eTELEMED 2013

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eTELEMED 2013 Editors

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eTELEMED 2013

Forward

The fifth edition of The International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED 2013), held in Nice, France, February 24 - March 1, 2013, considered advances in techniques, services, and applications dedicated to a global approach of eHealth.

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

eTELEMED 2013 provided a forum where researchers were able to present recent research results and new research problems and directions related to them. The topics covered aspects from classical medicine and eHealth integration, systems and communication, devices, and applications.

We take this opportunity to thank all the members of the eTELEMED 2013 Technical Program Committee as well as the numerous reviewers. The creation of such a broad and high-quality conference program would not have been possible without their involvement. We also kindly thank all the authors who dedicated much of their time and efforts to contribute to the eTELEMED 2013. We truly believe that, thanks to all these efforts, the final conference program consists of top quality contributions.

This event could also not have been a reality without the support of many individuals, organizations, and sponsors. We are grateful to the members of the eTELEMED 2013 organizing committee for their help in handling the logistics and for their work to make this professional meeting a success.

We hope that eTELEMED 2013 was a successful international forum for the exchange of ideas and results between academia and industry and for the promotion of progress in eHealth and Telemedicine research.

We also hope that Côte d'Azur provided a pleasant environment during the conference and everyone saved some time for exploring the Mediterranean Coast.

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Filling a Gap in eHealth Records:
The Development of a Home Care Records System

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***Abstract*—The process of developing an eHealth records system over the last six years is described. The work took place at seven care organizations in the United States, the United Kingdom and the Netherlands and was part of a series of pilot studies assessing the effectiveness of a behavioral monitoring system in the delivery of care to at-risk elderly. A research tool created to systematically collect data on alerts, care actions and health outcomes evolved into a home care electronic records system. The system is fully functional on any smart mobile device and can be used with a wide variety of pervasive health care applications or as a stand-alone. Five essential design features that impact the future of such home care electronic records system are discussed.**

Keywords—eHealth medical records; home care; mobile devices; self-management

I. INTRODUCTION

Over the last decade, there has been a general acceptance of the need for and use of electronic health care records, first in the hospital setting and later within physician practices. Initially in the United States, because of the cost, in time and money and disruption in the normal care delivery model, there was little enthusiasm for the use of electronic records. However, a combination of "encouragement" from the insurance industry and the insistence by government, the use of electronic records inexorably came to be the norm within hospitals, other institutional settings and physician practices. Even though the use of electronic records is not 100%, there is little doubt that the greater reliability of electronic records, the ease of storage and access and cost savings, will eventually achieve close to universal usage within institutions and among physicians [1, 2].

The home, however, is a different matter all together. Although delivery of care and services in the home has increased significantly and, if projections are correct, will accelerate at an ever more rapid pace over the coming several decades, the development and use of electronic systems to record the care and services has lagged behind the institutional sector. The acceleration of the delivery of care and services in the home is being driven by two main factors: demography and cost. The demographic trends are well known: dramatic increase in the number of elderly, especially the oldest-old; a concomitant increase in chronic diseases associated with aging, e.g., congestive heart failure (CHF), diabetes, dementia; and a decline in the number of informal carers—family members—who can provide care to the expanding elderly populations. Cost projections are similarly daunting: increasing cost for care delivery within the institutional setting; insufficient number of institutions—hospitals, nursing homes, rehabilitation facilities—to provide the care required for the elderly population and insufficient funds to build the large number of additional institutions; and prohibitive costs to government to provide care and services through current care delivery models.

It is generally agreed upon that the only way to meet the increasing needs brought about by the demographic trends, while at the same time not bankrupting national treasuries, is to provide more care and services in the home [3]. This is not a new idea, nor particularly radical, but as more care and services are being delivered in the home, several issues have emerged that raises serious concerns. In the first place, the care being delivered had steadily become more extensive. Whereas ten years ago rehabilitation after a serious illness or accident would have been undertaken in a specialized facility, increasingly these services are being provided in the home on an outpatient basis. But rehabilitation is just one of an escalating number of care services being provided in the home: nutritional counseling; wound care; psychological therapy; and medication adherence, to name several of the major ones. Additionally, the range of products and non-care services supplied to individuals in their own homes has increased significantly over the last few years: oxygen; specialized beds; monitoring systems—behavioral, vital signs, environmental extremes; meals; housekeeping; shopping; companion services. As the care and services have multiplied, so have the number of people providing the services, as well as the number of companies and agencies overseeing the provision of this care and services. Some of these companies/agencies may provide several services and products, but in most cases there are multiple providers and certainly multiple people providing the different services and products. These companies/agencies are, of course, in addition to any services provided by informal carers—family members, neighbors, friends.

Thus, the need for a means of recording and tracking the care and services provided in the home are essentially the same as for institutions: increased reliability; better

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coordination; appropriate level of care; and cost savings. As more care and services are delivered by more people representing different companies and agencies, just keeping track of who is providing what becomes increasingly difficult, especially if the individual receiving the care lives alone in her home and is experiencing cognitive decline or other impairments. Scheduling of visits and deliveries, ensuring the correct product or service, avoiding duplication all become difficult if records are scattered among various agencies, companies and individuals and are rarely, if ever, shared. It is also extremely difficult to evaluate if the care and services are having the desired impact on the individual if there is no systematic way to track the care and services. In other words, if records are non-existent or scattered there is no way to measure outcomes resulting in the inability to determine if the care and services are appropriate. The lack of systematic and comprehensive records also makes it difficult for other care providers, e.g., physicians, specialists, to make informed care decisions, since the reliance on the patient to remember specifics about the care and services in the home has proven to be suspect at best. In addition, if electronic records of care and services in the home do not exist, it is obvious that they cannot be linked with the records that have been created in the hospital and the physician practice, resulting in an incomplete record of care. Finally, even though delivering care and services in the home is more economical than in institutions, it still costs money and someone has to pay for it. As a result, from the point of view of the client receiving the care and services, as well as the insurance company and the government, there is a discernable need to track the care and services to ensure that what is paid for is provided and that everyone was paid appropriately.

This paper reports on the inception, design, development, implementation, testing and evaluation of an electronic records system developed for care and services delivered in the home: the Home Care Informatics System (HCIS). The first iteration of the HCIS was developed in 2006 and in the last six years three separate iterations have been used within seven different care delivery organizations in three countries—the United States, the United Kingdom and the Netherlands. As of September 1, 2012, the HCIS, in one of its iterations, has been used for over 400 clients receiving care and services in their own homes. Although at present the HCIS has only been used in conjunction with a behavioral/lifestyle monitoring system, it is designed to be used independently of any monitoring system.

II. THREE STAGES OF DEVELOPMENT

The HCIS developed out of a comparative research project on the effectiveness of a particular behavioral monitoring system—QuietCare®— as a passive emergency response system within different care delivery models. The sequential research began in 2003 and eventually encompassed 14 care organizations in three countries [4, 5, 6]. As part of the research, it was essential to track the care actions taken in response to an alert generated by QuietCare® in order to evaluate if the particular alert brought about an appropriate response by the care provider. Until 2006, the research had relied primarily on anecdotes (case studies) to understand how QuietCare® was used to help provide information to care givers on the needs of their clients. Although hundreds of such case studies had been collected and analyzed over the first four years of the research, there was no systematic means for the collection of data on the alerts, care actions and the health outcomes that could be subjected to a more rigorous analysis. A thorough review of the literature indicated that no such research tool existed that could automatically accomplish the goal of collecting such data and thus, a new research instrument had to be developed.

A. Stage 1—2006-2007

Research at Selfhelp Community Services, Inc. was undertaken on the use of QuietCare® within a care management model in a Naturally Occurring Retirement Community (NORC) in Queens, New York. In this care model, eleven geriatric social workers provided care management services to over 200 residents within the three buildings of the NORC. Twenty-seven of these clients agreed to have QuietCare® installed for a six month period and to have the social workers use the resultant data in care management decisions [7]. The first iteration of the instrument was labeled the **TAO**: standing for **Trigger**, the QuietCare® alert; **Action**, the care action taken by the social worker in response to the alert; and **Outcome**, the health or care outcome brought about by the care action. A brief example illustrates the initial design of the TAO:

> QuietCare® sends to the geriatric social worker an alert indicating an increase in overnight toileting for a particular client—the **Trigger**;
>
> The social worker who receives the alert, phones the client to inquire about the client's behavior—the **Action**;
>
> Finding out that the client was frequently in the bathroom because of a stomach flu, the social worker contacts the client's physician to obtain a prescription for medication—the health **Outcome**.

For the first month of the study, even though the social worker received the alert on her computer, she filled out a paper form with the relevant information, which was then entered into a computer data base for analysis. At the initial meeting of the study team, it was agreed that the paper version of the TAO was time-consuming to fill out, redundant with other forms that had to be filled out by hand and could not be easily shared with co-workers and supervisors. Thus, a computerized web-based version of the TAO was created and put in operation in the sixth week of the study. (See Fig.1)

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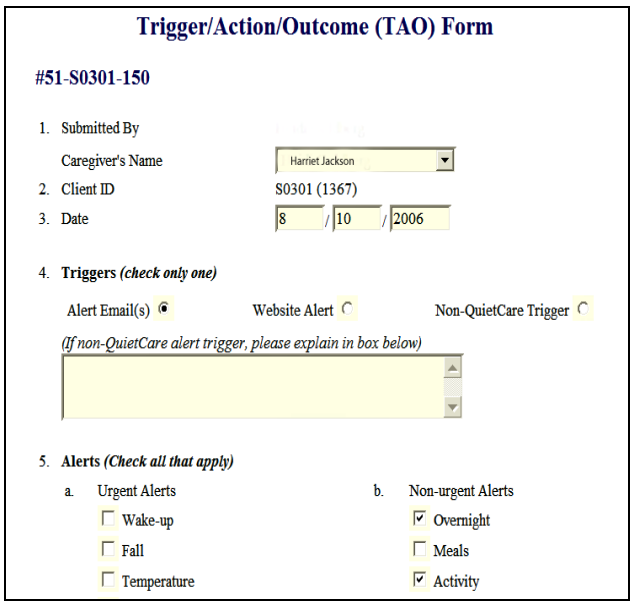

Figure 1. Web-TAO

The Web-TAO form took about five minutes to fill out, could be easily shared with others and, most importantly, could be updated as more actions and outcomes occurred. In the short run, this last feature proved beneficial for the social workers as they could quickly and almost effortlessly update the Web-TAO records for individual clients. In the long run, the need to have an update capability proved essential in the development of the HCIS. This is because, although the alert is a discrete event, care actions and health outcomes are not discrete, but instead roll out over time. The previous example of the TAO narrative has all three elements as discrete events—one Trigger, one Action, one Outcome—and this example corresponds to approximately 40% of the TAOs collected at Selfhelp Community Services. However, a majority of the TAOs corresponded more to the following example:

QuietCare® sends to the geriatric social worker an alert indicating an increase in overnight toileting for a particular client—the **Trigger**;

The social worker who receives the alert, phones the client to inquire about the client's behavior—the **Action**;

Finding out that the client was frequently in the bathroom because of a stomach flu, the social worker contacts the client's physician to obtain a prescription for medication—the health **Outcome**;

The social worker phones the client's daughter to report that her mother has the flu—**Second Action**;

Daughter visits her mother the next day finding out that her mother is no better—**Third Action, Second Outcome**;

Daughter phones social worker reporting on mother's condition—**Fourth Action**; social worker visits client, determines that she is dehydrated, phones physician—**Fifth Action**;

Physician decides to have client admitted to hospital—**Sixth Action, Third Outcome**;

Client is discharged after two days in hospital—**Seventh Action, Fourth Outcome.**

All of the above actions and outcomes were the result of the single alert and could now be entered into the Web-TAO as the events rolled out over time. As a record of care provided and outcomes generated, the Web-TAO proved extremely helpful to the geriatric social workers as they could more systematically track the progression of care and outcomes. However, the realization of how multiple care actions and outcomes could be gathered together in a single record proved invaluable for the future development of the informatics system that eventually became the HCIS.

The quantitative results, e.g., number and type of alerts over the six months, number and type of actions and health outcomes, of the study have been reported elsewhere [5, 7], and even though these quantitative results are interesting, they did not drive the development of the informatics system as much as monthly care review meetings with geriatric social workers, supervisors, administrators and researchers at which the entire study was discussed, in general, and the Web-TAO, in particular.

It was at the first of these meetings that the social workers strongly suggested that the TAO be put on the Web. At subsequent meetings suggestions were made to: add auto-populated fields to the Web-TAO; use check-boxes whenever possible; allow for easier follow-up entries; allow access to individual records by other social workers and supervisors. It was at the second meeting that two issues that would drive much of the development of the TAO came to light: 1) how could the information contained in the Web-TAOs be most effectively used in the delivery of care to clients; and 2) should the Web-TAOs be used by supervisors to evaluate the work performed by the social workers? Since the objective for these meetings was to review what had happened to each of the clients over the previous month in order to assess how QuietCare® had impacted the delivery of care, it was not surprising that the TAOs were the focus of the discussions—the TAOs did contain a comprehensive record of each alert, care action and outcome for each of the clients— but it was surprising how the social workers utilized the TAOs during the reviews. They placed the TAOs for each of the clients together and then worked their way chronologically through the TAOs. (All of the TAOs had been printed and each social worker brought the TAOs for their clients to the meeting.) By their actions, the social workers were constructing an on-going record for each of the clients by putting TAOs for the particular client together into a single "pile". This is what gave me the idea that the information contained in the TAO could be put together into an electronic record. This transition from a research instrument

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to an electronic record did not take place during the Selfhelp Community Services pilot, but the idea was planted and germinated quickly in the second stage of the development.

Another issue of concern on the part of the social workers over the use of the Web-TAO is the evaluation of their jobs. However, it was apparent after that second meeting that the information within the records could be used to evaluate work performance: how quickly did the social worker respond to the alert; how effective were the actions she took; did she follow up to determine the outcome of the action; did she recommend services provided by Selfhelp Community Services to the client—increasing revenue for the organization. For the supervisors, the Web-TAO provided an objective basis on which to evaluate the work performed by the social workers; for the social workers, the Web-TAO allowed supervisors to question their actions and professional conduct using information that had not been available previously. These issues were not resolved before the study ended, but as discussed subsequently, it remained a vexing problem for the future development of the TAO/HCIS. However, perhaps the most important thing that we learned from both sources was that just because "rules" for the use of the TAO are created at one care organization does not mean that the rules will transfer to another organization. Every organization's culture is different, meaning that the process of rule creation, as well as the rules themselves, will be different.

B. Stage 2—2007-2008

As the Selfhelp Community Services study was concluding, a new study commenced in London. Once again, the study consisted of the installation of QuietCare® in the residences of elderly individuals who were at risk for a variety of health and functional reasons and who were provided services by a care organization. However, unlike the Selfhelp Community Services study in which all clients lived independently and had their care managed by a single care organization, the London study involved several residential types and more than one care organization. All residents lived in Southwark, an area of Central London south of the Thames, and were provided services from one of three care organizations—Southwark Falls, Oasis and Hyde Housing. Although the organizations were "independent", they all operated under the broad umbrella of the Southwark Local Authority. Thus, the work undertaken by "carers" in these organizations was much more coordinated than would be found in three independent organizations in the United States. Each organization did provide services to a well-defined population: Southwark Falls, individuals living independently requiring a moderate level of care and services; Oasis, individuals living independently requiring a more intensive level of care and services; and Hyde Housing, individuals living in congregate housing requiring a very high level of care and services provided by residential staff. However, even though these organizations were "independent" and served distinct populations, for the discussion of the development of the TAO/HCIS it makes sense to view them as a single entity and to aggregate their clients. Therefore, the following discussion will refer to the Southwark Study and 97 clients rather than the individual care organizations and their clients: Southwark Falls—45; Oasis—16; Hyde Housing—36.

Based on the development work undertaken at Selfhelp Community Services, the Southwark Study began with a fully operational Web-TAO that had the ability to easily update a report as care actions and outcomes rolled out over time. Some changes had to be made in the Web-TAO's check-boxes and auto-populated fields to conform to the particular care management models used in Southwark and to make the Web-TAO more "British", e.g., English English rather than American English. Also based on development decisions made at Selfhelp Community Services, the Web-TAO implemented at Southwark had slightly enhanced information sharing ability which allowed easier access to individual client's records by authorized personnel.

The quantitative results from the Southwark Study, e.g., number and type of alerts over the eight months, number and type of actions and health outcomes, have been published elsewhere [4, 8, 9]. Also similarly, even though the quantitative results from Southwark are interesting, they did not drive the development of the electronic records system, but instead, it was findings from other sources, primarily a series of three meetings in London with carers from the three organizations and discussions by email and phone with carers about their usage of the Web-TAO.

Within the first six weeks of the study, it became apparent from the analysis of the material being entered into the Web-TAO that the carers were using the system much differently than the social workers at Selfhelp Community Services. This was due, in the first place, to the fact that the carers at Southwark had a working Web-TAO from "day one" and there were no delays in implementation. Second, the nature of the culture of care at Southwark was different from at Selfhelp Community Services. At Southwark, the culture was extremely collaborative and although particular carers had primary responsibility for specific clients, all carers engaged with all clients in some fashion. The Web-TAO was immediately conceived by these carers as a tool to allow for easier sharing of information among all carers rather than just a record of responses—actions and outcomes— to triggering alerts. Therefore, the ability for all members of the care team to not only see the information, but to contribute to the information stream became paramount. Additionally, by the end of the study, the carers were, on a regular basis, sharing information from the Web-TAO with family members of several of the clients.

The cultural imperative to share and contribute to the information of clients was very quickly reflected in the Web-TAOs. Instead of discrete, although often lengthy

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records of actions and outcomes, the Southwark Web-TAOs took on the appearance of "blogs" in which numerous carers listed their actions and the subsequent outcomes for particular clients. On the surface, this change appeared to be trivial, but in actuality it altered my entire thinking about the structure of the Web-TAO. The Web-TAO had already mutated from a research tool to a care provision tool that tracked responses to QuietCare® alerts, and now it had transformed again from a limited record of what transpired when an alert occurred, to a more comprehensive electronic record of all care being delivered to a specific client over time. Fig. 2 is an example of a typical "blog" for a single client. This example page not only shows the comprehensive nature of the information recorded, but also illustrates how many carers became involved in contributing care for this client, including specialists from outside the original set of carers.

Trigger	-Wake up
Actions	-Phoned client -Visited client -Spoke to care professional Care Coordinator, GP -Contacted other person Spoke to OASIS Support Worker -Other action taken: Support worker spoke to client face to face, spoke to the surgery concerning the medical health of the client, GP to call back.
Outcomes	10/25 10:04) Client has been complaining of hip pain for the last two days but on prompting to attend GP surgery or to have home visit, she declined. When support worker visited, she found out that the client appeared unwell and movement was very slow.. Client had not eaten since last night so Support Worker prompted nutrition and medication and asked the client's permission to call GP to look at her hip. Client has agreed and a call has been made to book for a GP to examine the client. GP is aware of the needs, we have left a telephone message on the Next of kin's mobile number and Care Coordinator has been informed. GP visited and assessed Mrs B yesterday. She prescribed paracetamol for pain relief as it was found out that the arthritis in her hip was causing her so much pain. Client is still not able to get out of bed earlier but we hope that the pain will subside. Plan: Monitor the effect and report to GP as the condition changes. Care Coordinator to note. (10/26 10:47) GP stated that Mrs B appeared confused when examined and advised her to increase her fluid intake and contact the Specialist Mental Health Care Coordinator to assess the situation. (10/30 11:42) Following GP's prescription for pain relief, QuietCare showed that Mrs B visited the bathroom at 4.53 am and got out of the bedroom at 9.59 am which was unusual from recent data. She has been on pain relief since Friday 26th October and there appears to be a marked improvement in her health.

Figure 2. Web-TAO blog narrative

It also became apparent that the "Smart Team"—the newly formed group of carers at Southwark who were now charged with making full use of the Web-TAO as a care tool—had other ideas for the use of the Web-TAO. One was to be able to send the "blog" to a client's physician prior to an appointment in order for the physician to have all relevant care information. This required no modification in the Web-TAO and was implemented before the mid-point of the study. Another idea was to allow the "blogs" to be sorted by alert, particular carer, type of care actions and date of entry. Although technically not a complex undertaking, the challenge was to understand the use to be made of such a sorting feature, before creating it. Unfortunately, the sorting feature was developed too late for it to be fully implemented in Southwark, but it became a key feature of the next iteration in the Netherlands. Unlike at Selfhelp, the fear that the information stored in the Web-TAO could be used to evaluate the work performed by the carers was not raised at Southwark, but this issue resurfaced in the Netherlands.

