [11]. They propose that personal reflection in care settings has three elements: self-reflection, empathetic reflection and reflective communication.

Keeping track of past experiences can also help someone with stress symptoms to recognize progression, i.e., positive results of changes made in life patterns, training, etc. [12]. This is regarded helpful for encouraging further changes.

Daily stress logs can be supportive in finding sources of stress and to look for effects from stress [13]. "Some scholars and practitioners distinguish between diaries, logs (a record of information that is a highly structured factual account maintained over time), and journals, which combine the objective aspect of a log with the personal aspect of the diary, but with a more reflective learning slant." [14, p 205]. The reflection in diaries or journals emphasizes the process of learning more than the product. The reflection activities itself helps to increase awareness.

In order to effectively document a situation, information about when and where the situation took place are needed, as well as situational context, level of stress experienced and emotions experienced as a result of the situation [15].

D. Self-Management and Social Support

Disease prevention and early interventions are essential in order to help groups of people from becoming patients of healthcare and from being forced to sick leave and long-term sickness absence. In order to achieve long-term and sustainable changes, interventions and support activities have to be continuous. Ongoing social support has shown to be crucial to develop a lifestyle that lasts [16]-[17]. It is in this context that e-health platforms can play an important role, since they can provide continuous interaction and information exchange between health professionals and also between people with lifestyle issues, who share a certain type of health concern.

Online support groups have shown to empower patients and citizens who suffer from different health problems. Through these online groups new relationships are developed, both strong tie relationships with friends and weak tie relationships with people who attend the online setting less often [18]. These groups support sharing of experiences and advice on particular health issues. The online groups enhance decision-making skills for people who are in distress, and they also foster well-being, a sense of control, self-confidence and overall help to increase abilities to handle specific conditions [19]. A crucial characteristic is their ability to foster social and empathical communication [20]-[21]. Previous studies have also shown that medical experts and peers contribute to knowledge sharing in different ways; while the experts offer detailed information and information on particularly rare issues, peers complement by giving practical advice and reflections based on experiences [22].

III. Social and Multiple Help Web Based Stress Management (Context)

It is not always an easy task to manage stressful life situations and to develop and maintain a healthy living. It involves learning how to balance perceived demands from working and personal life, and to question underlying thoughts and beliefs. E-health communities can assist in this process through continuous interactions between community members. Previous studies have shown that combining knowledge of health experts and the experiences of peers can create a good synergy. The use of question-response functions between citizens and experts and conversations among peers have seen to offer different and complementary support [22]-[23]. This section will shortly describe a web based system developed for stress management that considers social interaction and the integration of different actors and functions. It serves as background to the design of the mobile phone app to be presented in the coming sections.

The web based system for stress management is based on a holistic view of actors – both stress experts and peers - and the different types of support they can contribute with. The system offers the user information in the form of research and real life stories, practical exercises (both text- and video-based), and the opportunity to interact with stress experts and peers. Since different actors and functions are combined in one system, we call this a multiple help online system for stress management [1]-[2], [22] (see Fig. 1 for an illustration).

The web based system is also divided into four different stress intervention areas: sleep, work and studies, balance in life, and physical wellbeing [1]-[2], based on previous research [6]-[9]. This division makes it possible to organize conversations, counseling sessions, exercises and information around specific stressors and stress reactions. "Sleep" is a period of active recovery for the head and body; at the same time, it has been concluded that stress is strongly linked to disturbed sleep, insomnia and impaired awakening. "Work and studies" relates to exposure to stressful job conditions such as heavy workload, infrequent rest breaks, long work hours, shift work, and interpersonal relationships, as well as inappropriate perceptions of demands and fail in their coping ability. "Balance in life" refers to the challenges of coping with demands and to set limits to manage work, leisure time activities and time spend time with family and friends. "Physical wellbeing" is about individual interventions in the area of dysfunction due to negative stress exposure. Responses to stress are often manifested in body tension, and by using a combination of techniques; muscle relaxation and cognitive-

 ISBN: 978-1-61208-179-3

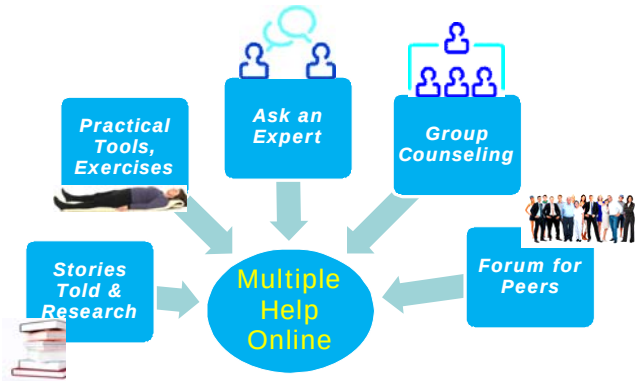

Figure 1. Web Based Social and Multiple Help Stress Management System.

behavioural skills, health promotion and prevention of stress-related disorders can be achieved.

A prototype of the web based stress management system is also available at: http://stress.dsv.su.se/.

IV. DESIGNING A MOBILE PHONE APP FOR SELF-REFLECTION

To continue the research work of the stress management system, and to extend it with a tool for self-reflection, a prototype of a mobile phone app was recently developed. This section will describe the artifact and the research process.

A. Design Science

Design science research is of importance to create successful artifacts [24], and it is a paradigm that looks to "extend the boundaries of human and organizational capabilities by creating new and innovative artifacts" [25, p 75]. Hevner et al. (2004) argue that effective design-science research is based on seven guidelines: design as an artifact, problem relevance, design as a search process, research rigor, research contributions, design evaluation and communication of research. Our work to create a mobile phone app for the stress management system was characterized by the ideas of design science. In the following sections, we introduce the developed prototype of the mobile phone app outgoing from the seven design science guidelines.

B. Design as an Artifact

In the area of information systems, design science is applied to come up with purposeful IT artifacts. The artifact can be a construct, a model, a method or an instantiation. In our research work, the purpose was to create an instantiation in the form of a prototype of a mobile phone app in the stress management area.

C. Problem Relevance

The problem domain that the mobile phone app is to be operating in is self-management and self-reflection for people with mild to medium stress symptoms. Since people with stressful lives can benefit from documenting real life situations and to reflect upon them, a mobile phone app developed for this purpose is regarded as a tool that could serve a purpose in stress management. The fact that the mobile phone is available in almost all situations during the day makes it easy to keep track of real-life stress situations while taking part in everyday life. The mobile phone app is also expected to be part of the larger stress management system that supports social interaction between different actors (described previously in section III). The overall stress management system therefore also serves as environment to the mobile phone app.

D. Design as a Search Process

The design science research is essentially a search process to find an effective solution to a problem. In search of an effective solution to the problem, the process needs to be iterative. Crucial to the design science research is abstraction and representation of appropriate ends, means and laws. During the iterative process, these things are refined. Design alternatives are generated and tested against requirements and constraints in The Generate/Test Cycle. In our search process, generation of new versions of the prototype were made regularly and tested against stress management requirements.

E. Research Rigor

Fundamental for design science research is to address two questions: "What utility does the new artifact provide?" and "What demonstrates that utility?" The artifact needs to solve the problem, map adequately to the real world, be unique in some sense and be demonstrated (evaluated) in a proper way. We will address these questions in the sections to come.

