



eTELEMED 2011

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

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Guadeloupe, France

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Foreword

The Third International Conference on eHealth, Telemedicine, and Social Medicine [eTELEMED 2011], held between February 23-28, 2011 in Gosier, Guadeloupe, France, considered advances in techniques, services, and applications dedicated to a global approach of eHealth, including a regard on federated aspects considering the mobility of population, the cross-nations agreements, and the new information technology tools.

We are facing the generalization of digital society across multiple social areas. The globalization imposes the revision of the health costs a society can support. The progress in difference domains, such as image processing, wireless communications, computer vision, cardiology, and information storage and management assure a virtual team to access online to the latest achievements.

Processing medical data benefits now from advanced techniques for color imaging, visualization of multi-dimensional projections, Internet imaging localization archiving as well as from a higher resolution of medical devices. Collecting, storing, and handling patient data requires robust processing systems, safe communications and storage, and easy and authenticated online access.

We assist to an unprecedented and rapid deployment of use of electronic imagery, navigation portals, positive attitude on telemedicine, distributed surgery teams, tele-cardiology, and remote medicine. Development of wireless homecare, of special types of communications with patient data, of videoconferencing and telepresence, and the progress in image processing and data 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.

We take here the opportunity to warmly thank all the members of the eTELEMED 2011 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 eTELEMED 2011. We truly believe that, thanks to all these efforts, the final conference program consisted of top quality contributions.

Also, this event could not have been a reality without the support of many individuals, organizations, and sponsors. We are grateful to the members of the eTELEMED 2011 organizing committee for their help in handling the logistics and for their work to make this professional meeting a success.

We hope that eTELEMED 2011 was a successful international forum for the exchange of ideas and results between academia and industry and for the promotion of progress in the areas of eHealth, Telemedicine and Social Medicine..

We are convinced that the participants found the event useful and communications very open. We also hope the attendees enjoyed the beautiful surroundings of Gosier, Guadeloupe, France.

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Table of Contents

Database Reengineering of the Registry of Tuberculosis <i>Peter Benedik, Vladislav Rajkovic, Andraz Jakelj, Mirjana Kljajic Borstnar, Uros Rajkovic, and Marjana Pikec</i>	1
Content-based Retrieval of 3D Medical Images <i>Yu Qian, Xiaohong Gao, Martin Loomes, Richard Comley, Balbir Barn, Rui Hui, and Zenmin Tian</i>	7
Long-term Preservation Solution for Complex Digital Objects Preserved as Archival Information Packages in the Domain of Pharmaceutical Records <i>Hrvoje Stancic, Arian Rajh, and Kresimir Pavlina</i>	13
Bridging the Gap Between Consumer eHealth and Public Health Through a Diagnostic Decision Support System <i>Takashi Okumura</i>	22
ePublic Health: Fresh Approaches to Infection Prevention and Control <i>Hans C. Ossebaard, Lisette Van Gemert-Pijnen, and Erwin R. Seydel</i>	27
Context-sensitive Communication in Hospitals: A User Interface Evaluation and Redesign of Ascom Wireless IP-DECT Phones <i>Terje Solvoll, Annelies Tiemersma, Edouard Kerbage, Stefano Fasani, Ashok Babu Ravuri, and Gunnar Hartvigsen</i>	37
Towards an Internet-based Infectious Disease Management Platform to Increase Patient Safety <i>Jobke Wentzel, Joyce Karreman, and Julia van Gemert-Pijnen</i>	47
A concept of a patient-centered healthcare system based on the virtualized networking and information infrastructure <i>Artur Binczewski, Krzysztof Kurowski, Cezary Mazurek, and Maciej Stroinski</i>	51
Play for Health: Videogame Platform for Motor and Cognitive Telerehabilitation of Patients <i>Francisco Tous, Pedro Ferriol, Alicia Domingo, Alberto de Rodrigo, Miguel Angel Alcalde, Miguel Angel Rujula, Olga Romero, Maria Angeles Farreny, Maria del Carmen Buen, Begona Llano, Elena Ponce, and Petra Vidal</i>	59
Designing User Friendly Mobile Application to Assist Cancer Patients in Illness Management <i>Jelena Mirkovic, Haakon Bryhni, and Cornelia Ruland</i>	64
Health Solutions Using Low Cost Mobile Phones and Smart Spaces for the Continuous Monitoring and Remote Diagnostics of Chronic Diseases <i>Carlos Rolim, Fernando Koch, Jim Black, and Claudio Geyer</i>	72
Using Soft Computer Techniques on Smart Devices for Monitoring Chronic Diseases: the CHRONIOUS case <i>Piero Giacomelli, Giulia Munaro, and Roberto Rosso</i>	77

Creating a Framework for Testing Wellness Visualization Systems <i>Chitsutha Soomlek and Luigi Benedicenti</i>	83
Large Scale eHealth Systems: Providing Information to Support Evidence-based Management <i>Hannele Hypponen, Johanna Viitanen, Jarmo Reponen, Persephone Doupi, Vesa Jormanainen, Tinja Laaveri, Jukka Vanska, Ilkka Winblad, and Paivi Hamalainen</i>	89
Design and Aims of Study to Measure Long-term Efficacy of Interactive Online Dietician Weight Loss Advice in General Practice <i>Vibeke Brandt, Mathilde Pedersen, Dorte Glintborg, Carl Brandt, Kirsten Brandt, Soren Toubro, and Cecilia Arendal</i>	96
Designing and Implementing an Active Personal Health Record System <i>Juha Puustjarvi and Leena Puustjarvi</i>	102
Protecting Patient Privacy when Sharing Medical Data <i>Stefan Benzschawel and Marcos Da Silveira</i>	108
Patient Empowerment and New Citizen Roles through Telehealth Technologies - The Early Stage <i>Jane Clemensen, Janne Rasmussen, Aske Denning, and Mette Atipei Craggs</i>	114
Stress Intervention Online - Designing for Self-help through Multiple Help <i>Asa Smedberg and Helene Sandmark</i>	120
Psycho-physiological Stress Monitoring using Mobile and Continuous Pulse Transit Time Measurement <i>Stefan Hey and Hatem Sghir</i>	126
Heuristic Evaluation for Interactive Games within Elderly Users <i>Jaime Andres Garcia Marin, Elaine Lawrence, Karla Felix Navarro, and Christian Sax</i>	130
Introducing eHealth Business Modelling Instruments for Implementing eHealth Technologies Based on an Integrated Approach with Human-Centered Design <i>Maarten van Limburg and Julia van Gemert-Pijnen</i>	134
A Dynamic and Customisable Layered Serious Game Design Framework for Improving the Physical and Mental Health of the Aged and the Infirm <i>Karla Felix Navarro</i>	140
Using Mobile Technology to Enhance Pediatric Diabetes Care Management <i>Robert Rosati, David Russell, and Joann Ahrens</i>	146
A Joint Organizational and Technical Development of a Telematic Rescue Assistance System for German Emergency Medical Services <i>Marie-Therese Schneiders, Daniel Schilberg, and Sabina Jeschke</i>	150

Transportation Scheduling Method for Patients in MCI using Electronic Triage Tag <i>Teruhiro Mizumoto, Weihua Sun, Keiichi Yasumoto, and Minoru Ito</i>	156
A Design Pattern for Information Sharing in Medical Emergency Response to CBRNE Events <i>Robert Dourandish</i>	164
Expectations and Fears of Urban Versus Rural Population Regarding the use of an Electronic Health Record <i>Rene Baranyi, Susanne Schinkinger, Wolfgang Schramm, and Thomas Grechenig</i>	169
Telediagnosics of Back Curvature and Posture for Elderly Patients and Remote Access to 3D Data <i>Wojciech Glinkowski, Jakub Michonski, Robert Sitnik, Bozena Glinkowska, Marcin Witkowski, and Andrzej Gorecki</i>	175

Database Reengineering of the Registry of Tuberculosis

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Abstract—Registry of tuberculosis is intended to record the clinical path of the treatment and for reporting statistics to the Institute of Public Health regarding the patients with tuberculosis. It has been entrusted to the University Clinic of Pulmonary and Allergic Diseases Golnik. To improve the efficiency of work a proposal of changes has been made to the database model of the registry of tuberculosis. The chosen methodology of information system development is based on the principle of the prototype modeling. It includes all necessary steps from the inventory of the work processes, collection of the maximum data set, development of the entity relational scheme, graphical user interface, risk analysis and logical access control. The proposed approach will not only increase the efficiency in the process view of organization and informatics but also reduce costs and make it more user friendly.

Keywords- tuberculosis; register; clinical path; database; computer solutions

I. INTRODUCTION

Tuberculosis (contagious airborne disease caused by *Mycobacterium tuberculosis*) is still one of the leading causes of death for adults [1]. TB (Tuberculosis) causes 49 new cases and kills 7 people every hour in the EU alone [1]. Escalating HIV infection as well as negligence in TB control have caused an increase in TB incidence over the last decade in both developing and developed countries [1,13]. Moreover, several other factors such as homelessness, poverty, lack of infrastructure in public

health, and inadequate access to health services have played an important role in worsening the situation. The management aspect of the TB control is one of the most important issues to consider in the prevention of TB infection, in particular, in urban setting. Management in terms of surveillance of tuberculosis aims to provide information to local teams to drive control efforts and, nationally, to inform policy. It is through surveillance that the general trends in cases can be determined.

The register of tuberculosis (RTB) records the course of treatment of patients with tuberculosis at a national level [6]. The data collection process of the tuberculosis treatment is recorded manually and is therefore quite time consuming. The aim of the proposed solution is to improve the process and design a new database, which would no longer require manual data entry through paper forms. It would provide direct data collection through e-forms. This would contribute to the promptness of the RTB, reduce possibility of errors in data entry and provide greater patient privacy. The following contribution shows systematic steps that were necessary to design the database model, graphical user interface and data access control.

This paper shows to show systematic steps that were necessary to design the database model, graphical user interface and data access control of Database Reengineering of the Registry of Tuberculosis. The first two sections of this paper provide the backdrop for understanding the necessity of Reengineering of the Registry of Tuberculosis and importance of the tuberculosis distribution, its influence

on healthcare system and society. Section III reveals working methods used for construction of new database, while Section IV illustrates how a prototype solution was developed.

II. AIM AND PURPOSE

With the proposed solution we aim to renew the RTB database by capturing the processes in e-form. The program is designed to be used throughout Slovenia, with the Golnik Hospital acting as the administrator of the RTB. The proposed solution assures interoperability with any system, i.e. for home care and system "computer beside the bed". Medical staff can enter data into the system directly at the site of treatment, using personal digital assistants (PDAs). Although this program is in a prototype stage new database and PDAs approach plays an important role in ensuring that high quality data can be quickly and reliably collected from numbers of patients who are distributed over different geographic areas in Slovenia. The proposed solution will allow different hospitals or individuals that need to record data of tuberculosis in dispersed locations to be able electronically capture data at the point of collection.

As this project is in a prototype form and was not yet implemented, we can not measure its true potential and benefits but, as shown within developed countries, personal digital assistants (PDAs) have promise as a new technology that can increase the quality and efficiency of data collection [14]. This study suggests that the design and implementation of the PDA intervention play a key role in a system's success.

Our research can be compared with the research taken in Peru by Joaquin et al. [15], where they implemented PDA approach for gathering data on multidrug resistant tuberculosis (MDR-TB) patients. They found that implementing information solution with PDAs approach decrease processing times, frequency of errors (as there is no transcription from paper based form to electronic one) and substantial reduction in the delays from collection to entry of laboratory results. Also it reduces workload for those involved in data collection and processing.

To better understand the importance of the new database and PDA approach we must look at simple case that is taken daily at RTB. Patients with latent form of tuberculosis are required to submit a monthly sputum sample at local health center or hospital. The sputum sample and smear result are then sent to the Golnik Hospital. The laboratory monitoring process begins with a smear microscopy test. Timeliness and accuracy of reporting laboratory results for these samples are essential to determine if a patient is responding to treatment and, if not, to alert physicians to the possible need for medication changes. In each health center the team records the smear test result on a paper form and in each regional laboratory

the team records both the culture result and the smear result sent by the health center on a similar paper form. These forms are then sent to RTB where the culture and smear results are verified and retyped into the information system that collects data. The major disadvantages of this paper-based method are the delays in processing and entering laboratory results and data quality issues stemming from multiple opportunities for transcription errors.

To avoid problems discussed above, the proposed solutions are integrated in the existing hospital information system. This way, later transcriptions of data become unnecessary, what reduces the possibility of transactional errors and assures data integrity. Furthermore, with the proposed solution we can avoid the paper records and therefore lower the storage costs and times for processing of patients' data [4], while significantly improving the quality of the whole process [1]. A user-friendly web application enables users to add and delete data records about patients anywhere and at anytime.

Our proposed solution can be compared with ETR.Net (The electronic Tuberculosis Register) which is an electronic tuberculosis register designed for TB/HIV surveillance, program monitoring and evaluation. The system consists of a database which is accessed by the user via the software interface, custom developed for the Microsoft Windows environment. Its main implementations are in East African countries like Botswana, Guatemala, and Mozambique. It is a stand alone windows application therefore those not allowed any connection with clinical information system neither can be accessed through internet.

III. WORKING METHODS

The construction method is based on the prototype modeling [3, 7]. Through interviews with the healthcare teams we have obtained the framework for functionality requirements. Critical analysis of the existing processes for data inputs and their processing provided insights regarding the existing ways of working with the registry exposed the requirements and the users' wishes. Based on the results of the current situation analysis, we constructed a prototype data model (ER diagram) which forms the basis for the construction of all required functionalities. We developed a graphical user interface with logical access control to enter, edit, view and analyse data about treatment of tuberculosis which can connect the web application and database registry.

IV. DEVELOPMENT OF A PROTOTYPE SOLUTION

A. Current Situation Analysis

The analysis of the current situation included the inventory process, paper documents and forms that support these processes substantially. In accordance with the analysis we defined five main processes as shown in Figure 1: A1 - The medical examination of the patient, A2 - Lab testing, A3 - Notification of tuberculosis, A4 - Medical treatment of tuberculosis, A5 - Final reports.

B. Data Model

The analysis of the current situation allowed us to obtain the information that is important for understanding the contents of the work processes. With the maximum set of data we were able to devise an entity relational model for RTB. The entity relational model is made in IDEF1X notation [11], which makes the informational structure of the applications easier. Through normalization and 5th normal form we created 21 entities which are related and form a complete data model for RTB as shown in Figure 2.

C. Graphical User Interface

In order to access and display data and information, it was necessary to make an integrated graphical user interface which provides a graphical look and navigation pages. The graphic interface is designed with the CSS technology which stands for Cascading Style Sheet [5]. Figure 3 shows the design of the master websites and its tabs.

Users of the RTB web application are divided into three groups: doctors, administrative staff of the RTB and select laboratories.

Each of the intended users has a personal account, username and password. This is then reported to the system via the login page. The web application window displays data, links and information adjusted to each user individually. The adjustments are made in terms of links, options and levels of access as well as rights for modifying, deleting or adding new information or data. The two groups, namely doctors and administrative staff, have access to the RTB through the patient page shown in Figure 4.

D. Ensuring Data Security

Due to the data sensitivity, it is important to ensure adequate protection against intrusion attempts or deliberate disclosure of data. The critical risk analysis showed that despite the changes and additional security modifications, there are still certain external security risks. To ensure that the access is restricted, we added the logical access control to the RTB web applications.

This includes the set up of the systematic logical access control and the appropriate use of various tools, such as the firewall, intrusion prevention systems and intrusion detection systems [2, 8] to control access to the RTB database from an external network. To establish a logical access control it is necessary to distinguish between the subjects and the objects of the Golnik Hospital's own information system KOPA. A subject represents an entity that can perform an activity within the information system (physician, administrator, laboratory), while an object represents an entity of information system that the subjects are accessing. The access should be monitored.

Logical access control is divided into means of identification, authentication, authorization and logging [10]. This way the safety of data entry is ensured, the access of unauthorized persons is denied, and unauthorized disclosure of patient's data is prevented.

V. CONCLUSION

The proposed solution includes a proposal for reengineering of the registry database for tuberculosis at the Golnik Hospital. For this purpose we designed a database model that can be realized in any relational DBMS (DataBase Management System) such as Oracle, MySQL, DB2 and others. This enables the independence of the DBMS used, faster performance, and flexibility [7]. The proposed solution is interoperable with the other hospital information systems and programmed for exchanging data via graphical user interface or database. In the future it is crucial to continuously improve data access control at both organizational and application levels. The solution will help the RTB to become more efficient in terms of data integrity and price-performance as well as more user-friendly in terms of efficient data entry and anyplace/anytime access. The proposed solution closely follows the ideas of eHealth [12]. As such it can serve as an example of good practice for other health institutions in Slovenia and across Europe.

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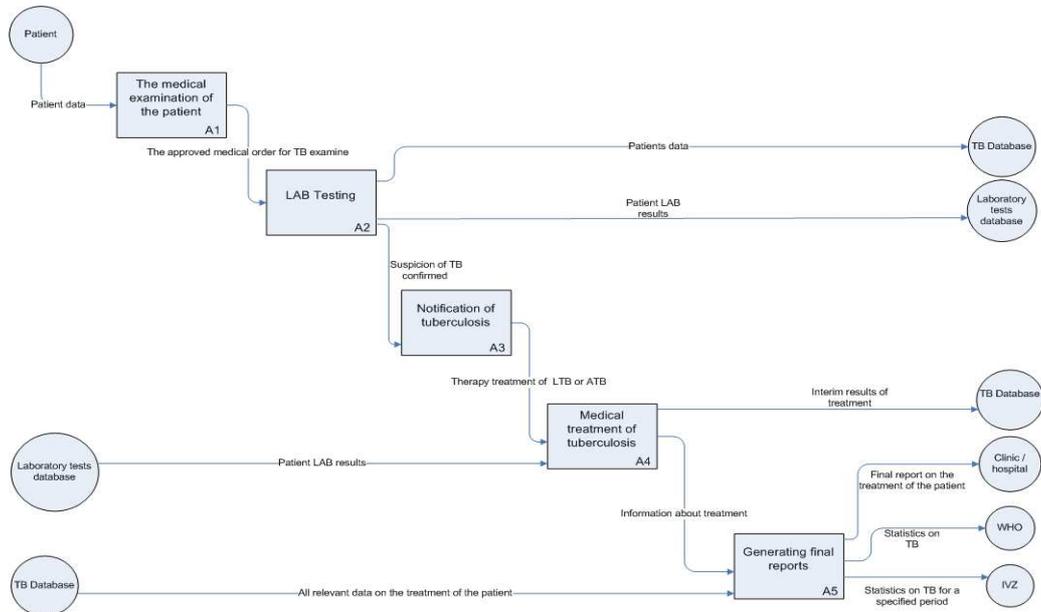


Figure 1. The treatment process in the frame of RTB.

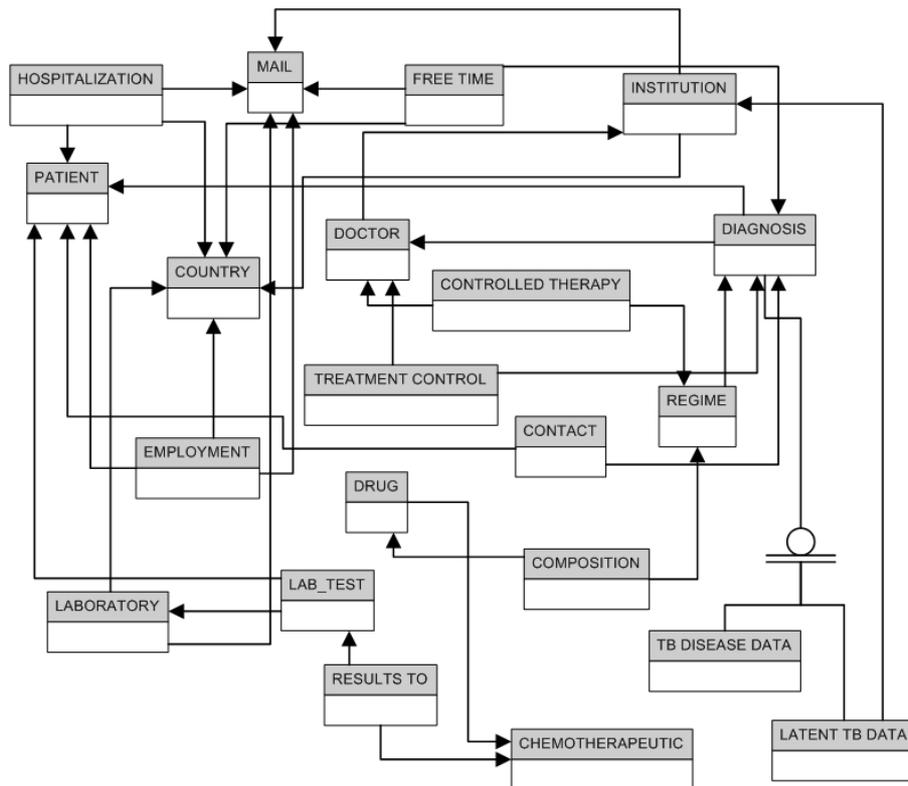


Figure 2. Entity-relational model of the RTB's database.

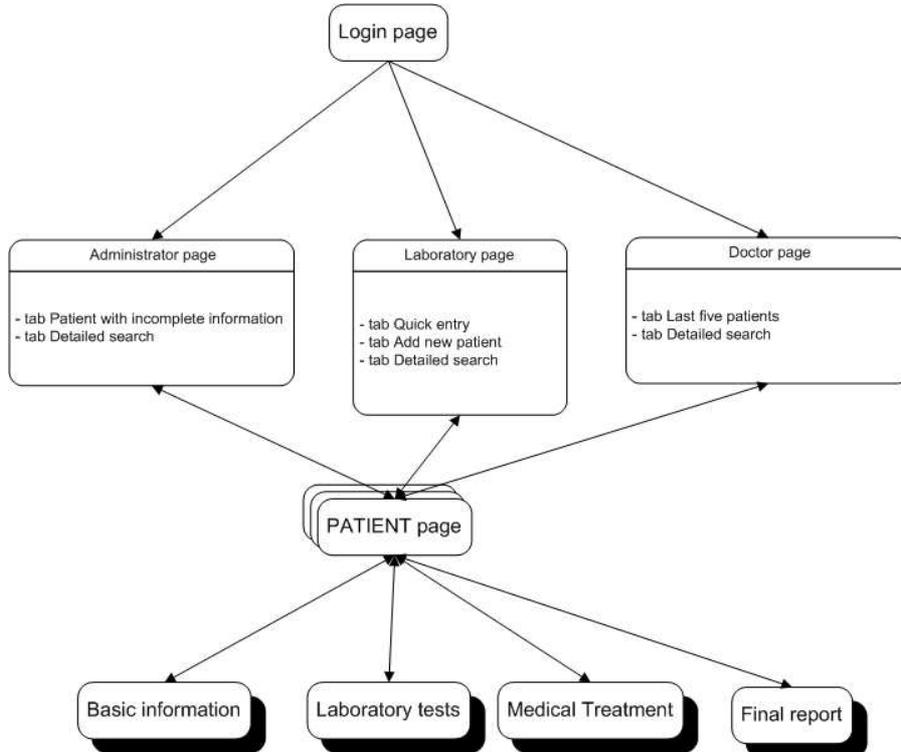


Figure 3. Site map of the RTB.



You are registered as:
 Janez Novak MD
 Hospital: KOPA Golnik
 Date: 16.1.2010

search You are working on patient: ACTIVE; Miha NOVAK, Šiškovsko naselje 2323, 4000 Kranj, roj: 22.4.1986

patient code

GENERAL INFORMATION THERAPY LABORATORY TESTS FINAL REPORT

Patient code: 9383938
 Surname and name: novak miha
 Maiden name: /
 Address: šiškovsko naselje 2323, 4000 kranj
 Date of birth: 22.4.1986
 The working hypothesis of disease (specify): /
 Specificity: Refugee Other:
 Country of birth: Slovenia Other:
 Start date of residence in Slovenia: month year
 Previous diagnosis of tuberculosis: Primary localization: Lungs Other: Anatomic code
 Additional spot of disease: Other: Anatomic code /
 Clinical signs consistent with a diagnosis of TB: Present
 Skiagram thoracic organs: Pathological-cavern
 Duration of symptoms: / weeks.
 BCG: No
 Tuberculin test: Negative The size of induration in mm:
 QuantiFERON TB-Gold test: Negative
 HIV testing: Negative
 Homeless in the last year: No
 At the time of diagnosis, the patient resided in the correction center: No
 Other, specify
 At the time of diagnosis, the patient resided in a medical establishment: Yes
 Other, specify
 Alcoholism in the last year: Yes
 Taking drugs in the last year: No
 Occupation in the last year: Worker in health organization
 Accompanying illness and treatment: Diabetes
 The time from first visit to the doctor until the start of treatment: weeks.
 Estimated control date:
 Date: Institution: Kopa golnik

BK status:
 Employment:
 1 Employed
 2 Unemployed

Figure 4. Patient data entry form taken from the RTB.

Content-based Retrieval of 3D Medical Images

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Abstract -- While content-based image retrieval (CBIR) has been researched for more than two decades, retrieving 3D datasets has been progressing considerably more slowly, especially in respect to its application to the medical domain. This is in part due to the limitation of processing speed when trying to retrieve high-resolution datasets in real-time. Another barrier is that most existing methods have been developed based on 2D images instead of 3D, leaving a gap to be filled. At present, a significant number of exploitations are focusing on the extraction of 3D shapes. However, it appears other information tends to be equally important in clinical decision making. In this paper, Local Binary Pattern (LBP), a texture based approach stemming from 2D forms, has been studied extensively through the application to 3D images from a collection of MR brain images in a content-based image retrieval system (CBIR). The initial results show LBP not only can achieve a precision rate of up to 78% but also can perform retrieval in real time with sub-second processing speeds. Comparison with the other three popular texture-based methods, namely 3D Grey Level Co-occurrence Matrices, 3D Wavelet Transforms and 3D Gabor Transforms, is also carried out. The results demonstrate that LBP outperforms them all in terms of retrieval precision and processing speed.

Keywords – CBIR, 3D image retrieval, 3D texture extraction.

1. INTRODUCTION

Due to the advances of medical imaging techniques, more and more images are in three (or higher) dimensional forms, allowing a coherent and collective view. Since many of these images are comprised of 2D slices, most current databases archive and index them in 2D form, especially for the systems that are indexed by their content. As a result, a number of limitations have arisen with the most significant one being that the information extracted from a single 2D slice can not be representative due to the fact that slices are getting thinner (i.e. resolutions are getting higher).

On the other hand, at present, content-based retrieval for three dimensional (3D) images has been researched primarily to meet the demand for 3D images over the internet. In this way, the main challenge facing the extraction of features from 3D images is that these features have to be invariant of viewing angles, i.e. invariant of rotation, in order to achieve the retrieval of relevant objects, even though sometimes they may not be visible from all the viewing angles. For example, if a query image is a 3D rabbit with a head facing the view, a good

retrieval system should bring back relevant objects including those showing only its tails as an exact match, i.e. the view angle is at the back of the object. In addition, in 2D cases, the viewing angle is always 0° , being normal to the computer screen, by which most existing algorithms can fulfill this request. The other characteristics of content-based image retrieval (CBIR) are shared between 2D and 3D, including scaling and translation of regions of interest. This has led to many current studies focusing on the invariance of transformations (including rotation, scaling and translation) of objects, which has more to do with shapes. In [1], 3D Zernike descriptors have been developed to describe shapes of objects, by taking advantages of polynomial representations, on which these descriptors are based, being invariant of transformations. In this way, a database has to consist of objects differentiated by shapes, such as airplanes, chairs, etc. Similarly, in order to achieve transformation invariance, a graph-based shape descriptor is created in [2] to determine similarity between 3D objects. More recently, the retrieval of 3D objects has been attempted using impact descriptors [3] to capture the surrounding areas of a 3D shape in order to offer a histogram of time-space curvature that are invariant of rotation and translation. Other shape-based 3D models are included in [4][5][6][7]. Because shape-based approaches only describe the surface of a 3D object, they tend to ignore the content inside that object. Depth based descriptors therefore have been developed as demonstrated in [8], which is however in principle, still capture the outline of a shape at each depth (z-buffer).

For application to medical images, a volume of interest (VOI) consists of not only boundary shapes, but also inside textures representing tissue properties of the VOI. The information extracted from these textures equally plays an important role in describing the VOI and is important to medical doctors most of the time. Therefore these texture features should be taken into consideration in the representation of an object as well.

One way to represent texture is 2D-based, since a 3D dataset is composed of a stack of 2D slices. However, using a slice-by-slice 2D approach suffers from the drawback that some important information inter-laced within the volumetric data is missing. Thus, in terms of a 3D form of texture, this spatial structural information should be extracted from a cube instead of a surface. With this in mind, in this study, the approach of

Local Binary Pattern (LBP) [9] is extended because of its discriminative power and computational simplicity, and applied to a collection of 3D MR brain images for extracting texture information that is subsequently utilized for indexing them. Comparison with the other three popular methods in texture representation is also carried out, including Grey Level Co-occurrence Matrices (GLCM), Wavelet Transforms (WT) and Gabor Transforms (GT). The novelty of this work is the extension of 2D texture features into 3D while minimizing the calculation cost. This is achieved by the introduction of a pre-processing stage of a selection of potential VOIs into query datasets. Through the use of statistically analysis of the bilateral symmetry of a brain MR image, a potential VOI of a query can be detected in real time, before proceeding with the extraction of 3D texture features and the calculation of similarities. This work forms part of our currently online CBIR system at [10]. The structure of the paper is in the following pattern. Section II explains the methods employed in the study, whilst Section III shows the experimental results. The conclusion and discussion are given in Section IV, which is followed by Sections of Acknowledgment and References.

II. METHODOLOGY

In this investigation, at the ingestion of data phase (at least two phases should be in place including ingestion and retrieval from the system), the collected data firstly undergoes a pre-processing stage to normalize them into the same resolution before the indexing stage, as shown in the flow chart in Figure 1. 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 can be extracted to create a feature database. On the query side, a pre-processing stage is introduced to detect a potential VOI after spatial normalization from a query image. Thereafter, 3D texture features from a query are only extracted from these potential sub-blocks of VOIs, which, in the retrieval stage, are compared with the corresponding features in the feature database to obtain retrieval results. Details are explained in the following sub-sections.

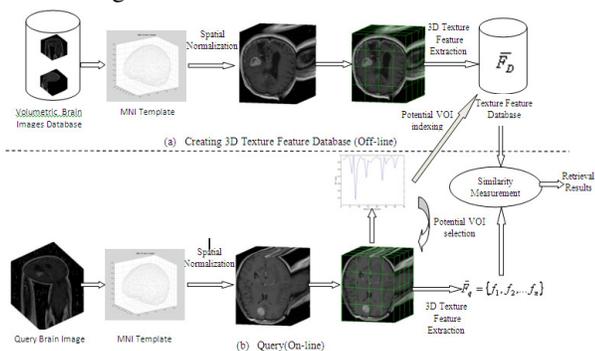


Figure 1. Framework of 3D MR image retrieval.

A. Spatial Normalization

In practice, data are collected from different sources, therefore brain images vary in both shape and size. To make inter-individual brains comparable, it is necessary to transform

the dataset of each individual brain into a standard brain template.

Statistical Parametric Mapping (SPM5) [11] is used in this regard to spatially normalize a brain image to an MNI template [12]. In this way, all the images in the database are of the same size of $157 \times 189 \times 69$ voxels.

B. Extraction of Volumetric Textures

In order to describe local features from different parts of a brain, a 3D volumetric brain is divided into 64 non-overlapping equally sized blocks, giving 4 blocks along each of x , y , z axes respectively, as illustrated in Figure 1. Texture features are then extracted using 3D LBP to create a feature database, upon which image searching and retrieval are performed.

C. 3D Local Binary Pattern (3D LBP)

The Local Binary Pattern operator is derived from a general definition of texture in a local neighbourhood (e.g. 8×8 pixels). In 2D form, for each pixel in an image, a binary code is produced by thresholding its value with the value of a centre pixel. A histogram is then generated to calculate the occurrences of different binary patterns. To extend this method to 3D images, similar to [13], a 3D dynamic texture is recognized by concatenating three histograms obtained from the LBP on three orthogonal planes. When applied to our normalized brain images, they are left-right (LR), Anterior-Posterior (AP), and Superior-Inferior (SI), as shown in Figure 2.

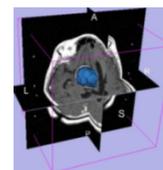


Figure 2. An example of three orthogonal planes in a 3D brain.

These three orthogonal planes intersect in a centre voxel. By selecting 8 neighbours as a local neighbourhood with the radius length being one voxel, fifty-nine uniform LBP codes are subsequently extracted from the planes of SI, LR and AP respectively, again as illustrated in Figure 2, producing a 59 bin histogram for each plane by accumulating 59 binary patterns. Finally, the three histograms are concatenated to generate a 3D texture representation, giving the size of a feature vector as being 177 (59×3) elements.

D. Lesion Detection

The main purpose of the development of this 3D CBIR system is to search images with lesions of similar location, size or shape (all the collections of images are with lesions). Although a feature database has been implemented in advance, the processing of a query has to be conducted in real time, i.e. after a query has been submitted, 3D texture features should be extracted from its 64 sub-volumetric spaces together with the calculation of similarity distances. To this end, while maintaining the overall performance of retrieval, the detection of potential lesions from sub blocks is carried out first to

highlight abnormalities, such as tumours, to speed up the retrieval process.

To do this, the characteristic of bilateral symmetry of a brain along its mid-plane (parallel to SI direction as shown in Figure 2) is assumed. Similar to [14], by comparing the left half with the right half of a hemisphere along this middle symmetry plane, the abnormality is envisaged to be singled out. Since a normalized brain image has been divided into 64 blocks, statistical features (e.g. mean, standard deviation, etc.) of each sub-block together with its mirror block are then calculated and compared to establish potentially abnormal sub-blocks.

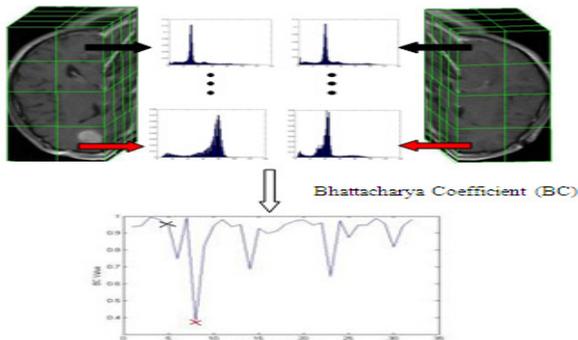


Figure 3. Potential VOI selection

As demonstrated in Figure 3, a normalized brain is divided into left (L) and right (R) parts by a sagittal plane, leading to 32 sub-blocks each, within which a grey level histogram is calculated. The Bhattacharya Coefficient (BC) [15] is then computed between two normalized histogram H_L and H_R , which are obtained from two mirror symmetric sub-blocks as defined in Eq. (1).

$$BC(H_L, H_R) = \sum_i \sqrt{H_L(i) * H_R(i)} \quad (1)$$

The more similar H_L and H_R are, the closer to 1 the BC value is. On the other hand, less similar histograms tend to have smaller BC values. In total, 32 BC values are calculated from 32 paired mirrored symmetric sub-blocks and plotted at the bottom of Figure 3. The horizontal axis points to the index numbers of sub-block pairs whereas the vertical axis represents the corresponding BC values. Also shown in the figure are the BC values presenting the top normal sub-block pair marked with a black 'x', and the bottom abnormal sub-block pair marked with a red cross. Therefore, the mean value of the BC range works as a threshold to be applied to detect the potentially abnormal sub-block (i.e. where $BC < Threshold$).

After the affirmation of a lesioned VOI from a query is established, the 3D texture features are extracted exclusively from this VOI of the query, and are later compared with the features from similar blocks of images in the feature database in an attempt to search images with similar lesions in terms of textures.

E. Similarity Measurement

To measure the degree of similarity between two images Q and I , a distance function should usually be in place calculating the distance between features of two images. For a 3D LBP, the

histogram intersection is applied to measure features of histograms that is given in Eq. (2),

$$D(Q, I) = \sum_i \min(Q_i, I_i) \quad (2)$$

where i represents each bin in the histogram. The more similar they are between a query (Q) and an image I , the bigger the value of the D is. Therefore, the retrieved results are ranked in descending order based on the value of D .

III. EXPERIMENTAL RESULTS

A. Data Collection

The database contains over 100 MR brain images with lesions (e.g. tumour, biopsy) and detailed diagnosis. Each dataset is of resolution of $256 \times 256 \times 44 \text{ mm}^3$, and is in DICOM (Digital Imaging and Communications in Medicine) format with 16 bit grey-level resolution.

B. Results on Detection of Lesions

Since the location of a lesion region plays an important part in retrieving relevant datasets, the evaluation on the detection of lesion positions is carried out first. In Table 1, the first row is the labeling number of the location of a VOI assigned by us for the convenience of calculations, e.g. '1' refers to the abnormal part in the front top left-most part of the brain. The second row is the total number of images containing VOIs in such positions in the database, whilst the number of correctly detected images by the LBP is given on the third row. Therefore the overall performance of the LBP in terms of VOI locations is calculated as the number of detected positive VOIs divided by the total positive VOIs and is 91.3% (168/184).

TABLE 1 VOI DETECTION RATE.

VOI Location	1	2	3	4	5	6	7	8	Total
Number of images	24	46	18	38	24	12	14	8	184
Correctly detected images	24	42	16	34	24	8	12	8	168
Correct Detection Rate (%)									91.3

In terms of precision, the retrieved accuracy is 78% based on ten query images with the ground truth being diagnostic information relating to the locations and sizes of tumours, demonstrating very promising results.

C. Comparison with the Other Texture-based Approaches

The other three methods widely employed in texture representations are also exploited in this investigation by their extension to 3D; including Grey Level Co-occurrence Matrices (GLCM), Wavelet Transforms (WT), Gabor Transforms (GT). These are summarized next.

In 3D form, grey level co-occurrence matrices [16][17] are defined as three dimensional matrices of the joint probability of

occurrence of a pair of grey values separated by a displacement $d = (dx, dy, dz)$.

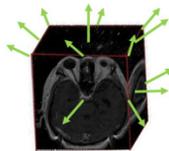


Figure 4. Thirteen directions in 3D GLCM.

For example, four distances with 1, 2, 4, and 8 voxels respectively and thirteen directions, as depicted in Figure 4, and chosen in this study, will produce 52 (4×13) displacement vectors, and thereafter 52 co-occurrence matrices. As a result, four Haralick texture features [18], being energy, entropy, contrast and homogeneity, are computed from each matrix, generating a feature vector with 208 components (4 (measures) × 52 (matrices)).

On the other hand, the 3D WT provides a spatial and frequency representation of a volumetric image, which can be achieved by applying both high-pass (H) and low-pass (L) filters along all three dimensions, which is then followed by a 2 to 1 sub-sampling of each output volumetric image [19], giving rise to eight wavelet coefficients sub-bands (one low frequency sub-band and seven high frequency sub-bands) at each scale, as schematically presented in Figure 5(a). The process is subsequently repeated in the lowest frequency sub-band (LLL_1), providing a 3D wavelet transform of two scales as shown in Figure 5(b).

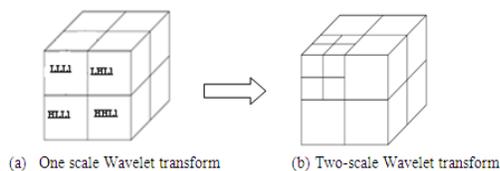


Figure 5. One scale and two scales of 3D WT.

With respect to Gabor Transforms, in order to extend GT into three dimension, a set of 3D Gabor filters are generated similar to [20][21] to detect spatial orientations and scale tunable edges and lines (bar), which can be formulated as Eq. (3).

$$g(x, y, z, F, \theta, \phi) =$$

$$\hat{g}(x, y, z) \exp[j2\pi(F \sin\theta \cos\phi x + F \sin\theta \sin\phi y + F \cos\theta z)] \quad (3)$$

where $\hat{g}(x, y, z)$ is a 3D Gaussian function, together with radial centre frequency F and orientation parameters (θ and ϕ), determining a Gabor filter in three dimensions.

To calculate similarity distances from these three methods, a normalized Euclidean distance is employed to compare two 3D patterns in a feature space, which is defined by Eq. (4).

$$D(Q, I) = \sqrt{\sum_i \left(\frac{Q_i - I_i}{\sigma_i} \right)^2} \quad (4)$$

where σ_i is the standard deviation of a set of representative features over the entire database and are utilized to normalize each individual feature component. The retrieved 3D images are ranked in ascending order of feature distances.

In summary, the above three 3D texture approaches together with LBP are applied to extract texture features from each sub-volumetric block. Furthermore, the dimension of a feature vector for a 3D brain is the size of local features multiplied by 64, the number of blocks each volumetric image is divided into, yielding 13312, 1920, 9216 and 11328 components for the approaches of 3D GLCM, 3D WT, 3D GT and 3D LBP respectively.

The performance of image retrieval is evaluated based on the Precision (P) and Recall (R). Precision is defined as the fraction of retrieved images relevant to a query whilst recall is the fraction of relevant images retrieved. Precision and recall values are usually presented together in a Precision-Recall (P-R) graph, which demonstrates the retrieval performance at each point in the ranking. In a P-R graph, the horizontal axis refers to a recall whereas the vertical axis shows the corresponding precision at each of standard recall points, i.e. 10%, 20%, ..., 100% or 0.1, 0.2, ..., 1. To represent a P-R graph using a single value, usually, the Mean Average Precision (MAP) value is employed to assess the overall performance for all queries and is calculated as:

$$\text{Mean Average Precision (MAP)} = \frac{1}{M} \sum_{i=1}^M AP_i \quad (5)$$

where M is the total number of the queries, AP_i is the average precision for the i^{th} query that is formulated as Eq. (6)

$$\text{Average Precision (AP)} = \frac{1}{N_r} \sum_{j=1}^{N_r} P_j \quad (6)$$

where N_r is the total number of relevant images in a dataset for a query, p_j is the precision when retrieving the j^{th} relevant image.

Figures 6 and 7 depict the average Precision Recall Graph for ten queries across the whole datasets with Figure 6 being the results without a pre-processing stage of VOI selection and Figure 7 with the pre-processing stage.

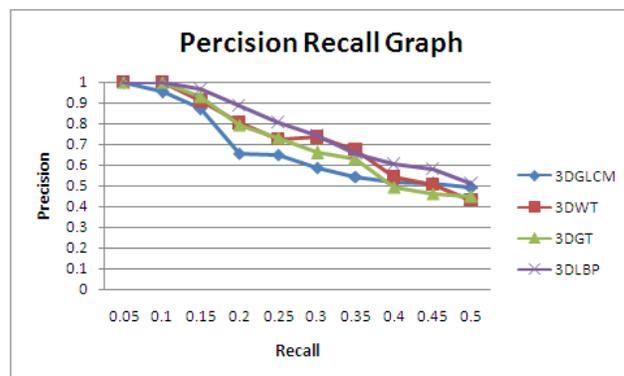


Figure 6. Average precision recall graph for ten queries without VOI selection.

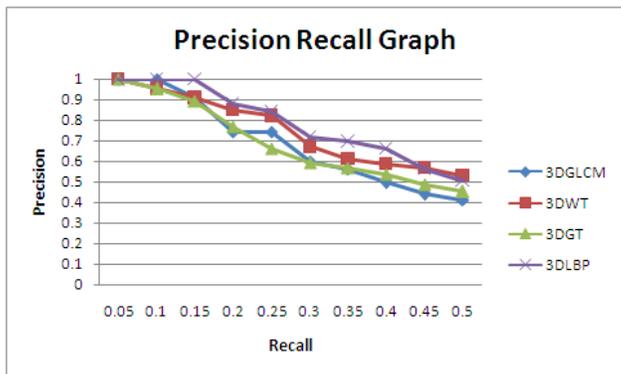


Figure 7. Average precision recall graph for ten queries with VOI selection.

In summary, the mean average precision (MAP) at 0.5 recall rate for ten queries across the whole database by using the approaches of 3D GLCM, 3D WT, 3D GT and 3D LBP are show in the following table.

TABLE 2 VALUE OF MEAN AVERAGE PRECISION

Methods	Without VOI selection	With VOI selection
3D GLCM	0.677	0.690
3D WT	0.731	0.749
3D GT	0.714	0.691
3D LBP	0.774	0.786

Comparing the value of MAP with and without potential VOI selection, the methods of 3D GLCM, 3D WT and 3D LBP with potential VOI selection show a slightly improved performance.

Figures 8 visualizes the retrieved results by using the four approaches with a pre-processing stage of VOI selection. The query image with a tumour in the middle is displayed in 3D fashion and 3 slices appearing in 3 orthogonal planes on the top row, i.e. in axial, sagittal, and coronal directions. The retrieval results are visualized by using an open source software 3D Slicer [3].

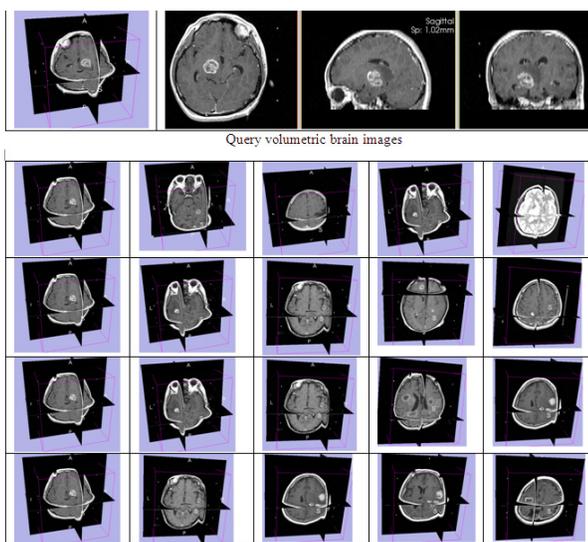


Figure 8. Retrieved results in top 5 ranking from 3D GLCM (row 1), 3D WT(row 2), 3D GT (row 3), and 3D LBP (row 4).

D. Query Time

It is understandable that retrieving images in 3D form might not be performed in real time, one of the drawbacks in the development of CBIR systems for higher dimensions. Table 3 demonstrates the average querying time, amounting to the times spent on both feature extraction and retrieval. The second column is the averaged querying time without a pre-processing stage while the third column is with VOI selection. All methods run in Matlab R2009a on an Intel P8600 1.58GHz CPU with 3.45GByte RAM.

TABLE 3 QUERY TIME

Methods	Without VOI selection	With VOI selection
3D GLCM	43.37s	10.96s
3D WT	4.46s	1.22s
3D GT	38.79m	10.77m
3D LBP	0.74s	0.21s

As can be seen in Table 3, the query time with VOI selection offers 4 times faster operation than that without. In particular, the query time for 3D GT takes a much longer time than the other methods spending 38 minutes, due to the employment of 144 times of 3D convolutions for each block, whereas the query times for the other methods are in the space of few seconds. The table also supports our choice of the 3D LBP approach with sub-second retrieval times and the highest precision rate of 78%, as given in Table 2.

IV. CONCLUSION

In this paper, a texture based approach that draws on the Local Binary Pattern technique has been employed through extension into 3D format, to retrieve lesioned MR brain images in a CBIR system. The results are very encouraging showing that not only higher precision rates can be achieved, but also that it can be done in real time. In comparison with the other three texture based methods, the 3D wavelet approach also performs well with similar retrieval accuracy, but with a poorer query time. In terms of processing speed, it appears the pre-processing stage of detection of potential VOIs is essential to highlight lesions, the regions of interest that retrieved images should contain.

Because of the time required in the establishment of a feature database in 3D form, i.e. normalization, feature extraction, etc., in particular by using the 3D GT approach (up to minutes are needed for each dataset), only ~100 datasets are included in this study. The next step is to process more datasets. Although the precision rate of 78% is very promising, a better rate should be possible with the combination of a few of these texture descriptors, while maintaining the short processing time. Comparison with shape based approaches is also in the pipeline, with the aim of developing CBIR systems for higher dimensional datasets.

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Long-term Preservation Solution for Complex Digital Objects Preserved as Archival Information Packages in the Domain of Pharmaceutical Records

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Abstract—The authors base their research on several standards: Reference Model for an Open Archival Information System (OAIS) ISO 14721 and Information and documentation – Records management processes – Metadata for records standard ISO 2381. They build a model for the long-term preservation of pharmaceutical records in the eCTD file format (electronic Common Technical Document – standard format for pharmaceutical documentation) stored in a digital archive. The model shows formation of archival information packages (AIPs) as structured, complex objects – based on eCTD’s XML elements, packaged together with the appropriate metadata in a single object and protected for the preservation reasons by an integrated checksum creating MDx algorithm. An application based upon the developed model, upon initial mapping of eCTD’s structure categories and metadata to the AIP’s structure, is shown to be able to automate this process as much as possible. This procedure should enable users to use the application even for different types of complex digital objects, not only for eCTD. In that sense the application could become a generic ‘preservation application’ for the AIP creation and long-term preservation. The authors conclude that the developed model, exemplified by the eCTD documentation format and appurtenant application, could improve the AIP creation of pharmaceutical records intended for the long-term preservation in digital archives.

Keywords—OAIS; eCTD; pharmaceutical records; long-term digital preservation; digital archive

I. INTRODUCTION

Electronic pharmaceutical records are complex objects. In the EU (European Union) they usually come in the eCTD (Electronic Common Technical Document) format [4][7]. Each eCTD document consists of a predefined folder/files structure [8]. Such documents are complemented with additional national-level documents and documents produced by the National Competence Authority (NCA). All this documentation together makes a record of one medicine and upon this record it is allowed to be put on the market. This paper will regard these electronic pharmaceutical records as very important and will try to contribute to the formation of actions toward their appropriate long-term preservation.

Long-term preservation of electronic records is, even when simple objects are considered, rather complicated and quite unpredictable process. This is caused by the constant change and advancement of technology – hardware, software, storage media and encoding standards. Bollacker states that “because any single piece of digital media tends to have a relatively short lifetime, we will have to make copies far more often than has been historically required of analogue media” [14]. In turn, the need for constant forward migration influences preserved records. If they are moved from one media and technology to the more advanced ones the authenticity, reliability, integrity, usability [10] and trustworthiness of the records could be endangered. These aspects of preserved pharmaceutical records, consistent with Stamatiadis, as in [1], are very important not only for the business purposes but, more importantly, for the health of patients. Gladney [6] explores the aspect of records’ authenticity stating that “a performance is called authentic if it has integrity and also conforms to a firmly bound, adequately informative, and honest provenance assertion.” Provenance, when once established at the moment of a record’s creation, becomes part of the record thus leaving the integrity problem. This article will focus on solving the problem of records’ integrity within the long-term

preservation environment in the way that the preserved records maintain their properties while the underlying technologies advance since “authenticity ... is closely related to demonstrating the integrity of documents, that is, ensuring that they are complete and unaltered from the time of creation” [3].

The structure of the research presentation in this paper is as follows. Firstly, the relevant standards are described at the level of complexity relevant to the discussion and analysis. Some standards, like OAIS, are considered as well known and therefore their deeper analysis is left out. Next, the concepts and entities of ISO 23081-1 (Information and documentation – Records management processes – Metadata for records) standard is described and mapped to the OAIS’s information packages’ structure. Further, the structure of eCTD is described in detail. The main part of the discussion is around the issue of creation of archival information packages (AIP), exemplified by eCTD based pharmaceutical records. Abstraction of that example leads to the suggestions of AIP creation in general if complex objects are to be preserved. To support this research the application ArhiMed, created by the authors, illustrate the functionalities of an application intended for the long-term preservation of authentic medical records in eCTD format.

II. OAIS RM

Preservation of complex digital objects in a digital archive is best if an archive formation is based upon internationally accepted standards. One of the important ones, although a highly abstract one, is the Reference Model for an Open Archival Information System, known as OAIS RM or ISO 14721 [9]. Since it is a very well known standard only a part of its structure will be described in this place – the one important to create a context for this research.

The OAIS RM consists of three models: Information model, Information package model and Functional model. *Information model* describes Information Object and Information Package. Information Object consists of Data Object (physical or digital) and Representation Information (in the form of Structure Information, Semantic Information or Representation Networks). Figure 1 shows Information Object structure. Information Package is structured into four main components: Content Information (consists of Content Data Object and Representation Information), Preservation Description Information or PDI (consists of Reference, Context, Provenance and Fixity Information), Packaging Information and Descriptive Information. Figure 2 shows Information Package structure. Further, *Information package model* describes three types of packages – Submission (SIP), Archival (AIP) and Dissemination information package (DIP). Figure 3 shows situations in which each of the package types appear. *Functional model* describes functions within a digital archive that need to be developed and their interconnections that need to be established in order for a digital archive to be OAIS compliant. Package concept and its structure from OAIS will be important and often referred to in this paper.

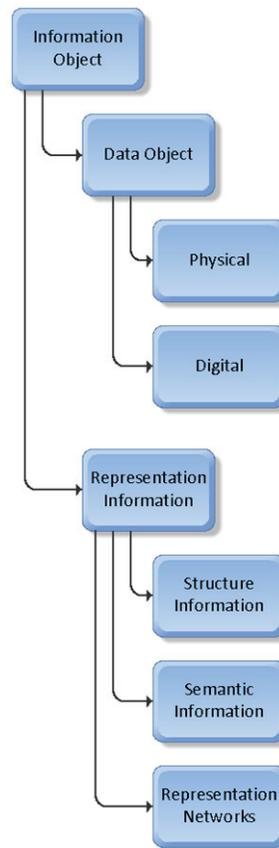


Figure 1. OAIS Information Object structure.

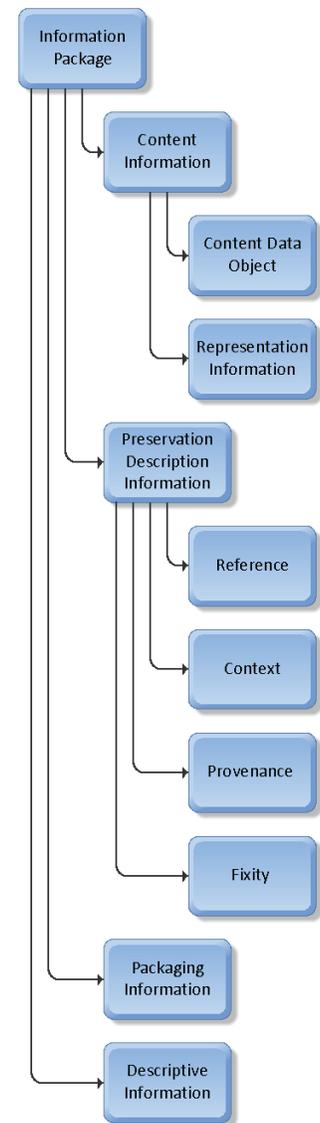


Figure 2. OAIS Information Package structure.

III. ISO 23081

ISO 23081-1:2006 Information and documentation – Records management processes – Metadata for records standard [12] (with part 2 ISO/TS 23081-2:2007 [13]) is addition to the ISO 15489:2001 standard. ISO 15489: 2001 Information and documentation – Records management – Part 1 [10] and Part 2 [11] standardise design and implementation of records management policies, programs and systems. Usage of that standard implies usage of some other standards for specific areas of programs and systems, such as these for work process analysis, quality management, information security, risk management, metadata etc. ISO 23081 standard supplements ISO 15489 by prescribing usage of unambiguous metadata and therefore, by making possible

to use records in different environments, to support interoperability and to disseminate content of recordkeeping systems between various systems and user communities. ISO 23081 standard deals with records' metadata management as a part of records management. Metadata exist to provide records' description but also to decide on records' authenticity (and integrity and reliability in sum), usability and interoperability for users or for other archives. Metadata needs to be captured at the beginning of records lifecycle, because electronic records need to be managed proactively and in advance. Metadata also need to be created after records' submission to a digital archive, i.e., registration, sometimes during their usage and always during automated and semi-automated execution of records management processes and procedures. It is recommended to store produced metadata in metadata database or repository, in the later case especially in the preservation-adequate formats like XML. Stored metadata should be inexorably linked with objects they are referring to, possibly packaged together for the long-term preservation reasons.

The following synthesis of the ISO 23081 standard is intended for better understanding of the importance of metadata and, sometimes, their complexity to either preserve in the present form or migrate to some other metadata standard, inevitably having similar, but never the same structure. ISO 23081 prescribes several *classes and types of metadata* – generally there are metadata on records, metadata on business rules and mandates, metadata on business processes, knowing that records and records management systems are considered to be in metonymic relationship with creator and its business processes, metadata on agents or business process roles, and finally metadata on records management processes and procedures. *Relationships* of these *classes of metadata entities* are as following: agents conduct business, create and use records, mandates govern business, records management subsystem is business-based, and business actions and transactions are interpretable and procurable to agents and other users as records. ISO 23081 provides conceptual model with classes and types of entities. *Class of records* includes aggregated types of records from item, sequence of transaction, file, series, archive and archives – nomenclature is non-enforceable and can be altered in practice to the extent that is necessary. Sequence of transaction is not a sequence of business transaction itself, as the smallest component of business process, but the sequence of physically or virtually linked items evidencing some enclosed business transaction. *Class of agents* includes person or instrument, work group, agency and institution. Persons and working group represent business process role. Business process roles can also be applications and IT sub-systems. Applications and systems can be considered as instruments from ISO 23081, but they are specifically defined as roles in business process management discipline, which is an affiliated realm to the ISO 15489 normative area. Institution represent creator in strictly archival sense. *Class of business* includes transaction, activity, function and ambient function. Ambient function is “a societal right or responsibility that exists outside the boundaries of

organization”¹, i.e., creator’s functional place in the wider society. *Class of mandates* consist of business rules as procedural instructions for execution, policies as generic instructions and legislation as legal environment of creator and direct context of his business and archive. ISO 23081 distinguishes *six broad groups of metadata*. Firstly, there are *identity metadata* with elements like entity type (e.g., file), aggregation, and registration identifier (ID of entity in a specific domain). Secondly, there are *descriptive metadata* with elements like title, classification signature, abstract, location information, jurisdictional domain, and external identifiers (if any). Third group is *metadata about usage*, i.e., elements describing technical environment, elements about rights, access/restrictions, intended users, language, integrity (e.g., checksums) and documentary form (structure). Fourth group of metadata, *event plan metadata*, includes elements like event plan (date/time, type of event, description of event, relation) and trigger. *Event history* is the fifth group of ISO 23081 metadata – it consists of identifier, date/time, type, description and relation of event and actions on both the entity and metadata. Sixth group of metadata is *relational metadata* which describes relationships between two or more entities. That relationship becomes a new entity, and its elements are identifiers of related entities, relationship type and relationship date. Metadata should be inherited from classes to types, by linking classes and types, copying metadata from class, or encapsulating aggregates. It should be possible to extract and reuse metadata, add additional elements, and maintain entities as sequences as necessary for the preservation reasons. Metadata support preservation of records but they should be preserved as well.

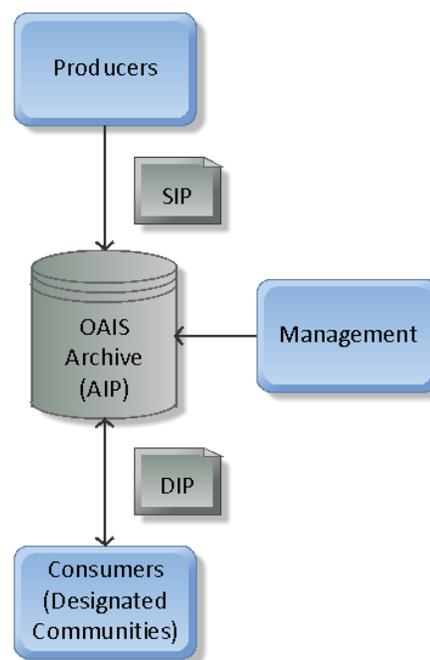


Figure 3. OAIS Information Package model.

¹ ISO/TS 23081-2:2007, Table 2 – Entity class: Business, p. 13.

It is possible and even implied to flatten the conceptual model given in ISO 23081 and to set out metadata entities in different views, e.g., record-centric view with records that interconnect business, mandate and agents, or business-centric view with business entity as nucleus etc. It should also be possible to nest ISO 23081 broad groups of metadata into wider preservation-oriented model, such as OAIS RM, especially into its preservation description information (PDI) and descriptive information – they can be enriched with constructive business-centric and creator-centric ISO 23081 metadata.

IV. ELECTRONIC COMMON TECHNICAL DOCUMENT (ECTD)

In the process of digital preservation sometimes complex digital objects should be considered. One of those objects is the medicinal documentation on a medicine a pharmaceutical company puts on the market. In the process of obtaining a license the medicinal documentation should be submitted for the registration procedure either to the *European medicines agency* (EMA, formally known as EMEA – European medicines evaluation agency) for the centralised EU level procedure or to a national agency (in the case of Croatia it is the Croatian Agency for Medicinal Products and Medical Devices) for the national level registration procedure.

eCTD DTD version 3.2

- m1-administrative-information-and-prescribing-information
 - [EU Module 1](#) [new]
- m2-common-technical-document-summaries
 - m2-3-quality-overall-summary
 - [Quality Expert Statement](#) [new]
 - m2-5-clinical-overview
 - [Clinical Overview](#) [new]
- m3-quality
 - m3-2-body-of-data
 - m3-2-p-drug-product [manufacturer: Big Factory] [product name: WonderPill] [dosage form: Tablets]
 - m3-2-p-1-description-and-composition-of-the-drug-product
 - [Description and Composition of WonderPill](#) [replace]
 - m3-2-p-2-pharmaceutical-development
 - [Pharmaceutical Development](#) [new]
 - m3-2-p-3-manufacture
 - m3-2-p-3-2-batch-formula
 - [Batch Formula](#) [replace]
 - m3-2-p-4-control-of-excipients [excipient: Compendial]
 - [Control of Excipients - Compendial Excipients](#) [replace]
 - m3-2-p-5-control-of-drug-product
 - m3-2-p-5-1-specifications
 - [Specifications](#) [replace]

Figure 4. eCTD content read from the XML backbone.

The documentation submission is obligatory in the processes of registration, re-registration or upgrading of the medicine's documentation. Pharmaceutical companies should submit documentation in the eCTD format [5]. eCTD is basically a set of directories and files grouped in an electronic dossier connected by the XML backbone. Figure 4 shows eCTD example of a fictitious medicine obtained from such XML backbone. Documentation includes administrative documents and summaries, documents on pharmaceutical-chemical quality of a medicine, documents on non-clinical and clinical testing. Parts of the documentation is usually submitted in various file formats, ranging from .pdf, .doc(x), .rtf to .jpeg, .svg, .png, .tif or .gif. The documentation submitted at one point in time, either to the national or international regulatory body, is called a *sequence*. The first sequence's directory is named 0000 (with the strictly defined subdirectory structure), the next one (e.g., for the dosage change) is named 0001 (with its own subdirectory structure repeated), etc. Each sequence contains *index.xml* file (XML backbone) and *index-md5.txt* file². Each sequence consists of *modules* (e.g., m1, m2, m3 etc.). Not all sequence has to have all modules. The most important is module 1 since its *eu* subdirectory contains *eu-regional.xml* file with the information on the medicine. The sequence with the highest number containing module 1 contains the most recent and therefore the most complete information. Figure 5 shows directory structure of a fictitious medicine and figure 6 shows a fictitious example of a medicine's documentation. There are already available commercial solutions for working with eCTD-based documentation and its validity checking, like *EURS is Yours – European Review System* for example.

V. PRESERVATION OF ECTD AS A COMPLEX ELECTRONIC OBJECT

So far the structure of eCTD was described. Nevertheless, eCTD documentation represents only a part of the record on a medicine to be preserved. It can be viewed only as a submission information package (SIP1). In the case of the national medicine registration process the pharmaceutical company has to submit additional documentation specific to the national legislative. Those documents are also organised into a predefined folder/files structure. The folder structure lies beneath the directory named the same as the sequence it refers to with the addition of *workingdocuments* in order to distinguish the two. Figure 7 shows an example of the *workingdocuments* folder additionally describing the 0000 sequence of a fictitious medicine.

This additional documentation is not part of the eCTD and it should be added to it when put in a digital archive (SIP2). Furthermore, there are documents that are created by the National Competence Authority (NCA), a regulatory body, in the process of registration, re-registration or upgrading/changing of the medicine's documentation. For

² Message Digest 5 checksum information intended for the e-dossier (i.e. SIP) integrity check. As it will later be explained, this MD5 information will not be sufficient for the preservation purposes and AIP creation since additional documentation should be added to create a complete record.

each sequence NCA creates documents. Therefore, the complete record of a medicine (see figure 8) consists of:

1. eCTD documentation,
2. *workingdocuments*, and
3. NCA documentation.

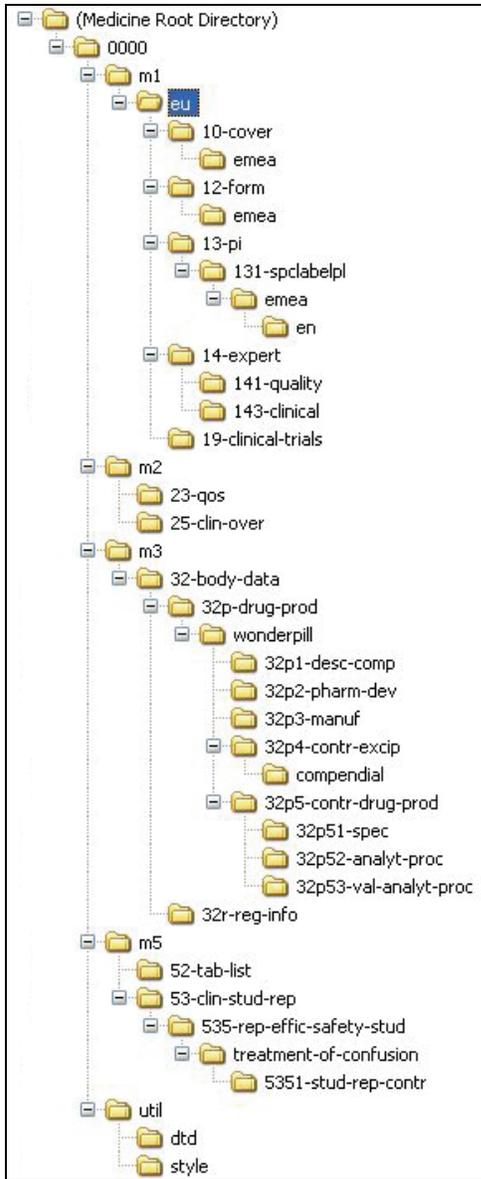


Figure 5. Directory structure of a fictitious medicine.

This is maybe a straightforward process when creating a record, but for the preservation process a digital archivist will encounter:

1. a complex record consisting of multiple folder/files structure,
2. several different file formats, each one in the need of a different preservation method,
3. one part of the record (eCTD) could be validated by MD5 check, while the other two parts can not,

4. some parts of the record are connected by the XML backbone while the others are not, and
5. there are no record-level binder.

EU Module 1

DTD version 1.4

Envelope for EMEA

Submission: Type: Variation Type IA
Mode: Single

Tracking Number(s): EMEA/HC/000123/IA/061

Applicant: PharmaCompany

Agency: EMEA - European Medicines Agency (EU-EMEA)

Procedure: Centralised Procedure

Invented Name: WonderPill

INN: Pioglitazone Hydrochloride

Sequence: 0022

Related Sequence:

Submission Description: Type IA Variation for Change of Address for Big Factory

Module 1 EU

1.0 Cover Letter
For EMEA:

- [Cover Letter for IA/061 \(new\)](#)

1.2 Application Form
For EMEA:

- [Application Form for IA/061 \(new\)](#)
- [Declaration of Change of Address \(new\)](#)

1.3 Product Information

1.3.1 SPC, Labelling and Package Leaflet

1.3.2 Mock-up

1.3.3 Specimen

1.3.4 Consultation with Target Patient Groups

1.3.5 Product Information already approved in the Member

Figure 6. Fictitious example of a medicine's documentation.

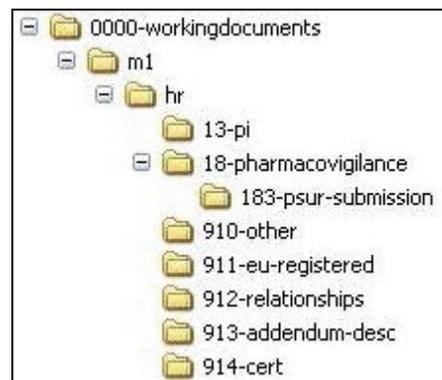


Figure 7. Example of the *workingdocuments* folder.

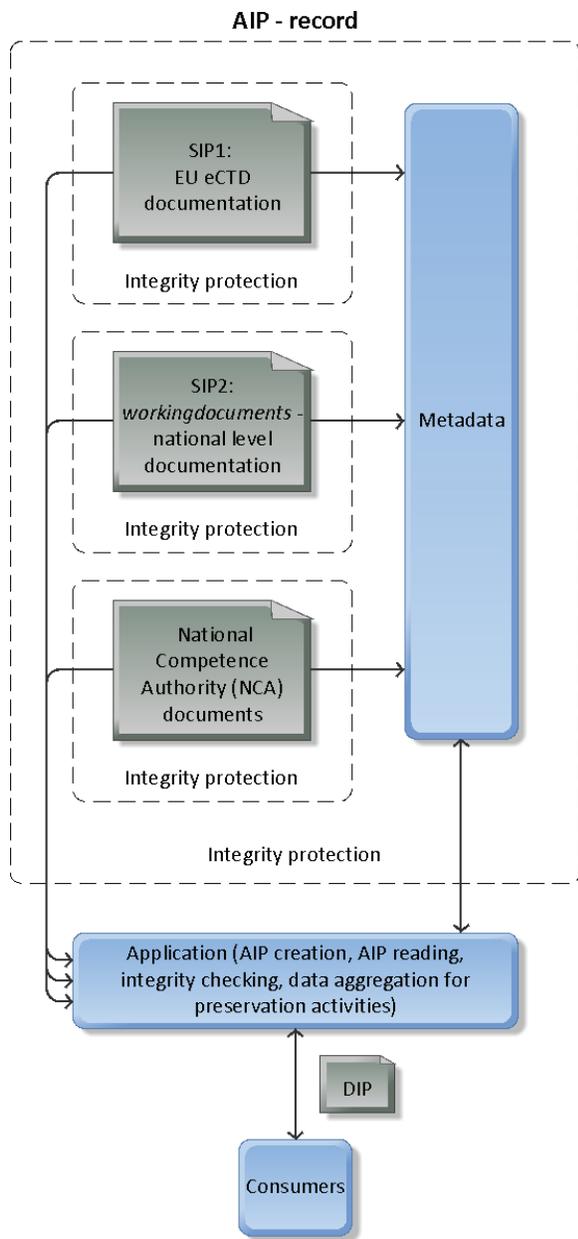


Figure 8. AIP – the complete record of a medicine.

The described situation could be improved by the creation of an application, or building functionality into an already developed digital archive, that can be used for the archival information package (AIP) creation or semi-automatic transformation of SIP into AIP. The functional specification of the application for preservation of pharmaceutical records presented in the following lines could even be made more general in order to be used in a wider spectrum of similar record-preservation situations. The idea underlying the application, which will be shown later in the application functionality description part of this paper, is to integrate all medicine’s documentation parts at the metadata level thus creating one record. It should extract all needed metadata

from the eCTD, enable the preservation person to add additional metadata, automatically add digital archive-specific preservation metadata, take care of the different file formats preserved within the record by triggering certain preservation actions, protect record’s integrity in order to preserve its authenticity, and it should finally create an all-connecting XML file. It would be a very good idea to code and structure metadata according to the internationally accepted standards such as OAIS, ISO 23081 and METS. Having this in mind, 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 at least have the following functionalities.

1. The application should be able to extract metadata from the *eu-regional.xml* file. From there it should extract (see figure 6 for this example’s data):

Applicant: PharmaCompany
 Agency: EMEA – European Medicines Agency (EU-EMEA)

Invented Name: WonderPill
 INN: Pioglitazone Hydrochloride

2. From all *m1* modules it should extract submission types of all sequences, e.g.:

Submission: Type: Variation Type IA
 and the DTD version, e.g.:

DTD_Version: 1.4

The submission information represents business procedure (registration, re-registration, upgrading/changing).

The metadata mentioned so far are extracted from the eCTD files. The following archival metadata should either be detected automatically from characteristics of the files to be preserved or manually entered by the preservation specialist.

3. **RecordCreationDate** – date of AIP creation.

4. Person who created AIP – **Agent**: Name, Role (Creator, Editor, Archivist, Preservation, Disseminator, Custodian, IPOwner, Other).

5. **Title** (AIP title = name of the medicine = Invented Name).

6. **AIP_Version** – for distinguishing possible additional sequences and supporting new AIP creation based on prior AIP and newly submitted sequences.

7. **AIP_History** – according to the ISO 23081 this is event history metadata – it records creation dates of all prior AIPs.

8. **RootFolderTitle** – sequences submitted at a later point in time are organised under the same root folder as the prior ones – all being part of the same medicine’s documentation.

9. **External_ID** – optional, free-text field for entering, e.g., NCA’s classification numbers.

10. **FileVersion** – extracts from the folder structure names of all files (**FileName**) and their relative locations, adds information on their **FileTypes** (e.g., pdf, doc, tif etc.) and version (e.g., 1.4). This is important for the later preservation planning process – the information on the precise location of files that need to be migrated could speed up the process.

11. **FileVersionAggregation** – aggregates information on types and versions of all documents and adds their total number in the AIP (e.g., PDF 1.4, 87; doc 2003, 14). This

TABLE I. MAPPING OF METADATA ACROSS DIFFERENT STANDARDS.

Description	Metadata	OAIS	ISO 23081	METS - sections
Who delivers the eCTD package?	Applicant	PDI – Provenance	Agency (identity metadata, entity class: agents, layer: 3)	dmsSec – rightsMD
To whom was initially delivered the eCTD package?	Agency	PDI – Provenance	Institution (identity metadata, entity class: agents, layer: 4)	dmsSec – digiprovMD
What is submitted?	Invented Name	PDI – Reference	title (description metadata; entity class: records, layer: 3)	dmsSec – sourceMD
What is submitted?	INN	PDI – Reference	title (description metadata; entity class: records, layer: 3)	dmsSec – sourceMD
What kind of activity?	Submission	PDI – Context	Activity / process (identity metadata, entity class: business, layer: 2)	dmsSec – digiprovMD
Contents standard	DTD_Version	PDI – Provenance	technical environment (use metadata, entity class: records, layer: 3)	dmsSec – techMD

information supports future preservation action time-frame planning.

12. **Checksum** – it should be created for the whole AIP after its creation.

13. **AIP_Check** – a trigger for AIP’s hash-check and hash-check of all its files (starts automatically after a predefined period of time or manually at any given time).

14. **AIP_VValidityDate** – either the date after which it is possible to (semi-automatically) delete the AIP or information on permanent preservation.

As it was mentioned earlier, the recorded metadata could be mapped to different standards thus enabling interoperability between different digital archives keeping similar records, but also making future preservation activities easier. For example, the metadata extracted from the eCTD files, described through the suggested functionalities 1 and 2, could be mapped across different standards – table 1 (see figure 6 for this example’s data).