C. Stage 3—2008-2012

Work in the Netherlands began in late 2007 as part of a demonstration project to evaluate the role of behavioral monitoring in the delivery of care both in the home of at-risk elderly and within an institutional setting in the Limburg Province. The initial demonstration project ran for six months during which time QuietCare® was installed in the residences of 12 individuals living independently and 13 individuals living within a sheltered housing facility. The success of the demonstration project led to a much larger study that began in 2008 and is scheduled to end at the end of 2012. As of September 1, 2012, QuietCare® units had been installed in the residences of 192 individuals living independently throughout the largely rural Limburg region. The lead care organization for both the demonstration project and the larger study is Proteion Homecare North Limburg, a full service care organization that provides both services and care in the home and within institutional settings. A second care organization, Zorgroep, which provides similar services and care as Proteion, is involved in the larger study, but its role is secondary to Proteion both in the number of clients served—128 clients for Proteion and only 64 for Zorgroep—and administrative responsibilities. Thus, similarly to how the three London organizations were combined, it makes sense to view these organizations, as well as the demonstration project and larger study, as a single entity and to aggregate the clients. Therefore, the following discussion of the development of the TAO/HCIS will refer to the Dutch Study with a total of 192 clients, rather than making reference to individual care organizations or differentiating between the demonstration project and the larger study.

Since the demonstration project in the Netherlands began as the London Study was winding down, it was possible to provide the Dutch with an enhanced Web-TAO which had the ability to produce "blogs", which we renamed the "Client's Journal", as well as a means of sorting the information by type of alert, date, client, care worker and type of care action. Of course, the content of the Web-TAO, e.g., check-boxes, auto-populated fields, instructions, had to be translated into Dutch. The care delivery model at Proteion and Zorgroep required their care workers to spend a considerable amount of each day traveling to and from the residences of clients throughout Limburg Province and they spent little time at the two organizations' administrative headquarters. In addition, few of the care workers had access to laptop computers and therefore their ability to both

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access the Web-TAO and to enter information became a real concern. This problem was solved by developing the capability for the Web-TAO, renamed the Home Care Informatics System (HCIS), to be accessed on any smart mobile device. Since each of the care workers had a smart phone, this solved the problem of access and entry of information. However, it also raised other challenges. First, everything had to be reformatted so that it could fit the small screen of the mobile devices. This led to an even greater reliance on check boxes and auto-populated features and to the development of more efficient scrolling features. Second, there was the challenge of making the HCIS display properly on the various smart devices used by the care workers. By the end of the demonstration project in the late summer of 2008, a fully functional HCIS was being used by the care workers. (See Fig. 3)

Figure 3. HCIS on smart mobile device

Similarly to both the Selfhelp Community Services and London studies, the quantitative results from the Dutch Study have been published elsewhere [4, 6, 10]. Also similar to the two previous studies, although the quantitative results from the Dutch Study are important for developing the HCIS, they did not prove as valuable as findings from other sources: direct interaction with care workers and administrators at Proteion and with the Dutch research team. This interaction allowed for the direct observation of the HCIS "in-the-field" which aided in modifying the system to operate efficiently on smart devices. By February 2009, a fully functional HCIS was operational for use by care workers at Proteion and Zorgroep. This iteration included all the features that had been developed during the Selfhelp Community Services and London Studies and the Dutch Demonstration Project: 1) wherever possible the HCIS used check-boxes and auto-populated fields; 2) the Client's Journal feature was fully operational and allowed entries by any authorized personnel; 3) the Journal could be sorted by alert, date, care worker, type of care delivered and outcome; 4) there was a new feature that allowed additions to a previous entry, but not the elimination of the original entry; 5) it was fully operational on a wide variety of mobile devices; 6) a series of pop-up prompts helped the user navigate through functions and avoid common errors; 7) additional security features had been developed to ensure that only authorized individuals could access and contribute to a client's record; and 8) a read-only feature had been made operational.

During the next few months several issues were raised by the care workers and administrators at Proteion and Zorgroep; some of which were not easily resolved. The first issue revolved around how care was provided on weekends and holidays. At both organizations, a team of care workers provides a range of services to a particular client, e.g., nursing care, rehabilitation services, shopping, house cleaning. One member of the team, usually, but not always a nurse, is designated the primary care worker. Although all team members have the ability to access and contribute to the HCIS, it is the primary care worker who is chiefly responsible for maintaining the HCIS record. The problem arises when the primary care worker, or for that matter any member of the team, is not on duty, i.e., weekends and holidays, and services are provided in the client's residence by a care worker who is not on the team. Since only a small percentage of care workers at the two organizations are participating in the Study, these substitute care workers are often unfamiliar with the HCIS and lack access. Thus, care is being delivered, but the HCIS record is not being updated. Although this issue does not directly concern the technical development of the HCIS, it certainly impacts the implementation of the HCIS.

A second issue that impacts directly on the implementation of the HCIS concerns the use of the HCIS record during care review meetings. These meetings included both individuals who have knowledge of and access to the HCIS and others who have neither. Since the client reviews are more thorough when everyone at the meeting has access to the information stored in the HCIS record, the question arose as to who should have access, how should they obtain access and who was in charge of making access happen? Once again, not a technical but, instead, a work rule issue. Ultimately, issues like these will only be solved when the care organization fully adopts the HCIS and all care workers, supervisors and administrators use the system. Until this occurs, ad hoc actions that attempt to solve the problems in the short run with the least disruption to normal work flow are the only recourse [4].

Perhaps the most vexing concern with the use of the HCIS in the Netherlands was over how the information stored in the records could be used by supervisors and administrators in the evaluation of work performance. On the surface, the concern expressed by the care workers in the Netherlands was similar to those raised by the social workers at Selfhelp Community Services. It was believed

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that these concerns could be fairly easily resolved by discussions of interested parties. This did not happen. This is such a serious issue for the Dutch that there have been discussions about the need for national legislation that would prevent the information stored in the records from being used to evaluate the performance of carers.

III. DISCUSSION

Six years of development of the TAO/HCIS has resulted in a journey from a technology that was initially envisioned and implemented as a research tool (TAO), to a web-based care provision tool (Web-TAO), to an interactive journal/blog that can be used on a smart device, to a full-fledged electronic records informatics system (HCIS).

The system that is currently in use in the Netherlands is significantly different in scope, operation and potential customers than the one envisioned six years ago. In fact, it was only a little over two years ago that I fully recognized that the HCIS is, in actuality, an Electronic Medical Records System (EMR), similar to those employed in hospitals and general medical practices. Thus, the HCIS has many features in common with these institutionally based systems: it allows for the creation of interactive records of care that can be accessed by any number of authorized individuals; the records can be sorted by any number of domains; the HCIS can be easily integrated with any other electronic records system; and it can be used as a billing tool. However, there are features that differentiate the HCIS from these other systems: 1) it was specifically created to be used to record the delivery of care and services in the home; 2) it can be used on any smart mobile device; 3) it can be seamlessly integrated with any residential monitoring system, e.g., behavioral, vital signs, environmental; and 4) it can be used either as a stand-alone system or with other pervasive health care applications.

Although it was not my intention in 2006 to produce an electronic medical records system, this was the result of six years of work with the seven different care organizations. In retrospect, the transition from a web-based research instrument (TAO) to an electronic records system (HCIS) appears intentional, but it wasn't. The transition was driven by the needs of the individuals within the care organizations (end-users), who kept asking for new features and used the existing features in ways that I had not anticipated. Again in retrospect, it is clear that, not being researchers, these carers were much less interested in systematically collecting data on which to assess the effectiveness of behavioral monitoring than in using the newly available tool—the TAO/HCIS—to provide more effective care to their clients. As a result, I relinquished a degree of control over the development process, which at times was both frustrating and difficult, but it was the only way that my overall goal—to produce a system that the caregivers would use, rather than something we thought the caregivers should use—could be accomplished.

IV. CONCLUSION AND FUTURE WORK

Based upon the six years of working on various iterations of the TAO and HCIS, the main conclusion is that it is possible to create an eHealth system for home care and that such a system can be used effectively to coordinate care and services and contribute to the maintenance of independent living. However, five key design issues appear to underlie the successful development and implementation of such an electronic records system for the home. First, the records system must be usable on smart mobile devices. Experiences, in both London and the Netherlands, make clear that any electronic records system must be able to be accessed and updated on a wide range of smart mobile devices, because by definition, providers of care and services are constantly traveling and rarely have timely access to computers. If the HCIS had not been "made" mobile, the Dutch carers would not have used it.

Second, any home care electronic records system must be able to be seamlessly integrated with other electronic health care records systems, e.g., hospital and physician practices. Although the information contained in the HCIS has been provided to physicians and other health care specialists in both the United Kingdom and the Netherlands, the system itself has not been linked to other electronic records systems. Discussions were held in 2009 with representatives of the participating care organizations about developing, if not full integration, linkage between various electronic records systems—health and fiscal—and the HCIS. At this time, such linking was premature, but it is clear that the full potential of any home care electronic health record system will not be achieved without its integration with other electronic health records. How and when this will occur depends largely on the wider acceptance of systems such as the HCIS. Once home care systems are widely used their integration with other electronic systems will take place rather quickly.

Third, any home care electronic records system must be flexible enough to be used with a variety of pervasive health care applications. The HCIS has been completely integrated with QuietCare®, a behavioral monitoring system, in the Netherlands and, although the project did not materialize, it was designed to be used with a vital signs monitoring system. The value of the HCIS as a means of recording the care actions and health outcomes brought about by alerts generated by QuietCare® indicate that the full potential of any monitoring system will not be achieved without some type of electronic records component. Consequently, the further development of pervasive health care applications for use in the home must incorporate some type of electronic records system or they will remain little more than passive emergency response systems [6, 11].

However, if home care electronic record systems are to achieve their full potential their use cannot be restricted to only pervasive health care applications, but they must be able to function as stand-alones. Demographics clearly indicate that the population that can benefit significantly

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from the use of pervasive health care applications is relatively small and that the vast majority of individuals receiving care and services in their homes will never have the need for such systems. And yet, the amount of care the majority of individuals living in their own homes needs will continue to increase and thus, the need to have a means of recording the care and services continues to grow. The need for any home care electronic records system to be able to stand alone became apparent during my work in the Netherlands and the HCIS has been modified so that it can be used without a monitoring system being installed. As yet, no test of the stand-alone capability of the HCIS has been undertaken, but discussions with several potential partners are on-going.

Finally, the need for any home care electronic records system to operate as a stand-alone raises the final design issue—the requirement that any system be able to be used for self-management, especially the self-management of chronic diseases. Once again, the demographic trends indicate that as the populations of all industrial societies increase, the number of individuals with chronic diseases, e.g., congestive heart disease, diabetes, will skyrocket. The need for these individuals, particularly at the early stages of the disease, to manage their health while living at home, is essential for the financial stability of every national health care system. An at-home electronic health care record is ideally suited for this purpose because, not only can it be used to track the disease state itself by recording and analyzing essential conditions, i.e., blood glucose level, it also can be used to chronicle specifics about care provided by both informal and formal carers. These issues have been discussed elsewhere [6], how the use of the HCIS has brought about a coordination of care among different formal and informal carers in studies in the United States, the United Kingdom and the Netherlands. These findings suggest that one of the more significant contributions of electronic home care records systems will be their ability to adapt to the ever changing care needs of individuals.

Although achieving the above design imperatives does not guarantee the successful creation and use of home care electronic records systems, ignoring these issues certainly increases the probability of failure. Unfortunately, there is no single road map to developing a successful home care electronic records system, but if one can learn from the adoption process of institutional and physician practice systems, the path will be long, expensive and difficult. However, as the past has also shown, the gains from undertaking the effort to create and implement electronic records systems are well worth the effort.

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Pharmer – Towards Semantic Medical Prescriptions

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***Abstract*—The recent proliferation of Linked Open Data that enables the integration of multiple disparate data sources brings into the spotlight a new generation of knowledge management applications. Particularly in the domain of pharmaceutical research and development, many efforts have been done to create a linked open drug data. In this paper we present the Pharmer as an approach to facilitate the creation of semantic prescriptions. Semantic prescriptions are intelligent e-prescription documents enriched by drug-related meta-data thereby know about their content and the possible interactions. In an e-health system, semantic prescriptions provide an interoperable interface which helps patients, physicians, pharmacists, researchers and companies to collaboratively improve the quality of pharmaceutical services by facilitating the process of shared decision making. Pharmer provides different views for the different personas involved in the process of e-prescribing. It employs datasets such as DBpedia, DrugBank, DailyMed and RxNorm to automatically detect the drugs in the prescription and to collect multidimensional data on them. Eventually it warns of the possible drug interactions in the prescription. We evaluate the feasibility of the Pharmer by conducting a usability evaluation and report on the quantitative and qualitative results of our survey.**

***Keywords*-Semantic prescription; e-prescription; semantic annotation; e-health;**

I. INTRODUCTION

As reported in MedicineNet [1], *medication errors* are the most common type of medical errors in health care. Errors such as improper dose of medicine, adverse drug interactions, food interactions, etc. often stem from invalid prescriptions and unawareness of the patients. Electronic prescriptions which are recently gaining attention in the e-health domain, are one of the solutions proposed to solve these type of errors. While even nowadays traditional paper prescriptions are commonly used, e-prescriptions offer several advantages. In an e-prescription system, prescriber electronically sends an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care. Reduction in medication error and decline in adverse drug events are more highlighted consequences of e-prescribing.

During the recent years, the adoption of e-prescriptions has been spreading rapidly. To illustrate, the Australian government started launching of e-prescription from March 2007 [2]. A system called epSOS [3] which performs the use of e-prescriptions all around Europe, is currently passing the extensive practical testing phase. The e-prescribing incentive program performed in US [4] is another example in this area. As a reporting program it uses a combination of incentive payments and payment adjustments to encourage electronic prescribing by eligible professionals.

One of the main challenges of e-prescription systems is the heterogeneity of available information sources. There exist already different sources of information addressing different aspects of pharmaceutical research. Information about chemical, pharmacological and pharmaceutical drug data, clinical trials, approved prescription drugs, drugs activity against drug targets such as proteins, gene-disease-drug associations, adverse effects of marketed drugs, etc. are some examples of these diverse information. Handling these dynamic information within current e-prescription systems without blurring the border of the existing pharmaceutical information islands is a cumbersome task. On the other hand, *Linked Open Data* as an effort to interlink and integrate these isolated sources of information is obtaining more attention in the domain of pharmaceutical, medical and life sciences.

Combining the best practices from Linked Open Data together with e-prescription systems can provide an opportunity for patients, researchers as well as practitioners to collaborate together in a synergic way. A consequence of introducing linked data in health care sector is that it significantly changes the daily duties of the employees of the health care sector. Therefore the most challenging aspect will not be the technology but rather changing the mind-set of the employees and the training of the new technology[5]. Furthermore, the information generated via that approach can be employed as a data source for researchers. Drug companies are also able then to take the advantage of considering these informative statistical data.

Semantic prescriptions as introduced in this paper are a proposed approach to utilize semantic web technologies in e-prescription systems. As intelligent prescriptions, they can automatically handle the medical errors occurring in prescriptions and increase the awareness of the patients about the prescribed drugs and drug consumption in general. Semantic prescriptions also enable the creation of more efficient and effective search approaches for drug discovery and consumption. We created a tool called *Pharmer* as a showcase application to facilitate the process of se-

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mantic prescription generation. Pharmer adopts a bottom-up approach for enriching the normal e-prescriptions with semantic annotations using a set of predefined datasets from linked open data.

The remainder of this article is structured as follows: Section II, Section III and Section IV provide a background on the basic concepts such as Linked Open Data, Semantic Content Authoring and E-prescriptions employed in this paper. In Section V, we describe the Pharmer as a solution to effectively create semantic prescription. Then we discuss the possible benefits of Pharmer in Section V-C. To better clarify the use cases of the Pharmer system, an example scenario is drawn in Section VI. In Section VII, Pharmer usability evaluation results are reported and finally Section VIII concludes with an outlook on future work.

II. Linked Open Data

In computing, *Linked Data* describes a method of publishing structured data so that it can be interlinked and become more useful. It builds upon standard Web technologies such as HTTP and URIs, but rather than using them to serve web pages for human readers, it extends them to share information in a way that can be read automatically by computers. This enables data from different sources to be connected and queried [6]. Tim Berners-Lee, the inventor of the Web and Linked Data initiator, suggested a 5 star deployment scheme for *Linked Open Data*: 1) make your stuff available on the Web (whatever format) under an open license, 2) make it available as structured data (e.g., Excel instead of image scan of a table), 3) use non-proprietary formats (e.g., CSV instead of Excel), 4) use URIs to identify things, so that people can point at your stuff, 5) link your data to other data to provide context.

Particularly in the areas of health care and life sciences with the wealth of available data, large scale integration projects like Bio2RDF [7], Chem2Bio2RDF [8], and the W3C HCLS's (Health Care and Life Sciences) Linked Open Drug Data (LODD)[9] have not only significantly contributed to the development of the Linked Open Data effort, but have also made social and technical contributions towards data integration, knowledge management, and knowledge discovery.

There are already many interesting information on pharmaceutical research available on the Web. The sources of data range from drugs general information, interactions and impacts of the drugs on gene expression, through to the results of clinical trials. LODD[10] has surveyed publicly available data about drugs, created Linked Data representations of the data sets, and identified interesting scientific and business questions that can be answered once the data sets are connected.

One of the use cases of LODD datasets is authoring of *Semantic Prescriptions* which are prescriptions enriched by linked open data.

III. Semantic Content Authoring

A *Semantic Document* is an intelligent document (with explicit semantic structure) which "knows about" its own content so that it can be automatically processed in unforeseen ways. Semantic documents facilitate a number of important aspects of information management [11]. For *search and retrieval*, they provide more efficient and effective search interfaces, such as faceted search [12] or question answering [13]. In *information presentation*, they support more sophisticated ways of flexibly visualizing information, such as by means of semantic overlays as described in [14]. In *information integration*, they provide unified views on heterogeneous data stored in different applications by creating composite applications such as semantic mashups [15]. For *personalization*, they provide customized and context-specific information which better fits user needs and will result in delivering customized applications such as personalized semantic portals [16]. For *reusability* and *interoperability*, they facilitate exchanging content between disparate systems and enabling applications such as executable papers [17].

The above benefits, however, come at the cost of increased authoring effort. A *Semantic Authoring User Interface* is a human accessible interface with capabilities for writing and modifying semantic documents which are either.

- fully semantic in the sense that their original data model uses a semantic knowledge representation formalism (such as RDF, RDF-Schema or OWL) or
- based on a non-semantic representation form (e.g. text or hypertext), which is enriched with semantic representations during the authoring process.

Medical prescriptions are a good candidate to be enriched by semantic annotations. Semantic prescriptions enable the traditionally written prescriptions to be utilized in novel ways as discussed above. In the following sections, we first describe the e-prescriptions and then discuss how they can be enriched as semantic documents.

IV. E-prescriptions

E-health has evolved and emerged recently in many forms. E-prescription is one of those forms and defined as a computer-generated prescription utilized by health-care providers. E-prescribing as it is commonly called, is the use of an automated data entry system to generate a prescription that is then transmitted through a special network to a pharmacy in such a way that the data goes directly into the pharmacy's computer system. It plays an important role in improving the quality of patient care. For the prescriber, e-prescribing happens when a physician uses a computer or handheld device with a software that allows him or her to (with the patient's consent) electronically access information regarding a patient's drug benefit coverage and

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medication history; electronically transmit the prescription to the patient's pharmacy of choice; and, when the patient runs out of refills, his or her pharmacist can also electronically send a renewal request to the physician's office for approval.

In order to see an increase in both quality and efficiency that can be attributed to e-prescribing, the system must be capable of performing key functions related to:

- Medication selection/decision support capabilities (e.g., diagnosis-based medication menus, evidence based information, drug interaction checking, safety-alerts, formulary checking, prescription renewal, and dosage calculation).
- Patient-specific information capabilities (e.g., current patient medication list, access to patient historical data, patient identification).
- System integration capabilities (e.g., connection with various databases, connection with pharmacy and pharmacy benefit manager systems).
- Educational capabilities (e.g., patient education, provider feedback).