F. Research Contributions – the Prototype

As a 'stand alone system', the mobile phone app offers the user a tool for self-reflection. The features were designed in accordance with results from research in stress and stress management. The system design considers also the connection with the overall web based stress management system which brings possibility of having group reflection activities as a complement to the personal reflections.

The mobile phone app has two main parts (see Fig. 2 for screenshot in Swedish). The upper part is for registration and management of stress situations and the lower one for displaying statistical data about the situations. There are four functions related to the first part, i.e., to the registration and management of stress related situations: one function to *register a situation*, one for *listing all situations* in order to look at specific information and also to add information about

Figure 2. Prototype of mobile phone application for self-reflection (start menu).

situations, another one to *list situations per month* to be able to navigate in larger amounts of situations, and a fourth to *send information to the web system*, which means that stored information about situations are sent to the web based stress management system.

In order to document a stressful situation, the user only has to press the button *register a situation* and save the registration (see Fig. 3 for screenshot in Swedish). When this is done, the app will automatically log time and location of the situation (current location is determined by using GPS). More information about the situation, such as contextual data, photos of the scene, perceived level of stress and reflections of experienced emotions are manually put into the system. Perceived level of stress is defined on a scale from "low" to "high" (1-100). Photos are taken by using the phone camera and stored together with the other information about the situation. The manual information can be added at the same time as the registration of a situation, or it can be added later when the user is not in a stressful mode. The exception to this is the perceived level of stress that should be documented at once to avoid difficulties recalling it later.

There are four ways to present statistics of stress situations from the past: number of documented *situations per month*, number of *situations during the hours of a day*, *perceived stress levels* and *locations of stress situations* to be presented on a map (see Fig. 4 for two screenshots of statistics).

G. Design Evaluation

The app prototype has been evaluated qualitatively. The evaluations considered usability for the target group, i.e., people with mild to medium stress levels, and effectiveness regarding self-reflection and connectedness with the bigger stress management system. The design process leading to the prototype of mobile phone app was supported by recurrent evaluations, when the programmer demonstrated the app through simulations. The research group, including medical and stress expertise, evaluated the app from a stress management perspective. Through an iterative process of evaluation, feedback, improvements, new evaluations and new feedback the prototype was developed. Continuous technical testing was done to ensure that the mobile phone app was technically sound. The prototype was also demonstrated through a scenario, to illustrate its utility when connected to the overall stress management system.

Figure 3. Screen of the form for registration of stress situations.

Figure 4. Sample screens of displayed stress situations: locations (left) and distribution during the hours of a day (right).

1) Simulations

In the first version of the mobile phone app, the registration of situations prompted the user to add information about the situation. When simulating this function, the stress expert of the research project expressed that it might be difficult to get a person with ongoing stress symptoms to manage more information. This feedback led to a couple of new attributes in the app. First and foremost, it became clear that it must be easy to register a stress situation to increase the likelihood that the app is used. Automatic registration of time and location of a situation was introduced. It made it possible to record a stress situation with just a couple of buttons to press. In order to clarify the situation, additional functions made it possible to add manual information at a later time. Another iteration concerned the menu system, that it should be as simple as possible, with few hierarchies, to lessen the mental load. Simulations of new versions of the prototype were made regularly during the development process, approximately every 10 day.

2) Evaluation of Stress Management Properties

To ensure that features of the mobile phone app meet the goals, they were qualitatively evaluated against stress management criteria (see Table 1).

H. Communication of Research

To communicate research effectively, it is important to define the target audience. For the programmers who are supposed to implement a certain design, or improve existing implementation, technical details are necessary in the communication. For a broader research community that includes systems scientists and health practitioners as well, communication has to focus on the instantiation of a health management idea and the system utility in this health domain. In this paper, our intention has been to address this latter group.

 ISBN: 978-1-61208-179-3

TABLE 1. EVALUATION USING STRESS MANAGEMENT CRITERIA

Stress Management Criteria	Mobile Phone App Feature
Information about experienced stress events over time helps the one with stress symptoms to reflect upon unhealthy patterns (e.g., [12], [14])	Statistical presentations of stress situations over a period of time
Information about stress reactions occurring at different times during the day constitutes valuable feedback on recurrent everyday activities	Statistical presentation per 2 hours during the day
Information should include when and where the situation took place, the level of stress, context and emotions that were experienced [15]	Automatic registration of time and place Additional information being manually registered: perception of stress level and description of the situation
Results of taken actions should be able to be measured, to motivate further actions [12]	Statistical data displaying changes in number of stress situations, levels, etc., over time
Continuous social support is important to change patterns [16]-[17]	Information can be sent to the web based system for ongoing conversations with peers
Personal reflection helps clarify and create meaning of the experiences to promote learning [11], [14]	Personal reflections on stressors and their impact can be described in the text field connected to the logged stress situation Information can be sent to the web based system for help from experts and peers in creating meaning of the experienced stress situations
Things that cause increased stress and mental load have to be avoided	Easy to register a stress situation: the system automatically logs time and place Hierarchy of menu system is low

V. RELATION TO THE WEB BASED STRESS MANAGEMENT SYSTEM

In this paper we have outlined the design and implementations of two interconnected prototypes: one web based stress management system and a newly developed mobile phone app for self-reflection. The mobile phone app will also be a complementary tool to the web based system (see Fig. 5). Technically, the mobile phone app uses Json objects to be able to send information from the app. This information can then be used in the web based system, after necessary adjustments in the web based system have been made.

The new mobile phone tool will contribute to the overall system in several ways; it will support the connection to the physical world and to everyday situations of the users, and bring support for personal self-reflection to the system. The overall system becomes extended due to this new tool. The strengths as a tool for reflection are enhanced through the connectedness with the overall stress management system.

Figure 5. Mobile phone app - a tool of the stress management system.

While the mobile phone app collects and presents information about the user stress image, the actors present in the web based system can contribute with reflections on the stress images. The user can therefore start to reflect upon the stress image on a personal basis, and then engage in learning activities and reflections together with others. The social aspect of learning will be handled by the web based system.

The overall web based stress management system enables different actors to contribute with their different knowledge and experiences. The users with stress symptoms are thereby enhanced as reflection peers and not only receivers of expert advice. Information and advice can be shared with other users of the web based system.

The mobile phone app provides user support in everyday situations and continuous feedback on stress situations. It keeps track of the number of stress situations, stress levels and descriptions/reflections allowing the user to learn about how stress characterizes one's life. Users' position history from the app can serve as a basis for ongoing conversations about registered problem situations, for example. The users can then become aware of their own learning processes through questions and conversations on practical situations, experienced and foreseen difficulties as well as motivational issues.

In general, the data from the mobile phone app could be used to initiate a variety of interventions. The mobile phone app in itself has no support for interventions, only for monitoring. Based on the picture of the documented stress situations, a stress expert in the web based stress management system can recommend relevant exercises and stress areas to work with.

There are individual differences due to diversity of personal stressors and reactions. This is reflected in the documented stress situations in the mobile phone app. This diversity needs also to be handled by the overall system. Information from the app could be processed through different stress intervention areas in the web based system based on the personal information sent.