VI. ARCHIMED – APPLICATION FOR ARCHIVING AND LONG-TERM PRESERVATION OF ECTD RECORDS

After the initial research in the field of digital preservation and applicable ISO standards, recognition of the potential problems with the long-term preservation, in this case, of medical records, analysis of the eCTD structure, and conception of the model of functionalities for a digital preservation application, we have developed an application called ArchiMed.

Here we will explain and illustrate the basic operating performance of the application. First, ArchiMed is capable of reading all the needed metadata from the eCTD document while enabling the addition of other AIP metadata (Figure 9).

This application form also enables manual input for the hash check interval. It can be set automatically at certain number of days, but can also be changed manually if needed. This example shows the interval set for 30 days. The same semi-automatic approach is applied with AIP validity interval – set for 2 years in this example. AIP validity should be decided upon and set wisely, because after that period AIP data should be examined more closely, i.e., their file formats should be tested for potential migration purposes. For this purposes ArchiMed offers package validation report

which lists name of the medicine, AIP creation date, root folder title, last hash check date and validity period of the AIP (Figure 10).



Figure 9. Creation of the new AIP

At any given moment one can manually initiate data integrity check and test whether any AIP has been either intentionally or unintentionally changed. ArchiMed report shows status of the data integrity check, the total number of packages and the number of those which failed the check (Figure 11).

ArchiMed also offers the possibility of checking which packages will expire in certain number of days. Figure 12, for the purposes of this demonstration, shows those packages which will expire in the next 1,000 days. In practice this feature gives opportunity to a records holding institution to prepare for the potential migration. For example, it can check

which AIPs will expire within, e.g., next 30 days and will need a potential digital preservation action. Along this line of thinking there is another feature in ArchiMed which makes potential migration procedures much easier – file type version report. This report lists all file types appearing in the AIPs (e.g., PDFs), their versions (e.g., 4) and gives the total number of such files. Figure 13 shows one such report. This is very important if it becomes necessary to migrate all PDFs v. 4.1 to the newer format. This report will show if there are any such files and if there are how many of them. It is not the same if you have to migrate 1,000 or 1 million files to the new format. Furthermore, the application can extract only those files needing a preservation action, thus preparing them for the external migration procedure, and later on import new, migrated versions, calculate new hash, and create new, migrated AIP. All this information about the migration procedure is added to the new AIP in order to document the changes. Only in this way, consistent with [2], the authenticity, reliability, integrity and usability of the preserved records could be confirmed and the system for their long-term preservation certified.

VII. CONCLUSION AND FUTURE WORK

The research in this paper showed the complexity of preservation if complex digital objects are to be preserved as authentic records. By using an example from the domain of pharmaceutical records – eCTD documentation – it was shown that the documentation which is submitted to a digital archive in the form of SIP, although structured in a standardised way and complemented by the integrity checking possibilities, still needs to undergo a lot of additional procedures in order to be transformed into an eligible and trusted AIP. In this process the national level documentation is added to the eCTD SIP as well as NCA documents. Only complete documentation can become AIP and stored in a digital archive as an archival record of a medicine's registration procedure. Since the significance of the preservation of the complete registration records in the electronic form for the long-term period needs not to be emphasised, it is of great importance to support such a process in a proactive way. This means to try to preserve as many important metadata about the records themselves, about their context and immediate environment responsible for their correct rendering, functionality and understanding as well as the metadata important for making future preservation actions easier and more efficient, at the point of creating a record. This was a key motivation for this research and analysis which resulted in suggestion of the procedures and functionalities for an application for creating AIPs in the domain of pharmaceutical records, and the creation of the application itself. Currently, ArchiMed is in the process of commercialization. It is planned to become a self-standing, expansion module of a pharmaceutical records management application but it will be possible to obtain it even without the accompanying application.

Future work will be focused on the modification of the model to fit any other type of AIP creating procedure by adding some specific types of metadata or by changing the source XML file to read them from. Coding the metadata

according to several standards, or creating mapping schemes between the standards, makes things a little bit more complicated, but this could, later in the preservation period, prove to be useful. It could also make different designated communities understand archived records better and make search procedures more efficient.

To conclude, the functional application called ArchiMed, built around this specification can produce AIPs securely, quickly and with the zero-error tolerance. By giving aggregated information on files being preserved it can also make migration procedures more easily to plan, test and carry out. Future research and modifications will bring more sophisticated versions having wider functionalities of offering users to customise it to best suite different complex objects' record-creating procedures. By implementing such an approach in the process of long-term preservation, any records holding institution, but also any institution in the pharmaceutical industry, can be sure that their important eCTD or other types of records remain unchanged, and can plan and conduct future migrations without breaching authenticity, reliability, integrity or usability of the preserved records.

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	Title	Creation Date	Root folder title	Last hash check	Valid until
▶	Demo	25.9.2010.	0022	25.9.2010.	25.9.2012.
	Test	25.9.2010.	0026	25.9.2010.	25.9.2012.
*					

Figure 10. Package validation report

	Title	Creation Date	Last hash check	Check
▶	Demo	25.9.2010.	25.9.2010.	OK
	Test	25.9.2010.	25.9.2010.	Failed
*				

Number of packages:2
Failed data integrity check:1 (50%)

Export Close

Figure 11. Data integrity check report

Show packages that will expire in 1000 day(s) Show

	Title	Creation Date	Root folder title	Last hash check	Valid until
▶	Demo	25.9.2010.	0022	25.9.2010.	25.9.2012.
	Test	25.9.2010.	0026	25.9.2010.	25.9.2012.
*					

Figure 12. Expired packages report

	File Extension	FileType Version	Files
▶	.dtd		4
	.mod		4
	.pdf	4	22
	.bt		2
	.xml		4
	.xsl		4
*			

Figure 13. File type version report

Bridging the Gap Between Consumer eHealth and Public Health Through a Diagnostic Decision Support System

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Abstract—For sound development of the consumer eHealth, the market needs to have proper connection to the public health authority. On the other hand, in public health, tracking of patients has been a bottleneck in the scientific process. To address the problems altogether, we propose an approach to automate the case registration through a diagnosis support system. In the proposed approach, we set up a diagnostic decision support system for physicians, coupled with a support system for patients, on the Internet. In this setting, symptomatic data of anonymized patients automatically accumulate from the physicians' search profile and the patients' reports. Then, researchers in need can find appropriate cases on the symptomatic database, to recruit them for further study. The paper illustrates the case registration model with decision support system, and discusses the pros and cons of the proposed model. The qualitative analysis suggests that the model can accumulate information of cases that cannot be collected at a reasonable cost using traditional approaches.

Keywords—Diagnostic decision support system; Patient registry; Patient diary

I. INTRODUCTION

Symptom checkers [1], [2] are considered to be embodiment of the consumer eHealth, which improves delivery of medical care in a novel and efficient way through information technology. They are a class of diagnostic decision support system, which can be used to guide patients to appropriate hospitals, or to clinics. It can also be used to suggest Over-the-counter (OTC) drugs, to avoid costly medical consultation for low income populations, which would contribute to save the rising costs for medical care in most countries. However, is it a truly reasonable way to take?

In the viewpoint of patients, convenience matters most, to find cheaper remedy, even without hospital visit, or to find doctors easily, who simply match their needs. However, the "consumers" are self-interested, and thus, just by meeting the needs of the consumers, the service would be detached from "public" health, which, in the long run, do harm the patients. They might decide not to visit a clinic, satisfied with the agreeable automated diagnosis, which could be an early symptom of fatal subarachnoid hemorrhage. If symptoms of a certain disorder do not impact the quality of life of the patients, they would not look for medical services, resulting in the poor understanding of such disease.

Accordingly, for further development of the consumer eHealth field, it would be crucial that the field satisfies patient's point of view, as well as more public point of view. This indicates that the consumer eHealth must be properly connected to public health authorities. The paper illustrates such a trial we made in Japan, a research for accumulation of unclassified disease profiles [3] through a diagnostic decision support system.

We first describe the motivation in Section II and illustrate the overview of the approach in Section III. These sections are followed by detailed description of our prototype in Section IV. We summarize the discussion for the proposed approach in Section V, and conclude the paper in Section VI.

II. MOTIVATION

In the heart of clinical research and public health lies "patient registry". However, it is not uncommon that the number of registered patients does not accumulate enough for statistical analysis in a given period. Indeed, it is the most laborious and time-consuming phase in clinical research, which annoys the steering committees of many research attempts.

The shortage of cases in clinical research might be ascribed to several factors. First of all, complicated registration process might serve as a barrier for clinicians to register their patients. Secondly, case registration would certainly be difficult for rare diseases, because of the scarcity of the qualified subjects. Third, it would be hard for researches to collect patients, if the case definition is vague. Indeed, there is a certain class of patients, who develop incomprehensible symptoms, which are called Medically Unexplained Symptoms (MUS). Most of these symptoms derive from psychosomatic disorder, but, they are also targets of modern medicine, as a task force of the US National Institutes of Health states; "Medically unexplained syndromes present the most common problems in medicine" [4].

Accordingly, the challenge for public health field is how to accumulate the information of patients, including vague symptoms, possibly from uncertain disorders. An approach for this goal is the Electric Health Records (EHRs) [5], in which all the data are digitally stored and exchanged through computer network [6], [7]. However, prevalence of such system is not at satisfactory level in most countries, including Japan, and

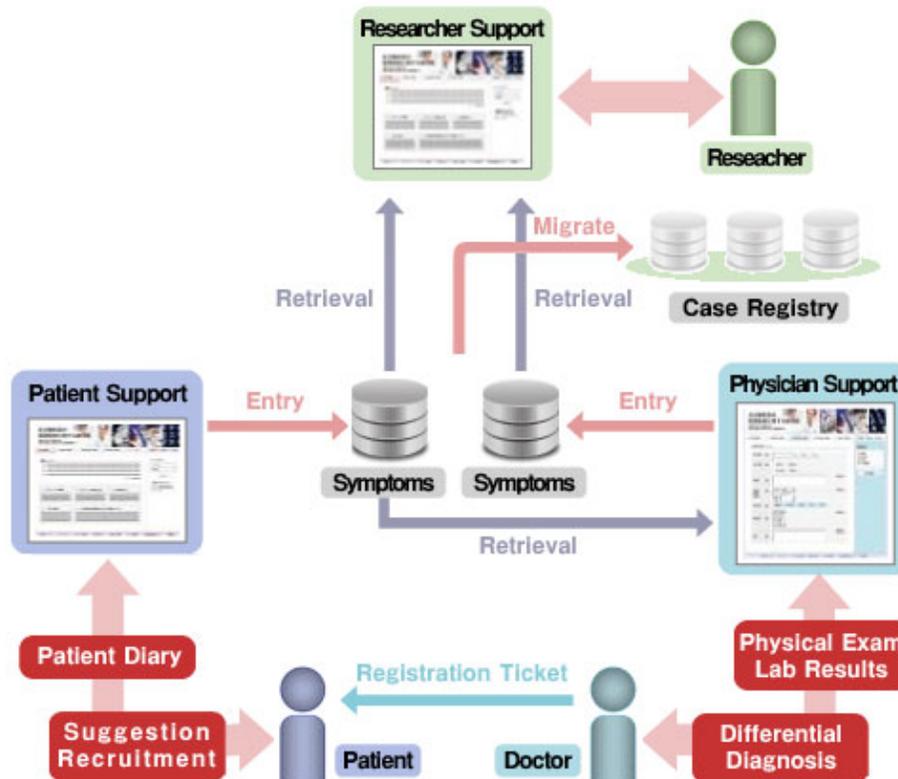


Fig. 1. Overview of the decision support system model for case registry

technology is not mature enough to comprehensively process the medical records written in natural languages.

Another approach that Google demonstrated is to harness the consumer behaviors to such a public health need. Google Flu-trend [8] utilizes Internet search trends to monitor prevalence of infectious agents, instead of gathering symptomatic data from medical institutions. This is based on an assumption that there is a strong correlation between search trends and prevalence of the disease in a region, inferred from the users' access profile. As the service suggests, careful design could bridge the consumer eHealth and public health. Next section illustrates such a model for case registry.

III. DIAGNOSIS SUPPORT MODEL FOR CASE REGISTRY

A simple approach for case registry is to store search profile of *symptom checkers* [1], [2]. In the same way as the Google flu-trend mechanism, the symptom checkers would be able to accumulate symptomatic information of patients, which might be useful for public health study. However, the straightforward approach is vulnerable to patients' biased self-assessment, and cannot accumulate objective information suitable for clinical research. It would be preferable that the data is qualified enough for epidemiological analysis. Further, the self-assessment model cannot accumulate lab results that can be obtained even at the smallest clinics.

Consequently, we propose a combined setting (Figure 1), in which the physician support system and the patient support system cooperate together, for collection of useful patient information. In the approach, the diagnosis support system for physicians takes symptomatic data, and returns a list of differential diagnosis. The system is built to support physicians, with features useful to make clinical decisions, and thus, physicians would willingly input their information for better patient care and to save their time.

For the patient part, the system issues a registration ticket for each patient, requested by a doctor. The ticket allows a patient to create an on-line account for an anonymous symptomatic diary system. The diary is reviewed by the physicians and by the researchers, who can send suggestions of diagnosis and recruitment messages for more detailed study to the patients. Because the patients with undiagnosed disease are highly motivated, they also willingly register their detailed symptoms and their history onto the system, expecting higher chances of diagnosis.

The registration ticket establishes the logical link, between the symptomatic data and the clinical findings, for anonymous patients. In this setting, subjective and objective data are independently collected and appropriately associated to each other, which serve as a virtual case registry for researchers.



Fig. 4. Patient Support System (In Japanese) - Showing a symptomatic diary for a registered patient

C. Researcher support system

For researchers, the prototype includes a search engine of the case registry, to find cases who present a certain set of symptoms. Then, they can contact the patients by sending messages, if they need further investigation. The system also provides a BBS and a Wiki for researchers. Additionally, to study disorders that do not fall in a known category of human disease, researchers need a database of known diseases. For this purpose, we also implemented a disease knowledge base, integrated into the automated diagnosis system, which can store information of disease and its major symptoms, coupled with epidemiological profile.

Note that a patient record comprises more various and more detailed information, including demographic information, past medical history, family history, medications, etc. The registry, on the other hand, provides a very primitive symptomatic database, and thus, it could be insufficient for clinical research. Accordingly, we are planning to provide a *data migration tool* and a more flexible patient registry, coupled with patient recruiting tool, so that researchers can start up a survey for specific purposes at low cost, utilizing the data in the primitive registry as a basis.

V. DISCUSSION

An advantage of the proposed model is that the model can extensively accumulate data of patients at low cost, including hard-to-diagnose cases, rare cases, and MUS cases. This property also favors the model as an outbreak monitor of

unknown health hazard, because the public health authorities cannot afford detailed surveillance of every patient. They can continuously monitor the search trends, and can even detect unclassified disorder, by matching the symptom set with the known disease profiles.

There has been many types of Computer-assisted diagnostic decision support systems; for general diagnosis, for each specialty, and for specific category of medical images [9]. Most of the systems have been built as stand-alone systems, or integrated into clinical workstations in hospital information systems. The proposed model, on the other hand, behaves like an Internet search engine, which takes symptomatic data as input and returns a list of possible diagnosis with a variety of useful Web links, while keeping a log of the search queries as a patient symptomatic database. Indeed, this model instantiates another application area for computer-based decision support systems, which automatically accumulate useful information at low cost.

As a diagnosis support system, the prototype currently covers roughly 1600 diseases, which exceeds 650 entries in INTERNIST-1 [9], but, the quality of the knowledge base and the diagnosis algorithm are still premature. Accordingly, we are now improving the algorithm and trying to extend the coverage through automated generation of disease profile by text-mining technique on rare disease database such as Online Mendelian Inheritance in Man (OMIM) [16] and Orphanet [17].

High-quality EBM resources, such as UpToDate [13] and DynaMed [14] are focusing on major diseases and topics, and emphasis is on their quality of the articles, not on the coverage. On the other hand, rare disease databases such as OMIM and Orphanet covers thousands of minor disorders, but, common disorders are out of their focus. Accordingly, our attempt may bridge the gap, between the common and the rare, by providing integrated interface for disease databases, as a disease search engine, searchable by symptoms and findings.

VI. CONCLUDING REMARKS

Patient registries are key components in public health, but require substantial commitment by physicians. Accordingly, most of the budget and the time are spent on this part in clinical research. However, physicians can hardly benefit from the case registration, which tends to result in the shortage of registered cases.

In the proposed model, patient data are submitted separately by physicians and patients, motivated for their own goal. This setting brings a unique property to the model that the participants voluntarily turn in their data, driven by their own incentives, which realizes exceedingly cost-effective surveillance.

This model also possesses a unique property, in respect to information security. For protection of patient privacy, clinical information systems have higher security requirements, which tends to compromise the system usability [18]. Indeed, the HIPAA Privacy Rule decreased the number of patients available for clinical research [19]. On the other hand, our proposed approach separates the registration of patient data

into two parts, one for automated registration of anonymized symptomatic data by physicians, and the other for description of the illness by the patients. Because of the separation, the physician support system can be optimized for system usability, without worrying too much about the patient privacy. The more detailed information is voluntarily provided by the patients themselves, which also minimizes the privacy concern in the system.

Although there is ample room for further improvement in the current prototype, the model has the favorable properties for consumer eHealth and for public health. We will continue the investigation of the data acquisition model, and will shortly proceed to a proof-of-concept study to prove the efficacy of the proposed model.

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ePublic Health: Fresh Approaches to Infection Prevention and Control

Social media in public health

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Abstract - Prevention and control of infectious diseases suffer from deficient compliance with preventive measures or guidelines of both professionals and general audience. This poses a threat to public health. Current approaches to prevent risk behavior are in need of innovation. Fresh approaches to education, information and communication are needed. In this study five social media tools i.e., (micro-)blogs, social networks, podcasts, mobile applications, RSS feeds, are (re)designed and operated with regard to four areas of infection prevention and control. They are evaluated according to their impact on public and professional adherence, compliance rate and other indices. Here we present outcomes of the first part of the study; a literature review of social media use in public health, specifically in the Netherlands. Empirical studies are scarce. However anecdotic studies, practices and experiences are reported that imply a range of innovative possibilities and potential impact of social media in the field of prevention and control of infectious diseases, as well as in public health at large.

Keywords - Information technology, Social media, ePublic Health, Participatory health care, Adherence, Infectious diseases

I. INTRODUCTION

Prevention and control of infectious diseases, in particular during large-scale epidemics or incidental high risk outbreaks, increasingly suffer from deficient compliance with preventive measures or guidelines of both professionals and general public. Examples are the no-show rate among the general audience after receiving a personal appeal to obtain an influenza or a human papillomavirus (HPV) - vaccination, or similar low compliance among health care workers with preventive measures such as wearing protective gear (like masks, gowns and protection glasses) during professional care for potentially infectious patients [1]. This is worrisome especially in view of recent developments of infectious diseases in the Dutch population and abroad. Antimicrobial resistance is increasingly observed in the

Netherlands, particularly in hospitals. Antibiotic resistance poses a potentially growing threat to public health because it is more difficult to treat infections with resistant pathogens. Compliance with preventive measures would make a difference. In the Netherlands, the use of antimicrobials is low in human health care, but high in the veterinary sector. This high level of antibiotic use may bring risks to humans, as resistant bacteria can spread from animals to humans. In addition, the emergence of ESBL (Extended Spectrum Bèta Lactamase) producing bacteria and enterobacteria resistant to multiple classes of antibiotics is a major threat to patient health care. It is anticipated that the use of antibiotics will increase in the future due to aging of the population, which will contribute to further increasing of resistance pathogens. It is therefore important to keep the use of antimicrobials as low as possible in the future. Cautious surveillance is a tool to identify and monitor resistant pathogens. But prevention and control are equally essential [2].

The Dutch RIVM Centre for Infectious Disease Control (CIb) has an executive and coordinating task in the national prevention and control of a wide range of infectious diseases manifesting themselves in incidental outbreaks of mixed origin, scale and risk level, as well as in various epidemics. This is one of RIVM's most important and most visible statutory public assignments.

In order to be able to effectively implement the national infection prevention and control policy in the near future it is of strategic interest to counter the abovementioned public health risks. From health sciences we know what psychological, social and cultural factors influence non-compliance. We also know that current approaches to collective prevention of risk behavior need innovative ways for education, information and communication [3].

Fresh approaches are needed. We find these in eHealth marketing; a sub domain of social marketing. eHealth marketing concerns public health practice. It draws from

traditional marketing theories and principles, and adds evidence-based strategies to prevention, communication, health promotion and health protection. It provides a framework of theories, strategies and techniques that can be used to guide work in public health research, interventions, and communication campaigns. eHealth marketing typically uses emerging technologies and 'new media' to improve the impact of health marketing and communication. Web-based and mobile technologies offer tools that are cheap, ubiquitous, interactive, real-time, many-to-many and that are participative in nature. They can be put to action for RIVM's objectives to make content, tools and services available when, where and how users want them. This we call ePublic health.

The present paper depicts a strategic research enterprise to study social media in public health. First it describes the background of emerging technologies and the five social media under study. Then it explains their relevance for public health i.c. infectious diseases. After stating the specific objectives of the study and the methodological design the outcomes are presented of the first part of the study; the assessment of current approaches in ePublic health via a literature review, with specific consideration for the Dutch situation.

II. EPUBLIC HEALTH

A. Emerging technologies

The utilization of information technologies, the Internet (Web 2.0) and communication technology could meet the need for improvements in infection prevention and control and other vital public health issues. Web 2.0 is a term that refers to a) improved communication and collaboration between people via social-networking technologies, b) improved communication between separate software applications via open Web standards for describing and accessing data, and c) improved Web interfaces that mimic the real-time responsiveness of desktop applications within a browser window.

These technologies, tools and services have already shown to influence behavioral and motivational compliance with preventive measures [4, 5, 6]. It is expected that these developments and approaches will profoundly affect the health information economy, public and professional engagement in health and health care, as well as biomedical research itself [7]. After the e-citizens, the Dutch e-patient is taking shape [8]. Gradually, the use of 2.0 technologies as well as semantic web (3.0) tools increase to facilitate social networking, participation, apomediation, collaboration, and openness within and between these user groups

Availability and accessibility of these technologies is evidently a condition sine qua non. Recent figures reaffirm high use of Internet by the Dutch population. In the

year 2005 a total of 78% of Dutch households had an internet connection. In 2010 that number has grown to 91% of all Dutch households. Over 75% of users use the Internet (almost) every day. Among younger people (<25y) this is 90%. [9, 10, 11]. Top of the list in broadband penetration - 38.1 broadband subscribers on every 100 inhabitants [10] - Dutch cell phone use is even higher, beyond the 100% mark.

Social media use continues to grow in popularity accordingly. From a global survey in 2010 [12] it appears to be the fourth most popular use of the internet, next to searching for information, emailing and checking the news. In the US, 57% of all 14-75 year olds use social networking sites like Facebook [13]. Furthermore, 10% of 14-17 year olds, 13% of 44-62 year olds and 17% of 63-75 year olds maintain a Twitter account [14]. Podcasting is slightly less popular, but still 25% of Americans age 12 and up have listened to or watched a podcast at least once [15].

In The Netherlands 70% of adults use social media. Mostly in their roles as 'spectator' or 'joiner' and mainly in the age of 18-44 years (Table 1) [16]. An estimated third of chronically ill people make use of on line communities for information and sharing. Young people use social media not so much for health information but mostly for other reasons [17a].

B. Social media

The present study examines five tools with regard to four distinct and limited public health issues. These five social media tools are selected for piloting because of their expected cost-efficiency, feasibility, operability. The selection may be adapted as a consequence of previous study outcomes. The developmental process will be guided by exemplary questions added below. Selected for piloting are:

- a) Blogs. A blog is a regularly updated online journal that anyone with an Internet connection can access. Some target a small audience, others boast a national readership. Microblogs, also known as 'tweets', are disseminated through Twitter.com and comprise short text messaging. Over 14% of Dutch internet users blog about health issues [17]. What can we learn from experiences in the health 'blogosphere' where e.g., bloggers and twitterers share information or communication techniques to prevent and control lice infestation or where on line seminars (webinars) are held for 'parent bloggers' to discuss basic information on RSV-infection and share research on key messages that have been proven to motivate people to take preventive measures?
- b) Social networks. Social networks are interactive websites in which users create a profile that may

contain photos, blogs, music, messages from friends, and other information. The high use of sites like MySpace, Hyves or Facebook [16] has been well documented. Many smaller sites for professionals, patients, parents, teachers or citizens have emerged, offering a targeted approach to increase reach. These networks are quickly becoming a mainstream format for information exchange, relationship building and knowledge sharing. Increasing amounts of Dutch Internet users participate in social networks while more and more patients make choices in healthcare after consulting friends and relatives in stead of medical professionals. Could we employ social networks to engage users in health topics (i.c. scabies) and empower stakeholders to comply with preventive measures at home, in (nursing) homes and risk settings?

- c) Podcasts. A podcast is a digital audio or video file that is episodic, downloadable, program-driven, mainly with a host and/or theme, and convenient, usually via an automated feed with computer software. Is podcasting for RIVM an opportunity to share information on *Pediculus humanus* infestation in an enjoyable way while allowing listeners to select topics relevant to them? Should RIVM develop a podcast library for the general public or for health care workers or their own staff (e.g., vodcasting conference proceedings)?
- d) Mobile applications. The ubiquity of mobile devices makes them an ideal medium for health messaging and promotion. Cell phones and other mobile devices have the potential to revolutionize public health communication. Research on how these devices can be used to provide immediate access to reliable just-in-time health information is rising; end 2009 the penetration of mobile internet is ca. 20%, while just under 2.8 people use their cell phone for internet access [17]. What innovative ways of exchanging vital information or technology to promote healthy and safe behaviors via mobile platforms could be envisioned e.g., for responding to sudden outbreaks of infectious diseases?
- e) RSS feeds. Internet users often subscribe to RSS (Really Simple Syndication) feeds of frequently read websites in order to receive notification of content updates. These feeds may empower individuals (teachers, parents, health care workers) to access and utilize the health information they view as most valuable. RSS feeds capitalize on this personalization of information by allowing users to select the topics that are most interesting to them. Will the impact

of RIVM's output increase by ensuring that timely and relevant health information is delivered to users when, where, and how they want it? Should we provide professionals and citizens with the opportunity to subscribe to RSS feeds for thematic website pages e.g., on lice prevention notifying subscribers whenever updates are made?

To create awareness, to encourage and to persuade the users to comply with prevention and control guidelines these tools are developed through participatory healthcare design and business modeling, explicitly engaging users and stakeholders from the start [18, 19].

C. Infestations and infectious diseases

The tools will accordingly be put into operation with regard to four distinct and limited public health issues:

1. Prevention and control of the common human lice (*Pediculus humanus capitis*) infestation among children (3-12y) in family and primary school settings;
2. Prevention and control of seasonal RSV-infection (respiratory syncytial virus) among young children (0-4 y) in 'crowded' kindergarten and pre-school settings. It is epidemic in that its incidence is circa 413 in every 100.000 children; resulting in 209 hospital admissions (0-4y) [20];
3. Prevention and control of scabies (*Sarcoptes scabiei*) in nursing homes and homes for the elderly. Prevalence among particular populations is estimated to amount to 30% [20];
4. Control of incidental, sudden outbreaks or explosions among limited populations e.g., at dance festivals, scouting jamborees or other mass gatherings.

All of these public health issues belong to the competence and responsibility of RIVM C1b. For 1-3 professional and public guidelines are in force and many different stakeholders (children, parents, teachers, kindergarten, schools, staff, residents, police, health authorities etc.) are directly involved. Though having relatively high prevalence and incidences figures in the Netherlands, they do not generally cause severe, primary and secondary health problems, rendering this a relatively safe area for exploration and study.

D. Objective and deliverables

The study's objectives recapitulated:

1. To develop five social media tools using participatory health care design method;
2. To operate these tools with regard to four areas of infection prevention and control;

3. To evaluate their impact on public and professional adherence, compliance rate and other indices;
4. To integrate 1-3 into a models/scenarios for development and operationalization of social media for health and risk communication and for disease prevention and control.

From this explorative and evaluative research we derive a) a *specific* model for development and application of mobile and web-based media for infection prevention and control; b) a *generic* model for development and application of mobile and web-based media interventions for safe, swift, effective and efficient health and risk communication and response; and c) an scientific evaluation tool to measure the effects of new media interventions.

III. METHODOLOGY

The present study uses principles of human centred design [19, 21-23] and a mixed model of quantitative and qualitative methods. In chronological order the following methods will be used to advance the project.

A. Assessment of current approaches

Prior to developing new tools an assessment will be done to establish the nature and the extent of social media use in current public health practices in the Netherlands and abroad.

Firstly, a literature review will be carried out to assess knowledge, practices and experiences with social media in public health as reported in peer-reviewed journals. Results of the latter are presented sub IV. of this paper. Secondly a consultation of (foreign) organizations takes place driven by the question of what underpins the choice of these media and what are the perceived benefits and shortcomings in current health and risk communication? The assessment is done by desk study and interviews of stakeholders and communication experts.

B. Reviewing new media use for infection control

A content analysis of social media like Twitter, Facebook, weblogs, wikis with respect to (seasonal) infections (i.c. RSV), infestations (i.c. lice and scabies) and outbreaks (unknown) is carried out over a period of time. Trends in communication, opinions and attitudes will be electronically monitored, analysed and reported. The outcomes provide input for the development of specific social media tools in the next stage.

C. Participatory design of social media

The tools are designed and developed through participatory health care design in order to use them in an effective, safe and efficient manner. Participatory health

care design is a human-centered design approach. It aims to engage all stakeholders (e.g., employees, partners, customers, citizens, patients, end users) in the design process to help ensure that the product designed meets their needs and is usable, thereby increasing chances for acceptance, adoption and adherence [21-23]. It relates to concepts of Health 2.0 and collaborative medicine where creating (virtual) environments that are more responsive and appropriate to their users' cultural, emotional and practical needs, is vital. The focus is on processes and procedures of design, not on design style. These processes are research in themselves, the outcomes of which will feed the production of 'persuasive' tools in order to put them to work in real life.

D. Knowledge to action

Once developed and constructed the tools will be put into practice with regard to four distinct and limited public health areas c.q. infectious disease prevention and control (sub II-C.). They have been selected to provide a safe test bed for the project since: i) no serious individual and public health damage is involved; ii) relatively high prevalence/incidence; iii) many stakeholders are directly involved; iv) preventive measures and/or guidelines are in force and available; and v) they belong to the competence and responsibility of RIVM Clb. The results will be used for RIVM's mission with regard to public health.

E. Evaluation

By webanalytic methodology we quantify, analyze and evaluate parameters of participation (rate, range et al.) and social media use by the stakeholders. Eysenbach [24] developed a set of useful 'infodemiological' methods to search and analyze communication behavior on the Internet and social media that will be used in the present evaluation. On line surveys, on-site focus groups and interviews with stakeholders will be used to collect qualitative data among the respective target groups (parents, teachers, health care workers, staff, nurses, kindergarten staff, police et al.). These methods are distinctly applied to the public health areas under study: lice, RSV, scabies and sudden outbreaks. For every area the effect of the five social media is systematically and longitudinally assessed in terms of knowledge, information needs, attitude, adherence (use, willingness-to-return, attrition), motivation (to comply with preventive measures), health behaviour (self-report), impact (perceived significance) and other social psychological indices. Special attention is given to the added value of the tools with respect to both traditional media (TV, radio, brochures) and convergent/cross-media use. Via analysis of reputation rate the image of RIVM as a credible and reliable source of information is observed.

F. Modelling scenarios

The outcomes of the developmental stage, the operational stage and the evaluation stage are used to

construct a practical model for immediate use in a wider public health context. Results and practical experience provide building blocks for a specific, evidence-based scenario to develop and operate evidence-based mobile and web-based media for infection prevention and control. The application of participatory design principles generates persuasive and motivational tools that allow for optimal adherence to prevention and control measures among professional and the general public. Once this succeeds the specific scenario is extended to a generic model to develop and operate persuasive mobile and web-based media interventions for evidence-based, safe, swift, effective and valid health and risk communication and response.

These models/scenarios may form part of RIVM 'toolkits' as offered to professional partners for disease prevention and health education or be disseminated in different ways. In the process the last product to be delivered is an evaluation tool that allows for measuring the effects of social media interventions on health information behavior

IV. OUTCOMES

In this paper, we present outcomes of the first part of the study c.q. III.A *Assessment of current approaches*. What kinds of social media are currently used in (international) infectious disease control to create awareness, to motivate or to persuade the public and health care workers to 'do the right thing' in risk situations?

A. Literature review

We have searched the databases Science direct, Scopus, PsychInfo, Picarta, PubMed, Google Scholar and Web of Science. We developed a search syntax composed of terms such as: infection prevention, infection control, social media, outbreak control, implementation, social networking, Netherlands, Twitter, new media and FaceBook, health communication, disease, web 2.0. and Dutch synonyms of these. The search was conducted during September-October 2010 and was limited to studies in English and Dutch published between 1990-2010.

If allowed by advanced search options adaptations to the syntax were made. Wildcards were used to account for differences in spelling of search terms or term endings. Identified 'key references' have been traced until saturation was reached (no new articles were identified). Excluded were advisory reports and articles that did not (also) treat the use of media. In this way we found 43 articles.

B. Results

Papers generally depict the authors' view (whether or not based on scientific theory) on how social media should be used rather than presenting empirical evidence. A minority describe the way social media are actually used and implemented for infection prevention and outbreak control, very few report on social, behavioral or health effects.

Both international and Dutch articles on social media use in public health may be grouped into five more or less distinct categories that indicate the primary objective; 1) distribution of health information, 2) delivery and promotion of health services or products, 3) peer-support, 4) education and training of professionals, and finally 5) research.

With regard to distributing *health information* we found promising outcomes e.g., in HIV/AIDS prevention information via chat sessions [25] or sharing health information via social networks [26]. Reynolds [27] describes how U.S. Centres for Disease Control and Prevention (CDC) use social media such as Twitter, Facebook, podcasts, YouTube and RSS feeds to inform the general public e.g with regard to the A/H1N1 epidemic in 2009. This resulted in an increase of visits to their websites and an improvement of CDC's trustworthiness in public perception. CDC's 'i know' campaign also uses Twitter, YouTube and Facebook for prevention of HIV/AIDS among African-American youngsters. The campaign employs social networks to reduce stigmatizing and taboo and to encourage participation in the campaign [28]. Murray et al. [29] describe several ways in which podcasts can be used in health-related settings.

Hivatlas.org is a social media initiative that aims "to collect, collate, classify and disseminate the information on HIV, TB & Malaria so that people living with HIV and the people working in the field can be on top of the information generating from more than 700 online and offline resources".

Anecdotic examples of social media use to disseminate information are an individual dermatologist using Twitter to share information about skin and skin care with her followers [30]; Medpedia, a wiki launched in 2009 by medical specialists on health information [31]; lay people disseminating medical news and information via blogs [32]; medical professionals blogging about medical news and knowledge [33]; ICYou, a site for sharing video material about experiences on treatments and disease or sites using RSS feeds to inform on pre-selected subjects [34]. Although such outcomes are interesting no empirical studies have been found with regard to the effectiveness

of social media use with regard to the distribution of health information.

With regard to *delivering and promotion of health services* it can be noted that anno 2010 in the UK social media, mainly Twitter, are used by 40% of health organizations for prevention [35]. Many American hospitals use social media for marketing & communication [30, 36]. They send general messages referring to their official home page via Facebook e.g., announcing an Open Day via Twitter, or an operation on YouTube for educational purposes or even release real-time progress reports via Twitter during surgery.

A survey by Beard et al. [37] reveals a wide range of health-related activities in the on line virtual world of Second Life. Agencies, companies and private groups apparently have chosen to integrate (features of) Second Life into their Web 2.0 communication strategies.

In spite of such findings no empirical studies have been found concerning the effectiveness of social media use with regard to the delivery of health services. In a randomised trial Lester et al. [38] find that mobile phones may be effective tools to improve patient outcomes in low-resource settings. Kenyan patients receiving SMS support had significantly improved antiretroviral therapy adherence and rates of viral suppression compared with individuals in the control group.

Peer-support was already a noticeable objective of internet activity before the dawn of Web 2.0. On line communities for support, comparison, advice and communication have grown and diversified. Murray et al. [29] also describe the use of blogs and wiki's in health contexts and Hardey [39] mentions user reviews of health services. Patientslikeme.com is a successful American social network site, sponsored by pharmaceutical industries, for chronically ill people with over 65.000 members. Patients follow new developments for their specific disease and have access to user generated information, tools and experiences to manage their condition.

Launching social media for reasons of *education, consultation and training* for health care professionals is gradually increasing. Yensen [40] mentions successful use of RSS feeds to provide up-to-date health information. Though many initiatives have been taken to use social media for educational purposes no empirical evidence is reported as of yet.

Social media and the internet can be used as a *research* environment for the study of human behavior. Eysenbach [41, 42] started to analyse behaviour and content on the internet and later in social media use. He

was the first to show a correspondence between influenza-related searches on Google and influenza cases occurring in the following week in Canada, later to be extended to analysis of A/H1N1 communications on Twitter, a discipline he coined 'infodemiology' or 'infoveillance' [24]. Corley et al. [43] used data-mining techniques to establish a strong correlation between blogposts mentioning 'influenza' (and related terms) and data of the Centre for Disease Control (CDC) on the influenza virus.

C. Social media and public health in the Netherlands

Reports on social media in all five categories can be found sparsely for the Netherlands. We generally find reports that advise public authorities to make use of social media (e.g. in infection prevention) or anecdotic studies. There are no empirical studies on the use of social media and its effects in this respect. Social media have not (yet) acquired an established position in public crisis communication, though some positive experiences have been reported [44, 45]. These have led Dutch ministries (Ministry of Economic Affairs, Agriculture and Innovation; Ministry of Health, Welfare and Sport; Ministry of Foreign affairs) to incorporate social media as instruments for crisis communication in a wider strategy. Especially micro-blogging (Twitter) seems to provide opportunities for authorities to communicate with citizens. In some instances it has been used for factual information on Q-fever and influenza. Some examples exist of training and education in social media for health professionals or civil servants. The latter have received guidelines on how to use social media responsibly and safely

In a wider health context there is more to be found. A remarkable case has been a Dutch private initiative (April 2010) to canvass new organ donors via social networking. Hyves-users received a question on their personal page if they would save someone's life. Consequently they could officially register for organ donation resulting in 25.000 new applicants, 80% of which became actual donors. In comparison; a large scale nationwide TV broadcast in 2007 resulted in 7300 new applicants. The Dutch Pink Ribbon campaign encourages people to actively take part and join in raising funds for breast cancer research (see: twitter.com/pinkribbon_NL).

Dutch hospitals increasingly use social media such as LinkedIn, Twitter or YouTube [46]. Use of LinkedIn rose from 2 % (Jan. 2010) to 53 % (Sep. 2010), and use of Twitter from 4,5% to 32,6%. Not so much for cooperation and dialogue with patients but rather for promotion and human resource management. Some have a Twitter account but never or rarely used it. Others send news-tweets about their hospitals, the consequences of budget cuts, or building activities. 26% of hospitals use YouTube

in ways that vary from uploading promotional corporate videos and material about special events to explanatory videos about daily routines or intake procedures. Approximately 21% use RSS, 15% Hyves (over 10 million users) while blogging is done from 6% of Dutch hospitals. Facebook - with over 2 million Dutch users - was not considered in the study.

Two Dutch general practitioners tentatively started a free primary care consultation service on Twitter in 2009 [47]. Their preliminary findings show that consultations via Twitter encompass all areas of regular primary care practice. About one thirds of the communication takes place on the public timeline, the other two thirds via the private Direct Message function.

On line communities on health issues are pervasive and participation increases. Patients clearly benefit from actively taking part while possible detrimental effects are rarely reported [48].

In conclusion, we observe that in spite of the country's high use of web based and mobile technology very little empirical research has been done in the Netherlands. However the body of literature on the subject is growing and interestingly shows the possibilities of using social media for health communication, prevention and control of infectious diseases. Dutch public health organizations increasingly use social media; mainly for conventional, one-way marketing, communication and information purposes but increasingly so for encouraging participation and interaction.

Lessons for the Dutch may be learned from the American Centres for Disease Control (CDC) that are collecting experience and building knowledge about using social media in crisis and emergency-risk communication. CDC developed guidelines on how to use such tools which are relevant for the Dutch situation. The importance of trust for the relationship with the general audience is emphasized. To establish trust and credibility four elements of persuasive communication are vital: expressing empathy and caring, showing competence and expertise, remaining honest and open and being committed. According to CDC their work was worth the effort, since social media helped to go where people are, tailor health messages, empower people when making health decisions and facilitate interactive communication. CDC claims to have gained more trust and satisfaction with the use of social media [27]. However, this can only be achieved if professionals have the skills to use them. The typical collaborative nature of Web 2.0 is only useful if health professionals overtly participate and refrain from 'old school', one way communication [35, 49].

McNab [50] mentions some guidelines to use social media for health communication wherein such professional participation is critical: "Be strategic and choose wisely. Identify what needs to be said and why, to whom and when. Focus efforts on the specific social media tools relevant to the audience and use them consistently. A string of abandoned or infrequently tended social media accounts hurts credibility. Critically, health professionals need to use social media to engage in a conversation, not only to "pass down" information. The global social media community expects to be able to add value to the conversation, to help correct rumors or misinformation, provide feedback or offer personal experience." Guidelines are also proposed by medical professional organizations such as the American Medical Association who emphasizes the ethical and legal aspects of social media use by doctors.

Vance et al. [51] acknowledge some disadvantages such as unknown authors, unclear sources or opinions presented as facts. From the advent of the internet these have been addressed in discussions on how to look after the credibility of medical information. Ethical standards such as the international Health on the Net code (HONcode) apply to professional use of social media as well as to the internet.

Though we have anecdotic studies, practices and experiences rather than empirical studies the available material implies a range of innovative possibilities and potential impact of social media in the field of prevention and control of infectious diseases, as well as in public health at large for a growing population of both patients and professionals.

V. DISCUSSION

Social media are popular sources for health information among (young people). Cheap, many-to-many, real time, ubiquitous and interactive as they are, social media offer many opportunities for much needed innovation in public health communication. They have changed the media landscape completely and the old 'trusted media' must relate to the new 'chaotic' media.

These can potentially connect the world of science, public authorities and the general public while maintaining balance between rational information c.q. education and irrational alarming is a responsibility for all party's involved.

Dutch health authorities have taken interesting initiatives in public health to improve health communication via social media. Though it seems sometimes, as a Dutch saying goes, that they "have heard the bell tolling but don't know where the tongue is hanging." The original 2.0

features make social media inherently suitable for peer-to-peer interaction on health issues, professional collaboration and education and health services delivery. Social media use can be studied as any human behaviour can be studied, and specific methods are currently being developed to obtain most of these data.

As is the case with other eHealth technologies [52] the lack of robust evidence prevents a clear assessment of the assumed benefits. More knowledge and practices are needed with regard to how social media could be successfully applied in public health to counter the never-ending threat of infectious disease. The actual experts in social media use are the users. Future research should focus on users and what works for them. Information from such studies should inspire effective social media use by organizations, and this in turn will increase the reach and impact of their public health message and contribute to close the science-practice gap [53].

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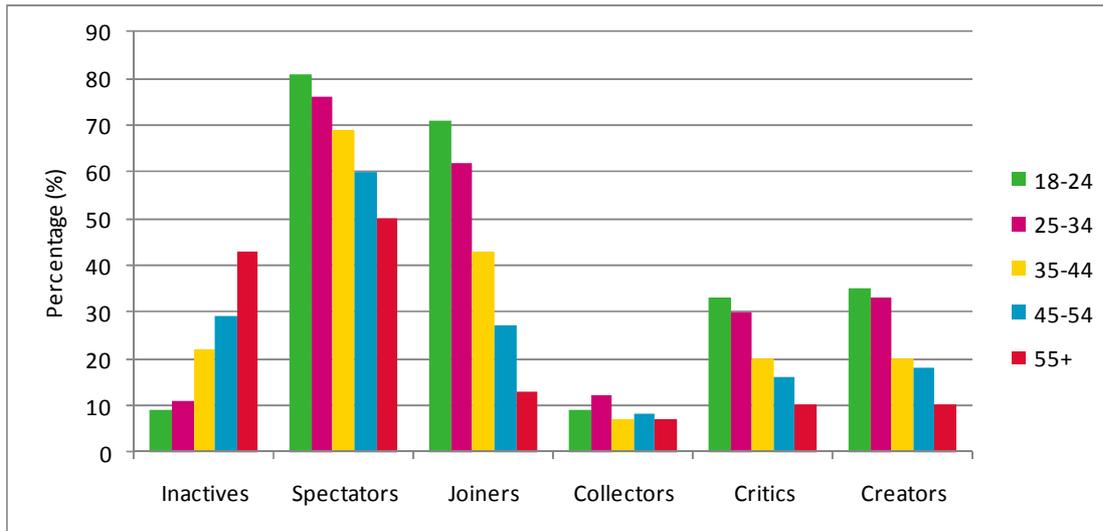
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TABLE 1. Figures on social media use in the Netherlands, October 2010 [16].



Context-sensitive Communication in Hospitals: A User Interface Evaluation and Redesign of Ascom Wireless IP-DECT Phones

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Abstract - A variety of issues related to communication is a common phenomenon in current hospital settings. Sharing information by contacting colleagues, medical attendants, investigatory facilities and other resources, results in many communication events. This generates interruptions from mobile communication devices, which is a big concern for many physicians. In general, wireless phones are not currently widely in use at Norwegian hospitals, due to suspicions of increased interruption rates. Only a few staff members carry a wireless phone. Before introducing such devices as standard equipment, usability and user satisfaction are important factors, and have to be accounted for. The fact that such devices could introduce unnecessary interruptions is a motivation for developing a context sensitive solution. Observations and interviews from a study carried out by the first author, regarding the use of wireless phones at a hospital in Norway, showed that users were unsatisfied with the phones user interfaces. This kept them from using the full functionality of the system. This article presents an evaluation of the existing user interface of two wireless phones intended for hospital use, and suggests an improved user interface, which also intends to support context-sensitive communication. The new interfaces were considered an improvement compared to the old interfaces.

Keywords – HCI; user interface design; context-sensitive communication; wireless communication; heuristic evaluation.

I. INTRODUCTION

Many activities within hospitals and healthcare processes require reliable communication systems. Sharing information by contacting colleagues, medical attendants, investigatory facilities and other resources, results in a lot of communication events. Clinical questions are often complex and not clearly defined, and will therefore require frequent conversations and discussions [1]. Devices currently used to communicate at hospitals, are mainly pagers, but

wired/wireless phones and Personal Digital Assistants (PDA), are in use [2]. These devices can both be personal and role-based, since communication in many cases is not aimed to one person, but to a role such as; ‘the nurse on call’, or ‘the physician on the next shift’ [3]. Because of this, some staff members at today’s hospitals are carrying multiple devices for different roles and purposes [2, 4].

However, communication in hospitals has shown to suffer from poor practice and inefficiency caused by an insufficient infrastructure, especially when the need of communication is urgent [1, 3, 5]. A more extensive use of mobile phones can offer a solution to this problem by improving accessibility and communication in hospitals [1, 5, 6]. Compared to the usage of pagers, important advantages can be achieved by offering two-way text and voice services. Providing smaller delays in communication may lead to improved patients care, and also reduce the risk of medical errors [5].

Despite the advantages of mobile phones, there are also well-known downsides to the usage of these devices. The increased availability and accessibility can cause an overload of numerous interruptions on key human resources, such as, senior physicians, or ‘on call’ staff [4, 7]. These interruptions can lead to a diversion of attention, errors, and may disturb in situations such as, in outpatient clinic, or in the operating theatre [4, 7]. A context-sensitive system can provide a solution to control availability and interruptions [4]. Based on the phones’ location, a person’s role and schedule, interruptions can be avoided, and calls can be redirected to other available resources. Combining the personal and role based devices into one single device, will also offer an improvement to the mobile communication [7].

In general, mobile phones are currently not widely in use at hospitals. Only a few staff members carry a wireless phone due to the suspicion of a phone interrupting more than a pager [2, 4]. Before introducing wireless phones as standard hospital equipment, usability and user satisfaction are important factors to account for. A study, carried out by the first author, regarding the usage of mobile phones at St. Olav’s Hospital in Trondheim, mid Norway (an early adopter of implementing mobile phones), observations and interviews showed that the users were unsatisfied by the current user interface of the phones [8, 9]. It kept them from

using the functionality of the system fully, especially the way messages were handled.

In this article, we investigate the role of user interface design on mobile communication devices used within health care, in order to improve the interface, and to include support for context-sensitive communication. We start out by presenting context sensitive communication systems for hospitals, in Section II. Section III describes the wireless phones subjected in this paper; the Ascom 9d24 and d62, and methods used. In Section IV we present the results from the evaluation, and our suggestions for an improved user interface. Further, in Section V, we discuss the evaluation and prototype, and then the limitations of the study, before we conclude and describe future work in Section VI.

II. CONTEXT SENSITIVE SYSTEMS FOR MOBILE COMMUNICATION IN HOSPITALS

We are involved in designing and developing a system for managing availability and interruptions from mobile devices, used by physicians in hospitals [7, 10-12]. The purpose of this work is to develop a new, low impact context sensitive communication system, based on existing infrastructure. Each physician will only need to be equipped with one mobile communication device for both personal and role based communication. The system will be connected to a reliable context aware communication system, which controls and reduces interruptions in a safe and reliable way [7]. Such devices or systems, based on existing infrastructure, are, by the authors' awareness, not currently available for hospitals. Due to space limit, we refer to [7, 10-12] for more details about our system.

However, several studies have been carried out within hospital settings with improved communication and interruption reduction in mind [1, 6, 13-16]. Other systems, like the AwareMedia and the AwarePhone systems to Badram et al. [17, 18], support context aware communication. These systems in combination form a complete communication system for clinicians in a surgical

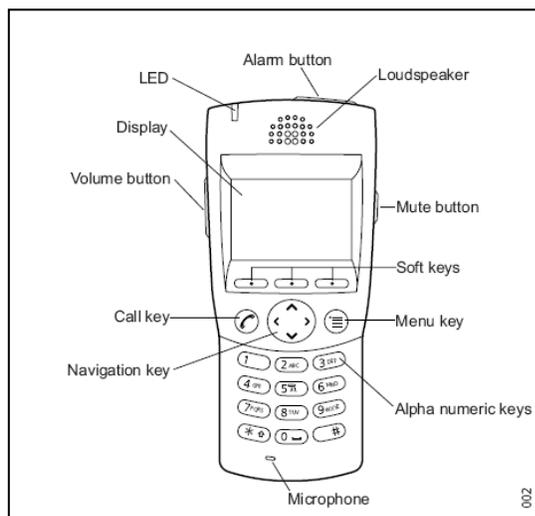


Figure 1. Ascom 9d24 handset.

ward. They are based on GSM/3G, and not systems more widely used in hospital settings, like; Digital Enhanced Cordless Telecommunication (DECT) / Internet Protocol (IP)-DECT, or wireless IP phones. We believe that systems connected to public phone networks could lead to further user resistance due to suspicions of more interruptions from outside the hospital, and will also be more expensive than the usage of existing infrastructure.

III. MATERIALS AND METHODS

The phones subjected in this paper are already in use in hospital settings, and also in the context-sensitive system being developed at the Tromsø Telemedicine Laboratory (TTL) at Norwegian Centre for Integrated Care and Telemedicine (NST) [7, 10-12]. The phones are based on an IP-DECT system, used for wireless communication, offering voice and text services, and also role-based communication and alarms. In this Section we present the subjected phones, and the method used in the paper.

A. Ascom 9d24

The Ascom 9d24 is a wireless handset designed for usage in demanding conditions like in offices, security and hospitals. The handsets are resistant to water, dust and scratches, and can withstand falling on the floor [19]. There are three different versions of the 9d24: The 'Talker', which only supports voice communication, the 'Messenger', offering both voice and text functionalities, and the 'Protector' with additional alarm functions, including an alarm button on top of the handheld, a man-down alarm and a pull-cord alarm.

As can be seen in Figure 1, the 9d24 has 3 soft keys that

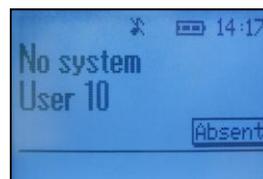


Figure 2. Main screen.

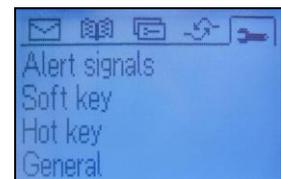


Figure 3. Main menu



Figure 4. Modes.

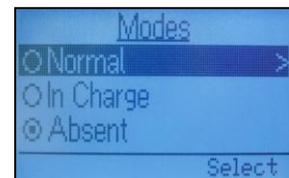


Figure 5. Edit screen

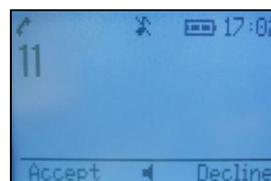


Figure 6. Incoming call

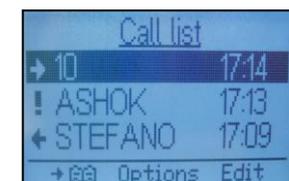


Figure 7. Call list



Figure 8. Ascom d62 handset.

correspond to the options on the display, a keypad, a call button, a menu button, navigation buttons and, on the side, buttons to regulate the volume. The one color display is illuminated in blue and has a resolution of 128x64 pixels. Due to space limits, we refer to [19] for further information about the phone.

1) *Ascom 9d24 user interface*

Figures 2-7 show screenshots of the graphical user interface. The main screen (Figure 2) displays the name of the user, and the current mode (Mode is the user profile of the phone, also called profile on other phones) in use. The top bar of the screen shows a clock and several icons, indicating new voice or text messages, audio settings, activated alarms, battery power and other events. The functions of the soft keys on the bottom of the main screen can be defined by the user, normally the most-used features.

By pressing the ‘Menu key’ (Figure 1), the main menu opens, consisting of 5 tabs with icons representing the function of the tab (Figure 3). The tabs can be opened to select an item in the list (Figure 4). The ‘>’ sign indicates that another menu will open when pressing ‘>’ on the ‘Navigation key’ (Figure 1). Options to edit the settings of the modes will open when pressing the ‘modes menu’ (Figure 5). These modes refer to profile settings, and will be applied when the mode is activated.

The ‘Call key’ (Figure 1) is both used to start and end a call. Figure 6 shows the screen of an incoming call. The number of the caller, or a name, when the number is listed in the local phonebook of the phone, is displayed. All incoming ‘⇒’, outgoing ‘⇐’ and missed ‘!’ calls are stored in the call list (Figure 7). Due to space limits, we refer to [19] for further information about the phone.

B. *Ascom d62*

The Ascom d62 is a wireless IP-DECT phone, designed, like the 9d24, for usage in demanding conditions (industry, offices, security, hospitals, etc.). As the Ascom 9d24, the Ascom d62 exists in three different versions. There is only one version of the physical phone, but as you buy different

licenses, you may improve the phone’s characteristics: The “talker” only allows voice communication and 12 character display messages. The “messenger” offers both voice and messaging communication. The “protector” offers alarm functions, and base station location [19].

The Ascom d62 looks more like a regular GSM phone than the 9d24 (Figure 8). It has a color display, and a five-directional navigation button. It has a “hook on” and “hook off” button, 3 soft keys, a keypad, and side buttons on the left to regulate the volume and to mute the phone. A headphone jack is present on the right side, and the alarm button is located on the top of the handset. The display has a resolution of 128*160 pixels and supports 65 000 colors and 6 lines of 20 characters.

1) *Ascom d62 user interface*

Figures (9 to 14) are screenshots of the graphical user



Figure 9. Main Screen



Figure 10. Main menu



Figure 11. Profiles



Figure 12. Profile options

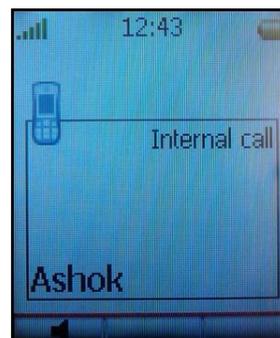


Figure 13. Incoming call

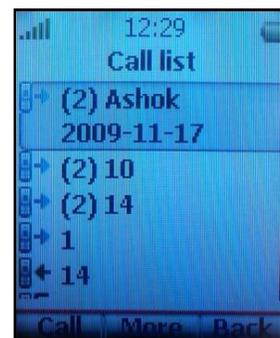


Figure 14. Call list

interface. The main screen (Figure 9) displays the name of the user (Owner ID) and the network the phone is connected to. On the top of the screen, time and date are displayed, and also several icons can be displayed, indicating new voice or text messages, audio settings, battery power, network reception, and other events.

The phone only displays a '?' icon beneath the battery icon, if the selected profile is not the default. The red icon on the bottom-right corner indicates the version of the phone (talker, messenger, and here protector). The functions of the soft keys, on the bottom of the main screen, can be defined by the user. The keypad can be locked and unlocked by pressing '*' and the left soft key.

By pressing the centre of the 'Navigation key' (Figure 8) in the main screen (Figure 9), the main menu opens. The main menu consists of 8 icons representing the sub-menus' functions (Figure 10). By opening a menu using the 'select' or the centre of the 'Navigation key', you end up in a sub-menu containing an item list. These items can be other sub-menus, or selectable items like; profiles (Figure 11). In some cases, by selecting an item, you can push a 'more' button with a soft key, which offers new options (Figure 12).

Figure 13 shows the screen of an incoming call. The number of the caller, or a name, when the number is listed in the local phonebook of the phone, is displayed. The left soft key enables the loudspeaker. All incoming, outgoing, and missed calls are stored in the call list (Figure 14). The left 'Call key' (Figure 8) is used to start and answer a call, while the right 'Call key' is used to end a call, or to cancel everything and go back to the main screen (Figure 9).

C. Methods

The method used to evaluate the user interfaces has similarities to heuristic evaluation where 3-7 usability experts identify challenges of an interface, using their experience and design heuristics [20, 21]. The challenges are then ordered according to their importance and expected impact on usability.

The test users involved here, all have a technical background within computer science and communication. The testing began by spending some time on using each phone, starting with the Ascom 9d24, and then the Ascom d62. Different tasks were performed, for example sending and receiving messages, calling, using the phonebook and changing settings. Initially the user manual was not used in order to test intuitive use, since the end users are not likely to pay close attention to the manual when start working with the handheld [22].

The various points raised in the Ascom 9d24 evaluation, were re-examined with the Ascom d62. In this way, we evaluated the differences between the two handsets, and revealed the resolved problems in the Ascom d62.

Based on guidelines for interface design [20, 23-25], we made a list of possible usability problems. Since the phones are intended to be used in hospitals, the context and requirements of usage in a health care environment was kept in mind when identifying the problems [26]. Also a set of guidelines for the design of context-aware mobile devices [27], was used to minimize usability risks.

To solve the revealed problems, and enhance the usability, we suggest adjustments to the user interfaces. This includes changes to support context sensitive communication. The new interface is visualized in a low-fidelity prototype, using Microsoft PowerPoint 2007, which should be advanced enough at this stage of the evaluation [21, 28, 29]. The prototype makes it possible to interact with the interface by simulating the button functions, and showing the design with enough detail to get feedback on the usability from test users.

To test the usability of the adjusted interface and compare it to the current version, a small scale user test is done. Four users with technical background, as the heuristic evaluation method recommends [20, 21], 3-7 usability experts, all familiar with the Ascom 9d24 and d62 phones, were asked to perform a number of tasks using the prototype. During, and afterwards performing the tasks, they gave feedback on the interface.

IV. RESULTS

In this section, we present the results from the evaluation, redesign, and the prototype evaluation.

A. Evaluation

To identify the most important usability challenges of the Ascom 9d24 and d62 phones, the current interface was evaluated, and some issues were found:

1) *Menu navigation* – is confusing and not consistent in the way of selecting items in the different menus, and also differences in returning to the previous menus (d924). Most of these issues are improved on the d62 phone.

2) *Messaging* – Before writing the message, the user has to select a number or person from the phone book. The number is not editable later. The message is also erased if an incoming alarm, message, or phone call occurs while writing the message. This also happens if you leave the phone unused for 2 minutes while writing the message. When reading a received message, it is not possible to return a call to the sender directly from the message. If the phone is switched off, all messages will be deleted (9d24). Most of these issues are improved on de d62 phone, but on both phones, the list of received messages only shows the first words of the message, and the date/hour you received it, while the name of the sender would be more informative.

3) *Calling* – When a call is not answered on the 9d24, an exclamation mark appears at the top of the main screen to notify the user of a missed call, and you have to go each step through the menu to the call list to get more information. This is not the case on d62, which shows this as a large message on the screen, and enables you to go directly to the call list by just pressing one button.

4) *Feedback* – In general, the feedback given on the phones is good. Feedback on the current mode of the 9d24 is displayed in the main screen, the placing of the text may however not be appropriate, because it appears just above the soft keys, which may lead the user to think it is a soft

key function. On the d62 it is impossible to know which mode is used.

5) *Buttons* – The phones have no on/off button. To switch on the phone the user has to press the call button for a few seconds. It is not clearly shown that the button has this function. On the d62, the same procedure is used for switching off the phone. While the 9d24 requires many steps; through the mode menu tab, the mode ‘switch off’ at the bottom of the list, has to be selected. However, this is because the phone is not intended to be switched off often. When the phone is not in use, it should be placed in the charger, which automatically changes its mode to ‘in charger’. Users have indicated that it is not clear how to enter the menu on both phones, and wants different buttons for answering/ending calls on the 9d24 like the d62.

6) *Other issues* – A general remark from the users about the overall appearance, is that both phones are quite large compared to ordinary mobile phones. This is mainly due to the large screen size, which was perceived as a positive property of the phone. A smaller device is more comfortably carried, for instance in a coat pocket, as health care workers often do [4, 7].

B. Redesign

Evaluation of the current interfaces resulted in ideas of improvement. A prototype with the proposed changes was made, and tested in a small-scale usability test.

1) *Prototype*

To simulate the functionalities of buttons, we used hyperlinks in PowerPoint to switch to the menu screen related to the particular button. In the following sections, we are presenting our suggested new user interfaces.

a) *Suggested changes to the Ascom 9d24*

Main screen: The new main screen (Figure 15) is quite similar to the original. However, the bar at the top of the screen is changed. Icons indicating signal strength and battery power are shown to the user. In critical situations, which may occur in hospitals, the user has to rely on the performance of the system. Also the mode of the phone is now shown in the top bar. We believe that this placing is more logic than on the lower part of the screen. When the location detection is activated, a “dot within a circle” will appear in the top bar. This informs the user that location information is shared, and mode will change automatically.

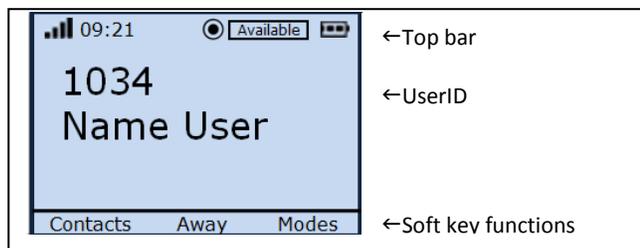


Figure 15. Ascom 9d24 prototype main screen

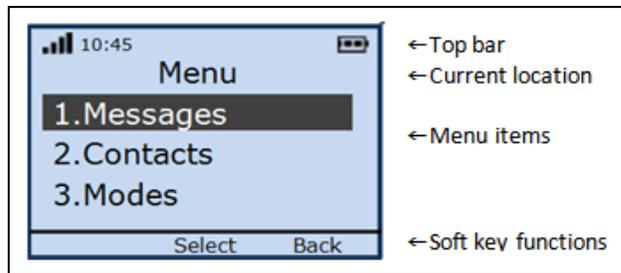


Figure 16. Ascom 9d24 prototype main menu

Functions accessible through the soft keys are; the phonebook, change mode to ‘away’, and the mode menu. From the phonebook users can start a call, or writing a message by selecting the receiver in the contact list.

Pressing the middle soft key will change the mode to ‘away’, e.g., when having an unexpected patient consult, or emergency situation where interruptions are not wanted. To select another mode, the right soft key will open the mode menu. This means that two soft keys are assigned to change the status of the phone. It is still possible to adjust the functions of the soft keys according to the user’s preferences, and also the four directions of the navigation key are programmable to open assigned features.

Main menu: The main menu in the new interface is presented as a list, and not by using tabs (Figure 16). The advantage of the tabs (Figure 3) was to show all the 5 items at once. However, this was not considered as added value in navigation representation, and therefore the list is chosen to make the main menu look more like the sub menus. It is now possible to scroll from the last item to the first in the list, and a quick jump to menu items is offered by using the numbers corresponding to the menu item.

Three menu items are shown at once. Design guidelines regarding number of menu items presented, recommends three or more items, which leads to better usability than one or two, due to human memory [21]. The main menu consists of six items, and showing only three lines is therefore not expected to affect the usability.

The soft keys in the main menu are ‘select’ on the middle key and ‘back’ on the right key. This placing will be the same throughout the whole menu. The middle position to select a highlighted item is chosen because it is closest to the navigation button used for scrolling, and therefore, the easiest button to press when navigating with one hand. Pressing the ‘back’ key will bring the user one step back, to the previous screen. The menu button will always return to the main menu.

Another change in the interface is battery power, signal strength, and clock, not only visible in the main screen, but also above the menus. They can be considered during use: Time, for instance, can influence the decision to call someone, or sending a message.

Messages: The inbox shows all received messages with the name of the sender, and date. New messages are

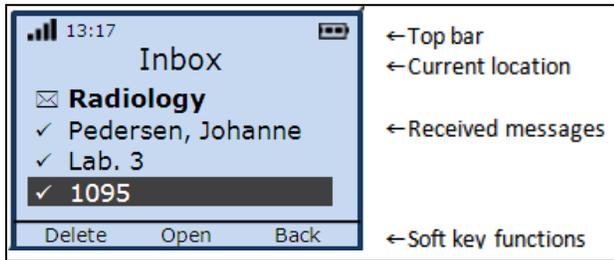


Figure 17. Ascom 9d24 prototype Inbox

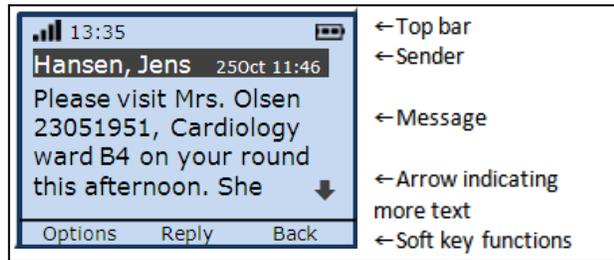


Figure 18. Ascom 9d24 prototype Messages

indicated with a closed envelope, and read messages with a check mark (Figure 17).

It is possible to call the sender directly from the message list, using the call button when the name is highlighted. When the message is opened (Figure 18), the name of the sender and time are displayed, followed by the message. An arrow appears when the message contains more text than is currently shown on the screen. The user can reply to the sender by using the middle soft key, or call back, using the call button. These actions, among others, are also accessible through the options menu on the left soft key.

Calls: When receiving a call, the name of the caller is shown, or the number, when the contact is not in the contact list (Figure 19). The call can be answered using the call button, or the middle soft key. During a call, a “hook off” icon is displayed in the top bar (Figure 20).

Modes: The mode, or profile of the phone, can be set using the mode menu, but can also change automatically based on for instance location, or calendar in a context sensitive system [7, 10-12]. The current mode is displayed in the main screen, but can also be shared with possible communication partners (Figure 21). In the new interface, the caller receives a message with predefined availability

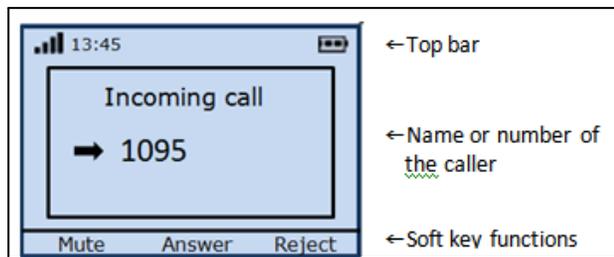


Figure 19. Ascom 9d24 prototype Incoming call (number)

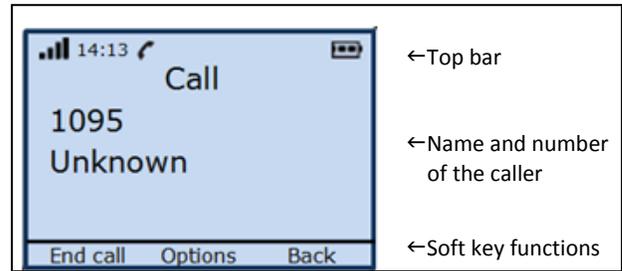


Figure 20. Ascom 9d24 prototype Incoming call (name & number)

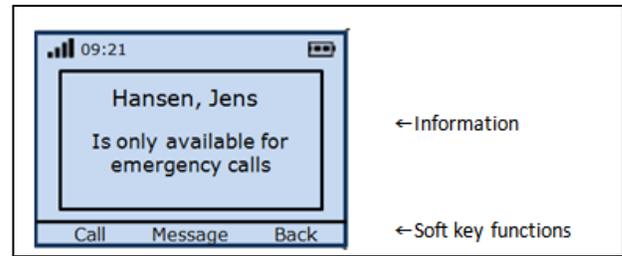


Figure 21. Ascom 9d24 prototype Availability check

information of the one he/she is trying to contact; for instance, ‘only available for text messages’. The soft keys offer the possible options for the caller to choose, based on the shared information. A similar principle is used by Schmidt et al. in an application for context aware telephony [30].

b) Evaluation of 9d24 prototype

A small usability test was done to evaluate the adjusted interface. A few tasks were performed by the test users, like placing a call, receiving a message, and changing modes. During and after the tests, they gave feedback and comments on the usability of the interface.

Main screen: The placing of the current mode in the right upper corner was perceived as good. Also the icon indicating the location detection switched on, was perceived as an improvement. One test user mentioned that it would also be useful to show the current detected location in the main screen. In this way the user can check whether this location is correct. However, we considered this as unimportant information to the intended user of the phone. Interaction with the interface will mainly happen when the user has a specific goal, like; writing a message, or answering a call. We believe that it is not beneficial for the usability, and may be distracting, if a lot of information is shown on the main screen.

Menu navigation: The possibility to use the numeric keys to select menu items seems useful; in this way users are able to remember their own sequence of numbers to frequently used items. There is, however, no indication whether the selected menu item is a branch item, opening another menu list or a leaf item, or starting an action. In the old interface, branch items were indicated with a > sign (see



Figure 22. Ascom 9d24 prototype Call list

Figures 6 and 7). Since the text usually clearly explained the function of the item, the test users did not perceive this as a usability problem. However, this will be considered in the next version of the interface.

Another remark regarding the menu navigation, was that the left and right buttons of the navigation key (Figure 1) are not used when browsing through the menu. In our prototype these buttons are not used at all, and seemed unnecessary. However, in the real interface they will be used when writing messages, or entering text or numbers. This was not a possibility in the prototype. The left and right button of the navigation key can also be set as shortcuts to preferred functions, accessible from the main screen.

Soft keys: The three soft keys in the main screen: contacts, away and modes (Figure 15), were evaluated as convenient. A soft key to write a new message were recommended, instead of the ‘modes’ key. On the other hand, it is easy to access the ‘new message’ function from the contact list, by selecting the recipient. There is a soft key, shortcut to ‘contacts’, therefore this is not seen as an important problem. It is also possible to change the functions of the soft keys to the user’s personal preferences.

Visibility: A general remark was that the text size is smaller in the prototype than in the original interface. More text on the screen is pleasant, especially when using the phonebook, contact list, and message list. However, making the text size too small might influence the visibility. For example, the time and date details in the call list (Figure 22).

c) Suggested changes to the Ascom d62

Main screen: The main screen is substantially identical to the original (Figure 23). The reception indicator, battery

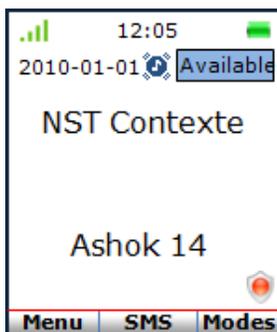


Figure 23. Ascom d62 prototype Main screen

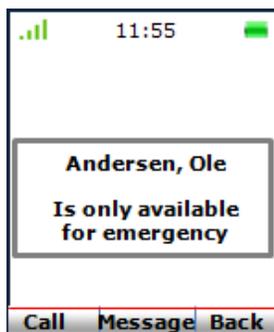


Figure 24. Ascom d62 prototype Availability

icon, and the clock is not moved, but the date is moved left to leave some space for the mode in use, here; ‘Available’. The ‘?’ icon is displayed if the automatic change of mode is activated. Network information, user, and license used, here; ‘protector’, are always located in the same position. The soft keys are default set for hospital use, but remain customizable.

The ‘SMS’ button is a shortcut to write a text message, the ‘Call key’ allows you to make a call from the call list, the phonebook, or by typing a number. The ‘Modes’ button, allows you to quickly change from ‘Available’ to ‘Away’, and enables or disables the automatic change of mode/profile. The ‘Menu’ key provides access to the main menu of the phone.

It is possible to create custom shortcuts with the navigation keys and the 9 numeric keypad keys, but the customization of these phones will hardly ever happen as shown by studies conducted in hospitals. Thereby, the most frequently used functions are set by default.

Modes: The modes can be set via the dedicated menu in the main menu, but can also, as explained above, automatically change by the position of the phone, the user’s schedule, his role, etc., as explained in [7, 10-12]. The mode in use is displayed on the main screen, but can also be shared with other users. This information is important, due to whether it is appropriate to contact this person (Figure 24). In the new interface, the caller receives a message with availability information of the person he/she tries to contact. The soft keys permit to choose whether you still want to call, to send a message, or if you want to cancel the call. It is, of course, always possible to define personal modes, and use them manually.

Messages: Previously, it was only possible to send a message to a single contact. This has been changed, and it is now possible to send messages to multiple contacts (Figure 25), both by typing a number manually, or by adding a number from the phonebook. It is also possible to send a message directly from the phonebook. The left soft key brings you directly to the phonebook, and if a number is entered manually, it will display an “ok” button to validate the given number. Once one or more numbers of contacts has been selected, the left soft key opens a menu to send the message, to remove a recipient, or to access the phonebook to add more recipients.

It is also possible to save a new contact directly from a message, either the senders’ number, or a number in the message. That is, when a number from a message (or call) is selected, a screen offers to save it as a new or existing contact (Figure 26). It is also possible to overwrite an existing number, or set a second number to the same contact. Originally, when one or more numbers were present in a message, it was only possible to save one of those numbers. It is now possible to record a number in a message, in addition to all the options already present (Figure 27).