One of the main challenges of the current e-prescription systems is the heterogeneity and evolving nature of available information sources. There exist already different sources of information addressing different aspects of pharmaceutical research. Handling these dynamic information within current e-prescription systems without blurring the border of the existing pharmaceutical information islands is a cumbersome task.

V. Pharmer: Semantic Authoring of Medical Prescriptions

Pharmer is an application created as a proof of concept for the authoring of semantic prescriptions. The Pharmer implementation is open-source and available for download together with an explanatory video and online demo at [18]. Pharmer adopts a bottom-up approach [19] for enriching the normal e-prescriptions with semantic annotations using a set of predefined ontologies.

A. Architecture

The Pharmer system architecture is depicted in Figure 1 and consists of three layers:

Document Layer: This layer includes the traditional e-prescription document plus two components as *Drug Detection* and *Drug Information Collector*. Drug detection component performs the natural language processing (NLP) of the e-prescription document to detect the terms referring to a drug in the prescription. The component uses DBpedia spotlight [20] and BioPortal annotator [21] NLP services to parse and analyze the text looking for known drugs. It is configurable so that users can easily add other existing NLP services for drug detection. When user is writing the prescription, this component asynchronously performs the drug recognition and adds the related annotations as real-time semantic tagging.

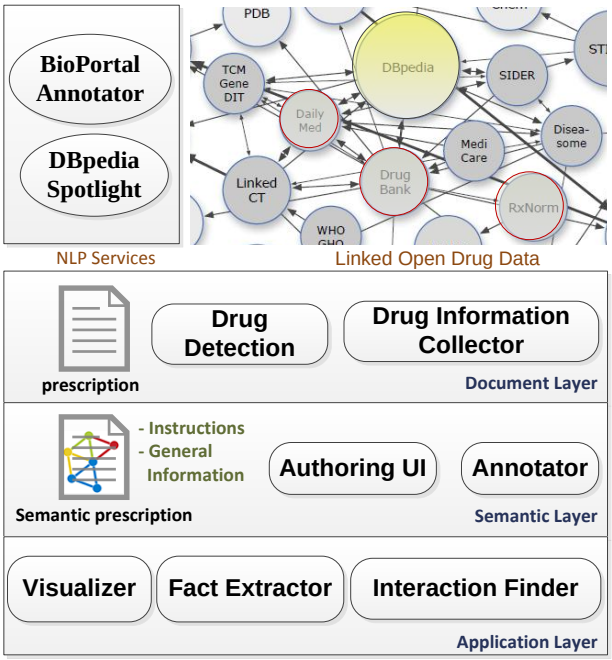

Figure 1. Architecture of the Pharmer system.

Another component in this layer is drug information collector which grabs all the information regarding a specific drug from Linked Open Data. To pursue this, it utilizes datasets such as DrugBank, DailyMed and RxNorm (available at [9]) by sending federated SPARQL queries.

Semantic Layer: There are two main components in this layer namely *Annotator* and *Authoring UI*. The *annotator* component handles the automatic annotation and embeds the general information of the drugs as meta-data into the e-prescription. Annotator adopts the RDFa format. *RDFa* (Resource Description Framework in attributes) is a W3C Recommendation that adds a set of attribute level extensions to XHTML for embedding RDF metadata within web documents. RDFa fulfills the principles of interoperable metadata such as publisher independence, data reuse, self containment, schema modularity and evolvability.

The *authoring UI* component provides users with a set of input forms to manually embed the meta-data related to prescription instructions into the prescription document.

Application Layer: This layer provides a set of applications on top of the generated semantic prescriptions. *Interaction Finder* checks the possible interactions between the prescribed drugs and warn the prescriber about them. *Visualizer* is responsible for graphically representing the embedded semantics of a prescription (e.g. as depicted in **??**). The *Fact Extractor* generates the RDF/Turtle representation of the semantic prescriptions.

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B. Features

The main features of Pharmer can be summarized as:

- *Providing Different Semantic Views*. Semantic views allow the generation of different views on the same metadata schema and aggregations of the knowledge base based on the roles, personal preferences, and local policies of the intended users. Pharmer suggests two types of views: generic and domain specific views. Generic views provide visual representations of drug information (e.g. as information view depicted in Figure 2 or graph view. Domain specific views address the requirements of a particular domain user (e.g. a researcher need specific views for visualizing the atomic structure of chemical compounds).
- *Real-time Drug Tagging.* Real-time tagging means creating drug annotations while the user is typing. This will significantly increase the annotation speed [22]. Users are not distracted since they do not have to interrupt their current authoring task. Pharmer has a client-side component which interacts with the server asynchronously to make real-time tagging possible.
- *Drug Suggestion.* When searching for a drug, Pharmer suggests the similar drugs by taking into account the history of search terms.
- *Automatic Drug Annotation.* Automatic annotation means the provision of facilities for automatic mark-up of prescriptions. The automatic process of annotating in Pharmer is composed basically of finding drug terms in prescription using an NLP service, mapping them against an ontology, and disambiguating common terms.

C. Pharmer Stakeholders

As depicted in Figure 3, Pharmer approach is very versatile and can be applied in a vast number of use cases by different stakeholders. The arrows in the figure can be summarized as the following:

1) The physician diagnoses the disease and writes the corresponding semantic prescription using the Pharmer. The patient's medication history is available to the physician as well.
2) Pharmer utilizes the Linked Open Data as its integrated information source.
3) The researcher can analyze the stored semantic prescriptions data.
4) Drug companies utilize the Pharmer data store in order to balance their production and distribution according to the market taste and demand.
5) The pharmacist verifies the prescription and hands in the medication to the patient.
6) The patient inquires drug information and can contact the related physician and pharmacist.

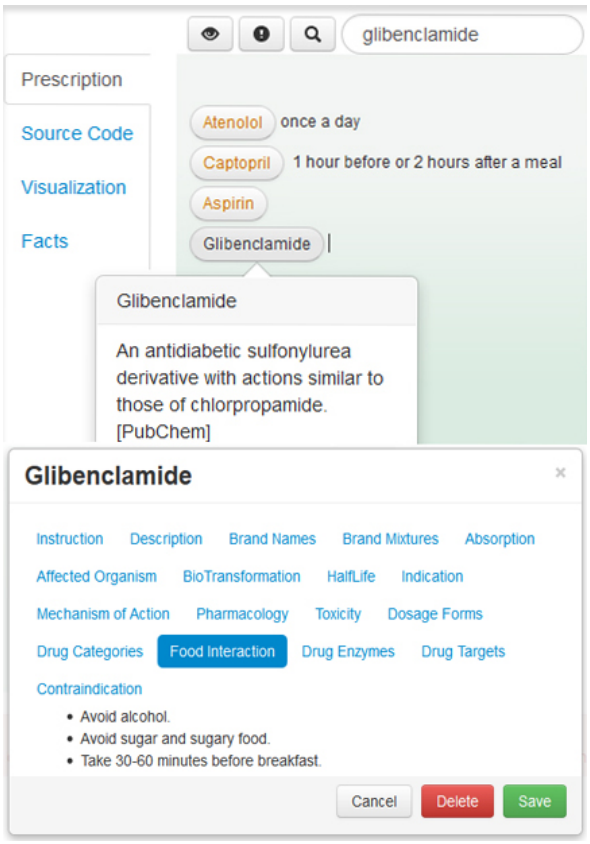

Figure 2. Screenshot of the Pharmer application.

The main benefit of using semantic prescriptions is the persistent connection to up-to-date drug information coming from multiple dynamic data sources. So, when a change occurs to a drug (e.g. change in its effects or interactions) the semantic prescription automatically adopts to this new change. Once writing a prescription it is very critical to consider drug interactions. Drug interactions are divided to three categories namely *food-drug*, *drug-drug* and *drug-plant* interactions. Coadministration can either be synergistic or antagonistic which respectively increase or decrease the drugs effect. The interactions may sometimes lead to change in the drug effect. By applying semantic prescriptions, all types of drug interactions are prevented and the probability of errors in prescriptions are reduced to a great extend.

A semantic prescription is a self-contained document which is aware of its content and is connected to the linked open data. In contrast to database-oriented e-prescriptions, semantic prescriptions can easily be exchanged among other e-health systems without need to changing their related infrastructure hence enabling a connection between physicians, pharmacists, patients, pharmaceutical researchers and drug companies.

Furthermore, semantic prescriptions increase the awareness of patients. They provide patients with all the related

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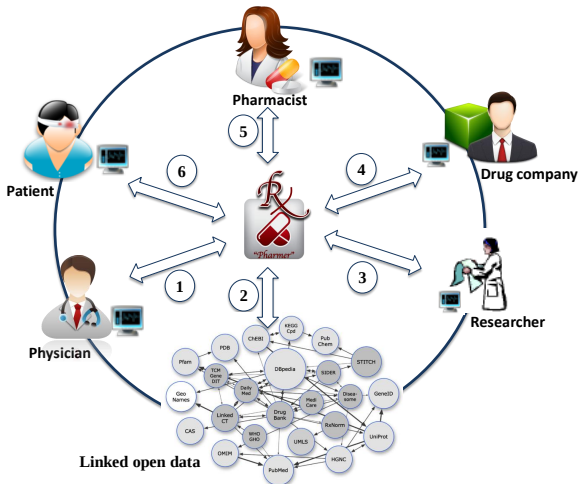

Figure 3. Pharmer ecosystem.

information of the prescribed drugs thereby mitigating the possible misuse of drugs. In addition, semantic prescriptions support shared decision making (SDM) by allowing patients and service providers to make health care decisions together. They connect the best scientific evidence available with the patient's values and preferences.

VI. Example Scenario

As a scenario; a 63 year old man with the history of MI (Myocardial Infarction) and type 2 diabetes visits a heart and coronary specialist complaining about frequent headaches and heavy head feeling. The specialist, after general inspection and monitoring vital signs, asks for a blood test. He then considers symptoms including high blood pressure (sys/dias:158/95 mmHg) and high Fasting Blood Sugar (150 mg/dl). He diagnoses high blood pressure plus severe type 2 diabetes. Thereby, The patient profile is defined in Pharmer by patient's information besides diagnosis. "no weight loss" is mentioned as a preference in the patient's profile. Regardless of the patient's preferences, the physician would prescribe `Metformin` as a drug of choice. However, since the major side effect of `Metformin` is weight loss, the physician replaces `Metformin` with `Rosiglitazone`. Considering the medication that the patient took before (`Glibenclamide` only), The specialist dispenses a new semantic prescription by entering the following drugs:

- **Rosiglitazone** 4 mg Oral Tablet once daily
- **Glibenclamide** 5 mg Oral Tablet bid
- **Atenolol** 50 mg Oral Tablet once daily

He then checks for the possible drug interactions by clicking the attributed button in the Pharmer software. As the Pharmer is connected to linked open data it is capable of recognizing the most recent updated drug interactions. He finds out that Sulfunyl Urea class drugs (here `Glibenclamide`) are not compatible to be coadministrated with beta-blockers (here `Atenolol`). So, he needs to replace it with another drug. Using the Pharmer and its connection to linked open data, the physician can find the possible alternatives. Then he decides to choose `Captopril` as replacement. The semantic prescription is then sent to the patient's pharmacy of choice. There, pharmacist is able to review the semantic prescription and comments on that directly in the system so that the physician is also aware of the corresponding changes. Pharmacist comments may cause minor or major modifications in the semantic prescription. For instance, using the Pharmer she is able to check the appropriate dose of each medicine or suggest cheaper alternatives (if possible). In this case, as the `Rosiglitazone` elevates cardiovascular risks, the pharmacist suggests `Rosiglitazone` to be replaced by `Pioglitazone`. This change happens as a realization of the shared decision making between physision, pharmacist and patient. Thereafter, patient who was referred to the pharmacy takes the prescribed drugs. Before he starts taking the tablets, he enters in Pharmer system with his ID as patient. There, he is able to observe drug information embedded in the error free semantic prescription besides the preferred time and drug intake instructions. He is also informed about the possible food interactions. The patient's profile completes as he visits physicians or ask for refills. Furthermore he is followed up by the physician and the pharmacist via the Pharmer. After 2 months the patient visits another specialist for his recurrent symptoms of diabetes. The specialist via the Pharmer accesses to the patient's medical profile and increases the anti-diabetic drug dose.

A researcher in an academy research institution investigates `Captopril` (as an Angiotansion II antagonist) effect on preventing diabetes recurrence. Having the data from the aforementioned patient follow up along with other similar patients allows investigator to lead her goal. In this case, for example, the `Captopril` along with anti-diabetic drugs led to diabetes recurrence. Observing all the corresponding patient profiles will either confirm or reject the research assumption.

A drug company manager requires to determine the compliance rate of `Captopril` in the market in order to balance the production based on market demand. Applying the Pharmer allows him to simply access to these data and decide how to go on with this product. He is also able to collect the evidence which may prevent further dispense of `Captopril` by physicians or consumption among patients.

VII. Evaluation

In order to determine whether we succeeded to facilitate the creation of semantic prescriptions using Pharmer, we performed a usability user study with 13 subjects. Subjects were drawn from 3 physicians, 4 pharmacist, 3 pharmaceutical researchers and 3 students. We first showed them a tutorial video of using different features of Pharmer then asked each one to create a prescription with Pharmer. After

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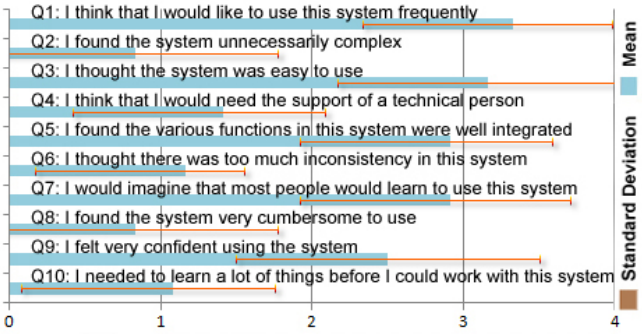

Figure 4. Usability evaluation results for Pharmer (0: Strongly disagree, 1: Disagree, 2: Neutral, 3: Agree, 4: Strongly agree).

finishing the task, we asked the participants to fill out a questionnaire which consisted of two parts: feature usage questions and usability experience questions.

We used the *System Usability Scale* (SUS) [23] to grade the usability of Pharmer. SUS is a standardized, simple, ten-item Likert scale-based questionnaire giving a global view of subjective assessments of usability. It yields a single number in the range of 0 to 100 which represents a composite measure of the overall usability of the system. The results of our survey (cf. Figure 4) showed a mean usability score of **75** for Pharmer which indicates a good level of usability. Participants particularly liked the integration of functionality and the ease of learning and use. The confidence in using the system was slightly lower, which we attribute to the short learning phase and diverse functionality. In addition to quantitative results, we also collected a number of user suggestions. For instance some users suggested to provide a print-friendly document with all the patient's desired information.

VIII. Conclusion

Providing a consistent connection between patients, physicians, pharmacists, pharmaceutical researchers and drug companies is a crucial step towards enhancing the quality of knowledge management and thereby e-health services in the pharmaceutical domain. With Pharmer, we presented in this article an approach for implementation of *Semantic Prescriptions* as intelligent medical prescriptions to improve the integration and interoperability of e-prescribing systems with other e-health services. Semantic prescriptions includes the important meta-data about the content of a prescription which will increase the awareness of their consumers.

We see the work presented in this article as an initial step in a larger research agenda aiming at promoting the authoring and annotation of semantically enriched medical documents. Regarding future work, we envision to extend the Pharmer application towards different modalities, such that the annotation of images and other medical objects is supported. Furthermore, we aim to integrate the other existing linked open datasets (e.g. related to publications, laboratories or insurance documents) into the Pharmer to extend its stakeholders.

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An Automated Motion Artifact Removal Algorithm in Electrocardiogram Based on Independent Component Analysis

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***Abstract*— Mobile ECG recordings are widely used to monitor abnormality of the cardiovascular system during daily life. However, ambulatory ECG recordings are often contaminated by many types of artifacts. In motion artifacts removal, because ECG and movement are not always independent, ICA based noise reduction may distort the signals. Thus, this paper introduces automatic noise detection and removal technique based on independent component analysis (ICA) preventing the signal distortion and attenuation. Using several proposed decision rules, 3-channel ECGs are analyzed their noisiness and Gaussianity to predict whether motion artifacts and ECGs can be separated and reconstructed without distortion. This method is evaluated by ECGs recorded during 0 to 7km/h rest, walking, and running exercise. Finally, its performance is compared to the conventional approaches of ICA-based noise reduction in ECGs. As results, the reconstructed ECGs by the proposed algorithm show higher correlation with estimated reference signals and there is no distortion in reconstruction of the signals.**

Keywords-Independent component analysis; Motion artifact; ECG; Noise removal

I. INTRODUCTION

Electrocardiogram (ECG) monitoring provides useful information to diagnose, evaluate, and treat cardiovascular related diseases. Conventionally, patients visited hospital, where the measurement devices and the physicians are available, to acquire the ECG for detecting abnormality of the cardiovascular system. However, this approach involves temporal and spatial limitation for the measurement, because it is only possible when patients visit the hospitals. For this reason, many portable devices measuring the signal everyday have been researched and commercialized. But, it still has challenge, the ECG recording is exposed to many types of environmental noise such as power-line interference and motion artifacts in long-term acquisition. Furthermore, in many cases of the ECG analysis, manual classification between motion artifacts and other events such as arrhythmia by cardiologists is intensive and time-consuming task [1]. Overcoming the limitation, many noise reduction algorithms have been introduced and applied to the ECG recording. The technique of adaptive filter for motion artifacts removal, which uses acceleration signals as references, has widely applied for the ambulatory ECG measurements [2-3]. However, low correlation values between complicated body movements during activities and acceleration signals restrict the use of the techniques. Independent component analysis (ICA) [4] has provided an effective method in the application of motion artifacts cancellation by assuming ECG and motion artifact are independent [5]. Practically, multi-channel ECGs with motion artifacts (mixture signals) are decomposed to motion artifacts and ECG components (source signals) which are relatively high correlated among each channel based on the matrix that maximizes the non-Gaussianity of mixture signals. Thus, the noise removal in ambulatory multi-channel ECG recording is possible by elimination of one source signal that is estimated to motion artifact. Applications of the ICA for motion reduction in ECG recordings have been introduced in many researches of which the algorithms automatically select and remove motion artifact in decomposed independent components [6-7]. However, the ICA also has drawbacks. For the actual measurement, the motion artifacts and ECG are not exactly independent, i.e. cardiac dynamics such as heart rate and ECG morphology are affected by body movements for instance, Head Down Bed Rest maneuver [8]. Moreover, the ICA is limited on non-Gaussian random variables. Thus, in the case of mixture signals which follow the Gaussian property, applying the ICA is not suitable, further it might cause signal distortion by eliminating meaningful information.

This paper is motivated by the above challenges: 1) automated noise detection from the acquired ECGs 2) automatic motion artifact component selection and removal from decomposed signals considering interdependency between ECG components and motion artifacts, 3) prediction of whether the multi-channel ECGs with motion artifacts can be decomposed or not before applying the ICA. In this paper, we present automated motion artifact removal algorithm based on ICA, which prevents reconstructive distortion and considers correlation between multi-channel ECGs and motion artifacts with several decision rules.

II. MATERIALS & METHODS

Fig. 1 shows schematic of motion artifact reduction algorithm. It basically consists of 5 parts: noise detection, signal status check, ICA, de-noising and reconstruction.

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Noise detection is the first layer that filters unnecessary signals, such as clean ECGs. To check the signal status predicts whether the motion artifacts and ECGs will be separated by the ICA or not. It is based on properties of the ICA. Through this process, we can avoid signal distortion which the necessary component is removed in the reconstruction process. After the ICA, estimated motion artifacts which show low cross correlation coefficient among the components are eliminated. Then, finally we can observe de-noised ECG signals.

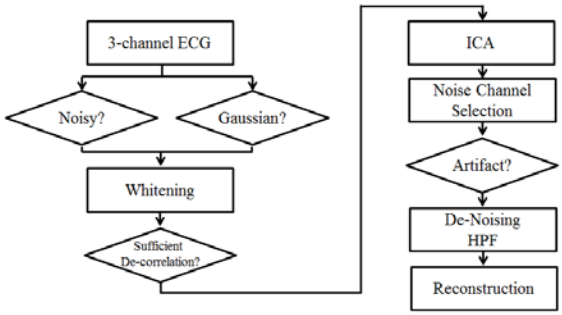

Fig. 1. Shematic of motion artifact removal algorithm.