The stress management system should include learning from the users. Users' logs of situations from the mobile phone

 ISBN: 978-1-61208-179-3

app can be used as a basis for adjusting the overall system. For example, stress patterns can trigger new types of exercises or even new areas of stress interventions in the web based system.

By comparing changes in stress patterns with the actual usage of the stress management system, it is also possible to get valuable information for system evaluation as well. This could be a good complement to other types of measurements, such as self-reported health status in questionnaires and user evaluations.

VI. CONCLUSIONS AND FUTURE WORK

Today, mobile phones are available in daily life. The presented phone app serves as a bridge between the physical and digital world of the ones with stress symptoms. It conveys stressful situations digitally, as text-based information, location positions, photos, and visually through diagrams. On its own, the app lets the user log perceived stress situations, and to reflect upon patterns of stress situations.

Technically, the mobile phone app is prepared to send information to the web based stress management system. However, the web based system needs to be adjusted as to present this information in a suitable way. Future research will discover how information from the user's app can be displayed as to form the basis of web based conversations with experts and peers.

So far, the system development has resulted in prototypes evaluated by qualitative methods within the research project. Next, the prototypes will be evaluated by a user group, and both qualitative and quantitative analyses will be carried out.

REFERENCES

[1] Smedberg, Å. and Sandmark, H. 2010. Multiple help online: an integrated e-health system for stress management. In *Proceedings of IADIS International Conference E-Health* (Freiburg, Germany, July 29-31, 2010). 151-158. ISBN: 978-972-8939-16-8.

[2] Smedberg, Å. and Sandmark, H. 2011. Stress intervention online - Designing for self-help through multiple help. In *Proceedings of the Third International Conference on eHealth, Telemedicine, and Social Medicine*. (Guadeloupe, France, February 23-28, 2011). 120-125. ISBN: 978-1-61208-003-1.

[3] McEwen, B.S., 2000. The neurobiology of stress: from serendipity to clinical relevance, *Brain Res*. 886, 172-89.

[4] Levi, L. 2005. Working life and mental health - A challenge to psychiatry?, *World Psych.* 4(1), 53-57.

[5] Kalia, M. 2002. Assessing the economic impact of stress--the modern day hidden epidemic, *Metabolism*, 51(6 Suppl 1), 49-53.

[6] Sandmark, H. 2007. Work and family: associations with long term sick-listing in Swedish women. *BMC Public Health* 2007, 7:287.

[7] Sandmark, H. 2009. Job mismatching, unequal opportunities and long-term sickness absence in female white collar workers in Sweden. *Scand J Public Health*. 37, 43-49.

[8] Preckel, D., von Känel, R., Kudielka, B.M. and Fischer, J.E. 2005. Over commitment to work is associated with vital exhaustion. *Int Arch Occup Environ Health*. 78:117–22.

[9] Siegrist, J. and Marmot, M. 2004. Health inequalities and the psychosocial environment—two scientific challenges, *Soc Sci Med*, 58, 1463–73.

[10] Folkman, S. and Lazarus, R.S. 1988. Coping as a mediator of emotion, *J Pers Soc Psychol*. 54, 466–475.

[11] Aukes, L.C., Geertsma, J., Cohen-Schotanus, J., Zwierstra, R.P., and Slaets, J.P.J. 2007. The development of a scale to measure personal reflection in medical practice and education. *Medical Teacher*. 29, 177–182.

[12] Bolger, N., Davis, A., and Rafaeli, E. 2003. Diary methods: Capturing life as it is lived. *Annual Review of Psychology*. 54, 579–616.

[13] Attwood, M., Curtis, A., Pitts, J. 2006. *Professional Development: A Guide for Primary Care*. John Wiley and Sons, Inc.

[14] Travers, C. 2010. Unveiling a reflective diary methodology for exploring the lived experiences of stress and coping. *J. Vocational Behavior*. 79(1), 204-216. DOI= http://dx.doi.org/10.1016/j.jvb.2010.11.007.

[15] Brozovich, F. and Heimberg, R.G. 2008. An analysis of post-event processing in social anxiety disorder. *Clinical Psychology Review*. 28, 891-903. DOI= http://dx.doi.org/10.1016/j.cpr.2008.01.002.

[16] K. Baughman, E. Logue., K. Sutton, C. Capers, D. Jarjoura, and W. Smucker, 2003. Biopsychosocial characteristics of overweight and obese primary care patients: do psychosocial and behavior factors mediate sociodemographic effects? *Preventive Medicine*, No. 37, 129-137, Academic Press.

[17] G. J. Norman. 2007. A review of ehealth interventions for physical activity and dietary behavior change. *Am J Prev Med*., 33(4), 336-345.

[18] Haythornthwaite, C. Social networks and online community. In A. Joinson, K. McKenna, T. Postmes & U-D. Reips (Eds.), *The Oxford handbook of Internet psychology* (pp. 121-137). United Kingdom: Oxford University Press, 2007.

[19] Barak, A., Boniel-Nissim, M. and Suler, J. 2008. Fostering empowerment in online support groups. *Computers in Human Behavior*. 24(5), 1867-1883. DOI= http://dx.doi.org/10.1016/j.chb.2008.02.004.

[20] Preece, J. 1999. Empathic communities: balancing emotional and factual communication. *Interacting with Computers*. 12, 63-77.

[21] Preece, J. 2000. *Online communities – designing usability, supporting sociability*, Wiley & Sons.

[22] Smedberg, Å. 2008. *Online Communities and Learning for Health - The Use of Online Health Communities and Online Expertise for People with Established Bad Habits*. Doctoral Thesis. Department of Computer and Systems Sciences, Stockholm University. ISBN: 978-91-7155-689-9.

[23] Smedberg, Å. 2007. To design holistic health service systems on the Internet. In *Proceedings of World Academy of Science, Engineering and Technology*, November 2007, 311-317.

[24] Peffers, K., Tuunanen, T., Rothenberger, M.A. and Chatterjee, S. 2007. A design science research methodology for information systems research. *J. Management Information Systems*. 24(3), 45-78.

[25] Hevner, A.R., March, S.T., Park, J. and Ram, S. 2004. Design science in information systems research. *MIS Quarterly*. 28(1), 75-105.

 ISBN: 978-1-61208-179-3

Representation System of Quality Indicators towards Accurate Evaluation of Medical Services Based on Medical Databases

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***Abstract*—Quality indicators play an important role in quantitatively measuring the quality of medical services. In this paper, we introduce a representation system that helps define quality indicators and calculate their values in a coherent manner based on the data in medical databases. The representation system primarily consists of three parts. The first one is an ontology to define concepts related to medical services. The second one is a set of graphs that express the targets of quantification. The third one is a set of quantifying concepts that abstract quantities of the target concepts. The proposed representation system adequately divides the work for defining quality indicators and calculating their values from the data in medical databases, and, hence, it assists medical staffs and system engineers who manage medical databases to perform their own work and to collaborate on the evaluation and the comparison of medical services.**

Keywords - quality indicator, evaluation of medical service, ontology, medical database.

I. INTRODUCTION

A. Background

It is important to fairly evaluate or compare the qualities of medical services that hospitals provide in order to improve the services. To this end, the qualities of medical services must be identified and adequate methods must be found to measure these qualities accurately [1]. Quality indicators, which are quantitative criteria for the evaluation of medical services, have been attracting attention [2]. Many quality indicators already have been defined by standards organizations and projects such as IQIP [3], MHA [4], and OECD [5].