Figure 25. Ascom d62 prototype sending message

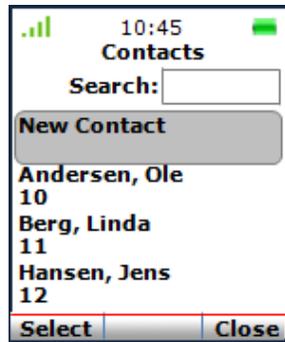


Figure 26. Ascom d62 prototype saving a number

Visibility improvements were also made on the inbox. Unread messages are displayed in bold, which divides them from the read messages. This allows you to quickly see if a message has been read or not (Figure 28). Previously, the only difference was the envelope icon. Also the sender's number and the time of the message are displayed on the selected message.

d) Evaluation of d62 prototype

Main screen: Placing the used mode in the upper right corner was perceived as a good improvement, and fits with the other information provided by the phone in this area of the screen (sound, battery, etc.). The icon indicating that the mode is changing automatically was also perceived as a major improvement. One of the test users indicated it is useful to show the current location detected by the device, so that the user can check the correctness. However, it is not expected that the end users will pay close attention to the main screen. The interaction with the interface is mainly about sending and receiving messages, or transmitting and receiving calls. We believe that showing extensive information on the main screen is not an improvement, but rather a possible distraction.

Soft keys: The choice of 'menu', 'SMS' and 'Profiles' for the soft keys, were perceived as a good choice. It is also possible to personalize these buttons, if a problem of effectiveness is found.

Contacts: The new principle of the contact list, allowing

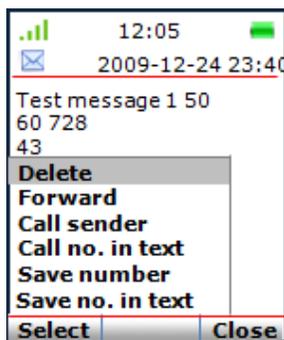


Figure 27. Ascom d62 prototype Message options

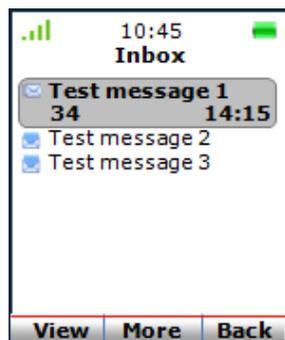


Figure 28. Ascom d62 prototype Inbox

to register a new contact, or to save a number on an existing contact, was received as an improvement, but not necessarily useful in everyday use. The new interface for sending an SMS to several persons was considered intuitive and efficient.

Calls: No major changes have been made on the calls, but having a confirmation when a call is rejected, were perceived as a significant improvement. Providing information on the screen about the status of the person you want to call, were also perceived as very positive feedback. This means that you can use context information to avoid interrupting someone, without blocking communication.

Visibility: In general, the visibility was already good in the original interface. However, some improvements have been greeted positively, like; using bold fonts on unread messages, and normal text for the read messages, the display of the sender's number, the date and time of reception, and the start of the message contents when selecting a message. Another improvement was proposed by one of the test users: Instead of putting many options for the recipient's number, or a number in a message, an option covering all the possible actions could be implemented under the name "use number", and thereby improve the visibility of the screen, and at the same time, avoiding having too many options, which uses almost the entire display.

V. DISCUSSION

It is well known that the usage of mobile phones enables higher availability and accessibility, but can also introduce a numerous of interruptions [4, 7]. This often leads to user resistance against wireless phones in clinical settings. A context-sensitive system for mobile communication can provide a solution to control the availability, and thereby the interruptions [4]. The easiest way to do this, is to introduce an already developed solution, like the AwareMedia and the AwarePhone systems to Badram et al. [17, 18]. But, we believe it is less expensive, and that the user resistance will be lower by utilizing an existing infrastructure, and well known devices used in clinical settings, but with user interfaces more equal to conventional 3G/GSM mobile phones.

The Ascom phones exploited in this article are used in existing infrastructures at several hospitals, and are thereby well known devices for health care workers. A new user interface is designed with the aim to improve the usability of two wireless Ascom phones. We have made an attempt to solve the usability challenges, which were identified in the current interfaces. Another goal was to suggest a user interface more suitable to context sensitive functions. It was not possible to deal with all the problems, since some of them concerned the physical design of the phone. Only the design of the graphical user interface is changed.

The design is implemented in a low-fidelity prototype, which at this stage should be advanced enough [21, 28, 29]. A low-fidelity prototype can be helpful in testing usability focused on the use and design of the interface, while not

being distracted by the design of the phone itself [28], which was not subject to this redesign. This prototype did not resemble the actual physical design of the device, but consisted of an image of the phone with different screens, which changed interacting with mouse clicks on buttons within the image. The ideas for the graphical user interface are displayed in detail. Although the prototype could be used to perform a few tasks, the functionality of the interface was limited. Selecting items and browsing through the menu, did not always work, but making a fully functional interface, was not the goal of the prototype. The intention was to give test users an impression of the design, choice of soft key functions, and the menu structure. During the user test it was sometimes difficult for the test users to focus on the design of the screen, and not on problems caused by incorrect links, or the fact that not all functionalities were implemented. This may have influenced the results of the usability evaluation, but it was helpful to see how the users performed the tasks, and the expected, or unexpected actions they performed to complete the task. Asking specific questions about the users' opinion on the design, or the location of items on the screen, also led to useful feedback.

Another problem with the prototype was that the users initially tended not to click on the simulated buttons of the real phone, but directly on the screen. This is a common problem when testing with low fidelity prototypes [21]. This was solved after a few minutes of training. A shortcoming of the prototype was that the size of the display in the prototype was slightly bigger than on the real phone. Feedback on visibility and size of items could therefore have been influenced.

Only four test users have evaluated the new interface, and critically reviewed the design, to see what could still be a challenge, or points of improvement. This is a low number of evaluators, but according to the method used, heuristic evaluation, where 3-7 usability experts identifies challenges of an interface, using their experience and design heuristics [20, 21], it turned out to be sufficient at this first stage of the redesign. Before more test users, and also the intended end users, like hospital staff, are involved, it has been useful to develop this prototype, which allowed us to see if the adjusted interface fitted the expectations of the usability experts, and whether they perceived it as an improvement compared to the old interface.

Our approach is limited to one manufacturer, but we believe that the ideas can be used in general, when designing user interfaces for mobile phones intended for use in context sensitive systems at hospitals.

VI. CONCLUSION AND FUTURE WORK

In this article, the user interface of two Ascom IP-DECT phones is evaluated, and improvements are suggested. These improvements include support for context-sensitive communication in hospital environments.

The most important usability challenges found were:

- No consistent way of selecting options or to return to a previous screen (9d24)
- Large text size (9d24)
- When writing a text message, it will be deleted if interrupted by a call or another message (9d24)
- No reply options of received text messages (9d24)
- Missed call list is not easily accessible (9d24)
- Not clear how to enter the main menu (9d24)
- No way to know which mode is used (d62)
- Undefined functions for the soft keys on the main screen (d62)
- Only one recipient possible when sending a text message (d62)
- Impossible to save a number on an existing contact (d62)
- Not enough visual difference between read and unread messages (d62)
- Dismissal of a call by the cancel button (d62)

An adjusted interface was made, with attention to the identified usability problems of the current phones. The new interfaces include aspects for using the phones within a context-sensitive communication system:

- Current status or mode displayed on the main screen
- An icon indicating that the location detection is activated and on the d62 an icon showing if the automatically change of mode is available
- A soft key on the main screen to quickly switch to the 'away' mode
- Easy access to the mode menu, to change availability status manually
- Automatic messages to show availability status to callers (d62)
- Automatic message to know the status of the recipient (d62)

The prototypes of the interfaces were evaluated by test users, and were considered to be an improvement compared to the old interfaces. However, some points of doubt were mentioned. Particularly about the many options available in some of the menus on the d62. In addition, questions were asked related to the preferences of hospital workers, the intended end users. To test the usability of the user interface, it is important to involve the actual end users. This will be done in the next phase of the project, where we also have to include and work closer with Ascom AB (during the project, we have discussed several solutions with some of their engineers), to plan and implement a more advanced prototype, running on the actual phones.

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Towards an Internet-based Infectious Disease Management Platform to Increase Patient Safety

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Abstract— An infectious disease communication portal will be developed guided business modeling and Human Centered Design principles. This platform will offer several features such as education, document sharing, decision aids, and outbreak and prevalence monitoring, depending on the needs of the key-stakeholders (caregivers, payers, insurance companies, patients, policy-makers). Data-mining will be applied to logged website use of a previously implemented infectious disease management information website. This will render an understanding of actual use patterns, information need, and search strategies. Preliminary results are presented and implications for further research and platform design are described. These results include: 1. Users most often skip the website's homepage, it is therefore important to support user orientation. 2. Users spend a considerable amount of time searching on the website, a more optimal fit between user and technology is needed. 3. Users switch between information meant for different target groups, information should thus be aimed towards user goals instead of user identity.

Keywords- internet-based communication platform; healthcare associated infection control; information need; patient safety; logfile analysis.

I. BACKGROUND

In this paper, we describe the development of the e-Disease Management Eursafety Health Net platform (eDEHN) based on the evaluation of a previously developed and implemented website [1] to promote patient safety. The eDEHN-platform will function as a disease management platform offering several features such as education, document sharing, decision aids, outbreak and prevalence monitoring, and video-conferencing, depending on the needs of the key-stakeholders (caregivers, payers, insurance companies, patients, policy-makers), see Figure 1.

The platform development will be guided by the ceHRes (center for eHealth research) roadmap that integrates business modeling and Human Centered Design [2]. By applying data-mining to the MRSA-net website, valuable information on actual use patterns renders focal points for the development of the new communication platform that shares MRSA-net goals. This summative evaluation can

serve as input for the up-scaling of the current website to an infectious disease management platform.

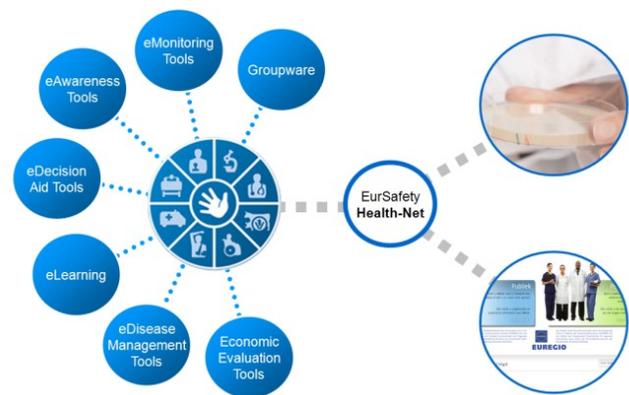


Figure 1. Eursafety Health Net feature overview.

A. Patient Safety

World-wide, patient-safety is increasingly seen as a focal area of healthcare. Due to increases in microbial antibiotic resistance, healthcare associated infections (HAI) form an increasing treat to patient safety [3], [4]. MRSA for example has received much attention in recent years for it is the cause of many HAIs, not seldom with fatal consequences. To fight this problem of microbial antibiotic resistance and subsequent difficult or untreatable HAIs, infection control strategies need to be applied. Since neither people nor bacteria are constrained by national or regional borders, cross border cooperation is needed to ensure effective infectious disease management [5]. Cautious antibiotic use, resistance pattern monitoring, and hygienic measures are among the necessary control measures to fight the spread of resistant bacteria and infections. To inform all actors involved in the care process on the exact measures they should take in case of infectious agents, good information, education, and communication is needed. Patient safety can benefit greatly from efficient communication, education, and information sharing.

B. eHealth technology

To enhance patient safety regarding MRSA, a website was developed using Human Centered Design methods. Information need and structure were identified and labeled through scenario-based testing and card-sorting. Subsequently, website design was tested and adjusted by using mock-ups [6]. Initial tests showed improvement: HCWs were significantly quicker in finding and using information in the internet tool than with paper-based protocols and they were significantly more successful in completing scenario tasks [7]. Likewise, content aimed at the public was created. Patient empowerment was stimulated since the website provides information to answer questions the public (or patients) may have about MRSA.

Since February 2008 MRSA-net can be visited online [1]. It currently pulls about 12,000 visitors per month, mainly originating from its target countries: the Netherlands and Germany. Regardless MRSA-net's success, eHealth technology evolves and successful disease management and infection control ask for a broader set of tools than protocol communication alone. MRSA-net is a starting point, but in our goal of supporting cross border infectious disease management we need to develop the tools HCWs need to control HAIs and deliver safe care.

Cooperation and information is not limited to HCW practice; in infectious disease management patient values cannot be overlooked. Participatory healthcare, healthcare that is organized towards enabling patients to be informed so that they can think and co-decide about the care and cooperate with HCWs, can be realized more easily with eHealth technology. This use of interactive health technology or Medicine 2.0, aims to use technology to involve patients in the care process and offer tools better equipped to meet user needs [8]. Applying eHealth to the broad field of HAI control seems logical and viable.

C. Infectious Disease Management

A variety of antibiotic-resistant infectious agents compromise safety and thus need to be controlled, as stated in World Health Organization fact sheet No. 194 [3]. Increasing patient safety through the reduction and control of HAI in Dutch and German border regions through cross-border collaboration is the goal of MRSA-net's successor: the Eursafety Health Net project [9]. Providing HCWs with knowledge on infection control protocols, facilitating information exchange and monitoring of resistance patterns, as well as creating and enabling public and professional awareness and adequate education is deemed necessary. One of the sub-goals of the project is the development of an ehealth communication platform that facilitates cross-border collaboration on infection control. This platform should support all project partners, HCWs, patients or public in the joint goal of infection control and patient safety. Because successful infection control asks for specific measures taken at different points in the care process, offering timely information and education on infection control is essential. E-learning and e-decision aids are among the tools that eHealth technology has to offer. Also, cross-border monitoring of resistance patterns and antibiotic use can be

realized in internet-based modules. To assess how the communication platform can support such activities, research will be done. Furthermore, to ensure a complete and successful implementation, a business model will simultaneously be created for this eHealth project [10].

D. Business modeling and eHealth development

Besides all good intentions eHealth technologies often lack a full implementation. Reasons for this unsuccessful implementation can be numerous, but a misfit between end-user needs and technology properties are not uncommon [11]. To ensure a good implementation, a thorough understanding of the user, his/her goal or task, and the context in which the application will be used are essential. Involving the users in different phases of the design process is important for researchers and developers. Participatory design, or co-creation, ensures that end-users are kept central throughout the development. The field of Human Centered Design offers methods to inquire users and accomplish user-driven applications [2]. In addition, applying business modeling to healthcare services can generate trust, commitment, and ownership among stakeholders. To illustrate this, MRSA-net design was not based on stakeholder participatory design, but on user participatory design which resulted in some reluctance of important stakeholders to accept and implement the technology [12]. Business modeling tackles this problem of unsuccessful implementation and creates new perspectives on user and stakeholder involvement in creating viable, implementable eHealth technologies [10].

Following the ceHRes roadmap, we aim to develop the eDEHN platform based on the right assumptions and observations regarding its stakeholders and users [2]. In the first phase of the ceHRes roadmap, contextual inquiry, the project is planned and the problem (for which a solution will be developed) is investigated. To ensure that the proposed solution (communication platform with various applications) really supports its users and fulfills a need, the problem (increasing patient safety with regard to infectious disease management) needs to be assessed and understood [2]. The eDEHN platform is currently in the phase of problem analysis: in order to design effective disease management technologies, we need to understand how the technology implemented in the MRSA-net project is used and what information is accessed or requested.

E. Summative Evaluation

Given the initial test results and formative evaluations performed on the MRSA-net website, its prospects were promising [7]. However, as many eHealth designers currently know or are discovering due to more stringent evaluations, actual use may differ substantially from intended use. In a similar way, the intended users may not be the actual users, since freely accessible websites that serve a broad audience can pull many different visitors. Summative evaluation is important because it tells us what information is requested through the MRSA-net website, and how this is done. It tells us what the important areas of interest regarding infection disease management are. Possibly, additional topics

of interest surface that need to be addressed to enable HCWs to provide safe care, or address the public's information need and enable patient empowerment.

To illustrate this, one assumption that is valid for MRSA-net's intended users but possibly not for its actual users is that MRSA-net users have a specific question or information need when searching for guideline-based information. However, translating an (sometimes implicit) information need into a well defined search query or recognize the topic of interest can be difficult. Especially when persons are familiar with a subject (as is probably the case with HCWs that use MRSA-net) they may be unable to form effective queries [13]. The so called 'exploratory seeking' may not be supported as well as 'known item seeking' by MRSA-net's question-answer set-up [14].

Further, taking a close look at use patterns can identify information processing problems. Information on MRSA-net contains a question-answer structure: predefined questions translating an information need are matched with protocol-based answers. This structure may be efficient in providing concise, ready to use information for persons seeking so-called procedural information (learning to do) [15]. However, MRSA-net users may find it difficult to process this question-answer structured information when they search for less action oriented information. To what extent the current structure of MRSA-net offers information that users can process effectively depending on their information need will be researched. Again, this will be applied in the new platform by adjusting the content and structure to user goals.

In sum, we apply the ceHRes roadmap by starting with a summative evaluation of MRSA-net. This evaluation also serves as input for the contextual inquiry phase of Eursafety Health Net and renders input for the eDEHN-platform. We start our research by posing the following questions:

II. RESEARCH QUESTIONS

1. How can the platform be positioned on the Internet in terms of accessibility?
2. How can we make navigation and content smart, simple, and tailored to user needs?
3. How can we supply content based on mental models of intended users?
4. Can we enhance the effectiveness in terms of successful information supply?

III. METHODS

A. Dataset (logfiles)

MRSA-net use has been logged and data on general use are available via the web-stats program (AWSTATS) in the content management system. This data consist of visitors, page views, users, entry and exit pages, etc. logged since March 2008 until present. To give an indication of the dataset's size: in 2009, MRSA-net was visited 154,894 times with on average 4.33 pages viewed per visit.

In addition, specific pages accessed have been extracted into a dataset offering more precise information on individual user actions: User type (public or professional,

German or Dutch), search strategy (web site search engine entry, frequently asked questions, or topic selection), viewed answer, and session duration are available for analyses.

B. Data-mining, content analysis, and card sort

Data-mining has been used previously to get an insight into use patterns and information need of website users [16] [17]. We decided to apply this method because since its launch, MRSA-net traffic has been logged and we thus have empirical data of > 2 years MRSA-net use. These log files can tell us how MRSA-net is used and to some extent by whom, or in other words, give a 'digital fingerprint' [18] of MRSA-net users. Similarly, information accessed on certain topics within MRSA-net can be identified and the extent to which the website fulfills the information need can be demonstrated through analysis.

To get an insight into MRSA-net use and its performance in meeting user needs, we start with giving an overall picture by reporting general statistics such as visit numbers and frequencies of certain topics accessed and search methods applied (macro-level log analysis).

To assess whether the actual topic structure fits the information need of MRSA-net users and whether new topics need to be addressed, we perform a content analysis on the questions posed via the website's search engine. Per user group (German/Dutch, Professional/Public) we will perform card-sorts with the questions posed on MRSA-net as input to identify new topics. These new topics as well as the 'fit' of the current information structure with actual user information need (number of topics accessed) will be validated subsequently in interviews with members of the MRSA-net target user groups.

Finally, we take a look at the sequence of activities performed by single users through micro mining analysis [17] to gain insight into the way the website is used, what purpose it actually fulfills opposed to initial design ideas, and to what extent user are successful in fulfilling their information goals with the website. For example, a single user who scrolls through many topics on the website may not indicate a user who has one practical (protocol) question, but points towards a user wants to learn more about MRSA control in a broad sense.

In sum, we will combine general log analysis on a macro level, content analysis of open search queries, and micro-mining analysis to answer our research questions.

IV. PRELIMINARY RESULTS

Although we have not yet terminated our analyses, we anticipate that our research results in more efficient ways of disseminating information regarding infectious disease management and patient safety. Thus, in the development of the eDEHN platform, information structure will be tailored towards user goals and needs based on MRSA-net analysis outcomes. User specific differences in information need and subsequent website use by the different user groups will be used as focal points in the development of the Eursafety Health Net platform to ensure the platform meets user (and stakeholder) needs.

1. Some preliminary findings include the observation that although users are expected to enter the website via the homepage where they are instructed and guided towards the information they need, users most often enter MRSA-net directly on answer pages via bookmarks, hyperlinks, or search engines. For example, it is observed that internet search engines (like Google) stably account for about 70% of all visits. This strategy of (knowingly or unknowingly) skipping the homepage holds implications for the positioning and timing of introductory information; the aims, trustworthiness, and reliability should be always recognizable for users regardless of how they access the information.

2. In addition, user-assisting features such as the breadcrumb trail become useless when users directly access answer pages. This means we should have a clear understanding of when these features are useful and supportive for navigation or user orientation, and apply them accordingly.

3. Another preliminary result that calls our attention is that some users tend to have long sessions (more than 20 minutes) on MRSA-net, accessing a multitude of (different) answers. This may indicate that these users cannot easily find the information they need on MRSA-net or that they have diverse or broad information needs. In both cases, a more optimal fit between user and technology (structure and content) is needed.

4. A remarkable finding is that professionals and public may have similar information needs, or they have no clear ideas about what they can expect when entering via the public professional entry. Users switch between professional and public content, indicating that (professional) guidelines insufficiently address public concerns. For example, a mental health care worker may start searching in public content, but finds out that professional content (guidelines/protocols for MRSA-control in health care facilities) apply to the institution where he/she works too. Thus, they cannot be divided into public or professional easily. Users may not always know which category they belong to, thus information should be aimed towards user goals instead of user identity. In addition, clinical guidelines should provide sufficient information on public-topics in (semi-)professional settings, since HCWs do not provide care in a professional vacuum.

The preliminary results indicate we need a better system for searching, finding, and using information. Eursafety Health Net platform can benefit from further research into information search behavior and dialogue optimization, which will be inspired by the upcoming results of the present research. It will be our challenge to supply information and facilitate communication in ways that keep adjusting and responding to our users' needs. Future research activities include:

- Positioning via stakeholder meetings via needs assessment and co-creation
- Focus groups with key stakeholders to define the features most in need and requirements for the platform
- Interaction, dialogue optimization based on needs assessment, experiments, and data-mining (current research)

- Content management optimization based on data-mining (current research) and user tests.

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A Concept of a Patient-centered Healthcare System Based on the Virtualized Networking and Information Infrastructure

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Abstract—In the paper we introduce and discuss the concept of an architecture of a patient-centered eHealth ecosystem. It is composed of three layers which were developed around three autonomic types of platforms of services in eHealth. The first platform is a corporate eHealth network which is based on the concept of the LivingLab system introduced earlier. This level is concerned with specialized reference centers and is a natural place for a broad range of advanced tools and eHealth infrastructures. The next level is developed basing on the concept of regional healthcare networks. Some examples of such networks or projects in Poland are mentioned. Regional Healthcare Networks are the most natural environments which bring together all the actors involved in patients' healthcare. The third level in the proposed architecture is related to the family (or individual) eHealth platforms. The environment of this kind is natural for storing, management of and access to personal health records. The concept of a proposed architecture was used to discuss its three main paradigms and their importance for the future global eHealth ecosystem. The presented approach assumes the evolutionary model which enables the virtualization on every level, new generation communication protocols between corresponding networks, and finally a smart electronic health record.

Keywords-Regional Healthcare Networks; Virtualization; Electronic Patient Records; eHealth; Resource Management

I. INTRODUCTION

These days, in the first two decades of the new century, we are becoming aware of rapid ICT development and widespread deployment of emergent services and applications across the world. Many barriers in further development of modern societies can be overcome since new services are enabled by ICT in sectors such as e-government, e-education and e-health. On the other hand, we are facing a new problem. The sustainable, dynamic growth of different local markets of new services creates new barriers aggravating the interoperability of systems like healthcare networks, which is crucial to enable users to access their data and services anytime and from any place.

The improvement of the quality in healthcare systems depends on the relation between medical processes and ICT. Such a trend is visible all over the world; it is also particularly noticeable that many initiatives are undertaken in the European Union. A substantial effort has been made in order to define a strategy for founding and development of Regional Healthcare Networks (RHCNs) – eHealth systems

on a macro regional scale. The example is the Baltic Sea macro region [1].

This scope of integration between medical systems and ICT is the one of the most popular trends in recent years [2][3]. Due to this fact, Section II shortly presents the European strategy regarding RHCNs, and next we give some examples of those systems which are currently under development in Poland. One of them, the Wielkopolska Center of Telemedicine, is managed by the authors.

However, the analysis of barriers and challenges in eHealth performed in the context of emergent new technologies, such as: Future Internet, grids, cloud computing, and ubiquitous computing [13] provides a basis for thoughts of fundamental manner. The principal sphere of healthcare is related to regional systems, but a very important place in the entire health ecosystem is assigned to other two areas: the domain of highly specialized medical aid as well as the field of at-home-care. The first one concerns specialized reference centers with adequate, knowledgeable human assets and equipped with unique diagnostic devices (which are very often associated with advanced ICT applications supporting medical processes). The second area is related to a patient home monitoring, assistance in chronic illness as well as prophylaxis. Though, these areas of medical treatment together with RHCNs, form a common, global system which the authors have compared to a tree structure in Section III (the Healthcare Tree). Next, through mapping this tree onto processes of integration with ICT we obtain the three-ply structure of networks: Family eHealth Net, Regional eHealth Net, and Corporate eHealth Net. We characterized them briefly in Section III.

When we take a global sight over such a structure of eHealth networks and we consider it as an integrated system, we will notice a problem of an interoperability assurance within the structure. In Section IV and V, the authors concentrate on two areas of interoperability: communication and data layer. In the first case, broader use of network virtualization techniques as well as intelligent management of network resources and connected devices is propounded, then the concept of Smart Electronic Health Record is introduced in the second case.

II. REGIONAL HEALTHCARE NETWORKS

For more than 10 years it has been regional e-Health systems which have been in close proximity to day-to-day health care, and in many cases have grown from the concept

of Regional HealthCare Networks [4][5][6]. These types of systems became broadly deployed in Europe as well as many other countries, and allowed to boost the quality of healthcare through integration with ICT, which was noticed by patients.

A. European Strategy

Improvement in healthcare in Europe is induced through setting appropriate priorities on the deployment of ICT means for health market (referenced as eHealth technologies). One of the fundamentals of the global strategy in this area was to build Regional Health Care Networks which aimed at combining three existing techniques into one regional health system:

- Internet and web techniques, making access to advanced communication functionality easy
- Security techniques, making the Internet usable for patient-related information.
- Standardisation techniques, making integration possible with existing IT systems already in use by the professionals in the region [2].

Rapid development of RHCNs was in line with European view on healthcare, which perceives macroregional connections as a way for providing patient-centric services. Such seamless integration can be achieved only when new technical means are deployed in order to ensure the interoperability of existing eHealth systems. An appropriate action has been taken to build a technical platform to implement this policy [1][7].

The strategic direction of the European Commission was also to enable the deployment of Europe-wide computer-supported networks based on broadband infrastructures and Grid technologies. In parallel, a substantial effort has been made in developments of these technologies which are crucial for eHealth as well as for other application areas.

B. Interoperability within common data space - examples

Common diagnosis and information space for patient-centered health services are related to all diagnosis devices which produce digital images that are gathered in electronic health records. These records collect all information about a patient (including the history of his/her medical examinations). It is obvious that all data must be organized in a completely secure environment and should be available for any kind of process related to patient treatment. Moreover, at the same time, all these data should serve as a basis for research related to early detection of diseases as well as prophylaxis. In particular, a patient who is treated outside the hospital or needs continuous medical surveillance should be remotely connected to his/her information space and parameters within this space should be monitored by his/her medical support.

1) Wielkopolska Center of Telemedicine

The Wielkopolska Center of Telemedicine project (WCT) aiming at establishing a telemedical infrastructure in the area of trauma in Wielkopolska started in May 2009 [8]. The objective of the project is to build a regional platform for remote medical teleconsultations allowing to introduce standardized communication in trauma. This platform will

connect 26 hospitals from Wielkopolska with 7 clinical departments. In addition to the deployment of the platform for medical teleconsultations, the project also constructs the Medical Digital Library which collects anonymous medical data and provides this information through accompanying telemedical services of educational nature [9][10]. Both subsystems are closely coupled with each other to enable the sharing of data between them and allow users to seamlessly utilize services provided by both of these subsystems. WCT is also the field for prototype implementation of the concepts discussed thereafter.

2) Pomerania

A telemedical network connecting 32 hospitals is under development in the Euroregion 'Pomerania'. The network is to link 11 hospitals in the Zachodniopomorskie region (Poland) and 21 hospitals in Meklemburg-Vorpommern and Brandenburg (Germany). It is aimed at increasing the quality of medical services and increasing the diagnosis success rate in the region facing the decline in the number of available medical specialists. The project develops a system which will allow to order medical expertise through submitting a request containing a full set of medical information related to a given patient. The information will be centered around radiological images and additional documents containing useful information concerning the requested expert opinion. The project tackles challenges in such medical domains as teleradiology, telepathology, telestroke, teleophthalmology, telecardiology and teleurology.

3) Regional System of Medical Information in Łódź

The Regional System of Medical Information in Łódź aims at supporting management of the regional healthcare system. Its main goal is to improve the efficiency and quality of medical services. The system will bring real benefits for patients, namely better management and planning of medical services, which should facilitate easier access to specialists and shorter waiting time for visits.

The new solution which involves 18 healthcare centers will have an influence on efficient administration of supplies. Additionally, through data aggregation, the system will facilitate the evaluation of regional public health.

4) Medical Information System in Podkarpackie

The Medical Information System in the Podkarpackie region will help in data exchange in the scope of:

- electronic transfer of medical documentation, routine access to electronic documents which are relevant to continued treatment and finally an admission of service provider with regard to information about medical history of the patient;
- access to electronic medical records enabled for patients and providing an information regarding planned and delivered healthcare services.

The main priorities of the System are related to interoperability of IT systems in the scope of access to electronic medical records, organization of medical processes, healthcare management as well as standardization.

C. Further development of RHCNs

Over the last ten years we could observe a process of intensive development of ICT as well as substantial

advancement in medical research. It also influenced the development of RHCNs. We are currently facing a new digital revolution. Its boundaries are set by way of expected fast networks/Internet, in which the user access interface is expected to be delivered at the level of 1 Gb/s (including mobile users) and backbone networks are headed towards terabit bandwidth. The most powerful computers will get to petaflops performance, and will be using advanced techniques of distributed processing in grids [11] and clouds [12] broadly. Technologies of Future Internet such as human (i.e. patient) digital surrounding, context- and semantics-based services, knowledge sharing and, last but not least, user-friendly, human-to-machine natural interfaces.

We have already set the concept of the integrated Health LivingLab platform against the above-mentioned trends in [13]. In this context a broader question about the significance of this development for eHealth global attitude and the role of future regional systems has to be raised.

III. EHEALTH ECOSYSTEM

A. The concept of eHealth ecosystem

To some extent the healthcare system should be a reflection of some reality. Patients live in smaller or larger families within a particular area (i.e. regions). Consequently, it is natural that they look for help and care in their proximate surroundings. However, in difficult cases both patients and regional healthcare 'actors' look for any kind of support in collective competences and experience. More often than not and at the same shared level, the scientific research is carried out, and the unique diagnostic laboratories can be accessed together with other resources which might be helpful and promising in solving complex problems. Such healthcare ecosystem can be visualized as 'the healthcare tree' (Fig.1).

After its integration with broadly understood advanced ICT tools, the healthcare tree makes up a three-layered architecture of the patient-centered e-Health ecosystem containing corporate eHealth platforms, regional eHealth platforms and family (or individual) eHealth platforms (Fig.2).

B. Corporate Networks

The first level of connectivity within the eHealth ecosystem is provided through the dedicated network. Parties which are usually connected to the Internet via different ISPs can join this backbone network through Virtual Private Network (VPN) connections provided for them by particular telecom operators or ISPs.

This level can be associated with the range of university hospitals and main (national) specialistic medical centers. They are usually equipped with rare, complex diagnostic instruments, specialized ICT applications, which support medical processes. They are very often related with research on understanding and eradicating diseases or drug discovery. Therefore, we define this level as a corporate networks level. The authors declare in [13] that this type of a network can be effectively developed and deployed using scientific IT infrastructure (e.g. eInfrastructure in Europe,

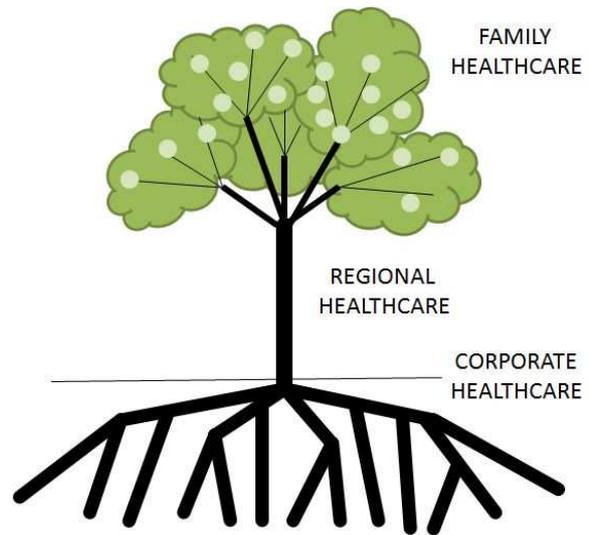


Figure 1. The Healthcare Tree

Cyberinfrastructure in USA). Such a trend has become a leading force for new strategies, e.g. ICT Infrastructures for e-Science in Europe [14] and US UCAN project with Internet2 in USA [15].

The corporate network level can connect and provide other components which are essential for applications delivery. They may include applications for disease research and treatment organization, teleconsultations, medical teleeducation, virtual laboratory for medical imaging studies and diagnosis, as well as diagnosis support.

C. Regional Networks

Regional Healthcare Networks have been established in Europe in many different regions. They are generally one of the most important outcomes of EC strategies in the development of infrastructure for healthcare. The region is the most natural environment which brings together all the actors involved in patients' healthcare. Some projects introduce collaboration as the most important feature of these networks at this moment [4].

D. Private Family Networks

The patient groups in private family networks will be,

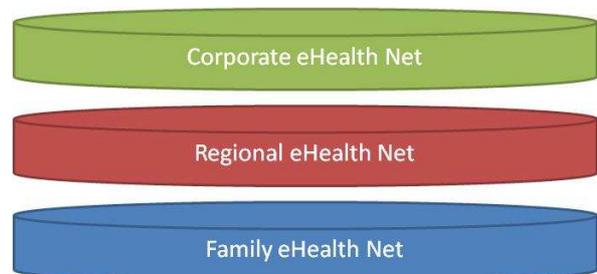


Figure 2. Patient centered eHealth ecosystem

first of all, families: it seems that due to the inheritance of certain diseases, or inheritance of susceptibility to diseases, enabling an integrated analysis of medical data concerning ancestors will potentially allow to diagnose diseases quicker or implement better prevention. As a new concept it requires more attention.

The patient environment includes various biosensory equipment allowing to measure vital health signals or otherwise (semi-)automatically control diagnostic or therapeutic processes. Some examples of such equipment are: pulse oximeters, blood pressure monitors, glucose meters, ECG meters, weight scales or insulin pumps. These devices are usually connected to mobile phones, PDAs or PC computers to allow receiving of data from the sensors and transmitting the data for further processing. Due to their personal character such devices are a permanent part of the Private Family eHealth Network of the given patient. On the other hand, the patient may also be temporarily exposed to the activity of other equipment, or find him/herself in an environment where a specific condition is also monitored in addition to the patient's vital signals. Such equipment includes various imaging modalities (e.g. USG or Computer Tomography) and public space environment sensors (e.g. measuring air temperature or pollution). Such devices will get connected to the Private Family eHealth Network for the time required to acquire the patient's data and transfer them to his/her PDL. Finally, the backbone eHealth network will include, in addition to all networking devices allowing to maintain an active link between all systems in question, systems that either contain some vital information concerning the patient or should receive the data stored in PDL. These systems are, among others, hospital information systems (and information systems installed at other healthcare institutions) that store parts of patient's Electronic Health Record (EHR) and serve as an entry point for the medical personnel supporting the patient. The concept of such network and application scenarios was introduced in [16].

E. The new concept for eHealth infrastructure

In corporate networks interesting medical data which are broadly used in research are gathered. However, when looking from the research perspective, those medical data which are gathered in network from other layers, i.e. RHCNs and Family Networks, are of great importance. Thus, the problem of using these data is the main reason for building global or federated repositories of medical data. Such a scenario can be realized through mechanisms of the Medical Digital Library [9][10]. However, modern medicine is currently facing the problem of searching and processing within mass data space. To reduce this problem we propose to apply in the medical data layer a solution of Smart EHR, which was originally designed in [40].

To illustrate the potency of integration with ICT and to show how fragmented and interregional communication between platforms could be changed, gaining from technological achievements we concentrate on two areas of the interoperability: communication and data layer.

IV. MECHANISMS FOR GLOBAL INTEROPERABILITY IN THE EHEALTH ECOSYSTEM

A. Communication interoperability conditioning in the global eHealth system

The internetworking communication is the first paradigm which is critical to guarantee the interoperability in the global eHealth system. This paradigm concerns both the communication between systems in the scope of the same architecture layer (i.e. within the corporate platforms or regional platforms or family platforms) and the communication between systems from separate layers.

Private, family healthcare networks form an environment for communication of digital medical devices, which can be located in the patient surroundings: in their house or in their private space. Moreover, an environment of this kind is natural for storing, management of and access to Personal Health Records (PHRs). According to concepts introduced and realized by our team within two projects [17] and [18], these records are to be stored in the so-called Patient Digital Library [19]. We will continue the discussion further on, but evade issues which are related to standards for data acquisition from medical devices, standards for storage and representation of medical data as well as standards for communication in telemedicine.

We will face the problem of communication between family eHealth networks with their neighborhood, mainly regional eHealth networks. This connection hereupon has to guarantee appropriate parameters in terms of bandwidth, robustness and security. Many authors (e.g.[20][21]) point out problems with sustenance and attainment of these parameters at the level required by eHealth applications. One should also remember that the communication with RHCN has the dynamic characteristics of the Internet (excluding specialized constant monitoring) in the extranet alike structures as well as that the patient exploits the Internet also (or even mainly) for the purpose of other services.

The crucial role in a substantial revolution in communication means will be played by widespread new networking technologies such as: fiber to the home (FTTH) in the structure of wired NGN [22] and LTE in wireless networks [23].

Target bandwidth, which is for instance expected to be offered within European home networks, is at a minimum level starting from 30 Mb/s, through 100 Mb/s and up to 1 Gb/s [24], and a wireless networks from 150 Mb/s to 1 Gb/s. Making such a breakthrough is expected to come not only in the stationary communication but also in the mobile one, which will influence patient availability anytime and anywhere.

This advancement will also enforce a comparative change in eHealth networks at the higher layers, i.e. regional and corporate ones, in which the necessity will occur to handle the aggregated traffic as well as the accessibility of networking and information resources with respect to economic factors, i.e. costs of network connections and other essential resources. This change has, among others, an effect on the necessity of building dynamic links but with predictable parameters.

In the authors' opinion, this problem can be solved by applying technologies and mechanisms of the Future Internet: virtualization of networks and protocols for integrated information and network resources management.

Virtualization can be applied to any resource which has a feature (possibility) of managing a part of a given hardware, software or information resource which can then make up a logical functional entirety. As an example we can quote wired and wireless networks appliances (e.g. switches, routers, access devices, base stations, controllers), computers, external storage, archive systems, operating systems, applications as well as content. Then, it is possible to create (also dynamically) virtual slices of physical resources which are dedicated for particular tasks, services, user groups in an economic manner (sharing of costs related to the usage of resource), with regard to security (dedicated resources) and reliable (easy options for resource multiplication and replacement of broken parts). The concept of virtualization is not new (compare [25]); however, nowadays it becomes a ruling paradigm for building emergent systems.

From the perspective of the main (common) communication medium the above mentioned concept enables the opportunity for building parallel (e.g. domain or service specific) Internets (e.g. MANA project [26]), parallel interfaces between user and internet and, moreover, information driven networks (e.g. 4WARD project [27]). As an example of such parallel internets an eHealth Internet can be considered.

Through virtualization the process of eHealth networks assembling will become easier. In networks of local operators and ISPs, users (Family Healthcare Networks - FHCNs) will obtain access to the eHealth Internet (see below), and thus to services provided by family doctors or specialists as well as to other healthcare services, realized in typical RHCNs. The system (cloud) of networks connected this way simplifies the development and deployment of new eHealth services, and facilitates the transfer of services available up to now in former systems of RHCNs towards a new, more efficient and secure platform (Fig.3).

The RHCNs cloud, understood as an eHealth Internet, allows any user of this system (i.e. patient) to choose best possible medical services, advice, consultancies, etc. with regard to individual requirements and priorities. This way, the competitiveness and quality of available services will grow. Particular RHCNs can also create eHealth federations which handle more complex services taking into account narrow specializations, consultations, respite care, etc. It is also natural that an opportunity for creating and management of virtual professional communities in RHCNs (e.g. oncologists, urologists, surgeons) is their important feature.

At the top level of knowledge and competence, very advanced eHealth services are generated, and research often related to grand challenges in medicine is carried out. Among such advanced services we can name processing and simulations of models of diseases, parameterized with individual patient data, searching for similar cases, clinical decision support, an access to medical archives, usage of virtual laboratories, immersive work, teleconsultations,

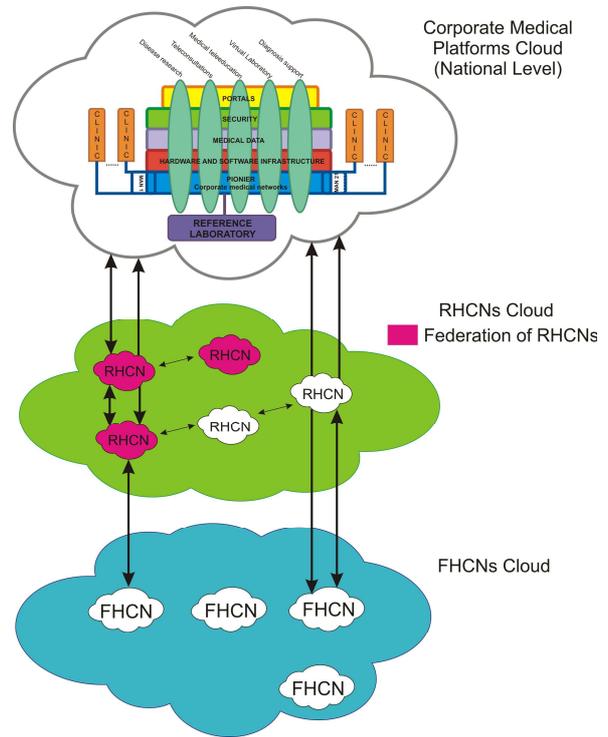


Figure 3. Family, regional and national levels of eHealth virtualized infrastructure

remote surgery transmission, teleeducation and telementoring. For this reason, in the last 10 years some successful approaches have been applied in the area of grid processing structures to build these types of systems [28][29][30]. Recently, this approach is referenced as cloud processing.

One of the main problems to be handled is the configuration of such resource virtual infrastructures to realize particular, dynamic tasks offered by RHCNs. It is a complicated and difficult process. Whenever any part of the requested infrastructure, at any level of the assumed architecture (e.g. eHealth corporate platform) is not available in the traditional system, then after allocated resources in lower layers (e.g. network) become available, the process has to be reiterated. The number of such iterations can be large and also economic calculation is not meaningless here.

In order to avoid aforementioned situations and make the process of building virtual infrastructures which are temporarily dedicated to handling of eHealth services faster, we propose to apply the specialized protocol for integrated control of networks and resource, namely G²MPLS. In particular, this protocol can be broadly used in communication between the eHealth corporate platforms cloud and RHCNs.

The protocol G²MPLS is an extension of ASON/GMPLS standard architecture. It facilitates one step allocation and provisioning of network and grid/cloud processing resources.

The protocol has been developed by the international team involved in the Phosphorus project, which was coordinated by our team [31].

G²MPLS Control Plane, its architecture, services and interfaces are precisely explained in [32][33][34]. The outlook for the model architecture is presented in Fig. 4.

The left part presented in Fig. 4 comes from [33] and illustrates the place in which the G²MPLS protocol is placed in the architecture of advanced systems of distributed processing (grid/cloud). Then, on the right side the corresponding layers of the corporate eHealth platform introduced in [13] are presented. It is important to remember that advanced applications which make use of grid/cloud processing in this platform own the resources that for efficient cooperation require very fast connections which can be obtained in optical networks.

In order to present the usage of this protocol for the purpose of eHealth tasks control, we can imagine several scenarios of communication between corporate networks and RHCNs which require allocation and provision of particular resources able to provide the requested functionality (Fig. 5).

B. Smart EHR

The EHR allows to provide health professionals with a better knowledge of the patient's history and of previous interventions by other colleagues. For many years different concepts of integrating patient medical records have been introduced, starting from [35]. Various concepts can be seen for example in [36][37][38].

The communication model defined for a Smart EHR is to be supported by particular services enabled in all layers of an eHealth ecosystem. The key difference between this concept and traditional PHR is that in our opinion most interactions between a patient and a doctor will happen at the regional level close to the patient's permanent location, whereas patient appointments with other doctors may happen spontaneously due to increased patient mobility. In this case, the patient will contact a doctor assigned to another hospital often located in a different region or country. However, patient's virtual health records should always be accessible on-line via the established Network of Trust connecting legal Trusted Third parties which protect and maintain patient records. The patient has full control over his or her data and can provide limited access to any doctor during a certain diagnosis or accident. However, even then the data transfer and all updates should be monitored and audited by a Center for Data Protection responsible for on-line transactions on health records. Thanks to innovative and powerful data integration and exploitation tools as well as multi-scale modeling and large-scale simulations that have been demonstrated in the ACGT project [39][40], we may also envision innovative healthcare services considering and integrating data from the molecular and basic organs to the living organism level that will also be part of the virtual health records. Thus, not only basic historical data will be collected in the trusted networks, but also more sophisticated data structures integrated with personalized computing models for better prediction and treatment of diseases will be available. Depending on regional health problems, local

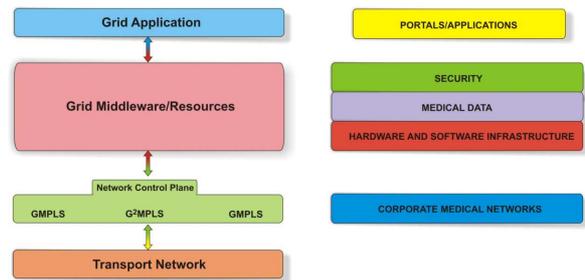


Figure 4. An outlook for G2MPLS architecture

epidemic warnings or key medical challenges (e.g. malaria and cancer treatment) patients will still be encouraged to grant access to their virtual health records to external researchers and medicine experts in a way they fully control and agree upon (e.g. only anonymized data access).

V. IMPLEMENTATION CONDITIONS

A. G2MPLS

For the aforementioned scenarios we can provide a simplified communication schema which is based on the G²MPLS Integrated Model (Fig.5).

In this model, G²MPLS is responsible for scheduling and configuring all the job parts, those related to the Grid sites and those related to the network. It seems that at the network level the knowledge has to be available, regarding grid/cloud resources. Regardless of this, to coordinate workflow services, the separate grid/cloud scheduler is required.

The major part of research and development work has to be done in the range of discussed technologies and mechanisms, however one can undoubtedly declare, that problems seem to be solvable within next 5 years and it is possible to provide the basis for the building of a New Generation eHealth System.

It is also worth mentioning that both the resource virtualization functionality and the new protocol for control of resource availability assume that previous communication standards in telemedicine (e.g. HL7RIM, HL7CCOW, HL7v2.x 3.0, DICOM) are applied in this architecture, the above described functionality of the Future Internet.

B. Smart EHR

The most important role in data integration is played by a Master Ontology developed for ACGT. It is used for

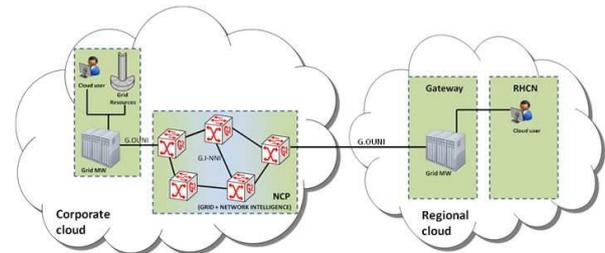


Figure 5. G2MPLS based simplified communication

describing (annotating) the information in the heterogeneous data sources integrated within ACGT environment (Fig.6).

The model chosen for data integration is Query Translation, therefore data stays in their physical location and a virtual view represents the integration. It is realized by

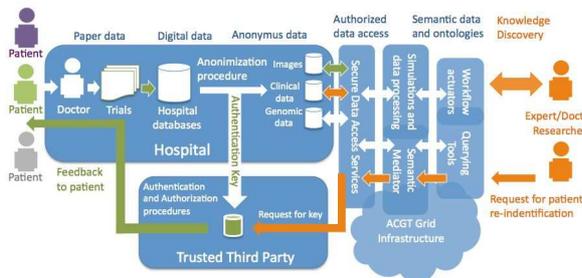


Figure 6. The example of logical data integration in Smart Electronic Health Record

introducing a Semantic Mediator. It requires the creation of a view for every single data source using terms and relationships from the Master Ontology. These views are created through a Mapping process. During the Mapping process, correspondences between elements in the data sources and terms and relations in the Master Ontology are created. These correspondences are used to carry out the query translation. Once a query is performed, the mediator splits it into the necessary queries dedicated to the underlying data sources. Each of these queries passes through the mapping filter which converts the terms and relationships from the Master Ontology to the original database vocabulary, generating the final queries in SPARQL to be sent to the database wrappers.

The results are obtained in the database wrappers result set format. The mediator annotates them using the Master Ontology and finally retrieves an integrated set of results in OWL.

VI. CONCLUSIONS

Recently, people have become more mobile and therefore more often than earlier require help, advice or even medical treatment provided outside their natural regional surroundings. Medical tourism becomes more and more popular, especially in Europe. Patients who need help, either occasionally or intentionally, may decide to be provided with medical services in any place and any time. To receive valuable service they will require access to their complete medical data records. Such patient-centered approach requires new approaches in the organization of the global eHealth system.

The proposed concept of communication between corporate eHealth platforms, regional healthcare networks and private family networks introduced in this paper builds upon the concept of an integrated eHealth LivingLab platform. The global eHealth ecosystem defined in the proposed architecture is related to three very important paradigms: virtualization on every level, new generation

communication protocols between these systems and finally smart electronic health records.

Previous achievements and the level of solutions available up to now set particular conditions for evolution in the process of migration from the existing architecture towards a global new generation eHealth system.

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Play for Health: Videogame Platform for Motor and Cognitive Telerehabilitation of Patients

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Abstract - This paper presents Play for Health platform for the rehabilitation of patients suffering from various diseases developed by iBit Foundation and Son Llätzer Hospital. The platform is basically formed by a management module intended for clinical therapies of telerehabilitation and an unlimited number of games that can be combined with different methods of interaction. Users interact with the computer in different ways according to their needs. These games provide an incentive for patients and promote the realization of the exercises planned by the medical staff in a fun, easy and intuitive way. Furthermore, this system is applicable to other fields such as education and social care.

Keywords - Telerehabilitation; videogame; user interaction

I. INTRODUCTION

Play for Health strategy in iBit Foundation intends to apply ICT (Information and Communication Technologies) to the processes of rehabilitation care through an open and scalable technology platform.

The first phase of this initiative has been funded by the Spanish Government and is called "Telerehabilitation for Elderly People (TeleRHB)", which has implemented a tool to perform remote monitoring of processes and physical therapy to patients with total knee replacement (Fig. 1).



Figure 1. Example of the user interface of "Telerehabilitation for Elderly People".

Currently it is ongoing the second stage of the strategy, which consolidates the platform, developed by the project "General Mobilization System for People with Disabilities (Rehab8)" funded as well by the Spanish Government and it is being prepared for exploitation.

Play for Health Platform is developed by iBit Foundation with the functional collaboration of Son Llätzer Hospital in Palma de Mallorca. This platform allows patients to follow a rehabilitation program tailored to their needs from their homes or care facilities.

This paper explains the technological platform starting from the related work and following the description and a real case game. Finally it presents the conclusion and the future work in this line.

II. RELATED WORK

In recent decades there has been significant progress in using information and telecommunication technologies in the field of health and more specifically in the case of telerehabilitation, both physical and cognitive. Many national and international pilot projects have been developed but few of them get to the production phase and become a real medical service.

Most projects in this sense refer to telemonitoring of chronic patients. It's briefly described some projects directly related to the remote rehabilitation:

- "Cognitive telerehabilitation platform (PREVIRNEC)". It is a system for conducting cognitive rehabilitation exercises in a virtual space that represents a daily routine for the patients, such as a kitchen. The concept is different from the one posed by iBit Foundation because PREVIRNEC interacts with the computer via a mouse and keyboard and the system can only train cognitive abilities (not both physical and / or cognitive as in the case of Play for Health).
- "Clinical Leading Environment for the Assessment of Rehabilitation protocols in home care (CLEAR)" [1] is implementing a telerehabilitation service at European level to contribute to the harmonization of

e-Health services in the European Union. This project focuses on the treatment of chronic diseases that are prevalent among the elderly. CLEAR is pursuing the design and implementation, validated by different testbeds, and a European standard for the development of telerehabilitation services.

Furthermore, there are many initiatives that use with good results the capabilities of current video game consoles like Nintendo Wii for the implementation of telerehabilitation projects. In comparison to the use of such technologies that are commercial and closed, Play for Health allows the development of personalized rehabilitation plans, adjustable to patient outcomes, the parameterization of the results to monitor and store and an Application Program Interface (API) for developing new content. Also, while the games used in these consoles are generally oriented to the leisure and wellness, the contents of Play for Health are specifically designed for specific diseases, in close collaboration with clinical teams to treat these diseases.

III. FUNCTIONAL OBJECTIVES

Currently the high rate of aging population in developed countries is an important social concern. In the medium to long term, the number of elderly dependents could become unsustainable for the socio-public health system unless we take appropriate action.

In this scenario, ICT for health and, in this case, telemedicine and more specifically telerehabilitation, can be a powerful tool to address this situation. On one hand, ICT offer great flexibility to adapt to the needs for treatment and allow better use of health resources and improve the quality of life of patients.

Therefore, telemedicine is seen as a tool to keep in line expenses without lowering service quality and effectiveness of treatments.

The principal objective is to enhance patient autonomy. The first step is identifying the patient's functional limitations by the rehabilitation team (rehabilitation physician, physiotherapist and occupational therapist), taking into account its primary disease and the implications or consequences of it. After identifying these functional limitations, the degree of collaboration of patients and their caregivers, mood and motivation, the rehabilitation team may decide therapeutic interventions through telerehabilitation [2].

The platform addresses the design and implementation of a therapeutic program of physical and psychomotor rehabilitation aimed at people with some kind of functional disability, regardless of the disease they have. It provides patients with various exercises to improve remotely the following aspects: functionality for activities of daily living, physical mobility, some cognitive functions and sensory perception (such as attention, memory [3] or visual perception), coordination [4] skills, psychological aspects such as motivation, handling some technical support and posture. In this way, and taking into account the patient's general condition, the functional team indicates games or exercises to be performed, frequency, repetition and rest periods.

IV. TECHNOLOGICAL DESCRIPTION

Play for Health platform provides resources and services needed for game development of the specific pathology. It is easily extensible in terms of functionality, either by adding new games or by the incorporation of new interaction methods.

Play for Health is based on the development of:

- The contents or games, each of them designed to improve skills within the rehabilitation process.
- The methods of interaction or interfaces. They are the tools with which the patient can interact. They may vary depending on the functional goal established by the medical team.
- The module for clinical staff interaction with the platform for the management of rehabilitation plans for each patient. Both the number of games and methods for interaction that can manage the platform are unlimited.

A. Contents

The contents are the games aimed at the rehabilitation of motor and cognitive functions. They are jointly designed by the technicians and clinical personnel.

Each game is developed independently, using the existing platform and methods of interaction available. Sometimes it is necessary to develop a new module for specific interaction for a game but once developed it can be reused in other games.

An example of the first games developed is a puzzle of pieces that aims to stimulate cognitive and motor functions. The patient may choose the right piece to put in the puzzle to develop the cognitive function. To improve the motor function the patient may move the piece of the puzzle to the right place using the hand.

During play sessions, the system is able to record interesting values such as response time, time to perform the movement, the precision of movement, the number of errors made and the number of steps needed to complete the puzzle. These data will be transmitted to the server system so that medical personnel can analyze and compare the evolution of these variables during therapy. Subsequently, the system may be changing the difficulty of the games automatically or manually by medical personnel, so that the patient continues to be challenged, to maintain its motivation and allowing a steady and gradual improvement of its capacities.

As for the customization of the games, the system adjusts its level of difficulty depending on both the results achieved by the patient and the clinical staff. In the first case, the games are designed to fit the clinical profile of patients. Different profiles of patients according to medical conditions (e. g., elderly profile, multiple sclerosis patient profile, etc.) adjust the scores to the results of the game. In the second case, clinicians analyze the results of the game and may change data and parameters of the game for that patient.

In terms of content, it has been created the games: "Puzzle Training" (see this game as a real case example on the next section), Rhythm (the game is to remember a

sequence of sounds) and Molobolos (it is to direct a ball through a maze).

B. Clinical management system

Play for Health Platform has a clinical module for:

- Setting up rehabilitation plans tailored to each patient by selecting the difficulty level, type of exercise, the location of the stimuli, providing reinforcement to the patient by positive or negative feedback, the type of activity and the execution time of that activity.
- Recording the activity of the patients.
- Viewing the progress: increase improvement of accuracy, decrease errors, increase responsiveness, speed of execution of the exercise, increase resistance to work.
- The use not only in private homes but also in public hospitals, health centers, nursing homes, etc.

C. Interaction methods

A method of interaction is composed of devices (mouse, camera, keyboard, tablet, dance mat, etc.) that record values such as motion, pressure, speed, etc. through different types of sensors that can capture functional changes of the patient, and the software needed to interpret and translate the data into commands that allow the execution of the game.

These interaction devices (interaction event producers) integrate with the video games (consumers of events) through a plug-in dynamic interaction system.

Currently it is implemented the following methods of interaction on the platform: detection of movement in one part of the body through webcam (recognition of the palm), dance mat, Wii Remote (Wiimote), keyboard and mouse.

To date it is combined with Puzzle Training the motion detection technology in an area with webcam, mouse and keyboard; with Rhythm: motion detection in an area with webcam, mouse and keyboard; and it is intended to integrate Molobolos with the Wii Remote and Wii Balance Board.

V. A REAL CASE: "PUZZLE TRAINING"

This section describes the experience of one of the games, Puzzle Training, and its applications in the field of rehabilitation in order to analyze the results of the project. Moreover, we present the clinical results as the analysis of indications and contraindications of the relevant parameters in the hospital.

A. Description

Puzzle Training is a puzzle game developed by iBit Foundation to run on the platform Play for Health, under the functional supervision of a clinical team of Son Llàtzer Hospital Rehabilitation services.

The game builds a puzzle by selecting different pieces, against a variable background. It consists of 9 pieces that must fit together (see Fig. 2). At the start, the game requests the piece to be fit. There are three possibilities, one correct and two incorrect.

The execution of the game is based on different systems: recognition of a sequence number, color recognition and

image recognition. The program treatment clinical team defines the level of difficulty determining the pace, speed, number of games and the duration in the patient's session.

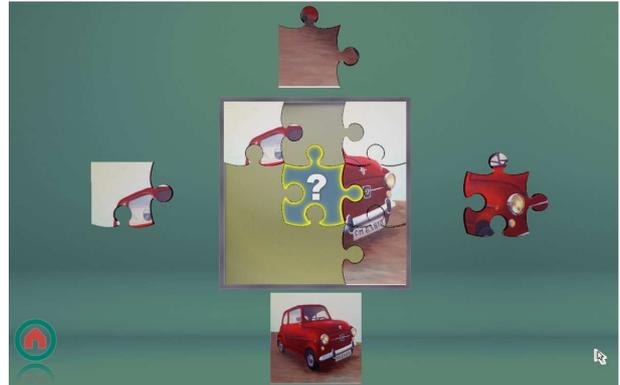


Figure 2. "Puzzle Training" screenshot.

B. Interaction methods

To date it is combined with Puzzle Training the motion detection technology in an area with webcam, mouse and keyboard. The methods of interaction intended to be used with Puzzle Training are:

- Detection of the palm of the hand through a webcam. It allows the detection of movement by using computer vision techniques. You can determine the position, velocity and relative size. Its handling does not require precise movement; it is possible to capture a global and gross upper limb movement when the user selects the correct puzzle piece that appears in different places on the screen (top, left or right) and also it allows use of the superior bilateral limb.
- Detection of a colored glove. It provides greater precision in the selection of the piece, upper limb coordination of shoulder elevation and elbow flexion and extension.
- Dance mat. It allows: improving standing balance (static or dynamic) and/or standing resistance (tolerance to the maintenance of that position); unipodal balance; the possibility of regulating the speed of stimulus presentation and response time; increasing the coordination of movement.
- Mouse. It allows focusing the patient's goals at the cognitive level. If the patient's requirements are physical, the use of this type of interaction permits to work the coordination shoulder - elbow - hand more accurately.
- Keyboard. It develops cognitive and mobility aspects of fine hand as is the identification of the fingers.
- Touch screen. It works the muscles of the hand: bidigital or three-digit clip, and the intrinsic muscles

of the hand. It can be combined with lifting exercises and elbow flexion and extension.

C. Getting results

When the patient completes the scheduled session, it automatically generates a document showing the minimum and maximum reaction time, the environment characteristics, the medals collected by the patient, the number of hits and misses, medals for speed and skill, etc.

It has been established the measurement of the sessions of patients from November 5, 2010 until December 12, 2010.

The patient age ranges from 31 to 83 years and the types of diseases treated are:

- Multiple Sclerosis (4)
- Brown Sequard Disease (1)
- Cerebrovascular accident (CVA) effects (4): hemiplegia / hemiparesis.
- Supraspinatus rupture (1)
- Parkinson (1).

The objectives for the patients using Play for Health are:

- Increase / maintain balance unipodal / bipodal.
- Increase / maintain laterality.
- Increase / maintain joint range of shoulder.
- Increase / maintain joint range of elbow.
- Increase / maintain joint range of wrist.
- Improvement of flexor and extensor muscles.
- Increase of resistance.
- Improvement / maintenance of grip.
- Improvement / maintenance of heavy manipulation with finger exercises.
- Improvement of body image.
- Improvement of coordination and trembling.
- Improvement of hand-eye coordination.

D. Analysis of indications and contraindications

The indications for this game provided by the clinicians are:

- Improvement of the limitations caused by diseases of diverse etiology: traumatic, neurological, neuromuscular and cognitive, always requiring mobility training, cognition, speed, coordination and balance.
- Completion of a treatment to be taken place in a rehabilitation center.
- Keeping the patient's functional status in chronic stages of the diseases mentioned above.
- Occasionally as a substitute for inside hospital treatments.

The contraindications for this game provided by the clinicians are:

- Lack of patient acceptance.
- Severe cognitive or sensory deficits that prevent learning.
- Severe physical deficits that impede the management of interaction interfaces

VI. CONCLUSION AND FUTURE WORK

The results of the use and management of the platform by both patients and therapists are:

- Good acceptance by the patient.
- Relative ease of programming from the therapists.
- Dynamic and stimulating treatment thanks to the existence of multiple programs.
- It permits the individualization of programs (response time, difficulty level, location of stimuli, the possibility to repeat many times) and a record of evolution (response capacity, working time, trial and error).
- Robust so far except for the hand movement that is vague.

The difficulties to face are due to ignorance of the elderly population, mainly the use of new technologies and the difficulty of learning, which is probably higher for patients with acquired brain injury (large group of current users).

So far the tests are being made only in the occupational therapy department and have not begun at home. This will need monitoring the patient by the healthcare professionals.

In cases where the work is only at home, it will be important to keep contact with the therapist to avoid frustration and ensure collaboration and stimulation of the patient.

In terms of objectives achieved it has been perceived:

- Better use of health resources.
- Treatment tailored to the characteristics and outcome of patients.
- Improved adherence and acceptance of the treatment by patients.
- Increasing role of patients in their own rehabilitation process.
- Facilitation of the progression of the daily work of health personnel.
- Creation of a basic structure, on which to develop a treatment for various diseases.
- Use of low-cost but high implementation system.

It's planned the growth of the system on several fronts: first the use of new interaction technologies to recognize the movements with greater precision and reliability and second the repository of video games will be increased, thus multiplying the number of potential patients who may benefit from using the system.

This platform is not only intended for telerehabilitation. It can also be used in other medical areas such as chronic patients, social health and education.

Video games, in addition to be an entertainment, have many applications. Some analyzed and studied areas are:

- Education.
- Continuing education related to work through the training of certain skills to become professionals and experts.
- Social care, through training programs for the elderly, people with mobility deficits, etc.

The intention of the iBit Foundation for the coming years is to continue working on the technology developed within

the Play for Health strategy, to extend to other areas and improve its functionality in general.

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Designing User Friendly Mobile Application to Assist Cancer Patients in Illness Management

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Abstract— Mobile terminals are well suited for providing information to patients at the point of need. In the CONNECT (Care Online: Novel Networks to Enhance Communication and Treatment) project, we have developed a mobile application, called Mobile WebChoice, as a part of a patient support tool that enables patients' access to a help and support system while they are away from hospital between treatments and during rehabilitation and recovery periods. Through our work we address research questions regarding: development of a user-friendly mobile application, user's expectations and requirements from the patient support system, and usability issues that affects acceptance of mobile applications in patients' health management process. We have used participatory design methods that included interviews and usability testing with patients and health personnel. As a result, we identified main usability requirements that must be taken in consideration when developing and adjusting patient support systems for mobile access and saw that patients find the mobile application useful and the patients are ready to accept it as an integrated part of their health management process.

Keywords- mobile application development; health management; patient support system.

I. INTRODUCTION

Due to the increasing costs related to health and long-term care and higher demand for healthcare personnel, there is increasing need for innovative methods and new approaches in interacting with healthcare services [1]. Mobile technology can offer great advantages for access to healthcare information. Widespread acceptance of mobile phones and their ability to provide access to services independent of time and user's current location make mobile terminals well suited for timely delivery of healthcare services to healthcare providers and patients.

Also, patients are becoming more and more involved in the management of their own healthcare conditions with support and help from healthcare professionals [2]. Using new technologies they become more informed about their current conditions and care process, and can become an important participant in the process of planning and management of their own care. Mobile devices can enable patients to collect, store, and transmit clinical data to

healthcare professionals and provide better and more complete insight in their health status.

This paper is organized as follows: Section II gives a brief overview of related work, Section III presents research questions we are addressing in our research work, Section IV describes research methods that are utilized together with results received through the mobile application development, Section V describes results from usability testing, Section VI presents discussion of the results and finally, Section VII gives a summary and conclusion of our research.

II. RELATED WORK

There are numerous projects that address utilization of mobile phones in healthcare management and it is shown that mobile phones can provide help for patients to understand the effects of their illness and treatment, and at the same time find a balance between seeking professional care and depending on their self-care abilities (e.g., [3][4][5]). Some researchers also describe how patients accept mobile health applications and feedback from patients regarding functionality and ease of use (e. g., [6][7][8]). Besides the research related to feasibility of mobile health applications and their potential to provide better patients' health management, we found less research addressing functionality and usability issues that have to be addressed during the development process (e.g., [9][10]). What we still found missing is research regarding more complex patient support systems, where patients are able to access the system over different terminals (mobile, PC, tablet PC). Most of the work addressing this issue in the healthcare area is describing development of mobile applications intended to be used by healthcare personnel (e.g., [11][12]). Some general guidance for developing and adapting a mobile application to a web version as [13][14][15] is present, but still we did not find the work addressing usability and mobility in the context of health support tools intended for patients use. We see that these systems are very specific, and users' needs can vary greatly from one person to other, so developing a system that is not just useful but also easy to use and adapted to users' specific needs and different terminal capabilities is very important for acceptance of the service.

III. RESEARCH QUESTIONS

As part of the CONNECT (Care Online: Novel Networks to Enhance Communication and Treatment) project it is developed an Internet-based support system for communication and information sharing between and among patients and care providers, and patients are enabled to access the system over different terminals (tablet PCs, stationary PCs, laptops or mobile phone). Through development, adaptation and testing of the system and its components our main goal has been to identify key factors that are related to successful adoption, implementation and maintenance of this kind of tools in a real world practice. In this paper we are addressing research issues regarding development process, adaptation and integration of a mobile application in a patient support system. The main research questions that we address here are: (1) what interface requirements and adjustments are needed for the mobile application to provide patients with context-sensitive, adaptive interfaces and seamless, easy access to healthcare information independent of their current location, (2) how does previous knowledge and experience with other parts of the patient support system affect understanding and operation of the mobile application, (3) what are patients' opinions regarding mobile access to the health support systems and the application's usefulness and ease of use, (4) what are patients opinions regarding acceptance of the mobile application as one type of access to the health support system in their own health management.

IV. THE DESIGN AND IMPLEMENTATION METHODS

To address set research questions we utilized participatory design methods that included interviews and usability testing with patients and health personnel. Phases of the process are: development and evaluation of the application interface design, low fidelity usability testing with patients, development of an user interface, expert reviews and high fidelity usability testing with patients. In this section we will describe each phase in more details.

A. Previous work

Previous to our work, the support tools Choice and WebChoice are developed as part of the CONNECT project [16]. The Choice tool enables patients to report their symptoms, health problems and concerns while in the hospital, rate the degree of distress and prioritize their needs for care from health care providers. The WebChoice tool allows patients to monitor symptoms through the Internet over time, and provides access to evidence-based self-management options tailored to their reported symptoms as well as a communication area where patients can ask questions to a clinical nurse specialist and exchange experiences with other cancer patients. After development of these tools, the next step in the project was to investigate how the support system could be enhanced with mobile access, enabling use independent of time and place. It was decided that only a limited set of functionalities from the WebChoice application should be made available in the mobile application (messaging, registration of problems and

an advice module) due to limitations of mobile terminal, and the first draft of design screenshots was developed.

B. Development and evaluation of the interface design

In the first step of the mobile application development we revised and adapted the first version of the application design screenshots that are developed in previous phase of project. We used general guidelines that we found in the literature (e.g., [17][18][19]) and in the same time tried to follow the recommendation given from mobile device and mobile operating system manufacturers (e.g., [20][21][22][23]).

One additional requirement that we set for our specific case is adaptation of the mobile application interface to be similar to the web version (some of the guidelines that we used are described in [13][14][15]). In this manner we adjusted the interface not only for general users but also to users with previous knowledge of other parts of the system and to provide them the feeling that they are accessing the same system through different terminals.

We adapted interface design screenshots using previously mentioned guidelines, but at the same time tried to find a good balance between general recommendations for mobile application design and specific requirements set for this type of applications. Some of the usability issues from the previous design version that we addressed and corrected are: provision of information to users regarding content on the screen (using scrollbars to give feedback about additional content that is not visible on the screen, and enabling users to always know where they are in the application through status bars and titles), consistency in name and place of commands (using just two-three standard commands per screen require us to keep consistent patterns and clear names) and text size adaptation (finding right balance between text size and amount of information on the screen to provide good readability).

C. Review of interface design by patients

When the main interface design screenshots has been created and reviewed, we organized usability testing with the low fidelity paper prototype. In the usability testing four patients participated [24]. During the test participants looked at nine interface screenshots representing different functionalities of the mobile application. They were asked about their opinions regarding the interface design (size of the text, colors, organization of element on the screen) and understanding of the interface functionalities.

Some conclusions from participants' feedback are:

- 1) When adapting interface from bigger screen to smaller, choosing the content that should be transferred requires cooperation with users and finding out what are their expectation from the specific system. For this type of systems we saw that all text that present description and do not give extra knowledge to users should be omitted (or transferred to a specific help page). For example, the login screen should be without introduction text and menus should contain just main command's names (without any clarifications).

- 2) Transferring extensive menus with deep structure on one screen (as in web applications) is not acceptable in the mobile application. The better solution is to make submenus, but there are still problems in connecting a few screens to correspond to the functionality of menu selection in a web application, and find the right level of granularity and amount of information to show per screen. To solve this problem, we used icons identifying the hierarchical menu level.
- 3) Having in mind that the amount of information per screen is very limited, it is very easy for the user to get lost in the application and do not understand what to do next. Providing users feedback regarding current place in the application help, but additional adjustments of menus and screens using familiar concepts from the web application helped the user to transfer previous user experience to the mobile application.
- 4) Even though content and concepts from the web application is transferred to the mobile application, in some situations it is better to adjust screens to more resemble standard mobile functionalities, like text input, menu organization and command organization. Other interface elements, such as colors and application specific icons should not be changed.
- 5) When adapting interface for small screens, the usage of right colors is very important. Colors on one hand could enable additional emphasis on more important interface elements, but just transferring the same colors from a web to a mobile version could result in low readability and clarity. In our example we saw that users had problems with reading text in bright color on dark background as implemented on the web version.
- 6) Selecting the right text size present important issue as we saw from previous steps, because there is need for a right balance between text size and amount of the text on the screen. From the users' feedback we saw that using one font size through all application is not good approach, but rather the size should be adapted depending on the screen size, resolution and amount of information on the screen.
- 7) Using icons and images should be very limited. If they are used just for descriptive purpose, and do not provide any other additional information to users they should be omitted (for example in menus when used in addition to the text). On the other hand in some situations it is convenient to use them to show some status or information to the user on the manner that is similar to the PC or other mobile applications (e.g. status about mail).

We saw that some of the results are in accordance with general mobile user interface development recommendations, but others are very specific for utilization in the context of the mobile applications in healthcare.

D. Development of the mobile application

For developing the mobile application we used Java Platform, Micro Edition (Java ME) [25]. The choice of the Java ME developer platform enabled us to make user-friendly and well-designed user interface adjusted for the majority of mobile terminals.

During application development we used mobile design screenshots that are developed in previous phases. Also while the mobile application was in the development phase, a new design interface was implemented for the WebChoice application; so the design of the mobile application was also adjusted to it keeping in mind previous gained knowledge about users and their specific needs. During development we made the application to dynamically change the interface according to the screen size of the device, so the main organization of the text on the pages stays the same regardless of the mobile device the application is running on. We also additionally addressed the problem of font size by making the user interface more comfortable for reading of longer texts. For example, if a patient reads text describing a self-management advice, he/she is able to change the font size, font type and orientation of the text and in this manner adjust it for better readability. This is normally not possible in a Java ME environment, which only support one font and 3 sizes. Our goal was to make the interface flexible and readable regardless of mobile phone limitations, like screen size and limited navigation possibilities. Additional adjustments are also made so the mobile application can support touch screens without a specific keyboard on the device.

We decided to develop a basic design of our application according to some general design recommendations as stated previously, but in this phase of development process we also implemented some device specific adjustments to change dynamically based on the device type. For example, in our application the right soft key command is used as a rule as back button (that is recommended in the guidelines for Nokia phones) but for writing text in input fields characters assigned to input keys are dynamically adjusted to device type.