A. Data Collection

The data was acquired from the portable device that is attached on the subject's chest. 3-channel ECGs (Lead1, Lead2, v2) were recorded simultaneously from 5 healthy subjects (5 male, 28.2±2.68) during the rest, 2, 4, 5km/h walking and 6, 7km/h running on a treadmill. Every exercise trial contains 5 seconds recording in rest state. Each experimental data was acquired over a minute with 500Hz sampling rate and transferred to the PC using the Bluetooth. The measured data were segmented by the corresponding data in 5 seconds. The proposed algorithm was applied to each segmented data.

B. Noise Detection

ECG shows different characteristics depending on patients. Furthermore, motion artifacts are differently influenced to the ECG recordings. Therefore, the noise detection should be accessed with individual property. Here, we compared ambulatory ECGs to the reference ECGs that were recorded before the exercise.

The Central Limit Theorem explains that the distribution of a sum of random variables tends toward a Gaussian distribution [4]. Therefore, ECGs during the exercise which contains motion artifacts are closer to Gaussian distribution. Thus, using negentropy (explained in *section C.*) which is one measure of non-Gaussianity, rest ECGs and ambulatory ECGs are compared. Proposed decision rule for detecting noisy ECG is as follows:

$$\alpha_k \times J_{ref}(k) > J_{test}(k) \quad (1)$$

where,
$J_X(k)$: *Approximation of negentropy for* k^{th} *channel ECG*
α_k: *postive constants, here* 0.8

C. Gaussianity

The fundamental limitation in the ICA is that the independent components must be non-Gaussian [4]. Eq. (2) shows joint density of x, y which are Gaussian variables with zero mean and unit variance.

$$p(x,y) = p(xy) = \frac{1}{2\pi} e^{\left(-\frac{x^2+y^2}{2}\right)} \quad (2)$$

In this case, the density is symmetric. Therefore it does not contain any information on the directions of the columns of the mixing matrix *A* [4].

The classical measure of non-Gaussianity is kurtosis, the fourth-order moment defined by

$$K(x) = E[x^4] - 3(E[x^2])^2 \quad (3)$$

Kurtosis is zero for a Gaussian random variable. However, it can be very sensitive to outlier [4, 9].

Negentropy which is based on informatics is another estimation of non-Gaussianity defined by Eq. (4).

$$J(\mathbf{x}) = H(\mathbf{x}_{gauses}) - H(\mathbf{x}) \quad (4)$$

$$H(\mathbf{x}) = -\int f(\mathbf{x}) log f(\mathbf{x}) f\mathbf{x} \quad (5)$$

where, $\mathbf{x}_{gauss}$ is a Gaussian random variable of same covariance matrix as **x**. However, its computational complexity, some approximations are used. Here, we adapted the approximation developed in [10]:

$$J(x) \approx \sum_{i=1}^{p} k_i (E[G_i(x) - E[G_i(v)])^2 \quad (6)$$

where,
k_i: *positive constants*, here k_i =1
v : a Gaussian variable of zero mean and unit variance

G is selected that have proved very useful:

$$G_1(w) = \frac{1}{a_1} log cosh a_1 w, \qquad G_2(w) = -e^{\left(-\frac{w^2}{2}\right)} \quad (7)$$

$$where, 1 \le a_1 \le 2 \ , \quad here\ a_1 = 1$$

The main purpose of the Gaussianity check is to give limitation for the suggested algorithm to eliminate chances that ECG components would be removed on the de-nosing process and the signals distorted. If the random variable is Gaussian, negentropy is zero. Thus, we give threshold of .00005 for the second rule. If the approximation of negentropy for each ECG is lower than the threshold, the signal is regarded as Gaussian, then the algorithm stops processing and returns the original ECGs.

D. Whitening

Whitening is a useful pre-processing before the ICA obtaining de-correlated data. In other words, covariance matrix of the de-correlated data equals the identity matrix.

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One popular method for whitening is to use eigenvalue decomposition.

In probability distribution aspect, de-correlation means probability distribution spreads out of mean value. Thus, we can decide whether mixture signals of ECG and motion artifact would be decomposed or not, by observing whitening results. Decision rule is as follow:

$$D_w = P_W(w) - P_M(m) \quad (8)$$

$$-a \le w \le a, -a \le m \le a$$

$$if, D_w > .01, go\ to\ next\ step$$
$$otherwies, stop\ processing$$

E. ICA

The ICA provides solution to find independent source signals *s* from the mixture signals *x*. It could be expressed as a linear equation with vector formation:

$$X = AS \quad (9)$$

where, S is source signals, X is observed mixture signals and A is transformation matrix. The idea of ICA is simple that S is statistically independent. From the Eq. (9), its inverse form is acquired:

$$S = W^T X \quad (10)$$

where, W is inverse of A matrix. With the assumption of ICA, W matrix should be set in direction to maximize independency of X. It means that W matrix is updated to maximize non-Gaussianity of mixture signals. There are several approaches in ICA such as Fast-ICA and Joint Approximate Diagonalization of Eigen-matrices (JADE) algorithm. Here, we chose JADE algorithm which consists of orthogonalization and rotation with advantage of avoidance convergence problem, fast processing and efficiency [11-13].

F. Noise Channel Selecion and Denoising

After the ICA, motion artifacts channel selection is required from the independent source signals to remove unnecessary component for the ECG reconstruction. Because motion artifacts have low correlation with ECG, it can be selected by Eq. (10).

$$r_{xy}(k) = \frac{E[(X_n - \mu_x)(Y_{n+k} - \mu_y)]}{\sigma_x \sigma_y} \quad (11)$$

Basic assumption of motion artifacts removal using ICA is that motion artifacts and ECG are independent. Therefore both signals should be completely separated under the condition. However, because the movements influence cardiac dynamics, it cannot be said ECG and motion artifacts are always and fully independent. Fig. 2 shows the independent components decomposed by the ICA. In Fig. 2 (a), estimated motion artifacts and QRSs are not completely separated. To overcome this problem, we applied the high pass filter with cutoff frequency 15Hz to selected channel instead of which motion artifacts component set to zero.

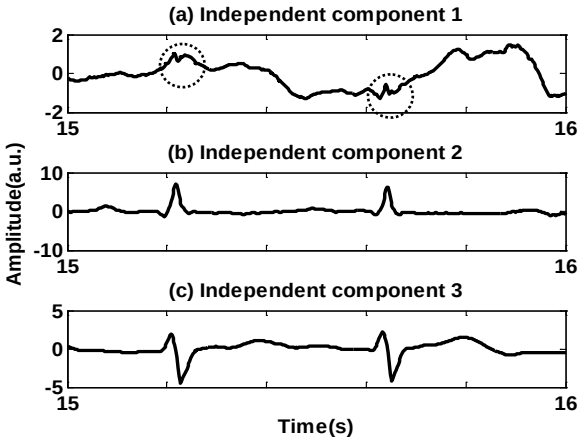

Fig. 2. Independent components decomposed from the 3-channel ECGs during exercise. (a) shows estimated motion artifacts with the rest of ECG components.

G. Analysis

A major problem of ECG signal processing is that it is almost impossible to measure ECG and motion artifacts separately during the movement. Thus, even though ECG is de-noised by the certain motion removal technique, quantitative analysis is limited without the reference signal.

In ensemble average, N sets of data are averaged together with fixed time *t* to reduce random fluctuations in the signal. From the measured ECGs in each trial, R-peaks are manually marked and set to central position of the ensemble with the size of 501 samples for each channel of ECG. R-peak-centered ensembles are averaged to acquire representative ECG waveform which regarded as the reference signal.

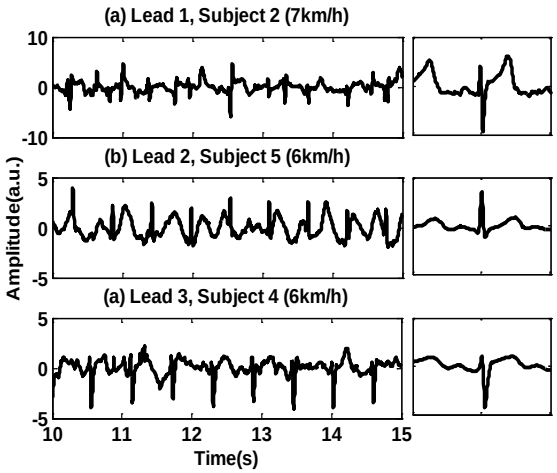

Fig. 3. Time series noisy ECG in each channel and its ensemble average signal. 501 sample ensemble average signals in each trial are set to the reference signals that are compared to processed signals.

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Fig. 3 shows the results of the ensemble average for ambulatory ECGs. By the average, motion artifacts which show random fluctuation property are attenuated and relatively regular and deterministic ECGs remain. Thus, we regard the ensemble averaged signal as the reference for the trial and compute cross correlation coefficient among the reference signal and the results of signals based on proposed and conventional methods.

III. RESULTS

Fig. 4 and Fig. 5 show examples of ECGs with motion artifacts (on the left side). For the cases, suggested algorithm removes both motion artifacts. The results are shown on the right side of each Fig.

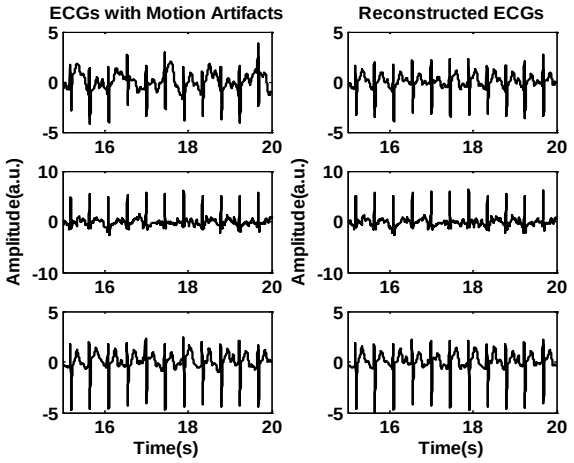

Fig. 4. An example of ECGs (Lead1, Lead 2, and v2 from the top) during exercise and reconstructed ECGs. Distorted T-waves and fluctuation in the Lead 1 ECG restored by the algorithm.

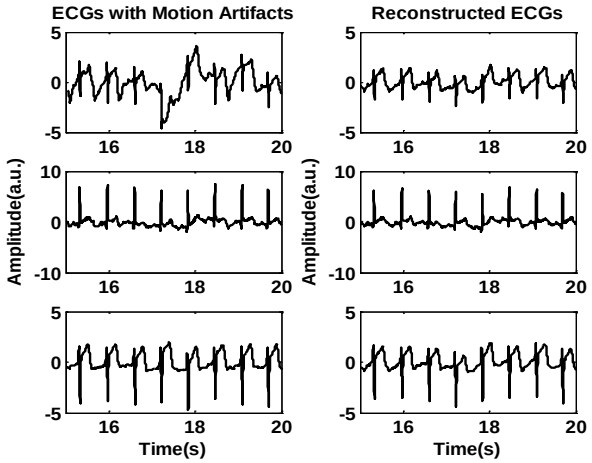

Fig 5. An example of ECGs (Lead1, Lead 2, and v2 from the top) during exercise and reconstructed ECGs. Sudden movement in the Lead 1 ECG restored by the algorithm.

Table 1 presents the mean value of cross correlation coefficients among estimated reference signals and the processed signals that were followed each processing path. 'Reconstruction' means the ECGs were noisy, non-Gaussian and, sufficiently whitened, thus, ICA was applied to remove motion artifacts. 'Low Gaussianity' means that the measured signals were noisy but, followed the Gaussian distribution. Therefore, ICA was not applied and the original signals were returned. Likewise, in the case of 'Insufficient Whitening', the algorithm moves onto the next segment data. The results arranged for the proposed algorithm (Prop.), conventional method (Con.), modified conventional method (*m*Con.) which is based on conventional method, but estimated noise vector is filtered by 15Hz BPF, not set to zero, and '*c*Prop.' which is based on the Prop., but estimated noise vector is set to zero. Thus, the results belonging to the 'Low Gaussian-Prop.' and 'Insufficient Whitening-Prop.' present cross correlation coefficients between the original signals and estimated reference signals. On the Table 1, reconstructed ECGs from our method show high correlation with the estimated reference signals with low variance. Fig. 6 shows the reconstructed Lead 1 ECG which underwent 'Prop.'(*Thick line)* and '*m*Con.'(*Thin line*). The ECG from the 'Prop.' displays less attenuated QRS and restored T-wave.

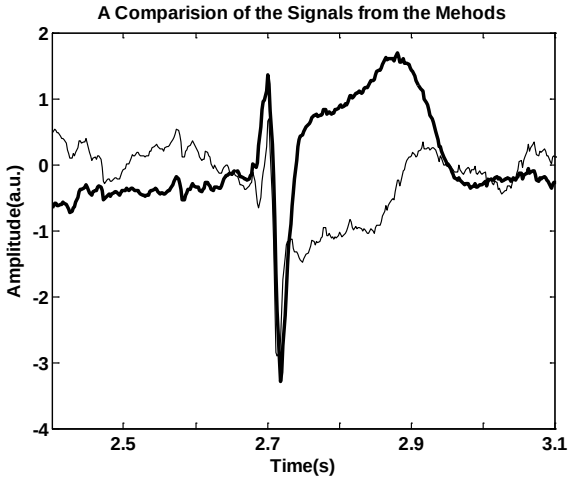

Fig. 6. A comparison of restored Lead 1 ECG from 'Prop.'(*Thick line)* and '*m*Con.'(*thin line*). The signal followed by the proposed algorithm shows less attenuated QRS and restored T-wave.

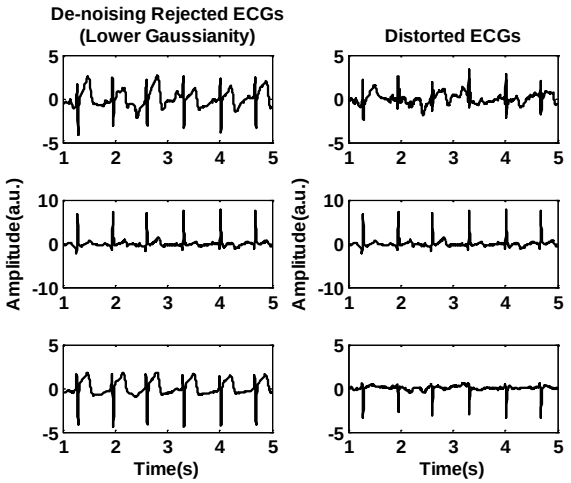

Fig. 7. Processed ECGs that are applied two different methods ('Prop.' on the left side and 'Con' on the right side) .

TABLE I. THE RECONSTRUCTION RESULTS OF THE ICA BASED NOISE REMOVAL ALGORITHMS

		Reconstruction				Low Gaussianity				Insufficient Whitening			
		Prop.	*Con.*	*mCon.*	*cPorp.*	*Prop.*	*Con.*	*mCon.*	*cPorp.*	*Prop.*	*Con.*	*mCon.*	*cPorp.*
S1	**L1**	.909	.846	.947	.845	.384	.781	.383	.644	-	-	-	-
	L2	.910	.902	.910	.906	.667	.736	.669	.738	-	-	-	-
	v2	.962	.849	.965	.904	.639	.816	.639	.807	-	-	-	-
S2	**L1**	.876	.306	.865	.397	.798	.436	.798	.501	-	-	-	-
	L2	.932	.940	.928	.942	.936	.933	.936	.934	-	-	-	-
	v2	.957	.486	.955	.591	.969	.552	.969	.636	-	-	-	-
S3	**L1**	.858	.855	.855	.853	.671	.566	.671	.569	.931	.789	.931	.885
	L2	.857	.839	.839	.852	.753	.757	.753	.743	.941	.935	.941	.917
	v2	.875	.863	.863	.871	.764	.485	.764	.521	.974	.705	.974	.863
S4	**L1**	.860	.766	.857	.796	.331	.363	.331	.376	-	-	-	-
	L2	.926	.918	.924	.922	.344	.326	.344	.397	-	-	-	-
	v2	.949	.917	.947	.930	.826	.859	.826	.859	-	-	-	-
S5	**L1**	-	-	-	-	.560	.613	.560	.619	-	-	-	-
	L2	-	-	-	-	.599	.679	.599	.701	-	-	-	-
	v2	-	-	-	-	.779	.771	.779	.775	-	-	-	-

Fig. 7 presents processed ECGs that is applied two different methods. ECGs on the left side were processed through the proposed algorithm. Even though the signals are slightly noisy, because the each ECG follows the Gaussian distribution, the ICA is not applied for the signals. On the other hand, ECGs on the right side were applied the ICA without any decision rules. After the ICA, the component which has the lowest kurtosis value is estimated to the noise component and set to zero. Then, necessary component can be eliminated. Finally, reconstructed signals are distorted as shown in Fig. 7.

IV. DISCUSSION

In order to evaluate our propose algorithm, ambulatory ECGs were acquired and applied, and the algorithm is compared with several methods including normally used algorithm. Since our goal was to eliminate the motion artifacts in ECGs without distortion, several decision rules were applied and evaluated their efficiency.

The ICA is popular blind source separation technique which has provided reliable solution for noise reduction problem in the ECG. According to the ICA, observed signals are separated to the independent sources by decomposing the mixture signals with direction to maximize non-Gaussianity. One important characteristics of the ICA is that the method is restricted to Gaussian random variable. Traditional assumption in ECG de-noising is that ECG and motion artifact are statistically independent corresponding to basic assumption of the ICA. However, movements influence to cardiac dynamics, thus it is not always satisfied. Furthermore, ICA based motion removal algorithm may distort ECG signals by eliminating important components. Thus, we proposed 4 decision rules to avoid above limitation. Noisiness and Gaussianity were considered by approximation of negentropy which shows zero for the Gaussian random variable under condition of the Central Limit Theorem. Because the distribution of a sum of random variables follows a Gaussian distribution, if the approximation of negentropy for ECG during exercise is decreased compared to the signal during rest, the segment of the signal regarded as noisy signal. Also, if the approximation of negentropy closes to zero, it is considered to the Gaussian variable. Under this condition, the algorithm regards it as out of processing range, and moves onto next segment of data.

Whitening is useful processing before the ICA. Through the process, observed random vector is uncorrelated and its variance equals unity. In the probability distribution aspect, it means that the distribution moves outside of mean value. If the distribution of the whitening result shows similarity with the distribution of the input random vector, it can be said vector is already uncorrelated. In this case, the algorithm also decides to stop processing and starts with next segment of data. After the ICA, motion artifact component was found using cross correlation coefficient. The channel which has the lowest correlation with each other was selected and filtered. To consider motion artifact and ECG were not perfectly separated, we applied HPF to selected component, not set to zero.

The algorithm was compared with several approaches to evaluate implications of the proposed method such as applying filter and decision rules. One of important problems in ambulatory ECG analysis is absence of reference signal. In this research, R-peak centered ensembles were generated and averaged data regard as the reference signal of each trial. Ambulatory ECGs in Fig. 3 are highly contaminated with motion artifacts (on the left side), but most of noise component are eliminated on the averaged signals (on the right side).

For the results shown in Table 1, our proposed method showed higher correlation with the reference signal. In some results presented better results than our algorithm, such as result from S1 using modified conventional method (‘*m*Con.’). However, stability which is based on variation of the results for the all results proves the proposed algorithm

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covers large range of movements for various subjects. The results 'Low Gaussian-Prop.' means cross correlation coefficient between observed ECGs and reference signals, because the algorithm detected the signals are Gaussian variables and returned original signals. These results can be regarded standard for 'Low Gaussian- '. Thus the results that are lower than this standard are explained that ECGs were distorted by the applied method such as 'Low Gaussian-Con.' of the subject 3. Also, there are the results that have high variation among the channels, such as 'Low Gaussian-Con.' of the subject 4. It is considered that the necessary components were eliminated during de-noising shown in Fig. 7, for instance.

It is not sufficient to compare the processing results with only one parameter. Therefore, it is needed to establish parameters which measure the degree of distortion.

In summary, we proposed motion artifact removal algorithm using the ICA that minimizes distortion. It is also expected to reduce processing rate by jumping over unnecessary processes. Moreover, the method which is based on short-term segmented dataset offers potential for real-time processing this algorithm.

V. CONCLUSION

In summary, proposed method successfully removed the motion artifacts in ambulatory ECGs without distortion. Furthermore, reconstructed ECGs processed by this method showed higher correlation with the estimated reference ECGs than the signals processed by other methods. Because the proposed algorithm jumps over unnecessary process, it is expected to reduce processing rate. In addition, the method which is based on short-term segmented (5 seconds) dataset offers possibility for real-time processing of ECG. Finally, the proposed algorithm has potential to be applied for long-term ECG monitoring in daily life.