However, although many good quality indicators have been developed, the following issues remain for using quality indicators to fairly evaluate and compare medical services among hospitals.

Issue 1: While many quality indicators (of medical services) are defined by terms in relation to medical care, many medical databases are developed from the aspect of accounting management. Moreover, many medical databases are developed in the vendors' or hospitals' own schema. Therefore, to calculate the values of quality indicators or to define them, it is often necessary for medical staffs to collaborate with system engineers who manage or developed the medical databases. However, the gaps in their knowledge and viewpoints often prevent them from collaborating to calculate the values of quality indicators and/or to define them accurately.

Issue 2: Many words for medical services have meanings that differ according to the hospital or community of the medical staff. For example, at least in our country, the meaning of "new patients" or "inpatients" sometimes differs according to the medical staff in some hospitals, even though the hospitals may belong to the same hospital group. Such different interpretations of words also prevent medical staffs from coherently calculating accurate values of the quality indicators among multiple hospitals.

B. Goal of this paper

In this paper, we introduce a representation system of quality indicators. The representation system helps to define quality indicators and calculate their values in a coherent manner that is based on the data in medical databases. The representation system primarily consists of three parts. The first one is an ontology to define concepts related to medical services. The second one is a set of graphs that express the targets of quality indicators. We call these graphs "objective graphs". The third one is a set of quantifying concepts that abstract the quantities of the subjects, which we call "quantifier concepts". The proposed system represents a quality indicator as a combination of an objective graph and a quantifier concept.

 ISBN: 978-1-61208-179-3

An objective graph can be interpreted as a set of instances of a concept. The set is defined by the properties described by the labels of the arrows in the graph. We also explain the interpretation of objective graphs for the sets in this paper.

C. *Significance of the proposed system*

One can define quality indicators by constructing objective graphs and selecting quantifier concepts. Objective graphs consist of concepts in the ontology of medical services. Therefore, medical staffs can define quality indicators in the representation system without knowledge of medical databases. The interpretation of objective graphs enables one to calculate the value of a quality indicator described in the representation system based on a series of virtual tables generated from the ontology of medical services. Thus, by establishing the mapping between the virtual tables and the corresponding tables of the database, the values of quality indicators in the representation system can be calculated by using the data in the database. As a result, medical staffs and system engineers who manage medical databases can perform their own work; the former can focus on defining quality indicators and the latter on establishing mappings.

By collaborating with medical staffs in other hospitals to develop the ontology of medical services and objective graphs, the gap between interpretations of quality indicators can be clarified, and, hence, the problems in the second issue (the use of words with different meanings) can be reduced.

Moreover, the quantifier concepts define adequate "rates", "averages", and so forth in templates, and so they provide a coherent way to abstract quantities from the target concepts and prevent defining unreasonable quality indicators.

D. *Organization of this paper*

The remainder of this paper is organized as follows. Section II briefly explains our framework to define quality indicators and to calculate their values based on the data in medical databases. Section III explains the representation system of quality indicators. Section IV briefly explains a way to calculate the values of quality indicators based on the medical databases. Section V concludes this paper.

II. FRAMEWORK TO DEFINE QUALITY INDICATORS AND CALCUATE THEIR VALUES

The framework to define and calculate quality indicators consists of (i) a representation system to define quality indicators, (ii) medical databases (or medical data warehouses) that are used in hospitals, (iii) several mapping systems that connect a data model generated from the medical service ontology defined in the next section and the data models of given medical databases (see also Sec. IV), and (iv) an assistance tool that helps users (medical staffs) to construct quality indicators based on the representation system. By using the framework, medical staffs, system engineers and designers of concepts (or words) of medical services can perform their own work while collaborating on the evaluation and the comparison of medical services in the manner illustrated in Fig. 1.

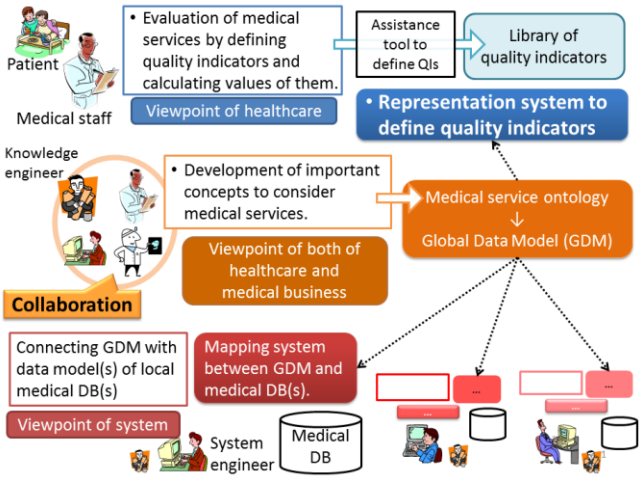


Figure 1. Framework to define and calculate qualitative indicators (QIs)

In this paper, we focus on the representation system of quality indicators.

III. REPRESENTATION SYTEM OF QUALITY INDICATORS

In this section, we define the three main components of the representation system of quality indicators: an ontology of medical services, objective graphs, and an ontology of quantifier concepts.

A. *Ontology of medical services*

The ontology of medical services is an ontology consisting of concepts related to medical services. Here, we define the ontology by defining its concepts and properties. (In ontology engineering, concepts are called classes, and properties in an ontology are often called roles or slots.) The ontology, which we define as follows, was developed based on an ontology developing tool called the "Semantic Editor" [6].

1) *Conceptss*

We first define concepts in the medical service ontology. Because of space limitations, we define some main concepts only. We describe a concept by the [*name of a concept*]. The concepts below are indicated by brackets.

1. Concepts of stakeholders:
[*patient*], [*medical staff*]
2. Concepts of events
2.1. Concepts of events with terms:
[*hospital stay*], [*hospital visit*]
2.2. Concepts of events with no terms
2.2.1. Concepts of scheduled events:
[*hospital admission*], [*hospital discharge*], [*diagnosis*], [*medical examination*], [*test*], [*operation*], [*prescription*]
2.2.2. Concepts of unscheduled events:
[*death*], [*bedsore*], [*falling*]
3. Concepts of states:
[*state of age*], [*state of life or death*], [*state of disease*]

4. Concepts of organizations:
[*department*], [*facility*], [*hospital*]
5. Concepts of items:
[*medicine*], [*clinical instrument*], [*medical device*]
6. Concepts of methods:
[*method*], [*cure*], [*method of examination*]
7. Concepts of diseases:
[*disease*]
8. Concept of time
8.1. Concepts of time points:
[*date*], [*clock time*]
8.2. Concepts of terms:
[*number of years*], [*number of months*],
[*number of weeks*], [*number of days*]

A concept can be regarded as a set of instances of a given concept. Thus, we often identify the concept [*patient*] with the set of instances of that patient.

2) Properties

The ontology has two types of properties: the first type is an attribute of a concept, and the second type is a relation between two concepts.

a) Attributes of concepts

In medical service ontology, the concepts of actors, events and states have their own attributes. As an example, we describe the attributes of state concepts in Fig. 2 and the attributes of event concepts in Fig. 6 on the last page of this paper, where yellow rounded rectangles denote concepts, and pink rounded rectangles denote attributes.