For development of this kind of mobile application, using just standard Java ME libraries do not provide enough flexibility. To overcome this limitation, we used the Faster Imaging library [26] that enables virtualization of the mobile terminal. The program library offers improved visual display quality, improved font handling and performance for image and interface intensive applications and is designed to execute on top of all Java ME virtual machines supporting Mobile Information Device Profile (MIDP) version 2.0 and Connected Limited Device Configuration (CLDC) version 1.1 available in almost all Java-enabled phones. A key challenge for us was to provide handling of text and images on a mobile device, with minimal requirements to the terminal, and using the proposed architecture we succeeded to leverage different character fonts and provide virtual machine independent display with low processing requirements, since only very basic operations and only integer arithmetic is used. Text is represented in a highly

compressed format that enable faster rendering. The readability and visual quality is preserved down to very small character size by performing “smooth-edge” technology that provides anti-aliasing with special attention to color blending, consistent view quality independent of rotation and scaling, scalable line thickness and non-isometric text handling.

E. Expert reviews

After prototype has been finished, we organized expert reviews with nurses that were involved in development and research work on other patient support tools, and are well acquainted with the Choice and WebChoice applications.

We utilized a heuristics evaluation and recruited four evaluators [27]. Guidelines that evaluators used for testing are based on the recommended heuristics for web applications [27], and we added heuristics specially addressing mobile device and mobile application characteristics found in [19][28].

The four evaluators were given the list with heuristics and short pre-evaluation session was conducted where the heuristics are explained in more details. They were asked to test the application in duration of one to two hours and note all nonconsistencies with the guidelines. After testing we organized a short debriefing session where evaluators described their experience of the process, and presented their results. Based on received feedback final corrections and adjustments were made on the application before start of a usability testing with patients.

Most of the feedback we received was regarding small interface adjustments, and more convenient organization of the content on the screen. Also, additional propositions were made to name commands more clearly and according to their specific functions and context in which they are used. Additionally, adding advanced features for the application navigation is proposed.

F. Usability testing

When we finished all previously described phases in the application development process, and addressed all usability requirements and problems that were identified we continued with a high fidelity usability testing with patients. A couple of screenshots of the mobile application that is used in the usability testing are shown in the Figure 1.

In this study we performed the usability test of two application scenarios. In the first scenario participants performed testing on just the mobile application, while in the second scenario participants performed testing first on the web application on the PC before they started testing on the mobile version. In the study participated ten patients, five for each application scenario. User group of ten patients is not large enough that represent general user population, but we think that it is large enough to get some first feedback regarding usability issues, acceptance and user needs from mobile applications used as part of the patient support tools.

The study was conducted on a Nokia 5310 phone with installed Mobile WebChoice application and access to the Internet. The test was conducted one participant at the time

Module	Screenshots
Login and main menu	
Registration	
Messaging	

Figure 1. Screenshots of the application’s modules.

in an enclosed environment with minimum background noise.

1) Test Process Design and Data Collection Method

On the beginning of the test participants were briefly introduced on the objectives on the study and the CONNECT project. They were informed that they would be recorded on a video while performing tasks for later analysis. Also, they were asked to try to perform tasks on their own, based on their previous knowledge of the mobile phones and computers, and to take time as they think it is needed. Participants were asked to think out loud during the tasks, and if unavailable to progress on a given task to ask for a help, but only after trying to perform the task first on their own.

The group of participants that tested both the mobile and web version of the application first received the list of tasks to perform on the web application on a desktop PC. After performing the tasks on the web application participant continued with mobile application testing.

Prior to the mobile application testing, participants performed pre-training exercise on the mobile phone. The task list was then given to the participants. During the test, every participant has been asked to perform a total of seven tasks. The tasks were grouped in four groups, based on the main functionalities of the application. For each task the

time, number of errors and number of requested help were measured. Between the tasks and at the end of the testing participants were asked the set of questions to gain more subjective and qualitative feedback regarding interface design, general impressions regarding the application and its usefulness and acceptance in their everyday health management, and answers and comments were recorded. The groups of tasks were designed as follows:

- Login to the application (task 1)
- Send the message to the nurse (task 2-3)
- Register specified problems (task 4)
- Find advices regarding previously selected and specified problems (task 5-8).

2) Targeted respondents

All participants in the study were women between 30 and 60 years old and in treatment for a breast cancer. Only one participant previously heard about the CONNECT project, and participated in previous organized usability studies. Average age of all participants was 46.5 years (average age for first group that tested just the mobile application was 49 years, and the second group that tested the mobile and the web version was 44 years). All of participants owned their mobile phone, eight owned Nokia phones, one Sony Ericsson phone and one HTC phone. According to their subjective opinions the eight participants had average previous experience with mobile phones usage and the remaining two participants had above average user expertise with a mobile phone.

V. RESULTS FROM USABILITY TESTING

In this section we present results recorded during the usability testing.

A. Quantitative results

The task completion times for both user groups are illustrated and compared in the Figure 2. We can see that for the most of the tasks completion time vary by the small values. The only higher variation in the task completion time can be observed for the task four (registration task).

In the Tables I and II are presented numbers of errors participants had while performing tasks and number of times they requested assistance while performing tasks. Here we also see the highest difference for the registration task.

TABLE I. NUMBER OF ERRORS

Task number	1	2	3	4	5	6	7	8	Sum
Mobile version	0	0	0	2	1	2	0	0	5
Mobile and Web version	1	0	0	0	0	1	0	0	2

TABLE II. NUMBER OF REQUESTED ASSISTANCE

Task number	1	2	3	4	5	6	7	8	Sum
Mobile version	3	0	2	12	1	3	0	0	21
Mobile and Web version	4	0	1	4	0	1	0	1	11

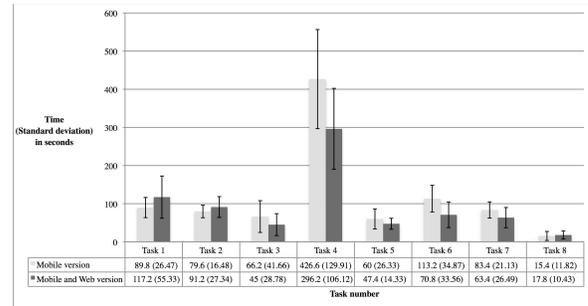


Figure 2. Task completion time for both user groups.

B. Qualitative results

Through the qualitative feedback we tried to identify main usability problems.

1) Task analysis – Login to the application and main menu

In general, participants did not have many complaints and problems regarding login functionality. Participants that owned Nokia phones managed to identify option for changing a text input type very quickly, but others requested help before completing the task. This problem was previously identified so the key for changing the text input type is assigned dynamically in the application dependent on the type of the mobile phone the application is running on. That was one of the limitations of the study because participants did not test application on their own phone, which would offer them probably more familiarity with the standard mobile phone functionalities. One participant suggested that it would be useful for her to have a dictionary option while writing a text.

All of the participants understood the main menu. Some of them commented that it is very simple, clear and easy to understand. For the six participants size of the text was good for reading, and four commented that they do not have problems reading but they recommend little bigger text to facilitate reading for them and for other potential users. All of the participants were satisfied with used colors, and just one complaint that the soft key menu is too dimmed.

In the main menu we used shortcuts (that are presented as numbers in the brackets after the menu item names) and enable more experience to move through the application more quickly. Three participants understood the meaning of numbers as shortcuts.

2) Task analysis – Send the message to the nurse

All participants understood the organization of this functionality and they were satisfied how it is working. It was very easy for them to find all the functions and perform required tasks. Two participants that tested the web application earlier stated that it is very good that the mobile version is similar to the web version. One also stated that it is very good that standard mobile phone functions are used, so she was already familiar with key functions like text input.

Just two participants have stated that they would prefer bigger letters while for others the size of the text was good

for reading. Three participants had problems identifying an option for writing a new message. One complained that the soft key menu is dimmed and other suggested to make this option more visible by emphasize it. All of participant also stated that now when they know where this option is they would not have problem using it.

3) *Task analysis – Register specified problems*

All of the participants were satisfied how organization of the problems were implemented. One that used the web version previously stated that it is very similar to how registration is organized there, and “if one see it on the big screen it is easier to recognize and understand it on the small screen also”. Two of the participants stated that they were a little confused, but if they will use this application regularly it would be easier to perform this task.

All of the participants were satisfied with the text size, and one just commented that it could be little bigger but then there would be less space for the text on the screen and that would be a bigger problem for her.

Just one participant stated that the task was little complicated for her (she used the web version previously) but the rest of them said that the task was not complicated. Also they said that they would be able to perform it again.

Three participants had problems finding the option for going to the next step in the registration process (two that used just the mobile and one that used the web version also), but this was more because they did not know and/or did not remember the name of the next step. Other participants stated that they did not have problems finding option for the next step, and one said that “this way is very similar to an usual use of mobile phones and very intuitive.”

4) *Task analysis – Find advice regarding previously selected and specified problems*

None of the participants had major complaints and problems performing tasks in this module. All of the participants said that they think it is not difficult to perform tasks. Four of them stated that they had little problems understanding it for the first time, but still thought the tasks was not difficult to perform. All of the participants said that they would be able to perform the task again. One participant said that “it looks much like the standard options on a phone”, so she did not have problems finding the right options.

In the application we implemented functionalities for changing font size and orientation of the text when there is much text on the screen, and seven participants stated that they see these options very useful and that they would use them. Two said that they personally would not use these options, but still think that they are useful for others. One said that she would not use it and she thinks it is not so important.

5) *Qualitative results – application usefulness and acceptance*

After testing the mobile application most of the participants were very satisfied how it is working and seven of them stated that they think the mobile application is useful and that they would use it for monitoring their health condition. One of them said that if she has a web application

available she would prefer to use the web application instead, but if not she would use the mobile application because she finds it also useful. One stated that she would not use the application because it is too slow for her, but if it was faster she would probably use it. One stated that she is not sure if she would use it and that she would have to try it and see.

When asked about usefulness of the application all the participants stated that they think the application is useful. Two participants said that today they use paper and pen to note when they have some problems and questions, and afterwards use this list as a reminder during consultation with the doctor. In these situations they think this kind of patient support system would be very useful because it will help them not to forget questions for doctors and nurses. Two participants stated that they do not want to call the hospital when they have minor health related problems because they are not sure how serious the problems really are, and access to this system could provide them first guidance and feedback if they need to make a trip to the hospital. Two participants stated that they liked the fact that the mobile application is always available, because they are not often in situation to use a PC. They said that now they have more free time, so for them using the mobile application would be very convenient. One participant stated that a positive side of the application is provision of a large amount of good and quality information that could help her monitoring her condition from one day to another, and not to just focus on a current problem.

VI. DISCUSSION

From the previous results we can see that the majority of participants are very positive regarding the mobile application as part of patient support system, and most of them think the application is very useful. After the first contact with the application most of the participants thought that if they are given the opportunity they would use it to monitor their health condition in addition to the web version. Most of the participants stated that they would prefer the web version, but they would use the mobile version if they do not have a PC with them. Also, they identified some advantages of the mobile version and found possible scenarios and situations where the mobile application could be more usable. There is also a question, if they would use the mobile application more if they were provided just mobile without web access. To find acceptance of just a mobile version, a new application should be developed that is optimized only for mobile operation.

From our usability testing we saw that users were able to use the application also when they did not have previous experience with the web application, but previous knowledge and experience help them in understanding functionalities better and performing tasks in shorter time period. Based on this, we do not recommend making a mobile application similar to a web-based application, but the interface should be familiar. We recommend to use the same colors, command names, menu items and icons/logos, but the presentation and interaction should be different, and leverage the capabilities of the mobile terminal.

From the qualitative feedback we gained participants comments and thoughts regarding functionality modules, and identified usability problems, additional requirements and expectations that could influence acceptance of the system. The module that had the biggest difference in quantitative measurement was the registration module and we tried to use qualitative feedback to identify the reasons for this. As we saw that there were no major usability complaints, we concluded from participants' comments and video recording that the major issue was that they did not understand the registration process and they did not read the introduction text that were given to them on the screen before the registration process started. They stated that the interface for each step is organized well, and the command for going to the next step was not hard to find, but the problem was to understand what is the next step that should be performed. This explains also difference in completion time, because participants that had performed the task before on the web version knew which options to look for going to the next step of registration. From this we saw that a more detailed description is needed in the beginning of the tasks, so the process is understood before registration is started. Additionally, when creating instructions and support documentation this module should be addressed carefully and in more detail.

We saw that the functionalities provided in the mobile application should be a subset of functionality offered by the traditional web or pc/tablet application. In this way, the application can be very simple, providing only the most important functionalities that are suitable for mobile use. One patient stated: "Basics were there. For me, as a not so frequent user of a mobile phone, it is very important to keep the application simple. Too many choices would probably make it more complicated and I would get lost."

From the participants' feedback we saw that following traditional design guidelines for development of mobile applications is not sufficient when creating a user friendly and intuitive application. General guidelines are often in contradiction to each other (especially if they are from different mobile OS or phone manufacturers) and it is difficult to identify which guidelines are important. This is why we have proposed a selection of general guidelines, which has shown to be important to users during our patient-based testing. We suggest balance of requirements such as providing back options, consistency of command names, feedback to user where they are in the application, and organizations of menus. In addition, we have proposed new guidelines for adaptation of a general mobile application across terminals. This includes adapting size of the text dependent of amount of content of the screen; avoid the use of icons and text for additional descriptions, allowing users to change font size and orientation of the text, and the use of shortcuts. One issue that we specially addressed during development of the application was finding the right balance between size of the text on the screen and amount of information on the screen. Most of the users were satisfied with the selected text size. Some of them stated that having little bigger font would be even better, but that would affect readability of the text. From this feedback and the previous

experience from the application development process we conclude that in the situation where there is large amount of text on the screen, it is better to use smaller text size and in this manner make text easier to read and understand. On the other hand, where there are just menus or small amount of information, it is better to use bigger font size.

The platform developed in the project provides unique support for adaptation to any mobile terminal, without requirements for a particular screen size. New methods for text manipulation has been developed, and as an example, we support arbitrary fonts with arbitrary size scaling in the application and the platform can adapt to most navigation methods, as for example navigation buttons, stylus, soft-keys, only numeric keys, and even touch screens in a consistent way. Thus, all patients can use their own mobile phone, and the application maintains an intuitive look and feel across terminals.

We finally observe that the mobile application is more suitable for younger people that are more acquainted with mobile technologies. One participant suggested that this application is most appropriate for the user group from 20 to 50 years. Our impression from this study where the mean age of participants was 46,5 years with average experience with mobile technology is that the application is very well accepted, easily understood and not seen as too complicated for everyday use.

VII. CONCLUSION AND FUTURE WORK

In this paper our main goal was to show the main user's requirements, expectations, acceptance and usefulness of a patient support tool that is accessible over mobile phone in addition to a web version. For development of the mobile application we used participatory design methods where we involved patients, usability and design experts, and also health providers that are well acquainted with patients needs. We saw that the mobile application we developed has good acceptance by a group of ten breast patients that participated in our usability study. We saw that most users accept a mobile application in addition to a web or tablet application. We think this is a very important fact, because until now mobile applications are often developed as a stand alone patient support tool and all system functionalities are provided through just one application. We recommend that a mobile application should be just a part of a more complete system including other types of terminals such as web or tablet for home/hospital use, and identifying guidelines for mobile application design and functionalities represent a new area in development of patient support systems.

We see that there are certain limitations and shortcomings in our usability study that can be addressed through future work, such as performing usability testing with a larger user group with different age ranges. Valuable feedback could be also gained from potential users with special needs, for example people with vision and motoric problems. Our plan for the next stage in the project is to start a pilot study where the group of patients will be offered both the mobile and web version of the support tool, and study differences in usability, usefulness and usage patterns.

In [29] it is described results of a clinical trial that showed “less symptom distress, depression, and better self-efficacy for the patients that used Internet support system through the WebChoice application”. We have proposed a selection of design guidelines for mobile applications for health care, and how the application should be aligned to existing web and tablet applications to improve usability and flexibility. We claim that an intuitive mobile application is an important part of a health management system for patients, and may result in faster recovery and better flexibility for patients and higher efficiency of healthcare providers.

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Health Solutions Using Low Cost Mobile Phones and Smart Spaces for the Continuous Monitoring and Remote Diagnostics of Chronic Diseases

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Abstract—Our research group is developing solutions for public health mixing mobile devices extended by low-cost sensing technologies, and ubiquitous computing. We seek solutions for mass distribution that (i) enhance the average investment per patient, (ii) reduce the cost of public health implementation, and (iii) improve end-user experience. Our solutions are tailored to monitoring and diagnosis of conditions associated to chronic diseases such as obesity, hypertension, diabetes and obstructive lung disease. We focus on innovative mobile health (mHealth) that provide one-on-one, in-field diagnostic and monitoring procedures allowing 'good enough' diagnosis. This project is motivated by the need to enhance public and individual health care provisioning for in-development communities and the extensive availability of mobile computing technology in this environment.

Keywords - Mobile phones; Smart spaces; Chronic diseases.

I. INTRODUCTION

We aim at creating applications that integrate techniques from the fields of mobile, ubiquitous, and pervasive computing in order to create low cost, comprehensive solutions for public health. With that purpose, we are exploiting the advances in mobile computing technology, which is promoting the massive use of phone-based applications by the diverse societal segments. This technology is becoming sophisticated enough to perform tasks comparable to their hospital equivalents, at price points accessible for members of emerging economies [1]. Moreover, solutions based on ubiquitous and pervasive computing enable the creation of dynamic and heterogeneous environments (the so called pervasive spaces or smart spaces). We envision exploiting this technology to automate and/or optimize the patients' daily tasks.

In specific, we are focusing on chronic diseases and risk factors such as obesity and hypertension. These conditions affect over 10% of the Brazilian population [2] and represent a major item in public health expenditures. The side-effects of the obesity (such as hypertension) are points of concern in public health. These condition leads to complications such as clogged arteries, stroke, and heart attacks that represent immediate risk to patients and potential high treatment costs.

In this context, we are developing low-cost solutions that mix mobile applications and ubiquitous computing. This technology will be used for continuous monitoring of risk factors and premature diagnosis of associated conditions. It will support both reactive actions in response to changes of patient' conditions and pro-active measures, such as proposing exercising and right eating habits.

We are exploiting the increasing the capabilities of commodity mobile devices, which are computational powerful and omnipresent. We are extending these devices with software applications and external sensors that provide non-invasive technologies for environmental and vital data monitoring.

The proposed technology provides the following benefits:

- Enhance average investment per end-user (patient), supporting the delivery of public health via mass distribution,
- Reduce costs of public health implementation, through mass distribution and the utilization of commodity devices. The delivery will be composed of free (open sources) software solutions, and low-cost (license free) sensor devices.
- Improve end-user experience by providing easy-to-use mobile computing interfaces and by exploiting the principle of "processing transparency" in ubiquitous computing.

This development is part of a larger research program at the Nossal Institute for Global Health, The University of Melbourne[3]. This work is structured as follows. Section II describes our motivation and related work. Section III presents the solution. The paper concludes in Section IV.

II. MOTIVATION

Several academic, governmental, and commercial institutions are already exploring the mobile and ubiquitous computing technologies for the creation of public health solutions. For instance, the "Compendium of ICT Applications on Electronic Government" [4] by United Nations Department of Economic and Social Affairs has more than 50 solutions being developed in several countries that scope and presentation, "Future of Health" prepared by the group PSFK for UNIFEC

[1]. This fact emphasizes the role of diagnostic and monitoring technologies to improve health systems.

Three facts motivate our research. First, mobile technology is widely available in developing countries, which provides the basis for extensive mobile health solutions. For instance, in Brazil there are over 187 million handsets (statistics from early-2010), present in 90% of municipalities and over 96% of population density [5].

In addition, several academic, governmental, and commercial institutions are already exploring the mobile and ubiquitous computing technologies for the creation of public health solutions. For instance, the "Compendium of ICT Applications on Electronic Government" [4] by United Nations Department of Economic and Social Affairs which has more than 50 solutions being developed in several countries that scope and presentation, "Future of Health" prepared by the group PSFK for UNIFEC [1]. This fact emphasizes the role of diagnostic and monitoring technologies portable and easy to spread to improve health systems.

Finally, there is a demand for home-base health monitoring solutions for chronic diseases. The Brazilian Institute of Geography and Statistics (IBGE acronym in Portuguese) shows that there are 17 million obese people in Brazil, representing 9.6% of the population. The Ministry of Health reported that the proportion of Brazilian adults diagnosed with hypertension increased from 21.5% in 2006 to 24.4% in 2009. Of these, the percentage of hypertensive patients is only 14% of the population until age 34. From 35 to 44 years, the proportion rises to 20.9%. And the rate jumps to 34.5% from 45 to 54, and 50.4%, from 55 to 64 years. This increase in the occurrence of the disease, according to age, is the result of eating patterns and lack of physical activity throughout life, in addition to genetic factors, there also stress and obesity.

Motivated by this scenario, we focus on the research and development of diagnostic solutions based on low-cost technology. It extends the mobile phone's capabilities towards mobile health and ubiquitous computing applications. We aim at solutions to monitor health conditions associated to chronic diseases (*i.e.*, obesity, hypertension and diabetes). We also promote academic research on smart environments and environmental sensors for telemedicine and developed by the authors presented in [6], [7].

This development draws on existing experience from other projects in developing low-cost sensors and associated software and user interfaces on mobile platforms. For example, [8], [9] show that governments, companies, and non-profit groups are already developing mobile health applications to improve healthcare. These reports present several programs, either currently operating or slated for implementation in the near future.

Moreover, [10], [11], [12], [13] propose alternative solutions that address relevant issues of (i) education and awareness; (ii) remote data collection; (iii) remote monitoring; (iv) communication and training for healthcare workers; (v) disease and epidemic outbreak tracking, and (vi) diagnostic and treatment support. We leveraged from these experiences and design

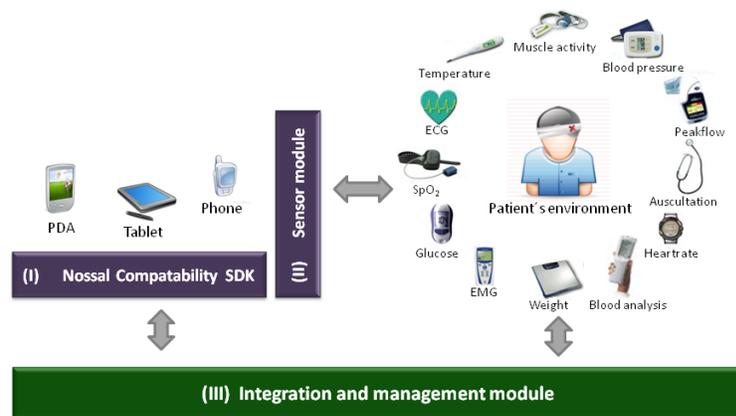


Fig. 1. System Architecture - Adapted from [14]

principles in composing our solution.

Next, we introduce the proposed system architecture and present the current prototypes.

III. PROPOSED ARCHITECTURE

We propose a model of for an easy development of mobile health applications through a framework of software and hardware components. The new solutions will be composed of software applications that read data being collected by data sensors connected to commodity mobile phones. The solution complies with the existing standards such as programming languages, libraries, and hardware interfaces. These features facilitate dissemination to heterogeneous devices and also help reduce development and distribution costs.

Figure 1 illustrates the system architecture. There are three distinct modules:

- (A) the *Nossal Compatibility SDK* that provides the framework for software application development.
- (B) the *Sensor Module* that provides the (software and hardware) support for external sensor integration.
- (C) the *Integration and Management Module* that provides support for the management of smart space and the integration of software applications and sensor hardware.

These modules are described below.

A. The Nossal SDK Module

This module (Figure 1(I)) provides the execution environment for the application. It allows for applications to utilize abstract, reusable modules. It provides re-usable functionality in the domains of data gathering, data processing, and human interfacing. This component accomplishes our goals of compatibility, integration and standardization. Some of the design principles for this module are:

- Portable to different operation platforms (*e.g.*, Symbian OS, Windows) while preserving the same functionalities and programming interfaces.
- Provides a scripting language that supports basic data processing functionality, fully integrated to the data gathering

and human interfacing functionalities. This provides a “compilation free” entronement for application writing. That is, applications are developed as scripts (plain text), which are loaded, parsed and executed by the operation environment.

- Provides the basic functionality to support the varying human components available in different devices, as for example keyboard, screen, audio, microphone, and others. The design is flexible to adapt to the available hardware support.
- Extensible through the development of external packages that can be added to the operating environment both during the development phase and at run-time.

B. Sensor Module

The Sensor Module (Figure 1(II)) provides the interface to attach external sensors to the mobile phone. This module is composed of a microprocessor that controls a number of external Analogue/Digital (A/D) ports where the sensors are attached. On the other side, there are the *de facto* standard USB interface and wireless BlueTooth interface (in research) to connect to the mobile phone. Once plugged into the phone, it is recognized as a standard USB device.

The A/D ports allow the connection of “sensor modules” such as the pulse oximeter, ECG, and phonocardiogram. Other sensors can be developed and attached to this interface, as long as they respect the electronic parameters established by the module’s configuration. The design allows the integration of up to 12 sensors. Virtually any type of sensor can be plugged in as long as it provides a signal output between 0V and 5V. The electronics are composed of inexpensive elements that cost less than USD10.00 (ten American dollars) in the retail market.

We apply the 32-bit MCF51JM128 microcontroller (which costs around AUD 4.00) from Freescale Semiconductor Inc. This component can be programmed using the C language. It also provides integrated flash and RAM memory for the application and data storage. In addition, it supports interface to external devices via USB interface. Figure 2 has a picture of our current development prototype. We intend to produce this module in a reduced form factor to facilitate distribution and portability.

Figure 2 has a picture of our current *Oximeter sensor prototype*. It displays the following elements:

- (i) *External Sensor Module*, in its prototype version: we intend to produce this module in a reduced form factor to facilitate distribution and portability; the prototype version contains the microcontroller (square in the bottom-left corner), the module’s electronics (square circuit board on the right), and a “debug board” (underneath the microcontroller) that will not be part of the final product.
- (ii) *USB Interface*: provided as output by the *External Sensor Module*; it requires a common mini-USB cable to connect this module to the mobile phone.
- (iii) *Mobile Phone*: we use a HTC SmartPhone running Microsoft Windows Mobile 6.1 for the prototype; we

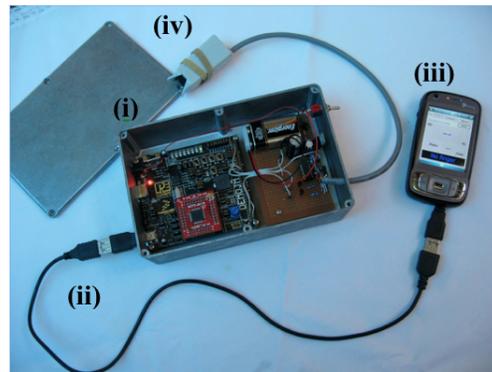


Fig. 2. Oximeter Sensor Prototype

opted for this development platform due to hardware availability as Microsoft Research sponsored this project,

- (iv) *Oximeter Probe*: attached to one of the A/D ports of the *External Sensor Module*, which controls its functionality such as activating the LEDs and collecting the results from the light sensors.

C. Integration and Management Module

The Integration and management module (Figure 1(III)) is mainly responsible for management of smart space. It has internal sub-modules used by context-awareness, discovery, adaptation, localization services and other common services in ubicomp area. This module also is used to provide applications to environment and to integrate sensors and other devices immersed there but that was not connected via sensor module. This module currently is under construction and is the main focus of Brazilian chapter of Nossal Institute project.

D. Current applications and future extensions

Based on this architecture, we are developing applications for data collection, monitoring, and diagnosis of symptoms related to chronic diseases. We are researching and developing the following applications.

The *Intelligent Activities Manager* provides a solution to monitor patient’s daily activities. It includes an environment monitor composed of sensors and accelerometers. Once certain conditions are detected, it reminds the patients on the importance of performing certain activities, such as scheduled medical appointments, exams, drug dosage reminding, and even conditions like laziness and lack of physical exercises. The design aims at flexibility, user-friendliness, and context awareness. The goal is to provide a personalized solution to motivate patients to perform physical activities and take care of their health and well-being to prevent the condition escalation.

The *Integrated Solution for Collecting and Monitoring of Vital Signs* provides a solution for integrating vital data from multiple sensor units - e.g., from our low-cost phonocardiogram, our clinical thermometer, our respiratory rate calculator and others. The solutions supports remote monitoring by transmitting the collected information to health centres. The integration of external sensors happens through an open



Fig. 3. "Ready Set" Application Prototypes

interface, as well as the development of the data collecting and transmission applications. Thus, we foresee the integration of multiple sensor coming from different research initiatives, transforming this application into a platform for combined remote monitoring.

The *Low Cost Piezo-Electric Scale* is a hardware-software development initiative that complements the sensing capability required for the monitoring of chronic diseases' conditions. It provides the tool for continuous weight monitoring and control, communication the measurements to the health central (using the "Integrated Solution for Collecting and Monitoring of Vital Signs" described above). For example, the application can provide notification of encouragement when the patient loses weight and the other way around. We emphasize that this application is also useful for the diagnosis and monitoring of malnutrition conditions, allowing for further project extensions.

In addition, we will be integrating these solutions to some of the existing applications of the Nossal Institute for Global Health that add-value to our project, *viz.*:

- The *Nossal Oximeter Sensor*: it works by measuring the difference in absorption in two wavelengths of light. With each pulse of arterial blood into the fingertip or ear lobe it is possible to calculate the percentage saturation of haemoglobin with oxygen. The primary use of this sensor is to be in the diagnosis and assessment of the severity of respiratory disease and hypoxaemia in an outpatient setting.
- The *Respiratory and Pulse Rate Calculator*: this application uses the system clock inside the mobile phone to capture the time that the health worker begins and ends

counting just 10 respiratory cycles; it provides tools to aid health field-workers counting respiratory or pulse rates.

- The *Formulary/Drug Dose Calculator*: this application records a subset of the information in the local formulary - the names, indications for use, dosing regimens and presentations of drugs available for health workers to prescribe to their patients. When the health worker selects a drug, an indication and a presentation (*i.e.*, capsules, tablets, ampoules, and others) the application calculates the appropriate dose for that patient, along with other supporting information relevant to the prescribed drug.
- The *Drip Rate Calculator*: this application prompts the user for the volume to be infused and the infusion period. It then calculates the corresponding number of drops per minute. No need for calculations or a wristwatch.
- The *Drug Reminder Alarm*: this application makes use of the built-in digital camera that is present in mid-range/sophisticated phones, and in some basic phones as well. It is meant to be used by pharmacists when they dispense complex drug regimens. The pharmacist lays out the correct number of tablets or capsules to be taken at a given time of day, takes a digital photograph, and then adds the photo and the time details to the application's task list. The alarm will then ring at the set interval, and show the photo on the screen to remind the patient to take the prescribed medication.

As part of the development cycle, each application must be field tested after appropriate testing and debugging. We will perform qualitative research studies using experts to assess the internal validity of the diagnostic and management algorithms, and the correctness of final recommendations. Moreover, the results from each solution will be compared to the current best methods for measuring the same parameters in order to validate the approach.

IV. CONCLUSIONS

This project is motivated by the need to enhance public and individual health care provisioning for in-development communities. We focused on creating the software and hardware infrastructure required to facilitate the development of low-cost health-care solutions. We are exploiting the use of commodity mobile phones and ubiquitous computing to create a solutions for mass distribution that (i) enhance the average investment per patient, (ii) reduce the cost of public health implementation, and (iii) improve end-user experience.

The solution contributes to improved health and well-being by providing a comprehensive, flexible, and low-cost mobile health diagnosis, monitoring and management solution. We are bound by the necessities and requirements of the Brazilian government health programs, thus creating a solution that is suitable for immediate implementation by that institution. The solution complies with the existing standards such as programming languages, libraries, and hardware interfaces and operates using minimum computing resources. We anticipate the following benefits from this technology' implementation:

- To provide the assistance tools to support for home-based health programs, improving end-user experience.
- To improve the performance and scope of the health system, by reducing the costs of health delivery programs, thus enabling the implementation of prevention, monitoring and diagnosis tools by a ubiquitous, pervasive and inexpensive technology.
- To deliver extended support for health programs to prevent chronic diseases, contributing to the larger goal of overall health is to promote the diagnosis, prevention and treatment of health for the largest portion of society possible. The results contribute to promoting an innovation culture and economy with the development of frontier technologies for public health improving health care conditions.

The current implementation is limited by the needs of the immediate problem – *i.e.*, a solution to monitor health conditions associated to obesity. Hence, the prototypes are being developed for a specific purpose and have limited scope. Nonetheless, the framework components – *i.e.*, the Nossal SDK and the sensor interface – are device agnostic and can be used for general purpose. They can be re-used in future projects that we will run in other problem domains.

Future developments include refining the technology and developing new applications for the diagnosis of other diseases and health conditions. We intend to create the distribution device in compact format based on the technology already developed. Moreover, we must extend the Nossal SDK, especially concerning the capabilities of the scripting language and support to hardware technologies. Finally, we intend to conduct extensive tests from the technical and clinical perspectives to ensure the portability, robustness, and accuracy.

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Using Soft Computer Techniques on Smart Devices for Monitoring Chronic Diseases: the CHRONIOUS 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 touchscreen) 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 cure purpose. This paper illustrates how some machine learning algorithms and a rule based decision support system can be used in smart devices, to monitor chronic patient. We will analyse how a set of machine learning algorithms can be used in smart devices to alert the clinician in case of a patient health condition worsening trend.

Keywords- Telemedicine; chronic disease management; machine learning; soft computing techniques.

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 (ie diseases not involving healing), that will therefore increase the cost and effort over health care facilities [1]. 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 disease, by limiting the hospitalization only to a severe worsening of patient's condition. This was the original idea behind the CHRONIOUS project: constructing a generic platform to monitor, in an unobtrusive way, a chronic disease patient with two goals[2]:

- Improve the patients quality of life, by reducing as much as possible the hospitalizations.
- Allow the clinician a continuous monitoring the patients, both in standard and potential risk situations.

To gain this two goals, the CHRONIOUS platform has to integrate different technologies and hardware and software modules that need to interact among themselves. This paper

is organized as follows: in the first section, the general structure of CHRONIOUS hardware and software modules are described. A deep analysis of the preprocessing algorithms covers the entire second section. Section three is dedicated to illustrate the machine learning algorithms. In last section we will evaluate possible improvements to the Chronious intelligence system.

II. THE CHRONIOUS SYSTEM: AN OVERVIEW

CHRONIOUS system deals with COPD and CKD: for these different types of chronic diseases, according to the medical guidelines, it is important to monitor different data in a way to check patient health status and to activate suitable emergency alarms for the clinician (for the COPD: ECG, SPO2 and respiratory rate; for CKD: glucose level, body weight and blood pressure) in case of critical event.

The CHRONIOUS platform consists of many modules that act together.

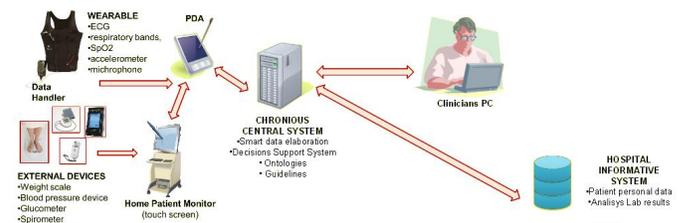


Figure 1. Chronious modules

We can organize them in three frameworks

- Patient Sensor Framework
- Communication Framework.
- Monitor Framework.

The Patient Sensor Framework consists of hardware devices used to grab data from the patients. The hardware equipments, installed at patient's home, are

- Wearable and external devices.
- Touch screen Home Patient Monitor(HPM).
- Personal Digital Assistant (PDA).

The data collected are of two types:

- silent, when the data recording is automated and it does not involve the patient interaction, as respiratory

frequency measurement for COPD patients from the wearable device

- no-silent, when it is requested a direct patient or caregiver interaction with the device, as for the blood pressure and questionnaires inputted by the HPM for diet, activity and food intake monitoring. The no-silent data acquisition is particularly important for monitoring CDK patient lifestyle.

During the day there are several measurements, with different time intervals and different frequencies; only one data transmission is done, if there is no worsening in patient parameters. For COPD patient all the data are collected in a silent mode from a wearable t-shirt and transmitted to the PDA via Bluetooth; for CDK patient all the measurements, including a lifestyle questionnaire are stored in the HPM and transmitted in silent mode to the PDA. PDA is in charge of doing the following action

- Collect all the data from the devices.
- Use a set of machine learning algorithms to determine if it is needed to force a non scheduled transmission to the Monitoring Framework.
- Transmit the collected and analysed information to the Monitoring Framework and receive back the changes, that will affect the interaction between the patient and the other devices.

The Communication Framework is in charge of transmitting data among devices and from PDA to Central DB. This transmission is done using messages in a predefined xml format. The device that is in charge of doing the transmission of the xmls is the PDA.

The Monitor framework is the principal interface between the clinician and the patient. It receives data from the remote PDAs and it transmits back the therapy for food intake, drug intake, activities and scheduled measurements. The PDA is equipped also with a rule based decision support system, that contains an updatable set of rules created from the literature and validated by clinicians.

The rule based decision support system is in charge of analysing the data arrived from the PDAs and deciding if there is a grave or mild worsening of patient's conditions. It is also able to alert the clinician and propose the suggestions about the action to do in several cases. In the next section we will analyse the preprocessing phase needed to activate the intelligence in the PDA.

III. THE PDA CHRONIOUS PREPROCESSING PHASE

As we pointed out above, the Personal Digital Assistant is a smartphone equipped with WINDOWS MOBILE 6.5 Operating system, a SQL SERVER 2005 COMPACT database and a .NET FRAMEWORK 3.5. The data registered by the PDA are the following

- Data from the wearable jacket.
- Answers to questionnaires concerning dietary habits, drug intake and lifestyle of the patient.

- Data from the home patient monitor like blood pressure, glucometer measurements and body weight.

Once these data are collected they are saved to the PDA database and a set of algorithms are triggered to analyse these data. Since the PDA analyzes data for two different diseases, two sets of different algorithms are used. The fundamental data needed by COPD treatment are ECG signals and Respiration data, so in case of a COPD patient we have a first processing Electrocardiogram Pre-processing. After that a Feature extraction phase is needed and at the end an Evaluation phase of the extracted features is done to determine if an alert must be triggered to the Central System. For external devices used in particular by CDK patients, there is no need of a preprocessing phase because fundamental measures are the ones provided by the glucometer, the weight scale and the blood pressure measure; so they are discrete time and directly used by the set of machine learning. Combined with these data, the answers to a set of queries concerning food intake, drug intake, lifestyle and mental status are passed to a set of machine learning algorithms to evaluate the whole patient condition. In next subsections we will analyse first the COPD set of algorithms used.

A. Preprocessing of COPD signals

The aim of Preprocessing Phase is to improve the general quality of the ECG, for more accurate analysis and measurement, because there's the possibility to have some noises on the signals. Possible noises in the signal include

- Low frequency Base Line Wandering (BW) caused by respiration and body movements.
- High frequency random noises caused by mains interference (50 or 60Hz).
- Muscular activity and random shifts of the ECG signal amplitude caused by poor electrode contact and body movements.

The preprocessing comprises:

- Removal of base line wandering.
- Removal of high frequency noise.
- QRS detection.

The BW which is an extraneous low-frequency activity which may interfere with the signal analysis, rendering its clinical interpretation inaccurate and misleading. Two major techniques are employed for BW removal:

- Linear filtering: involves the design of a LTI high pass filter with cut off in way that the clinical information in the ECG is preserved and the BW is removed as much as possible.
- Polynomial fitting: includes the fitting of polynomials to representative points (knots) in the ECG, with one knot for each beat. Knots are selected from a silent segment, e.g. the PQ interval. A polynomial is fitted so that it passes through every knot in a smooth fashion.

The High Frequency Noise can be caused by the high frequency as well as power supply interference from the ECG signal. It's removal is done using:

- The Daubechies (DB4) wavelet employed on the basis of the resemblance and similar frequency response characteristics of the db4 basis function with the ECG waveform.
- Using wavelets to remove noise from a signal requires identifying which components contain the noise, using optimal methods to threshold them, and then reconstructing the signal using the thresholded coefficients.

The preprocessing phase finally deals with the QRS detection. The main features that should be calculated: the Inter-beat (RR) interval and the Heart Rate Variability (variation in the beat-to-beat interval). For the Inter-beat (RR) interval, two methods have been explored

- Filtering the ECG signal with continuous (CWT) and fast wavelet[3] transforms (FWT)¹.
- Following Pan-Tompkins[4], wavelets are used to remove noise from a signal requires identifying which component or components contain the noise, using optimal methods to threshold them, and then reconstructing the signal using the thresholded coefficients².

All the previous features are extracted from ECG signals. For COPD patient also the Respiratory Rate is a fundamental parameter that need to be analysed. In order to calculate the respiration rate using the reference respiration signal, a dominant frequency detection algorithm, based on short-time Fourier transform (STFT) [5], is applied.

The STFT is a localized Fourier transform, utilizing a Hamming window:

$$STFT(f(t)) = STFT(\omega, \tau) = \int_{-\infty}^{\infty} f(t)w(t - \tau)e^{-j\omega t} dt \quad (1)$$

where $w(t)$ is the window function, commonly a Hann window or Gaussian hill centered around zero, and $f(t)$ is the signal to be transformed. Because frequency components of the respiration signal are very low (<2Hz), a window size of 60 seconds is selected. Every 60s, the hamming window is multiplied to the respiration signal, and the result is transformed to the frequency domain using Fourier transform. The dominant frequency is then detected by finding the maximum amplitude of the spectrums. When the

¹The reconstructed ECG signal after denoising contains only spikes with non-zero values at the location of QRS complexes. From this signal, the PQ junction and J point can be located as the boundaries of the spike. If the length of the spike is more or less than a predefined QRS length range it is annotated as noise and if the voltage is below a certain threshold, it is annotated as an artifact. The next stage is the detection of the T wave, and the P wave in the PQ interval. The peaks of Q, R and S waves are identified in the annotated part of the ECG signal from the PQ junction to J point.

²The algorithm includes a series of filters and methods that perform lowpass, high-pass, derivative, squaring, integration, adaptive thresholding and search procedures.

dominant frequency components are found, inverse numbers are calculated in order to obtain the respiration rate. After this first preprocessing phase for COPD patients we will now analyse the which kind of Features are extracted.

B. Features Extraction for COPD patients

From the Inter-beat (RR) interval and the Heart Rate Variability, several features can be extracted, either in time or in frequency domain.

Dealing with Time domain the values extracted are

- 1) SDNN(msec): Standard deviation of all normal RR intervals in the entire ECG recording using the following

$$sdnn = \sqrt{\frac{1}{n} \sum_{i=1}^n (NN_i - m)^2} \quad (2)$$

where NN_i is the duration of the i -th NN interval in the analyzed ECG, n is the number of all NN intervals, and m is their mean duration.

- 2) SDANM(msec): Standard deviation of the mean of the normal RR intervals for each 5 minutes period of the ECG recording.
- 3) SDNNIDX (msec): Mean of the standard deviations of all normal RR intervals for all 5 minutes segments of the ECG recording.
- 4) pNN50 (intervals that are greater than 50 msec, computed over the entire ECG recording.
- 5) r-MSSD (msec): Square root of the mean of the sum of the squares of differences between adjacent normal RR intervals over the entire ECG recording the formula is

$$rMSSD = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (NN_{i+1} - NN_i)^2} \quad (3)$$

where NN_i is the duration of the i -th NN interval in the analyzed ECG and n is the number of all NN intervals.

If we now move to the frequency domain the Feature Extraction on the PDA studies two bands:

- 1) The Low Frequency band (LF), which includes frequencies in the area [0.030.15] Hz.
- 2) The High Frequency band (HF), which includes frequencies in the area [0.150.40] Hz.

If we now move to the Respiration signal several features can be extracted either directly or indirectly we focused on:

- 1) Respiration Rate: The number of breaths per minute.
- 2) Tidal Volume (VT): The normal volume of the air inhaled after an exhalation.
- 3) Vital capacity (VC): The volume of a full expiration. This metric depends on the size of the lungs, elasticity, integrity of the airways and other parameters, therefore it is highly variable between subjects.
- 4) Residual volume (VR): The volume that remains in the lungs following maximum exhalation.

After all the preprocessing phase of the data gathered by the wearable devices, all these information are passed to a Classification System. The classification system is responsible for the analysis of the outcome from the preprocessing phase for the COPD patients and of the data gathered by the external devices and questionnaires inputted by the patient himself. Below we will see how the software is used to transform all these rich set of data in an information to be, in case, transmitted real-time or scheduled to the Monitoring Framework.

IV. THE CHRONIOUS CLASSIFICATION SYSTEM

After the collected data have been preprocessed for COPD patient and all the CKD patient input have been acquired, a set of machine learning algorithms are fired up to decide if a potentially risky situation is present. The aim of these tools is alerting the Central System that contains a rule based decision support system, for a better evaluation of the message triggered by the PDA. In case the message containing an alarm for life risk danger, the Central Decision Support System is able to alert the emergency staff or to suggest the clinician to modify the therapy approach. Most of these tools need a preprocessing phase for identifying the correct parameters that need to be validated by the clinicians. This means that in the first validation of the CHRONIOUS project a large amount of efforts has been dedicated to gather feedback from the clinicians about the correctness of the rules / parameters that have been inferred by the algorithms. In these phase another important effort has been dedicated by the technicians to evaluate some probability index for fuzzy data measures.

The CHRONIOUS Classification System is composed of the following part:

- A light rule based expert system.
- A supervised classification system.

The light rule based expert system is an xml parser that is able to extract from an xml a set of "if then" rules created and validated by the clinician. With these rules combined with the data collected, the rule base system is able to decide if a patient is in a potentially life-risk situation. For example the following rules will generate an immediate alarm to the central system:

- The Heart Rate is above 120 bpm for both COPD and CKD patient.
- If the weight increase by 2% in the last 24 hour for CDK patient .

These rules are most for alarm triggering. It means that they aren't use for light monitor alerting. In the CHRONIOUS PDA system the Supervised Classification System is composed of the following machine algorithms:

- Support Vector Machines [6]
- Random Forest [7]
- Multi-Layer Perceptron [8]

- Decision Tree [9]
- Naïve Bayes [10]
- Partial decision Trees [11]
- Bayesian Network [12]

Apart from Bayesian Network, the other algorithms have been trained with a dataset to generate a set of rule that have been validated by clinician. The Bayesian Network have been used to identified possible rules about the mental and stress evaluator of the patient. This means that once trained, the rules generate can be used to identify is some stressfull condition can alter some parameter and leading to a worsening of the general state of the patient. The use of these algorithms was needed because for the CKD patient the diet covers the most part of the medical treatment, so any factor that can influence a changement on the diet intake, would potentially and indirectly lead to a worsening of the patient condition. For example, if a female CKD patient feel sad, these condition could lead her to eat a bigger piece of pie for satisfatcion purpose. In general a bad feeling could lead chronic patients to be uncompliance with the medical treatment. However the kind of rules aren't liked the vital signs so their fuzzyness could be identified by these type of algorithms. Clearly while diet is important to avoid worsening on CDK patient conditions, on the other side the lifestyle could be and indirect cause of COKD worsening condition. Nevertheless for both of them we need static rules to have alarms sending, because for both for example having a body temperature above 38 could be a risky situation were an hospitalization is needed for both COPD and CKD patients. Considering the training dataset a set of 41 attributes have been identified. These data comes from the 2 sets of 2 hours health recordings (11 attributes), food input module (12 attributes), drug intake module (1 attribute), activity input module (2 attributes), questionnaire (13 attributes) and external device (2 attributes). Some of the results of some classifier are shown in table 1.

Table I
CLASSIFICATION SYSTEM: MAE: MEAN ABSOLUTE ERROR, RMSE: ROOT MEAN SQUARED ERROR, RAE : RELATIVE ABSOLUTE ERROR, CI: CORRECTLY/INSTANCES

Method	MAE	RMSE	RAE	CI
PART	0.1336	0.312	57.81 %	2.67
J48	0.1336	0.321	57.81 %	2.67
Forest	0.2	0.341	86.52 %	1.75
Naïve	0.127	0.343	54.95 %	2.67

Again we point out that even if there are some errors due to false positive matches, the PDA system in these case would only generate a rule that will send a message to the clinician that most of the times would only say that a light worsening is present. The core intelligence that deals with the central system would be the real suggestion system that would indicate to clinician a suggestion on how to act to possibly revert the trend. The Bayesian Network is the

fundament algorithm for the Mental support tool. It uses a set of attributes that affect a stress index and they weight based on the clinician’s feedback as shown in table of Figure 2. When the total stress indicator is above a certain value a light alarm is triggered to the Central Database to inform clinician of a potentially worsening of patient conditions. In the same way a module in the PDA is in charge of the rules concerning the lifestyle od the patient: the lifestyle tool. It collects data inputted by the patient or caregiver in a validation phase and using a Bayesian Network is able to compute an index of good or poor lifestyle of the patient also in this case if the poor lifestyle is find a light alarm is sended to the clinician for monitoring purpose.

Attribute	Different States	Probability of causing Stress (%)
Smoking	YES	90
	NO	10
Environmental Noise and rowded/Noisy places	High	70
	Medium	25
	Low	5
Hypoglycaemia	YES	85
	NO	15
Heart Rate	High	85
	Normal	15
Skin Temperature	Cool	35
	Sweat	65
Breathing asynchrony	YES	90
	NO	10
Sleep Disturbances (Questionnaires)	YES	62.5
	NO	37.5
Mood (Questionnaires)	Better	5
	Same	25
	Worst	70
Activity Comments	Feel sick, nausea	18
	Exhaustion, fatigue	23
	Discomfort in the chest, upper body, or jaw	23
	Irregular or extremely rapid heart beats	28
	None	8

Figure 2. Attributes

V. CONCLUSIONS AN IMPROVEMENTS

In these paper we presented a set of machine learning algorithms store in a smart phone that, combined with some external devices and patient inputted data, can be used for a first monitor/alert system for treatment of patient affected by chronic diseases. Dealing with telemedicine application these kind of software could help to improve patient life quality and could be also be a valid help for clinician to allow a more precise monitoring of patient conditions without need of the physical presence of the clinician. Apart these potentially advantage a PDA equipped with these kind of application can suffer of some limitations. During developing phase we face these problems:

- Heavy resource consumption of preprocessing algorithms.
- Updating a trained supervised algorithm.

The preprocessing algorithm for COPD parameter denoising is the most memory/CPU consumption. This potentially can became a problem when we deal with life risk situations, because in the time that the algorithm denoise the ECG signal, the patient can became unconscious and so precious time can be lost in these phase. Other time is losed due to the huge amount of signal trasmitted from the wereable, this because we deal with an ECG signal that is composed of a mean of ten measurements per second so this means that 5 minute of ECG signal became nearly 3000 sql commands to a SQL SERVER 2005 COMPACT that is not so performant in these case. Increasing hardware requirements of the PDA can be a first solution however it would be interesting to understand if a relational database is the best solution for storing these type of data or other structure would be more comfortable for storing purpose. The other important issue is that once the supervised learning algorithms are trained also a little change in one parameter will need to retrain the algorithms and most important, it would need a new validation of the outputs by the clinicians. These can lead to difficults when after these phase the new trained algorithms need to be updated on the pda, this because the Chronious Communication Framework is only able to transmits value from the PDA to Monitor Framework and back. In these case an interesting solution could be also to allow remote updating of the structure validated. For example a trained neural network could read the weights matrix from a structure upgradable by the communication framework. Apart from these improvements, and many others that could lead to a software system closer as much as possbile to the clinician and patient needs, it is our opinion that with the smart devices that are closer to a normal PC, the algorithms presented in this paper could become an important part of the telemedicine platforms.

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Creating a Framework for Testing Wellness Visualization Systems

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Abstract—This paper presents a methodology for creating a framework to test wellness visualization systems. The methodology is applied to our research on an agent-based wellness visualization system to create a framework for testing the wellness visualization systems we created in our research. The proposed framework employs both technical-oriented and user-oriented testing tools and methods in the measurement. A comprehensive testing plan is also provided.

Keywords—system testing; testing methodology; wellness visualization system; information visualization

I. INTRODUCTION

An agent-based wellness visualization system has been previously proposed in [1-2] as an alternative solution to help an individual to learn, to monitor, and consequently to promote a personal state of wellbeing; it also designed to support a caregiver's tasks. An operational wellness model was then created as a basis for developing a wellness visualization system [2]. The operational wellness model designed for the agent-based wellness visualization system has been presented and peer reviewed in [2]. In order to ensure that the agent-based wellness visualization system meets all of the research goals, is usable, and can be compared to other published results; an effective evaluation method is required.

Since a wellness visualization system is constructed from the knowledge of various fields, employing techniques in software testing alone is not sufficient. Software testing can verify that the software system works as expected and can provide benchmarking results in term of software quality [6], but it cannot evaluate a wellness visualization system in term of usefulness, impression, satisfaction, etc. E-health system evaluation criteria are also available to employ, e.g. [8-9], but they do not specifically focus on the main objectives and goals of a wellness visualization system. Thus, it is important to find a testing method that covers all possible areas of wellness visualization system, can be repeated, and its results are comparable.

In this research, the methodology for creating a framework for testing wellness visualization systems derives from the Goal-Question-Metric (GQM) approach [6-7]. The framework in this research is developed by combining the testing tools and methods used in software testing, usability testing, and techniques for finding an impact on a user's impression toward the system together. As a result, a

wellness visualization system can be measured from different aspects. It is also possible to compare different wellness visualization systems adopting this framework.

This paper is organized as follows. Section II describes the methodology for creating the framework. Framework creation and a comprehensive testing plan are given in Section III. Conclusion and future work are given in the last section.

II. METHODOLOGY

A. What should be measured?

In order to list what is needed to be measured, the definition and the generic goals of wellness visualization systems have to be identified.

A wellness visualization system is a software system and an information visualization system that can communicate wellness information by employing graphical presentations. Information visualization is the use of computer-support, interactive, and visual presentations of abstract data to amplify cognition; where cognition is the acquisition or use of knowledge [3].

Based on the definition, it is obvious that the quality of the software product is to be measured to ensure that the software system works as expected and meets technical requirements. Moreover, the main functionality of a wellness visualization system is to communicate wellness information that can promote cognition. In order to ensure that the system can present key information effectively, the visual presentations must be usable. They should create a good impression and should not engender frustration. Thus, usability testing is required. Both desirable and undesirable effects caused by a wellness visualization system also have to be identified.

Software testing involves the verification and validation of a software system and of the functionalities provided by the system [6]. In case of usability testing, a wellness visualization system is usable when it is useful, efficient, effective, satisfying, learnable, and accessible [4]. Also, it should be easy to use to eliminate frustration and even create a positive impression on users. In summary, the aspects that should be tested are *system verification, system validation, verification of system's functionalities, validation of system's functionalities, usability of the*

Graphical User Interface (GUI) and graphical presentations, accessibility, and impression.

The aspects given above are created for the general definition and generic goals of a wellness visualization system. More aspects can be added to measure additional properties and goals of a particular wellness visualization system.

B. Procedure

When measuring something, a goal is needed as a reference point of achievement and also a reference point for failure. Thus, testing goals must be set up before a testing session is started. Testing goals should be linked to research goals because research goals represent what the research is trying to achieve.

The following steps are the main activities of this framework:

- Step 1 – Clarify research goals and link the goals to the testing aspects
- Step 2 – Form testing goals regarding the research goals and the aspects
- Step 3 – Select testing tools/methods for each testing goal
- Step 4 – Set up a testing plan
- Step 5 – Conduct a test as planned

C. Testing Tools/Methods

A variety of tools and methods can be employed to test a wellness visualization system because they are constructed for different purposes. Since a wellness visualization system involves both technical requirements and users' requirements, testing tools and methods from both sides should be employed.

As a result, the testing tools and methods used in this framework can be divided into two categories: technical-oriented and user-oriented testing tools/methods. Technical-oriented testing tools/methods focus on benchmarking and technical requirements, for example, error rate and start-up time. User-oriented testing tools/methods focus on subjective data such as feeling, impression, and satisfaction of a user toward a wellness visualization system.

III. FRAMEWORK CREATION

This section uses our research on the agent-based wellness visualization system as an example of how to employ the framework to test a wellness visualization system.

A. Research Questions

A state of wellbeing is definitely desirable at both personal and the public levels [1-2]. Many efforts are required to achieve the desirable wellness level [1-2]. Our research intends to assist a person to have the best possible state of physical wellbeing by employing existing technologies and electronic resources [1-2]. All research questions are listed as follows:

- How can we communicate wellness information to persons who do not have any specific level of medical knowledge, by using existing technologies and electronic resources?
- How can we assist people in having a better understanding of their wellness status based on the information from electronic resources?
- How can we assist people to keep track of their state of well-being and consequently improve their personal wellness status?
- While assisting someone, how can we assist the tasks of that person's caregiver?

B. Research Hypothesis

After analyzing the research questions, our research hypothesis is formed as follows:

"An information visualization system containing appropriate graphical presentations for wellness information and supporting tools can answer all of the research questions given above."

C. Research Goals

1. To develop an agent-based wellness visualization system that can support both general users and healthcare professional users.
2. To develop an information visualization system containing appropriate graphical presentations that can communicate wellness information effectively to both general and healthcare professional users.
3. To develop an information visualization system that can assist an individual to track on his/her wellness status and encourage the person to improve the state of wellbeing.
4. To develop an information visualization system that can support a caregiver's tasks.
5. To develop an information visualization system that has simplicity, understandability, expandability, and modularity characteristics.

D. Testing Goals

One research goal involves with one or more testing aspects. One testing aspect can form more than one testing goals; this depends on a number of sub-goals (regarding the testing aspect) lies within each research goal.

If a testing goal is derived from a users' requirement, then a relevant user-oriented testing tool/method is selected. On the other hand, if a testing goal is relevant to a technical requirement, then a technical-oriented testing tool/method is employed. More details about each testing tool/method will be described in the next subsection.

Table I presents the testing goals as well as the relationships among research goals, testing aspects, testing goals, and testing tools/methods. The highlighted testing goals are relevant to the users' requirements and the un-highlighted testing goals are relative to the technical requirements. The highlighted testing tools/methods are in

the user-oriented testing tools/methods category and the un-highlighted testing tools/methods are in the technical-oriented category.

E. Testing Tools/Methods Description

The followings are the description of each testing tool/method presented in Table I.

1) *Questionnaire*: a data collection tool that can collect subjective data and get opinions from the participants [4]. In this research, two different sets of questionnaires will be used. One is created for a general user. Another one is created for a healthcare professional user. During a testing session, all activities will be recorded in video, audio, or both formats if the permission from a participant is granted. A participant might be contacted after the testing session is over for an interview or to clarify the information that is filled in the questionnaire.

2) *Error rate*: a number of errors each participant encounters during a task divided by time spent on the task (in minute). The average error rate will be compared to the acceptable error rate from literature. The description of each error will also be collected for future improvement.

3) *Unit testing*: is performed during the implementation phase of the research to verify that each unit of the system works correctly as expected. The results of each unit of the visualization system are evaluated against the design and research goals.

4) *Integration testing*: is performed regularly to confirm that a group of software units works correctly as designed.

5) *Comparative method*: compares the results generated by two or more activities against each other. In this case, the comparative method is performed differently regarding the testing goals and the types of users. The three different comparative approaches presented in Table I are:

Comparative method (1) – the results generated by the wellness visualization system will be compared with reliable external sources to confirm their validity.

Comparative method (2) – a raw data set and a set of questions will be given to a general user to answer. Then, the participant will be asked to use the wellness visualization system to answer the same set of questions. The results from both set of answers will be compared.

Comparative method (3) – healthcare professional users will be divided into two groups. The first group will receive a raw dataset and a set of questions. The time the first group spent on answering the questions will be recorded. The second group will use the wellness visualization system to answer the same set of questions. The time the second group spent on answering the questions is also recorded. Both the recorded time and the answers produced by the two groups of participants will be compared.

6) *Exploratory study*: is created to find the “unknown”; in this case, the unknown is an impression on the wellness

visualization system. It can be both desirable and undesirable effects left on a user after using the system. Examples of the effects in questions are “Does the wellness visualization system make you feel like learning more about your personal state of well-being and how to improve it?” and “Does the wellness visualization system make you feel stress or too worried about your wellness status when you see the overall wellness level moved down?”. An exploratory study is performed by employing a questionnaire and conducting an interview.

7) *Peer review*: gets opinions and acceptance from experts in the field.

8) *System Architecture Analysis*: employs the structure, characteristics, and properties of the system as a proof against the testing goals.

F. Testing Plan

The testing process in this research is divided into three phases: preparation phase, testing sessions, and analysis phase. The activities in the test process will be performed according to the recommendation in [4-5].

In the preparation phase, all materials needed, e.g., questionnaires and orientation scripts, will be prepared. A number of volunteers will be recruited, categorized by user type, and divided into groups of 3-4 people, as this is an appropriate number of participants per testing session [5]. The subsequent activities are making appointments with every group and setting up the testing environment.

During each testing session, an introduction and a set of guidelines will be presented to the participants [4-5]. Some background information will be collected, followed by testing tasks. Making observations and note taking during the phase is a must [4-5]. A checklist will be employed before closing each testing session to ensure that everything is covered [4-5].

In the last phase, the collected data must be compiled, summarized, and analyzed [4-5]. Then, the results will be employed to create a testing report, and the conclusion and future plan of this research.

TABLE I. RELATIONSHIPS AMONG RESEARCH GOALS, TESTING ASPECTS, TESTING GOALS, AND TESTING TOOLS/METHODS

Research Goals No. ^a	Aspects of	Testing Goals ^b	Testing Tools and Methods ^c
1	System Verification	1. To verify that the functionalities provided by the wellness visualization system meet the expectation and needs of both types of users	Questionnaire
		2. To verify that the functionalities provided by the wellness visualization system work correctly and effectively from the users' viewpoints	
		3. To verify that the functionalities provided by the wellness visualization system work correctly and effectively as planned and designed	Error rate Unit testing Integration testing
	System Validation	1. To confirm that the agent-based wellness visualization system is satisfying and delightful to use	Questionnaire
		2. To confirm that the functionalities and information provided by the visualization system can support both types of users	
		3. To confirm that the information provided the wellness visualization system is valid	Comparative method (1)
Impression	To find both desirable and undesirable effects on users, e.g., impression and stressful	Exploratory study Questionnaire	
2	Usability of the GUI ^d	To verify that the wellness visualization system is usable in term of usefulness, efficiency, effectiveness, learn-ability, satisfaction [4], and ease of use/simplicity	Questionnaire
	Usability of the Operational Wellness Model	1. To verify that the model is acceptable to be used by the experts in the field	Peer review
		2. The results produced by the model are easy to understand	Questionnaire/Comparative method (1)
		To verify that: 1. the model has the ability to produce the wellness status of a person 2. the model is computable 3. the results produced by the model can be presented in graphical formats	Unit testing
	Accessibility ^e	1. To verify that a user has the ability to access to the visualization system through a desktop within an acceptable time frame	Questionnaire
		2. To verify that a user has the ability to access to visualization through a mobile device within an acceptable time frame	
	Appropriate graphical presentations (that can communicate wellness information effectively)	1. To confirm that the graphical presentations are easy to understand and simple, i.e. a user can perceive some information correctly without any explanation	Comparative method (2) Questionnaire
		2. To confirm that the graphical presentations have the ability to communicate certain information	Questionnaire
		3. Learn-ability, i.e. a user can perceive more information or have an insight after a period of training/using the system	Questionnaire
3	Verification of the following functionalities: - Viewing current wellness information - Viewing history information - Finding alerts with relevant description, suggestion, and links to external sources - Exploring more about personal wellness status by employing analytical tools provided by the visualization system - Recording and reporting short complaints to authorized caregivers	1. To verify that each functionality meets the expectation and needs of a general user	Questionnaire
		2. To verify that each functionality works correctly and effectively from the general user's point of view	
		3. To verify that the each functionality work correctly and effectively as planned and designed	Error rate Unit testing

	<ul style="list-style-type: none"> - Creating personal indicators - Choosing viewing mode, i.e. regular and advance modes - Performing general setting 		Integration testing	
	<p>Validation of the following functionalities:</p> <ul style="list-style-type: none"> - Viewing current wellness information - Viewing history information - Finding alerts with relevant description, suggestion, and links to external sources - Exploring more about personal wellness status by employing analytical tools provided by the visualization system - Recording and reporting short complaints to authorized caregivers - Creating personal indicators - Choosing viewing mode, i.e. regular and advance modes - Performing general setting 	<p>1. To verify that each functionality is satisfying and delightful to use by a general user</p>	Questionnaire	
	<ul style="list-style-type: none"> - Recording and reporting short complaints to authorized caregivers - Creating personal indicators - Choosing viewing mode, i.e. regular and advance modes - Performing general setting 	<p>2. To confirm that the results generated by each function is valid</p>	Comparative method (1)	
	<p>Impression</p>	<p>1. To verify that the visualization system can encourage a person to be more aware about his/her wellness status and that of the public</p> <p>2. To verify that a person feels more confidence in realizing and learning about his/her own state of wellbeing from the visualization than from raw data and other sources, e.g., internet and pamphlets</p>	Questionnaire	
4	<p>Verification of the following functionalities:</p> <ul style="list-style-type: none"> - Viewing current wellness information of each patient under care - Viewing history information of each patient under care - Finding alerts with relevant description, suggestion, and links to external sources generated for each patient under care - Performing further analysis by employing analytical tools provided by the visualization system - Recording and reporting short notes to each patient - Defining indicators for each patient - Setting weight for each indicator for a patient - Performing general setting 	<p>1. To verify that each functionality meets the expectation and needs of a healthcare professional user</p>	Questionnaire	
		<p>2. To verify that that each functionality works correctly and effectively from a healthcare professional user's point of view</p>	Error rate	
		<p>3. To verify that the each functionality works correctly and effectively as planned and designed</p>	Unit testing	
			Integration testing	
		<p>Validation of the following functionalities:</p> <ul style="list-style-type: none"> - Viewing current wellness information of each patient under care - Viewing history information of each patient under care - Finding alerts with relevant description, suggestion, and links to external sources generated for each patient under care - Performing further analysis by employing analytical tools provided by the visualization system - Recording and reporting short notes to each patient - Defining indicators for each patient - Setting weight for each indicator for a patient - Performing general setting 	<p>1. To verify that each functionality is satisfying and delightful to use by a healthcare professional user</p>	Questionnaire
		<ul style="list-style-type: none"> - Recording and reporting short notes to each patient - Defining indicators for each patient - Setting weight for each indicator for a patient - Performing general setting 	<p>2. To confirm that the results generated by each function is valid</p>	Comparative method (1)
	<p>Supporting a caregiver's tasks</p>	<p>To verify that the wellness visualization system can support a caregiver's tasks</p>	Comparative method (3)	
5	<p>Simplicity</p>	<p>To verify that the wellness visualization system has the simplicity characteristic</p>	Questionnaire	
	<p>Understandability</p>	<p>To verify that the wellness visualization system has the understandability characteristic</p>	Questionnaire	

	Expandability	To verify that the agent-based wellness visualization system is expandable	System architecture analysis
	Modularity	To verify that the wellness visualization system is modular	System architecture analysis

a. Refer to Section III, C for details.

b. The highlighted sections are relative to the users' requirements and the un-highlighted sections are relative to the technical requirements.

c. The highlighted sections are in the user-oriented category and the un-highlighted sections are in the technical-oriented category.

d. Measuring what makes the GUI usable [4].

e. Measuring the ability to access the agent-based wellness visualization system to accomplish a task, not what makes the system usable for people with a disability [4].

IV. CONCLUSION AND FUTURE WORK

A wellness visualization system is constructed by employing the knowledge from various fields such as wellness, information visualization, software engineering, human-computer interaction (HCI), art, and many other sources. Thus, a methodology for measuring a wellness visualization system in all possible aspects is required to evaluate the performance of the system and to compare it with other wellness visualization systems.

We have presented a methodology for creating a framework for testing wellness visualization systems. The method is applied to our research on the agent-based wellness visualization system to create a framework which forms a reference for testing our wellness visualization system and can be applied to other research in the same area.

Currently, the framework leads us to a comprehensive testing plan. This plan will be expanded further and refined for more details. Then, it will be implemented to measure our agent-based wellness visualization system [1-2].

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Large-scale eHealth Systems:

Providing Information to Support Evidence-based Management

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Abstract—This article describes lessons from a large scale eHealth system implementation in Finland from the viewpoint of evidence-based management. All European Union member states have a documented policy on eHealth. A quick literature review showed that documented evidence-based management strategies for large-scale eHealth system implementation are rare. The Finnish framework for providing formative and summative evidence for the national eHealth system implementation was generated guided by some other large scale IS assessment frameworks, especially the Canadian approach. First results of the framework's implementation for collecting baseline data are presented together with a plan to use the data for decision making in the national eHealth system development. The main outputs of the paper are 1) the categories of evidence collected in Finland to support decisions in the national eHealth system implementation and follow-up, 2) demonstration of use of these categories in providing results from the baseline situation.

Keywords - Medical informatics; eHealth Policy; electronic patient record system; evidence based management; evaluation

I. INTRODUCTION

Evidence-based management (EBMgt) is an emerging management strategy, where the current, best evidence is sought for management decision-making. In evidence-based medicine (EBM) the idea is defined as: "*The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*" [1]. This definition has been modified for management by leaving the object of decision open. The idea of EBMgt is relevant particularly to large and complex systems like the national health systems [2].

We argue that a National Health Information System (NHIS) is also a complex system in itself. The Finnish NHIS with its elements and network of actors has been described elsewhere [3-4]. Legacy systems and regional systems with interfaces to the national archive and prescription database form an important element in the NHIS. The core system consists of a comprehensive electronic patient records including narrative text as well as

summary and administrative data. This is augmented with integrated picture archiving and communicating systems (PACS) and electronic laboratory systems. Even though registry keepers are legally separate entities, patient data is shared on a secure manner with electronic referral and discharge letters and regional databases. Already today, much of this data is available regionally, and shared between primary and secondary care electronically following the care chain of the patient [5, 10-13]. Added with a national archive, ePrescription and eViewing system to be implemented by 2015, the NHIS fits well with characteristics of complex systems with many interconnected human and non-human components, which may interact unpredictably. It has a structure, defined by parts and their composition, behavior, which involves inputs, processing and outputs of material, energy and information (or data). It also has interconnectivity: the various parts of a system have functional as well as structural relationships between each other. Change in one of the components can have an impact on some or most of the other elements.

The evolving Health Care Information and Communication Technology Systems (eHealth Systems) need to project the features of evolving health care delivery systems. For example in Finland new legislation on health care service contents and organizational structures is being issued during the NHIS development. Decisions regarding the development of one complex system (NHIS) and its integrating in order to function as part of another evolving complex system (the National Health System) would undoubtedly benefit from current evidence.

Section II describes the state of the art of EBMgt in the context of NHIS implementation, shortcomings of it and how this study aims to contribute to EBMgt in NHIS implementation. Section III describes the materials and methods used in this study. Section IV elaborates the previously published assessment framework by defining data dimensions, categories and measures used in baseline data collection, as well as first results of the baseline

situation from the viewpoint of one of the key actor groups: the doctors. Section V discusses use of the results, their shortcomings and future work needed.

II. STATE OF THE ART IN NHIS EBMGT

In European countries there has been considerable progress in both eHealth policy and deployment in the past years. By the end of 2006, 25 of the 27 European Union (EU) Member States and the four other European countries represented in the i2010 Subgroup on eHealth had a documented policy on eHealth [6]. In relation to the vigorous development of eHealth programs in different countries, national follow up and evaluation policies of these programs have emerged slowly [7].

The idea of basing decisions on evidence is embedded e.g., in the framework of health technology assessment (HTA). National HTA programs review and advice on adoption of new health care interventions. Telemedicine interventions have been assessed in this context, but complex national scale information systems are basically beyond the scope of (traditional) HTA focusing on single technologies.

In Finland, a national framework was constructed in 2009 for providing national level information to support implementation of the NHIS and monitor its success [3-4], with review of HTA information categories [8]. A quick literature review was conducted as part of the work in early 2009, where UK, Canada and Australia were found to have documented national evaluation frameworks, which were included in the review. Most EU Member States are now becoming aware that there is an urgent need for (continuous) evaluation activities, both to better control policy progress and learn from challenges and experiences [9], but documented comprehensive frameworks defining the needed information for EBMgt in different stages of NHIS implementation are still few.

The study questions are: 1) What kind of information is needed for EBMgt and monitoring success of NHIS? 2) What results can be obtained by collecting this information by a nation-wide questionnaire? 3) How can the results be used for concrete EBMgt of NHIS implementation?

III. MATERIALS AND METHODS

The materials and methods for creating an overall evaluation framework have been published elsewhere [3-4]. One set of data within it - diffusion and use of eHealth systems - has been collected in Finland three times [5, 10-13]. The study does not cover other aspects of system success defined in the overall framework. A complementary dataset was compiled in collaboration with the Finnish Medical Association, National Institute for Health and Welfare (THL), Aalto University (Usability experts) and University of Oulu/ FinnTelemedicum (impact assessment experts) using conceptual models described in Section IV. The first data collection was targeted at baseline prior to NHIS implementation focusing on the viewpoint of doctors.

An electronic survey method with 5-point Likert scale questions was used. For the results, points 1-2 were combined to form category 'disagree', and 4-5 to category 'agree'. The Web-survey, conducted in early 2010, was targeted to all 14 411 doctors of working age in the Finnish Medical Association register, actively engaged in clinical work. Responses were received from 3 929 doctors. Respondents' age, gender and working sector distribution were compared to those of the target group. Women responded slightly more actively than men, younger slightly less than older. Distributions of working sector were identical. The respondents were thus regarded as forming a representative sample of the target group [14].

The respondents were asked to reply to questions from the viewpoint of the system they mainly use and the context where they mostly work. In the initial analysis, data categories defining the organization type (public inpatient vs. outpatient) and the legacy systems used were regarded as the first background variables against which the system success was viewed. The first results including cross tabulations depicting co-variation between the system success variables and varying legacy systems used in different contexts have been published in the Finnish Medical Journal [14, 15].

The 're-conceptualization' of the questions was needed to detect possibilities for creating sum variables as well as identifying categories, which require the collection of stronger evidence. It also helps in defining such indicators, which can be used to monitor (NH)IS success in a context and to detect interactions between the social and technical system elements. Two researchers first individually grouped the questions with the framework elements. An agreement was gained in a joint meeting, after which comments from others from the team were searched.

IV. RESULTS

Two main results are described in this section: Subsection A depicts the dimensions, categories and measures of evidence of NHIS success. Subsection B depicts the deployment of them in a national level questionnaire and consequent results.

A. *Combining three models for definition of assessment dimensions, categories and measures*

Complex systems are composed of many interconnected elements. The concept of network was thus used as a general concept depicting the entity of NHIS. Nodes of the network have been conceptualized with help of a *model of an activity system* used in activity-theoretical analyses of information systems, especially in the field of Computer Supported Cooperative Work (CSCW). Karasti et al. have investigated collaborative work in a telemedicine setting and noticed that molding two different organizations together with health ICT tools requires rethinking of the attributes that support actual patient work [16, 17]. Actor network theory and activity theory have been used as theoretical

basis for a conceptual framework in assessment of the contexts of IS use and co-construction of social and technical systems [e.g., 18]. The framework sees the evolving NHIS elements as tools for the evolving social system (the National Health System). Inherent in the model of an activity system is its open nature and evolution.