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Modeling the Clinical Observation Space of Electronic Medical Record in Primary Care

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***Abstract*—We present a new model for structuring clinical data in primary care, denoted by the observation space. This model is intended to be used within Electronic Medical Record (EMR), and is designed to meet the requirements of clinical contexts and nuances that characterize primary care practices. While these contexts are generally captured with free-text descriptions, structuring them makes the use of EMR very attractive, since it opens many possibilities such as clinical data exchange and the design of Clinical Decision Support Systems. In partnership with practitioners, the results presented in this paper are being used to build clinical patterns.**

Keywords-Electronic medical record; clinical data modeling;

I. INTRODUCTION

Although the Electronic Medical Record (EMR) is clearly identified as one of the tool that may help manage the many primary care challenges such as population aging, its use is far to be generalised [1]. Many authors noted that the use of EMR is not systematic since there is no clear consensus on how clinical aspects of EMR should be processed [2]. While practitioners see that coding clinical data will limit necessary nuances required for describing the clinical context and argue to use free-text data for this purpose, managers see that coding clinical data is important for information gathering, searching and comparing as well as the possibility to use upstream Clinical Decision Support Systems (CDSS) [3].

We have initiated a research project in order to design an intelligent clinical module to deal with clinical aspects in primary care. Such a module may be part of any EMR, and will have the ability to address the needs of practitioners in their diagnosis process. We have started with the needs to diagnose and monitor chronic diseases. The project has four phases as follow: Phase1 deals with the capture of clinical data in primary care. Phase 2 deals with the design of aggregation and fusion of that clinical data in order to extract patterns. Phase 3 deals with the build of the reasoning capability. Finally, phase 4 deals with medical knowledge management. This paper presents some results obtained in phase 1 of that project, and dealing with the structure of the observation space.

In primary care, clinical information, denoted in this article by Primary Care Clinical Data (PCCD), may be classified in nine categories, namely symptoms, signs, review of systems, medications, labs, personal history, family history, style of life and demographic data [4]. In their study of the applicability of medical data standards in clinical research, Richesson and Krischer [5] concluded that there is still much work to be done since many gaps have been identified, especially in the area of physical exam: "There is a conspicuous lack of medical standards for the structuring of questions and case report form, particularly in the areas of physical exam, medical history, family history, and eligibility criteria". Interestingly, the major gaps concern directly structuring and standardizing PCCDs.

The present work investigates on how to structure some of the PCCD, especially those describing the clinical observation. In addition to the first classification of the PCCD in nine classes, it is possible to consider a further categorization following the approach recommended by Scheuermann [6] for treating diseases and diagnosis within an ontological point of view. The approach suggests that diseases may be considered as predispositions rooted in physical disorders in the organism and realized in pathological process. This conceptualization of diseases helps to divide PCCD in two main categories. On one hand, the observation space groups PCCD that describe the manifestation of the disease phenomenon, namely symptoms, signs and review of the systems. On the other hand, the predisposition space groups the remaining PCCD and describes pre-clinical and pre-conditions that make the disease follows a given course. This article will focus on the structuring of the observation space and propose a global model of it.

This paper is organized as follow. Section 2 introduces the PCCD's and will focus on the description of the observation space. Section 3 discusses how it is possible to structure it in order to capture clinical nuances and contexts. Section 4 presents results of the application of the observation space model to a real clinical case.

II. PRIMARY CARE CLINICAL DATA (PCCD)

PCCDs are categorized following their functional characteristics, independently of patient's health and disease diagnosis. It is possible to further categorize PCCDs in order to understand the clinical data structure in primary care. For this purpose, it is important to return to the pathophysiological basis of diseases [7]. Contemporary classification of human disease derives from observational correlation between pathological analysis and clinical syndromes, which makes diseases primarily described by symptoms and signs they cause.

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However, diseases are dispositions rooted in physical disorders in the organism and realized in pathological processes. The disorders are active and the organism as a complex system will use all required metabolic fluxes to recover the homeostasis. If a deregulation exceeds a given threshold or organisms fail to recover the homeostasis, a pathological process triggers and a disease course, which may vary widely between patients who have the same disease, starts [6].

A. Observation Space

The observation space is the clinical picture of a patient on a given point in time of a disease evolution.

The *observation space* contains the PCCDs symptoms, signs, and review of systems. It describes the condition of the patient's organism due to the effect of the disease. From this space, a practitioner should answer the question, *what is the clinical condition of the patient given these observations?* Theoretically, to construct the *observation space*, physicians are not required to know the diagnosis or the disease of the patient.

B. Predisposition space

The predisposition space represents all preclinical conditions of a patient that may variably influence the evolution of a disease course.

The predisposition space contains the PCCDs labs, demographic data, past medical history, present medical condition, family history, present medication, and style of life. It represents the preclinical conditions of a patient independently of any actual pathological process. The predispositions will condition any disease course. From this space, the practitioner should answer the question: *Given the information gathered from the predisposition space, what should be the clinical picture of the patient for a given pathology?* Many clinical researches concentrate on discovering relations between some predisposition space PCCD and disease severities.

This paper focuses on the structuring of the *observation space*.

III. Structuring Of The Observation Space

Due to the presence of symptoms, the *observation space* is subjective and contextual. It is, however, this space who introduces the major clinical nuances which require free-text description. The present work will focus on describing how data and information that constitute this space may be structured and modeled in taking into account appropriate medical knowledge and practices.

A. Symptom model

Symptoms are the kernel of the *observation space*. A symptom is a subjective evidence of a disease perceived by the patient. Psychological aspects have seldom evident effects on how patients perceive and report what they feel. It has been reported that patients that categorize themselves with a group of people that have a given illness will perceive concurrent symptoms relevant to that illness to be more severe [8]. This is a clear evidence of the subjectivity character of symptoms. They are also the main input of CDSS due to the fact that knowledge on diseases is described in terms of symptoms. Major CDSS, such as rule-based, model disease knowledge as causal relevance between symptoms and diseases, and symptoms are generally described by only their intensities [9]. Innocent [10], however, proposed a way to add temporal aspects to model the causal relevance between symptoms and diseases, and proposed rules such as: *Influenza always causes symptom fever in day one to day 3*.

Providing only few attributes to describe symptoms is far to be enough for practitioners who want to capture different clinical nuances and contexts. In a specialized literature, symptoms are described by many attributes.

Here are two examples of symptoms that need many attributes to be described:

"*Complains of intermittent severe pain in lower abdomen since the last three weeks".*

"*Severe pain in the upper abdomen for five days. Burning in nature especially occurs at night in bed".*

It is possible to categorize the clinical information of each symptom as illustrated in the following table:

TABLE I. Clinical Information Categories

Descriptors	Description1	Description2
Onset		-
Duration	3 weeks	5 days
Intensity	Severe	Severe
Location	Lower abdomen	Upper abdomen
Quality	-	Burning
Periodicity	Intermittent	-
Factors	-	Night in bed

We propose, in this work, to define symptoms with a set of attributes as follows:

Standard Symptom Qualifiers (SSQ) is defined to be a set of attributes that describe a symptom SSQ = {onset, duration, periodicity, intensity, quality, site, factors}.

The actual symptom model does not take into account influences other than those of the observed disease, such as associated symptoms, previous episodes, etc.

B. Sign model

A sign is an objective evidence of a disease perceptible to the physical examiner. Signs are findings resulting from the physical examination of the patient. This definition compared to that of symptoms doesn't allow to totally discriminating between these two concepts. The borders are fuzzy and there is an overlap. However, in order to understand the *observation space*, it is important to examine how signs information is present and what are their relations with symptoms. In the literature, signs are not always defined as a medical entity that may be analyzed independently of diseases. In this work, signs are classified in two main categories, which we may call respectively signs and symptom-signs.

A symptom-sign is a sign that is associated with a symptom and will fuse with it once evaluated.

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The fever symptom is an example. A patient may report a fever as symptom, and the physician will measure objectively the value of the fever. We say that the value of the temperature (fever sign) will fuse with the fever symptom, since the fever symptom will remain, and the value of its intensity will be changed by the taken temperature.

Definition: A sign is not related to a symptom.

Blood pressure is a good example of a sign. Signs by this definition are different than vital signs. Signs have generally an explicit and direct link to pathologies. They constitute for this purpose an objective description of the *observation space*.

In this work, we also propose that signs are characterised by the SSQ model. Thus, they are identified by their onset, duration, periodicity, intensity, quality, site and factors. In doing so, fusing signs with symptoms will be very obvious. The degree of objectivity that a sign may bring to a symptom will be discussed in another article.

C. Review of Systems (ROS)

The review of systems is a head-to-toe survey to screen for additional symptoms not related to the patient's main complaint. The information obtained from a ROS has its own weight to the final diagnosis. A typical ROS is composed of a set of symptoms classified by body systems or physiological functions and are symptoms that have no SSQ.

D. Observation space model

Figure 1 shows a general structure of the *observation space* model.

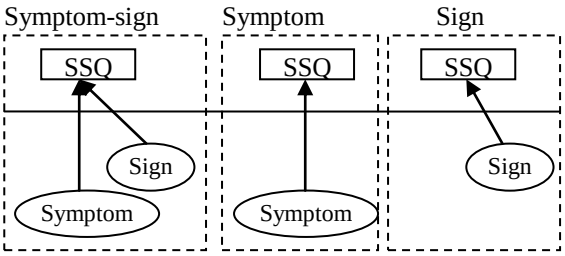

Figure 1. *Observation space* general structure

There are three main structures that form the *observation space*; Symptoms that do not possess signs, symptoms that possess signs (symptom-signs), and signs. Each structure has its SSQ.

IV. RESULTS

This section presents some results on the application of the *observation space* model to a real clinical situation. It will be used a clinical story of a 38 years old man with fatigue as chief complaint.

A. A clinical story example

This clinical sample story was extracted from [11].

1) Patient story

"*Mr. X, a 38-year-old homeless presented to a primary care clinic with severe, progressive fatigue of one month's duration; progressive weakness and shortness of breath while engaging in any kind of physical exertion and dizziness whenever he tried to get out of bed. Mr. X reported that he had not felt like eating for a month; whenever he ate something, he experienced severe abdominal pain. It usually occurred during the evening hours and was always triggered by eating.*

The patient had lost 20 pounds during the previous month, which he attributed to poor intake due to abdominal pain, anorexia, nausea, and fever. He reported having a mild, intermittent fever during the last month, particularly during the evening, which he attributed to fatigue".

2) Physical examination

Looking tired; Signs of pallor and jaundice. Brown coated tongue with no atrophy or inflammation.
Temperature: 100.4°F; blood pressure: 140/90
Cardiovascular system: bounding pulse, evidence of 3rd heart sound, no murmur.

Gastrointestinal system: abdomen: lower border is 1 inch down the costal margin; no liver tenderness. The spleen is 2 inches below the costal margin.

B. Discussion

The following table captures the clinical case described above using the *observation space* model. The observed symptoms and signs are listed in the rows. The SSQ attributes are listed in the columns. The ***Type*** columns in the table indicates which of the three types (symptom: Sym; Sign: Sig; Symptom-Sign: SS) the observation belongs to. The last column denoted symptom-sign gives the correspondent symptom or sign for a given symptom-sign observation. Indeed, in this example there are three symptom-signs, namely (fatigue-tired), (Pain-Abdomen) and (Fever, Jaundice).

The value of each SSQ attribute for symptoms and signs in the table are not dealt with in this article. For symptoms, the values such as described in the patient story are used. For signs, a +1 value in the intensity means that there is evidence that the sign is observed. Moreover, how symptom-sign SSQ values may be merged is not dealt with in this article.

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TABLE II. CLINICAL DATA CAPTURED USING THE OBSERVATION SPACE MODEL

SSQ	Onset	Duration	Period.	Intensity	Quality	Site	Factors	Type	Symptom -sign
Symptom									
Fatigue		1 month		Severe	progressive			Symp	Tired
Weakness				Severe	progressive			Symp	
Shortness of breath				severe			While engaging in physical exertion	Symp	X
Dizziness							Get out of bed	Symp	X
Pain	When eating	1 month	Evening hours	severe		abdomen		Symp	Abdomen
Weight lost		Previous months		20 pounds				Symp	X
Fever		Last months		mild	intermittent		During evenings	Symp	Jaundice
Signs									
Tired				+1				SS	Fatigue
Pallor				+1				Sign	X
Jaundice				+1				SS	Fever
coated tongue				+1	Brown		no atrophy or inflammation	Sign	X
Temperature				100.4°F				Sign	X
Blood press.				140/90				Sign	X
Cardiac auscultation					Evidence	3rd	No murmur	Sign	X
Hepatomegaly				1 inch	Down		Lower	SS	Pain

V. CONCLUSION AND FUTURE WORK

This paper presented a pathway on how to structure *the observation space* of PCCD. Despite the existence of many standards for medical data, it has been shown previously that PCCD is poorly represented by them, and this contribution is primarily intended to fill some of the associated gaps.

However, the most innovative aspect in this article concerns signs and their characterizations. Signs are described only in a very specialized literature and are complex to structure. The use of the SSQ model will help represent them and formalize their relations with symptoms.

Finally, the next steps are to use the same methodology to structure *the predisposition space*, as well as to describe how it is possible to use aggregation and fusion technics to extract patterns from PCCD. Results will be presented in another contribution.

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Modelling Patient Medication Usage in Secondary Care Research Systems

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***Abstract*—Medication usage and administration are key areas for standardisation and interoperability in specialty-agnostic, secondary care research systems. Based on the requirements of four medical research specialty areas in Central England, we developed a medication record model, for the purpose of keeping track of medications the patients are taking, both from a patient-care and future research-participation perspectives. In this paper, we present the model that is flexible enough to capture the core requirements of all research specialty areas, but also extensible to include more specific, non-generic requirements. This work supports the electronic health data standardisation and interoperability efforts within the secondary care domain.**

Keywords-standardisation; electronic health record; patient medication

I. INTRODUCTION

The interoperability and standardisation of medical information in secondary care is an ongoing challenge, also reflected in secondary care research, where information is collected, processed, queried and exchanged for clinical studies within various specialty research areas. A recent report [1] highlighted the disparity between the primary and secondary care sectors, in terms of the systematic application of information technology in healthcare. In the eight countries studied, secondary care adoption of health information technology and health information exchange was behind that of primary care. This was particularly the case in England.

Our work aims to find solutions towards the increased interoperability and standardisation of information in secondary care research. One specific area focuses on patient medication recording, that is, the recording of medications administered to patients by healthcare professionals, and also other medications self-reported by the patients. Medication usage information is necessary for the clinical care of the patient—the knowledge of treatments for particular conditions; for safety—the interactions of drugs; and for including or excluding patients from participation in clinical studies.

In this paper, we present a patient medication model, developed to capture the requirements of four research specialty research areas: asthma, bronchiectasis, chronic obstructive pulmonary disease (COPD) and early arthritis. While medication recording is common to all four, the level of detail captured varies. The proposed model captures the links between medication, patient and healthcare professional; and it also fits within the extensible **C**omprehensive **U**nified **Re**search (CURe) framework for developing secondary care research systems. Our model builds on existing efforts by the English National Health Service (NHS), such as the dictionary of medicine and devices (dm+d) [2], prescribing model [3] and dose syntax model [4]. Our medication model addresses a specific context—monitoring medication usage by patients—and differs from the contexts addressed by e-prescription, medication adherence and management, which are the focus of many of the research work on the subject of medication. Although the model describes the set of medication data elements useful for secondary care research registries, we will illustrate the data items recorded in the CURe applications for the four specialty areas.

II. RELATED WORK

Our work currently applies to the Central England region and as such, we have looked into the models used by the NHS, the main provider of healthcare. We have also considered relevant work in the literature regarding the medication datasets and their standardisation.

A. Prescribing and Dose Syntax Models

In July 2012, the NHS adopted the dm+d as the standard dictionary of medicines licensed in the United Kingdom [5]. The dm+d is the basis for all medicine and device codes forming the SNOMED CT UK Drug Extension, following the need to integrate dm+d with the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), the NHS strategic clinical terminology solution, necessary for the interoperability of electronic health records [6,7]. Dose-based prescribing is normal practice in secondary care [3]. On paper, this combines the generic drug name (virtual therapeutic moiety, VTM), dose, route and frequency, for example: Paracetamol (drug name), 500 mg (dose) — oral (route) — qds

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(frequency, Latin abbreviation for four times a day). In electronic prescribing systems, the dm+d implementation guide suggests using VTM concepts to prescribe generically, while taking into account some exceptions and the prescribing rules [3]. The dm+d is structured around five key components, ranging from a generic drug (VTM, e.g. Atenolol) to an actual medicinal product pack (AMPP), which is drug manufactured by a specific supplier with the drug having form and strength values, e.g. Atenolol 100 mg tablets (Alpharma) x 28 tablet.

Although the dm+d provides a standard description and electronic identifier for medicines, there is no standard structure for representing dosage instructions, for example, "take two tablets three times a day". Without standardisation, this information can only be sent and stored electronically using free text. Work is ongoing to develop standard dosage syntax so that this information can be sent in a standard coded format, which will enable diverse clinical systems to manipulate the data transferred, for example calculate a dose or quantity. This will also improve patient safety by standardising the way that dosage instructions are communicated and reducing the potential for misinterpretation. The dosage syntax model was developed by the NHS Information Authority in conjunction with the international health standards organisation, HL7 [8, 9], with a cut down version of the dose syntax model for e-prescribing [10].

B. *Medication Datasets*

A number of related projects on electronic health records have defined datasets for medication, with different usage to supporting research. MyMedicationList [11] is a prototype application that helps users to manage their personal medication record. The medication record is based on a document model that captures the medication name, interval, quantity, frequency, patient instruction, indication, available generic substitute of a branded drug, prescriber and supplier.

The Continuity of Care Record (CCR) schema is a core dataset of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare [12]. It is one of suite of standards for health information systems used in the United States, developed to organise and make transportable a set of basic healthcare information that can be accessed by medical practitioners and patients. The CCR schema defines a medication object to describe a patient's current medications. Similarly, openEHR [13] develops open specifications for health information systems. For medication management, openEHR has identified data groups relating to medication order or administration [14].

The above works have informed our medication model, developed to capture routine medication usage information useful for research studies. The following sections describe how our model captures user requirements, and its implementation within CURe.

III. SCOPE AND CONTEXT OF WORK

A. *CURe Framework*

The CURe framework has been developed as part of the design and development of a research system to be used for clinical research databases and clinical studies across multiple research specialty areas in secondary care. The extensible framework adopts a modular approach to solve some of the problems of localised clinical research systems, where a system is built for a single clinical unit to solve immediate localised problems, without considering the possibility of similar requirements from other units or research specialty areas, irrespective of location [15]. User requirements are used to build generic models of common data elements between specialty areas. By using an extensible design pattern, the common elements create scalable object oriented taxonomies designed around generic and non-generic data objects. Our work also includes an adaptation and implementation of technical standards, especially in data recording, which facilitates interoperability across research systems for different specialty areas.

B. *User Requirements*

The knowledge elicitation process, aided by the participatory approach with the domain experts, led to the gathering of the medication recording needs of users in the four research specialty areas. The common data items include generic drug name; drug category; active ingredient (name, strength); dosage (value, unit); start and stop dates; frequency. Other data items include brand name; and route of administration.

IV. MEDICATION MODEL

Based on the user requirements and the medication standardisation decisions, we present the core medication model, as well as aspects of the extended model that cater for some of the additional requirements within CURe.

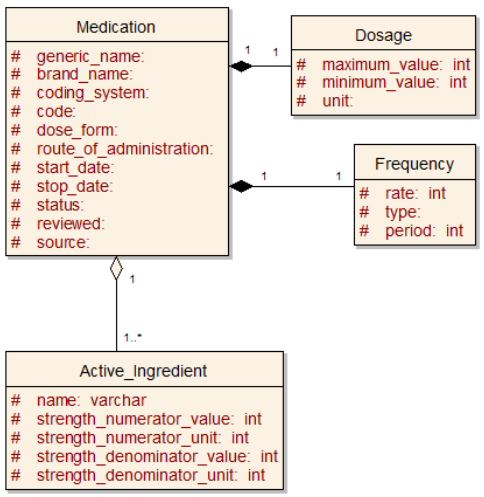

Figure 1. Medication entity model

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The entity model (Figure 1) presents the components of the medication model, specifically highlighting their relationships from an architectural design perspective.