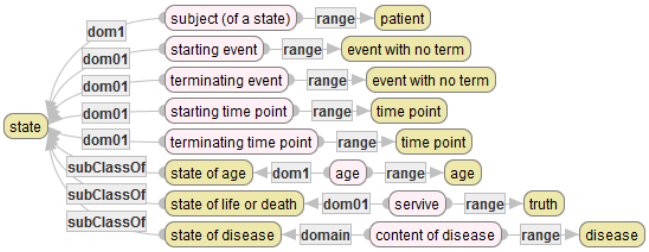


Figure 2. Concepts of states

b) Relations between concepts

We define the primary relations between concepts. We describe a relation by ⟨*name of a relation*⟩. Relations are denoted in the angled brackets.

Relations of patients and events: The relations are defined between the [*patient*] and all event concepts. For example, the following relation denotes the relations between patients and their hospital stays.

⟨*subject (of an event)*⟩ ⊆ [*patient*]×[*hospital stay*].

Note that these relations share the same name "subject (of an event)". We omit the explanation of the relations between patients and other events.

Relations of patients and states: The relations are defined between the [*patient*] and all state concepts. For example, the following relation denotes the relationship between patients and their states of diseases.

⟨*subject (of a state)*⟩ ⊆ [*patient*]×[*state of disease*].

Note that these relations also share the same name "subject (of a state)" and that all concepts of states have the attributes of starting time points and terminating time points. We omit the explanation of the relations between patients and other states.

Relations of time ordering: The relations are defined between the concepts of events and the states. For example, the following relations denote the relationships between operations.

⟨*more than <p> before*⟩ ⊆ [*operation*]×[*operation*],
⟨*less than <p> before*⟩ ⊆ [*operation*]×[*operation*],
⟨*less than <p> after*⟩ ⊆ [*operation*]×[*operation*] and
⟨*more than <p> after*⟩ ⊆ [*operation*]×[*operation*].

Here, "<*p*>" denotes a parameter. For example, the relation ⟨before more than <2 weeks>⟩ consists of a pair <*op1*, *op2*> if *op1* and *op2* are performed and if *op1* is performed more than two weeks before *op2*.

Belonging relations of events: The relations are defined between concepts of events with no term and events with terms. For example, the following relation denotes the relations between operations and hospital stays that have operations.

⟨*belonging*⟩ ⊆ [*operation*]×[*hospital stay*].

The relation contains a pair (*op*, *sty*) of an event of an operation *op* and that of a hospital stay *sty* if *op* is performed in the duration of *sty*.

B. Representation of objects of quality indicators

In this subsection, we define a graph that represents a target of quantification based on the medical service ontology defined in the previous subsection. We call such a graph an "objective graph". An objective graph is defined as a finite and labeled directed graph with a root node.

1) Definition of objective graphs

An objective graph $\mathbb{G}$ consists of the five components (N($\mathbb{G}$), R($\mathbb{G}$), E($\mathbb{G}$), L($\mathbb{G}$), C ($\mathbb{G}$)), where
(i) N($\mathbb{G}$) is a set of nodes,
(ii) R($\mathbb{G}$) is a root node,
(iii) E($\mathbb{G}$) is a set of edges,
(iv) L($\mathbb{G}$) is a label function on N($\mathbb{G}$)∪E($\mathbb{G}$), and
(v) C($\mathbb{G}$) is a concept.

We define these components by induction on the structure of the node labels, as follows.

Case 1. Assume that the following data are given:
(a) concept C,
(b) attributes $A_1,\ldots, A_n$ of C, and
(c) values $a_1,\ldots, a_n$ of $A_1,\ldots, A_n$, respectively.
Then, we define an objective graph $\mathbb{G}$, as follows.
(i) N($\mathbb{G}$):={$*_0, \ldots, *_n$},
(ii) R($\mathbb{G}$):=$*_0$,
(iii) E($\mathbb{G}$):={$f_1,\ldots,f_n$}, where each f_i is an edge from $*_0$ to $*I$,
(iv) L($\mathbb{G}$)($*_0$):=C,
L($\mathbb{G}$)($*_i$):=a_i for i =1,..., n, and,
L($\mathbb{G}$)(f_i):=A_i for i =1,..., n, and
(v) C($\mathbb{G}$):=C.

Note that if $n=0$, then N($\mathbb{G}$) is the singleton set {$*_0$} and E($\mathbb{G}$) is the empty set.

Case 2. Assume that the following data are given:
(a) an integer n with $n\geq 1$,

(b) a set of objective graphs $\{\mathbb{G}_0, \ldots, \mathbb{G}_n\}$,

(c) a set of relations $\{R^1,\ldots, R^n\}$, where each R^i is a relation between $C(\mathbb{G}_i)$ and $C(\mathbb{G}_0)$,

(d) a set of integers $\{n(i,j)\}_{0\le i\le n, 0\le j\le n}$ and,

(e) for each i with $0\le i\le n$ and j with $0\le j\le n$, the set of relations is $\{R^{i,j}{}_1,\ldots, R^{i,j}{}_{n(i,j)}\}$, where each $R^{i,j}{}_k$ is a relation between $C(\mathbb{G}_i)$ and $C(\mathbb{G}_j)$. (Note: if $n(i,j)=0$, the set $\{R^{i,j}{}_1,\ldots, R^{i,j}{}_{n(i,j)}\}$ is the empty set).

Then, we define an objective graph $\mathbb{G}$, as follows.

(i) $N(\mathbb{G}):=\{*_0, \ldots, *_n\}$,

(ii) $R(\mathbb{G}):=*_0$,

(iii) $E(\mathbb{G}):=\{f^1,\ldots, f^n\}\cup(\cup_{0\le i\le n,0\le j\le n}\{f^{i,j}{}_1,\ldots, f^{i,j}{}_{n(i,j)}\})$, where each f^i is an edge from $*_i$ to $*_0$ and each $f^{i,j}{}_k$ is an edge from $*_i$ to $*_j$,

(iv) $L(\mathbb{G})(*_i):=\mathbb{G}_i$ $(i = 0,\ldots, n)$,
$L(\mathbb{G})(f^i):=R^i$ $(i = 0,\ldots, n)$,
$L(\mathbb{G})(f^{i,j}{}_k):= R^{i,j}{}_k$ $(i, j = 0,\ldots, n$ and $k = 1,\ldots, n(i, j))$, and

(v) $C(\mathbb{G}):= C(\mathbb{G}_0)$.

Each f^i is called a main edge of $\mathbb{G}$ and each $f^{i,j}{}_k$ is called an optional edge of $\mathbb{G}$.

2) Example of an objective graph

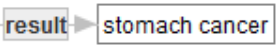
We give an example of an objective graph. For example, let us consider the quality indicator "5-year stomach cancer survival rate". The definition of the quality indicator is the ratio of the number of 5-year surviving patients to all stomach cancer patients, where a "stomach cancer patient" is a patient who had a diagnosis whose result was stomach cancer, and a "5-year surviving patient" is a patient who had a diagnosis whose result was stomach cancer but who is alive 5 years after that medical examination. Thus, we express the set of 5-year surviving patients in Fig.3. We first construct three objective graphs $\mathbb{G}_0$, $\mathbb{G}_1$, and $\mathbb{G}_2$, as follows.