Model of an activity system as a node in the network depicts the elements of the context of NHIS use, and their interaction. With the help of the model, the contextual variables depicting the health care system - as well as those interrelated systems that provide e.g., norms for the health care activity - can be grouped into the following dimensions and categories:

- (network of) health care service users, providers and regulators (affected activity systems, nodes of network)
- Activity system (node of the network) consisting of:
 - inputs: actors (user characteristics), tools and resources, rules, environment, objects->objectives,
 - processes: combining the inputs, division of work
 - outcomes => impacts

Dimensions of *the IS system success model* [19, 20] fit within the model of activity system, helping to focus on the quality of the Information Systems as tools for an activity system (care providing organization). The elements of the model are:

- System quality
- Information quality
- Service quality
- Use
- User satisfaction
- Net benefits: quality, access, productivity

Dimension 'use' is an attribute of the activity system element 'processes'. Dimension of 'net benefits' is an attribute of 'outcomes' of the activity system that can be impacted by the NHIS. For defining these, the impact mechanisms of each element of the NHIS need to be known.

These dimensions and data categories were used to provide questions regarding the (baseline) NHIS success in context, against which post-implementation situation can be compared. They also help specifying the needs for development as problems detected in certain categories of the data. The elements in the two models thus provide data for both monitoring the NHIS success (summative evaluation) as well as for learning for the development.

The *model for human-centered design of interactive systems* [21] depicts phases of developing new tools for the activity system. The model has consequent elements interacting in iterative cycles that can be used as checkpoints for collecting evidence for management of the development (learning and system development):

- The plan and management of the HCD process
- Understanding & specification of the context of use
- Specification of the stakeholder and organizational requirements
- Producing design solutions to meet requirements

- Evaluation of designs against requirements (iterating with previous phase where appropriate)
- Introducing the system that meets user requirements

'Understanding the context of use' and 'specification of the stakeholder and organizational requirements' refer to information produced in the Activity and IS success models.

The original IS system success model has been criticized for not taking into account contextual and business process-aspects [22]. Suggestions to add contextual elements have included addition of meso-level categories of 'people', 'organization' and 'implementation' and macro-level categories of 'standards', 'legislation, policy and governance', 'funding' and 'societal, political and economic trends' [23]. The Finnish framework contains macro-level elements as interrelations between the activity systems in the network (e.g., norm- or funds-providers and health care providers) and meso-level categories within each activity system. The added value of the theory-based conceptual model used in the Finnish framework is depicting the interrelations of the contextual elements on macro-, meso- and micro-level and IS system elements. It sets the IS system as part of this socio-technical system as a whole. The detailed categories and measures for context and success variables are presented in Table II in annex 1.

B. NHIS success (Baseline): doctors' views

There were 919 replies from public outpatient units/health centers. 63 % of respondents were women, 37 % men. Average age was 48 years (from 24 to 64 yrs). Almost half of the respondents (48 %) were from units using system 'A' as the legacy system. Over third used system 'B' (39 %), 5 % used system 'C', and 5% used system 'D' (5 %). The rest used several other systems. Three out of four respondents had over 3 years experience in using the respective legacy system, and only 3% were novice users (less than 6 mths experience). [14]

Big differences in the baseline situation were detected between the two contexts (public sector outpatient units and hospitals) [14-15]. Results of the private sector have not yet been processed. Table I presents results within public outpatient units. There are differences between IS success variables as well as legacy systems used. Some of the IS system quality variables got poor scores from users of all systems, e.g., response time and IS compatibility, some better (e.g., error rate). Availability of radiology results and content of laboratory results (information quality variables) scored relatively well across legacy systems, availability of patient information from other organizations, including medication information and summary view got poor scores. IS system support for collaboration between workers within organizations scored better than collaboration between organizations (outcome variables). Major differences between the legacy systems were identified in ease of use, decision support systems, content of nursing record, medication list, prevention of medication errors and help in achieving health outcomes.

TABLE I. CO-VARIATION BETWEEN IS SUCCESS VARIABLES AND LEGACY SYSTEMS USED IN PUBLIC HEALTH CENTRES: BASELINE SITUATION [15]. RED =VERY STRONG (≥ 75 % OF RESPONDENTS), PINK = RELATIVELY STRONG (50 - 74 % OF RESPONDENTS) AGREEMENT OF A PROBLEM. LIGHT GREEN = RELATIVELY STRONG (50 – 74 % OF RESPONDENTS), DARK GREEN = VERY STRONG (≥ 75 % RESPONDENTS) AGREEMENT OF SUCCESS. ALL DIFFERENCES ARE STATISTICALLY SIGNIFICANT (P<0,05)

Information system			A'		B'		C'		D'		
Dimension	Category	Measure	N	Disagree %	Agree %	Disagree %	Agree %	Disagree %	Agree %	Disagree %	Agree %
System quality	Stability [31] Reliability [32][34][17]	The information system I use as a tool in my work are reliable and stable	914	34	55	38	49	18	66	11	77
		Response time [31][34][17] Efficient to use [32]	912	25	58	56	28	22	62	16	77
	Ease of use [31][17]	Compilation of statistics takes too much time	903	25	58	16	67	24	56	13	60
		Fields and functions in windows are logically placed	907	22	60	60	20	30	54	33	62
		Searching, documenting, checking and editing patient information is easy	913	41	36	70	15	46	48	45	36
		The information system tells me clearly what is going on and the outcome (e.g. saving of data)	914	25	55	49	30	38	40	32	45
		Terminology (e.g. headings) is clear and understandable	910	17	65	42	39	14	57	30	61
		The system process model is stiff and does not fit to my work process.	908	29	49	10	76	36	42	24	57
		Performing routine tasks is simple and can be done without too many 'clicks'.	915	39	47	71	16	26	64	32	55
	Easy to learn [32][17]	Information system use logic is easy to learn	914	12	74	56	28	16	60	18	66
		Use of the system does not require long training	915	29	50	62	17	30	46	27	48
		System errors[31] Few errors [32] Error rate [17]	912	51	29	53	26	58	28	51	23
	Compatibility [32] Integration of systems [17]	It takes too long time to sign in to use the systems	912	20	66	10	81	24	62	2	91
		Type of features and level of decision support [34] Usefulness of specific functions, DSS [17]	906	46	30	46	26	30	42	73	9
	Usefulness of specific functions			Functions listed in questionnaire, respondents selected best and worst functioning							
Service quality	Responsiveness [34], User training, technical support [34]	I get enough help in problems related to information systems use	912	23	55	34	44	28	66	16	63
		Big portion of my working time is spent solving the problems with information technology	911	40	33	27	48	56	24	30	52
Information quality	Availability [33], Accessibility (distance, availability)[34][17]	Radiology results are easily available	907	28	63	34	52	24	53	28	56
		Information about medication prescribed in other organizations is easily available	902	83	6	92	4	86	8	86	7
		Accessing patient information from other organizations takes too much time	905	22	67	12	82	14	84	16	82
	Content quality [33], Completeness, accuracy, relevance, comprehension, consistency [34][17], precision, currency, timeliness, reliability, completeness, format [17]	Laboratory results are presented in a logical format	908	22	66	20	66	36	54	34	57
		Patient data (also from other organizations) is comprehensive, timely and reliable	901	40	37	59	19	52	28	50	20
		Information system provides a summary view about the situation of the patient	559	70	15	82	8	50	32	60	27
		Nursing record content is easy to read	888	39	43	63	24	38	44	48	41
		Patient's medication list is clearly presented	897	58	27	57	28	42	52	35	49
User satisfaction	Satisfaction [34]		7,1		6,2		6,9		6,9		
Use	System usage	Frequency, duration, location, type and flexibility of usage [34]	Measured in a separate survey								
Net benefits/outcomes	Productivity: Efficiency of care (resource utilization, output improvements, management improvements, effects on patient flow [34])	The Information systems help reduce duplicate tests.	911	50	37	49	38	37	47	57	32
		Quality of care [34]: Appropriateness effectiveness (Adherence to guidelines, continuity of care [34] Health outcomes [34])	914	26	49	31	43	28	48	32	43
	Quality of care [34]: Patient safety (preventable adverse events, near errors, reduction in patient risks)[34]	Information systems help improve health outcomes	910	25	40	34	32	22	54	30	48
		The system has caused or nearly caused a serious adverse event to a patient	902	45	25	39	32	48	30	31	36
	Care coordination (doctor-nurses) [34]	The Information systems help prevent medication errors	905	39	44	32	48	25	67	70	18
		The system monitors reception of orders I have given to nurses.	533	81	5	74	4	63	13	79	8
	Care coordination (doctor-doctor within organisation) [34]	System supports flow of information between doctors and nurses	908	17	62	25	50	14	66	23	56
		System supports flow of information between doctors in same organisation	916	10	75	19	63	14	74	11	73
	Care coordination (doctor-doctor between organizations) [34]	System supports flow of information between doctors in different organizations	910	62	19	78	8	60	20	77	14
	Care coordination (doctor-patients) [34]	System supports flow of information between doctors and patients	897	59	10	61	7	58	12	62	5
Patient-centeredness of care	The information systems use requires too much attention away from the patient	913	24	62	14	73	36	52	18	77	
Support for development of own work[31]	The information systems support development of my work	906	46	25	65	13	37	37	49	23	

V. CONCLUSIONS

The study offers for the first time a nationwide snapshot of success of the IS tools for patient care. The results show that the view of the doctors is relatively critical. The IS systems are regarded too slow, partly unreliable, not offering the type of information (e.g., summaries) needed, and they may even create patient safety problems. Similar results have been received from other studies [8, 24-27]. User experiences need to be better incorporated into IS development [8]. Results like the urgent need for summary data, comprehensive medication list and easier access to patient information across organizations can directly be used when making strategic decisions about trade-offs in NHIS implementation. The differences between legacy systems provide important benchmarking data for the vendors.

Establishment of an operational steering unit for NHIS development and implementation within THL in the beginning of 2011 paves way for integration of the evaluation framework as part of the EBMgt strategy of the NHIS implementation. The unit will use results of the study as one means in setting priorities for action.

There are several limitations in the study in respect of evidence required from the baseline situation for NHIS development, which need further work or consideration. ICT support needed by physicians' out-patient consultations is used as an example for the model use. Other set ups are needed for identifying critical elements in different processes such as chronic care or surgical theaters or emergency care settings.

Legacy systems form only one element in a complex NHIS, and doctors are only one user group impacted by the implementation of the NHIS. Reply rate (27%) was low even though sample was representative. The proportion of neutral ('3') responses was not reported.

Questionnaire-based studies offer a relatively comprehensive but shallow view to the phenomenon studied. Even though doctors were involved in formulating the questions, the method is prone to different interpretations of questions, and complementary methods are required for more detailed information on issues that are identified in a survey. Analysis of the data needs to be continued by comparisons between contexts as well as co-variation of different contextual variables with the success factors.

Further research is also needed regarding formulation of the measures in order to capture the potential impacts in varying clinical processes in a language that is meaningful to the doctors and at the same time true to the framework. The 24 questions used in the Canadian framework [22] were not regarded sufficient to reflect the different impact mechanisms of different elements in the NHIS for doctor consultations, where the clinical work processes were taken as the starting point for the questionnaire (to speak the doctors' language).

Re-conceptualization of the questions revealed several variables, which could be used to create sum variables. There are also variables, for which there is data available in national level statistics (especially for actor- and patient- as well as outcome-variables). Further research is required to achieve the long term aim of condensing the data and combining it to such indicators, which can be used to monitor (NH)IS success in varying contexts and processes and to detect interactions between the elements of social and technical systems.

Variation of the elements and conceptual frameworks in international studies makes it difficult to sum up previous experiences [28]. According to literature reviews [e.g., 29] many theoretical models exist for measuring IS success, and most of the studies only employ a subset of proposed dimensions, the relevance of which is still debated [30]. The indicator work that has started in Finland would greatly benefit from at least some level of international agreement on the 'minimum data set' for (NH)IS success and contextual variables in order to collect data that can be used also for international comparisons, as suggested in Medinfo 2010 panel on 'Monitoring the effects of health information systems' by the Danish, Canadian and Norwegian colleagues.

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TABLE II. DIMENSIONS, CATEGORIES AND MEASURES FOR IS SUCCESS IN CONTEXT. THE DARK FRAME DEPICTS THE IS SUCCESS MODEL DIMENSIONS AND MEASURES (DETERMINANTS OF THE IS SYSTEM) AS A TOOL WITHIN THE CONTEXT - THE SOCIOTECHNICAL SYSTEM - DIMENSIONS AND MEASURES (DETERMINANTS OF THE HEALTH CARE SYSTEM)

Dimension	Category	Suggested measure	Questions in questionnaire
Network of affected activity systems	Organizations, stakeholders	Network analysis with Organizational/ stakeholder characteristics	-
		Roles of and division of work of different organizations/ activity systems in the use network of (NH)IS	-
Activity system (organizations as "nodes" in the network)	Objects and objectives of activity system	<i>From the viewpoint of health care providing systems: The diagnosis related groups treated, short and long term objectives targeted</i>	<i>(from statistics)</i>
	Actors	Affected professional groups, client groups within each activity system, where NHIS is implemented: Age, gender, education, attitude towards information technology, experience with patient information system use	Age, gender, specialty, phase of residency, title, IS attitudes (3q:s), IS experience (3 q:s)
	Rules	Written and non-written "codes of conducts", norms, rules, strategies in relation to IS use	-
	Organization	The determinants of the physical environment of respondents that can impact (NH)IS adoption (including type of patients, occupancy rate, Diagnosis Related Groups (DRG) weight)	Hospital district, sector (public/private), type of unit (tertiary-secondary-primary inpatient/outpatient)
		Organizational culture	Decision making (7 q:s) participation possibilities (3 q.s), stress (3 q:s)
	Tools	Existing (health information processing) tools that actors have at their disposal to work towards the objectives (legacy systems, regional health information systems)	IS tools in use (4 q:s)
	Processes	Information system quality	Functionalities (5 q:s), reliability, response time, interoperability, errors, learnability, ease of use, flexibility
		Information quality	Content quality (5 q:s), availability (3 q:s)
		Service quality (For support for old tools and implementation of new ones)	Support (7 q:s)
		User satisfaction	Grade given to system
		<i>Use of (NH)IS tools</i>	<i>(monitored with a separate eHealth survey)</i>
		<i>Key processes and tasks where tools are used, division of work between actors involved in different process phases</i>	<i>(monitored with a separate eHealth survey)</i>
	Outcomes, impacts, net benefits	Measured outcomes and activity system impacts on quality, access and productivity (input, process, output, outcome quality and amount in relation to inputs**	Productivity, care coordination (3 q:s), care quality (appropriateness, safety, participation (2 q:s)), continuity, work development
Human-centred IS development	Actor participation	Willingness, role and participation of actor groups in development/ implementation/ of new IS	Willingness (3 q:s), Feedback (6 q:s), participation modes (4 q:s)

Design and Aims of Study to Measure Long-term Efficacy of Interactive Online Dietician Weight Loss Advice in General Practice

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Abstract—Obesity is an increasing drain on the resources of general practitioners, who have few effective options for treatment other than surgery and (often prohibitively expensive) personal dietician advice. A study has been designed to investigate the effects of internet-based dietary advice compared with a placebo non-interactive web-support to conventional practice during 24 months. Using data from a previous pilot project for the power calculation, by recruiting 300 patients we will obtain sufficient power to reliably detect a long-term weight loss of 2.5 kg, or, if this figure is higher, to obtain more detailed information about criteria distinguishing patients more or less likely to benefit from this type of Internet based weight loss program.

Keywords—obesity; Internet community; treatment; preventive medicine

I. INTRODUCTION

Obesity is a growing problem and up to 30% of Europeans are obese, with body mass index (BMI) $>$ or $=$ 30 kg/m² [1]. Obesity increases the risk of type 2 diabetes, cardiovascular disease, joint-, and musculoskeletal diseases and cancer. Furthermore the fertility decreases and the risk of spontaneous abortion increases. According to the Framingham study, obesity shortens life with 3 to 8 years for a 40-year-old person [2]. The general recommendations

for a weight reduction consist of a change in life style. Form and content of communication are important for the modification of life style factors [3].

Treatment results are modest, except from surgery, but surgery is only recommended to people with BMI $>$ 35 kg/m² with complications, or BMI $>$ 40 kg/m² without complications [1]. This treatment is expensive, which limits the number of operations that can be performed. In addition, many early and long-term complications with surgery that can reduce the quality of life are reported [4], and there is still uncertainty about the long-term results.

Cochrane reviews show only a very modest effect of conventional advice in general practice compared to placebo [5], while several randomized trials have shown a greater weight loss by adding online dietician advice [6][7][8].

Recent studies suggest that an Internet community with experts is the most effective nonsurgical way to lose weight [6][9]. Online contacts can be an economically attractive contact form for optimizing guidance on diet and exercise and in keeping the patients motivated [10][11][12][13].

There is evidence from some long-term studies that support the choice of such treatment form [5][14], however it is not sufficient to provide a definitive recommendation.

Eighty-six % of the population in Denmark has Internet access at home [15]. This makes it possible to reach most of

the patients via online intervention. The Internet also provides the benefit of self-monitoring, which has been used successfully in other approaches of Internet based weight loss interventions [7].

Conventional dietician advice is costly and access to professional dieticians is limited. Therefore, it is important to ensure that resources are being used in the best way possible. In Denmark it is possible to employ dieticians in general practice and health care centers. Many practices are however experiencing difficulty organizing the activities in a way that makes it economically feasible to offer diet treatment to patients within the rates provided by the Danish National Health Service. In a previous uncontrolled prospective pilot project [13], using an Internet based interactive weight loss program in a clinical practice setting, we found a sustained average weight loss of 7 kg (95% CI: 4.6-9.3 kg) during 20 months among obese patients with average initial BMI of 36.4.

The present paper describes the rationale and elements of an evidence-based protocol for investigating the long-term efficacy of this Internet based weight loss program, in the context of the capabilities and resources available in typical publicly funded Danish GP practices.

II. OBJECTIVE

The objective is to examine how Internet consultations, with dieticians and personal trainers, as well as an Internet community, in combination with dietician consultations using an existing commercial weight loss program "Slankedoktor" [16] (designed for healthy overweight users) for obese patients in a general practice setting, affects body weight during 24 months compared to the usual treatment of obesity in general practice, supported by a placebo website without interactive online communications.

III. STUDY DESIGN

The study is designed as a randomized controlled single-blind trial.

A. Before randomization

- Patients from 10 medical centers are consecutively offered study inclusion.
- Inclusion criteria are BMI ≥ 27 kg/m² or BMI ≥ 25 kg/m² plus at least one risk factor (infertility caused by obesity, hypertension, hypercholesterolemia or diabetes).
- Patients are continuously invited until there is a total number of 150 patients randomized to the intervention group and control group respectively.
- Patients who receive oral information concerning the study and who agree to participate are scheduled for an appointment with a nurse. By

receiving the first information at the doctor, full confidentiality is secured and the patient will be able to bring a companion.

- The appointment with the nurse must be scheduled within 14 days after the oral information, thus the patient has 14 days to reflect on the decision.
- The nurse obtains the approved informed consent and proceeds with weighing and measuring the patient (Figure 1) moreover the patient is instructed to use a web link to a standard questionnaire from the webpage "Praksisdiætisterne" and thereby supplying basic personal information such as age and gender as well as approval of study conditions (Figure 1). These are necessary requirements in order to participate in the trial.
- Patients are randomized immediately after the questionnaire is filled out. The computer will perform the randomization.
- Based on this scenario drop outs can be recorded, as well as certain characteristics for the patients who choose to drop out.

B. Randomization

- Patients are invited to a consultation where the first physical examination by a nurse takes place (0 months). Afterwards patients are randomized to the intervention and control group respectively (Figure 1). Patients, who are randomized to the intervention group, are instructed on how to fill in information on the website before the initial consultation with the dietician.
- Each medical centre receives two randomization lists, one for females and one for males. Patients are assigned to treatment groups according to the next available item on the list, The relatively low number of patients per centre, the likely gender imbalance and the competitive recruitment may result in some centers recruiting very few patients within a gender. Due to this, the randomization list sequences will be sequential with a base number of two with 20% random offset (for each two consecutive patients, the first one is randomly assigned to one treatment group, the subsequent patient is then assigned to the other group, and an additional patient is inserted at random before 20% of these pairs), hereby minimizing the risk of unbalanced allocation of treatments within a gender at each of the medical centers. If all patients of one gender from one centre who complete the study are in the same treatment group (e.g. if there is only one patient), then the data from these patients will not be used in the overall analysis.

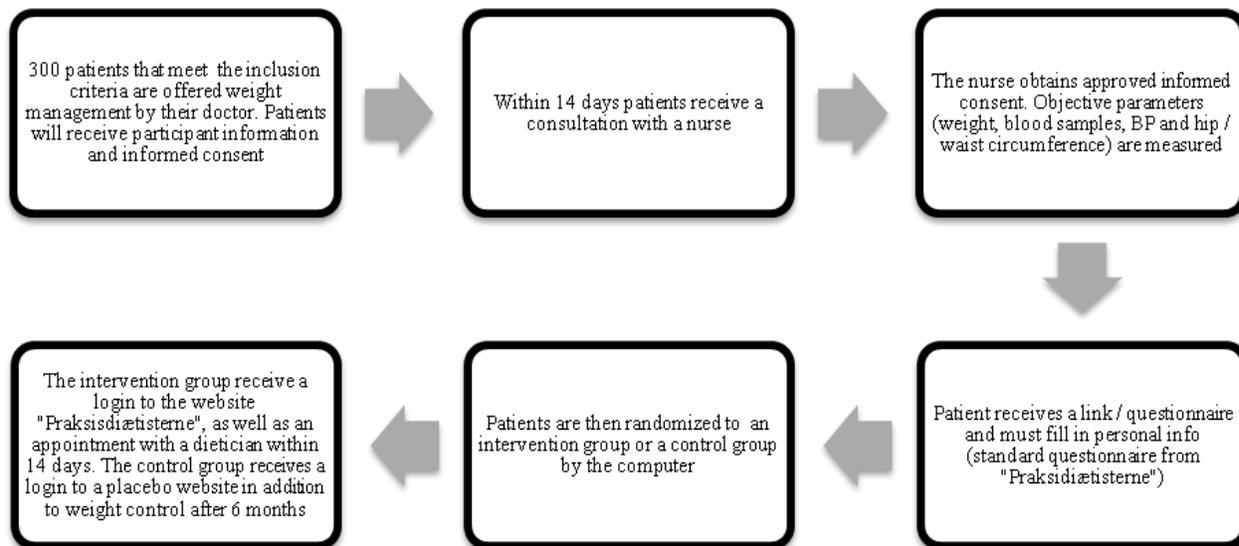


Figure 1. Flow chart of inclusion and randomization. BP = blood pressure.

- Intention to treat method in data handling is used.

D. Control group

- The control group participants receive placebo treatment by getting a login to a website that looks like “Praksisdiætisterne”. It will contain dietary advice (e.g. the National Food Administration’s (Fødevarestyrelsen) "all about diet") and exercise advice, but with neither dietician consultations nor community membership (Figure 2).
- They will receive usual care according to the medical centre they are assigned to and attend weight control sessions where the objective parameters are measured (Figure 2).

C. Intervention Group

- The intervention group receives a login to the website “Praksisdiætisterne” as well as a consultation with a dietician within 14 days (Figure 1).



Figure 2. Treatment of the control group.

- At “Praksisdiætisterne” the patients will have to fill in a daily diet record as well as their doubts and questions to the dietician, who will have access to all patient profiles. Patients will be able to keep up with their weight loss progress by using the website. They will have access to a community where they are able to chat with other participants and share weight loss experiences as well as give advice and support to each other.
- Patients receive subsequent consultations with the dietician by appointment (Figure 3).
- The dieticians provide therapy individually according to their patients' needs and based on information supplied via the website “Praksisdiætisterne”, which will use the same technology and procedures for communicating with the patients as the publicly available slimming program ‘Slankedoktor’ [16] and described in more detail by Brandt et al. [13]. The dietician will generate a personalised daily caloric reduction plan of approximately 1600-4800 KJ based on the patients’ diet record. The dietary advice should be as standardized as possible, by following the same simple dietary guidelines that are given at “Slankedoktor” [16].
- Patients are measured and weighed at the start, after 6, 12, 18 and 24 months and blood pressure is measured and blood samples taken at start, 12 and 24 months (Figure 4).
- Patients are reminded by SMS in order to maximize attendance.

E. Standardization of measurement methods

- The measurements must be standardized to avoid

bias in internal validity (e.g., hip / waist circumference guidelines and standardization of blood pressure measurements), using detailed Standard Operating Procedures (SOPs) agreed among all centers before the start of the study.

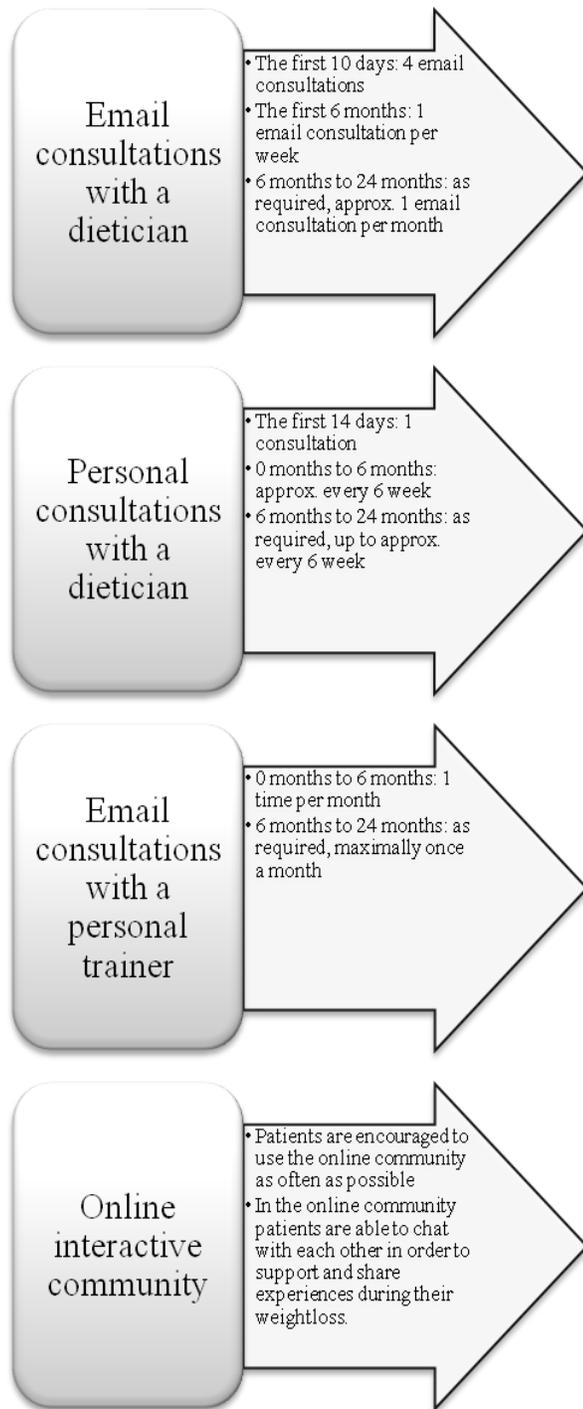


Figure 3. Consultation schedules in the intervention group.

F. Collecting data

- Data will be continuously added to a database, making it easy to extract relevant information. The dietician will be using a standardized questionnaire in order to collect data.
- This data includes: weight, waist/hip circumference, blood pressure, number of logins to “Praksisdiætisterne” and number of comments added to the online community.
- In the case of exclusion before the end of the trial, for example by moving or pregnancy, the patient will be encouraged to complete a final questionnaire and objective parameters (Figure 4) in order to provide surrogate endpoint data. The medical centers will be responsible for this.

G. Inclusion Criteria

- BMI $\geq 27 \text{ kg/m}^2$.
- BMI $\geq 25 \text{ kg/m}^2$ plus a risk factor in the form of:
 - Hypercholesterolemia
 - Hypertension (systolic $\geq 140\text{mmHg}$, diastolic $\geq 90\text{mmHg}$) or patients receiving treatment for hypertension
 - Infertile women (where infertility is considered to be caused by obesity)
 - Type 2 diabetes
- Age at least 18 years.
- Obtained informed consent for use of data in an anonymous form.
- Communication with the patient via cell phone is required.

0 months	6 months	12 months	18 months	24 months
weight, W/H circumference				
Questionnaire BP, BS		Questionnaire BP, BS		Questionnaire BP, BS

Figure 3. Measurement of objective parameters W= waist, H= hip, BP= blood pressure, BS= blood sample.

H. Exclusion Criteria

- Patients without daily access to the internet.
- Patients who fail to complete the initial questionnaire online.
- Patients who are incapable of using the Danish language, based on writing and reading skills.
- Patients who cannot be expected to use a computer or cell phone for any kind of physical or psychological reason.
- Patients who do not wish to participate.
- Pregnancy at the time of enrolment.
- Weight loss > 3 kg within the last 2 months

I. Study Program

Medical history is obtained by questionnaire at study inclusion, 12 and 24 months:

- Name, age, occupation, marital status.
- Cell phone number, email address.
- Number of family members, number of pregnancies.
- History of obesity (always, since youth, max and min weight in adult life).
- Instances of weight loss events > 10 kg during adult life, for example pregnancies.
- Current illnesses.
- Education history.
- Current medication, smoking, use of dietary supplements, use of alternative medicine.
- Working hours (full time, part-time, overtime), hobbies, habits of exercise (type, times per week), transportation (bike, train / bus, car, walking).
- Food intake (morning, afternoon, evening and snacks), cooking (own, purchase, fast food), use of canteen.

The objective parameters continuously recorded by the user at "Praksisdiætisterne":

- Height
- Weight
- Hip measurement
- Waist measurement

Objective measurements obtained by a dietician, nurse or doctor (Figure 3):

- Weight
- Permanent lipid status
- HbA1C
- BP
- Hip and waist circumference

IV STATISTICS

The primary objective of this study is measurement of changes in body weight and waist circumference. Weight loss in the intervention group and control group will be

compared and analyzed using an unpaired t-test. A weight loss of 5-7 kg in the study group and 2-3 kg in the control group is expected after 6 months of treatment. After 2 years we expect the control group to return to the starting weight, while the study group is expected to maintain a weight loss of 3-5 kg. Power calculation based on standard deviations observed in a previous pilot project [13], shows that to detect a difference in weight loss of 2.5kg with a power of 90% requires 142 patients per group. 150 patients will be randomized to each group to allow for dropouts. If the difference is greater than 2.5 kg, the planned total of 300 patients will make it possible to examine interactions between treatment and gender, age and obesity level. Due to this, the randomization will be stratified by gender, while age and obesity level will be analysed as continuous variables.

V. ETHICS

The intervention is not considered to cause any side effects or discomfort. Obesity can cause illness and death. Therefore it is essential to find a validated method for weight reduction with a long-term follow-up. Patient data is handled and stored on the servers of "E-Doktor" and "Praksisdiætisterne". This approach is approved by the Danish Data Inspectorate (Datatilsynet).

VI. CONCLUSION AND FUTURE WORK

The study with the described protocol will provide definitive data on the efficacy of the use of a commercially available interactive Internet based weight loss program in the context of the GP practices in the Danish health care service, with a power to detect a long-term weight loss difference of 2.5kg. If the program turns out to be successful (more effective and/or cheaper than existing options), the collected data will further allow the generation of hypotheses on how the program can be further improved to increase efficacy and/or extend to other patient groups with high frequency of internet access such as younger teenagers.

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Designing and Implementing an Active Personal Health Record System

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Abstract— Current personal health record (PHR) systems are passive in the sense that they just provide a means for storing individuals PHR but they neither analyze nor provide potential improvements to individual's healthcare. This is regrettable, as active PHR systems could provide a wide variety of opportunities for improving the quality of healthcare in a cost effective way. In this paper, we describe our work on designing and implementing an active PHR system. In order to achieve semantic interoperability between the system and its information sources, we have developed a specific ontology for the active PHR system. The ontology based (RDF coded) PHRs are physically stored in a relational database as the active features of the PHR system can be easily implemented by the triggers supported by most relational database systems. We also give rules and illustrative examples how ontology based RDF data can be transformed into relational model, and how database triggers can be specified on that data.

Keywords - personal health record; ontologies; OWL; RDF; active databases; relational databases; triggers

I. INTRODUCTION

Currently there is no generally accepted definition of personal health record (PHR). In general, the term PHR is variably used to describe either a data file or a software application using either personal computer or Internet technologies [1, 2, 3].

In this paper, by the term PHR we refer to a collection of information about individual's health and health care that is gathered from different sources such as from health care providers, pharmacies, insurers, the consumer, and third parties such as gyms. A PHR typically includes information about medications, allergies, vaccinations, illnesses, laboratory and other test results, and surgeries and other procedures [4]. By the term PHR system we refer to a software application that manages PHRs.

Through the introduction of sophisticated PHR systems we can contribute to preventive medical care and achieve better health and well-being while reducing healthcare cost. However, achieving this goal presupposes that many changes on current PHRs and PHR systems are met.

A key requirement of PHRs is that it should be based on controlled vocabulary [5]. By controlled vocabulary we refer to an organized collection of words and phrases that some group has placed [6]. Further, controlled vocabulary should be shared by PHRs and the sources from which data is gathered into PHRs; otherwise the gathered data have to be transformed into format that is compliant with the vocabulary.

XML based CCD- [8] and CCR-standards [9] have commonly used as controlled vocabularies within PHRs. Also, in order to increase the expression power of vocabularies, ontology-based vocabularies for PHRs have been developed.

The controlled vocabulary that we use is ontology based. The reason for not using CCR – or CCD –standard is that these standards are based on XML-schemas. The problem with XML-schemas is that they only specify the structure of the documents (i.e., nesting of tags); and due to the lack of semantics we cannot represent them in a format that is compliant with the database schema, which specifies the semantics of the database.

Also a problem with XML schema based PHRs is that they organize data in document-centric way, i.e., they are collections of documents such as documents including lab tests, prescribed medications and illnesses. By contrast, PHR's effective usage and analysis is data centric, meaning that data should be extracted from various documents and then integrated according to specific criteria. Unfortunately the computation required by such queries is not provided by the query languages that are designed to address XML documents, e.g., XPath [10] and XQuery [11].

Apart from the problems of PHRs representation formats is the problem of current PHR systems' passivity, i.e., they just provide a means for managing individuals PHR but they neither analyze nor provide potential improvements to individual's healthcare. This is regrettable, as active PHR systems could provide a wide variety of cost effective opportunities for improving the quality of healthcare.

In this paper, we report our work on developing and implementing an active PHR system. The key idea is to implement an active PHR system by exploiting the functionalities provided by active relational database systems. The key point of active database systems is their ability to support *alerts* in the form of SQL triggers [9].

An SQL trigger is procedural code that is automatically executed in response to certain events on a particular relation (table) in a database [9]. For example, when inserting a new test result occurs then an analysis on the new values are executed, and based on the analysis a possible action is taken (e.g., generating an email to patient's physician or updating another relation).

In this paper, we restrict on the issues that relate to the designing and implementing an active PHR system for open environment. By open environment we refer to an infrastructure where systems are open in the sense they can interoperate, and so also the organizations are able to work together.

First, in Section 2, we represent our developed controlled vocabulary, called *extended PHR-ontology*. It does not only include concepts that relate to individual's health but also information that is required for conceptualizing information therapy as well as the active elements of the ontology; and hence we use the adverb *extended*. In particular, we represent a subset of the extended PHR ontology in a graphical form and in OWL. We also illustrate how its instances are presented in RDF as the PHR system receives all imported data in RDF-format. This format is compliant with the extended PHR ontology.

In Section 3, we first give the rules that are used in transforming the extended PHR-ontology into relational model. Then we give rules and examples how RDF coded instances of the OWL ontology are transformed into tuples and stored in relations. We also illustrate the role of the notion of *views* in storing PHRs in relational databases. In addition, we give an example of defining an SQL trigger for a PHR. Finally, Section 5 concludes the paper by discussing the advantages and limitations of our developed solutions as well as our future research.

II. EXTENDED PHR ONTOLOGY

A. Graphical Representation of Extended PHR Ontology

In the context of computer science, an ontology is a general vocabulary of a certain domain, and it can be defined as "an explicit specification of a conceptualization" [13]. It tries to characterize that meaning in terms of concepts and their relationships [14]. It is typically represented as classes, properties, attributes and values. As an example consider a subset of the *extended PHR ontology* presented in Fig. 1.

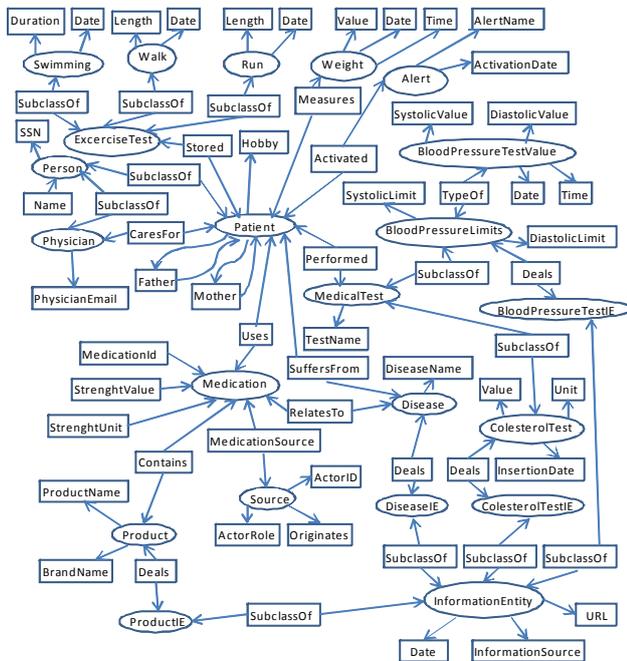


Figure 1. A subset of the extended PHR ontology.

In this graphical representation ellipses represent classes and subclasses while rectangles represent data type and object properties. Classes, subclasses, data properties and object properties are modeling primitives in OWL (Web Ontology Language) [15]. Object properties (e.g., Uses) relate objects to other objects while data type properties (e.g., MedicationId) relate objects to datatype values. In Fig. 1 we have presented only a few of objects' datatype properties.

B. Developing Extended PHR Ontology

Ontology development process is comprised of many stages. First, the scope of the ontology should be specified. The purpose of the PHR-ontology is to describe the concepts of the domain in which PHRs take place. Hence, a PHR-ontology describes the concepts (as well as their relationships) such as demographics, immunizations, allergies, diagnoses, procedures and medication.

In developing a PHR-ontology we do not have to start from scratch as we can find the most relevant concepts from the XML-Schema of the CCR-file [9]. In transforming the XML Schema to OWL-ontology we have used on the whole the following rules.

1. The complex elements of the XML-Schema are transformed into OWL classes.
2. The simple elements of the XML-Schema are transformed into OWL data properties such that the complex element is the domain of the data properties.
3. The attribute of the XML-Schema are transformed into OWL data properties.
4. The relationships between complex elements must be named and transformed to OWL object properties.

In order to illustrate these rules consider the following simplified example of a CCR-file [9] in Fig. 2.

```
<ContinuityOfCareRecord>
  <Patient> <ActorID>Person.12345</ActorID></Patient>
  <Medications>
    <Medication>
      <Source>
        <ActorID>Pharmacy of Kaivopuisto</ActorID>
        <ActorRole>Pharmacy</ActorRole>
      </Source>
      <Description>
        <Text>One tablet ones a day</Text>
      </Description>
      <Product>
        <ProductName>Voltaren</ProductName>
        <BrandName>Diclofenac</BrandName>
      </Product>
      <Strength>
        <Value>50</Value><Unit>milligram</Unit>
      </Strength>
      <Quantity>
        <Value>30</Value><Unit>Tabs</Unit>
      </Quantity>
    </Medication>
  </Medications>
</ContinuityOfCareRecord>
```

Figure 2. A simplified example of a CCR file.

This figure represents a CCR file that has a medication list (element Medications), which is comprised of one medication (element Medication) that is source stamped by the Pharmacy of Kaivopuisto.

Actor is a complex element as it includes simple elements *ActorId* and *ActorRole*. Hence, according to rule 1, complex element *Source* is transformed into OWL class *Source*. According to rule 2, simple elements *ActorId* and *ActorRole* are transformed to OWL data properties such that the domain of these elements is the OWL class *Source*. According to rule 4, the relationship between the complex elements *Medication* and *Source* should be named and transformed to OWL object property. As presented in Figure 1, we have named this object property '*MedicationSource*'.

Note that in the extended PHR ontology, besides the health related concepts, we have presented information that is used by the alerts. For example, the class *Alert* is comprised of the alerts that a patient can activate for his or her PHR. Further, the data properties *SystolicLimit* and *DiastolicLimit* (a patient's blood pressure is usually expressed in terms of the systolic pressure and diastolic pressure (mmHg), e.g., 130/80) are patient specific limits for blood pressure in the sense that if patient's blood pressure is below or over these values then an alert can take an appropriate action, e.g., generate an email to patient's physician. An SQL specification of such an alert will be given in the next Section.

C. Capturing Information Entities into PHR Ontology

A useful feature of the extended PHR ontology is that it also supports information therapy. The goal behind information therapy is to prescribe specific evidence based medical information to specific patients at just the right time to help them make specific health decisions or behavior changes [16, 17]. Through the extended PHR ontology we can easily contribute to information therapy as it models information entities (class *InformationEntity* in the graphical ontology in Fig. 1) as well as their relationships to relevant terms (e.g., *Disease* and *BloodPressureTest*) in the ontology. As a result, we can specify an alert, which is activated when a disease is discovered from a patient, and then the information entities or their links (if any), which deals the disease, are automatically delivered to the patient.

Fundamentally extended PHR ontology comprises the vocabulary that the patient can use in describing his or her personal health information. Hence we do not assume that a patient uses all the terms of the vocabulary (ontology). For example datatype properties *Father* and *Mother* are included in the vocabulary, but the patient does not have to give values for these properties.

Note also that the datatype property *Activated* connects classes *Patient* and *Alert*. By giving the values for the datatype properties of the class *Alert* the patient indicates, which alerts he or she has activated. That is, activating an alert requires only an update of patient's ontology. Based on patient's ontology the PHR system then generates an appropriate SQL trigger [12] in the database.

D. Representing the extended PHR Ontology in OWL

A subset of the graphical ontology of Fig. 1 is presented in OWL in Fig. 3.

```
<rdf:RDF
  xmlns:rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
  xmlns:rdfs="http://www.w3.org/2000/01/rdf-schema#"
  xmlns:xsd="http://www.w3.org/2001/XMLSchema#"
  xmlns:owl="http://www.w3.org/2002/07/owl#"

  <owl:Ontology rdf:about="" Extended PHR Ontology />
  <owl:Class rdf:ID="Person"/>
  <owl:Class rdf:ID="Alert"/>
  <owl:Class rdf:ID="Medication"/>
  <owl:Class rdf:ID="Disease"/>
  <owl:Class rdf:ID="Patient"/>
  <rdfs:subClassOf rdf:resource="#Person"/>
  <owl:Class>

  <owl:DatatypeProperty rdf:ID="ActivationDate">
    <rdfs:domain rdf:resource="#Alert"/>
    <rdfs:range rdf:resource="xsd:string"/>
  </owl:DatatypeProperty>

  <owl:DatatypeProperty rdf:ID="ISSN">
    <rdfs:domain rdf:resource="#Person"/>
    <rdfs:range rdf:resource="xsd:string"/>
  </owl:DatatypeProperty>

  <owl:ObjectProperty rdf:ID="Activated">
    <rdfs:domain rdf:resource="#Patient"/>
    <rdfs:range rdf:resource="#Alert"/>
  </owl:ObjectProperty>

  <owl:ObjectProperty rdf:ID="Uses">
    <rdfs:domain rdf:resource="#Patient"/>
    <rdfs:range rdf:resource="#Medication"/>
  </owl:ObjectProperty>

  <owl:ObjectProperty rdf:ID="Suffers">
    <rdfs:domain rdf:resource="#Patient"/>
    <rdfs:range rdf:resource="#Disease"/>
  </owl:ObjectProperty>
  .
  .
  .
</rdf:RDF>
```

Figure 3. A subset of the extended PHR ontology in OWL.

In importing data into active PHR the data items are presented in RDF, which is a standard model for data interchange on the Web. It has come to be used as a general method for conceptual description of information that is implemented in web resources, using a variety of syntax formats. RDF data is often stored in relational database.

RDF itself is a data model. Its modeling primitive is an object-attribute-value triple, which is called a statement [18]. In order that RDF data can be represented and transmitted it needs a concrete syntax, which is given in XML, i.e., RDF statements are usually coded in XML. Hence, RDF inherits the benefits associated with XML. However, other syntactic representations are also possible, meaning that XML-based syntax is not a necessary component of the RDF model.

One *RDF description* may contain one or more *RDF statements* about an object. For example, in Fig. 4, the description concerning "Voltaren" contains two RDF statements: the first states that its type is *ProductName* in the extended PHR ontology, and the second states that its *BrandName* in the extended PHR ontology is Diclofenac.

```

<rdf:RDF
  xmlns : rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
  xmlns : xsd="http://www.w3.org/2001/XMLSchema#"
  xmlns : po=http://www.lut.fi/Extended_PHR_Ontology#>

  <rdf:Description rdf:about="120962-K3">
    <rdf:type rdf:resource="&po;Patient"/>
    <po : PatientName>Lisa Smith</po : PatientName>
    <po : Uses>MO-5481</po:Uses>
    <po : Performed>H-257L</po : Performed>
  </rdf : Description>

  <rdf:Description rdf:about=" MO-5481">
    <rdf:type rdf:resource="&po;Medication"/>
    <po : Contains>Voltaren</po : Contains>
    <po : StrenghtValue rdf:datatype="
      "&xsd;integer">30</po : StrenghtValue>
    <po : StrenghtUnit>Tabs</po : StrenghtUnit>
  </rdf : Description>

  <rdf:Description rdf:about=" 211708-8">
    <rdf:type rdf:resource="&po;Source"/>
    <po : ActorRole>Pharmacy</po : ActorRole>
  </rdf : Description>

  <rdf:Description rdf:about=" Voltaren">
    <rdf:type rdf:resource="&po;ProductName"/>
    <po : BrandName>Diclofenac</po : Contains>
  </rdf : Description>
</rdf:RDF>
  
```

Figure 4. An instance of active PHR in RDF.

III. STORING ACTIVE PERSONAL HEALTH RECORDS IN A RELATIONAL DATABASE

A. Transforming OWL Ontologies into Relation Schemas

In a relational database, all data is stored and accessed via relations [19]. A relation is defined as a set of tuples that have the same attributes. A tuple usually represents an object and information about that object.

For example in Fig. 5, the first tuple in the first relation indicates that the SSN of Lisa Smith is 1112444-A2 and her SystolicLimit is 157 and DiastolicLimit is 71. The second relation indicates three test values of Lisa Smith’s blood pressure tests.

BloodPressureLimits (SSN	Name	SystolicLimit	DiastolicLimit
	111244-A2	Lisa Smith	157	71
	121248-B9	John Kent	171	77
	120351-A2	Jack Cruz	144	61
	120941-C5	Bob Jones	164	68

BloodPressureTestValue(SSN	Date	SystolicValue	DiastolicValue
	111244-A2	06042011	142	75
	111244-A2	07042011	155	79
	111244-A2	09042011	160	64

Figure 5. Relations BloodPressureLimits and BloodPressureTestValue.

We have used the following rules in transforming the extended PHR ontology into relational schema:

1. The name of the OWL class is the name of the relation.
2. Each property of the OWL class is an attribute of the relation.
3. The key of the relation is comprised of the identification of the OWL class and of the identification of those OWL classes that are in a multivalued relationship to the OWL class.

B. Transforming RDF descriptions into Tuples

We can easily transform the information presented in RDF into tuples as each tuple presents information of an object, and so a tuple corresponds a RDF-description (a set of RDF statements about an object). For example, the first tuple of the relation BloodPressureLimits is derived by transforming the following RDF-description:

```

<rdf:RDF
  xmlns : rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
  xmlns : xsd="http://www.w3.org/2001/XMLSchema#"
  xmlns : po=http://www.lut.fi/ontologies/p-ontology#>

  <rdf:Description rdf:about="111244-A2">
    <rdf:type rdf:resource="&po;Patient"/>
    <po : Name>Lisa Smith</po : Name>
    <po : SystolicLimit> 157</po : SystolicLimit>
    <po : DiastolicLimit> 71</po : DiastolicLimit>
  </rdf : Description>
</rdf:RDF>
  
```

C. Specifying Views on Perwsonal Health Records

Unlike ordinary relations in a relational database, a view does not form part of the physical schema: it is a dynamic, virtual relation computed from data in the database [19]. Technically, a view consists of a stored query accessible as a virtual relation composed of the result set of a query.

Views have an important role in implementing the active PHR system by relational database systems: as PHRs are only accessible by the patient and those that are authorized by the patient, we have to control the access of PHRs. This control can be easily carried out by views. For example, the first tuple of the relation BloodPressureLimits in Fig. 5 should be only accesses by Lisa Smith. To enforce this we can specify a view ‘SmithBloodPressureLimits’ as follows in SQL:

```

Create View SmithBloodPressureLimits AS
SELECT *
FROM BloodPressureLimits
WHERE Name = ‘Lisa Smith’;
  
```

Now, the virtual relation behind the view ‘SmithBloodPressureLimits’ corresponds to the relation presented in Fig. 6.

After the view is specified, we can then easily set restrictions on its use, e.g., that Lisa Smith has rights to read and update it while her physician Ian Taylor has only rights to read it.

SmithBloodPressureLimits (SSN	Name	SystolicLimit	DiastolicLimit
	111244-A2	Lisa Smith	157	71

Figure 6. The virtual relation of the view SmithBloodPressureLimits.

D. Specifying Triggers on PHRs

A database *trigger* [20] is procedural code that is automatically executed in response to certain events on a particular relation or view in a database. Triggers are commonly used to enforce and execute business rules, e.g., notify a manager every time an employee's bank account number changes.

Technically we use triggers in a similar way as in business applications. The domain is only different: we restrict on PHR related data and on physicians and patients rather than on employees and managers.

Triggers, also called *event-condition-action rules* or *ECA rules*, contain the following three parts:

- *Event*: A change to the database that activates the trigger.
- *Condition*: A query or test that is run when the trigger is activated.
- *Action*: A procedure that is executed, when the trigger is activated and its condition is true.

The SQL trigger statement gives the user a number of different options in the event, condition and action parts. As a result, there is a wide variety of useful triggers that can be specified on PHRs. For example, the following trigger sends an email to Lisa Smith's physician, if her systolic value exceeds her systolic value limit (157mmHg).

```
CREATE TRIGGER SmithSystolicAlert
AFTER INSERTION OF SystolicValue
ON BloodPressureTestValue
WHEN SystolicValue > SystolicLimit
EXEC sendmail'physician.ian.taylor@health-house.com,
'Lisa Smith's systolic limit is exceeded'
```

Assuming that Lisa Smith is authorized his physician Ian Taylor to access her PHR, thus the physician can after receiving the email analyze Lisa Smith's blood pressure values, and then contact Lisa Smith either by email or phone.

E. Examples of Useful Triggers

Obviously there is a wide variety of triggers that are useful for patients. Here we give examples of some potentially useful triggers:

- When a new medicinal information entity is published (inserted into the extended PHR

ontology), it is checked whether it is relevant for a patient, and then delivered to the patient. For example, if a new information entity deals diabetes, then it is delivered for the patients that suffer from diabetes.

- When a new disease is discovered (inserted into patient's PHR), relevant information entities are delivered to the patient.
- When a new drug is prescribed (inserted into patient's PHR), drug-drug interaction analysis with patients previous medication is done, and based on the analysis appropriate actions are taken.
- When a predefined amount of test results are inserted into PHR, then a graphical summary is generated to patient.
- If patient's medication is changed, then the changes in medical test values are delivered to patient's physician.

Which triggers are appropriate for a patient must be determined on case-by-case. By the term *PHR customization* we refer to the process of specifying appropriate alerts (triggers) for a patient.

Note that the data stored in PHR is also dependent on the triggers included in patient's PHR system. For example, if Lisa Smith would not have chosen the *SmithSystolicAlert* then neither her systolic limit value is required to be stored in her PHR.

IV. CONCLUSION

A variety of health care information services, software companies and insurers are beginning to provide PHR tools and services. However, many key challenges to the widespread adoption and exploitation of PHR tools have not been fully addressed. One interesting challenge is the inclusion of active elements in PHR systems.

Our argument is that through active PHR systems we can provide a wide variety of opportunities for improving the quality of healthcare in a cost effective way. It, however, requires that active PHR systems are customized according to individual's needs. That is, in installing a PHR system only those active elements are installed, which are appropriate for the individual.

In this paper, we have restricted on technical aspects of active PHRs. In particular, we have described our work on designing and implementing an active PHR system. Our key idea has been the exploitation of the triggering mechanism supported by most relational database systems. Exploiting relational systems is also a natural choice as they are also suitable for storing RDF coded data.

Using RDF for representing PHRs has also many gains over XML coded PHRs such as CCR or CCD based PHRs. The main defects of such PHRs are due to the fact that XML schemas only specify the structure of the documents while

not expressing any semantics. As a result, semantic interoperability cannot be achieved through such solutions, and so the interoperation must be implemented by hard-coding.

An important requirement in introducing our developed solutions is that the sources of the data that are stored in the personal health ontology transform the delivered data in the format that is consistent with the personal health ontology. This is the extra work required from the health care organizations producing data into the extended PHR ontology.

In our future research we will focus on developing the set of active elements (alerts) that will contribute patient centric healthcare. In particular, we will estimate the gains of the active elements as well as the complexity in introducing and deploying the elements. In addition, an important research problem of active PHRs relates to the risks of using active elements in healthcare. That is, an open research problem is the survey of the healthcare decisions and recommendations, which prescribing can be safety automated, and thus can be carried out by active elements.

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Protecting Patient Privacy when Sharing Medical Data

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Abstract— This paper describes a national eHealth platform concept with a multi-level privacy protection in order to improve the security and privacy of medical information on their storage locations as well as during the exchanging/sharing processes. The key idea is to classify and split-up data into different servers. A Trusted Third Party server manages personal identifying data together with the related pseudonyms while the medical information server manages the related medical data assigned to pseudonyms. The well known IHE-XDS profiles are enriched by Public Key Infrastructure, symmetric and asymmetric encryption together with pseudonymization methods. IHE-XDS promote the interoperability level and the extensions increase the security level.

Keywords— *eHealth; Patient Privacy; Electronic Health Records; Secure Patient Data Storage*

I. INTRODUCTION

Healthcare technologies are moving from isolated and autonomous solutions to more interoperable ones. The main expectations of this change are to provide better ways to exchange and share medical information and to improve the quality of services offered to the patients.

In this context, medical data is supposed to be available online where healthcare professionals can access it at any time and from any place. Basically, it will be transmitted over Internet, dedicated Virtual Private Networks (VPN), and hospital networks. The on-line access to medical information can have two major consequences: it can support healthcare professional to take better decisions; it can increase the risk of loss of privacy and malicious attacks. The goal of designing and implementing eHealth platforms is to reinforce the former consequence and to reduce or eliminate the second one. This paper focuses on the strategy to widely reduce the malicious attacks' risk and to assure the privacy of patients during the storing and exchange (sharing) of medical information by using the eHealth platform.

Some cryptographic protocols have proved their efficiency to provide data-security for communications over networks but they do not fully prevent attacks to users' computers or servers. An eHealth platform has to deal with these risks, control authentication, authorization, and integrity. Several countries are implementing different

solutions to satisfy these needs, but the evolution of the applications, methods and laws had forced some of them to review partially or completely their approaches.

The terms "central" and "decentral" mostly refer to the location of the information repositories. In enlarging this interpretation towards different components of a system, the term "central" refers to a system where the components are in one location, managed by one staff of administrators. The term "decentral" then refers to a distributed system. The security advantage of decentral systems is that an attacker will get only a part of the stored information. The disadvantage is that the components (satellites) of the distributed system may not be protected in the same "best" way, as one can do for a centralized system.

The proposed solution respects both aspects – (1) avoid a single attack point and (2) data-security for the satellites' data. If the information stored in one satellite is unusable for an attacker as long as information from other satellites is missing, thus the hacked information of one satellite is worthless alone. This paper describes a secure IT-platform based on this idea. It protects the stored information against external intruder attacks as well as against internal administrator attacks. The layout is based on the IHE-XDS [1] profile, extended with pseudonymization, encryption, and signature functionalities.

Patients' data are distributed within the system in two main parts: One for storing the medical information under pseudonyms and the other for mapping the pseudonyms to the patients' identity data. The benefit is: if one part of data is stolen, the information is useless. Neither the mapping table nor the medical database with pseudonyms is really useful alone.

In the case where medical data contains additional person identifying information, like a name printed on an X-ray picture, then the medical data (i.e., the X-ray) is encrypted and stored under a pseudonym.

The access to the stored information is realized with a web application. As the web-server in the Internet is a high security risk, the patient's identifying data are hidden against the web-server. Illegal server logs on the web-server are useless. Also to avoid illegal web-server logs, the transferred medical results are encrypted on their way over the web-server.

The platform is protected against unauthorized access by multiple security levels. The initial login is done with a

personal ID-card. A user&role directory guards the legal access to the system.

Finally, an elaborated consent management protects any undesired access on the base of the patients' will. The special case of an information access during an emergency situation of the patient implies sending an information about the data access to the patient, his family doctor or any other named contact person.

In the next section, some related works are shortly presented and discussed. Section III introduces the architectural approach.

II. RELATED WORK

Data stored in and transmitted through an Internet-based platform are confronted with a set of attack possibilities. In health care domain, medical data and personal data can be exchanged and managed by services provided in a platform. It also includes privacy and data protection. Patients want to be sure that their personal and medical information is not misused. They want to know how their data is utilized, disclosed, and protected, and the degree of control they will have over the dissemination of this information. They are also worried about possible undesirable economic and social consequences from the misuse of such information [2][3]. Users of healthcare services are unwilling to have their personal information distributed other than for purposes of clinical care and they would like to be consulted before their information is released. The right to decide which personal information can be communicated to others and under which conditions constitutes their privacy rights and need to be implemented in the platform system. Assuring privacy implies that the platform needs to deal with, at least two attack risks eavesdropper and server intruders or curious insiders [4]. Three potential types of attackers are described in [4]: *Client intruder*, which attack the client computer (e.g., trojan); *Eavesdropper*, which compromise or owns a subset of communication's nodes to collect and analyze messages that are routed over them; *Curious insider or server intruder*, this attackers have administrative privileges and can access all data in the server.

For the client intruders' risk, we assume that users are responsible for the protection of their own system and of data saved in their computer. The access to the platform is protected by a system based on the electronic cards that provides identification and signature services. If an intruder steals the identity of the user he will need to have his card and know his password to use the platform. Other countries have also adopted electronic cards for health data management and patient identification (eCard in Austria[5], eGK in Germany[6], Vitale in France[7], etc), this type of card has shown its efficacy in banking domain and are widely accepted by users.

The other two types of attacks are directly related to the security strategy of the platform. Cryptography (e.g., Public Key Infrastructure) is commonly used in eHealth platforms

to avoid eavesdropper, however a communication protocol should be defined to avoid that encrypted data and decryption keys cross the same node without a specific protection. The Belgium platform deals with this problem by implementing an end-to-end communication [8], then the private key is expected to never leaves the client computer. However, this solution does not allow sharing data when the receiver is unknown. For example, a prescription cannot be accessed by a pharmacy if the pharmacy was not chose by patient/doctor at the moment of the e-prescription creation.

In Luxembourg [9], the eHealth platform has been designed to store (temporarily) medical data, and users will be able to access this data. In this case, the information cannot be encrypted with the public key of the (unknown) receiver and saving unencrypted data will open a door for server intruders or curious insiders attacks. The protocol proposed in this paper deals with this situation using symmetric encryption associated to asymmetric encryption for the symmetric keys [10], an identity and role control system and a pseudonymization of unencrypted data [11]. This encryption technologies are well known by Network administrators, however, associating it with pseudonymization techniques are not usual, as much as we know the proposed solutions use proprietary message structures. As semantic interoperability is an important step to promote sharing/exchange of information in the medical domain, the contribution of our work is the association of these technologies within the IHE-XDS profile.

Ideally, privacy is assured if a consumer uses a resource or service without disclosing his consumer identity; the resource or service can be used multiple times without others being able to link these uses together (unlinkability) or observe that this resource is being used (unobservability) [2]. In medical domain, it can be illustrated by a doctor accessing a set of data of one patient stored in several repositories. The system need to assure that nobody else can know that all these data belongs to the same patient (unlinkability). Or, when a patient access his own data, the system should assure that nobody will observe it (unobservability), because if the user (patient) is associated to the data, the unlinkability criteria is lost. The encryption and the pseudonymization techniques can not solve this problem. An organizational strategy is necessary to improve the privacy of patients, and this is another contribution of the paper.

The eHealth architecture detailed in the next section shows how privacy, hiding users' identity and assuring authenticity/integrity of documents and messages can be established. The approach is based on a multi-level architecture where: users are authenticated by a trust authority and associated to a set of rights access; data are pseudonymized; non-anonymized documents are encrypted; strict sequences of activities are provided; and messages are stored encrypted for audits purposes.

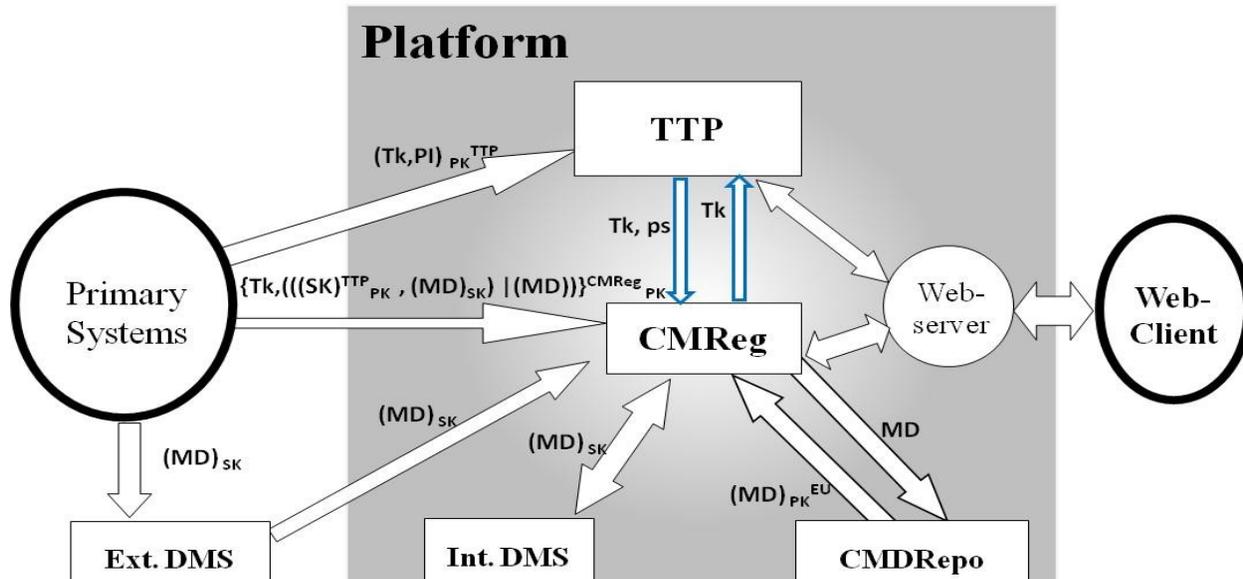


Figure 1: Architecture of the Platform

III. ARCHITECTURAL OVERVIEW

The main components of the proposed eHealth platform are presented in Figure 1. Some components (e.g., LDAP, CA, STS, etc.) are omitted to improve the visibility and the architecture explanation. The technology used to implement these components are out of the scope of this paper. The architecture was defined to support centralized and decentralized information repositories, based on the IHE XDS infrastructure profile with a central registry, one or more centralized repositories and one or multiple decentralized repositories.

The heart of this platform is the *Central Medical Registry* (CMReg). Each document provided by the primary systems is registered in the CMReg with its physical location in one of the repositories. For illustration, Figure 1 shows two centralized repositories: (1) the *Centralized Medical Data Repository* (CMDRepo) stores unencrypted information without any person identifying data; and (2) the *Internal Document Management System* (Int. DMS) that stores encrypted medical information, which may contain, as well, person identifying data. External storage of data is also supported by the platform. For example, Primary Systems may decide to use their own repositories (Ext. DMS), placed in a DMZ (Demilitarized Zone) from their network. Those external repositories always contain encrypted information.

This organization allows normalizing data storage and data retrieving within all data repositories. CMReg keeps meta-data of all information registered in the platform, what makes the CMReg a potential target for malicious attacks. Protecting the CMReg is one priority of our security strategy. A set of components is combined to improve the

security of the system. In order to describe the data exchange protocol, it is assumed that an existing Public Key Infrastructure (PKI) is in place and each registered entity has a public/private identity key pair. The notations introduced in Table 1 are used.

Table 1: Notations

Notation	Meaning
PI	Patient Identifying Data (name, address, sex, ...)
MD	Medical Data (lab results, diagnosis, ...)
EU	End User. Can be patients, health providers, researchers, etc.
SK	Symmetric key
Tk	Token
ps	Pseudonym
$(m)_{SK}$	Message encrypted with a symmetric key
$(m)_{PK}^U$	Message encrypted with the public key of a user U

A. User identification

Two groups of users are considered for the eHealth platform, according to the role that they play: (1) Primary Systems, who uses the platform to send medical data produced by healthcare providers (ex., laboratory results, x-rays, or discharge letters) via the “Push” web-service; (2) End Users, healthcare professionals or patients that use the platform to acquire stored medical information.

The procedure to use the platform is the same for both groups. Users need an electronic card (eID for short) for authentication and for data integrity (through e-signature of documents).

The access to the system requests the following steps:

1. Users holding their eID to request an “entry ticket” to the Secure Token Service (STS). The user can request an entry token via Web (i.e., as data consumer through a Web-client – right side of Figure 1) or via an Intranet (i.e., as data producer through HealthNet – left side of Figure 1). The request message is signed on user's side and encrypted with the STS public key.

$$\text{User} \rightarrow \text{STS: (eID)}_{\text{STS_PK}}^{\text{STS}}$$

2. STS verifies the signature with the certification authority (CA). If refused, the user's access is denied.

$$\begin{aligned} \text{STS} &\rightarrow \text{CA: (eID)}_{\text{PK}}^{\text{CA}} \\ \text{CA} &\rightarrow \text{STS: (Check result)}_{\text{PK}}^{\text{STS}} \end{aligned}$$

3. STS requests access rights information to Lightweight Directory Access Protocol (LDAP) manager. The answer is a set of roles that this user can play.

$$\begin{aligned} \text{STS} &\rightarrow \text{LDAP: (eID)}_{\text{PK}}^{\text{LDAP}} \\ \text{LDAP} &\rightarrow \text{STS: (roles)}_{\text{PK}}^{\text{STS}} \end{aligned}$$

4. STS prepares the entry ticket, encrypts it with the user's public key and sends it to the user.

$$\text{STS} \rightarrow \text{User: (entry ticket)}_{\text{PK}}^{\text{User}}$$

For the client, the entry ticket will give the access to a set of Web-applications in the Web-Server and for the Primary Systems, it will allow them to use the “Push” web-services provided by CMReg system.

This protocol requires that users are pre-registered at STS, that they have an eID recognized by a certification authority (CA) and that he uses this eID during the whole process (entry and service request). Data (e.g., the entry ticket) will be rendered encrypted and the user needs his private key to decrypt. This strategy protects users from eID stealers.

B. Pseudonymization

As medical data are registered in the CMReg, they are associated to pseudonyms and stored in one of the data repositories. The mapping between pseudonyms and the corresponding person identifying data is stored in a Trusted Third Party (TTP). We use the term TTP for the mapping software and TTP driver for the organization that operates this software. The mapping between the person identifying data and the pseudonyms must never be disclosed. To assure this, a «token» is used and all communication is encrypted. The pseudonymization service can be summarized in the following 6 steps:

1. The Primary Systems (PrS) provides a clean separation of person identifying data and its related medical data (i.e., two separated documents are created). The medical data may be unencrypted but without any person-identifying information, or encrypted.
2. The person identifying data is sent to the TTP together with a token. $\text{PrS} \rightarrow \text{TTP: (Tk,PI)}_{\text{PK}}^{\text{TTP}}$
3. The medical data (or a reference to the medical data) is sent to the CMReg (Push service) with the same token. The document itself is stored in one of the repositories. $\text{PrS} \rightarrow \text{CMReg: (Tk, MD)}_{\text{PK}}^{\text{CMReg}}$
4. The TTP generates a pseudonym, stores it besides the person identifying data and waits for the CMReg asking for the pseudonym.
5. The CMReg sends a request to TTP with the “token” and gets back the generated pseudonym:

$$\begin{aligned} \text{CMReg} &\rightarrow \text{TTP: (Tk)}_{\text{PK}}^{\text{TTP}} \\ \text{TTP} &\rightarrow \text{CMReg: (Tk,ps)}_{\text{PK}}^{\text{CMReg}} \end{aligned}$$

6. CMReg establish a mapping between the pseudonym and the (encrypted) document with the medical data. The pseudonym becomes part of the metadata of the document and is not visible outside of the platform;

Additional security packs can be used to improve the privacy of patients. For example:

- Scheduled pseudonym exchange: The pseudonyms will be exchanged on a regular basis each hour or if necessary in shorter intervals. The stolen mapping table of a hypothetical evil TTP administrator only works if the hypothetical evil PMIP administrator has stolen the medical databases during the same time interval. If this extension gets necessary further elaboration concerning the switching time has to be done.
- Multiple pseudonymization: To further enlarge the trust level, multiple pseudonymization steps are possible. The first pseudonymization service maps real identities to pseudonyms. The second pseudonymization service maps the first pseudonym to a second pseudonym. The n-th pseudonymization service maps the (n-1)-th pseudonym to an n-th pseudonym. Each pseudonymization mapping is hosted by an independent trusted N-th party.
- A combination of scheduled pseudonym exchange and multiple pseudonymization with different pseudonym exchange intervals of the different levels is possible.

C. Encryption/Re-Encryption

When the separation of person identifying data and the related medical data is not possible (e.g., X-ray image), the privacy is guaranteed by a combined encryption strategy. It consists of 5 steps:

1. The medical document (MD) is symmetrically encrypted with a symmetric key generated by the PrS – one for each document, respectively;

$$\{(MD)_{SK}\}$$
2. The symmetric key is encrypted with the public key of TTP;

$$\{(SK)^{TTP}_{PK}\}$$
3. The encrypted document and the encrypted key is stored together in one of the repositories.
4. When requested by an authorized user, the encrypted key of the document is separated from the document, sent to TTP, which will be in charge of re-encrypting the key with the public key of the legal requester, and regrouped with the document:

$$\begin{aligned} \text{CMReg} &\rightarrow \text{TTP: } \{(SK)^{TTP}_{PK}, EU\}^{TTP}_{PK} \\ \text{TTP} &\rightarrow \text{CMReg: } \{(SK)^{EU}_{PK}\} \end{aligned}$$

5. Both, the encrypted document and the re-encrypted key, are sent to the end-user.

$$\text{CMReg} \rightarrow \text{EU: } \{(SK)^{EU}_{PK}, (MD)_{SK}\}$$

This distributed encryption/re-encryption strategy prevents both insiders' server attacks and eavesdroppers. The repositories store the encrypted documents with the encrypted keys. The re-encryption of the encrypted symmetric keys is done at the TTP side. The TTP never has access to the encrypted document while the repository never has access to a disclosed symmetric key. For eavesdroppers of the repository or eavesdroppers of the TTP the same argument holds like for the corresponding administrators. Only with simultaneous access to TTP and repository the information can be disclosed. In this process, the pseudonym of the patient can differ from one primary source to another, what improve the unlinkability of the solution.

D. Hiding information from the servers' administrators

Two types of files with medical data are stored in the platform one unencrypted/pseudonymized and the other encrypted/pseudonymized. At least 4 servers compose the platform infrastructure (TTP, CMReg, Repositories, Web-server). TTP and Repositories are protected by the trick described above. The Web-server is often the main target of attacks because it is used to transmit data to/from the end user. A malicious administrator may install an illegal logging, catching the requests containing patient names and

catching the results containing medical data for those patients. With a simple strategy, after cumulating this log information, the administrator may associate the set of health data with patients' identity. To prevent this, patient identifying data are encrypted with the public key of the TTP. Then the web-server only transmits the information to the TTP. And the TTP has one additional step to do: it has to decrypt the patient identifying data. Then it continues by looking-up and providing the pseudonyms and waiting for the CMReg request for the pseudonym-list. An analogous tunneling method is applied for result transmission over the web-server to the receiver.

E. Consent and User Management

A secure token service with a healthcare related LDAP guards the access to the whole system. Users need to be pre-registered and associate to a set of access rights to use the applications of the system. An elaborated consent management system protects medical information from any unwished access on the basis of the patient's will. For example:

- for all documents, for an episode, for a medical case;
- for all doctors, for all doctors of a special discipline, for named doctors;
- for exchange over borders;
- for access in emergency case;
- ...

A specific consent description language [12] has been proposed to declare consents. CMReg checks the conformance of an access first with the patients' consent declaration for each requested document. Patients can access the system via web-applications and their identity will be substituted by a pseudonym define by TTP (following the same process described in 3.2).

F. Trustful statistics

Pseudonymized results in the platform offers the possibility of using data for statistics analysis without the risk of data protection violations. Therefore a preparation process is necessary to exchange the internal used pseudonyms by other pseudonyms created for the statistics purposes. Internal used pseudonyms are supposed to be hidden from external users. Statistics analysis can use a predefined set of not encrypted medical data that must not contain patient identity information. If further statistical research has to be done, where personal data like age and sex are necessary, exceptions can be created. But, it may require special authorizations from public authorities in order to guarantee citizens' privacy.

IV. CONCLUSION AND FUTURE WORK

This paper has presented an architecture for eHealth platforms that combine different methods for data protection in order to improve the security level and assure the privacy of patient's data.

The architecture's concept was developed based on standards protocols and proposes some extensions for multi-level privacy protection. The extensions consist mainly on the communication with the Trusted Third Party server and are shown to be necessary when considering potential intern attacks (malicious administrators). A "ticket" based protocol is proposed to assure authentication of users. It is associated with an electronic card (provided by a certification authority) that offers signature and identification services.

The architecture was designed to promote exchange and sharing of medical data and to collect/store data for statistics finalities. Thus, the collected data could not be encrypted, but the identity of the patients is never exposed. The proposed approach uses pseudonymization methods for hiding patient's identifying data. But, during the data exchange process, even pseudonymized data are encrypted using PKI solutions to avoid eavesdroppers attacks. As the platform was not conceived to provide P2P communication, a strategy to safely store unanonymized data was necessary. An association of symmetric and asymmetric encryption is proposed, which involves at least two different servers to provide the necessary information to the end user. This approach has shown to be efficient against insiders' servers attacks and against client intruders that try to steal the client identity.

Future works are planned to improve the identity protection when the patient should be able to access his own data. This particular increase the risk of eavesdroppers attacks over the web-server because the identity of the patient is known (equal to the requester identity). We are also working on the implementation of the platform and on the validation with case studies specified with user groups.