A. Medication Data Group

Medication-related data elements are presented in Table 1. The last three rows are attributes relating to the links among medication, patient and healthcare professional, that we model in CURe for validation and auditing purposes. The second column of Table 1 describes each data element and gives examples of what data values we have used in CURe. The generic drug name is a key element in this group. In CURe, we adopted the NHS dm+d VTM for the standardised generic drug names as used in the UK. Similarly, to make the drug information interoperable, we are using SNOMED CT codes to uniquely identify each generic drug. This has an advantage over the British National Formulary [16], which, although widely used by healthcare professionals for prescribing, it does not have unique codes for drugs. For users who want to specify the brand name, we are using the SNOMED CT Trade Family concepts. For data values, such as units of measure, frequency and route of administration, we have used dm+d editorial policy guidance and international standards where applicable.

Table 1. Medication model.

Attribute		Description/Usage in CURe
Generic drug name		dm+d VTM or VMPs with no VTM parent
Brand name		SNOMED CT Trade family
Coding System		SNOMED CT
Code		SNOMED CT Term ID
Active Ingredient (1..M)	Name	e.g. Amoxicillin
	Strength Numerator Value	500 in 500mg (strength is of an available product)
	Strength Numerator Unit	mg in 500mg
	Strength Denominator Value	e.g. 5 in "Amoxicillin - 125mg/5ml oral suspension"
	Strength Denominator Unit	e.g. ml in "Amoxicillin - 125mg/5ml oral suspension"
Dose Form		e.g. tablet, capsule
Dosage	Minimum Dose Value	Quantity of medication to be taken or administered at one time
	Maximum Dose Value	If only one recommended dose, use the maximum dose.
	Dose Unit	"mg" in 60 mg
Frequency		e.g. once a day, hourly
Route of Administration		e.g. oral route
Start date		Date the medication is started
Stop date		Date the medication is stopped
Status		Medication continued or stopped
Medication reviewed		Medication check at a patient visit
Source		Source of the medication information.

B. Medication Record Examples

Based on the above model, we now show how the two example records are represented. Example 1 (Table 2) shows a medication where the application user is interested in recording the dosage, rather than the strength of the product. Example 2 (Table 3) is a combination drug, where the two active ingredients are important for the medication recording.

Table 2. Example 1: An Arthritis patient using Naproxen, a maximum of 1 gram daily.

Attribute		Value
Generic drug name		Naproxen
Coding System		SNOMED CT
Code		DescriptionID (20444015)
Dose Form		Tablet
Dosage	Maximum Dose Value	1
	Dose Unit	g
Frequency		1 time in 1 day (daily)
Route of Administration		Oral
Start date		15/06/2010
Stop date		
Status		Ongoing
Medication reviewed		Yes
Source		Other CURe specialty area prescription (verified)

Table 3. Example 2: A COPD patient is on Seretide, a combination drug of Fluticasone + Salmeterol, 500 micrograms/50 micrograms, 1 puff, twice a day.

Attribute		Value
Generic drug name		Fluticasone + Salmeterol
Brand name		Seretide
Coding System		SNOMED CT
Code		DescriptionID (2576281011)
Active Ingredient [1]	Name	Fluticasone
	Strength Numerator Value	500
	Strength Numerator Unit	microgram
Active Ingredient [2]	Name	Salmeterol
	Strength Numerator Value	50
	Strength Numerator Unit	microgram
Dose Form		Nebuliser liquid
Dosage	Maximum Dose Value	1
	Dose Unit	Dose
Frequency		2 times in 1 day (twice a day)
Route of Administration		Inhalation
Start date		01/01/2005
Stop date		
Status		Ongoing
Medication reviewed		Yes
Source		Current CURe specialty area prescription (verified)

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V. DISCUSSION

A. Interoperability

The medication model presented caters for the major aspects of interoperability in terms of drug names, coding system and common dosage instructions. While in this model, active ingredient strength and dosage use a single unit, some specialties have indicated the need for multiple units, or conversion units, e.g. for inhaled steroids. References to standard conversions can be made available to users on the user interface, instead of representing them in the medication model.

B. Recording of unlicensed drugs

The medication information recorded concern prescribable licensed drugs. However, some domain experts have requested the recording of clinical trial drugs or unlicensed drugs. The medication model presented is not for an e-prescribing system. As such, it does not limit the recording of only licensed drugs. However, to differentiate between licensed and unlicensed drugs, the model could incorporate a data element to indicate this, hence preserving the meaning of the information recorded. Moreover, this requirement will impact on the standardised terminology for drugs and ensuring that both licensed and unlicensed drugs are present.

VI. CONCLUSIONS AND FUTURE WORK

In this paper, we presented a medication model to record the medication usage of patients in secondary care. The need for such a model arose from the lack of integration between healthcare systems, especially those developed for research. The medication model has been developed to allow patient medication information to be recorded and queried across multiple medical research specialty areas. Existing drug dictionaries and datasets have been developed mainly to standardise electronic prescription and medication order and management. We have adopted some of the relevant elements to develop a medication model to support secondary care research.

In future work, we will be investigating the categorisation of drugs by experts to facilitate the selection of drugs. This is aimed towards providing an agreed shortlist of medications based on each specialty area, or other grouping, such as inhalers, to enable users to select drugs from the shortlist rather from the list of all drugs. In the CURe application, we are also working on enabling users in different research specialty areas to view medications recorded across specialty areas, for the safety and care of the patients, while respecting the ethical and authorisation measures in place.

ACKNOWLEDGMENT

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The Bravehealth Software Architecture for the Monitoring of Patients Affected by CVD

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***Abstract* — The Bravehealth project is a large scale Integrated Project (IP) launched in the 7th Framework Programme. Bravehealth proposes a patient-centric vision to Cardio Vascular Disease (CVD) management and treatment, providing people already diagnosed as subjects at risk with a sound solution for continuous and remote monitoring and real time prevention of malignant events. Mainly, this paper describes the BVH Software Architecture. The role and the rationale behind the various system components is widely explained. The set of adopted technological solutions is presented and, finally, it is shown how the architecture succeeds in achieving a flexible, scalable and efficient system able to cope with many different medical scenarios.**

Keywords-Cardio Vascular Disease; Architecture; DSS; Data Mining.

I. INTRODUCTION

E-Health is largely recognized (see for instance [4], [5], [7] and [9]) as one of the most promising and powerful solutions to address Cardio Vascular Disease (CVD), being able to ensure an increase of the quality of care delivered and of the quality of life of patients, while decreasing overall healthcare costs. Nevertheless, in spite of these widely agreed and demonstrated benefits, the technical maturity of the majority of the solutions implemented is poor, the concrete use of e-Health services for supporting remote management of CVD is still very limited, there is a lack of a standardized approach, the market remains highly fragmented and focused on specific scenarios. Moreover, even though Decision Support Systems (DSS) can be a key added-value of the e-health (see for instance [1] and [2]). no convincing and standardized approaches for such an issue have been developed yet, especially regarding the use of Data Mining [3] techniques, applied to data related to patients affected by CVDs.

The Bravehealth (BVH) project [6] aims at coping with these problems introducing an efficient, flexible and scalable patient-centric system including a Software Architecture suitable for being applied to a plenty of different scenarios. The BVH focus is on CVD, but the designed Software Architecture (based on standard protocols and languages) and the Decision Support System, which is a key element of such an architecture, are so flexible that they can be reused for different diseases and for different typologies of patients.

The main objective of the proposed architecture is to enable the cooperation among the *Patients* and the *Medical Supervisors* (e.g., physicians, nurses, etc.) following the Patients, finalized at an early diagnosis and prevention of the occurrence of malignant events or complications. Another ancillary aspect is the capability of providing the Medical Supervisors with suggestions concerning the most appropriate provisions to be taken in case the system detects anomalies in the Patient health status. This will be obtained thanks to a synergistic approach of a compact wearable device with the capability of monitoring several clinic parameters in order to perform a timely diagnosis of patient's conditions, with advanced data fusion techniques implemented on it and with innovative algorithms and solutions for the Decision Support System. The correct way of working must be continuously monitored by appropriate technicians, referred to as *Technical Supervisors*.

This paper is organized as follows. Section II introduces the main components of the proposed architecture, along with a brief description of each of them. Section III details the main macro-tasks considered in the Bravehealth project and their relation with the architecture, with particular focus with the Decision Support System. Finally, conclusions are drawn in Section IV.

II. BVH MAIN COMPONENTS

The main actors and components of the BVH system are shown in Figure 1, using UML [8] formalism. The BVH main components are: (i) the *Wearable Unit (WU)*, (ii) the *Patient Gateway (PG)*, (iii) the *Remote Server (RS)*, (iv) the *IPTV*, (v) the *Patient Client (PaC)*, (vi) the *Medical Supervisor Client* and (vii) the *Technical Supervisor Client*.

The *Wearable Unit (WU)* is the component the Patient "wears" and includes the sensors responsible for sensing Patient's physiological data, as well as the functionalities for collecting the relevant measures and for transmitting them towards the Patient Gateway (PG). Such functionalities can be properly configured by the Remote Server (RS) (in cooperation with the PG). Then, the WU also includes the functionalities for actuating the received configuration information. Physiological data transmission towards the PG

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takes place either periodically, following the instructions deduced from the configuration information, or after properly selected triggering events again deduced from the configuration information, or on-demand following specific requests. Finally, the WU interfaces the Patient through an ad hoc interface which is intended to provide the patient with very simple status messages such as the WU battery charging status or possible malfunctioning/misplacing (more elaborated information is sent to the Patient by the HMI Component embedded in the PG, as detailed later).

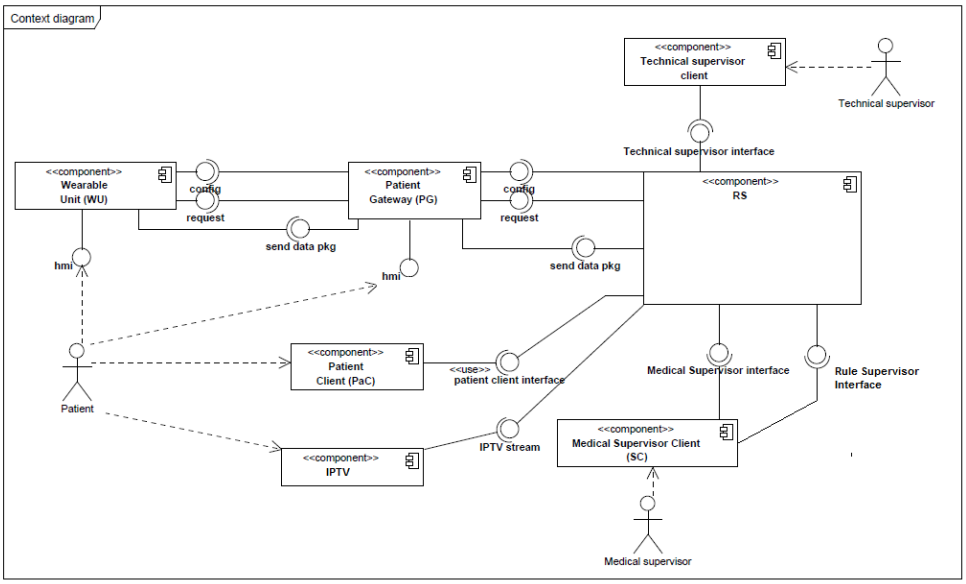

Figure 1. Main components of the BVH architecture

The *Patient Gateway (PG)* proposed Software Architecture is shown in Figure 2, using UML formalism. The PG is the Component which represents the mean by which the information data flow from the WUs to the RS and vice versa. Moreover, the PG is devoted to perform a preliminary analysis on raw data (physiological and context) collected from the WU, to store data into a local memory cache and to forward them (both raw and elaborated) to the RS. The above-mentioned preliminary analysis makes use of Data Processing and Decision Support capabilities running at the PG finalized at deducing elaborated information from raw data collected by the WU to be exploited by the RS Decision Support System and at detecting, in a fast way, anomalies with respect to the regular Patient behavior. The PG is configured (in terms of scheduled activities) by the RS. The PG also receives from the RS the configuration for the WU: this configuration could be modified by the PG on the basis of some internal elaboration and then forwarded to the WU. The PG can request specific data from the WU. Finally, the PG is able to provide the Patient with information about the status of his health, as well as specific instructions determined by the Medical and/or the Technical Supervisors.

The *Remote Server (RS)* proposed Software Architecture is shown in Figure 3, using UML formalism. The RS is the core architectural component of the BVH system and contains most of its intelligence. The RS performs the complex algorithms of the Decision Support System (DSS) component, stores data (physiological and context data, both raw and elaborated) collected from all the PGs (related to all patients) with which it is connected and provides the front end logic of the interfaces with the BVH actors (Patients, Medical supervisors and Technical supervisors). The RS is in charge of computing (automatically or by means of the intervention of Physicians/Technicians) the most appropriate configurations for the PGs and the WUs. Such configurations, among other information, include the scheduling of the activities to be performed by the WUs and by the PGs. The RS can request data stored into the PGs and/or the WUs (raw or elaborated context and physiological data). The RS provides the front end logic to the users' client components (*Medical Supervisor Client* (MSC), *Technical Supervisor Client* (TSC), *Patient Client* (PaC) and *IPTV*) through the set of exposed interfaces, illustrated in Figure 1.

The *IPTV* is a Component which is used by the Patient in order to interface with the BVH system: thanks to it, the Patient could visualize the status of his health, as well as a list of specific instructions and/or high resolution videos.

The *Patient Client (PaC)* is a Component which is used by the Patient in order to interface with the BVH system. Through this interface, the Patient is able to visualize the status of his health, as well as a list of specific instructions and/or low resolution videos.

The *Medical Supervisor Client* is the Component which is used by the Medical Supervisors in order to interface with the BVH system. The Medical Supervisors could use this component (i) to access (including insert, modify or delete) configuration or sensor data of a particular Patient, (ii) to manage notifications/suggestions produced by the BVH DSS, (iii) to access all patient history.

The *Technical Supervisor Client* is the Component which is used by the Technical Supervisors in order to interface the BVH system. A Technical Supervisor could use this component to monitor and to modify the status of the PGs

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and of the WUs or the patients' data and to apply diagnostic operations in order to correct possible malfunctions.

III. BVH MACRO-TASKS DESCRIPTION

In order to facilitate the understanding of the rationale behind the proposed Software Architecture, the description of the BVH Components appearing in Figures 1-3 will be performed with reference to five specific *BVH Macro-tasks*. A BVH Macro-task includes all the procedures which aim at the same high level objective.

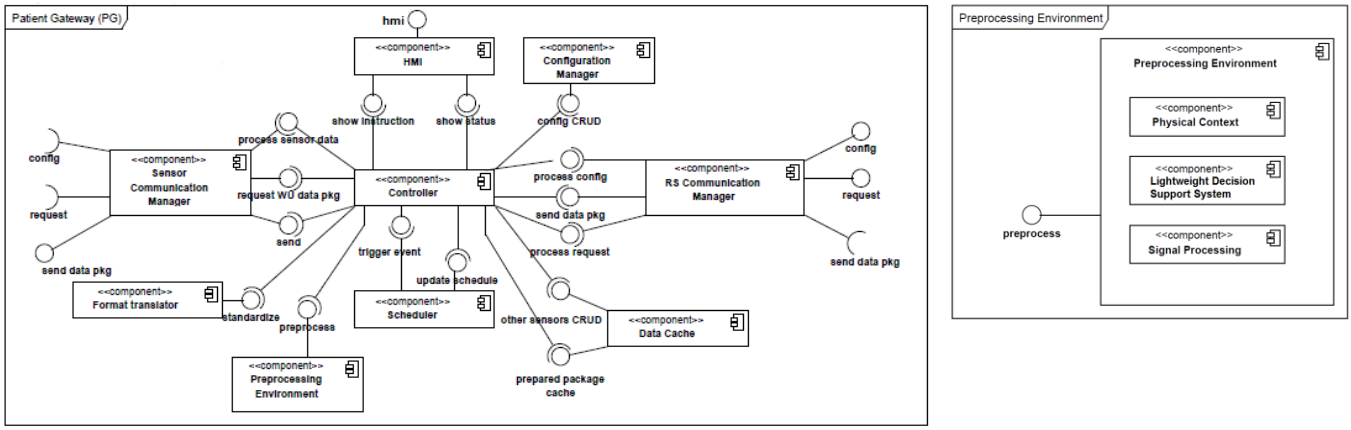

Figure 2. Patient Gateway (PG) Software Architecture

A. PG and RS orchestration

This macro-task deals with the orchestration of the PG and RS Components. The main components involved in this macro-task are, at the PG side, the PG Controller, whilst, at the RS side, in consideration of the complexity of the involved tasks, in order to get a real-time processing speed, the orchestration task is distributed among the RS Gateway Controller and the RS Patient Configuration Manager, involved in the management of the Sensor Data and of the Configuration Data, respectively. The above-mentioned components operate according to a flexible logic guaranteeing a high degree of reconfiguration and, in particular, assuring the possibility to replace, in a natural way, the current WUs/PGs with more advanced ones, as well as to add/remove/replace storage, pre-processing, decision support system, configuration and interfacing capabilities.

The *PG Controller* is devoted to orchestrate all the PG components in order to execute the whole logic of the PG. The PG Controller is triggered by events coming from the PG Scheduler: the latter is updated by the former and includes the scheduling of the events involving the PG.

The *RS Gateway Controller* is in charge of the whole logic related to the communication with the PG and the management of the Sensor Data, which include both the raw data produced by the WU sensors and transmitted by the WU to the RSs through the PGs, and the elaborated data which are the output of the pre-processing of the above-mentioned raw data performed at the PGs and/or at the RS.

The *RS Patient Configuration Manager* is in charge of the management of the Configuration Data, i.e. the data relevant to PG and WU configurations. In particular, the RS Patient Configuration Manager is in charge of managing the configurations of the PGs and of the WUs on the basis of Patient information (e.g., status, case history, medical protocols, the output of the DSS, etc.) and of physicians' or technicians' decisions. Moreover, the RS Patient Configuration Manager is the Component of the RS in charge of performing the whole application logic related to the management of the Patient Data, which include the patient personal information, as well as the data relevant to the patient status validated by medical diagnoses.

B. Flow and Management of Sensor Data and of Configuration Data

This macro-task deals with (i) the flow of the Sensor Data collected by the sensors (the ones embedded in the WUs, as well as other kind of sensors such as environment sensors) to the PGs (where they can be subject to formatting and preprocessing) and eventually to the RS, (ii) the flow of Configuration Data (for PG/WU configuration) from the RS to the PGs and, eventually to the WUs. Each WU is configured by the RS (with the possible cooperation of the PG) to send, either periodically, or whenever events occur, patient specific information (e.g., physiological data) to the PG. In addition, a PG could also request to a WU on-demand data or other types of information.

The *PG Sensor Communication Manager* is in charge of interacting with the WU and/or with other kinds of sensors in order (i) to receive Sensor Data and (ii) to send either Configuration Data or data requests to the WU. In particular, such component has to interwork with the communication channel (e.g., Bluetooth) which is used for the data exchange between WUs and PGs.

The *PG Format Translator* is a Component able to translate the Sensor Data collected by the sensors, which are raw data, into a standard format suitable for the PG Preprocessing Environment (see next section).

The *PG Data Cache* stores all Patient related data (measurements, scheduling information, status, configuration, etc.), i.e., the raw ones, the ones formatted by

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the Format Translator component and the ones elaborated by the PG Preprocessing Environment.

The *PG RS Communication Manager* (PG side) and the *RS Gateway Controller* (RS side) interwork with the communication channel (e.g., UMTS) which is used for the data exchange between PGs and RS. In particular, these components manage the sending of Sensor Data (which could include both raw data coming from the WU and/or data formatted by the PG Format Translator and/or data elaborated by the PG Preprocessing Environment) from the PG to the RS, as well as of Configuration Data in the opposite direction.

Aiming at enhancing RS performances, two main database components with associated database management (updating, adding, removal) logic have been foreseen at the RS, namely the RS Sensor Data Management System and the RS User Management System storing the Sensor Data and the Configuration/Patient data, respectively; these two databases are managed by the RS Gateway Controller and by the RS Patient Configuration Manager, respectively.