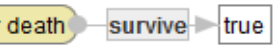
(1) $\mathbb{G}_0 = (\{*\}, *, \varnothing$ (the empty set), L_0, [*patient*]), where $L_0(*)$=[*patient*].

(2) $\mathbb{G}_1 = (\{*_0, *_1\}, *_1, \{f_1:*_0\to*_1\}, L_1,$ [*diagnosis*]), where $L_1(*_0)$ = [*diagnosis*], $L_1(*_1) = \langle\langle$*stomach cancer*$\rangle\rangle$, $L_1(f_1) = \langle$*result*$\rangle$ and [*diagnosis*] denotes an event concept, $\langle\langle$*stomach cancer*$\rangle\rangle$ denotes an instance of the concept of diseases, and $\langle$*result*$\rangle$ denotes an attribute of the concept [*diagnosis*]. Note that the range of $\langle$*result*$\rangle$ is the concept of diseases.

(3) $\mathbb{G}_2 = (\{*_0, *_1\}, *_1, \{f_1:*_0\to*_1\}, L_2,$ [*state of life or death*]), where $L_2(*_0)$ = [*state of life or death*], $L_2(*_1) = \langle\langle$*true*$\rangle\rangle$, $L_2(f_1) = \langle$*survive*$\rangle$, [*state of life or death*] denotes the viability status of a patient, $\langle\langle$*stomach cancer*$\rangle\rangle$ denotes an instance of the concept of diseases, and $\langle$*result*$\rangle$ denotes an attribute of the concept [*diagnosis*]. Note that the range of $\langle$*result*$\rangle$ is the concept of diseases.

(1) $\mathbb{G}_0$=

(2) $\mathbb{G}_1$= 

(3) $\mathbb{G}_2$= 

We next construct an objective graph of "5-year surviving stomach cancer patients" $\mathbb{G}$, as follows.

(i) $N(\mathbb{G}) = \{*_0, *_1, *_2\}$,

(ii) $R(\mathbb{G}) =*_0$,

(iii) $E(\mathbb{G}) = \{f^1:*_1\to*_0, f^2:*_2\to*_0, f^{21}:*_2\to*_1\}$,

(iv) $L(\mathbb{G})(*_i) = \mathbb{G}_i$ $(i = 0, 1, 2)$,
$L(\mathbb{G})(f^1) = \langle$*subject (of the event)* $\rangle$,
$L(\mathbb{G})(f^2) = \langle$*subject (of the state)* $\rangle$,
$L(\mathbb{G})(f^{21}) = \langle$*after more than* <5 years>$\rangle$, and

(v) $C(\mathbb{G}) = C(\mathbb{G}_0) =$ [*patient*].

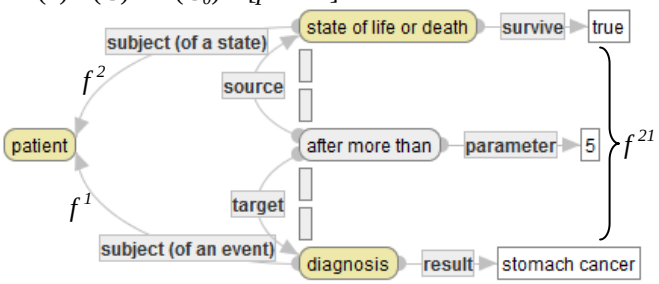


Figure 3. 5-year surviving patients with stomach cancer (objective graph $\mathbb{G}$)

3) Segments of an objective graph

In the following subsection (Sec. II.*C*), we interpret an objective graph $\mathbb{G}$ as a set that is obtained from $C(\mathbb{G})$ by adding the conditions defined by $L(\mathbb{G})$. We define an objective graph $\mathbb{G}^*$, which is called a segment of $\mathbb{G}$ and which can be interpreted as a super set of a given objective graph $\mathbb{G}$, as follows.

Case 1. If $\mathbb{G}$ is an objective graph defined in Case 1 of the definition of objective graphs, then graph $\mathbb{G}^*$ defined in the following properties is a segment of $\mathbb{G}$.

(i) $N(\mathbb{G}^*) \subseteq N(\mathbb{G})$,

(ii) $R(\mathbb{G}^*) = R(\mathbb{G})$,

(iii) $E(\mathbb{G}^*) \subseteq E(\mathbb{G})$,

(iv) $L(\mathbb{G}^*) = L(\mathbb{G})|_{N(\mathbb{G}^*)\cup E(\mathbb{G}^*)}$ (the restriction of $L(\mathbb{G})$ to $N(G^*)\cup E(G^*)$), and

(v) $C(\mathbb{G}^*)= C(\mathbb{G})$.

Here, for sets X and Y with $Y\subseteq X$ and for a function f on X, $f|_Y$ denotes the function of Y that is defined by $f|_Y(y) := f(y)$ for all $y\in Y$. We often refer to $f|_Y$ as the restriction of f to Y.

Case 2. Let $\mathbb{G}$ be an objective graph defined in Case 2 of the definition of objective graphs. Then, graph $\mathbb{G}^*$ defined in the following properties is a segment of $\mathbb{G}$.

(i) $N(\mathbb{G}^*) \subseteq N(\mathbb{G})$.

(ii) $R(\mathbb{G}^*) = R(\mathbb{G})$.

(iii) $E(\mathbb{G}^*) \subseteq E(\mathbb{G})$, where, for all $*_i \in N(\mathbb{G}^*)\setminus\{*_0\}$, the main edge from $*_i$ to $*_0$ in $E(\mathbb{G})$ is contained in $E(\mathbb{G}^*)$. Note that, for sets X, Y with $Y\subseteq X$, $X\setminus Y$ denotes the set $\{x\in X| x\notin Y\}$.

(iv) $L(\mathbb{G})(*_i):=\mathbb{G}^*{}_i$ for all $*_i \in N(\mathbb{G}^*)$, where $\mathbb{G}^*{}_i$ is a segment of $\mathbb{G}_i$,
$L(\mathbb{G})(f^i):=R^i$ for all $f^i \in E(\mathbb{G}^*)$ and
$L(\mathbb{G})(f^{j,i}{}_k):= R^{i,j}{}_k$ for all $f^{j,i}{}_k \in E(\mathbb{G}^*)$.

(v) $C(\mathbb{G}^*) = C(\mathbb{G})$.

4) Example of a segment of an objective graph

For the objective graph $\mathbb{G}$ in Fig. 3, the objective graph $\mathbb{G}^*$ in Fig. 4 is a segment of $\mathbb{G}$, which expresses the set of stomach cancer patients.

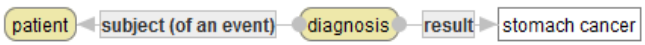


Figure 4. A segment $\mathbb{G}^*$ of $\mathbb{G}$

C. Values of objective graphs

1) Definition of values of objective graphs

For an objective graph $\mathbb{G}$, we define a set $[[\mathbb{G}]]$, as follows.

Case 1. Let $\mathbb{G}$ be an objective graph defined in Case 1 of the definition of objective graphs. Then,

$[[\mathbb{G}]]:=\{c\in C \mid f_1(c.A_1)=a_1 \wedge \ldots \wedge f_n(c.A_n)=a_n\}$, where $c.A_i$ is the value of the attribute Ai on c and the symbol $\wedge$ denotes the logical connective symbol of "and."