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Patient Empowerment and New Citizen Roles through Telehealth Technologies

The Early Stage

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Abstract - The aim of the present article is to explore the potential for citizens to gain new empowered roles through the use of health technology. The authors propose the distinction between citizen roles on two levels: the role of the citizen as patient actively involved in his own treatment and then an 'extended citizen role'. Findings are based on a literature review combined with lessons learned from two telehealth projects currently running in Denmark. The authors find that the empowerment happens through information-sharing; offering the patients a visual overview of their course of treatment, letting the patients take their own measurements, and letting them provide verbal and written inputs. Finally, perspectives on communities of shared care and 'ambient assisted living' are discussed.

Keywords - telehealth; patient involvement; telemedicine; home monitoring; citizen roles

I. INTRODUCTION

When studying recent literature on the delivery of health services it becomes clear that health sectors all around the world are overburdened and under severe pressure. The demographic challenges faced by the aging nations of the developed world as well as the developing nations with a new, growing middle class, combined with the increasing need for treating chronic illnesses, imply that the relationship between citizens and their health sector is bound to change. The use of information and communications technology (ICT) in telehealth programs is a part of future health care, but in order to significantly reduce the burden of health sectors, citizens must know how to help themselves – and each other.

The present article reflects upon experiences and potentials in terms of patient involvement from two telehealth projects carried out in Denmark, both of which rely partially on self-management, and discusses these experiences in relation to findings from the literature. The focus of the present article is telehealth technologies that are related to the ideal of 'ambient assisted living' as described later. The projects included are Tele Ulcer Care and DREAMING (eDeRly-friEndly Alarm handling and MonitorING).

Tele Ulcer Care demonstrates the use of ICT in the treatment of patients with diabetic foot ulcers. The project started as a research project in which video conferencing was

used, i.e., synchronous treatment [1,2]. After the research phase, the project entered a development phase in which transferring images and notes via mobile phones and a web-based ulcer record was introduced, i.e., asynchronous treatment involving the patient, the visiting nurse, and the ulcer specialist. During the development phase, a mini-Health Technology Assessment (HTA) was produced [3] in which the benefits for the patient were established; reduced time spent on waiting and commuting, faster diagnosis and treatment, and fewer hospitalizations and visits to the outpatient clinic. The mini-HTA also states that the web-based ulcer record allows for patient involvement in own treatment, which is discussed later. Currently, the project is demonstrating the asynchronous system at various sites in Denmark and is aiming for national implementation.

DREAMING is a research project under the auspices of the European Union, which tests a range of welfare technology services in real life pilots in cooperation with public authorities under a randomized control trial. The project tests elderly-friendly alarm and monitoring technology in the citizens' home. The technology consists of medical measuring equipment, environmental monitors, and video conferencing. The citizens included must be at least 65 years old and suffer from diabetes, heart failure, or COPD (Chronic Obstructive Pulmonary Disease). The citizens take their own measurements, which are transmitted wirelessly to a portal accessible for the visiting nurses. The project is currently trialed at pilot sites in six European countries: Denmark, Sweden, Germany, Estonia, Italy, and Spain.

The two projects are at different stages in their life cycles: Tele Ulcer Care has been through its research and development phases and is currently demonstrating the technology as the final step before national implementation, while the DREAMING project is currently collecting its initial research results. Note also that the projects are primarily relying on tele-monitoring and are not examples of self-management in its full form. Despite these factors both projects present relevant experiences and elements of patient empowerment and self-care, and the authors believe that the projects teach us some important lessons in terms of technology and patient roles, that are relevant for future self-management projects. Finally, the projects differ in the degree to which they are currently relying on patient empowerment. This will be discussed later.

In terms of citizen roles, this article suggests distinguishing between two levels: the first level is the

citizen as a patient actively involved in his own treatment, the second level is the citizen as actively involved in the general delivery of health care services to the social environment, e.g., a senior community or a virtual network, in which the citizen lives. This level is what we call 'the extended citizen role'. The first level is very present and widely discussed in published literature, while the second level is a somewhat novel, undocumented idea, but nonetheless an important perspective that can help us imagine how the future of health care might look like.

The aim of this article is to explore the potential for citizens to gain new empowered roles through the use of telehealth technology. The following section is based on a literature review in which these questions are attempted answered: How does telehealth technology influence the way health care services are delivered in terms of the patient's role? What barriers and issues are important to keep in mind when attempting to empower the patient?

Section II outlines research on telehealth and patient involvement. Section III describes the methods used in the research of the present article. Section IV presents results from the two projects Tele Ulcer Care and DREAMING and Section V discusses these results in relation with the findings of Section II. Section VI draws conclusions from this discussion, and finally, in Section VII, perspectives beyond the scope of the present article are presented.

II. BACKGROUND

Telehealth, including telemedicine, programs are feasible for the education and involvement of patients in their own illness and for motivating them to engage in self-monitoring [4-7]. ICT in general allows for a more interactive patient-provider relationship based on information-sharing [8]. For instance in ulcer care, appropriate information about options, benefits, and risks, helps the patient make better decisions in daily, or even acute, self-treatment [9,10]. Note however, that others have documented that telemedicine does not necessarily facilitate self-care [11].

Studies have shown that patient education has the potential to improve the quality of care, including improving patient satisfaction with the treatment [9,12,13] and enhancing the patient's access to information [13,14], sense of control [5,14] and quality of life [15]. Other studies have documented improved patient-provider relationship (despite a decrease in the amount of personal contact) [5,6] and reductions in the number of readmissions [15] as well as in the duration of face-to-face consultations [9] due to patients' better understanding of their illness.

Particularly synchronous telehealth, i.e., tele-consultation using video-communication, allows for a dialogue between e.g., patient, visiting nurse, and expert, through which the patient becomes empowered and more actively involved in the planning of his or her care [10,16]. Asynchronous telehealth (e.g., utilizing and transferring digital images in ulcer care), on the other hand, results in easily accessible visual data that allow patients to follow the progress of their treatment, which gives a significant psychological boost [17]. Involving the patient is beneficial for the providing organization as well; including the patient's perspectives in

the telehealth program improves the implementation of such programs, since it allows for continuous adjustments [14].

Certain barriers to patient involvement have been identified: the need for training and getting used to communicating via e.g., video, which lacks the natural flow of face-to-face communication [16], hesitation towards self-care due to unfamiliarity with the technology [18], inadequate video quality and internet connections [7], and finally, impairments of vision, hearing, psychomotor skills, and cognitive skills, esp. with elderly patients [15].

Although some studies document patients' enthusiasm about the new technology [4,14], patient involvement is crucial in overcoming potential opposition towards the technology, and studies show that the longer patients have been involved in a telehealth project, the more likely they are to accept the technology [10,12]. Note that it is crucial to identify the personal characteristics of the target patient, e.g., urban/rural, young/old, since these will give an indication of potential patient-barriers to unfamiliar technology [19]. Since the target group of many telehealth programs is the elderly population who often have special needs when it comes to home care, it is especially important that these citizens and their daily lives are involved in the planning of care. Generally, it should be recognized that when care takes place in the patient's home, it must be carried out on the patient's terms [20]. In one study, it is stated that patients are of the opinion that home hospitalization results in an easier and quicker return to everyday life both physically and mentally [21].

There are a number of ethical issues to consider in telehealth programs, some of which are related to the empowerment of the patient: privacy of information, informed consent, the accessibility and usability of the technology, and the danger of making patients too dependent on technological support instead of making them more autonomous [22].

The project MethoTelemed has published the manual Model for ASsessment of Telemedicine (MAST) [23] in which issues and perspectives relevant for the evaluation of telemedicine programs are outlined. The MAST manual considers patient empowerment a sub-topic to 'patient perspectives', which mainly focuses on patient satisfaction and perception. In general, the manual only briefly discusses the concept of patient empowerment and focuses mainly on the *delivery* of health care services, instead of the patient's *active involvement* in these services. Further, a gap in the literature on this topic is also revealed. The MAST manual does however include aspects that are central to the present article: The patient's relatives' perceptions of telemedicine, changes in the patient's role in social life, and changes in the way responsibility is allocated.

The present article focuses on the potential of patient empowerment in order to contribute to the debate on the future of health care and the role of the individual citizen.

III. METHODS

The present article applies findings from the literature to the experience and lessons learned from two telehealth projects, Tele Ulcer Care and DREAMING. The emerging

perspectives are then analyzed in relation to the theme of the 'two levels of citizen involvement'.

The literature used was found in the databases ACM Digital Library, Cochrane Library, CSA Illumina, Ovid Medline, and PubMed. We used the following search strategy: (telemedic* OR telehealth OR telecare) AND ("self care" OR "self treatment" OR "patient involvement" OR "patient empowerment"), and ended up with approx. 30 articles of significant relevance.

IV. RESULTS

Tele Ulcer Care is founded on the research of [1,2,24] who used participatory design methods, field observations, semi structured interviews, focus groups, and qualitative analysis of transcriptions of telemedical consultations to investigate experiences with telemedical treatment. The authors propose a joint treatment between the expert, the visiting nurse, and the patient, and they find that telemedicine improves the specialist's basis for decision, and enhances the confidence and the satisfaction for both the patients and the visiting nurses.

As mentioned above, we distinguish between two levels of patient involvement: 1) involvement in own treatment and 2) the extended citizen role. In terms of patient involvement on the first level, Tele Ulcer Care has experience which sheds light on this aspect: Firstly, the joint care between patient, visiting nurse, and expert, whether it is through video conference, transfer of digital images, or communication via an electronic record, allows for the patient to learn more about his own illness and which precautions to take without physically having to seek expert advice. Secondly, the patients perceive, to a great extent, the applied technology (a web browser and a mobile phone or video conference equipment) to be simple and familiar, which is essential in patient involvement. Finally, since foot ulcers can cause social stigma, the patient is likely to be interested in being in charge of his own life as much as possible and to reduce the extent to which he is perceived as being 'ill'. In terms of the extended citizen role, Tele Ulcer Care has no experience yet, but there is a potential as discussed in the next section.

In the DREAMING project, the citizens are involved at both of the two before mentioned levels. At the first level, involvement in the citizen's own treatment takes place from the moment he enters the project. In terms of the second level, the technology included in the project opens up for the possibility of creating an 'ambient assisted living' (AAL) society like the one described in the next section.

Lessons learned in the project so far have shown that when introducing the technology to elderly citizens, appropriate training and involvement in the process promotes a positive attitude towards the technology. This experience has also been described in [25] along with challenges and lessons learned in other areas within the project. Thus, the DREAMING project has acquired important knowledge about how to successfully bring together the elderly and the technology. After having become involved in the project, the citizens see how the project will benefit them and want to be empowered through the technology. Furthermore, they do

not find the technology intrusive, but clearly feel safer with the technology in their home than without.

At an early stage of the project, the first Danish citizen included in DREAMING had the technology installed in her home on a small, isolated island. Despite her previous occupation as the head of the island's post and ferry office, this particular citizen had never used a computer in her life and always wrote down everything using pen and paper. However, after instructions from the project team, she had no difficulty using the equipment and was happy to avoid some of the time consuming trips to her doctor on the mainland [26].

V. DISCUSSION

One way to realize the concept of patient empowerment, i.e., allowing the citizen to undertake some of the visiting nurse's former tasks, is to create ambient assisted living-spaces where self-care technologies are integrated in the citizen's daily life in a non-intrusive way. Self-care is made easier if the technology utilized is already familiar to the citizen and even easier still if the technology is integrated into other familiar, non-technological objects. An AAL-space could be the citizen's home, or it could be a senior community, or even village, where the inhabitants all have social roles to fulfill and are empowered in such a way that they are capable of helping each other in their respective management of care. In an AAL-environment, the citizen is autonomous, but never isolated.

In Tele Ulcer Care, the visiting nurse is currently responsible for treating the patients' ulcers, taking pictures of the ulcers with her mobile phone, and uploading the pictures along with any additional notes to a web-based ulcer record accessible to the ulcer specialists at the hospital and to the general practitioners (GP). The ulcer record works as a platform of communication between the patients and the health professionals, and the patient himself and his relatives can also gain access to the patient's personal data in the ulcer record and this is where the project includes elements of patient empowerment: The patient can keep track of his treatment and the healing (or deterioration) of the ulcers. It is then interesting to note that although findings from the literature supports the idea that telehealth motivates the patients to be actively involved, Tele Ulcer Care's mini-HTA states that the patients' request for gaining access to their personal data in the ulcer record was not as present as expected. A possible explanation might be that we as patients have yet to get used to the idea that we have the authority to be more than just passive receivers of health care services. Another explanation for the degree of patient motivation might be whether the telehealth technologies are perceived by the patient as being user friendly. Note however that since 2009, as can be seen in Fig. 1, the number of notes uploaded to the electronic ulcer record by the patients has increased gradually. This might indicate that appropriate training and enough time to get familiarized with the technology can facilitate patient involvement.

The research on which Tele Ulcer Care is based found that telemedicine has the potential to bridge the gap between the medical experts (i.e., doctors and/or nurses at the

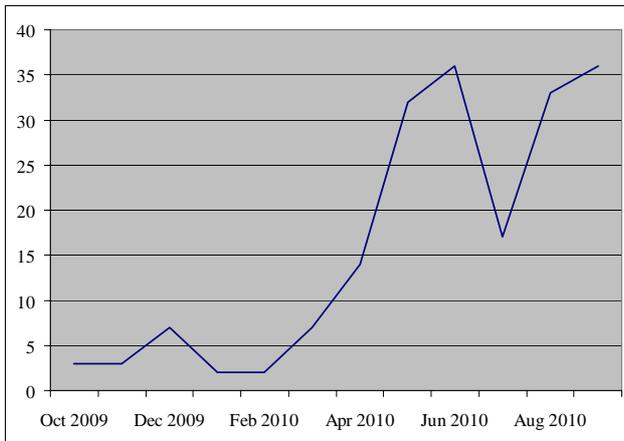


Figure 1. Development in the number of patient notes uploaded.
Source: Dansk Telemedicin.

hospitals) and the visiting nurses treating the patients in the sense that the triangle of patient, visiting nurse, and medical expert is completed (Fig. 2). This might be perceived as leaving the patient out of discussions on his treatment but it has quite the opposite effect: Instead of having to act as the intermediary between expert and visiting nurse, i.e., having to answer questions about the treatment, which the patient might feel insecure about, the completed triangle ensures that he no longer has to worry about the communication between expert and visiting nurse. Instead, he can assume the role of the patient that is actively involved in a three-way dialogue, knowing that his inputs are valuable in the course of treatment and that they are received by both the expert and the visiting nurse. The asynchronous telemedicine system of transferring images and notes, currently demonstrated in the project, has the potential of further enhancing the level of patient empowerment: instead of having to be present at the same time as the visiting nurse and medical expert as with video conferencing in synchronous treatment, the patient can access his data in the ulcer record whenever he has the time, and he can even write notes in his own record for the health care professionals.

Note that although the work of [24] takes a patient-involvement approach, it still focuses mainly on the patient as a receiver rather than an active user. However, an important perspective can be drawn from the research: the patients' feelings of satisfaction, security, and confidence with this new kind of treatment might be an indication of the patients being ready for health care services in which they are more actively involved.

The technology of telemedical ulcer treatment is very simple; the phone is an off-the-shelf mobile phone with camera and the electronic ulcer record is a user friendly browser, hence patients are likely to easily familiarize themselves with the technology and not to have significant resistance towards using it.

The simplicity of the technology and its non-intrusive, mobile nature combined with the potential for this kind of

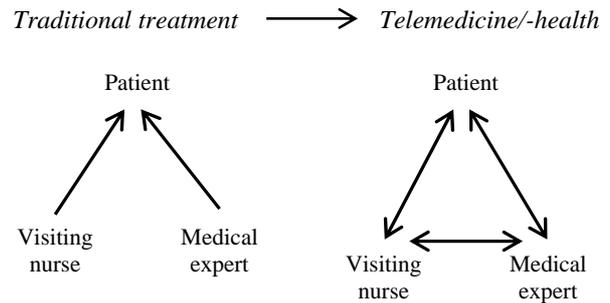


Figure 2. The new joint triangle of care

treatment to reduce some of the social stigma related to foot ulcers shows that telemedical ulcer treatment can live up to the ideal of ambient assisted living. Future perspectives on citizen involvement in ulcer treatment are presented in section VII.

In DREAMING, the citizens assume a new role as patients from the very beginning in that they manage a number of tasks previously handled by the visiting nurses. By taking their own measurements and communicating with the nurses via video conference, the citizens become involved in their own course of treatment in a way that is radically different from traditional patient roles. In fact, they take over some of the central nursing tasks and are thereby largely in charge of their own treatment. Thus, the treatment of chronically ill elderly citizens takes on a new aspect of self-management and moves away from the traditional treatment methods concerning this demographic group living in their own homes. By having the necessary measuring equipment at home, the citizens are not only more independent, but also safer as they can take measurements if they feel unwell and because they know that their daily measurements are evaluated continuously by the nurses who used to actually take the measurements. This assertion is supported by statements from one citizen who says: "I like the fact that we are closely monitored" and continues by agreeing with a statement made by the project nurse: "It gives a sense of freedom to be able to handle your own treatment, while knowing that you are still being looked after. That's really an advantage." Another citizen states: "It is so simple" and continues "Technology really is genius" [27].

Video conference technology opens up for a more active dialogue between the citizens and the visiting nurses, and for citizens to take their measurements on their own and thereby to gain a better understanding of their particular condition.

Earlier studies of a similar nature have reported positive effects on patients' health and quality of life as well as cost-effectiveness and structural aspects [28-37], and it is anticipated that the solutions applied in DREAMING can improve health care services dramatically.

The technology applied in DREAMING also allows for the citizens to take on an extended role in the larger perspective of society. AAL technologies offer a new freedom for chronically ill elderly citizens and allow for them to be actively involved in society for longer. In

DREAMING, this is particularly pertinent to the video conference component. This system is connected to and runs via the citizen's own TV and therefore constitutes a familiar interface for the citizen. The system brings society into the citizen's own living room, so to speak, by offering the possibility of face-to-face contact with nurses, GPs, family, and friends, including other elderly citizens experiencing similar health problems.

In the abovementioned MAST manual, potentials of patient empowerment is not listed as one of the preceding considerations deemed necessary when evaluating telemedicine programs. It might be beneficial to include this aspect in the preceding considerations since the opportunities that patient empowerment allows for, are likely to significantly influence the assessment of telemedicine.

VI. CONCLUSIONS

The present article has shown how, in research projects, citizens' role as patients in health care has already been influenced by telehealth technology. Examples have been presented that show telehealth technologies can empower patients in such a way that they are actively involved in a new triangle of care. The empowerment happens through information-sharing; offering the patients a visual overview of their course of treatment, letting the patients take their own measurements, and letting them provide verbal and written inputs. Further, the idea has been presented that the technology can pave the way for citizens to take care of each other. Also, both projects show that old age is not necessarily a barrier in the use of ICT.

Of the two projects presented, DREAMING relies on patient empowerment the most due to these factors: The patients themselves are already taking their own measurements and the flexible video conferencing system makes it easy to establish contact with health professionals.

In order to fully realize the second level of citizen involvement, the extended citizen role, in telehealth projects, it is crucial that it is made clear to the patients, relatives, etc. that their inputs are valuable and that the health professionals have an interest in empowering the patients since this improves the basis for decision and ultimately the quality of the treatment.

The success of telehealth programs rely heavily on patient inclusion in the planning and development processes as well as the technology being non-intrusive and user-friendly, even elderly-friendly; potential factors such as comorbidities and reduced cognitive and psycho-motor skills have to be taken into consideration. Both projects have experienced how appropriate training and patient inclusion have lowered potential resistance to the technologies.

VII. PERSPECTIVES

In its fullest form, patient empowerment through telehealth technology allows for direct communication between the patient and the medical expert. Note however, that this does not mean that visiting nurses become redundant, but it does imply that as patients will become

more competent in their own care, the visiting nurse's professional role is likely to change. Training the patients in self-management does not, of course, entirely substitute the competences of the visiting nurses but it does have the potential of reducing their burden of tasks. More research on how telehealth technology will affect the roles of health professionals would be valuable.

The next step in terms of citizen involvement in ulcer treatment would be letting the patients take the pictures themselves and to upload both the pictures and comments on the state of their ulcers to the electronic record. In DREAMING, this is already taking place as the citizens are taking their own measurements instead of leaving the task for the visiting nurses. The second level of citizen involvement, the extended citizen role, in telemedical ulcer treatment as well as treatment for diabetes, heart failure, and COPD would be letting citizens perform this kind of treatment on each other and/or educating the relatives in performing it. In other words, to extend the above-mentioned triangle of care to include patients' relatives, neighbors, or other persons from the patients' social network as well. In this connection, the video conference component opens up for the possibility of a new network comprising not only medical specialists and relatives, but also new acquaintances in terms of other citizens in a similar situation. This would allow for the citizens to exchange experience and help each other. This is a valuable feature as other patients are often a better source of advice for how to live with a chronic illness than medical specialists who are primarily concerned with treatment of the illness.

An important lesson from the DREAMING project is that the more encompassing telehealth technologies are the better. For instance, since a diabetes patient is likely to suffer from several co-morbidities it would make good sense to provide this patient with a technology that is able to measure and/or monitor e.g., both his glucose levels and his foot ulcers.

To help relieve the strained health care sectors it might be necessary to let health professionals focus more on the actual treatment and then empower patients and their relatives to deal with the more care-related tasks. This might be realized through the use of AAL-communities in which non-intrusive technology, telehealth technology being only one kind, empowers citizens to be involved in their own care and the care of their fellow citizens. Ideally, the design of such AAL-spaces will be based on continuous user feedback. Self-care programs require patient involvement at every stage, as well as user-driven innovation, sharing of knowledge between providers and patients, and education about preventive care and treatment that the patient himself can be in charge of.

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Stress Intervention Online

- Designing for Self-help through Multiple Help

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Abstract— E-health has undergone many changes during the years. One is the development of web-based self-help services for patients and citizens with health concerns. This paper presents design ideas for a stress management web-based system that takes the development of self-help services further. The aim of the system is to help people with mild to intermediate levels of stress problems change patterns of behavior and take control of their stressful life situations. The system includes not only self-help through individual work with stress-related issues, but it also complements the individual efforts with help from peers and medical professionals. The system then becomes a platform for combining multiple help online. The system design ideas have resulted from research studies and practical experiences of stress management and web-based self-help systems. The paper also presents a couple of scenarios to illustrate in what ways the system usage can be characterized by multiple help online and a holistic approach to stress intervention.

Keywords— stress intervention; web-based; self-help; multiple help; communication.

I. INTRODUCTION

E-health systems have evolved in many different health areas. Both patients with physical and mental conditions and citizens with health concerns, such as unhealthy lifestyles, use the Internet to search for information and seek help from medical professionals and peers. One area is self-help for people who experience unhealthy levels of stress and high stress responses.

Studies have shown that many people in working life are on sick leaves due to high levels of stress [1]-[2]. In Sweden, stress related dysfunctions have become the second most common reason behind sickness absence [3]-[5]. By changing unhealthy lifestyles, people can reduce the risk of getting severe illnesses. Preventive healthcare and early interventions are therefore recognized as important in order to help groups of people from becoming patients of the healthcare system and from being forced to sick leaves and long-term sickness absence.

Stress research has since a long time been oriented toward studies involving the physiological response (= the body's reaction) to stress and the cognitive processes that influence the perception of stress. However, the social perspective of the stress response has established that people with similar life

conditions are not necessarily affected in the same way, which indicates that stress is caused, at least in part, by a person's mind or way of thinking. To change a certain way of thinking and to tackle an unhealthy behaviour includes promotive and preventive interventions and an ongoing support [6]-[7]. This is where the Internet and web-based systems can play an important role through available information of different kinds and continuous communication with others. Intervention systems need flexibility that allows people to find their own ways through the system.

The use of self-management intervention systems on the Internet today is characterized by information management, interactivity and communication. However, the use of the different online health services for information and communication with experts and peers has not yet reached the level of integration and holistic thinking. The paper addresses this gap. The paper introduces the design of a new type of web-based stress intervention system that considers integration, flexibility and individual differences. It includes different ways to approach stress, both from a stressor perspective (triggers) and a response perspective (stress reactions). However, the main focus is on the individual intervention. It also includes different sources of help, from research findings to real life stories, communication with peers and practical tools and counseling.

The following sections are organized as follows. To start with, background knowledge and understanding of stress, stress interventions and internet self-help services will be presented. Thereafter, we will introduce our design for a new web-based stress intervention system based on a holistic approach using multiple help online.

II. RELATED RESEARCH AND KNOWLEDGE

A. Stress

According to the bio-psychosocial model of stress, it is stated that biological, psychological and social factors are linked in the progress of promoting health or causing disease [8]. In this model the mind and the body are well connected and interdependent, which means that biological, psychological, and social issues operate together to affect the health status. The model is somewhat more comprehensive and

could be considered a development of Selye's original model [9]. The stress response is elicited by a many different psychosocial stimuli which can threaten the homeostasis, which is the ability to maintain internal equilibrium by adjusting its physiological processes. Stress is experienced negatively when this imbalance occurs between the individual's perceived demands and the ability to respond to these demands. In today's life the psychosocial stressors are the most common. To let a thought or an event be appraised as a stressor, there is a perceived mismatch between the demands and the individual's resources to cope with it [10].

B. Stress Intervention

In stress intervention empowerment is a central concept. The strategies can be concluded as the processes leading to increased stress management and better health in different populations and groups of people. Empowerment helps people to increase control and manage their lives according to their needs and preferences. The key question is how to build on and reinforce authentic participation ensuring autonomy, feelings of value and sense of mastery in decision-making. Learning and problem solving abilities are important assets for any organization or work site wishing to reach its full potential, and empowerment within the individual stimulates job satisfaction. The educational approach to stress management is concerned to enabling people to make informed choices, set limits, and increase coping ability. The preventive and promotive approach are aimed to achieve behavior changes: Internal locus of control is a key factor in efforts to create empowered environments and empowered individuals able to meet stressors at work and in private life [11]-[12].

C. Self-help and Different Actors Online

There are different types of self-help services on the Internet today for people with lifestyle issues such as stressful lives. One is the Ask-the-Expert that lets users post questions directly to the system to be answered by an expert, and the users can also choose to browse the system for stored questions and answers [13]. This function in the e-health area is believed to offer value to people who need to gain new health knowledge and guidance [14]. The users can get health recommendations and advice from a medical expert [15], and this health service is also recognized to offer a new type of continuous relationships with medical experts [16].

Another self-help service on the Internet is the community forum systems for peers. These community forums on health issues have become popular lately and are used regularly by patients and citizens with different physical and mental conditions [17]. These systems let people share experiences and offer each other advice on how to cope with different health concerns [18]-[19]. Research gives that patients online tend to be well informed today, and that they act both as producers and consumers of health information [20]. This blur between being a producer and a consumer of health information and services is also named 'prosumption' and the user a 'prosumer' (e.g., [21]-[22]).

When the web-based communities on lifestyle problems for peers have been compared to the Ask-the-Expert systems, the two types of systems were shown to offer the users complementary contents and knowledge [23]-[24]. Advice and information given in the two types of systems were seen to be of different characteristics, allowing people with lifestyle problems to get diverse and complementary views of their problems. While answers from health experts were characterized by detailed descriptions of health subjects, the peer conversations emphasized personal experiences and more practically oriented advice. By linking the different answers – the ones from health experts and the ones from peers in community conversations – the users are assumed to benefit more [23]. This leads us to believe that a combination of different types of health services and actors in the stress management area would help people with mild to intermediate levels of stress problems change patterns of behavior and take control of their stressful lives. To integrate knowledge and experiences of medical professionals and peers is believed to make an advantage.

Many people who suffer from stress related disorders prefer to get interventions through the Internet, and studies have also shown positive effects on health outcomes. However, there are probably high rates of drop-outs [25]-[26]. There is also little known about the participants' use of the web-based stress intervention programs, what the communication patterns are like, and what support the participants take advantage of. How to make use of technological possibilities and human resources in this field needs to be further explored.

III. DESIGNING A STRESS INTERVENTION SYSTEM

A. Multiple Help Online – Five Types of Help

The system for stress intervention online that we propose is designed as to form a whole of different help services and actors who contribute together. The system consists of five types of help: Ask-the-Expert, Counseling room, Community forum, Exercise programs and Stories told & research results. Below, the basic characteristics of each of these five are described.

1) Ask-the-Expert

Ask-the-Expert is where the user can ask medical professionals for help and advice on different stress related concerns. This help can be used both for direct questions and also for browsing for previously popped questions and their answers. This part of the system is based on communication between one user and a medical expert as well as on storage of these interactions.

2) Counseling Room

The counseling room is a chat area in which users and medical professionals can meet in smaller group sessions. The counseling room is based on synchronous communication among the participants. Different predefined topics related to stress management can be addressed during these sessions. Cognitive behavioral therapy for stress management addresses

topics such as excessive job involvement, low self-esteem, lack of recuperation, work-family imbalance, job mobility and competence matching.

3) *Community Forum*

Communication between peers is also important for keeping up with ongoing stress interventions. Community forum lets the users have conversations together on current topics in their daily lives, related to sleep, work situation or balance between work and family, for example. The forum is based on asynchronous communication, and communication can therefore take place whenever the users have the need for it. The web communication with peers can help people get new insights and encouragement to develop new habits.

4) *Exercise Programs*

The fourth function of the system is exercise programs. Depending on the stress issue, there are different available exercises that the users can do on their own. Reflection exercises on work or study situation, relaxation techniques and abdominal breathing exercises to ease physical tensions are examples. The exercises are presented in textual form, audio and video, depending on the purpose of the exercise.

5) *Stories Told & Research Results*

The last function of the system is about giving the users access to stress-related research results and stories told by others who are, or have been, in similar situations. This part of the system is mainly based on storage of textual information. By letting the users read about other people's stories together with comments from medical professionals, the users can learn to see their own situations clearer. It also helps to reduce stigmatization.

B. *Stress Intervention Areas*

There are different areas that need to be addressed in order to ease the stress levels of the users. The system's multiple help is therefore structured in accordance with four main stress intervention areas: sleep, work/studies, balance in life and physical wellbeing. Figure 1 shows a design of this structure. The stress intervention areas are introduced in the following sub sections.

1) *Sleep*

It has been concluded that stress is strongly linked to disturbed sleep, insomnia and impaired awakening. The inability to relax and to let work issues act as stressors is probably an important link in the relation between stress and sleep. The quality of sleep has thus shown to be of great importance for the onset of stress-related dysfunctions as well as the recovery. It is therefore an impending risk that a person with high levels of stress ends up in a negative loop of increased sleeping disturbances and high level of stress. Assessments of sleeping quality and insomnia and exposure to stress as well as the effects of interventions need to be further investigated.

2) *Work/Studies*

An overcommitment at work could entail increased risk to experience work issues as stressful [27]-[28]. Exposure to stressful job conditions such as heavy workload, infrequent rest breaks, long work hours, shift work, and interpersonal relationships, can certainly have a direct influence on workers' health. Overcommitted co-workers often suffer from inappropriate perceptions of demands and fail in their coping ability. Also, perfectionists have been described as people who are highly responsive to stress, and they tend to generate extensive stress for themselves [29]. Concern over mistakes and automatic thoughts of perfectionism are examples of things that can increase the level of stress.

Both work and studies nowadays include a great amount of flexibility and ability to stay connected independently of time and space. In general, this is a positive development since it allows for distance work and studies. But at the same time it increases the risk of having more people ending up in active work and study lives without boundaries. To be able to negotiate about expectations regarding availability, and to set limits, are important for a healthy work and study life [30].

3) *Balance in Life*

Stressors related to occupational work such as a frustrating work situation or a work-family imbalance are often major causes of strain, and mental ill-health, as well as psychosomatic conditions [4], [31]. Especially job strain with exposure to

Stress Intervention

A System for Multiple Help Online

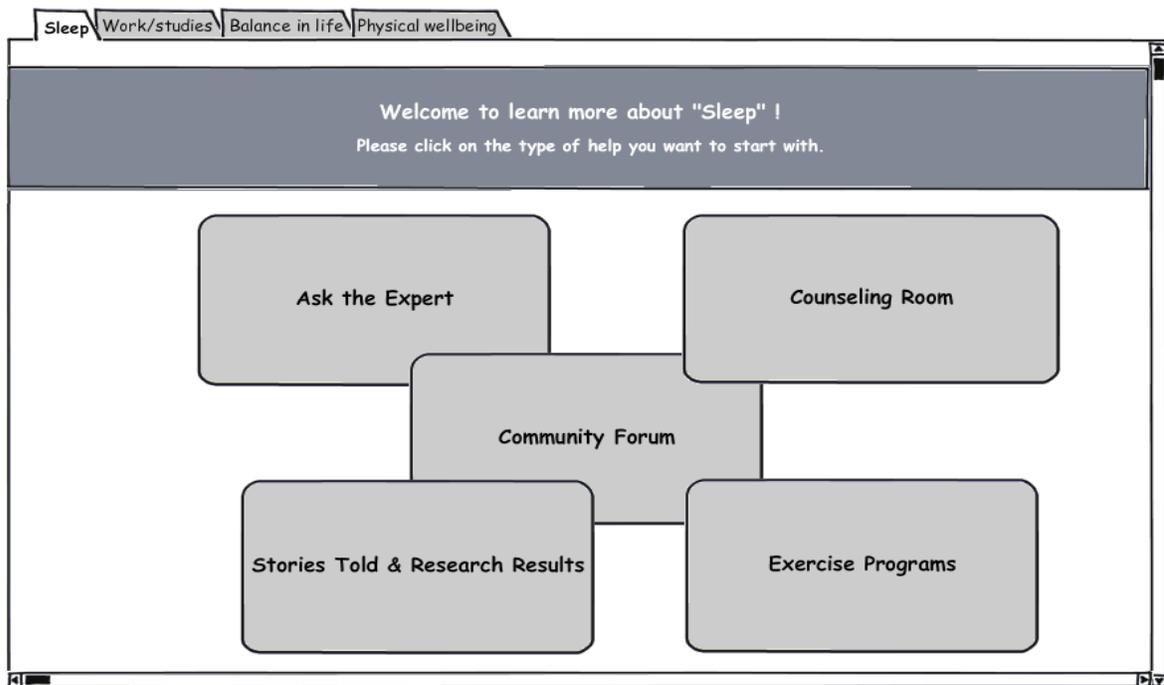


Figure 1. Mockup design of the stress intervention system showing the multiple help functions and stress intervention areas.

stressful job conditions could certainly be a health hazard to those who have additional strain from family life. Perceptual distortion can prevent people from accurately assess cost-gain relations and to set limits [27].

4) Physical Wellbeing

Responses to stress are often manifested in body tension. Regarding individual interventions in the area of dysfunction due to negative stress exposure, progressive muscle relaxation was originally designed by Jacobson to guide people through successive tensing and relaxation of the body muscle groups from toe to head to achieve overall body relaxation [32]. This process is easy to learn and teach, safe, non-threatening and non-competitive. Since then it has been concluded that the effectiveness of the interventions varied according to the health-outcome measure used. Cognitive-behavioural skills were more effective for psychological outcomes, whereas muscle relaxation techniques were more effective for physiological outcomes. Using a combination of techniques; muscle relaxation and cognitive-behavioural skills seemed to be more effective across outcome measures than using a single technique. Deep, diaphragmatic breathing is known to counteract the fight or flight response symptoms that are often associated with anxiety and negative reactions on stress exposure. Also meditation can be used to counteract stressful situations, as it is a technique to develop concentration and awareness to produce a calming effect. Here diaphragmatic breathing is central to any meditation practice. It has been found that there could be a lowering of blood pressure during

deep breathing, which is interesting to consider in stress management [32]-[35].

C. A Holistic Design with Multiple Help Integration

The stress intervention system proposed in this paper applies the concept of multiple help online for different stress intervention area. From this follows that peer conversations, questions to as well as answers from medical experts, counseling sessions, research results, life stories and exercises are available in each of the stress intervention areas.

The different stress intervention areas aim at letting the user choose his or her way into the system based on what is believed to be the most urgent stress-related concern. At the same time, it is important to offer easy ways to navigate between the different intervention areas. The technical system can assist in this through links and navigation menus, but also medical professionals, as well as the peers, can support this by referring to other intervention areas. In a conversation on sleep, for example, there could be references to related conversations on work issues within the work/studies intervention area.

The same idea is applied on the five types of help in the multiple help concept. The different types of help are linked together so that the users can navigate easy between them, but also the medical experts can encourage the users to take advantage of other help types for complementary support and knowledge. In the Ask-the-Expert answers, there can be references to relevant peer conversations that the user could join, for example. This can be implemented manually to start with, by having the medical expert suggesting peer

conversations in his or her answer. In a future setting, it is also possible to implement automatic matching techniques in order to generate links to similar stress-related topics in different parts of the system.

IV. SCENARIOS

Below, there are two short examples of scenarios aiming to illustrate in what ways the web-based stress intervention system can be used to let the different stress areas, information sources, tools and actors work together.

A. Scenario 1: Chain of Complementary Support

Eve, 52 years, is a middle manager in a company. She is ambitious and has always felt that people around her have high demands on her. Today, her employees and family take almost all her time, which has led to a stressful life situation with too little sleep and unhealthy food and exercise habits.

Eve enters the stress intervention system by visiting the stress intervention area “balance in life” and its community forum for peers. She finds a conversation that is ongoing, on a theme close to her own situation. She reads the conversation for a while, and then adds a posting telling the others that she finds it difficult to make room for herself and her needs. The conversation continues with the problem of saying no and to delegate responsibilities. One peer recommends Eve and the others to sign up for an online counseling session on how to set limits. Eve signs up, and later she joins the counseling session together with a handful of peers, moderated by a medical professional. During the session, the medical professional refers to an exercise on how to practice limit settings present in the help function “exercise programs”.

B. Scenario 2: Complementary Stress Intervention Areas

Johan is a 37-year old man who works with systems analysis at a big IT-company. He works very long hours in front of his computer. His back has started to hurt, and his body is stiff and his eyes dry. Recently, his sleep has been affected as well. He finds it difficult to fall asleep and he often wakes up at night.

The first thing Johan does when entering the stress intervention system is to open the intervention area called “sleep”. He starts to search for similar stories from others, and he also posts a question to the Ask-the-Expert service to find out about what he can do to ease his sleeping problems. The medical expert who answers the question from Johan presents some practical advice on how to relax before going to bed. But, since Johan has several concerns, the expert also recommends exercises that Johan can do at work, both to increase the variety of physical work activities when using the computer and to reduce strain on the eyes. These exercises are found in the stress intervention area called “work/studies”. The medical expert also recommends Johan to visit the stress intervention area called “balance in life”, to read about research results and to join conversations with peers on how to make room for other activities besides work.

V. CONCLUSIONS AND FUTURE WORK

This paper has outlined some basic foundation of a new and holistic web-based system for stress intervention. The novelty of the system lies in the holistic approach considering both different aspects of stress and stress intervention and also different supportive roles and functions. Not only have attention been drawn to self-help through information access and exercises, but also to the necessity of having support and guidance from peers and medical professionals to ease the individual struggle for sustainable new habits and improved health. To make the system holistic, web links between the different intervention areas and also between the different kinds of help are considered. Additionally, the medical professionals and other actors in the system can amplify the holistic view of the system by making references to different system parts. This will let the user navigate more easily between the different parts of the system and to use different kinds of help in combination.

Next step is to have the system design implemented, and then evaluated by a pilot test group. Research studies will also be conducted on the system usage and online communication patterns.

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Psycho-physiological Stress Monitoring using Mobile and Continuous Pulse Transit Time Measurement

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Abstract—In the last years stress has become one of the most serious health problems in industrialized western countries. It is one of the most common reasons for a number of serious diseases and an important factor for increasing cost in health systems. Beside this, over the last years there has been an increasing interest in finding new methods for capturing psychological, behavioral and physiological data in real-time using in-field data acquisition systems. Within our research group a system for ambulatory assessment of psycho-physiological signals for real-time data capture was developed. Because of the multivarious influences of stress on the physiological response of the body, a stress measurement system has to take into account as many parameters as possible. Pulse transit time (PTT) gives comprehensive information about the cardiovascular system. It is determined by measuring the ECG and the pulse wave; the latter is noninvasively measured either on a finger or on an earlobe. In a further study we discovered a strong correlation between stress and PTT and that PTT is an appropriate parameter for stress measurement. The paper describes the use of a mobile PTT-measurement system for monitoring stress in everyday life.

Keywords-component; stress; mobile; PTT; ECG

I. INTRODUCTION

Excessive stress releases reactions on different levels in the human body. One can observe reactions on the cognitive level [1], the emotional state of a person, the vegetative-hormonal system, as well as on the muscular level.

Predominantly the reactions on the vegetative-hormonal level of the body can be measured by different methods. For the measurement of stress, one can distinguish between invasive and non-invasive methods, or between stationary (laboratory) equipment and mobile measurement systems.

The physiological reactions are caused by an activation of the sympathetic nervous system and by the release of hormones (adrenalin, noradrenalin, testosterone and cortisol). These hormones are released as a consequence of the activation of the hypothalamic-pituitary-adrenal axis (HPA or HTPA axis), the neuroendocrine system that controls reactions to stress and regulates many body processes, i.e., mood and emotions, the immune system, as well as many others.

Consequences arising out of this are: an increase of the respiration and heart rate, a constriction of the blood vessels, an increase of the blood pressure, a reaction of the electrodermal activity and energetic metabolism [4].

The goal of a reliable measurement of stress is to obtain a comprehensive overview of the entire reaction chain within the body by a simple monitoring system. The monitoring system has to be non-invasive, mobile and unobtrusive in order to be accepted by a user as part of their everyday life.

Under these circumstances the use of the pulse transit time seems to be an ideal parameter for stress measurement. Almost all of the cardiovascular parameters (heart rate, blood pressure, artery resistance) can be linked with one another. The PTT could be measured non-invasively by a system that simultaneously records ECG and photoplethysmogram.

Several workgroups are trying to make the psycho-physiological load on people measurable, in order to help people adapt to their stressful everyday life in a simpler fashion. In other words, to investigate the different possibilities of balancing one's physical and mental resources thereby achieving one's best cognitive performance.

In fact, they are attempting to find indicators which could show and quantify one's stress and activity level and thusly give an idea about one's physical and mental state.

This paper is organized as follows: in Section II, a description of the methods used to extract stress indicators and to validate PTT as an appropriate indicator for the acute stress level is given. Following this, the research results on the topic will be presented in Section III. Lastly, a discussion on future research plans and concluding remarks are presented.

II. METHODS

A. Pulse Transit Time

The pulse transit time or PTT represents the time needed by a blood pulse wave to exit the heart and reach the PPG (PhotoPlethysmoGramm) measurement site. To increase the accuracy of the measurement, the distance between that site and the heart should be as long as possible. In this case, the impact of measurement errors in time domain is smaller compared to the measurement result. Beside this, the measurement site must to be accessible for the sensor device and robust enough against artifacts, e.g. caused by

movements. For this reason the pulse wave is detected at the finger tip [2].

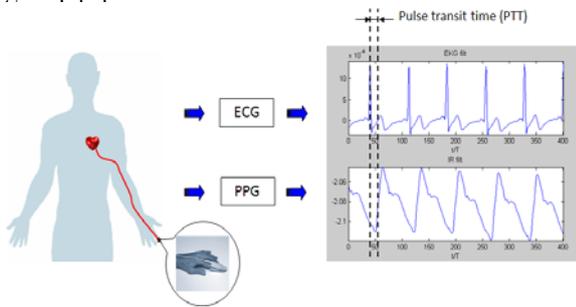


Figure 1. Measurement of pulse transit time from ECG and PPG.

As shown in Figure 1, the PTT can be determined by calculating the time difference between the r-wave of the ECG signal and the virtual base point of the PPG signal. This latter corresponds to the intersection point between the tangent to the pulse wave at the point with the maximal slope during the systolic rise phase and the horizontal line going through the point having the absolute minimum. The main advantage of using the base point to calculate the PTT is that the p-base point, which is determined out of two characteristic points in the pulse wave, guarantees a better noise and artifact robustness compared to other possible points of the photoplethysmogram like the maximum of the p-wave.

B. Mobile Measurement System

This section describes the mobile measurement system used in this study. For the assessment of the biosignal, the SOMNOscreen plus system from somnomedics (Randeracker, Germany) was used. With this system we measured ECG-signal, photoplethysmograph signal, the electrodermal activity and the respiration signal.

These signals could be relevant for the determination of the stress level of the test person. Furthermore, a 3D acceleration sensor-node [3], [9] is used to simultaneously collect information about the activity of the user. The measurement of physical activity is important to interpret the cardio-respiratory physiological signals in field studies.

1) *ECG-Sensor*: We are using the two-lead method to detect ECG-Signal with a sample rate of 1024 Hz. By means of gel electrodes we measure the skin potential on the chest of one person. To eliminate motion artifacts, the cables of the electrodes are fixed to the surface of the body.

2) *Photoplethysmograph*: A finger clip transmission photoplethysmograph is used to register the PPG. The signal of the photodiode correlates with the amount of blood in the finger and thus reflects the pulse wave in the blood vessels. The PPG signal is also acquired with a sample rate of 1024 Hz.

C. Simulation of stress in laboratory environment

The „Trier Social Stress Test“ (TSST) [5] is used in laboratory environment for induction of moderate psychological stress responses. A meta-analysis conducted by

Dickerson and Kemeny [6], reviewing 208 laboratory studies of acute psychological stressors, demonstrated that the TSST is a reliable instrument eliciting robust physiological stress reactions.

The TSST consists of an anticipation period (10 min) and a test period (10 min).

In the anticipation period three persons are introduced as a selection committee. The subjects are told that after a preparation time a job interview will take place, in which they have to deliver a free speech introducing themselves and answer questions asked by the committee (5 min).

Following these instructions the subjects were instructed to prepare their talks, in which they had 10 minutes. After this they made their short presentation to the committee and responded to the panel's questions. Following this interview, one member of the committee presented a second task the participant must partake in. The test person has to subtract the number 13 from 1687, backwards in sequence. Each mistake restarts the subtraction from the beginning at 1687. During the whole test period subjects are filmed by a video camera [5], and they are informed, that these film are used for further analysis of the test.

D. Measurement of baseline during night

Normally, baseline values of physiological data in „Trier Social Stress Test“ (TSST) experiments are measured at the beginning of the test. After connecting the sensors to the test persons, baseline values are captured just before the anticipation phase starts. But a number of people show increased vital parameters when coming to the laboratory for a test, even if they don't know exactly what happens during the experiment.

To obtain a reliable baseline value of physiological data, monitoring during the night after the laboratory test is necessary. To measure the physiological signal during the night an unobtrusive measurement system is needed, so that it does not disturb the sleeping pattern of the user to maintain the influences of the measurement signals as small as possible.

E. Subjects

28 students (14 female, 14 male) from the Karlsruhe Institute of Technology were selected to participate in the study. They were misleadingly informed beforehand that the goal of the study was to test a new medical device; they were not told that the actual intentions of the study were to measure stress. This procedure was necessary in case of a stress study to avoid influences on the measurement result.

F. Study procedure

We designed a detailed and complex procedure for this study (see figure 2).

After the reception of the participant, an informed and written agreement is given by each individual. Some common information about the person is collected from questionnaire. After this, the system for measurement of pulse transit time was applied to the subject and the recording was started. Immediately they were instructed to take a 5 minute pause. After this phase, a first saliva cortisol

measurement and a subjective assessment of the mental state (MDBF) were collected. This was followed by a second phase, where the subjects had to lie down (baseline phase). In the next 20 minutes the anticipation period and the test period of the TSST took place. At the beginning and the end of each phase, saliva cortisol levels, as well as MDBF, were assessed.

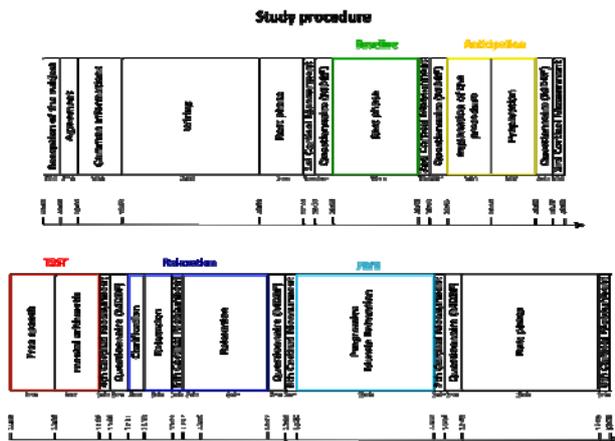


Figure 2. Study procedure in laboratory environment.

Following the TSST procedure consisting of the job interview and the arithmetic problem, subjects stayed in rest again for recovery from the stress reaction (10 min), a cortisol and MDBF measurement followed. Then a special relaxation technique, the so called progressive muscle relaxation (PMR), was performed during a period of time of 20 minutes. With this procedure we can get valid data for relaxed state as a reference that could be compared to the phases during the stress test. This phase also ended with saliva cortisol an MDBF measurement. The last phase of the laboratory period was a normal passive phase with no action for again 20 minutes. After the laboratory phase, the study procedure included a monitoring phase of the daily activities of the individual, including the night after the experiment. The measurement devices were removed from the individuals that following morning.

G. Biosignal processing

The digital signal processing has been done in MATLAB with an integrated analysis environment for psychophysiological signals. ECG and PPG biosignals have been filtered in respect to the nature of the signal in order to suppress noise (e.g. power line interference). The feature detection of the r-wave in the ECG signal has been done with the OSEA algorithm [7]. Heart rate has then been calculated using the adjusted data. Furthermore, an automatic artifact inspection process did not take in account the r-waves, whose corresponding heart rate differs more than 30% from a moving average [8].

The p-base point in the PPG signal has been detected as described in section II.A. As a result, the pulse transit time could be obtained as the time difference between both of the

identified features namely the r-wave and the p-base point. Subsequently a validation operation assured that the PTT is within a reasonable interval. Finally, the arithmetic mean value has been calculated over the defined phases.

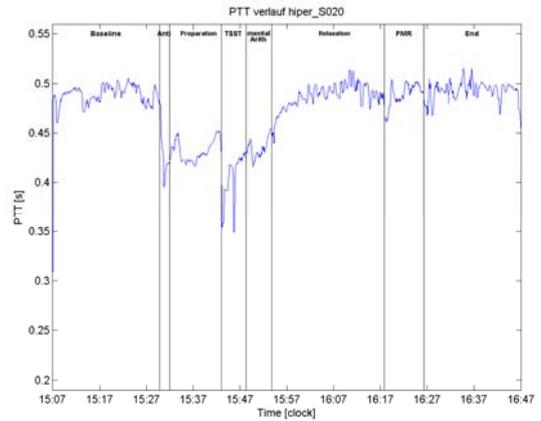


Figure 3. Pulse transit time plotted over time for a test person.

Figure 3 shows the typical signal sequence of the registered pulse transit time curves during one stress test in the laboratory environment using mobile PTT-sensor. In this figure, at the beginning of the measurement one can see the baseline phase with a relatively high value of PTT, followed by a sudden decrease at the beginning of the anticipation phase. At the beginning of the TSST, one could see another decrease in PTT. During the Relaxation a PMR, the PTT rises up to the level at the beginning of the test.

In comparison to this, the signal sequence of the heart-rate for the same individual is shown in Figure 4. One can see an inverted course of the graph. There is also a difference in the reaction time of the parameter at the beginning of a stressful phase.

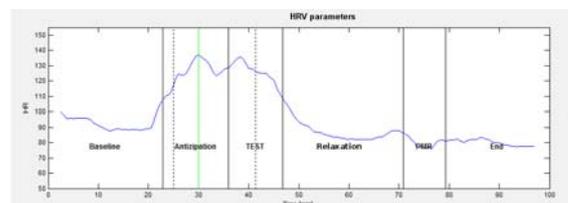


Figure 4. Heart rate plotted over time for a test person.

To control the evidence of the physiological signals during the different phases of the study, we calculated a Poincare-plot of the R-R-intervals in the baseline phase, the anticipation phase and in PMR-phase. As we can see in figure 5, there is a significant difference in HRV in phases with stress (anticipation) and phases of relaxation (PMR).

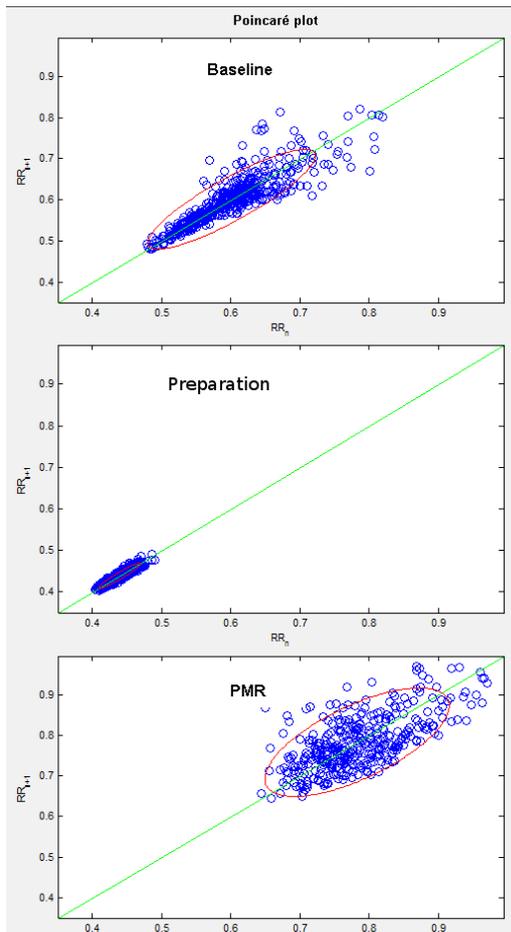


Figure 5. Poincaré plot for a test person.

III. RESULTS AND DISCUSSION

The study shows that a mobile acquisition of pulse transit time (PTT) is possible.

The expected behavior of the PTT according to the defined phases could be registered. In fact, one could identify the stressful moments during the TSST test by the corresponding changes in PTT curve. Further analyses needs to show the benefit of a measurement of PTT during night. The analysis of this data is still in progress and will be presented in a later paper.

In Addition to other methods of psycho-physiological monitoring, the mobile measurement of pulse transit time for stress detection appears to be a very significant method as described in this paper.

Due to the fact that pulse transit time comprises much more information than heart rate and heart rate variability, this parameter provides more precise estimation of a person's stress level. This was shown in a previous work [8].

IV. FUTURE WORK AND CONCLUSION

A more detailed analysis of the whole data acquired in this study is necessary in order to consolidate the preliminary results shown in this paper and to be able to draw a more reliable conclusion.

A further psycho-physiological analysis that compares the cortisol level to a subjective behavior state needs to be done in order to endorse the proposed method. In the next studies, an integrated sensor platform combined with a PDA-based e-diary method using myExperience software [10] will be used.

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Heuristic Evaluation for Interactive Games within Elderly Users

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Abstract—This paper presents the results obtained after performing a number of demonstrations followed by a series of interviews concerning the usage of interactive games as a tool to improve both physical and mental well-being of elderly persons. This study points out the importance of a proper design regarding the usability of video games for the aged to ensure the elderly benefit from such games.

Keywords—elderly; game design; interactive game; usability.

I. INTRODUCTION

According to recent studies, both Australia and the entire world, are dealing with a dramatic increase of the aged population which could be considered a crisis, if this problem is not addressed effectively and in a timely fashion [1]. Furthermore, there has been a huge increase in the development of systems which have improved the well-being and quality of life of seniors looking for the prevention of diseases and injuries related to ageing. The usage of some interactive technologies such as video games, has shown a positive impact in health outcomes for the elderly [2]. Research has been applied to find feasible methods to encourage and engage seniors with the use of these games [3], [4]. However, recent studies [4], [5] also state that those practices could result in undesirable consequences, even negative impacts regarding issues related to the usability of the video games among older users.

The goal of this paper is to present the results of the evaluation of four Nintendo Wii balance games under the observation of six experts in health and wellbeing techniques. For our research, we conducted a series of recorded and transcribed structured interviews where the suitability of the games for the elderly users was assessed.

This paper provides an overview of previous studies related to this topic, a description of the games assessed and the scenario of our interviews. We present the factors assessed and the results that we obtained, as well as a discussion concerning the findings, followed by our conclusion.

II. BACKGROUND

The usage of video games as a method to keep and / or improve the health condition of the elderly has shown both positive and negative effects [4]. Regarding the former, there have been improvements after the use of videogames as a tool for balance disorder treatments and post-stroke

rehabilitation [3], [6], [7]. These practices have demonstrated the benefits of involving interactive technologies for maintaining wellbeing and improving health outcomes. However, the usability of these games for the elderly needs to be improved [5]. It is relevant to mention that the new genre of games require a different way to interact with them. Currently the youth-oriented interfaces feature sounds, flashing lights and colours which create enjoyable experiences for young players, but could lead to negative feelings for the elderly users. Some of the most notable problems include confusion caused by pressing or releasing buttons in the appropriate time or anxiety and stress engendered by the inability to reach the game goals [4]. Because of the above, efforts have been made to establish formal methods and techniques to assess the usability of videogames. Some methods are focused on technical issues such as the game aesthetic, sound events and programming errors instead of evaluating game interfaces, the mechanics of the game and how enjoyable it could be. One approach to this is the ISO 9241 standard of usability which uses *effectiveness*, *efficiency* and *satisfaction* as basic metrics [8]. However, the technique of heuristic evaluation of video games has been gaining status because of its flexibility and adaptable nature [9]. The term *Heuristic Evaluation* is an inspection technique where a set of usability principles is established and used by evaluators to explore an interface. These principles are called heuristics.

In [8], the heuristic evaluation is divided into five stages. These are: (1) the identification of usability problems as well as their categorization; (2) the observation of players while interacting with the videogames under the observation of evaluators; recording facial expressions, verbal reactions, etc; looking for new problems which could be missed from the first stage; (3) the re-categorization of usability problems; (4) the description of the ways to resolve problems encountered previously by the creation of heuristics; (5) the testing of heuristics applying the methodology of user logging combining the thinking aloud protocol.

TABLE I. INTERVIEWEES' DETAILS [10]

Traditional Medicine	Expert 1:
	Professor Aged Care, Sydney Hospital Researcher and director of Health and the Aged Centre.
	Expert 2:
	Physiotherapist at an large Aged Care Facility in Sydney
Alternative Health Techniques	Expert 3:
	Associate Professor Chronic Care at a Sydney university.
	Expert 4:
	Certified Feldenkrais Movement Practitioner in Sydney.
	Expert 5:
	Certified Alexander Technique Practitioner in Sydney. Own Practice.
Expert 6:	
Expressive Arts & Music Therapy Specialist at a university in Sydney as well as having a Sydney private practice.	

III. METHODOLOGY

During July and August 2010, we demonstrated and then evaluated four Wii balance games (see Table 2) with the cooperation of six health professionals, three of them representing alternative health techniques, and the other three representing traditional medicine (see Table 1).

Overall, the sessions were conducted by following these stages: (1) One semi structured interview with each health professional concerning the procedures which each one performed with the patients over 65, as well as their experience, if any, involving interactive technologies within their practices. (2) A demonstration of the four Wii balance games which were: Skate Board Arena, Tightrope Walk, Balance Bubble, and Table Tilt; all of them part of the Wii Fit Plus suite (see Table 2). These demonstrations were performed by one of our researchers. In one interview, our interviewee offered to perform the activity. During all the demonstrations, the interviewee was providing oral feedback by remarking on the strengths and weaknesses of the video games. They offered suggestions to make the games much more enjoyable and suitable for their elderly patients.(3) This material was transcribed and has been analysed using Leximancer, a specialist analytics technology for unstructured, qualitative, textual data [13].

IV. THE HEURISITC EVALUATION

Based on previous studies, our heuristics were focused on the usability of videogames for elderly users. They concerned factors such as: engaging with the game, avoiding mental distress and physical damage by controlling extreme emotions and considering the changes related such as loss of cognitive and motor abilities.

TABLE II. GAME'S DESCRIPTION [11]

Game	Objective ¹	Procedures ²	Rules ³	Conflict
Balance Bubble	Navigate it along a river to the rainbow finish line.	Shift weight to propel the bubble along the river.	Hazards such as rocks and river banks, and bees.	Reach the goal avoiding hazards and respecting the time limit.
Table Tilt	Tilt the tables so that the balls drop into the hole(s).	Shift weight to tilt the table. The table could have at least one hole in it; the balls must be guided into the hole(s).	Hazards such as: unguarded edges, slopes, blocks.	Dropping balls could lose more balls as well as causing delays, time limit.
Tightrope Walk	Walk a rope strung between two buildings.	Walk across the rope, jump when biting machines appear.	Biting machines, obscured view, and wind.	Leaning, falling off the rope, unbalanced jumps, time limit.
Skateboard Arena	Show off your technique with a skateboard.	Turn the balance board through 90 degrees clockwise, push off with your back foot to start and jump when obstacles.	Ramps, half-pipes, etc.	The scoring depends on your tricks on ramps or half-pipe.

After following the heuristic evaluation methodology we developed this list which contains a general categorization of the problems found [8], [9]:

- a) *Customization Issues:* User cannot modify the game settings according to their needs.
- b) *Inability to avoid non-playable content:* User cannot skip introductory videos or parts of the game which are repetitive.
- c) *Control of actions:* Excess or deficiency of sensibility of controllers.
- d) *Training:* The video game does not provide training practices before playing the real game.
- e) *Goal feasibility:* Extreme difficulty to avoid hazards respecting the time limits. Too many obstacles and limited time periods.
- f) *Correspondence between user movements and display:* The game must respond according to the user movements, mirroring the real world. Connection between what the users see and do.

¹ According to the game design theory, *Procedure* is everything that player can do respecting the rules.

² The *Rules* describe objects and behaviours.

³ *Conflict* is everything which does not let you reach the goal directly. [12]

g) *Provision of Rules, Information and Instructions:* Lack of explanation, inadequate timing, content and/or format of the provided information. For example the inappropriate usage of language.

h) *Mental Health:* Feelings of stress, anxiety and/or disturbance due to excessive memorization, inadequate concentration requirement and dealing with the conflict of the game.

i) *Physical Health:* Physical issues caused by tightening up, falls, loss of balance, excessive requirement of workout, coordination and flexibility.

j) *Engagement:* Lack of commitment and/or engagement due to the thematic, challenges and/or *diversion factors of the video game.*

TABLE III. GAME'S DESCRIPTION [11]

Categories	Experts						Total
	1	2	3	4	5	6	
D. Training	1						1
E. Goal feasibility	1				1		2
F. Correspondence between user movements and display				1		1	2
G. Provision or Rules, information and Instruction	1	1			3	3	8
H. Mental Health	1				1	1	3
I. Physical Health		1			2	2	5
J. Engagement	2	1	1			1	5
Total	6	3	1	1	7	8	26

After categorization, we developed our heuristics. Some categories were deleted due to their lack of occurrence (Category A, B and C) and one resulted in the union of related categories (Category H and I which became Heuristic V). The final game heuristics are listed below:

1) *Provide training phases:* The game should have training phases before the real game starts, allowing the users to become familiar with the technology. Additionally, these training stages must be easy to skip when they are not required anymore

2) *Create feasible goals:* The goals must be reachable by adapting the difficulty of hazards to take into account the physical abilities of the aged cohort.

3) *Establish appropriate relations between movements and display:* The game must respond according to the user movements.

4) *Provide rules, information and instructions in an adequate way:* The information regarding rules, suggestions and instruction should be given before and during the game, so the user does not have to read instructions and operate at the same time. Also, this information should be provided by audio.

5) *Consider the mental and physical condition of the player:* The player should not feel frustrated and upset because of hard goals. The objective of a game is to

entertain the player, so practices involving excessive memorizing must be avoided. Avoid unnecessary requirements for workouts involving coordination and flexibility outcomes. If possible, preclude the need for complex movements so the elderly users do not require frames to maintain balance.

6) *Engage the user:* The thematic of the video game must be in accordance with the audience's interest to avoid lack of commitment.

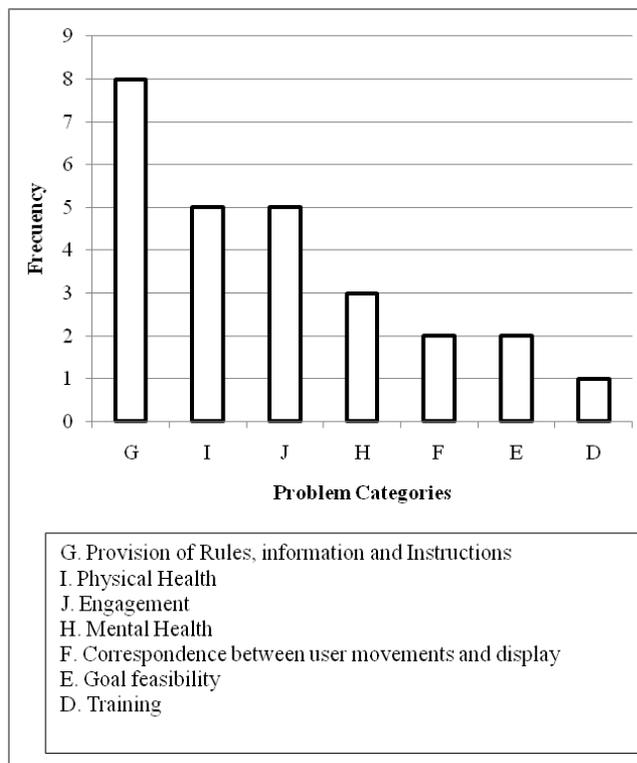


Figure 1. Frequency of the problems ordered by their occurrence.

V. RESULTS

After running the evaluation and categorizing the problems found, we concluded that the total number of unique usability problems was 26. Each health professional found around 4 problems on average and the range of problems seen for each specialist was between 1 and 8 (see Figure 1 and Table 3). We now map the appropriate heuristic to address each particular problem that has been identified.

Figure 1 shows the frequency of problems found for each category ordered by their occurrence. It was found that the main problems were related to the provision of rules, information and instructions. One participant mentioned *that reading instructions spread across the screen may be confusing and less compatible with kinesthetic awareness than auditory feedback.* Such games require a variety of instruction mechanisms such as text and audio together (Heuristic IV).

The next three most common problem categories were concerned with the physical health, engagement and mental health of the user. One of the experts stated *that falling from a tightrope between two skyscrapers is an anxiety-producing stimulus, which makes people tighten their necks and shoulders and sabotages their balance reflex* resulting in risks for the physical condition of the elderly. Additionally, when playing the Balance Bubble, one of our interviewees said *If the elderly are learning from this game to lean back in response to wanting to slow down it could actually lead to falling backwards*, that is potentially dangerous for the aged (Heuristic V). Also, some of our evaluators believed that providing a balance frame could be useful for older people when playing this kind of game, so they could hold onto it to gain confidence and avoid getting injured. During the evaluation of the *Skate Board* game, some of the experts stated that elderly people could reject playing this game because it was outside their own experiences and more suited to a younger audience. This supported the idea that the thematic of a video game is a relevant factor when trying to engage an elderly user (Heuristic VI).

The remaining categories F, E and D concern problems relating to the correspondences between the user movements and display, goal feasibility and training. We found that games like *Tightrope could be a bit confusing for the user as the picture is opposite to what they do e.g. the picture shows one foot in front of the other; however, on the board, the feet are apart* (Heuristic III). Although game theory points out that the conflict of the game creates a challenge which is the main reason to engage the user [12], one of our experts claimed that *you don't want to have activities that are impossible to achieve as it becomes too distressing for people and they just give up*, losing their commitment to the game (Heuristic II). Consequently, it was found that some games could require preliminary training as well as customisation allowing the aged user to get familiar with the activities provided by the video game. Regarding the above, it was suggested that *they could pick up speed over time: Start very slowly until they get used to these things* (Heuristic I).

DISCUSSION

As explained earlier in this paper, the use of videogames by aged people requires a deep inspection to guarantee optimum results on health outcomes. The use of heuristic evaluation to assess the usability of interactive video games, and the insights of health specialists, revealed some unexpected results about the mental and physical health of the elderly. A disconnect between what is on the screen and what the user is actually doing, may cause confusion for the player, resulting in feelings of anxiety and frustration while also affecting their balance reflex and mental satisfaction. As users age, their sight and hearing often deteriorates making it difficult for them to read or listen to instructions while the game is running.

CONCLUSION

The usage of video games and interactive technologies for health purposes has shown positive outcomes for the aged. However, these practices could also result in drawbacks for them if their mental and physical conditions are not taken into account. Furthermore, testing the usability and suitability of videogames is critical to obtain the improvements expected. In this paper we have applied heuristic evaluations to assess the suitability of such games for the elderly. The interviews with six healthcare experts were crucial in this investigation. They helped us to identify hidden problems in the chosen video games. We believe that much more effort should be applied to develop reliable guidelines which would help designers to create games especially for the elderly. In our next investigation we will be examining the suitability of the Kinect system for this cohort [14].

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Introducing eHealth Business Modelling Instruments for Implementing eHealth Technologies Based on an Integrated Approach with Human-Centered Design

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Abstract- Many eHealth technologies struggle with their implementation. Too often a well-designed eHealth technology fails to be successful in practice. One way to assess the implementation early in the development of an eHealth technology is by eHealth Business Modelling. This paper introduces the use for business modelling in eHealth and what business models are. Followed by a brief description of the ceHRes roadmap, which is our development approach for eHealth technologies that connects Human-Centered Design with eHealth Business Modelling. We then focus on the business modelling part of this roadmap and describe the instruments we currently use for eHealth Business Modelling to work towards a sustainable implementation for an eHealth technology. With the resulting business model, the potential implementation of the eHealth technology can be assessed a priori with its relevant stakeholders and strategic choices for an optimal value co-creation can be made and operationalized.

Keywords- *business model; co-creation; collaboration; eHealth; evaluation; implementation; roadmap; stakeholder; value creation*

I. INTRODUCTION

eHealth technologies are advancing towards a better fit with user needs and user behavior through User-/Human-Centered Design, however the implementation of the technology often remains poorly prepared and executed. This results in a well-designed eHealth technology that still fails to be successful in practice [1]. Often the implementation is evaluated ex post, so after the eHealth technology is fully developed and already deployed in its environment or market. The lack of stakeholder involvement, lack of cost-effectiveness analysis and uncertain sustainability leads to a suboptimal or even failing implementation.

eHealth Business Modelling is a promising way to evaluate the implementation of an eHealth technology a priori – so already during its development - by co-creating a business model for the technology with the relevant stakeholders and with the goal of collaborative value (co-)creation [2]. By involving the stakeholders in the implementation processes, the eventual implementation will better match with practice. It can be implemented in a way that matches their needs best. Besides, if stakeholders cannot cooperate already in thinking about a fitting implementation it is unlikely the value co-creation will go smooth either.

User-/Human-Centered Design are good for improving the eHealth technology itself, to make the technology reflect the needs of its users [3, 4]. But, users are only one subset of the entire ecosystem around an eHealth technology; there are many more stakeholders that will influence the technology. Maybe not in defining the specifics of the technology per se, but its implementation will depend on collaboration and co-creation of multiple stakeholders. Developing eHealth technologies is a multidisciplinary venture [5] where multiple stakeholders with multiple disciplines need to collaborate in the development of the technology but also in determining its implementation so it will ‘survive’ in practice. Basically anyone or any organization that affects or gets affected by the technology can be considered a stakeholder [6]. An eHealth technology faces many multidisciplinary stakeholders: policymakers, vendors, insurers, care organizations and care providers, home care, employers and patients [7]. These stakeholders all influence the implementation of the eHealth technology and thus influence the value of the entire technology.

Value in eHealth can be diverse; it can be monetary value (e.g., revenues, cost reductions), quantitative value (e.g., treatment time, number of patients, etc) or benefits [8]. The benefits from eHealth technologies are often complex to address, especially when these benefits are on a social level. Such social benefits are difficult (or perhaps even impossible) to quantize or monetize towards the eHealth technology directly. For example, if an eHealth technology speeds up a certain treatment, healthcare professionals can treat more patients; these treatments can become cheaper for healthcare organizations or the insurers; patients get home quicker, they consume less time and resources from the healthcare system, employers can benefit as patients get back to work faster, etc. eHealth technologies that offer such social benefits are hard to finance as the benefits are too obscure or indirect for the stakeholders that are supposed to finance the technology. In other words, it is imperative to assess what benefits are possible and thus what value an eHealth technology can offer to its entire ecosystem of stakeholders and more importantly, what this value means to each stakeholder. All stakeholders need to be inspired to collaborate and co-create value for themselves and each other and need to discover how this co-created value can be properly divided among the stakeholders. This is important for the implementation as the eventual value co-creation

determines whether the eHealth technology is considered sustainable and cost-effective.

How this value co-creation is ultimately done can be described in a business model as it is geared to describe the total value creation with multiple stakeholders [9]. A business model can transcend just one focal organization and looks at how value can be co-created and shared with other stakeholders [9]. This makes it suitable for guiding an implementation for an eHealth technology.

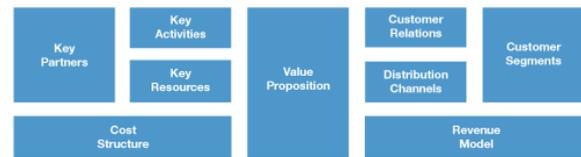
II. BUSINESS MODELS

Attention for business models grew in the last decade when the methods of doing business became more complex and more networked due to globalization and the rise of the Web 2.0 that made a whole new range of value creating opportunities appear in the form of Internet-based products and services [10]. Prime examples of successful Internet companies are e.g., Google, eBay and Facebook that totally rely on making money through Internet services. These companies experimented with totally new business models that fitted these new opportunities that Web 2.0 brought [11].

Known as eHealth [12], the Internet is seen as a promising venture to reorganize current healthcare services. Healthcare services currently are under a lot of stress when it comes to their affordability, accessibility and quality [13]. Grossman even states that with the current organization of the healthcare system in the USA about 30 to 40% of the healthcare costs are spent on inefficiency [14]. In many cases the “business” of business models in eHealth lays not directly in making profit, but the real profit lays in reducing costs at other stakeholders. However new ideas to improve healthcare - and that captures these cost reductions at the right stakeholders - require attention for new business models that fit eHealth in order to successfully implement these new ideas [14].

A business model is defined as the rationale of how an organization creates, delivers and captures value [15]. As mentioned earlier, value is determined by the stakeholders as they want to benefit from the eHealth technology, then they consider the technology valuable. A business model contains a strategic and bird’s eye description of how stakeholders cooperate and co-create value, how the eHealth technology reaches its users and how the value can be offered in a sustainable and cost-effective way. Figure 1 shows the Business Model Canvas by Osterwalder, a currently popular business model ‘blueprint’ containing nine core concepts that constitute the whole rationale of value creation. Through market analysis, stakeholder needs assessments and various other instruments this canvas can be filled up with strategic choices that determine the rationale of value creation. The left side (key partners, key activities, key resources and the costs they generate) describes the organizational aspects of the value proposition, the right side (customer segments, customer relations, distribution channels and the revenues they generate) the customer/market side.

Figure 1. Business Model Canvas



For example, a business model can describe how a tele-dermatology website can reduce time at dermatologists by letting patients upload photos of their skin problems. They do not have to visit and the dermatologist can perform his diagnosis on the uploaded photo. This saves healthcare insurance companies and employers a lot of time and money. In this example the healthcare insurance companies have to pay a fraction of the original fee for dermatologists and, because of this optimization, benefit financially. Other benefits are that the dermatologists can diagnose more patients a day, patients can ‘see’ the doctor when it fits their schedule and there are even possibilities for social benefits that might interest health insurance companies, government and employers. This example shows that as long as all these stakeholders enjoy benefits from this tele-dermatology website they are willing to cooperate and collaborate. Here are opportunities for an eHealth technology. It is the challenge in defining a business model to find this ideal ‘fit’ for the stakeholders. The better this ‘fit’, the more value the business model yields and the implementation is more cost-effective and sustainable.