The *RS Sensor Data Management System* stores all Sensor Data, both the ones directly arriving at the RS from the PGs and the ones resulting from elaborations of these data performed by the RS DSS and/or the RS Preprocessing Environment. RS components such as DSS, Preprocessing Environment, Patient Service, Medical Supervisor FE and Gateway Controller could use these data through the *DATA CRUDS* interface.

The *RS User Management System* stores all Configuration Data and Patient Data (these two kinds of data, being strictly related since PG and WU configurations are tailored to the associated patient, are stored in the same database component). The RS Medical/Technical Supervisor FE, the RS Supervisor Management System and the RS Patient Configuration Manager could use/update these data through the *Patient Record CRUDS* interface. Moreover, the RS User Management System has the key role of interworking with the Hospital Information System (HIS), in order to extract information relevant to enrich the Patient Data.

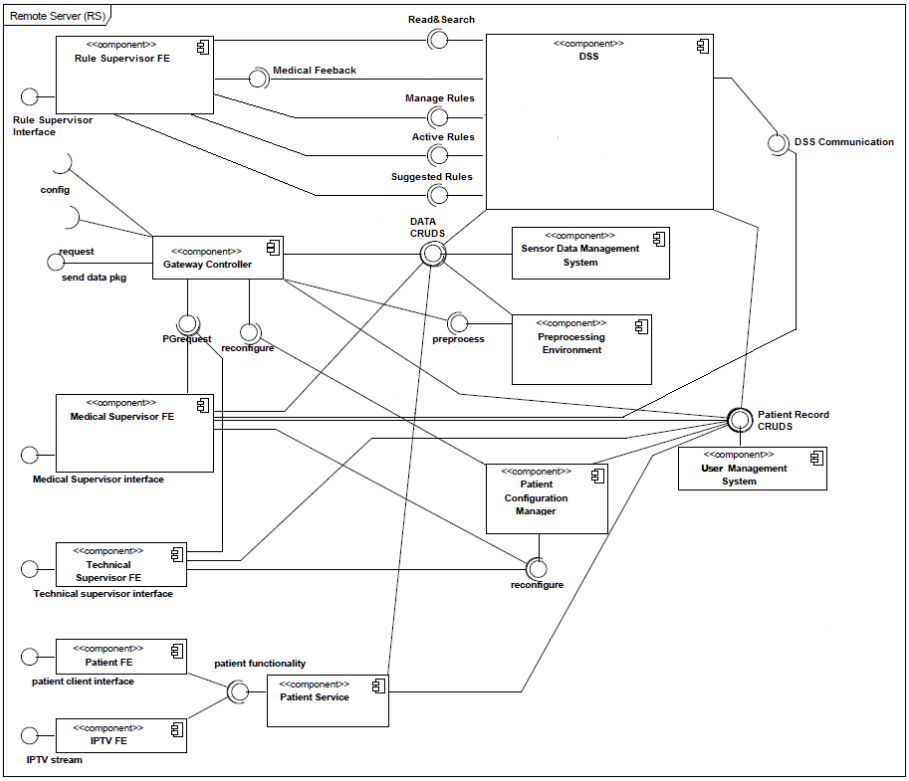

Figure 3. Remote Server (RS) Software Architecture

C. *Data Processing and Decision Support at the PG*

A key feature of the BVH architecture is the fact that some light processing of Sensor Data already takes place at the PG, whilst an heavy processing of Sensor Data is demanded to the RS. This issue adds many degrees of flexibility to the whole system allowing to perform the most urgent elaborations close to the patient, with evident advantages in terms of privacy/security, decoupling from both possible PG-RS communication link and RS server problems, saving PG-RS communication channel capacity, etc. The PG processing in question is performed within the *PG Preprocessing Environment* component, in turn, including its subcomponents: (i) the *PG Signal Processing*, (ii) the *PG Physical Context* and (iii) the *PG Lightweight Decision Support System*.

The *PG Signal Processing* includes algorithms for filtering and processing the signals coming from the WU, e.g., in order to remove noise and compute a set of ECG descriptors (or features), e.g., QRS-T-Angle [10], QT-

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dispersion and so on. These descriptors are used for measuring the distances among different electrocardiograms with the aim of detecting anomalies, detecting and segmenting heart beat and supporting physician's diagnosis.

The *PG Physical Context* includes algorithms that, on the basis of the signals coming from the WU and/or from other possible sensors, extract context information (e.g., information about the activity, the location, the environment related to a certain patient): such information will be made available by computing a family of physical context factors (e.g., location of the patient, etc.). These factors will be made available to other data processing modules (e.g., the Lightweight Decision Support System described below) for further information extraction procedures.

The *PG Lightweight Decision Support System* analyses the Sensor Data available at the Patient Gateway (raw data coming from the WU, ECG descriptors and other physiological parameters/context factors coming from the PG Preprocessing Environment) with the aim of identifying specific patient profiles and abnormal behaviors. This analysis is performed by using unsupervised machine learning algorithms (e.g., data clustering) with the aim of identifying patterns that are typical of a given patient. In turn, these patterns are used to detect anomalies with respect to the regular behavior of the specific patient.

D. Data Processing and Decision Support at the RS

The *RS Preprocessing Environment* includes Signal Processing and Physical Context functionalities, whose rationale is similar as the corresponding ones at the PG.

The *RS Decision Support System (DSS)* (see Figure 4), following the on-line application of appropriate rules to the Sensor, Configuration and Patient Data, provides the Medical Supervisors with Notifications and Suggestions. The rules which are used for deriving notifications and suggestions are stored in the database component referred to as *Medical Knowledgebase Management System (MKMS)*, also providing the associated database management (updating, adding, removal) logic. Such rules are managed by the Medical Supervisors authorized to manage the DSS, through the *Rule Supervisor FE*. In particular, as shown in Figure 4, the DSS component consists of the following subcomponents: (i) the *Notification Rules Engine*, (ii) the *Data Mining*, and (iii) the *Suggestion Rules Engine*.

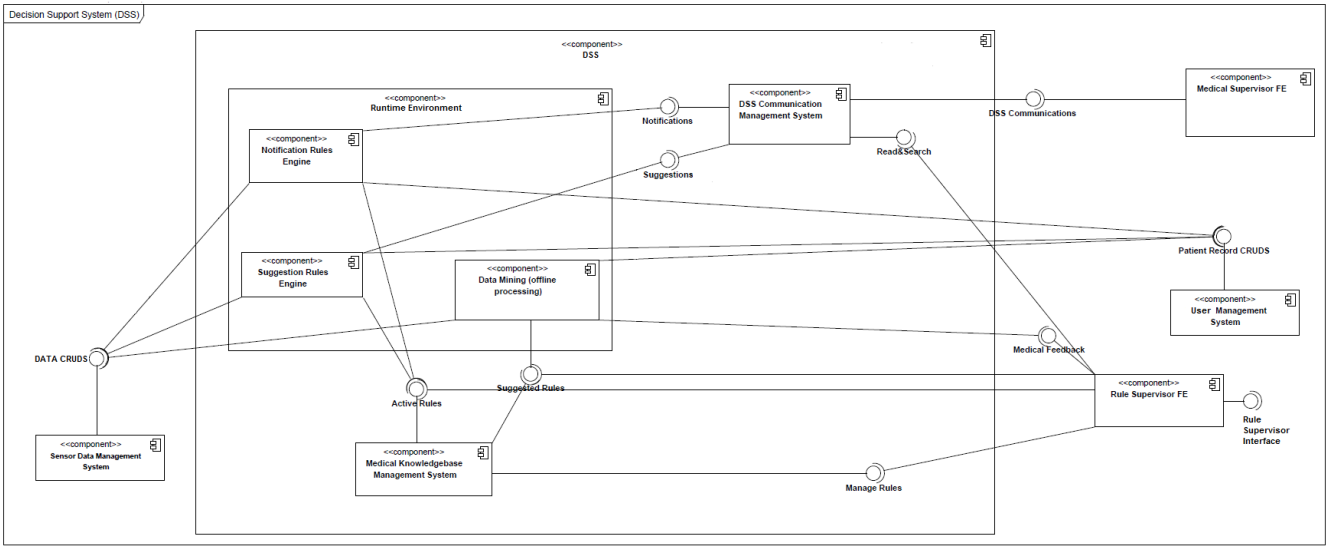

Figure 4. RS Decision Support System (DSS)

The *Notification Rules Engine* is the engine that interprets the logic rules defined on the basis of medical protocols and standard procedures adopted by physicians. These rules are directly uploaded by the Medical Supervisors in the MKMS, where they are labeled as "*Active Standard Rules*". The Notification Rules Engine *on-line* applies the Active Standard Rules to both the Sensor Data coming from the RS Sensor Data Management System and to the Configuration/Patient Data coming from the RS User Management System. Following the application of each rule, the Notification Rules Engine takes a decision in the form of a "notification" which is sent to the Medical Supervisors, via the DSS Communication Management System.

The *Data Mining* is the core Component of the DSS. It analyses (through an *off-line* processing, but continuously in progress during the BVH system operation) the available historical data (i.e. the Sensors Data stored in the RS Sensor Data Management System and the Configuration/Patient Data stored in the User Management System) with the aim of identifying correlations, regularities and patterns that represent the information extracted from data. The analysis is performed through both unsupervised (e.g., data clustering) and supervised (e.g., data classification and regression, pattern recognition) machine learning algorithms in order to identify correlations, regularities and patterns in the data. This information is used to infer new rules which are stored in the MKMS being initially labeled as "*Suggested Inferred Rules*". Then, following the approval from a Medical Supervisor authorized to manage the DSS (performed by means of the *Rule Supervisor Front End (FE)*), each rule can be labeled as "Active Inferred Rule" and can be interpreted and used by the Suggestion Rules Engine.

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The *Suggestion Rules Engine* is the rule engine that interprets the Active Inferred Rules derived by the machine learning algorithms running in the Data Mining module. The Suggestion Rules Engine *on-line* applies the Active Inferred Rules to both the Sensor Data coming from the RS Sensor Data Management System and to the Patient/Configuration Data coming from the RS User Management System. Following the application of each rule, the Suggestion Rules Engine takes a decision in the form of a "suggestion" which is sent to the DSS Communication Management System and, eventually, to the Medical Supervisors.

E. User Interface

In the BVH system there are three kinds of users, namely the Patients, the Medical Supervisors and the Technical Supervisors. For each kind of user a specific interface is foreseen. The *Medical Supervisors* access the BVH system through the Medical Supervisor Client. They could use this Component to manage (insert, modify or delete), through the Medical Supervisor FE, specific Configuration, Patient or Sensor Data, as well as to manage, through the Rule Supervisor FE, the notifications/suggestions produced by the DSS. The *Patients* can access the BVH system both at the PG, via the PG HMI (Human Machine Interface) and at RS, via the Patient Client (PaC) and/or the IPTV. The PG HMI is a simple, usable and friendly interface which can display physicians-filtered instructions and/or proper information stored in the PG Data Cache Instead, the RS Patient Service is delegated to provide a "device-independent" RS HMI functionality to the Patients which can access the Sensor Data and the Configuration/Patient Data stored in the RS databases, via both their television set (via the IPTV and IPTV FE Components) and/or via their personal computers/smartphones (via the Patient Client (PaC) and Patient FE Components). The *Technical Supervisors* access the BVH system through the Technical Supervisor Client and the Technical Supervisor FE. They could use this Component to monitor and modify the status of the RS, the PGs and the WUs and to apply remote diagnostic operations.

IV. CONCLUSION AND FUTURE WORK

The proposed BVH architecture includes a set of consistent technological solutions which, considered altogether, contribute for achieving a flexible, scalable and efficient system able to cope with a plenty of different scenarios. The most meaningful of such solutions are: (i) the PG and RS orchestration, thanks to the adoption of general purpose, event-driven controllers, is not customized for a specific scenario, but is conceived for allowing, in a natural way, the adding/removing/upgrading of the various system components; (ii) the decoupling of the Sensor Data handling from the Patient and Configuration Data handling allows a faster and more flexible data management; (iii) the use of a two-scale Decision Support including a *light* processing of Sensor Data taking place at the PG, and a more *heavy* processing of Sensor Data demanded to the RS, allows to perform the most urgent elaborations close to the patient, with evident already depicted advantages in terms of privacy/security, decoupling from PG-RS communication link problems, decoupling from RS server problems, etc; (iv) the use within the RS Decision Support Systems (DSS) of two set of rules deriving from medical protocols and standard procedures and from machine learning algorithms running in a Data Mining module allows the DSS to produce notifications/suggestions for the Medical Supervisor integrating the medical experience with advanced data extraction techniques. In addition, in the proposed DSS all heavy computations are demanded to an *off-line* (non real-time) Data Mining component, whilst the *on-line* (real-time) Rules Engines have to perform light/standard computations, with the evident advantages in terms of reaction speed; (v) the use of several user interfaces tailored to the requirements of the three BVH system users.

As far as future work is concerned, the next research step will be the tailoring of appropriate algorithms for the PG and RS Decision Support components (algorithms already partially identified by the authors), to perform effective data extraction from a huge amount of CVD related data.

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A Rule-based Approach for Medical Decision Support

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***Abstract* —This paper describes the medical Decision Support System (DSS) designed in the framework of the Bravehealth (BVH) project. The DSS is the heart of the data processing performed in Bravehealth, and it is aimed at enriching the medical experience to support the doctors in the decision-making processes. The paper focuses on the flexible and effective DSS architecture placed at a Remote Server side. Moreover, a Data Mining prototype algorithm, supported by the architecture, is proposed, along with encouraging test results.**

Keywords–Medical Decision Support; Data Mining; Machine Learning.

I. INTRODUCTION

Recently, machine learning methods have been largely applied to a high number of medical domains. Improved medical diagnosis and prognosis have been shown to be achieved through automatic learning from past experiences, to detect and translate regularities in analytic rules that can be used to classify new patient records. Machine learning algorithms have been shown to be very successful in cardiovascular disease analysis and detection [2,6,10] and electrocardiogram (ECG) beat classification [3,4,5].

In a recent study [7], the cardiovascular diseases are indicated as the first mortality cause in women. In Europe, approximately 55 percent of women's deaths is caused by cardiovascular diseases, especially coronary disease and stroke. The Framingham heart study [8] gave a significant contribution by revealing the impact of factors as smoking, hypertension, dyslipidaemia, diabetes mellitus, obesity, male gender, and age on developing of cardiovascular disease. That was the basis for defining a classification system for identifying the cardiovascular risk class (low, medium, and high) for women on the basis of their characteristics in terms of relevant impact factors [7,9,16]. In Europe, the cardiovascular mortality and morbidity in women are some of the highest. Typically, for confirming the presence of cardiovascular disease, the patients are submitted to different tests (biochemical tests, rest ECG, stress test, echocardiography or angiography). Some of them are invasive for patients, and expensive and time consuming.

In [6], Data Mining techniques were used to identify the high risk patients and evaluate the relationships between cardiovascular risk factors and resulting cardiovascular diseases, differently by the gender of patients. The purpose of study proposed in [6] was to compare the capacity of different data mining methods: the study was conducted on an 825 people sample and the data were collected from general practitioners' files (including, for every patient, information about blood pressure, hypertension, body mass index, glycaemia, the presence or absence of cardiovascular disease on the basis of standard medical definition, etc.). The complete sample included 825 data records of 145 attributes, which reduced, after data cleaning up process, to 303 of the initial set of patients. Two data mining algorithms were used to analyse the sample and to identify the relationships between the attributes and the label indicating the presence or absence of cardiovascular disease. The former one, the Naïve Bayes approach, provided acceptable results regarding identification of patients with coronary artery disease and acceptable results in identification of patients without stroke or without peripheral artery disease (in particular, only 62% of patients with coronary artery disease (in particular, only 62% of patients with coronary artery disease were classified). The latter was a decision tree training algorithm that succeeded to capture 72.6% of relevant information in patients with coronary artery disease but was also incapable to capture relevant information for those with strokes or peripheral artery disease (percentages being also equal to zero). These results were absolutely satisfactory if compared with the success rate achieved by data mining methods applied to different medical test (Liver diseases, Breast Cancer, etc.) and, in particular, to specific heart disease data sets (as the Cleveland HEART data set of UCI repository). Nonetheless, they were totally unsatisfactory for safe clinical protocols. This was due, in authors' opinion, to: (i) the number of patients in the data set and the cleaned data were insufficient to assess the quality of any method; (ii) the use of standard methods, taken "off the shelf" from the literature, without any specific reference to heart disease environment, was not able to produce effective classifiers.

Consequently, a double effort was necessary. On one side the Bravehealth project will be able to collect, validate and clean large amount of patient data. In this respect the idea of remotely collecting patient data directly from a so-called *Wearable Unit* (see [1] for further details) was crucial. The reported description of the logical architecture of the Bravehealth Decision Support System (DSS) highlights its capability to collect and validate large amount of data related to "real" patients. The second effort was that to devise *new classification methods*, able to cope with the large datasets and to be "tuned in" the specific medical application of Bravehealth. For this purpose, Bravehealth proposed a Boosting algorithm based on a "problem specific Kernel". The Kernel of a boosting algorithm embodies the similarity (or dissimilarity) of the different patients. One could use a simple Linear Kernel (inner product of the data vectors) or a standard Gaussian Kernel (as in many algorithms proposed in the general literature). The Bravehealth approach is to devise, on the contrary, a *specific Kernel* for the problem and data faced in Bravehealth and testing its efficiency. This definition, along with the test, could be done only using the

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massive amount of patient data collected in Bravehealth. Nevertheless, the authors had already started the design of a prototype algorithm briefly described in Section IV, based on the boosting algorithm, in order to check, on well known and available test problems, the effectiveness of the boosting method. The results obtained by the proposed prototype algorithm on the widely used for new data mining methods validation *Cleveland HEART* dataset (available at the UCI Data Mining repository and comparable, in size, with the experiment in [6]) are very promising (as reported in Section IV) compared to the literature. As far as the authors know, the best results obtained by all the other research groups oscillate around 80% of accuracy (better than the results obtained by the "off the shelf" algorithms of [6]).

This paper is structured as follows. Section II illustrates the DSS architecture. Section III, IV, V and VI focus on the description of the sub-components defining the whole DSS (in particular Section IV illustrates the proposed algorithm and the results of the performed test). Finally, brief conclusions are drawn in Section V.

II. BVH DECISION SUPPORT SYSTEM (DSS)

The Bravehealth Decision Support System (DSS) has been conceived as a patient-centric, adaptive and flexible system capable to meet both patients' and physicians' needs, in order to support medical decisions and to account the actual expectations of both patients and physicians. Two main guidelines led to the Bravehealth DSS design and development: (i) the DSS is expected to be "close" to the patient, in the sense that the decision making process is fully affected by the patient's actual health conditions and, in some cases, does actively involve the patient; (ii) the main users of the DSS (hospital physicians and medical researchers – hereinafter, these kind of users will be referred to as *Medical Supervisors*) must be granted the access the DSS and to insert or to update data about patients in a secure, immediate, efficient and effective way. Moreover, they expect that standard clinical models are implemented in the Bravehealth DSS ensuring that routine clinical consultations are made more consistent and informative. In addition, the DSS is supposed to support decision making by possibly providing additional information about potential new clinical models, that means useful information extracted from patients' data by means of sophisticated data retrieval and Data Mining techniques. Taking into account these expectations, the Bravehealth DSS was designed to enhance the standard basic features of current medical DSSs.

On one side, the Bravehealth DSS is close to the physicians, in the sense of being a real decision support tool (not a "Doctor Substitution System", as explicitly refused by physicians). Thus, the main components of the Bravehealth DSS are located at proper Remote Servers (RSs) located at the Medical Supervisors premises (e.g., in the hospitals). Hereinafter we will refer to these components as RS DSS. Using standard medical protocols, the RS DSS is able to classify patients affected by CVD into one of three categories: *High*, *Medium* or *Low Risk*. These definitions are based on rules drawn from clinical practice. Accordingly, the RS DSS can automatically generate notifications to be sent to the physicians on the basis of deterministic rules derived by clinical practices and medical protocols. Each notification is part of a specific patient model, derived by standard Clinical Models, whose description is fully provided by the medical responsible. In addition, the Bravehealth RS DSS analyzes medical parameters and context data in order to extract useful information, in terms of rules and patterns for patient classification and profiling, by means of the Data Mining module. This additional feature is the most innovative part of the RS DSS, since advanced Data Mining algorithms, tailored to the Bravehealth environment, are adopted. These algorithms can require rather heavy processing capabilities; nevertheless, as hereafter explained , the RS DSS is organized so that the heavier calculations are performed off-line. The extracted information is real-time presented to the Medical Supervisors as suggestions.