Case 2. Let $\mathbb{G}$ be an objective graph defined in Case 2 of the definition of objective graphs. Then,

$[[\mathbb{G}]]:=\{x_0\in[[\mathbb{G}_0]] \mid \exists x_1\in[[\mathbb{G}_1]],\ldots,\exists x_n\in[[\mathbb{G}_n]]$
$(\wedge_{i=1,\ldots,n} R^i(x_i, x_0))\wedge(\wedge_{i,j=0,\ldots,n}(\wedge_{k=1,\ldots,n(i,j)} R^{i,j}_k(x_i, x_j)))\}$.

Lemma. For an objective graph $\mathbb{G}$ and a segment $\mathbb{G}^*$ of $\mathbb{G}$,

$$[[\mathbb{G}]] \subseteq [[\mathbb{G}^*]].$$

Proof. One can easily show the lemma above by induction on the structure of $\mathbb{G}$.

D. Quantifier concepts

A quantifier concept plays a role in a function that has an objective graph and optional parameters as input data and that outputs a numerical value. In general, one can classify quantifier concepts into three types. In the following, we explain each type of quantifier concept. We describe a quantifier concept by ⟨⟨*name of a quantifier concept*⟩⟩. Note that we often identify a concept with a set and that all sets are considered to be finite.

a) Total numbers

For a finite set S, the summation of numbers obtained from elements of S is called the total number of S. For example, if each element is assigned to 1 as the existence of the element, then the total number is the same as the cardinality of S. The quantifier concept ⟨⟨*cardinality*⟩⟩ is regarded as a function that has an objective graph $\mathbb{G}$ as input data and that outputs the cardinality of $[[\mathbb{G}]]$.

For a concept S, attributes $A_1,\ldots, A_n$ of S, and the real-valued function f on the set of values of instances of S with respect to $A_1,\ldots, A_n$, the summation $\sum_{s\in S} f(s.A_1,\ldots, s.A_n)$ is called the total attribute number of S with respect to $A_1,\ldots, A_n$ and f, where $s.A_i$ denotes the value of an instance s with respect to A_i, is an attribute quantifier function**.**

The quantifier concept ⟨⟨*total attribute number*⟩⟩ is regarded as a function that has the following data as input data:

1. an objective graph $\mathbb{G}$,
2. attributes $A_1,\ldots, A_n$ of C($\mathbb{G}$), and
3. $f: C_1\times\ldots\times C_n\rightarrow\mathbb{R}$, where $C_i := \{s.A_i \mid s\in[[\mathbb{G}]]\}$.

⟨⟨*total attribute number*⟩⟩ outputs the total attribute number of $[[\mathbb{G}]]$ with respect to $A_1,\ldots, A_n$ and f.

b) Rate

For a finite set S and a subset S^* of S, the rate of the total number of S^* among the total numbers of S obtained in the same way as that to calculate the total number of S^* is called a rate of S^* among S. In particular, the rate of the cardinality of S^* among that of S is called the cardinality rate of S^* among S. Moreover, the rate of the total attribute number of S^* with respect to $A_1,\ldots, A_n$ and f among that of S with respect to the same attributes and the same attribute quantifier function is called the total attribute number rate.

The quantifier concept ⟨⟨*cardinality rate*⟩⟩ is regarded as a function that has the following data as input data:

1. an objective graph $\mathbb{G}$, and
2. a segment $\mathbb{G}^*$ of $\mathbb{G}$.

In contrast, the quantifier concept ⟨⟨*total attribute number rate*⟩⟩ is regarded as a function that has the following data as input data:

1. an objective graph $\mathbb{G}$,
2. a segment $\mathbb{G}^*$ of $\mathbb{G}$,
3. attributes $A_1,\ldots, A_n$ of C($\mathbb{G}$), and
4. $f: C_1\times\ldots\times C_n\rightarrow\mathbb{R}$, where $C_i := \{s.A_i \mid s\in[[\mathbb{G}]]\}$.

⟨⟨*total attribute number rate*⟩⟩ outputs the rate of the total attribute number of $[[\mathbb{G}]]$ with respect to $A_1,\ldots, A_n$ and f among that of $[[\mathbb{G}^*]]$ with respect to the same attributes and the same attribute quantifier function.

c) Average

For concept S, attributes $A_1,\ldots, A_n$ of S, and attribute quantifier function f, the ratio of the total attribute number of S with respect to $A_1,\ldots, A_n$ and f and the cardinality of S is called the average of the value of S with respect to $A_1,\ldots, A_n$ of f. The quantifier concept ⟨⟨*cardinality rate*⟩⟩ is regarded as a function that has the same input data as that of ⟨⟨*total attribute number*⟩⟩ and that outputs the average of the value of S with respect to $A_1,\ldots, A_n$ of f.

E. Examples of quality indicators in the representation system

A quality indicator can be represented as a combination of an objective graph and a quantifier concept. In this subsection, we describe one of the typical quality indicators "stomach cancer 5-year survival rate" with objective graphs and a quantifier concept. This indicator is defined to be the rate of the number of patients diagnosed with stomach cancer surviving 5 years after diagnosis among the number of patients diagnosed with stomach cancer. Thus, the numerator and the denominator of the indicator can be described to be objective graphs $\mathbb{G}$ and $\mathbb{G}^*$ in Fig. 3 and Fig. 4, respectively. Thus, one can describe the quality indicator by using $\mathbb{G}$, $\mathbb{G}^*$, and the quantifier concept ⟨⟨*cardinality rate*⟩⟩ as the graph in Fig. 5 on the next page.

IV. Calculation of Values of Quality Indicators Based on Medical Databases

In this section, we briefly explain how to calculate the values of quality indicators described in the representation system by using medical databases. One can obtain an entity-relationship model [7] from the medical service ontology in Sec. III.A by translating the main concepts to entities and the properties between them to the relationship between entities obtained from the given concepts. Moreover, by translating the attributes of a main concept to those of the entity translated from the concept, one can obtain a relational data model, which we call the global data model (GDM) of medical service ontology.

By the interpretation of Sec. III.C, one can perform a query on the GDM from a given objective graph $\mathbb{G}$ by translating the condition of $[[\mathbb{G}]]$ in a way based on relational calculus [8], since the condition of $[[\mathbb{G}]]$ is defined as a formula in first-order logic on the concepts and properties, and all properties are simple so that one can translate them to queries on the GDM automatically. Therefore, for a given medical database **MD**, if one has a suitable mapping between the data model on the **MD** and the GDM, one can automatically calculate the value of quality indicators based on the data in the **MD**.

V. CONCLUSIONS

It is important to describe quality indicators that have no ambiguity of interpretation and to calculate their values accurately in a coherent way. In this paper, we introduce a representation system of quality indicators, which consists of (i) an ontology of medical services, (ii) objective graphs to represent the subjects of quantification and interpretation of objective graphs as sets, and (iii) quantifier concepts. We also briefly explain the whole image of our framework to define quality indicators and to calculate their values and a way to calculate the values of quality indicators based on the medical databases. The proposed representation system plays a central role in the framework and assists the specialization of jobs of the medical staffs, who evaluate their medical services, and the system engineers, who develop or manage medical databases, and the collaboration between them.