The market and technological possibilities evolve rapidly and these uncontrollable changes have consequences for the eHealth technology: The technology has to be kept up-to-date technically and that it still meets the user needs, but also the implementation needs to be dynamic as the business model needs to be kept up-to-date too [16, 17]. That is why eHealth Business Modelling is a continuous process that carries on even after the eHealth technology is deployed. Stakeholders can come and go, their value needs can change over time, all these things need to be dealt with when business modelling. A good business model needs to be a continuous rediscovery by constantly evaluating and improving earlier made assumptions [16].

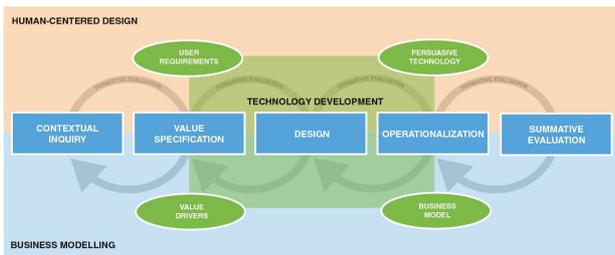
Despite the fact that every organization operates with an underlying business model (even if the organization never explicitly made one they still operate with certain strategic objectives that can be seen as a business model) and the currently growing attention for business models in popular literature [18], research into business modelling is still a novel phenomenon and in the eHealth context even more so. eHealth development requires methods how eHealth business models can be defined, what eHealth business models are possible, what these business models exactly mean to the implementation of different types of eHealth technologies, etc.

III. CEHRES ROADMAP

We developed the ceHRes Roadmap (Figure 2) that combines the principles of Human-Centered Design and eHealth Business Modelling in a holistic and interwoven approach.

In each of these concepts both Human-Centered Design and eHealth Business Modelling have a set of instruments that can be used to develop and implement the eHealth technology. This combination of Human-Centered Design, eHealth Business Modelling and the technical development is similar to the idea behind Yusof's HOT-fit framework [19], who states that eHealth technologies need to be evaluated on the Human, Organization and Technology dimensions. Our roadmap takes it further than evaluation but guides the entire development of an eHealth technology on the same dimensions.

Figure 2. CeHRes Roadmap



The whole development of an eHealth technology goes through five concepts:

- contextual inquiry,
- value specification,
- design,
- operationalization,
- summative evaluation.

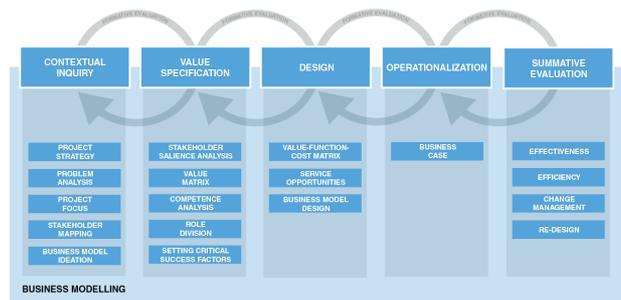
Every step in between the concepts is also evaluated; hence the iteration loops in the figure. This evaluation is formative as it improves earlier findings and assumptions with new insights.

The approach described by the roadmap allows the developed eHealth technology to be persuasive and sense-making so that it meets its users' needs and behavior and at the same time the attention for the business model makes the development of the eHealth technology value-driven by involving the relevant stakeholders. This way the implementation gets prepared during the whole development and is an important part of development. Developing a good eHealth technology but with a poor implementation forfeit a lot of potential value.

IV. EHEALTH BUSINESS MODELLING INSTRUMENTS

In this article we focus on the bottom part (Figure 3) of the roadmap, the eHealth Business Modelling part, and we will introduce the current lineup of eHealth Business Modelling instruments per each of the aforementioned five concepts.

Figure 3. eHealth Business Modelling Instruments



A. Contextual Inquiry

In this stadium it is important to prepare and plan the project as well as finding out whether what the exact problem is and if an eHealth technology is the right solution to this problem.

First the project strategy needs to be determined. There will be certain predetermined goals, conditions and constraints (finances, time, etc) that will influence the project straight from the start and these have to be well documented and communicated in a project strategy.

The next step is to analyze the problem. An eHealth technology is a solution for a certain problem. For example, by improving an inefficient process, by fixing inefficient information sharing, or by creating a new tool. It is dangerous to leap too quickly towards a solution as in those cases the technology might not properly solve the problem as the exact problem is more complex than assumed. The development of eHealth technologies is often too technology-driven, resulting in great state-of-the-art technologies but with problematic implementations. In order to take the proper action, the problem needs to be carefully assessed [20].

When the problem is understood it is possible to choose a focus on what problems the eHealth technology shall deal with and what solutions can be offered, obviously this focus needs to fit within the project strategy.

Also while analyzing the problem, the persons or organizations that experience the problem become apparent. These people are all stakeholders [6] and influence the implementation. In a relationship diagram these stakeholders can be mapped (Figure 4).

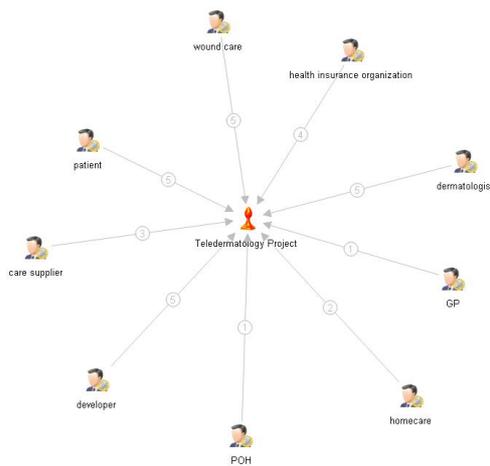
Before starting with the actual development of the technology its implementation can already be explored in the 'ideation'-phase [15]. Obviously these ideated business models contain a lot of assumptions but the opportunities of the technology can be assessed and communicated with the stakeholders already to assess whether or not the eHealth technology can be made sustainable.

B. Value Specification

The eHealth technology will face different type of stakeholders each with their own value needs. How can these value needs be input for the implementation? What value can the technology offer?

First, the salience of the stakeholders to the project can be ranked [21]. Obviously the value needs of important stakeholders will have more effect on the technology and the implementation than the value needs of less important stakeholders. In Figure 4 we gave the stakeholders from the tele-dermatology example a salience number in between 1 to 5.

Figure 4. Stakeholder relational diagram



The same ranking can be applied on all the value needs that stakeholders specify. Some value needs are considered more important than others. These rankings can be put in a value matrix that calculates weighted rankings taking the importance of stakeholders and the importance of value needs in account. This helps in comparing and accumulating value for the design phase.

In the competence analysis the organizational consequences for offering these values can be surfaced by analyzing the necessary activities and resources.

The next step is to find the optimal distribution of these competences. eHealth technologies need to deal with multidisciplinary stakeholders so some activities can best be performed by specific organizations. This will result in partnerships and possibly even in an open or networked business model [22, 23] where organizations depend their value creation on each other. For co-creation of value,

willingness for continuous cooperation and collaboration among stakeholders is very important. Cooperation can lead for individual organizations to reach their goals more fully [23]. This continuous cooperation will determine the sustainability of the eHealth technology.

Some value needs are vital for the success of the technology and its implementation (they will score very high in the value matrix). In management these elements are often referred to as Critical Success Factors. In order to monitor these factors later on in the evaluation, they have to be set first.

C. Design

After completing most of the analyses to understand the environment, stakeholders and value of the eHealth technology, this phase deals with synthesizing the actual business model.

First, the value-function-cost matrix allows comparing value with estimated costs. With User-/Human-Centered Design the value can be specified into functional design conform the needs of the users. The development costs per value can be estimated. Functionalities that cost a lot of money but add little extra value to the technology and its implementation should be less interesting. Besides that, functionalities that score high in the value matrix should be prioritized to be developed first.

Not all value can be captured with the technology itself, some value derives from offering services next to the eHealth technology. These service opportunities are part of the business model as they improve the overall value of the eHealth technology and implementation.

The final stage of the design is to actually combine all insights from previous instruments together in a business model. There are various existing business model templates (Figure 1 for example) that can be filled up with the strategic choices that will yield the most optimal sustainability and cost-effectiveness for the eHealth technology.

D. Operationalization

The business model is a strategic tool; it still needs to be operationalized so that it can be put to practice. This can be done by specifying a business case based on the business model. A business case contains financial calculations, scenarios and is much more concrete in describing the activities, resources and planning necessary for the eHealth technology and its operationalization.

E. Summative Evaluation

Once the business model is operationalized and the eHealth technology deployed in practice, it is imperative to monitor the sustainability and cost-effectiveness. This can be done by monitoring the previously set Critical Success Factors and through technical monitoring tools that keep track of usage parameters.

When it starts to show that the sustainability and cost-effectiveness are becoming weaker, it is time to take action. A business model is a dynamic object and thus if it really shows necessary, changes have to be planned and made to the implementation of the eHealth technology and maybe also the eHealth technology itself.

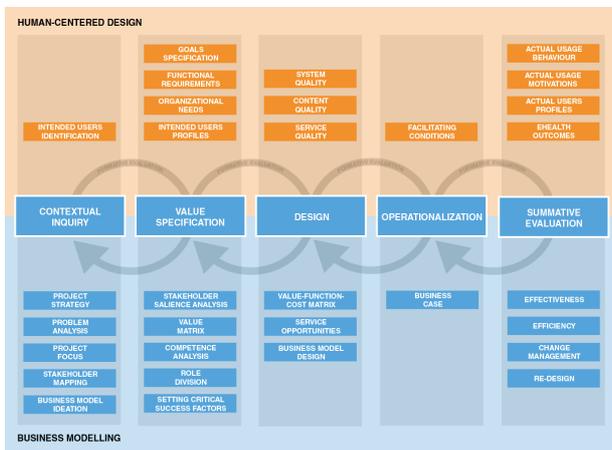
When small changes seem not enough anymore to keep the implementation sustainable, a big overhaul in the form of a total re-design is an option to improve or redo the eHealth technology and its implementation. This may sound drastic but technologies come and go, so a re-design is only a matter of time.

V. FUTURE RESEARCH

We are testing the eHealth Business Modelling instruments in various eHealth research projects. We see the eHealth Business Modelling as an opportunity to improve the sustainability and cost-effectiveness of the implementation of eHealth technologies. It is imperative that the current instruments fit multiple eHealth projects, add the right input in the implementation process, and can deal with the multidisciplinary nature of eHealth.

Our current piloting projects are in various phases of the roadmap. Future publications will further specify the instruments one concept at a time, and our learning experiences from how they were applied on said pilot projects.

Figure 5. Current state of instruments in the ceHRes roadmap



Also we will continue our research in the combination (Figure 5) of Human-Centered Design, and eHealth Business Modelling to improve our ceHRes Roadmap into a holistic, interwoven approach for successfully developing eHealth technologies.

VI. CONCLUSION

Attention for the implementation of eHealth technologies should not happen ex post of the development, but a priori and during the development. The development and implementation are strongly interwoven with one other and interdependent. Developing a technology that cannot be implemented is obviously not helpful and not really a worthwhile venture. Our roadmap combines eHealth development techniques and eHealth Business Modelling as implementation-approach to avoid such problems by making the development of the eHealth technology a value-driven process instead of the currently common technology-driven processes.

We hope that with the instruments introduced in this article, the development and implementation of eHealth technologies can advance and that this implementation through business modelling improves the sustainability and cost-effectiveness.

We are aware that a big challenge (and maybe even the biggest) in defining business models for eHealth technologies lays in finding an optimal 'fit' for all stakeholders. The goals and general need for eHealth technologies may be mutually accepted without much effort, but getting the stakeholders discuss their different needs and value perceptions and finding the right combination and right 'fit' for the eHealth technology and its implementation is a complex and lengthy task.

eHealth Business Modelling offers instruments that help finding these needs and how these needs can be transformed into value and eventually into a fitting business model that helps deploying the eHealth technology in its practice.

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A Dynamic and Customisable Layered Serious Game Design Framework for Improving the Physical and Mental Health of the Aged and the Infirm

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Abstract— This paper proposes a dynamic and customizable layered serious game design framework for improving the physical and mental health of the aged after presenting the results obtained from a study with mainstream and alternative/complimentary health professionals concerning the usage of interactive games as a tool to improve both physical and mental well-being of the elderly. This study reports on the commonality of design and health factors regarding the usability of video games for the aged to ensure the elderly benefit from traditional and alternative healthcare professionals' perspectives.

Keywords-healthcare; elderly; serious games; game design; interactive games; usability; balance.

I. INTRODUCTION

According to recent studies, the majority of the developed countries are dealing with a dramatic increase of the aged population which could result in a crisis, if the problem is not addressed effectively and in a timely fashion [1]. As a result of this predicted crisis, there has been a huge increase in the development of systems to improve the well-being and quality of life of seniors looking for the prevention of diseases and injuries related to ageing. The usage of some interactive technologies such as video games, has shown a positive impact in health outcomes for the elderly [2]. Research has been applied to find feasible methods to encourage and engage seniors with the use of these games [3], [4]. The strategy of using game technology and game design principles for a primary purpose other than pure entertainment is referred as "serious games". The definition of serious games according to [5] is "a mental contest, played with a computer in accordance with specific rules that uses entertainment to further government or corporate training, education, health, public policy, and strategic communication objectives.". From the aforementioned description it could be inferred that the more aligned these game design rules and usability factors are to the ultimate objective of a serious game the more effective this serious game results in achieving its primary goal. The primary goal of utilising game technology in this preliminary study is that of improving the mental and physical health of the elderly.

This paper reports and comments on a study regarding the suitability of four Nintendo Wii balance games under the

observation of six experts in health and wellbeing techniques [6][7]. This study presents a further analysis and discussion over the results gathered from the observations of health professionals from traditional and alternative healthcare professionals' perspectives. Finally this paper proposes a dynamic and customizable layered serious game design framework with the purpose of aligning and targeting game design rules and usability factors for the enhancement of the physical and mental health of the user.

This study was performed via a series of recorded and transcribed semi-structured interviews where health design factors and the suitability of the games for the elderly users were assessed [6][7]. The authors present the emerging factors from the observations of the games and results of the interviews and a discussion concerning the findings followed by the proposed framework and the conclusion.

II. METHODOLOGY

In order to identify the barriers, drivers and usability factors of the use of the assessed interactive technologies, the authors utilized the following two (2) combined methodologies:

- 1) the modified Analytic Framework used by Jamieson et al [8] in their landmark study on Consumer Health Information Technologies used by the elderly, chronically ill and underserved (see Figure 1). The modifications limited the technologies to Interactive Game Technologies, in this case, four (4) Wii games that concentrate on balance.

- 2) a heuristic based evaluation technique for the identification and categorization of the interactive technology usability factors. This video games heuristic evaluation technique was selected due to its flexibility and adaptable nature [9].

Figure 1 below sets out the Analytical Framework which served as a basis for our semi-structured interviews and demonstrations.

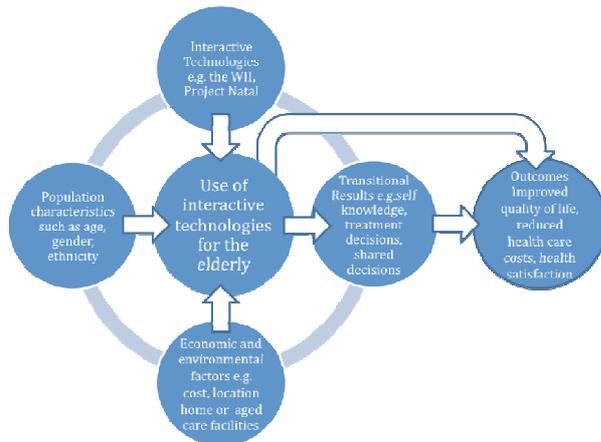


Figure 1. Jimison's Analytic Framework [8].

The Analytic Framework followed by an heuristic evaluation technique were applied to evaluate of the usability of the video games by interviewing health professionals who had experience with elderly patients [6][7]. The researchers did not run experiments with older users at this preliminary stage due to the risks inherent in this practice.

During July and August 2010, the authors evaluated four Wii balance games (see Table 2) with the cooperation of six health professionals, three of them representing alternative health techniques, and the other three representing traditional medicine (see Table 1).

TABLE I. GAMES' DESCRIPTION [11]

	Objective	Procedures ¹	Rules ²	Conflict ³
Balance Bubble	Navigate it along a river to the rainbow finish line.	Shift weight to propel the bubble along the river.	Hazards such as rocks and river banks, and bees.	Reach the goal avoiding hazards and respecting the time limit.
Table Tilt	Tilt the tables so that the balls drop into the hole(s).	Shift weight to tilt the table. The table could have at least one hole in it; the balls must be guided into the hole(s).	Hazards such as: unguarded edges, slopes, blocks.	Dropping balls could lose more balls as well as causing delays, time limit.
Tightrope Walk	Walk a rope strung between two buildings.	Walk across the rope, jump when biting machines appear.	Biting machines, obscured view, wind.	Leaning, falling off the rope, unbalanced jumps, time limit.
Skateboard Arena	Show off your technique with a skateboard.	Turn the balance board through 90 degrees clockwise, push off with your back foot to start and jump when obstacles.	Ramps, half-pipes, etc.	The scoring depends on your tricks on ramps or half-pipe.

¹ According to the game design theory, *Procedure* is everything that player can do respecting the rules.

² The *Rules* describe objects and behaviours.

³ *Conflict* is everything which does not let you reach the goal directly. [12]

T. Fullerton, *Game Design Workshop*, Second Edition ed.

Burlington, MA: Elsevier Inc., 2008.

Overall, the sessions were conducted by following three stages: (1) One semi structured interview with each health professional concerning the procedures which each one performed with the patients over 65yrs, as well as their experience, if any, involving interactive technologies within their practices (see Table 2).

(2) A demonstration of the four Wii balance games, namely Skate Board Arena, Tightrope Walk, Balance Bubble, and Table Tilt; all of them part of the Wii Fit Plus suite (see Table 1). These demonstrations were performed by one of our researchers. In one interview, the interviewee offered to perform the activity. During all the demonstrations, the interviewee was providing oral feedback by remarking on the strengths and weaknesses of the video games. They offered suggestions to make the games more enjoyable and suitable for their elderly patients.(3) This material was transcribed and analyzed using Leximancer, a specialist analytics technology for unstructured, qualitative, textual data [10].

TABLE II. INTERVIEWEES' DETAILS AND PSEUDONYMS [7]

Traditional Medicine	Expert 1: Professor Aged Care, Sydney Hospital Researcher and director of Health and the Aged Centre.
	Expert 2: Physiotherapist at an large Aged Care Facility in Sydney
	Expert 3: Associate Professor Chronic Care at a Sydney university.
Alternative Health Techniques	Expert 4: Certified Feldenkrais Movement Practitioner in Sydney.
	Expert 5: Certified Alexander Technique Practitioner in Sydney. Own Practice.
	Expert 6: Expressive Arts & Music Therapy Specialist at a university in Sydney as well as having a Sydney private practice.

III. CATEGORISATION OF USABILITY FACTORS

In order to identify and categorize usability factors a modified version of the Heuristic Evaluation was utilized. This methodology was slightly modified in order to adapt to Jamieson’s framework.

The term Heuristic Evaluation is an inspection technique where a set of usability principles is established and used by evaluators to explore an interface. These principles are called heuristics.

The heuristic evaluation [8] was applied by following the following five (5) stages: (1) the identification of usability problems as well as their categorization; in order to be able to identify not only the ‘problems’ or barriers, but also the drivers mentioned in Jamieson et al [8]. The scope of the term ‘problems’ was expanded to a more generic neutral term that we refer to as ‘factors’ in this paper; these factors can be of a positive or negative nature; (2) the observation of players while interacting with the videogames under the observation of evaluators; recording facial expressions, verbal reactions, etc; looking for new factors which could be missed from the first stage; (3) the re-categorization of usability factors; (4) the description of the ways to resolve problems encountered previously by the creation of heuristics; (5) the testing of heuristics applying the methodology of user logging combining the thinking aloud protocol.

The list below describes the final categorization of the appeared usability factors [7]:

I. Provide training phases: The game should have training phases before the real game starts, allowing the users to become familiar with the technology. Additionally, these training stages must be easy to skip when they are not required anymore.

II. Create feasible goals: The goals must be reachable by adapting the difficulty of hazards to take into account the physical abilities of the aged cohort.

III. Establish appropriate relations between movements and display: The game must respond according to the user movements.

IV. Provide rules, information and instructions in an adequate way: The information regarding rules, suggestions and instruction should be given before and during the game, so the user does not have to read instructions and operate at the same time. Also, this information should be provided by audio.

V. Consider the mental condition of the player: The player should not feel frustrated and upset because of hard goals. The objective of a game is to entertain the player, so practices such as the ones involving excessive memorizing or unnecessary cognitive complexity to understand the game must be avoided.

VI. Consider the physical condition of the player: Avoid unnecessary requirements for workouts involving coordination and flexibility outcomes. If possible, preclude the need for complex movements so the elderly users, if at all possible, do not require frames to maintain balance.

VII. Engage the user: The thematic of the video game must be in accordance with the audience’s interest to avoid lack of commitment.

Tables 3 illustrates the frequency and total number of usability factors found with each heuristic as identified by the alternative and mainstream practitioners. Table 4 shows the frequency and total number of positive and negatives for the heuristics.

TABLE III. NUMBER OF USABILITY FACTORS FOUND WITH EACH HEURISTIC BY ALTERNATIVE AND MAINSTREAM PRACTITIONERS.

Count of Category (Stage1) Category (Stage1)	Medical Approach		Grand Total
	Alternative / C	Traditional / M	
Physical Health	11	8	19
Engagement	1	12	13
Providing Rules, information and Instructions	6	2	8
Co-relation between movements and display	6		6
Difficulty to reach the goal	1	4	5
Mental Health	2	2	4
Requirement of Support (e.g. Rollator)		3	3
Training		2	2
Grand Total	27	33	60

TABLE IV. TOTAL NUMBER OF POSITIVE AND NEGATIVES FOUND WITH EACH HEURISTIC

Count of Category (Stage1) Row Labels	Column Labels Comment	Column Labels			Grand Total
		Negative	Positive	Suggestions	
Co-relation between movements and display		2	4		6
Difficulty to reach the goal		1	2		5
Engagement		2	4	6	13
Mental Health			3	1	4
Physical Health		1	6	12	19
Providing Rules, information and Instructions			6		8
Requirement of Support (e.g. Rollator)				3	3
Training		1		1	2
Grand Total		5	23	26	60

IV. RESULTS

After running the evaluation and categorizing the problems, the total number of unique usability factors was 60. The distribution of the total number of occurrences per medical approach was 45 % (27 occurrences out of 60) for the “Alternative/Complementary” group against 55 % of the “Traditional/Mainstream” (33 occurrences out of 60) respectively.

Figure 2 provides a graphical representation of the frequency trends of the two (2) medical approaches per usability category. Factors such as Physical Health had the major number of occurrences for the two medical approaches whereas Engagement seemed to present a large discrepancy between the two.

Figure 3 presents the total granular frequency of usability factors (positive or negative) found for each usability factors’ category. The major numbers of negative occurrences were related to the Physical Health category followed by the Provision of Rules, Information and Instructions.

Table 5 presents a subset of the pre-processed results with detailed occurrences related to Physical and Mental Health usability factors.

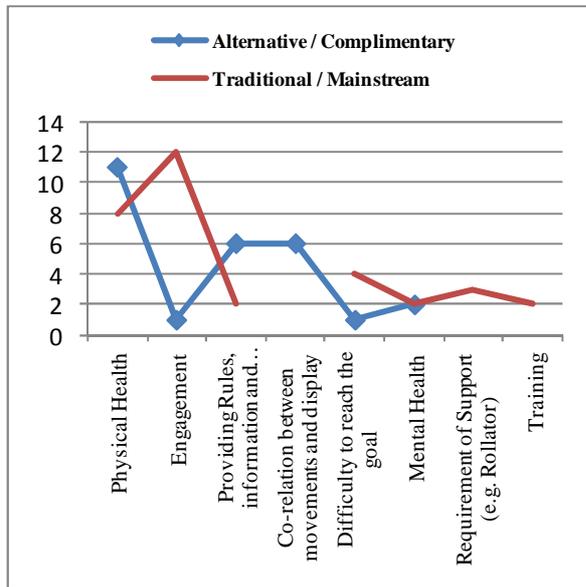


Figure 2. Frequency trends of the two (2) medical approaches per usability category.

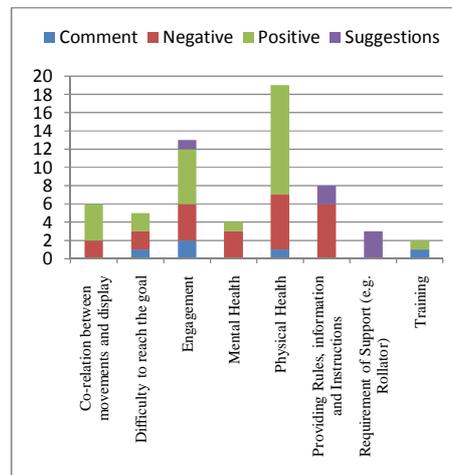


Figure 3. Frequency trends of the two (2) medical approaches per usability category.

TABLE V. LIST OF MENTAL AND HEALTH USABILITY FACTORS (BARRIERS AND DRIVERS)

Category (Stage1)	Impact	Detail (Level2)	Game
Mental Health	Negative	Upsetting particularly if the avatar fail	Tightrope
	Negative	Anxiety producing stimulus makes people tighten their necks and shoulders and sabotages their balance reflex	Tightrope
	Negative	Hitting the side the whole time could be frustrating, worrying	Bubble
	Positive	Good for concentration	TableTilt
Physical Health	Negative	Patients could have issues with putting the foot on and off	SkateBoard
	Negative	Encouraged patients to tense up and lose balance instead of relaxing and loosening up	TableTilt
	Negative	Potential dangerous for the elderly (learning unwanted movement patterns)	Bubble
	Negative	Backward lean may be tricky for the elderly	SkateBoard
	Positive	Good for balance and weight shifting	Tightrope
	Positive	Allows movement forwards and backwards and side to side, which is a good strategy	Bubble
	Positive	Good for counterbalance	SkateBoard
	Positive	Good for locomotion practice	SkateBoard
	Positive	Good exercise and suitable	TableTilt
	Positive	Good for counterbalance	TableTilt
	Positive	Good for stimulating body awareness of weight distribution on the feet	Bubble
	Comment	Use of quads and bit of his core	Tightrope
	Negative	Not useful for cardiac rehabilitation patients as it did not raise their heart rate sufficiently	Bubble
	Negative	Useful for younger and more able patients (Coordination and flexibility are needed)	SkateBoard
	Positive	Useful exercise for balance and shifting weight	Tightrope
	Positive	Gentle and safe	Bubble
	Positive	Better workout, Expert likes it	SkateBoard
	Positive	Not a problem for stroke patients if able to walk independently	Tightrope
	Positive	Relevant fine balance movements	TableTilt

V. DISCUSSION

As explained earlier in this paper, the use of videogames among the aged population requires a deep inspection to guarantee optimum results on health practices. Thanks to the use of methods like the heuristic evaluation to assess the usability of interactive video games as well as the co-operation of health specialists, we found that there are some characteristics, which could bring out unexpected results regarding the mental and physical health of the elderly. Problems such as the lack of relation between what it is supposed you do and what you see on the screen, could cause confusion for the player giving as a result a feeling of anxiety and frustration affecting, at the same time, the balance reflex and mental satisfaction. Also, it is important to mention that due to the changes which the human body suffers in advanced ages, the users could lose the accuracy of senses such as sight and hearing, making it complicated for the elderly to read or listen to instructions while the game is running.

VI. FRAMEWORK

The majority of the barriers in this preliminary study were related to the physical and mental conditions of the elderly (e.g. muscle strength, balance, memorization or cognitive capacity to perform concurrent activities). Another major factor was the lack of alignment in between the game

rules or goals which in many cases lead to undesirable physical and/or mental user behaviors and the primary goal of improving the health of the user. These game rules should be not only aligned to the user health condition profile, but also customizable and automatically adjustable to the user's progress. Granularity for specific user health conditions should be specifically targeted, measurable and adjustable to multivariate skill progress during the evolution of the game.

The proposed Dynamic and Customizable Layered Serious Game Design Framework in Figure 4 is proposed as an aid to serious game design for health purposes. This framework attempts to align to Jamison's major positive user effect instigators which should provide a complete feedback loop that includes:

- (a) monitoring of current patient status, (b) interpretation of this data in light of established, often individualized, treatment goals, (c) adjustment of the management plan as needed, (d) communication back to the patient with tailored recommendations or advice, and (e) repetition of this cycle at appropriate intervals. Systems that provided only one or a subset of these functions were less consistently effective [8].

The proposed framework aims to alleviate design customizable problems improving the Physical and Mental Health of the Aged.

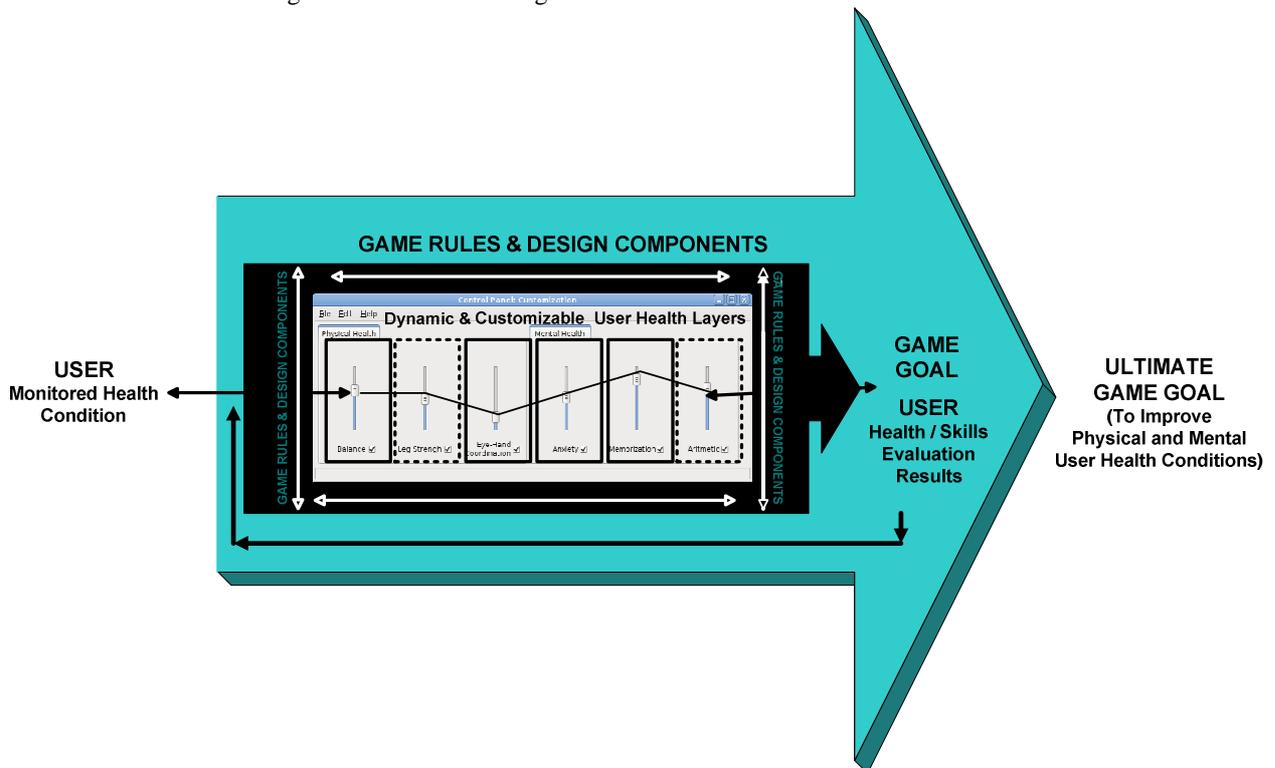


Figure 4. The Dynamic and Customisable Layered Serious Game Design Framework for Improving the Physical and Mental Health of the Aged.

VII. CONCLUSION

Previous research has shown that the usage of video games for health purposes provides some positive outcomes for the elderly. This is evidenced by the successful result of research which treated diseases related with getting older by using video games and interactive technologies. Despite this, these practices could result in drawbacks for the elderly when their mental and physical conditions before playing video games are not considered. Furthermore, testing the usability and suitability of videogames is crucial to obtain the improvements expected. Consequently, in order to identify the barriers, drivers and usability factors of the use of the assessed interactive technologies, the authors utilized the modified Analytic Framework used by Jamieson et al [8] in their landmark study on Consumer Health Information Technologies used by the elderly, chronically ill and underserved (see Figure 1), as well as a heuristic based evaluation technique for the identification and categorization of the interactive technology usability factors. This video games heuristic evaluation technique was selected due to its flexibility and adaptable nature [9].

The use of an extended heuristic evaluation and the interviews with six healthcare experts have shown effective results in assessing the usability of videogames; this flexibility has allowed the researchers to discover and categorize hidden usability factors regarding the suitability of Nintendo Wii games for aged users.

The analysis of the results obtained during this study led the researchers to the proposed dynamic and customizable layered serious game design framework for improving the physical and mental health of the aged.

Although this topic is currently being researched world wide, the complexity in the alignment of the game design components with the granularity and dynamics of the targeted, measurable and customized user health conditions locates this multidisciplinary area of research at the beginning of a long road ahead of discoveries in disciplines of game design, health and behavioral sciences among others.

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Using Mobile Technology to Enhance Pediatric Diabetes Care Management

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Abstract—Pediatric diabetes is an increasingly prevalent public health problem, especially among low-income and minority populations. In an effort to address disparities in care management among inner-city adolescents with diabetes, the Visiting Nurse Service of New York developed a two-year intervention program that combines structured education and lifestyle visits by a diabetes educator with a mobile technology application. This paper provides an overview of the program and describes the design of an evaluation study to assess outcomes among clients who complete the program. The evaluation study employs data collected through the mobile technology devices and a clinical website portal where the diabetes educator records demographic information, clinical characteristics, and service utilization.

Keywords—mobile technology; home health care; pediatric diabetes; evaluation

I. INTRODUCTION

An increasing number of children are diagnosed with diabetes each year [1]. This trend is especially notable in low-income and

minority populations, among whom hospitalization rates for adverse diabetic events are very high [2]. In an effort to address disparities in effective diabetes self-management, the Visiting Nurse Service of New York (VNSNY), the largest not-for-profit home health care agency in the United States, developed a home-based care management program for inner-city adolescents with diabetes. The program focuses on behavior modification and is facilitated by trained clinicians educated in diabetes care management. The program is enhanced by a mobile technology application and clinical website developed to provide feedback to patients and clinicians. This paper provides an overview of the program and information about the mobile technology application, and presents preliminary data from an evaluation designed to monitor program activities and assess outcomes among patients who complete the two-year program.

II. PROGRAM OVERVIEW

The Diabetes Care Management (DCM) program targets inner city adolescents with

uncontrolled diabetes for a comprehensive intervention. On a pilot basis, approximately 50 patients will be recruited from two local health care providers that specialize in treating pediatric diabetes. The program enrolls adolescents 11-17 years old who are residents of the Bronx or Upper Manhattan and have Type 1 diabetes with an HbA1c level greater than 8.0% in the past six months. Patients are ineligible if they do not speak English or Spanish, are pregnant, show signs of or are being treated for substance abuse, are under mental health care for psychosis or schizophrenia, or live in an unsafe home environment.

Patients enrolled in the DCM program receive home visits provided by a Certified Diabetes Educator (CDE). The CDE assesses patients' clinical stability and acuity (e.g., blood glucose), describes the program to patients and attains their informed consent, conducts clinical and environmental assessments, and provides structured education to patients about their diabetes. The CDE or Care Manager (a social worker trained in behavioral management) also visits patients to counsel them and their family on making sustainable lifestyle changes. These visits are made to patients in their homes 12 times during the first year, and are followed by 12 phone calls over the course of the second year.

III. USING MOBILE TECHNOLOGY TO ENHANCE PEDIATRIC DIABETES CARE

The DCM program utilizes a cell phone-based diabetes management software system and a web-based clinical portal. These tools, designed by WellDoc™ Communications [3], provide an interactive platform for patients and providers to receive real-time diabetes management information. During the DCM program development phase, this mobile application was customized for a pediatric population.

Patients enrolled in the program receive a Blackberry cell-phone equipped with the WellDoc™ diabetes software. The phone includes a plan with phone services and

unlimited text messaging. Patients receive individual instruction on how to use the phone and features of the application.

IV. PROGRAM EVALUATION AIMS

An evaluation is underway to understand challenges to implementing program elements and to provide an initial assessment of the impact of the program on clinical and behavioral outcomes. The evaluation has two primary aims. The first aim includes monitoring the process of providing care and instruction to patients who enroll in the program and summarizing the performance of key program activities and outputs (e.g., the number of visits and phone calls to patients among each type of care provider, program attrition, usage of the mobile technology application, achievement of targeted program objectives). The second aim involves assessing the impact of program participation on clinical and behavioral outcomes (e.g. A1c, diabetes knowledge and self-care activities).

V. DATA AND MEASURES

Data collected from the mobile diabetes application is stored in a central database maintained by WellDoc™. The database also includes demographic, behavioral, and clinical information entered into the web-based clinician portal. The complete database is then transmitted to VNSNY in a secure format on a monthly basis and transformed on-site for statistical analysis.

Demographic measures that are collected at baseline include age, sex, race/ethnicity, language, and level of education. Clinical measures that are collected at baseline and at three month intervals include A1c, hospitalizations and emergency visits, and hypoglycemic and hyperglycemic events. Behavioral measures collected at baseline and at six-month intervals include patient self-care practices, willingness to change [4], diabetes knowledge [5], quality of life [6], and depression [7].

VI. PATIENT DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

The program has enrolled approximately 30 patients between February and September 2010. The demographic and clinical characteristics of patients who are currently enrolled in the program are presented in Table 1. The average baseline A1c of patients currently enrolled in the program is 11.6, which is substantially higher than the target recommended by the American Diabetes Association (A1c < 7.0%) [8].

TABLE I. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

<i>Variable</i>	<i>Mean/Percent</i>
<i>Sex</i>	
Male	45.1
Female	54.8
<i>Age (SD)</i>	14.1 (2.0)
11 ≤ Age < 13	26.6
13 ≤ Age < 15	23.3
15 ≤ Age ≤ 17	50.0
<i>Race/Ethnicity</i>	
Hispanic	82.7
African American	13.7
Other	3.4
<i>Geographic Area</i>	
Bronx	74.1
Manhattan	22.5
Yonkers	3.2
<i>Baseline A1c Level (SD)</i>	11.6 (1.9)

Table 2 presents results from preliminary analyses of data collected from the mobile phone application. On average, patients have submitted 2.9 blood glucose entries per week and 1.2 carbohydrate entries per week since they began using the mobile application.

TABLE II. UTILIZATION OF MOBILE APPLICATION

<i>Variable</i>	<i>Mean (SD)</i>
<i>Average Number Entries Per Week</i>	
Blood Glucose	2.9 (4.5)
Carbohydrates	1.2 (3.1)

VII. SUMMARY

The DCM program aims to improve self-care management among inner city adolescents with diabetes through a combination of mobile technology and structured clinical education and support. The use of the WellDoc™ application and clinical website portal has enabled VNSNY to gather a broad range of data on patients for program evaluation purposes. When completed, the evaluation will produce useful information for program stakeholders and provide an initial assessment of the program’s clinical effectiveness. An analysis of the evaluation data will also indicate whether the mobile application is a popular mechanism for sending and receiving diabetes-related information and feedback to a pediatric population.

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A Joint Organizational and Technical Development of a Telematic Rescue Assistance System for German Emergency Medical Services

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Abstract— The German research project Med-on-@ix aims at optimizing the efficiency and quality of preclinical emergency health care by introducing a Telematic Rescue Assistance Systems into the Emergency Medical Services. Paramedics and emergency physicians will be supported on site by a specialized physician in a remote Competence Centre. During the last three years, an interdisciplinary project team of emergency physicians, university scientists and developers supported by industrial enterprises developed a telematic system supporting the emergency care. The Telematic Rescue Assistance Systems provides the real time transmission of voice communication, vital parameters, pictures and videos from any emergency site using mobile radio networks. Both the technical development of the Telematic Rescue Assistance System and the organizational implementation into the regular operations of the Emergency Medical Services constitute the central pillars of the research project. Beside the technical requirements, the user centered requirement management applied within Med-on-@ix identified the necessary organizational changes to realize the introduction of the telematic system into Emergency Medical Services. This paper traces the joint organizational and technical development of the Telematic Rescue Assistance Systems based on a consistent user involvement into the development process. Simulation studies have been used to identify the main challenges regarding the implementation process. Exploring the impact of the system on the working process, organizational changes have been worked out, aiming at the design of a successful implementation process.

Keywords - *Telematic Rescue Assistance System; German Emergency Medical Services; telemedicine; joint organizational and technical approach; implementation process.*

I. INTRODUCTION

German Emergency Medical Services (EMS) professionals are supported in 50% of all missions by a qualified emergency physician to guarantee the highest quality of care on emergency sites. These days, demographic development contributes amongst others to a considerable rise of missions involving EMS physicians

[1]. Whereas the demand of EMS has doubled since 1990, a serious lack of physicians particularly in rural areas can be considered. The closing of various EMS physician stations lead to a delayed arrival of the physicians on scene and thereby to an augmented interval without sufficient therapy. As paramedics and EMS physicians are organized in a so-called “rendez-vous system” [2], physicians and paramedics arrive at the accident scene in different vehicles. The ambulance, staffed with paramedical professionals, reaches the patient in general within the statutory period of 12 minutes after the emergency call. Whereas mainly in rural areas the physicians gets delayed to the emergency patient, making it decisive to bridge the time period before the arrival of the emergency doctor [3].

To secure a high quality of treatment in the chain of survival [4], innovative strategies to assure an early professional aide on scene are needed. As the German EMS is one of the highest qualified in the world, efforts are made to stick to the physician-led EMS in Germany by structural measures and hereby to provide the highest medical qualification to the patient. The expensive German emergency care gets a lot of stick these days, innovative solutions are needed to preserve the fundamental philosophy of bringing physician-centered definitive care to the patient, rather than bringing the patient to the care, as paramedic based EMS systems do.

The legislators have paved the way by assimilating rescue service acts, restructuring the rescue service catchment areas and the introduction of integrated demand-oriented control stations with a consequent quality management system as well as the implementation of a medical leader for each rescue department. Besides these improvements, the technological support of EMS offers a wide scope of possibilities to reduce the “no-therapy-time” by referring to communication technology that is used as self-evident in non-professional context.

The quality of EMS work is directly related to an efficient information management. As everyday experiences of EMS personnel are characterized by adverse surrounding conditions of work, it is furthermore affected by a constant lack of information regarding the specific emergency situation, the patient’s history or his

actual medication. The use of modern information technologies has the potential to intensify and to accelerate the information flow related to the actual mission.

So far research and development activities focus in particular the transmission of vital data from an ambulance to a hospital. The German project “Stroke Angel” [5] transmits audio and video data from the ambulance in order to diagnose and pass on stroke patients directly to the nearest stroke unit. Using telemedicine the contact-to-balloon time decreased on average from 32 min to 16 min. Various similar publications testify that teleconsultation systems are considered potentially lifesaving [6]. The necessity to increase the mobility of telemedical support systems for EMS operations is evident. Furthermore to avoid the development of isolated telemedical solutions and to foster the adoption into regular practice of EMS, integrated development and implementation approaches are needed.

Within the research project Med-on-@ix, the Telematic Rescue Assistance Systems (TRAS) offers the possibility to make medical know-how available at any time for professional helpers on scene. Medical and mission tactical data is transmitted via 3G mobile radio networks from the place of emergency or the ambulance vehicle to the remote emergency physician in the Competence Center (CompC), communicating with the staff at the place of emergency via audio connection. The CompC also helps to optimize workflows by arranging communication with the health care facilities to which patients subsequently will be sent [7]. The technical components on site are connected to a communication which connects to the ambulance vehicle via an 802.11 network or directly to Public Switched Telephone Network (PSTN) and the Internet through GSM/TETRA and GPRS/UMTS. On the CompC’s side the servers are connected to the PSTN via ISDN and to the Internet. The Clients in the CompC connect to the Servers through a reliable local network or VPN [7].

The application scenario shown in Figure 1 illustrates the central position took up by the remote EMS physician in the CompC.

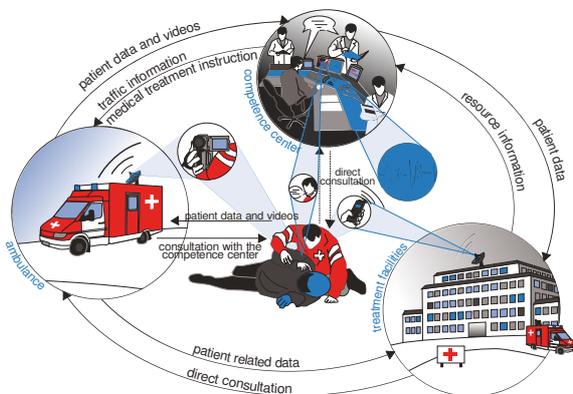


Figure 1. The Telematic Rescue Assistance System

The CompC serves as an information hub between the involved clinical and preclinical facilities. The use of the TRAS in the work of EMS is related to decisive changes in working processes. The remote emergency physician is confronted with an unknown job specification and a new working environment. The EMS team on site has to handle new medical equipment and modified team and communication processes.

By a constant participation of the University Hospital Aachen (UKA) in the requirement management process as well as the technical development and the implementation process, a one-year trial run could be realized (2009-2010). The trial run – as well as the preceding simulation studies – focused two possible scenarios involving on first level physicians and on second level paramedics on site being supported by the CompC. The elaboration of the organizational concept enabling the EMS to implement the system was designed in line with the requirement management used for the technical development.

This paper outlines the approach for a joint organizational and technical development of a TRAS referring to two simulation studies carried out within the last two years. Based on the example of the identified impact of the TRAS on communication processes on the emergency site, the change management approach is described. By the use of user group surveys, necessary changes and measures for a successful implementation into daily work of EMS were identified. Finally the described example will show the possibilities to face organizational and technical requirements regarding the operation of a TRAS.

II. JOINT ORGANIZATIONAL AND TECHNICAL DEVELOPMENT

The TRAS can be described as a sociotechnical system [7] considering the relevant interactions between social, technical and organizational aspects in line with the development and the implementation of the system.

An iterative and incremental requirement management constitutes the core of the development process within Med-on-@ix. The agile development of the TRAS [9] foresees the consequent involvement of the users at different stages of development. The applied research methods within Med-on-@ix meet this approach by considering aspects of human, organization and technology in every research question. The progressive specification of the TRAS is realized by the identification of the relevant functional and non-functional requirements within the scope of two experts workshop [7] and two simulation studies.

The development process regarding both organizational and technical requirements is consequently attuned on the involvement of the different user groups (emergency physicians, paramedics), to increase system quality, user satisfaction and at least the usage of the TRAS. Both product requirements and functional specification have been elaborated in cooperation with the medical partners from UKA.

User involvement is referring to the participation of a representative group of potential users especially in two relevant areas: participative decision making and planned organizational change. The involvement of the target group contributes in both areas to higher motivation of users and the success of change processes **Fehler! Verweisquelle konnte nicht gefunden werden.**

In the Med-on-@ix project opinion surveys and interviews involving EMS professional have been used for example in line with the studies focused in this paper.

EMS teams and emergency physicians tested within different simulated rescue scenarios the telematic support system at different stages of development. Different social research methods were applied to survey 135 test persons (87 in the first study in 2008, 48 in the second study in 2009) in terms of acceptance and utilization issues [10]. The studies targeted on technical, as well as organizational and human research aspects. The test persons were trying out the main functions of the TRAS in simulated rescue scenarios, to test the handling of the technical system and to evaluate the impact on the working process. The developers gained awareness of usability aspects and susceptibilities of the system, whether the social scientists acquired knowledge about the impact of the TRAS on teamwork and communication processes.

Using replicated emergency situations as a testing environment the studies have specified and validated the implemented exigencies. The simulated test setting aimed at encouraging new behaviors dealing with the TRAS and at least to promote shared meanings about the system. Fostering the dialogue between developers and users especially in line with the requirement management has been contributing to a positive trend in terms of user acceptance of the TRAS [10]. The latter important results, described in related publications, reinforced the chosen research strategy of joint organizational and technical development combining user involvement and a holistic requirement management.

In addition, the present paper focuses the possibility using the described research approach to design a user oriented technology implementation process. The pursued change management approach based on transferring research results into change tasks will be described in the following by reference to the simulation studies.

III. EXEMPLIFIED CHANGE MANAGEMENT APPROACH IN MED-ON-@IX

The implementation of the TRAS into German EMS goes in line with the several changes regarding the working process in EMS Teams. To meet those challenges, the changing aspects have been identified at early stage in the development process in line with the incremental requirement management. The change tasks regarding in particular the organizational development of EMS have been detected for example in line with the conducted simulation studies. To illustrated the change

management used in the Med-on-@ix project the concept and gained results of the simulation studies are exemplarily presented here.

Meeting the user centered research approach the studies encouraged paramedics and physicians to enter a dialog with developers and by there aimed at a system improvement through reflective practices using different methods of social sciences. Based on the results of those surveys the necessary changes were detected and transferred into change measures.

A. Simulation studies

Within the scope of the simulation studies carried out at the Interdisciplinary Medical Simulation Center (AIXSIM) of the UKA, one main research question referred to the impact of the TRAS on the teamwork on site. The first survey in 2008 addressed the support of an emergency physician by another highly involved physician in two standardized simulated missions (ST-elevation myocardial infarction; severe traumatic brain injury). The second simulation study tackled the support of an EMS Team (two paramedics) by the remote emergency physician in the CompC. Five different scenarios (a diving accident, a renal colic, a second-degree burn, an intoxication and a hypoglycaemia) partly performed by patient-actors playing patients partly by involving a patient simulator offered the possibility to analyze the handling with and the potential of assistance of the TRAS.

To allow a comparison of the quality of treatment with and without the application of the TRAS, control groups acting without the telematic support were drafted in. Questionnaires and group interviews were used to survey the EMS Teams after the simulated operations. The issue-focused interview guide, applied within the semi-structured interviews, enabled the scientists to focus on behavior patterns observed before. The video-documented interviews were transcribed and put to a qualitatively oriented content analysis.

B. Results

Taking into account the results from both simulation studies, the impact of the TRAS on team internal processes turned out to be one of the main challenges within the organizational development of the system. The involvement of the remote physician created an unusual working environment, adding to the demanding emergency situation a new communicative arrangement and the use of supplementary equipment.

The communication structure during the operation is illustrated in the following Figure 2: the standardized scenario foresees an EMS Team consisting of a physician and two paramedics respectively only two paramedics in the second study. As a new participant the remote emergency physician in the CompC is connected via mobil radio to all members of the team.

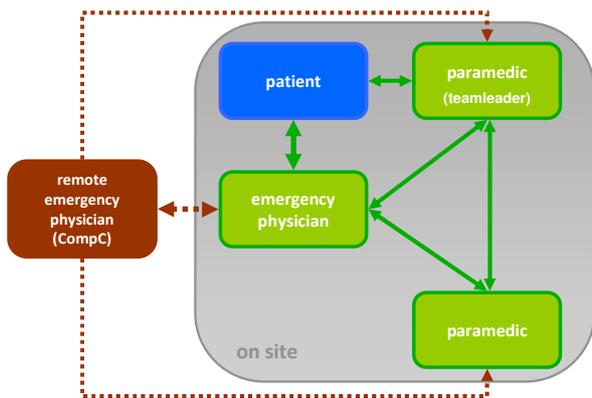


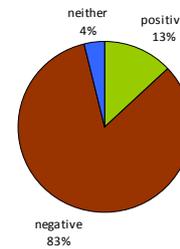
Figure 2. Mission-related Communication structure

The first simulation study immediately revealed the main changes in the working situation. The test persons experienced an altered situation having a remote team member being involved into the scene. The interviews revealed a negative impact of the TRAS on the communication with the patient. The emergency physician was struggling to concentrate on both the communication with the remote colleague and with the agrieved patient on site. The interviewed paramedics underlined furthermore the necessity to be connected to the CompC, to be able to follow the diagnoses and treatment discussion between the physicians. 83% of the interviewees stated in 2008 a negative impact of the TRAS on the communication situation during the operation.

Based on these results communication rules were elaborated and evaluated in the 2nd simulation study (2009) to prevent miscommunication, as the loss of information can be related to a safety hazard for the treatment of the patient. These rules compromise a clear role allocation between the team members assigning a standardized information committal between the physician (alternatively the team-leading paramedic) on site and the CompC after a first anamnesis. Furthermore the test persons in the second study were instructed in thinking loud, to reduce the necessity for the remote physician to ask question. The standardization of the working process on site using the ABCDE (Airway Breathing Circulation Disability Exposure) mnemonic, usually used for the prioritization in the management of trauma patients, also follows the aim of reducing the quantity of possible follow-up inquiries by the CompC.

The application of the elaborated communication rules clearly had a positive effect on the team communication in the 2nd study. Figure 3 indicates that over 50% of the questioned test persons stated a positive or no impact of the TRAS on team communication, compared to 83% complaining about negative impact in the first study.

Impact of the TRAS on team communication (1st simulation study 2008)



Impact of the TRAS on team communication (2nd simulation study 2009)

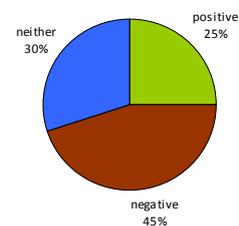


Figure 3. Comparing results from simulation studies

Besides the importance of communication rules, the simulation studies uncovered the importance of mutual confidence between all members of the EMS team, including the remote EMS physician. The interviewees pointed out the importance of working on both sides, the CompC and on site, to acquire a team spirit that fosters the efficiency of teamwork, being exposed to stressful working conditions as in EMS missions.

Regarding the results of the studies three main challenges have been identified:

- The alternate communication structure needs to be supported by the use of communication rules.
- Both sides the CompC and the team on the emergencies site have to follow standardized procedures to avoid miscommunication.
- The success of the teamwork is mainly related to a sense of belonging between all involved team members.

To meet these requirements organizational changes have been designed and implemented to support a successful trial run.

C. Identification of change management tasks

The selected results from the simulation studies were transferred into the change management concept, coming along with the implementation of the trial run in Aachen.

The standardized management of operations in the emergency department improves significantly the outcome of prehospital care [12]. The upcoming training concept of Prehospital Trauma Life Support® (PHTLS) teaches a standardized and established approach to the trauma patient in EMS operations [12]. This concept for

prehospital management includes the ABCDE approach instructing EMS personnel to act according to the principle „treat first what kills first“:

- Airway management, cervical spine stabilization
- Breathing (ventilation)
- Circulation (hemorrhage and perfusion)
- Disability
- Exposure/Environment

By using these steps, the EMS personnel on site follow the standardized process, consisting in a primary survey focusing the vital functions of the patient, followed by a secondary survey to identify the relevant injuries. The application of this concept helps the remote physician to follow and to document the ongoing operation easily.

The achievement of a standardized working process using the ABCDE concept was supported by the implementation of a digital checklist (Figure 4) in the CompC, supporting the physician in following step by step the work of his team on site.



Figure 4. ABCDE Checklist in the CompC

The EMS personnel were trained on the use of the concept mainly on the job, supported by debriefings of the missions. Within the first phase of the trial run, the EMS teams got used to the standardized procedures.

The compliance of the defined working process was additionally fostered by the implementation of job rotation for the involved physicians between the CompC and the mission site. Furthermore the rotational assignment between the two positions counteracted the lack of mutual confidence required by the users. The experience of working together on site and knowing the working processes in the CompC encouraged the manageability of the TRAS.

To prepare the EMS personnel for the trial run of the TRAS, a specific training was inserted into the regular weekly classes at the fire department. Besides lessons on the content of the project, the regulatory framework of the trial run and the intensification of pharmaceutical

knowhow, the formation comprised trainings on operational techniques like the initialization of intravenous accesses. In line with these courses the communication rules were integrated into a specialized lesson on communication in critical situations. The participants were put into the complex communication situation by different exercises, to be able to reflect the situation on site as well as the challenges, the remote physician is facing at. The lessons were used to discuss and first of all to further develop the rules of handling the TRAS. The training was consequently used to enhance the involvement of the user groups into the research project and hence to affect the user acceptance of the TRAS.

IV. CONCLUSION AND OUTLOOK

The TRAS as a sociotechnical system comprises beside technological challenges particularly many organizational challenges, critical in view of a successful implementation of the TRAS into daily work of EMS. The development of such assistance systems therefor requires the involvement of all relevant stakeholders. The approach by a joint technical and organizational development has enabled the scientists to identify the necessary change management tasks. The latter were developed in cooperation with the user groups. The described results demonstrated the importance of user involvement right from the beginning of a development project. Various research results have shown so far “that user engagement during the installation phase is strongly associated with user satisfaction” [13]. The described research results underline the necessity of a development approach regarding both technical and organizational challenges enabling thereby an accepted implementation into the target organization.

The aim of Med-on-@ix is to support EMS in their daily work by using today’s technological innovations. To achieve an optimized work in emergency missions the user has to identify the requirements in terms of both types of requirements technical and organizational. Neglecting the latter is oftentimes the reason why innovative technological assistance is not turned into daily operation.

The final evaluation of the Med-on-@ix trial run by the end of 2010 will identify further change management tasks, which will support the implementation of the TRAS. To be able to run in a future scenario the telematic support of EMS paramedics throughout the “no-therapy-time”, the system will be further developed in a follow-up project already started in August 2010. The challenge of the latter will be the parallel implementation in five other regions around Aachen. The one-time approved change management approach developed within the Med-on-@ix project will be further developed in view of the design of an incremental implementation concept deserving at a time five emergency departments.

Due to the federal topology of the German EMS the user groups from different emergency department will differ particularly in qualification, but moreover in the handling of medical instruments or supporting systems. Therefore the organizational and technical requirements

from the user groups have to be consistently refreshed and adopted to the specificities of the involved emergency department. This matter of fact reveals a further research subject: Besides the realization of a multi-case implementation the change tasks have to meet the individual requirements of the target departments.

The methodology of transferring the identified technical and organizational requirements into implementation measures of different types will be carried on in the coming month, on the one hand to develop an optimized change process but also to gain the necessary user acceptance by consequently involving the target user groups.

V. ACKNOWLEDGMENT

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Transportation Scheduling Method for Patients in MCI using Electronic Triage Tag

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Abstract—A method for determining the priority of patients treatments called *triage* is used to direct rescue activities during a Mass Casualty Incident (MCI). In present disaster medicine, patients with the highest priority (with a red tag attached) are transported to the hospital in random order, although their expected probability of survival (Ps) may differ. Recently, an electronic triage tag (E-triage) that is able to sense the patient's vital signs in real time has been developed. Moreover, based on the sensed vital signs, the physician's remarks about the patient, and medical treatment statistics, each patient's Ps can be estimated. In this paper, utilizing E-triage and the latest medical treatment statistics, we first formulate the problem of determining a transportation order of patients that maximizes the life-saving ratio, given the latest vital signs and temporal variation in the survival probability of each patient, the time for an ambulance to transport the patient to an appropriate hospital, and other factors. Since this problem is NP-hard, we propose a heuristic algorithm based on a greedy method that transports patients in the increasing order of their expected survival probability at the time they will arrive and be treated at the hospital. To prevent the case that rescuing a patient earlier results in the death of two or more patients, our proposed algorithm also considers, for each low survival probability patient, the two cases of rescuing the patient or not and derives the transportation order that keeps the most patients alive. Through simulations, we confirmed that the proposed method can transport about a 25% larger number of patients to the hospital before their expected survival probability gets lower than a marginal probability than conventional methods.

Keywords-ambulance scheduling; disaster management; disaster medicine; electronic triage.

I. INTRODUCTION

Recently, natural disasters, terrorist attacks, and large-scale accidents have occurred all over the world. In a mass casualty incident (MCI, hereafter), rescue teams are likely to be confronted with too many patients, overwhelming the medical resources, such as the number of rescuers (responders, paramedics, and physicians), ambulances, and the capacities of hospitals. The lack of adequate medical resources makes it difficult to allocate necessary resources to each patient, resulting in a *Preventable Trauma Death (PTD)* in some cases. In such events, the rescuers are supposed to apply *triage* to patients, which is a paper tag with four categories (red is the most serious) attached to each

patient to determine the priority of the medical treatment among the patients in a short time. Patients with paper tags are then carried to the hospital based on their categories. However, attaching paper tags is a time consuming task and prone to human errors. Moreover, inherently, paper tags cannot reflect changes in a patient condition for the worse. Paper-based triage, then, has the following critical drawback: there is no priority among the patients of the same category and the rescue commander cannot grasp the patients' conditions in detail, resulting in random order of transportation of the same category patients. Therefore, in an MCI, the transported patient is not always the one who needs first aid most urgently.

Worldwide, many research efforts have examined ways to improve the life-saving ratio and efficiency in an MCI. There is a project "Advanced Wireless Communication Technology for Efficient Rescue Operations" that is developing an electronic triage tag (E-triage) [1]. The E-triage is a small embedded device that can sense the vital signs of patients such as heart rate, respiration rate, and blood oxygen level (SpO₂) in realtime. Moreover, the E-triage can send the sensed information to a medical server through built-in ZigBee radio communication. E-triage can help reduce the triage operation time, avoid human error, and quickly reflect changes in the patient condition.

Some studies focused on estimation of the patient's survival probability from medical statistics have also been applied to emergency medicine. The *Trauma and Injury Severity Score (TRISS)* methodology estimates the *probability of survival (Ps)* based on the patient's vital condition and the site of trauma [2]. Ps has a closer relationship to the actual mortality rate and it is known that more than 75% of the patients whose Ps is under 30% at the time of arrival at the hospital will die. Utilizing E-triage and the survival probability estimation method together, we believe that it is possible to schedule a transportation order of patients that maximizes the overall life-saving ratio.

In this paper, we propose a new method for scheduling a near-optimal transportation order of the patients from an MCI, taking into account available medical resources and estimating the temporal deterioration of their survival

probability. The purpose of the proposed method is to maximize the average survival probability of all patients at the time of arrival at the hospital as well as the number of patients whose survival probability is more than a marginal level $\alpha\%$ (where α is constant number, such as 30) while satisfying several constraints such as the hospital capacity. The transportation scheduling problem of patients scattered over multiple disaster sites is NP-hard and the number of possible schedules exponentially increases as the number of hospitals, ambulances, disaster sites, and patients increases. Therefore, it is difficult to derive an optimal solution in real-time. In the proposed method, assuming that the vital signs of each patient and an estimation function of P_s 's temporal deterioration are available from a server, we calculate a value called the *marginal treatment time* when each patient's survival probability gets lower than a predefined marginal level $\alpha\%$, and generate a transportation list based on the ascending order of the patients' marginal treatment time. However, this greedy method may produce cases where transporting a patient will cause two or more other patients' death (i.e., the hospital arrival time will be after their marginal treatment time). To prevent such cases, we propose a more sophisticated algorithm that explores, for each patient of top k order in the list calculated by the greedy algorithm, the two cases of rescuing the patient or not, and derives the transportation order that keeps the most patients alive.

Through computer simulations, we compared our proposed method with some existing approaches. As a result, we confirmed that the proposed method transported about a 25% larger number of patients to the hospital before their marginal treatment time than those existing methods.

II. RELATED WORK

In this section, we briefly survey related work in the following two categories: disaster medicine and patient transportation scheduling.

A. Application of ICT to Disaster Medicine

Unlike ordinary medical treatment where sufficient medical resources are provided for each patient, in an MCI, rescuers must provide the best treatment for many patients with limited time and resources. In primary triage, the responders attach paper tags to patients according to the START method [3]. Four color codes are used to distinguish the severity of the patients' injury. Patients with red tags have the highest priority and need an immediate treatment for survival. For patients with yellow tags, a few hours delay in treatment may not influence their survival probability. Patients with green tags do not need a specific treatment. Patients with black tags are already dead or considered to have no chance of survival and are given null priority.

Rescuers transport patients to a first aid station within the disaster site according to their color code and secondary triage is performed there. In secondary triage, paramedics

perform a re-triage, schedule the transportation order of the patients, and decide the hospitals to which they will be transported. Secondary triage aims to increase the life-saving ratio by determining in a short time the transportation order of patients taking into account the severity of their injuries. In an MCI, this operation must be finished within one minute for each patient. However, the paper triage tag method has the following problems:

- Even when the patients' conditions change, their triage tags cannot reflect the change.
- Since there is no priority among patients with the same color tag, they are transported in random order.
- Human errors cannot be avoided.
- The responder's feeling of oppression (on a possible wrong diagnosis) in deciding the color code for each patient is heavy.

1) *Electronic Triage Tag*: Many studies have addressed computerization of the triage method. Gao et al. developed the AID-N electronic triage system with electronic triage tags using biomedical sensors [4] [5]. This system monitors the vital signs of patients and delivers the patient's information to first responders. The Advanced Wireless Communication Technology for Efficient Rescue Operations project also studied computerization of the triage method [1] [6] [7] [8]. This project developed an embedded sensor device called the *electronic triage tag (E-triage)* capable of sensing a patient's vital signs and wirelessly sending/receiving the sensed information with ZigBee. The vital signs monitored by the E-triage are the heart rate, respiration rate, and blood oxygen level (SpO₂). Moreover, the E-triage performs a semiautomatic triage using the patient's vital signs based on the START method and sends the collected information as well as the triage result (color code) to the server located at the rescue commander's site. This project aimed to construct an Emergency Medical Service (EMS) system that monitors, aggregates, and visualizes patients' information in real-time. Suseki et al. proposed a system that collects vital signs from patients equipped with E-triage in realtime and decides the priority of treatment based on deviation of the patient's vital signs from a predefined threshold [9].

2) *Estimation of Probability of Survival*: The TRISS method, which combines Revised Trauma Score (RTS) and Injury Severity Score (ISS), is used to estimate the probability of survival for patients [2]. RTS can be calculated from vital signs such as the respiration rate and blood pressure which can be measured. On the other hand, ISS can be calculated based on the patient's diagnosis given by a physician.

Recently, various trauma data have been registered in a trauma database. Some studies have provided more accurate models to calculate the patient's probability of survival than the TRISS method by using a trauma database. A model called the Harborview Assessment for Risk of Mortality (HARM) was developed using 33,990 trauma data items

registered in the Harborview Medical Center Trauma Registry [10]. In addition, the Trauma Mortality Prediction Model (TMPM) was developed using trauma data from 702,229 patients who sustained 2,207,823 instances of 1,322 distinct AIS injury codes registered in the National Trauma Data Bank (NTDB) [11]. Japan Trauma Care and Research (JTCR) makes up a report on trauma data registered in the Japan Trauma Data Bank (JTDB) every year and describes the relationship between P_s and the actual mortality rate in the report [12]. The above research results suggest that if enough trauma data can be collected, it will enable more accurate P_s estimation and thus a more accurate temporal P_s deterioration function than TRISS.

B. Patient Transportation Scheduling in MCI

In current disaster medicine, patient transportation scheduling just transports severe-condition patients (red tags) at random. The rescue commander collects information about patients and capacities of hospitals using a cell phone, a transceiver, and/or a memo, then schedules the patients' transportation order based on this collected information. Thus, the transportation order is likely to be based on the order in which the information is received. However, the transportation order by this method may be far from optimal since it cannot adapt to changes in the patients' conditions and newly arriving casualties. We need a better scheduling method to transport patients to hospitals.

Jotshi et al. proposed a transportation scheduling method considering the existence of errors in the collected information about casualties [13]. In this method, the disaster area is divided into clusters and some ambulances are allocated to these clusters depending on the following three factors: the number of patients in the cluster, the distance from the ambulance to the cluster, and the distance from the cluster to the hospital. In this method, the ambulances are dispatched to clusters rather than to patients so that an error in the patient's information does not result in a waste of the transportation resource. However, since this method does not focus on the injury type and/or the condition of the patient, it cannot identify patients who require earlier treatment for survival than others.

C. Contribution of the Proposed Method

We focus on the transportation scheduling problem after the secondary triage of the patients. Using the temporal survival probability deterioration function, we define a problem that maximizes the number of patients transported to hospitals within their marginal treatment time (the time when each patient's survival probability gets lower than a predefined marginal level). Since this problem is NP-hard as we prove in Section IV-A, we propose a heuristic algorithm that provides a semi-optimal solution in a short time, taking into account the availability of the hospitals, the locations of first-aid stations, the number of ambulances, and the

number of patients. We also conduct computer simulations to show the performance of the proposed method, supposing an instance of a large MCI.

III. PATIENTS TRANSPORTATION SCHEDULING PROBLEM

This section describes assumptions for the target MCI and formulate the patients transportation scheduling problem.

A. Assumptions

We assume that several on-site first aid stations and a rescue command center are set up when an MCI happens. In the command center, the patients' transportation schedule is planned and ambulances are dispatched to the rescue sites. We also assume that E-triage tags have already been attached to all patients in the rescue sites. Thus, the rescue command center can grasp all patients' vital signs and their location in real time. Moreover, the center can grasp the hospitals' information such as capacity, possible treatment types, location and so on, and know the transportation time between any pair of on-site first aid stations and hospitals. Based on the above information, the center makes a patients' transportation schedule and dispatches ambulances to some of the on-site first aid stations to transport patients as scheduled. We assume that the temporal deterioration of survival probability for each patient p at time t can be estimated by a function $P_s(p, t)$ that is calculated based on the latest vital signs and the injury type of the patient.

According to the statistics in the Japanese Surgery of Trauma Data Bank, 95% of patients eventually die if they cannot receive medical treatments before their survival priority gets below 10%. The mortality rate is 80% with survival probability below 20%, and 75% with survival probability below 30%. This means that in order to increase the life-saving ratio, we need to transport patients to a hospital before their survival probability falls below a certain threshold. We denote this threshold by α .

B. Problem Definition

Our target problem is to derive a schedule that maximizes the number of patients who are transported from rescue sites to hospitals before their survival probability gets lower than α . Let P , S , H , and Am denote the set of patients, the set of rescue sites (first-aid stations), the set of hospitals, and the set of ambulances, respectively. Let $tl(p) = \langle p, s, h, at, ps \rangle$ denote the transportation information of a patient $p \in P$ existing in the first aid station $s \in S$ where $h \in H$ is a hospital to which p is transported, at is the estimated hospital arrival time, and ps is p 's survival probability at time at . Let $am.TL$ denote the list of the transportation information of patients who are transported by ambulance am . For each hospital $h \in H$, let $h.cap$ denote the latest accommodation capacity.

Table I
SYMBOLS USED IN PROBLEM FORMULATION

Symbol	Meaning	Symbol	Meaning
P	set of patients	p	patient
S	set of rescue sites	s	on-site first aid station
H	set of hospitals	h	hospital
Am	set of ambulances	am	ambulance
TL	list of transportation information	$tl(p)$	transportation information for patient p
$h.cap$	accommodation capacity of hospital h	at	estimated arrival time at hospital
ps	survival probability at the hospital arrival time		

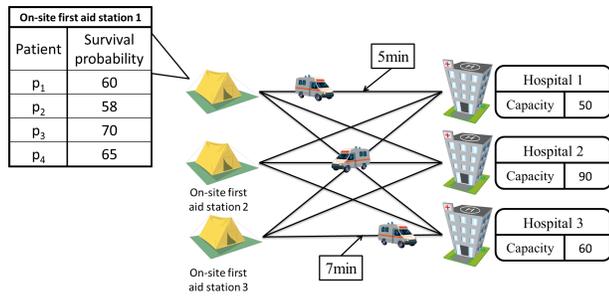


Figure 1. A Network Model for the Problem of Patients Transportation

We summarize the symbols used for the problem definition in Table I.

The patient transportation process from rescue sites to hospitals can be represented by a network as shown in Figure 1. Our target problem is deciding an optimal transportation schedule consisting of the transportation information $tl(p)$ of each patient p .

In a disaster area, many people are injured and transported to several on-site first aid stations S . After a patient receives first aid, the patient will be transported to an appropriate hospital selected from several hospital candidates H . To transport patients, several ambulances Am shuttle between on-site first aid stations and hospitals. We assume that a function $Tt(s, h)(s \in S, h \in H)$ can derive the time of an ambulance to move from on-site first aid station s to hospital h . For example, when an ambulance am located at hospital h_1 transports a patient p from on-site first aid station s to a hospital h_2 , the hospital arrival time at can be calculated by $at = t + Tt(s, h_1) + Tt(s, h_2)$. According to the assumptions in III-A, the survival probability of patient p at time at can be derived by the estimation function $Ps(p, at)$. Based on the above conditions, the transporting schedule TL for all patients can be derived. Let $count(Am, h)$ denote the

number of patients transported to hospital h in $am.TL$. The number of patients to be transported to hospital h must not exceed the accommodation capacity $h.cap$, this constraint is denoted as follows.

$$\forall h \in H, count(Am, h) \leq h.cap \quad (1)$$

The transported patient's survival probability must be no less than α , this constraint is denoted as follows.

$$\forall am \in Am, \forall tl \in am.TL, tl.ps \geq \alpha \quad (2)$$

Our goal is to maximize the number of transported patients while satisfying constraints (1) and (2). We also want to increase the average survival probability of the transported patients. Thus, we define the objective function by the following equation (3).

$$\begin{aligned} \text{Maximize : } & \frac{\sum_{am \in Am} \sum_{tl \in am.TL} tl.ps}{\sum_{am \in Am} |am.TL|} \\ & + \sum_{am \in Am} |am.TL| \\ \text{subject to } & (1) \text{ and } (2) \end{aligned} \quad (3)$$

IV. AMBULANCE SCHEDULING ALGORITHM

A. Problem complexity

We prove that the transportation scheduling problem defined in Section III is NP-hard by reducing the shortest Hamilton path problem known as a NP-hard problem to this problem.

The shortest Hamilton path problem is a problem to derive the shortest path that traverses each vertex in the given graph exactly once. Let $G = (V, E, cost)$ denote a undirected graph with weights, where V, E and $cost$ are the set of vertices, the set of edges, and the weight function $cost : E \rightarrow \mathbf{R}$.

Below, we transform a graph G to an instance of the transportation scheduling problem. We use V' and E' as variables representing the set of vertices and the set of edges, respectively. Initially, these sets are empty.