ACKNOWLEDGMENT

The authors would like to thank Professor Mitsuru Ikeda for his many fruitful advices.

REFERENCES

[1] A. Donabedian, “Evaluating the quality of medical care”, The Milbank Memorial Fund Quarterly, Vol. 44, No. 3, Pt. 2, 1966, pp. 166–203.

[2] J. Mainz, “Developing evidence-based clinical indicators: a state of the art methods primer”, International Journal for Quality in Health Care 2003; Volume 15, Supplement 1, pp. i5-i11.

[3] International Quality Indicator Project (IQIP), http://www.internationalqip.com/index.aspx.

[4] K. J. Scheiderer, "The Maryland Quality Indicator Project: searching for opportunities for improvement", Top Health Inf Manage. Volume 15, No. 4, 1995, pp. 26-30.

[5] S. Mattke et al. (2006), “Health Care Quality Indicators Project: Initial Indicators Report”, OECD Health Working Papers, No. 22, OECD Publishing. http://dx.doi.org/10.1787/481685177056.

[6] K. Hasida, “Introduction to Semantic Editor” (in Japanese). http://i-content.org/semauth/intro/index.html.

[7] P. P. S. Chen, "The entity-relationship model—toward a unified view of data", ACM Transactions on Database Systems, Volume 1 Issue 1, 1976, pp. 9-36.

[8] S. Abiteboul, R. B. Hull, and V. Vianu, “Foundations of Databases”. Addison-Wesley, 1995.

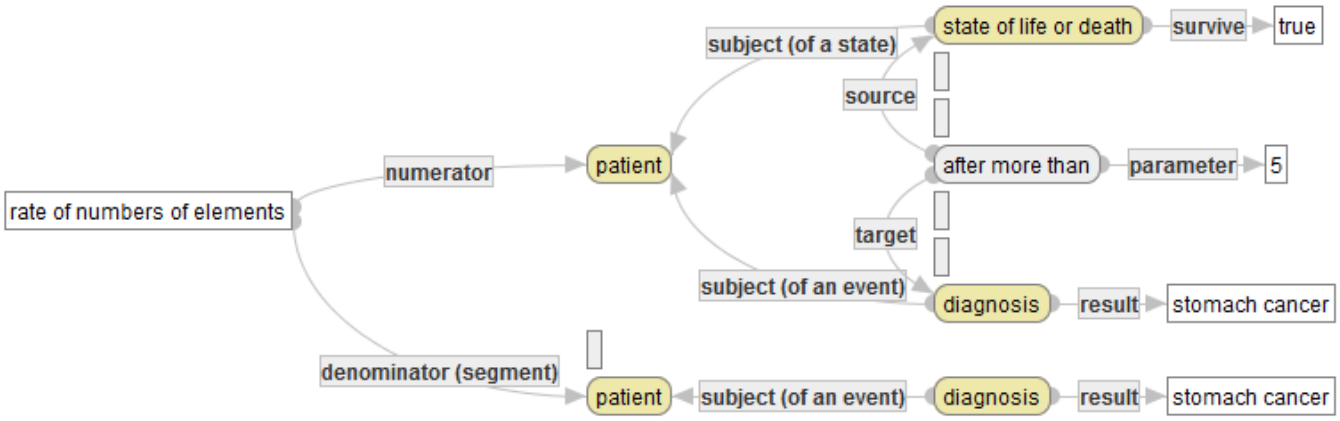


Figure 5. Stomach cancer 5-year survival rate

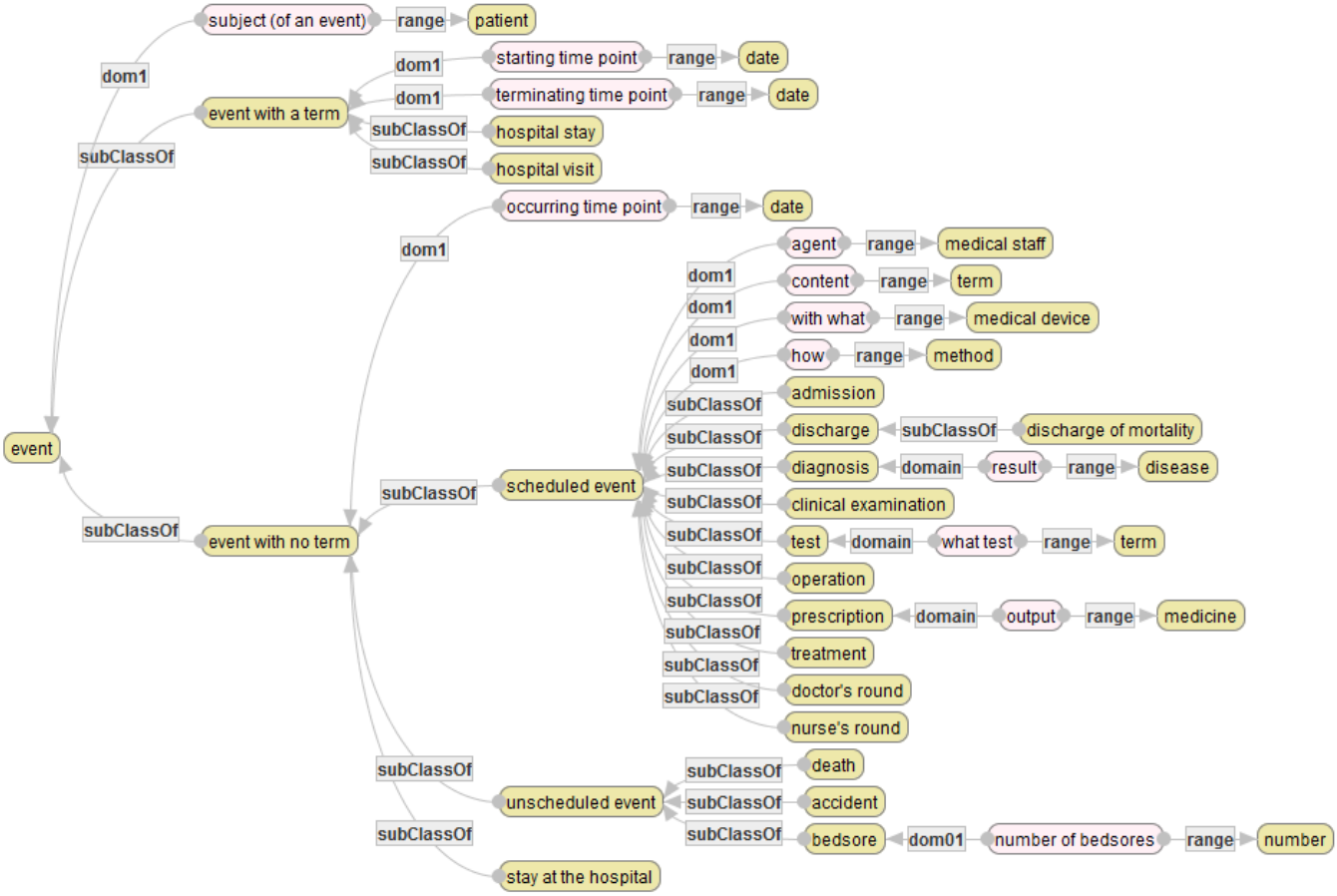


Figure 6. Concepts of events

 ISBN: 978-1-61208-179-3