In the graph $G = (V, E)$, for each edge $(u, v) \in E$, we make two edges (u, w) and (w, v) by introducing a new vertex w which is not an element of $V \cup V'$, and put these two edges in E' and w in V' . Then, we construct a new graph $G' = (V \cup V', E', cost')$ where we define a new cost function $cost'$ as follows.

$$\forall (u, v) \in E \exists w \in V' \quad \begin{aligned} cost(u, v) \\ = cost'(u, w) + cost'(w, v) \end{aligned} \quad (4)$$

$$\forall u \in V \left(\prod_{(u, w) \in E'} cost'(u, w) \right) = 0 \quad (5)$$

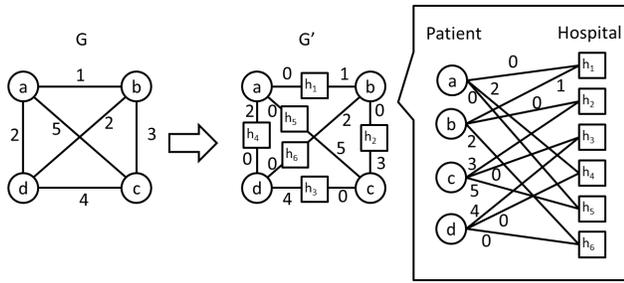


Figure 2. Transforming a graph to instance of transportation scheduling problem

The above equation (4) shows that the sum of the weights of two new edges in E' is equal to the weight of the original edge in E . The equation (5) shows that the cost of at least one edge that connects to each vertex u in V must be 0.

An example of transformation is shown in Figure. 2. In G' , we regard that V and V' correspond to the set of patients and the set of hospitals, respectively. In the figure, patients are $V = \{a, b, c, d\}$ and hospitals are $V' = \{h_1, h_2, h_3, h_4, h_5, h_6\}$. We also regard that the cost for each edge in E' corresponds to the moving time of an ambulance between the patient's location and the hospital. Moreover, let us assume that the expected survival probability of each patient monotonically decreases and equation (2) always holds.

From Figure. 2, it is obvious that solving the transportation scheduling problem for graph G' is equivalent to solving the shortest Hamilton path problem in graph G . Therefore, the shortest Hamilton path problem is a special case of the transportation scheduling problem and thus the latter problem is NP-hard.

B. Heuristic algorithms

Since the transportation scheduling problem is NP-hard, it is difficult to derive the optimal solution in a practical time. Therefore, in this section, we propose heuristic algorithms that derive a semi-optimal solution in a short time. First, we give a greedy algorithm called the *baseline algorithm* that transports patients in increasing order of their expected survival probabilities when arriving at the corresponding hospitals. Then, we give a more sophisticated algorithm called the *Depth-k Brute-Forth Search (DkbFS) algorithm* that investigates for each patient of the ordered list decided by the baseline algorithm, both cases of transporting the patient to the hospital or skipping the patient to explore the possibility of saving more patients with the later order.

1) *Baseline algorithm*: To increase the patients' survival probability, each patient must be transported to an appropriate hospital while the patient's expected survival probability

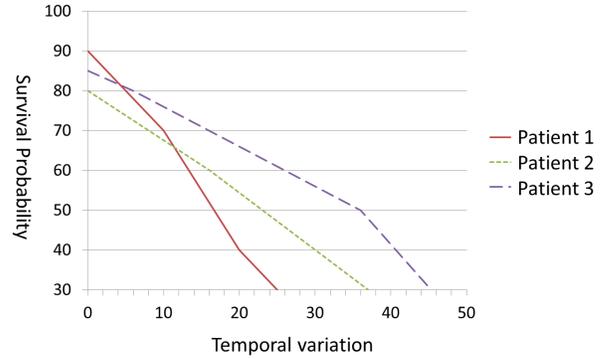


Figure 3. Example of temporal variation of survival probability

Algorithm 1 Baseline algorithm

```

Input: Ordered patient list  $PL$ , set of hospitals  $H$ , set of ambulances  $Am$ 
1:  $TL \leftarrow []$ 
2: for  $i = 0; i \leftarrow i + 1; i < |PL|$  do
3:    $h_c \leftarrow nearHospital(H, p_i.pos)$ 
4:    $am_c \leftarrow fastAmbulance(Am, p_i.pos, h_c)$ 
5:    $at_c \leftarrow am_c.nowtime + Tt(am.pos, p_i.pos) + Tt(p_i.pos, h_c.pos)$ 
6:    $ps \leftarrow Ps(p_i, at_c)$ 
7:   if  $ps \geq \alpha$  then
8:      $tl \leftarrow \{am_c, p_i, p_i.pos, h_c, at_c, ps\}$ 
9:      $TL.append(tl)$ 
10:     $am_c.nowtime \leftarrow at_c$ 
11:     $am.pos \leftarrow h_c.pos$ 
12:     $h_c.cap \leftarrow h_c.cap - 1$ 
13:   end if
14: end for
15: return  $TL$ 

```

remains higher than the threshold α . Thus, we use the expected survival probability estimation function $Ps(p, t)$ and compute the time t called *marginal treatment time* for each patient p such that $Ps(p, t) = \alpha$. Then, we build the patients list PL where the patients are sorted in increasing order of their marginal treatment time. Patients with the earlier order need earlier transportation. For example, if there are three patients p_1, p_2 , and p_3 whose expected survival probability estimation functions are given in Figure. 3 and $\alpha = 30\%$, the patients transportation list PL will be $[p_1, p_2, p_3]$.

Given the patients transportation list PL , the set of hospitals H , the set of ambulances Am , and other information such as the ambulance travel time between each patient's on-site first aid station and each hospital, we compute the ambulance scheduling list TL indicating in what order, when, and where each ambulance transports patients. We

show the baseline algorithm in Algorithm 1.

The baseline algorithm processes patients in the specified order by PL and assigns for each patient the ambulance which can transport the patient to the nearest hospital with a capacity (Algorithm 1, line 3) in the shortest time (line 4). Then, the algorithm computes the time at which the patient reaches the hospital (line 5) and the patient's expected survival probability at that time (line 6).

Since the baseline algorithm sequentially processes patients in the order specified in PL , it cannot avoid the case where two or more patients cannot be transported to the hospital before their marginal treatment time by transporting a patient with earlier order. In the following subsection, we propose an extended version of the algorithm that can avoid the above case and maximize the number of patients who are transported to the hospitals before their marginal treatment time.

2) *DkBFS (Depth-k Brute-Forth Search) algorithm:* We want to explore the possibility of "making two or more patients survive by giving up one patient." Thus, we consider for each patient p_i in PL the two cases where p_i is transported and not. If we consider two cases for each patient's transportation in PL , that is, 2^n patterns overall, we can find the optimal transportation scheduling list. However, deriving the optimal list for a large value of n is not feasible. Hence, we design the *DkBFS* algorithm so that it searches 2^k transportation patterns for the first k patients in PL and applies the baseline algorithm to the remaining $n-k$ patients for each pattern.

We say that a patient is *rescued* if the patient's expected survival probability at the time when the patient reaches a hospital is no less than α .

We show the details of the algorithm below.

- (1) Compute the number of rescued patients for all cases where each of first k patients in PL is transported and not transported. The baseline algorithm is applied to $(k+1)$ -th and later patients.
- (2) Select the pattern that has the largest number of rescued patients and put the rescued patients and their order in the pattern into the transportation scheduling list TL .
- (3) Remove the first k patients from PL and repeat the steps from (1) while PL is not empty. Finish if PL becomes empty.

For example, when $PL = [p_0, p_1, p_2, p_3, p_4, p_5]$ and $k = 3$, the *DkBFS* considers all possible patterns of transporting each of three patients p_0, p_1 and p_2 or not. The patterns are: $\{p_0\}, \{p_1\}, \{p_2\}, \{p_0, p_1\}, \{p_0, p_2\}, \{p_1, p_2\}, \{p_0, p_1, p_2\}$.

In the case of $\{p_0\}$, the algorithm transports p_0 even if equation (2) does not hold¹, but transports neither p_1 nor p_2 . The baseline algorithm is applied to the remaining

¹We consider this case because p_0 cannot reach the hospital while p_0 's expected survival probability is over α , but more patients followed by p_0 might be rescued due to ambulance movement.

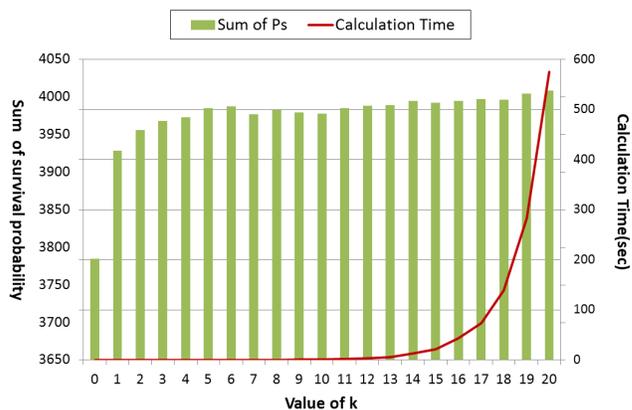


Figure 4. Computation time for different values of k

patients p_3, p_4 and p_5 , and the number of rescued patients (with at least α survival probability) as well as the average expected survival probability are derived. This process is applied to other patterns, and the pattern with the highest value for the objective function (3) is selected and added to the transportation scheduling list TL . Then, the same process is applied to the next three patients (in this example, only two are remaining).

3) *Deciding the best value for k:* To know the best value for k , we measured the total sum of expected survival probabilities for 100 patients and the computation time by changing the value of k between 0 and 20. We used the same experimental configuration as in Section V-A. We show the result computed by the average of 20 runs in Figure 4. Here, note that the case of $k = 0$ corresponds to the baseline algorithm.

Figure 4 suggests that the total sum of expected survival probability increases as k increases. In this example, the value almost converged when k is over 5. The computation time is reasonable while k is less than 13, but rapidly increases as k increases beyond 13 since the algorithm complexity is $O(2^k)$.

V. PERFORMANCE EVALUATION

We conducted simulation experiments to confirm performance of the proposed method. We compared our method with several conventional methods and show the results in the following Section V-B.

A. Simulation Configuration

We consider a large-scale disaster in the simulation experiment. The assumptions of the disaster area are collected in Table II.

Table II
THE STATUS OF THE ASSUMED DISASTER AREA

# On-Site First Aid Stations	# Patients (red)	# Hospitals	# Ambulances	Transportation Time (1-way) 3min – 18min
20	100	8	24	

Table III
SIMULATION RESULTS FOR PATIENTS WITH TYPICAL Ps FUNCTIONS

		DkBFS	BA	Jotshi-G	Jotshi-R	Greedy
# Rescued Patients (Ps ≥ 30)	Max	98	98	82	68	95
	Avg	92	89	68	59	64
	Min	85	80	39	47	44
Avg. Ps (rescued)	Max	47	44	50	72	74
	Avg	43	41	46	60	57
	Min	40	38	43	51	43
Avg. Ps (all)	Max	44	42	38	40	42
	Avg	40	37	30	36	36
	Min	36	32	19	33	31

In the disaster area, there are a total of 20 on-site first aid stations, and at each station there are 5 seriously-injured (red tag) patients. There are 8 hospitals located in the area where each hospital has 3 ambulances. Each patient’s initial survival probability is decided at random between 70% and 90%. We suppose that there are four types of Ps estimation functions that make Ps of a patient with 100% initial Ps gradually fall to 0% in 55, 65, 75, and 90 minutes, respectively. These 4 types of Ps estimation functions are equally distributed among 100 patients (25% for each). The conventional methods for comparison are shown below.

Greedy method: transports the current lowest survival probability patient first.

Jotshi’s method [13]: considers only the moving time between first aid stations and hospitals, and is denoted by *Jotshi-R*. *Jotshi-R* is close to the actual rescue transportation activity. However, this method does not decide patient transportation order and thus transports patients in random order. For fairness in comparison, we prepared a modified version called *Jotshi-G* method, which transports the current lowest Ps patient first in each on-site first aid station.

Baseline algorithm: this method was described in Section IV-B1.

Based on the results of preliminary experiments, we set the value of *k* to 10, and the value of α to 30%.

We simulated 1000 times and calculated average, minimum, and maximum numbers of rescued patients (patients who arrived the hospital with Ps over α) and their survival probability.

B. Results and Discussion

The simulation results are shown in Table III.

Table IV
SIMULATION RESULTS FOR PATIENTS WITH RAPIDLY DECREASING Ps FUNCTIONS

		DkBFS	BA	Jotshi-G	Jotshi-R	Greedy
# Rescued Patients (Ps ≥ 30)	Max	95	95	78	63	73
	Avg	85	82	63	54	51
	Min	74	70	43	44	37
Avg. Ps (rescued)	Max	47	44	47	71	81
	Avg	43	41	44	61	64
	Min	40	38	42	54	53
Avg. Ps (all)	Max	41	39	35	37	39
	Avg	37	33	28	33	33
	Min	32	29	19	29	28

1) *Number of Rescued Patients:* In Table III, the proposed method (DkBFS) showed the best performance among all methods. The greedy method transports the current most-serious (lowest Ps) patient first. So, if there is no changes in patient conditions, it achieves a good result (95 rescued patients for the best case). However, for the cases that patients’ conditions change, the results become worse (the average and minimum numbers of rescued patients are 64 and 44, respectively). The results of Jotshi-G are similar to the greedy method, but it showed a better performance than Jotshi-R since Jotshi-G considers patients’ current Ps. However, like the greedy method, Jotshi-G does not consider changes in patients’ conditions. For this reason, the difference from the proposed method is large. The performance of the baseline algorithm (BA) is similar to the DkBFS method, but it does not optimize the schedule, causing a gap from the DkBFS method.

2) *Average Survival Probability:* Average survival probability of rescued patients (rescued) of Jotshi-R and the Greedy method is higher than the proposed methods but the average survival probability (all) of the proposed methods is higher. These existing methods transported some patients with higher survival probability, but patients who need earlier treatment were transported later. As a result, with these methods, many patients with higher current Ps (priority should be low) are transported earlier, but the patients with lower Ps (priority should be high) are transported late and do not arrive before the marginal treatment time. On the other hand, since our proposed methods can transport patients taking into account expected Ps at the hospital arrival time, the number of rescued patients is higher than other methods.

3) *Additional Experiments:* We also conducted additional simulation experiments in two cases where patients’ Ps more rapidly and more slowly decreases, respectively. For this purpose, we changed the distribution of the four Ps estimation functions used in Section V-B2 so that 40, 30, 20, and 10% of patients have the Ps functions that make 100% initial Ps fall to 0% in 55, 65, 75, and 90 minutes, respectively, for rapid decrease case. For the slow decrease case, we used the reverse distribution: 10, 20, 30, and 40%. We show the results in Tables IV and V.

Table V
SIMULATION RESULTS FOR PATIENTS WITH SLOWLY DECREASING P_s FUNCTIONS

		DkBFS	BA	Jotshi-G	Jotshi-R	Greedy
# Rescued Patients (P _s ≥ 30)	Max	100	100	90	77	100
	Avg	97	96	76	65	89
	Min	89	86	46	52	44
Avg. P _s (rescued)	Max	48	48	50	70	73
	Avg	43	42	47	60	46
	Min	40	39	44	53	41
Avg. P _s (all)	Max	48	48	43	44	49
	Avg	42	41	36	39	41
	Min	38	34	22	34	36

Table IV shows that when more patients’ P_s rapidly decreases, our proposed methods kept similar performance to the previous experiment (in Table III), whereas the results of other methods got worse.

Table V suggests that when more patients’ P_s slowly decreases, the proposed methods rescued all patients in the best case and larger number of patients for average and worst cases than other methods. Other methods rescued more patients than previous cases in Tables III and IV, and the difference from our methods got smaller.

The above results suggest us that the proposed methods can more effectively schedule patients transportation in the cases where many patients need early treatment.

VI. CONCLUSION AND FUTURE WORK

In this paper, we formulated the transportation scheduling problem for patients in an MCI assuming utilization of E-triage and proved that the problem is NP-hard. To efficiently solve the problem, we proposed a heuristic algorithm that explores a search space represented by a binary tree within depth *k* and finds a near-optimal transportation schedule that achieves the maximal life-saving ratio. Through computer simulations, we confirmed that our method outperforms other existing methods in terms of the average survival probability and the expected number of patients surviving.

In the proposed method, we assumed that temporal deterioration of survival probability for each patient can be estimated from the type of trauma diagnosed by a physician and vital signs sensed by the E-triage tag. We believe that an accurate estimation method will be realized in the near future as studies about collection and analysis of patients’ trauma data progress.

As part of our future work, we will conduct computer simulations for performance evaluation of the proposed method when patients are dynamically added and/or the conditions of patients change during transportation.

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A Design Pattern for Information Sharing in Medical Emergency Response to CBRNE Events

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Abstract - Responding to large-scale medical emergencies tends to quickly overwhelm a single agency's resources and demand multi-jurisdictional response. As the number of responder organizations grows so does the importance and complexity of effective, efficient, and timely information sharing. This is particularly true in the context of operations that may demand collaboration between military and civilian agencies, such as responding to Chemical, Biological, Nuclear, or Explosive (CBRNE) events. With the addition of digital infrastructure and wireless data networks as intrinsic Incident Command tools, a significant barrier to efficient information availability and dissemination is the tiered, multi-domain access paradigm that is typically employed by response agencies, particularly military organizations. While treaty-based response protocols can successfully create digital shared domains, information sharing, particularly in an automated or software-driven fashion, remains exigent. Fundamentally, the challenge lies in the need for heterogeneous system infrastructures and architectures to rapidly fuse in an adhoc fashion, a task that raises wide ranging technical challenges. The cross-domain access mitigation is particularly important in the context of medical information since providing timely care has to be balanced against patient privacy and, in events that may involve biological or nuclear agents, against the best interest of the community at large. Asynchronous Web Services offer a practical solution to the problem of multi-organizational information sharing in the context of time-critical medical emergency response. However, asynchronous operations are not a native component of the W3C standards and while a number of approaches have been suggested, none meet the security and privacy requirements of medical emergency response. This paper describes a design pattern that addresses many challenges of deploying web services in support of information sharing processes across heterogeneous domains in the particular context of the medical component of large-scale multi-jurisdictional emergency response.

Keywords - CBRNE, Collaborative Emergency Medical Response, Service Oriented Architecture, information Sharing

I. INTRODUCTION

Medical emergency response is inherently a collaborative, multi-organizational operation where patients are cared for in a continuum, by professionals who specialize in various aspects of rescue, treatment, and rehabilitation. In most emergency operations responding organizations belong to the same jurisdiction and, as such, work and train together

on a regular basis. This level of exposure helps local responders develop a familial sense about how to best support each other to ensure a successful operation. However, as the incidents grow beyond a single jurisdiction, such as in the case of CBRNE events, the response operation requires inclusion of mutual-aid resources that can only relate to local responders via protocol [1].

Medical component of collaborative response to large scale incidents is an arduous task due to a number of unique properties. For example, while delivering rapid and appropriate care is absolutely vital to victim survival, it must be done in compliance with privacy laws in the response jurisdiction. Furthermore, a complex set of legal and case laws stipulate information dissemination guidelines to other sources, such as the press or law enforcement agencies, that have a legitimate mandate to protect the community. The latter is particularly relevant in incidents involving biological agents with high risk of spreading through human contact, when the need to identify and locate specific individuals may be the key to a timely or effective response. Other unique properties of medical emergency response are the incident tempo that can range from minutes to months; impact on a single individual or the global citizenry; The scope of the incident that can quickly create a chain reaction straining social services; and the secondary societal impact that can inflict severe financial damage to industries such as travel.

Given these attributes, a key success factor in effective large scale medical emergency response is managing information distribution and access amongst the myriad of responders and stakeholder. Due to the increased availability of reliable and persistent digital infrastructure in emergency operations, automated information sharing holds the promise to offer significant benefits in joint operations [2][3][4].

Here we describe a design pattern that eliminates much of the a priori work required in implementing digital data sharing eco-systems. In particular, it will obviate much of the treaty-based agreements in information sharing, such as common servers and data formats. This paper first reviews the background of our research as well as the relevant related work to date. We then focus on the technical implementation details.

II. RELATED WORK

For the past several years, we have been researching massively scaled, multi-jurisdictional, automated information sharing infrastructures, with a focus on emergency response. The discipline is a uniquely challenging example of a time-sensitive, complex, distributed, and networked eco-system because of the extremely broad range of competencies, technologies and resources of network participants. Therefore, as response operations grow in scale, the task of maintaining a shared informational framework becomes increasingly difficult.

While it is possible to create treaty-based, umbrella digital shared domains for a group of response organizations, a Service Oriented Architecture (SOA) is the only logical choice to create a common operational environment that does not require prior technical or policy agreements between all participants [2][5]. Furthermore, the emergency response domain has a number of properties that ideally fit Service Oriented Architecture as the architectural underpinning of a field-deployable information management framework. A number of these properties are:

- Domain is extremely fragmented, with participants having a wide range of capabilities, training, and resources;
- There are key regulations in the US and Europe that limit how health care data is managed and shared. The US Health Information Portability and Accountability Act (HIPAA) regulates data sharing across domains (i.e., police and hospital, or state and federal) as well as temporally along the continuum of care;
- In most cases response must be rapid and decisive, with minutes making the difference between life and death; and finally
- There is frequent need to consult with specialists and other experts on cases such as poisoning or CBRNE response.

The SOA is the only approach that would allow all responders to use their existing infrastructures while cooperating via the wide-area connectivity afforded by the Internet. Using IP-based networks inside the firewall, also a common practice, allowed us to implement the services without the need to distinguish where they were running (e.g., inside or outside an organization's network) and secure the communication using standard strategies such as creating a Virtual Private Network (VPN) to support each incident.

Employing a Service-Oriented Architecture also solves the challenge of duplicating the infrastructure underpinnings, particularly with respect to adhoc coalitions that are formed in response to specific incidents. Service Oriented Architecture alone, however, does not address the single,

most prominent attribute in emergency response, Asynchronicity, which is amplified exponentially as the number of responders increases. Asynchronous operations, however, are not a native component of the W3C standards. This paper describes a Design Pattern that implements a transaction-based, secured, verifiable, and auditable extension to the W3C Web Services Standards.

Exploiting technology in medical emergency response is not a new research topic. The field of practice largely grew out of the desire to reduce response times as detailed in [3][4], with a current survey of the field presented in [6].

In terms of CBRNE response, most jurisdictions use technology to support high-risk response operations. Almost all agencies also carry some variation of sensors to detect presence of CBRN agents on the scene and there is a desire to couple wireless-capable sensors with real-time analysis. Numerous modeling and simulations activities are currently underway to support medical response. Noteworthy in context are EPA's MENTOR-2E [7], a collection of models that use an integrated, mechanistically consistent source-to-dose-to-response framework to quantify inhalation exposure and doses resulting from emergency events; the Integrated Weapons of Mass Destruction Toolkit (IMWDT) that is used to support our research [8], and the DHS effort to create models of bio-terrorism risk assessment [9]. Active research also includes study of Time Critical Information Services [10]. Furthermore, research is in progress to develop methods of introducing domain expertise in emergency response, for example via Ontology [11][12]. Given the significant collaborative nature of CBRNE response, and large-scale emergency response operations in general, relevant research also includes collaboration and cross-domain information sharing. Of particular relevance are efforts reported in [12], investigating use of Ontologies as knowledge representation instrument in the emergency response domain to enhance automated information sharing. Finally, CBRNE events almost always require multi-jurisdictional response, possibly including support from the military. Research in Command and Control in multi-organizational mission operations includes work reported in [6][11][12].

III. DESIGN PATTERN

This pattern is designed to support tactical operations between networked cooperative participants. As visually depicted in Figure 1, the pattern has two major components: Nodes and Transaction Object. A node, synonymous with a "server", is a collection of web services that are cooperating in support of a mission. The transaction object is used to create and maintain a persistent state throughout the networked environment and to exchange information.



Figure 1: Communications Pattern

The key is that the node must support a default connection service that accepts a transaction as the only argument. The default service is one that is activated when the node is referenced using a normal http or https reference. In networks with high security considerations, the connection service may be “hidden” behind a specific socket¹, and the network may further require human intervention to receive the connection specifications. The node itself may be architected using any number of patterns that utilize an Edge Service. A sample pattern is shown in Figure 2. As depicted, the transaction arrives, (1), and is received by the node’s Edge Service, (2). The service will immediately off-load the transaction to a staging area, (3), where it will wait for processing. The rapid off-load enables significantly higher performance by the Edge Service, particularly if connection is made over UDP². In our implementation the staging area is a directory on disk. While the staging area could be implemented in a database, we found the overhead of database write operations an unnecessary burden in this specific case.

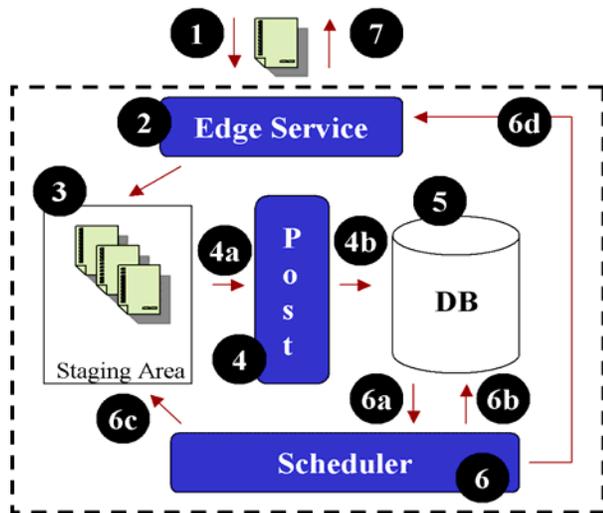


Figure 2: Components

In our implementation redundancy, not shown in figure, was provided via RAID-0 (mirroring) of disks and audit trail, also

¹ Security operations are generally easier when using a single Edge Service vs. a directory approach that publishes numerous services supported by the node. This, however, does not reduce the security burden beyond easing connection security issues.

² For completeness: While UDP connections are not lossless operations, they are the ideal connection type for peer-to-peer operations since the server will not need to maintain a persistent connection. This is property is particularly useful in massively scaled, peer-to-peer networks, such as emergency response where the nature of an incident will determine the response network and a-priori network design is fundamentally futile.

not shown, can be implemented using the disk logs. A post process, (4), will loop over the staging area. New transactions are pulled off, (4a), from the staging area written, (4b), to an operational database, (5). The post process may perform additional security or assurance operations before inserting the transaction in the database. Note that, as discussed in the Section entitled ‘Transaction Processing’, the transaction may include encrypted components. A third process, a scheduler, (6), loops over the operational database. This process will examine, (6a), each transaction and dispatches it to an appropriate internal service for processing. Based on results, the system may update the transaction in the database, (6b), may place a new transaction in the staging area for re-posting, (6c), or may send an outbound transaction, (6d), to the edge service, (2). This outbound transaction is, most likely, either an acknowledgement or response to a transaction and is sent to the originating node, (7). Since this process is duplicated on each node, a collective system state is established and maintained.

A. Database Tables

Two database tables are used in support of transaction management; a *Queue* table, and a *Transaction History* table. Both have the same schema, shown in Table 1, that matches the transaction object.

TABLE 1: TRANSACTION TABLE

Column	Meaning
TID	Transaction ID (originator)
TRefID	Transaction ID (recipient)
Tchannel	Self-explanatory
Priority	
Ttype	See Transactions Processing
Tcode	See Transaction Processing
Tformat	TXT, XML, Binary, Etc.
Tlength	Length of this Transaction
TinitDate	Self-explanatory
TlastTouched Date	Self-explanatory
TcaseInfo	Additional Reference Number or designator, if needed.
TCRC	Self-explanatory
Treserved	Self-explanatory
Tdata	Data Segment. Variable length See Transactions Processing
Tsender	Self-explanatory
Ttarget	Self-explanatory
TStatus	Current Status. See Transactions Processing.

To ease implementation and improve performance the Queue Table can further be sub-divided into three tables, *Low Priority Queue (LPQ)*, *Medium Priority Queue (MPQ)* and *High Priority Queue (HPQ)*.

B. Transaction Processing

As compared with traditional client-server, transaction processing in a distributed environment and dynamic peer-to-peer connection is somewhat more complex.

As with a client-server environment, a *Transaction ID*, (**TID**), is assigned to each transaction at initiation time by the node that is acting as the “sender”. The TID alone, however, is not enough of a tracking instrument in a distributed system since it is not possible to guarantee system-wide uniqueness. To address the issue the pattern employs a second field, a *Transaction Reference ID*, (**TrefID**), that is assigned by the target of the transaction, or the node that is acting as a “recipient”. The combination is guaranteed to uniquely identify the transaction system-wide. Actions are requested through the combination of *Transaction Type* (**Ttype**), and *Transaction Code* (**Tcode**) determines the action being requested, by the sender or an acknowledgement or reply to the request, by the recipient. Transaction codes and types are shared by all nodes and are part of the foundational core system that is shown Figure 2, and a sample code is shown in below.

```
// GENERAL STATUS CODES (00)
int GENINIT=0x0000; //init
int GENFINOK=0x0001; //finished w/o err
int GENFINERR=0x0002; //finished w/err
int GENUNRESP=0x0003; //unreponsive proc
int GENORHPAN=0x0004; //orphaned process
int GENWAIT=0x0005; //Waiting.
int GENREADY=0x0006; //txn ready to run
int GENPRIHOLD=0x0095; //priority hold
int GENADMINHOLD =0x0096; //adm hold
int GENSECHOLD=0x0097; // security hold

//DAT STATUS CODES (02)
int DATBegin=0x0200; //query begin
int DATEnd=0x0299; //End of Data
int DATWait=0x0201; //Waiting for data
int DATAck=0x0202; //Data-related ACK
int DATQuery=0x0203; //new query
int DATSend=0x0204; //Ready for data
int DATReceive=0x0205; //Rdy to send
```

All necessary parameters are transmitted through the *Transaction Data* (**Tdata**) component of the transaction object. This component can be encrypted. The ability to encrypt data and parameters, coupled with the singular edge service, substantially addresses many of thorny cross-domain data access and information sharing issues – this is simply accomplished by the intermediary node, placed between higher and lower echelon nodes, duplicating segments of an incoming transaction, then forming a new transaction and submitting that transaction for processing to a lower echelon node for processing. The two transactions can be related by utilizing either the *Transaction Case Info* (**TcaseInfo**) field, or as another encrypted element in the data component of the transaction (Tdata).

C. Transaction History and Audit Trail

A Database Trigger, shown below, accurately manages the transaction history table.

```
create trigger txnq after insert on txnhistory
for each row begin
delete from lpq where tid = new.tid; -- delete it if exists
insert into lpq values (new.TID,...);
end;
```

A similar trigger is implemented to execute after update. The net effect of the triggers is that a copy of the *old* transaction (before the queue is updated) is inserted into the *Transaction History* Table and the entry in the *Queue Table*, e.g., *LPQ*, is overwritten with the most current status. Querying the transaction history table on a single node (based on the TID) will provide an audit trail on that node. To produce a system-wide audit trail all nodes must be queried.

D. Scheduling

As shown in Figure 2, a scheduler loops over the transaction queue(s) – tables – in the production database. If the *transaction status* (**TStatus**) is not any of the hold status codes, i.e., priority, administrative, or security holds, the transaction will be dispatched, as discussed in the next Section. The scheduler will update the status code before dispatch. This act creates an entry in the transaction history table, providing an audit trail. The Scheduler has a discrete component that will dispatch – execute – code that perform tasks necessary for, or requested by, other nodes via the transaction object.

E. Dispatch

Tasks, i.e., responding to a request for data, are accomplished by dispatching the transaction to a handler code. Handler codes do not have to be determined in advance and a default handler is available as part of the core foundation. Each handler may be a Web Service inside the fire wall (behind the Edge Service) and is not visible to outside callers. Handlers can also be implemented in different forms, such as libraries or class that are loaded or linked dynamically at run time. This allows each node full capability to customize handling of each transaction.

Handlers are specified via a database table in the production database. This table can be stored in a separate or more secure database, or be encrypted for additional security. Table 2 shows the schema for the handler table in the production database.

TABLE 2: HANDLER TABLE SCHEMA

Column	Meaning
CMDGroup	Transaction Type
Handler	Handler Name
CallType	Handler Type

Each handler is tied to a transaction type via the *Command Group*, (**CMDGroup**), field. The *Handler Name*, (**Handler**), specified the programming name for the handler. The final database column, (**CallType**), specifies the specific handler type, for example a servlet, a class, or a dynamic library. An actual sample of the table is shown in Table 3. Note the relationship to the sample code above.

TABLE 3: HANDLER TABLE

CMDGroup	Handler	CallType
CNC	C2	1
DAT	dataManager	1
GENACK	GENACKClass	0
ICH	InfoChain	1
INIT	INITClass	0
RDR	fileReader	1

The dispatcher follows a relatively simple algorithm: it determines, based on the transaction type, which handler to invoke. It then applies the appropriate call type sequence based on the information in the handler table (**CallType**), and passes the entire transaction object to the handler code. Nothing else is passed on, expected, or accepted as a parameter. This approach drastically simplifies not only management and maintenance of the database support for scheduling and dispatch operations, but also measurably reduces the complexity of extending the environment through custom code.

IV. CONCLUSION AND FUTURE WORK

Asynchronous operations are the cornerstone of all but the simplest of collaborative tasks. As such, they are an important component of joint operations, particularly in specialized, non-persistent or mission-based tasks such as military-civilian disaster response. Unfortunately, asynchronous operations are not part of the W3C standards specifications for web services. In this paper we discussed a transaction-based design pattern to implement massively scalable, cooperating asynchronous web services. The pattern was developed and tested as part of a research project focused in the military-civilian information sharing and has, thus far, proven functional, stable, and consistent. Consistency is a large component of a useful pattern since building extensive exceptions will eventually render the pattern useless. We have not thus far encountered a situation where the pattern needed to be augmented or mediated through exception processing. Our future work in this regard is now shifting to application of the pattern to additional domains such as simulation and training.

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Expectations and Fears of Urban Versus Rural Population Regarding the use of an Electronic Health Record

Qualitative Survey About Usage and Acceptance of an Electronic Health Record in Austria

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Abstract—Nowadays electronic health records are evaluated and implemented worldwide. Future stakeholders, especially patients are not always integrated into all aspects of this process. An important problem with the rollout of a countrywide e-health project is the unequal distribution of the access to modern media, especially to computer and internet (“regional digital gap”), of people living in urban and rural areas - and if there are differences regarding the usage of an electronic health record between these two groups. Differences in these aspects between urban and rural areas were evaluated using an empirical trial. This qualitative survey was based on 20 interviews focused on the discrepancy between urban and rural areas regarding the opinion on the electronic health record in Austria. The results show that differences in some aspects regarding “personal data input”, “health information”, “own usage” and “data abuse” of an electronic health record exists.

Keywords - *electronic health record; patient empowerment; qualitative survey; medical informatics.*

I. INTRODUCTION

The commonly used term for the country wide electronic health record in Austria is ELGA (which is a German acronym for electronic health record) and defined as followed: “ELGA consists of multimedia and health related data and information corresponding to a unique identified person. The data and information originate from different sources of the health sector and may also come from the patient himself and are stored in multiple information systems (virtual record). The data and information can be accessed by authorised people according to their roles and data privacy rules in a tailored way wherever the patient is treated (time- and location-independent)” [15].

The health reformation law, which defines the goal of a nationwide electronic health record, can be considered as a starting point for ELGA and was legislated in 2005 [16]. The next important step was a feasibility study [13] where the situation in Austria was analyzed and a few important concepts towards a nationwide ELGA were identified. It was stated, that one important part for the realization of ELGA is the acceptance of the Austrian citizens, which means, that opinions, wishes and fears of the population should be considered in the design and implementation process. For the

realization of an electronic health record (EHR) several important aspects were identified: preliminaries (e.g., acceptance), basic components (e.g., patient portal) and core functions (e.g., exchange of lab reports) [14]. The patient portal includes some important functions for patients: “Health information”, which allows the patient to get access to public accessible health information. The second function “result retrieval” allows patients to read all their results, which were created and stored at registered doctors - e.g., from general practitioners. The last function “personal data input” allows patients to store health related personal data in their EHR, e.g., blood pressure [14][17].

The latest implementation of an EHR related project in Austria is the patient portal (www.gesundheit.gv.at), which was released in 2010. At present other defined aspects (e.g., standardization and physician index) are investigated and looked into. More information about past and defined milestones toward an EHR in Austria can be found in [7].

This paper is structured beginning with a description of related work (Section 2), the methodology and the used tools within the study (Section 3). Afterwards the results are presented (Section 4) and discussed (Section 5). Finally some conclusions of the gained results are listed (Section 6).

II. RELATED WORK

A few interesting studies among patients and physicians concerning the above stated aspect about acceptance of an EHR were published [1][4][5][10] but none of them consider differences between rural and urban areas. The paper published by Hoerbst [1] describes attitudes and behaviours among Austrian and German citizens from urban areas. The results point out, that citizens have a positive attitude towards an EHR but also some concerns (e.g., data protection) including problems with information deficits. Another study with patients from London point out, that they are interested in accessing their records to improve the relationship with the clinicians [5]. Requirements for an EHR from the point of view of citizens, physicians and other relevant stakeholder were identified through an Austrian pilot project. Citizens want a secure access, to add own entries and to have control about the access privileges. Physicians wish to have a time- and location-independent

access to relevant information for the treatment in a short time, and the opportunity to write an electronic prescription [10]. The uncertainty among physicians in Austria as well as fears (e.g., additional workload and cost, data will be used by unauthorized people) was shown in another study [4].

People in Austria are spatially not homogeneously distributed, which results in differences between people and their characteristics, which have to be considered in terms of an EHR and its acceptance. The regional digital gap is one of these differences, which describes not only the unequal distribution of the access to modern media, but also considers social environment, education, finances and infrastructure aspects in urban and rural areas. And even though this digital gap is getting smaller over the years, studies can demonstrate that it is still existing [6][8][9][11].

III. METHODS

To gather the required information from the people from urban and rural areas, an empirical comparative study was used. The aim of the study was to gather relevant data covering different characteristics of people’s opinion through interviews. The whole study setting was divided into four parts (see Figure 1 for a detailed methodology description). First we conducted some preliminary tasks. Afterwards the study population was acquired for the next step, in which the interviews were conducted. In the last step, the data was analyzed in terms of different aspects through a qualitative content analysis according to Mayring [3].

A. Preliminary tasks:

First a literature research was carried out to get fundamental information about current research in the topics EHR and qualitative surveys as well as state of the art publications about acceptance of EHRs. Afterwards this information was used to conduct 10 pre-interviews (5 people from urban and 5 people from rural areas). These interviews were used to get a baseline opinion of people from urban and rural areas. The interviews were open like a discussion and the relevant answers were noted. For a good validity of the results an equal distribution among the attributes “age”, “gender” and “education” was used (which is also called parallelization [12]). The results of these pre-interviews as well as the literature research were used to define the

questions for an interview guideline and the definition of the study setting (e.g., which people form where should be asked).

The study population for the empirical study was constructed by choosing people living in Austria who belong to a rural or a urban area. For correctness of the study the sample had to be stratified. The stratification characteristics were “area” with the groups “rural” and “urban”. The criteria for people belonging to these groups can be found in Table 1. Every person had to fulfil each criterion of one particular group to be considered as part of this group sample. Additionally everyone had to meet the definitions of rural or urban (see Table 2) according to their belonging group.

B. Acquiring test people:

At the beginning of this phase a flyer was created, which should be used to help finding participants from urban and rural areas. On this flyer the important facts of the study and their activities were clearly stated and contact addresses were given. Afterwards this flyer was given out using digital copies and on paper. After someone expressed interest in participating in this study, an appointment was made for conducting the interview. People who participated in the study were also found by using gatekeepers (people who help finding participants). These gatekeepers were informed about the content of the study and asked to find people matching the criteria in Table 1 and Table 2 and who like to participate in the study.

C. Realization:

Upon the defined questions and study settings in phase 1 an interview guide and a short questionnaire were created for conducting the (qualitative) problem centred interviews according to Witzel [2]. Before using the interview guide/questionnaire a few test interviews were conducted among friends and relatives of the study authors to see if the questions are understandable. A few adaptations were necessary before the interviews could be conducted. The interviews itself were held were the interviewee was comfortable, in most cases their homes or working places, only a few interviews were held in public places. The course of action was always similar - after a small talk the next steps were illustrated and the participants had to fill out the short questionnaire. Afterwards a tape recording was started and

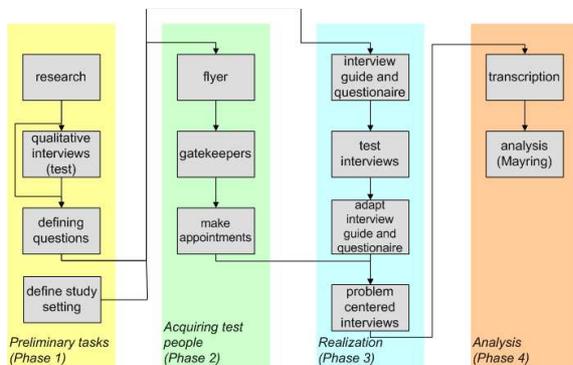


Figure 1. Methodology used in the study setting

TABLE I. CRITERIA FOR THE TWO STUDY GROUPS

criteria	characteristics	
	rural	urban
living & working	Person is now living & working in an rural area	Person is now living & working in an urban area
childhood	Person has grown up in an rural area (especially between the age 6 and 18)	Person has grown up in an urban area (especially between the age 6 and 18)
sense of belonging	Person feels related to a rural area	Person feels related to a urban area
place of residence	Person spent a big part of its live in a rural area	Person spent a big part of its live in a urban area

TABLE II. DEFINITION FOR RURAL AND URBAN AREAS

definition	characteristics	
	rural	urban
Population density	max. 200 residents/km ²	min. 1.000 residents/km ²
Agglomeration	no agglomeration	with agglomeration
residents	max. 2.000 residents	min. 20.000 residents

the interview began. Subsequently all questions were answered and the interview ended by stopping the tape recording.

D. Analysis:

After finishing all interviews the corresponding tape records were transcribed for further analysis. Then the interviews were analyzed in terms of different aspects through a qualitative content analysis by Mayring [3].

IV. RESULTS

The study population consisted of 20 participants – 10 from urban and 10 from rural areas. In each group (urban and rural) one female and one male person from each of the following age classes were asked: 18-30 years, 31-43 years, 44-56 years, 57-69 years and 70-82 years.

A. Planned EHR-functions

Three of the planned EHR functions in Austria were evaluated with regard to the frequency of utilization and a possible discrepancy between people from urban and rural areas.

1) personal data input

The results show that 60% (6) of the sample from urban areas in relation to 30% (3) of the sample from rural areas would like to use this function and preferring it over a paper-based documentation of their personal health data. Figure 2 shows the results for the planned EHR-function “personal data input”.

The answers to this topic were divided into three categories:

- “utilization” – the participant would use the function,
- “utilization after demand” – the participant would use the function only when the doctor requests it,
- “no utilization” – the participant would not use the function and prefer a paper-based documentation of the personal health data.

In terms of age the results in Figure 3 show that 50% (3) of the interviewed people from urban areas older than 43 years would use the planned EHR-function “personal data input” after a request from their doctors. In comparison with the interviewed people from rural areas older than 43 years who would not use the planned function at all and prefer a paper-based documentation of their personal health data in case of need over an EHR.

The data was analyzed and is displayed in Figure 4 and demonstrate that 80% (4) of the interviewed women from urban areas would use the planned EHR-function “personal data input” after the request from a doctor. In contrast only 40% (2) of the interviewed women from rural areas would do likewise.

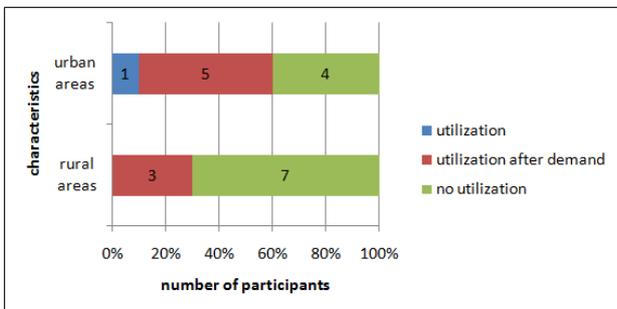


Figure 2. Planned EHR-function “personal data input”

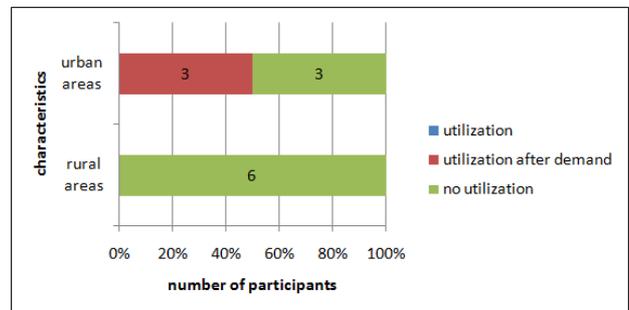


Figure 3. Planned EHR-function “personal data input” with focus on people older than 43 years

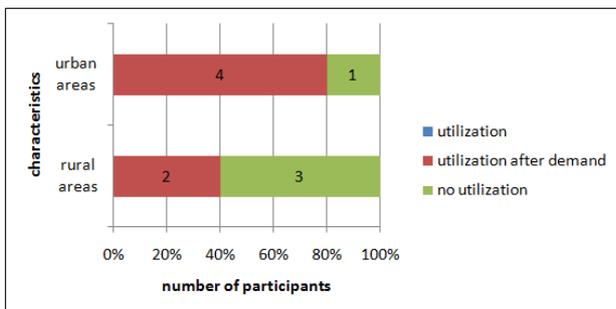


Figure 4. Planned EHR-function “personal data input” with focus on women

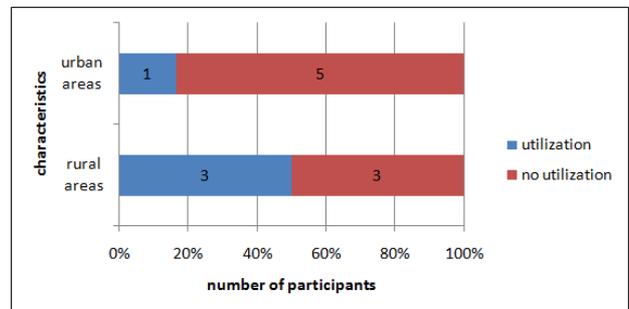


Figure 5. Planned EHR-function “health information” with focus on people older than 43 years

2) health information

The general results for the second planned EHR-function “health information” shows no discrepancy between the participants from urban and rural areas. But with the focus on age (refer to Figure 5) 50% (3) of the participants from rural areas older than 43 years in comparison to 16,67% (1) of the participants from urban areas older than 43 years would use the offered function “health information” of the EHR in Austria.

Independent of the discrepancy, participants who said that they would probably not use the planned EHR-function “health information” explained their decision with the following arguments:

- Enough other information sources exist.
- Loss of anonymity.
- General practitioner is the only information source.

The other information sources were defined upon request as internet, media and institutions like health ministry, health insurance, etc.

3) result retrieval

The evaluation of the third planned EHR-function “result retrieval” shows no differences between the sample from urban and rural areas.

B. Utilization of an EHR and its related functions

During the evaluation of the results and the question if the participants trust themselves about using an EHR and its related planned functions with their own computer and internet skills, it turned out that the assessment was independent of the particular EHR-functions.

As shown in Figure 6, 90% (9) of the participants from urban areas estimate their own computer and internet skills good enough to handle an EHR and its functions on their own. As opposed to this only 50% (5) of the participants from rural areas would estimate their computer and internet skills good enough. The rest feels incapable about using an EHR on their own and would submit this task to somebody else (e.g., general practitioner, or relatives).

C. Fears and anxieties

In terms of fears and anxieties the results show some differences between people from urban and rural areas.

Table 3 shows how the answers from the participants regarding the topic of fears and anxieties about a possible data abuse when using an EHR were divided into three categories.

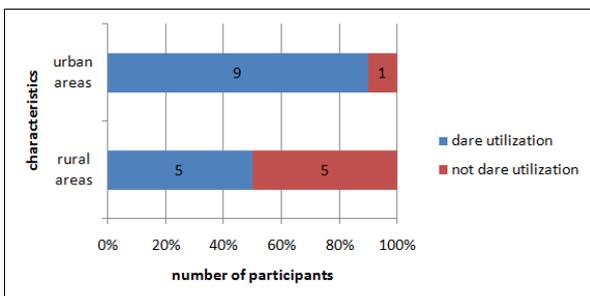


Figure 6. Dare of utilization of an EHR and its related functions

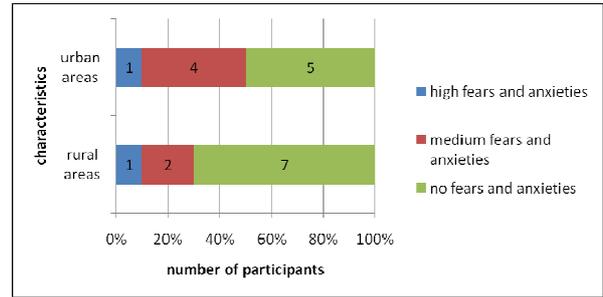


Figure 7. Fears and anxieties about using an EHR

TABLE III. CATEGORIES OF ANSWERS REGARDING FEARS AND WORRIES

category	characteristic			
	Data risk in comparison to the condition without an EHR		Concerns that the employer can get one's hands on the data stored in an EHR	
	increased	steady	yes	no
High fears and anxieties	X		X	
Medium fears and anxieties		X	X	
No fears and anxieties		X		X

Figure 7 shows the results of analyzing the data and demonstrates a discrepancy: 70% (7) of the sample from rural areas indicate that they have no fears and anxieties about a misuse of data through the utilization of an EHR. They don't believe that the risk of data fraud is increased by using an EHR in contrast to the condition without an EHR.

They also have no concerns that the employers can get one's hands on the data stored in an EHR. In the contrary only 50% (5) of the sample from urban areas think about this topic in the same way.

D. Confidence in the general practitioner

The answers from the interviewed people regarding the issue of confidence in their general practitioner were divided into four categories dependent on the approval to the

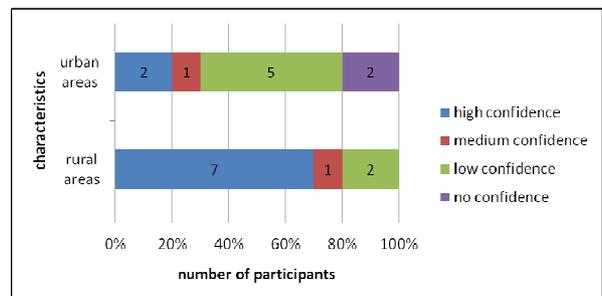


Figure 8. Confidence in the general practitioner

following statements:

- Satisfaction with the general practitioner.
- General practitioner as first contact point for all health problems.
- Provision of information by the general practitioner.

Depending on the amount of approvals to the statements, the four categories were characterized as follows:

- “high confidence”: approval to all three statements
- “medium confidence”: approval to two of the three statements
- “low confidence”: approval to one of the three statements
- “no confidence”: no approval to any of the three statements

As shown in Figure 8, 80% (8) of the participants from rural areas have confidence in their general practitioner, which can be classified from medium to high. In comparison to this only 30% (3) of the participants from urban areas who classify their confidence in their general practitioner equally. Furthermore 20% (2) from the participants from urban areas in relation to 0% (0) from rural areas have no confidence in their general practitioner at all.

E. Information needs

The participants were asked if they estimate that they have enough information about the upcoming introduction of an EHR in Austria and about the EHR itself or if their information needs about the current situation are satisfied yet.

Figure 9 shows the results and demonstrates that 100% (10) of the sample from urban areas still need more information about an EHR in Austria beyond the information they received by now through media (e.g., newspaper, TV, radio) and/or physicians. In the contrary only 70% (7) of the sample from rural areas who also still have information needs. The rest is satisfied with the information they have about an EHR and don't need more details.

F. Attending a course in using an EHR

The interviewed people were asked if they would embrace the opportunity if a course of learning how to handle an EHR provided for instance by the health ministry. The general results show no differences between the interviewed people from urban areas and those from rural areas. But in terms of age (shown in Figure 10) 50% (3) of the

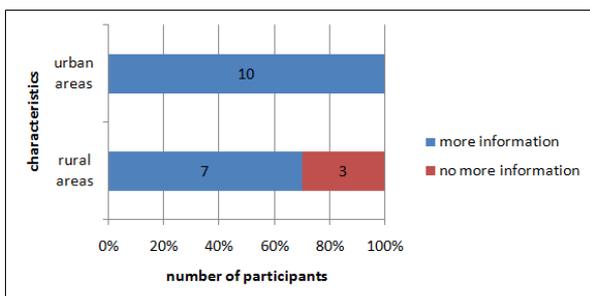


Figure 9. Information needs about the introduction of an EHR in Austria

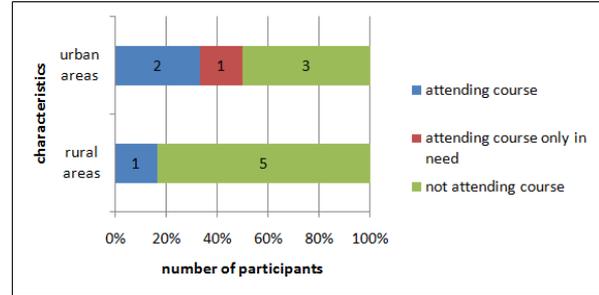


Figure 10. Willingness of attending a course about using an EHR

participants from urban areas older than 43 years would attend such a course. As opposed to this only 16,67% (1) of the participants from rural areas older than 43 years would also attend a course of learning how to handle an EHR.

Those participants who said that they would attend a course were also asked if they would pay for it: 66,6% (2) of the sample from urban areas and 100% (1) of the sample from rural areas would pay a small amount. The rest thought that such a course has to be offered for free.

Independent of the discrepancy, participants who said that they would not attend a course assume that an EHR can be handled with average computer and internet skills. As a result they would use tools like online help, hotline and/or user manuals.

G. Bias

During the implementation the following points may have influenced the results:

The sample size (20 people) is small and the results should be only considered as a trend. During some interviews other people like husband/wife or children were present: Some of them were only listening to the interview. But some of them were interrupting the interview many times and/or wanted to answer for the participants. Therefore the answers of the participants could be influenced in a way and/or the participants receded from their opinion.

V. DISCUSSION

The trial pointed out differences in the acceptance and the utilization of an EHR between people from urban and rural areas, although there is no direct connection regarding EHR in terms of membership to one of these areas. One deciding factor of this discrepancy can be the “regional digital gap”, which could influence people from rural areas for a lack of motivation in using an EHR compared to people from urban areas, because fewer opportunities for access, low frequency of use and poor skills in handling computer and internet may exist. Also the utilization of the planned EHR-function “personal data input” might be associated with these reasons: The computer and internet is more part of the daily living by people from urban areas than from those from rural areas. Therefore people from urban areas are possibly more willing to use this EHR-function than people from rural areas who use computer and internet less.

Furthermore there might be a relation between the regional digital gap and the attending of a course about using

an EHR: People from urban areas older than 43 years are more willing to attend such a course because they own more often a computer with internet access in comparison with people from rural areas older than 43 years. People from rural areas older than 43 years may have less experience with using a computer and/or with utilizing the internet and think that they are too old for these things and that such a course would be useless for them.

People from rural areas have less fears and worries about a possible data abuse when using an EHR. One reason for that could be that more people from rural areas work in family businesses and therefore may not have issues, that their employer – who is at the same time a family member – is informed about their personal health data.

For quite a lot of people from rural areas the only contact point for questions about health topics might be their general practitioner: Commonly general practitioners have a more important role for patients in rural areas than in urban areas. As a consequence people from urban areas may have apparently more sources where they get the needed information about health topics and do not have to use the planned EHR-function “health information”.

More information about an EHR and its introduction in Austria is needed probably by people from urban areas because they are very critical and want to know all about it before they decide to use it or not. As opposed to this people from rural areas seemingly trust their general practitioner and would probably follow their attitude according to their statements.

VI. CONCLUSION

Based on the results different actions could be taken to support the introduction of an EHR and to improve its acceptance for people from urban areas and rural areas:

- It is important that people from urban areas are informed about the introduction of an EHR through media or corresponding institutions (e.g., health ministry) to dispel concerns about data abuse. Whereas people from rural areas should be informed via the general practitioner: Therefore it could be useful to inform the general practitioners who are working in rural areas in detail about an EHR so that they can pass the information to their patients.
- The planned EHR-function “health information” should be promoted more to people from urban areas. People from urban areas will use this function hereafter as an equal or better substitute for their previous sources.
- Establishing an online help, hotline and user manual is a crucial measure to support the potential user with problems.
- People from rural areas might get trust in themselves about using an EHR on their own if they will be shown how an EHR can be handled.

Follow up studies are necessary because of the small sample size. However this trend can act as a starting position for a quantitative trial with a large sample size. The objective of such a trial should be to gain more comprehensive results.

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Telediagnosics of Back Curvature and Posture for Elderly Patients and Remote Access to 3D Data

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Abstract — Telemedicine services for the ageing population are expanding recently. Postural screening assessment is usually focused on children and adolescents. Elderly population is endangering on kyphotic deformations due to osteoporotic fractures. Yearly three dimensional (3D) examinations may be applicable to monitor postural deterioration among elderly. Remote assessment of back shape seems to be an option to measure kyphosis angle and postural worsening. The aim of this study is to present the archiving and assessment system and its applicability. The proposed system has two main components: measurement module with data analysis and storage one. The measurement module is based on structured light method. The technique for 3D imaging of back shape is based on temporal phase shifting and Gray codes. Acquired “images” are transferable to Telediagnostic Center. Preliminary analysis was performed on selected cases from database of patient’s cohort. The average age of analyzed patients group was 72 years. Bone mineral density in the analyzed group was below 80 mg/cm³. Kyphosis angle was measured in the range of 32 to 60 degrees, assessed by the clinical team. Shape of the elderly patient’s backs was acquired and sent over the Internet connection. Presented, originally developed system combines postural telediagnostic screening and monitoring. The development of automatic anatomical structures detection shall be able to prompt final diagnostic procedure and make draw of the trend of measured values changes over the time. The safety and procedure of presented examination method was highly accepted by elderly patients.

Keywords-telediagnosics; posture; kyphosis; osteoporotic vertebral compressive fracture.

INTRODUCTION

Telemedicine services for the ageing population are expanding recently. Postural screening assessment is usually focused on children and adolescents. Among teenagers round back is observed in up to one third of examined population. Elderly population is endangering on kyphotic deformations due to osteoporotic fractures. Yearly three-dimensional (3D) examinations may be applicable to monitor postural deterioration among elderly. Remote assessment of back shape seems to be an option to measure kyphosis angle and postural worsening. The proposed system has two main

components: measurement module and data analysis and storage one (Fig. 1). The measurement module is based on structured light method. The technique for 3D imaging of back shape is based on temporal phase shifting and Gray codes. Measurement process consists of projection of sequence of raster images on surface under investigation and their simultaneous acquisition. The hardware components are designed in a way that allows for easy transportation and mobility. Acquired “images” are transferable to Telediagnostic Center. The aim of this study is to present the archiving and assessment system and its applicability.

In the second part of the paper the technology used for capturing 3D shape of human body and flexible data archiving is described. The third part presents how the designed database structure was used in the particular case. Next, the calculation and diagnosis support is covered along with some early results and finally the applicability of the system to the diagnosis of hyperkyphosis and osteoporosis in elderly is presented.

MEASUREMENT SYSTEM

The measurement system consists of four modules which simultaneously measure patient’s skin surface from four directions. Each directional module is an optical full-field 3D scanner based on structured light projection method. The main components of each module are: projection unit, which is a Digital Light Processing (DLP) projector, detection unit which is a Charge Coupled Device (CCD) or a Complementary Metal-Oxide-Semiconductor (CMOS) camera and a PC-class computer. During the measurement

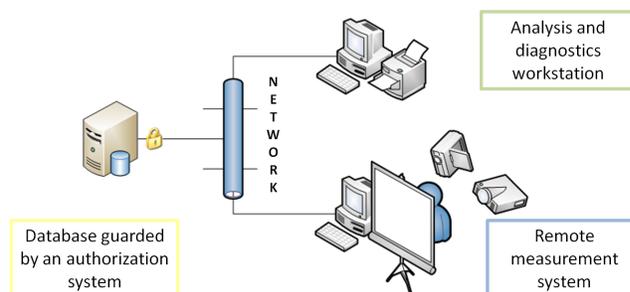


Figure 1. Modular structure of the system

process the patient is placed inside a calibrated measurement volume while a series of patterns is projected onto his or her body surface. These patterns include sinusoidal fringes and modified binary Gray codes. The shape of body surface is calculated based on the raster deformation according to the Temporal Phase Shifting (TPS) method [1]. Dataset produced by the measurement system is in the form of a set of (x, y, z) points that represent the sampled surface of patient's body. The electro-optical hardware setup utilizes TDP-MT700 projectors by Toshiba Corp. and Flea B&W cameras by Point Grey Research Inc. In order to avoid interferences caused by the overlapping of raster images originating from adjacent projectors spectral filters are mounted on projector and detector lenses. This allows projecting raster images simultaneously and conducting measurements using all modules at the same time. Directional point clouds originating from measurement modules are merged automatically based on a global calibration. The metrological values of the measurement system are as follows:

Measurement volume size: scalable from 1.0m x 1.0m x 1.0m to 1.5m x 1.5m x 2.0m,

Accuracy: 0.2mm to 0.4mm (depending on the measurement volume size),

Data acquisition time: 0.7s (all modules simultaneously), maximum number of points: 4 million.

Depending on the size and position of the calibrated measurement volume the resulting point cloud may represent patient's thoraco-abdominal region or the whole body surface.

Measurement data acquired with use of the measurement system along with patient's textual data are stored in a dedicated database. The database is the heart of the system and serves two main purposes – archiving of data and guarding it from unauthorized access. All operations on the database are performed using a specially designed XML interface, which makes the system independent of the

underlying database implementation (Fig. 2). The interface fulfills different functions, including user authentication, data import and user queries. The structure within the database can be in full defined using XML without any necessary knowledge about the system itself and can be extended on the fly in case any additional information or data are required. This database can be seen as a document-oriented one, which is built upon a relational system. The interface thus has to be able to translate the tree structure of the data (described in XML documents) into tables within the actual database taken into account, possibly numerous, changes of the structure definition.

Total dissimilarity of the structures makes it difficult to store the data efficiently – the actual data are kept in the leafs of the XML tree, but still the path to each leaf from the root of the tree is what differs it from other leafs. The solution might be to introduce a separate definition of the structure in the database which is stored only once, keeps the whole tree and can be extended easily, and a separate set of records which store the actual data, at the same time keeping reference to the leaf of the tree which it is representing. The structure should also have the knowledge about types of each leaf in order to be able to perform type checking. One does not have to limit oneself to the types defined within the RDBMS, but can define arbitrary types for the structure intended for the specific application which could be either decomposed into built-in types or validated by some predefined rule. If the structure is broken into separate elements, each of which being a semantic entity, a way to connect elements between each other should be provided. This supplies a robust method of defining complex relationships between elements and creating a hierarchy.

Moreover, the queries system mustn't limit the broad possibilities given by SQL used in the relational database. Such a system has to connect the ease of definition which parts of the structure are the constraints and what type of relation should be applied, and which parts of the structure are requested by the user – this strongly implies that the queries should also be built using XML. Additionally, the system should provide cascade queries in order to facilitate the construction of sophisticated queries and an extra set of constraints concerning the linkage between elements. All these features provide a robust and easily-extendable system of data management. However, if such a system was to be available over the network, some sort of access control should also be given. If the system was used on a larger scale, with a number of users accessing it, a distinction should be made between users that are able to modify the structure within the database, users that are able to import new or edit existing data and ones that have read-only access. Additionally, some elements may be said to be more significant (so shouldn't be modified by the same set of users that are able to modify other data) or confidential (so should be viewed only by certain users). This leads to the

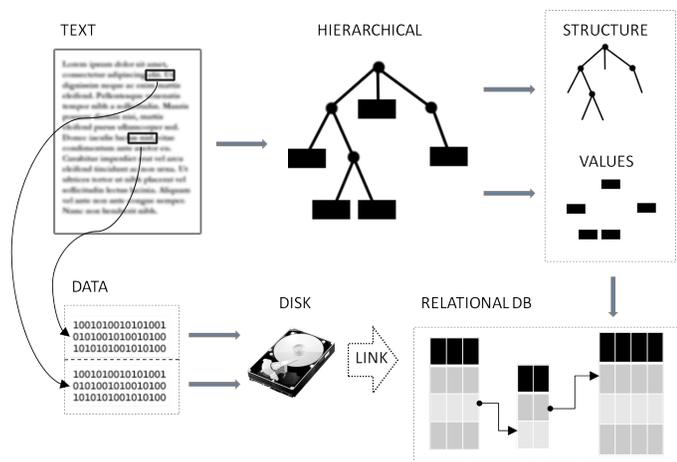


Figure 2. Mechanism of data storage – XML documents translated into records in a relational database

conclusion that the authorization system should be defined as access relationship between each element and each user in the database and separated between data and structure access. These features altogether form a complete system which can be securely used over any network, be it a local area network (LAN) or the Internet.

DESIGNED STRUCTURE

Data can be assigned to three main groups – objects, which are the core entities keeping data universal during system's lifetime, data elements, which are supposed to be assigned to each object, keeping information variable in time, and additional elements which are all kinds of data derived from the original data elements. The elements can further be linked with each other in an arbitrary way, thus creating a hierarchical structure. The structure (division into groups and linkage of elements) used in this case is shown in Fig. 3.

Communication between modules is performed over the TCP/IP protocol, incorporating two different channels for each client, dedicated to two kinds of data – text channel, for transmission of the XML documents and binary channel for the transfer of large binary objects, such as clouds of points or photographs. Such a structure is asynchronous and allows performing traffic inexpensive operations such as user logon or querying for text data independently of binary transmission, very costly in terms of network transfer. To further decrease this cost data compression was implemented and was also incorporated in data storage.

The data gathering and analysis module provides a complete interface for the database, allowing the user to manage the information and perform certain operations on the archived measurements. It supports automatic analysis – so called pattern calculation – a series of operations that can be automatically performed on a subset of data according to a predefined scheme. The module is constructed in a way which assures that no data becomes overwritten – any number of derived information can be saved in the database and linked to the parent measurement, thus keeping it consistent and easy to browse. It also makes it possible to compare different measurements, allowing the estimation of patient's improvement in time. This requires good repeatability of measurement and a method to correlate two measurements of the same patient in space. System's vertical,

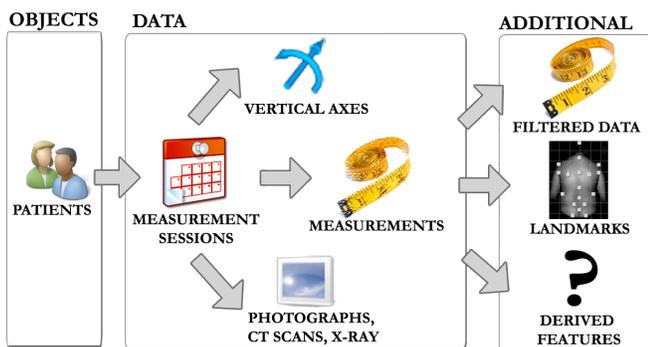


Figure 3. Structure designed within the database

additionally measured for every configuration of the setup and assigned to measurement, and two points within the measurement are sufficient for absolute alignment. Since fine alignment uses two landmarks (dimples of pelvis) for accurate positioning, it is preceded by a coarse operation which detects the general position of the body.

CALCULATION AND DIAGNOSIS SUPPORT

Analysis can be carried out in two ways – discrete, based on a set of landmarks on the surface of the body or on a more global shape analysis. The discrete analysis itself can be performed either using manual indication of points or an algorithm of automatic landmark detection. Such algorithms are currently under development, at the moment the landmarks are acquired from a team of trained physicians, which will help in the development process and provide the assessment of algorithms' reliability. Additionally, the points provide interesting information about the interobserver and intraobserver reliability for evaluated measurements. A preliminary algorithm for automatic landmark extraction is built upon a modified back diagram for a number of predefined landmarks, of which starting positions are pre-calculated using an averaged set of manually selected points, scaled for each measurement with respect to a simple 2D bounding box generated around it. Such a processing path is easily extendable to an arbitrary number of characteristic points, thus providing a versatile detection method.

The method assigns an area to each landmark, within which the exact position of the landmark is searched for. The 3D shape contained in each cell is analyzed based on maps of parameters C1 and C2¹. These parameters were developed in order to accurately and efficiently describe surface shape of full 3D point clouds [2]. The C1 parameter describes how much the surface in the neighborhood of the considered point deviates from a plane, its values are positive for convex areas, negative for concave areas and zero for planes. The C2 parameter describes the distribution of normal vectors in the neighborhood of the considered point in a way allowing distinguishing areas of unidirectional curvature, such as cylindrical areas, and omnidirectional curvature, such as spherical areas and takes values equal to zero for planes and

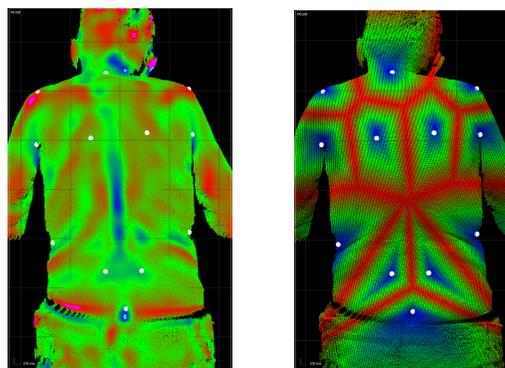


Figure 4. C1 parameter and weights from Voronoi diagram, landmarks shown in white

¹ Names C1 and C2 must not be confused with the designation of cervical vertebrae

cylindrical surfaces and positive for other surface types. The highest values of C2 are obtained for sphere and for saddle shapes. The analysis of distribution of C1 and C2 parameter values allows discrimination of various surface types in a way similar to used with mean and Gaussian curvatures, yet the former are faster to calculate and more resistant to noise in the analyzed dataset.

Division of the back into subregions makes it possible to avoid global analysis of the back surface. Moreover, the landmarks are in reality not single points, but rather regions on the surface of various scale and as such require computation of the C1 and C2 maps with different input parameters. Each landmark also exhibits specific properties depending on the type of posture which implies the use of different detection paths and an algorithm which would provide some general, coarse information about the posture of the patient, or possibly an adaptive path of detection which would modify its parameters based on some overall properties of the shape of the back. An additional potentially interesting feature is the possibility of comparison of the 3D shape with volumetric data, such as a CT scan. Exemplary map of C1 parameter and weights calculated on the basis of a Voronoi diagram are shown in Fig. 4.

EARLY RESULTS

Clinical evaluation of patients body was performed from August 2008 till march 2009. The average age of analyzed 30 patients group was 72 years. Bone mineral density in the analyzed group was below 80 mg/cm³. Kyphosis angle was measured in the range of 32 to 60 degrees, assessed by the clinical team. Average time for assessment was calculated from logs of user entering the system. Shape of the elderly patient's backs was acquired and sent over the Internet connection. The average 3D image size for each examined patients was 5 MB, which takes about 20 seconds to transfer using a broadband connection. Average time for assessment was estimated to be around 3-4 minutes based on information gathered by the analysis client module. Patients were asked about discomfort during the structural light examination. No patient reported side effect or discomfort during the 3D examination. All patients declared positive attitude towards next follow up 3D examination.

DISCUSSION ON KYPHOSIS

Spinal sagittal curvatures and their deformities are described in relation to the anatomical planes of the body which are the coronal (frontal) plane, the sagittal (lateral) plane and horizontal (transverse or axial) plane (Fig. 5).

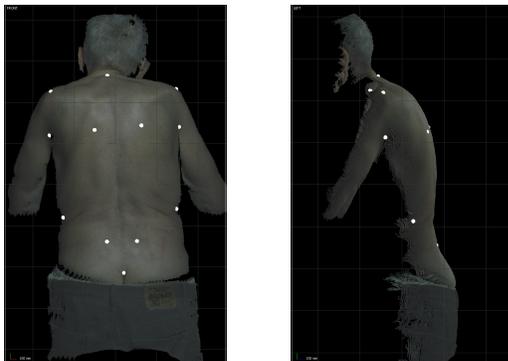


Figure 5. Cloud of points from measurement, frontal and sagittal plane,
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There are natural curvatures in the sagittal plane. Hyperkyphosis, colloquially called “dowager’s hump”, refers to excessive kyphotic, or anteriorly concave, curvature of the thoracic region of the spine. A kyphosis angle over 40° - the 95th percentile value for young adults - is currently used to define hyperkyphosis [3]. It is often observed in elderly due mostly to osteoporosis. Most of the studies refer to normal values of kyphosis among older adults at 20% to 40%. Hyperkyphosis is not only a cosmetic back deformation but it may impair pulmonary decreased physical function capabilities, increase risk of future fractures [4-6]. Kyphosis can be measured clinically or from radiographs. Several devices have been developed for kyphosis measurement like Debrunner kyphometer, goniometer, inclinometer, flexible ruler and various optical methods [4,7,8]. Thoracic kyphosis can be measured on lateral radiographs of the thoracic spine globally (T1–T12) and regionally (T4–T9) using Cobb and vertebral centroid angles. Surface topography evaluations utilizing structural light technique was used to evaluate kyphosis angle and lordosis angle. The kyphosis angle was measured from prominent vertebra to lower neutral zone of inclination (VRS method) as described by Weiss and Elobedi [9]. Patient’s back surface 3D image was obtained using a high-accuracy optical markerless 3D measurement system for non-invasive, quick and relatively inexpensive assessment of back deformity [10]. Optical methods like photogrammetry and structural light method are currently under development [9]. The second method allows snapping ideal surface shape of the back in digital format. Traditionally, the Cobb angle is measured from standing lateral spine films because measurement in the lying position may underestimate kyphosis. The slight overestimation of Debrunner method versus the Cobb angle was found but the mean difference between the 2 measures was only 4° [4]. Postural changes affecting the cervical, lumbar, and sacral spinal areas and postural flexibility may influence thoracic curvature. The simple method of thoracic kyphosis based on that observation was utilized in cohort Rancho Bernardo studies [11].

Osteoporosis and a history of fragility fractures are both associated with age of 75 years and over and thoracic kyphosis. Ettinger et al. [12] measured thoracic curvature, using an architect’s flexicurve. Their study suggested that kyphosis is associated with decreased BMD and loss of height but does not cause substantial chronic back pain, disability, or poor health in older women. Only tendencies were confirmed by this study. Ensrud et al. [13] estimated that kyphosis increased by 4.4 per decade of additional age. Milne and Lauder [14] reported a 20% increase in the kyphosis index per decade in women aged 62 to 90 years. In older adults, the mean kyphosis angle rises to about 50° in women and about 44° in men [13,15-17]. In a study by Singer et al. [18] of women aged 50 to 90 years, kyphosis ranged from 40.9 to 57.5° and the highest values were found in the oldest women. In many studies, kyphosis was measured clinically using the Debrunner kyphometer [8] or the flexicurve ruler [14]. In the study by Cortet et al. [18] patient’s mean kyphosis was measured 59°. Further studies

are needed to determine the correlation between spinal curvatures and spinal bone density measurements to allow physicians to better predict patient's risk of fractures and better plan for surgical or medical intervention.

CONCLUSIONS

Presented, originally developed system combines postural telediagnostic screening and monitoring. The development of automatic anatomical structures detection shall be able to prompt final diagnostic procedure and make draw of the trend of measured values changes over the time. The safety and procedure of presented examination method was highly accepted by elderly patients.

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