On the other side, the Bravehealth DSS is close to the patient in the sense that a secondary subsystem, namely the Lightweight Decision Support System (LDSS), is completely dedicated to the patient care. The LDSS component is de-centralized with respect to the main RS DSS components and is located at the Patient Gateway (PG): so, hereinafter we will refer to this component as PG LDSS. The main aim of the LDSS is that of filling the gap between patients and physicians when the patients are at home, especially in critical situations (emergencies, PG-RS communication link problems, RS server problems, etc.). Even the PG LDSS is supported by Data Mining algorithms; nevertheless, these algorithms have been designed with the requirement of being particularly light so that they can run even on a low processing computer implementing the PG located at the patient's premises. This paper mainly focuses on the description of the architecture, the features and the embedded algorithms of the DSS at the RS. Nevertheless, the concept of a Data Mining intelligent agent "close to the patient", represented by the PG LDSS, is an innovative concept proposed and being developed within the Bravehealth project and further research papers will be dedicated to its architectural, algorithmic and test results.

Figure 1 shows, using the UML formalism, the functional blocks of the DSS at the Remote Server (RS DSS), and details its components and both its internal and external interfaces. The architecture components are described in detail in [1]. The following sub-sections describe in detail the subcomponents of the *Runtime Environment*, namely the core of the RS DSS, which is in charge of extracting from all the available data the useful information to be presented in real-time to the Medical Supervisors.

III. NOTIFICATION RULES ENGINE AND SUGGESTED RULE ENGINE (ON-LINE PROCESSING)

The Sensor Data Management System and the User Management System store patients' measured data (ECG, Breath rate, SpO2, Arterial Blood Pressure, Activity level, Fluid Index or bioimpedance, Temperature), and consolidated medical evaluation (e.g., in terms of risk classes: *Low Risk*, *Medium Risk*, *High Risk* provided and validated by doctors and physicians), respectively. All these data are provided to the Runtime Environment via the *Data*

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CRUDS and the *Patient Record CRUD* interfaces, respectively. These data are properly pre-processed by an ad hoc pre-processing module as explained below.

The above-mentioned data are used, on the one hand, by the Notification Rules Engine, which is in charge of applying to these data the logic rules defined on the basis of medical protocols and standard procedures adopted by the physicians. These last rules are uploaded by the Rule Supervisors (these are particular kinds of Medical Supervisors authorized to manage the DSS rules) by means of the Rule Supervisor FE in the Medical Knowledgebase Management System (MKMS), in charge of storing the various rules. Since these rules are trusted, they are labeled in the MKMS as "Active Standard Rules". Thus, the Notification Rules Engine uploads the Active Standard Rules from the MKMS and on-line applies each Active Standard Rule to the data acquired from the Sensor Data Management System and from the User Management System; the application of such rules possibly leads to "notifications", which are sent to the Medical Supervisors. On the other hand, such acquired data are also used by the off-line Data Mining component, detailed in the next section, to produce new rules, which are stored in the MKMS being labelled as "Suggested Rules", since these rules, differently from the ones based on medical protocols, are inferred on the grounds of Data Mining techniques and therefore need to be validated by the Rule Supervisors case by case. For this reason, the Suggested Rules are not active by default. Nevertheless, as these rules are validated by the Rule Supervisors, they become "Active Inferred Rules" and can be used on-line by the Suggested Rule Engine. Thus, the Suggested Rule Engine uploads the Active Inferred Rules from the MKMS and on-line applies each Active Inferred Rule to the data acquired from the Sensor Data Management System and from the User Management System; the application of such rules possibly leads to "suggestions", which are eventually received by the Medical Supervisors. All the rules (both the Suggested and the Active Standard/Inferred ones) are stored in the MKMS.

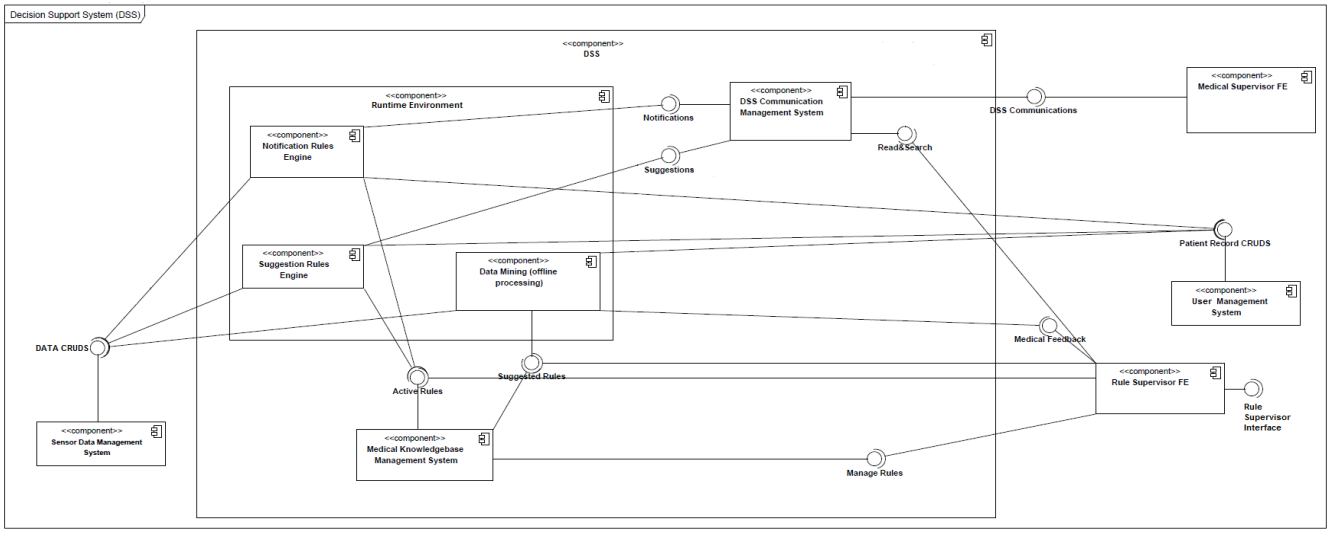

Figure 1. RS Decision Support System (DSS)

IV. DATA MINING (OFF-LINE PROCESSING)

The RS Data Mining component is in charge of the main advanced features of the Bravehealth DSS. The Data Mining component is split in the following four sub-modules:

A. *Pre-processing module*

Data Mining algorithms cannot be fed with raw data: pre-processing of data greatly increases the reliability and the performance of the algorithms. This module is in charge of selecting, organizing and processing the available data in the most suitable way for the data analysis, performed by the Data Mining Engine. The data available in this module are: (i) *medical parameters* coming from the Wearable Units through the PGs and stored at the Sensor Data Management System; (ii) *ECG descriptors and/or other physiological parameters* coming from the Signal Processing performed at the PG and/or at the RS and stored at the Sensor Data Management System; (iii) *context factors* elaborated at the PG and stored at the Sensor Data Management System; (iv) configuration and patient data coming from Medical Supervisors and stored in the User Management System.

The first task of the pre-processing module is to render all the data homogeneous. Then, three main pre-processing techniques are applied: (i) *Sample selection*: some data may be unreliable (e.g., because of typos in data enter, imprecise medical measurements, etc.); and an expert (doctor or medical researcher) is needed to decide their relevance for data analysis. If the sample selection is not provided, the system extracts the sample data in unsupervised way, according to the statistical distribution of the available data set. The well known structured k-fold cross validation procedure is adopted by Bravehealth system for sample validation and test. (ii) *Feature selection*: besides the sample selection, proper feature selection and extraction algorithms can be adopted in order to complete the set of significant features by means of specific indexes defined ad hoc by pre-processing environment. In the Bravehealth system, these

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algorithms are based on a well known supervised machine learning model, namely the L_1-norm Support Vector Machines [14]. (iii) *Denoising*: finally, standard denoising algorithms are applied to correct statistical errors.

B. Data Mining (DM) Engine

The Bravehealth RS DM engine is the "core" of the RS Data Mining component. It includes innovative models based on data analysis and machine learning algorithms able to infer, in an off-line fashion, new rules which, after being properly validated by the Rule Supervisors, are applied by the on-line Suggestion Rules Engine to the pre-processed data. The DM engine conceived in Bravehealth includes several machine learning based models, all tailored to the specific cardiac diseases considered in Bravehealth: all these models are simultaneously active and automatically selected. These models have to operate under the control of specialized Rule Supervisors, not only authorized to access the DSS (via the Rule Supervisor FE and the *Medical Feedback* interface), but also to manage the models in question and tune specific parameters.

The DM engine analyses all historical pre-processed data with the aim of identifying correlations, regularities and patterns in such data and to s*erve as a predict*ion on the patients' health conditions. Information is extracted in the form of general patterns, such as logical rules or decision trees, that are stored in the Medical Knowledgebase Management System (MKMS) as "suggested rules" and then are studied by Rule Supervisors both to validate the suggested rules in question and to further refine the adopted models. In addition, the DM engine is able to identify abnormal behaviors or risk situations which are notified to the Medical Supervisors. The above-mentioned analysis is performed by both unsupervised (e.g., data clustering) and supervised (e.g., data classification and regression, pattern recognition) machine learning algorithms. Some of the models adopted for performing this analysis are open source implementation (e.g., WEKA), whereas other ones (e.g., exact boosting model) have been developed and implemented ad hoc for the Bravehealth purposes. Data Mining based medical models are independent of the medical protocols and standard procedures; conversely, they are totally based on proper Data Mining models, such as Decision Trees, Bayes Networks, Rule Induction Algorithms and Neural Networks, Boosting and Kernel models (e.g., Support Vector Machines). In particular, Boosting techniques have emerged in machine learning as ones of the most promising and powerful methods for supervised learning [11]. These techniques are the ones which have been selected for being designed, developed and implemented in Bravehealth. In this respect, the innovative Boosting model which has been defined and is being developed ad hoc for the Bravehealth environment, is obtained through a proper combination of a set of given base classifiers, usually called *weak learners*, to yield one classifier that is stronger than each individual base classifier. In Bravehealth we coped with the problem of combining Support Vector Machines (SVMs), properly adapting to the Bravehealth environment the approach presented in [12]. Following [14], the Boosting problem is formulated as a Linear Programming problem (LP). The dimension of the LP problem is related (via the Kernel matrix representing the similarity measure) to the number of test points (number of patient records) and hence the LP to be solved will be larger as the patient data will be collected, cleaned and stored by the DSS. The algorithm proposed in Bravehealth tackles the problem of solving LP problems with a huge number of variables by improving the solution scheme proposed in [14] and adapting to the boosting environment a standard technique used in LP theory: *Column Generation*. Column generation is a general method for solving large LP problems by iteratively solving a "reduced problem" on a subset of variables and fixing the others to zero. The solution of the "reduced problem" is optimal for the original problem if suitable values associated with the zeroed variables (the "reduced costs") are non-negative. At each step, the reduced costs of the variables fixed to zero are evaluated, and only a limited number of "promising" variables (named entrant columns) with negative reduced cost are included in the set of variables considered in the current iteration (the so called "auxiliary problem"). Each entrant column is chosen by a "look up" procedure that automatically evaluates the reduced cost of the variables fixed to zero. The related Support Vector Machine is inserted in the subset of promising columns. By generating automatically one additional column at each iteration, the dimensions of the master problem to be solved increase slowly, and the solution algorithm is very fast. When the number of generated columns becomes considerable, the algorithm selects a subset of columns of the master problem that can be removed without affecting the current solution.

This paper shows the results obtained through the implementation of this algorithm when applied to the problem *Cleveland HEART* (303 patient data concerning heart diseases) available at the UCI data mining repository [15]. These results indicate that the "boosting + column generation" approach is capable to find very good accuracy results and ready to solve the mining problems (of increasing dimension) generated by the routine activity of Bravehealth DSS (patient data collection via Wearable Unit, in primis). A brief description of the main features of the proposed method must start from a quick sketch of the standard learning protocol. The preliminary action is the partition of the dataset in two sets: the *training* and the *test set*. The *training set* simulates the data available in the (off-line) learning phase. The classifier (its parameters) is (are) defined on the basis of the information carried by the training set, ignoring the data included in the test set. The *test set* simulates the data that will become available on line (i.e. the vital parameters measured by the Wearable Unit of a new patient and acquired by the DSS). The DM Engine uses the "boosting+column generation" approach to define a classifier which consists of a linear combination of Support Vector Machines (SVM). The classifier is defined on the basis of known and clean data represented by the training set. The classifier will subsequently be used on-line to assess the criticality of the vital parameters of unknown patients (represented by the test set in our experiment).

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The main purpose of the training phase is to define a classifier which determines whether a patient is in *critical conditions* or not, under some pre-defined medical point of view, only for those patients in the training set that *it is known in advance that they were in critical conditions* for that parameter. Such a knowledge is used to assess the quality of the algorithm. The most diffuse wrong idea is to consider the "best" classifier as the one that provides the correct answer for every patient in the training set, but this simply means that the classifier is tailored for the training set and often unable to generalize its diagnosis to a new, unknown, patient. This is the so called *overtraining effect*. Conversely, the correct learning strategy is that of optimizing a functional which takes into account both the *prediction accuracy* over the training set and the capability of recognizing cases not included in the training set (*generalization*). In the proposed algorithm, this multi-objective problem is solved by maximizing the accuracy on the training set, while constraining the capabilities of the classifier (reduced set). By constraining the classifier into not performing excessively well on the training set, it should be able to generalize to the test set. In more detail, the proposed classifiers are linear combinations of Support Vector Machines (SVM) and each SVM is defined by an *hyperplane* whose variables correspond to the components of the training points (indeed this is true only if the Kernel is not used but let assume it for simplicity). The proposed solution to the "overtraining effect" is to reduce the set of SVM to be included in the linear combination (boosting) by imposing an upper bound to the norm of the coefficients of the hyperplane defining the SVM (*norm-UB*). A very low value of the upper bound produces classifiers unable to properly classify the elements of the training set, while a very high value (infinite) for the upper bound imposes no limit upon the choice of the optimal classifier and produces the feared "overtraining effect". The optimal upper bound and hence the optimal classifiers in terms of accuracy and generalization must lay in the middle and correspond to the optimal value of the norm-UB.

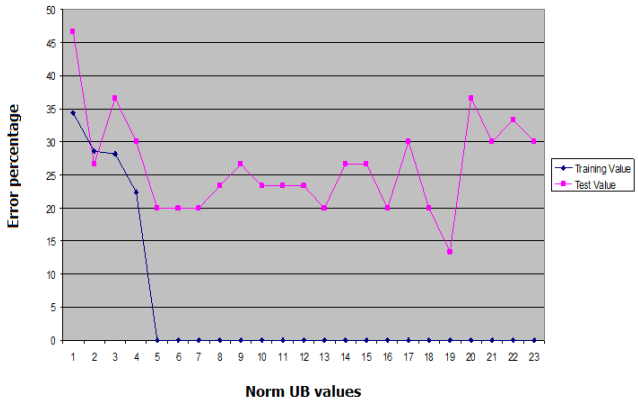

Figure 2. Value Function test results

A way to visualize the overall behavior of the learning process is by plotting the so called *value function* of the proposed optimization problem for increasing values of the norm-UB. The value function is the value of the error percentage of the optimal classifier on the training set obtained by restricting the choice of the SVMs to those having coefficient smaller than a suitable value of the norm-UB. The value function of the tests performed by the authors is plotted (in blue) in Figure 2. The y-axis reports the percentage error while the x-axis represents 23 different and increasing values of the norm-UB (the values are not important since it is important to have an increasing series of upper bounds). The behavior of a value function for increasing values of the norm-UB is quite predictable. It starts from high values of prediction error in correspondence of the lowest values of the norm-UB and decreases to 0 (equivalently 100% prediction accuracy on the training set).

But what happens to the prediction accuracy on the *test set*? Two phases are present: a first phase in which the quality of the results on the test set follows the quality of the result in the training set and the prediction error on the test set decreases; and a second phase in which the improvement of the accuracy on the training set produces an increasing percentage of wrong answers on the test set. This second phase can be defined the *overtraining phase* and the error correspond to the fact that the algorithm is performing "too well" on the training set. The best classifiers should be searched at the interface of the two phases. This area is here informally defined as the *knee* of the curve corresponding to the accuracy error on the test set. Figure 2 reports the experimental results, in terms of prediction error in percentage constrained by the norm-UB on the x-axis, of the proposed prototype algorithm upon the Cleveland HEART data. The 303 patients of the data set have been partitioned in a training set containing 270 of them (a lower number would have made the test of the boosting+column generation procedure non significant) and leaving 33 patients unknown to the algorithm (test set). The value function starts from a 35% error for the lowest value of the norm-UB. In this case, the UB is so low that it is not possible to find a classifier which properly classifies the patients in the training set. By increasing the norm-UB the error percentages decreases until it reaches the value zero (the fifth value of the norm-UB). The error percentage remains to zero even though it is related to different classifiers for each different value of the norm UB (with different generalization capabilities).

The red plot shows the classification results on the test set, obtained by the classifier produced for each value of the norm-UB. As one can easily see the prediction error on the test set has an almost descending trend up to the 19th value of the norm UB (corresponding to a 13.33% error) and then it increases above 30% for all the subsequent values of the norm-UB. Hence, a "knee" has been found and an optimal classifier with 86.66% accuracy corresponding to the knee. As far as the authors know, this is the best classifier obtained so far for this particular problem.

V. MODEL SELECTION MODULE

As a request arrives to the Data Mining component, all the realized algorithms implementing different machine learning models are executed (Neural Networks, Decision Trees, Boosting, etc), and their outputs are automatically evaluated

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in terms of accuracy and reliability. This module has the task of selecting the model (or the combination of models) which is the most appropriate to the current request on the basis of specific parameters and criteria provided by the Medical Supervisors. Driving parameter can be accuracy and reliability determined according to the examined case; model selection can be automatically performed basing those parameters. Moreover, the Bravehealth system foresees a hybrid automatic-manual model selection in which Medical Supervisors can express their preference to a particular model for each examined case.

VI. PATTERN VISUALIZATION MODULE

An important issue in Data Mining applications for medical diagnosis and risk prediction models is that the results of computer-based analysis have to be communicated to people in a clear way, to facilitate the interaction in the decision making process. The output of the DM Engine is represented by general patterns (logical rules, decision trees, etc.) that are provided to Rule Supervisors for inspection and validation. The output may not be immediately clear to non-specialized operators; therefore, a Pattern Visualization module is needed, to represent the patterns found by the DM Engine in a graphical representation, suitable for doctors and medical researchers. The Bravehealth Pattern Visualization module stores and displays data in a customizable way, offering efficient access to data and data managing tools for continuous patient monitoring.

VII. CONCLUSION AND FUTURE WORK

A key characteristic of the Bravehealth approach is that all the data processing procedures, from the data pre-processing to the output visualization, is performed according to a patient-centric vision and with tight control of doctors and medical researchers, also to encourage its use by the medical audience, usually skeptical about automatic assistance. Moreover, the Bravehealth approach includes several innovative features: (i) the use of a two-scale DSS including a *light* data processing taking place at the PG, and a more *heavy* data processing demanded to the RS; (ii) the adoption of a flexible architecture of the RS DSS based on an off-line Data Mining engine including several Data Mining models which can be adaptively selected (either in an automatic, or in an hybrid automatic/manual fashion) on the basis of the examined case for providing on-line (real-time) notifications and suggestions to the Medical Supervisors; (iii) the adoption of Data Mining models tailored to the Bravehealth environment (e.g., Boosting models based on SVMs as the proposed one); (iv) the adoption in the PG LDSS of powerful clustering algorithms tailored to the real-time classification of patient records filled with the data received from the WU.

This paper has presented the basis, along with very encouraging results of tests applied on well known available data, of the on-going Data Mining algorithms development, which, compliantly to the best practice in Data Mining, will be carefully tailored to the actual data which will be available either during the Bravehealth or other similar projects, and/or in eHealth based industrial applications. The expectation is that, thanks to specific Kernels, **t**he proposed boosting algorithm could represent a ”quantum leap” of the capacity of (i) predicting heart diseases and (ii) providing a more accurate classification of the patients’ health status.

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The Work Practice of Videoconferencing in Acute Stroke Treatment

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***Abstract*—In Norway, a local hospital and a specialist hospital have implemented real-time videoconferencing to exchange knowledge in order to obtain more complete stroke diagnoses and increase the thrombolytic treatment supported by specialists. In this paper, the objective is to explore the tension between the potential for using videoconferencing and its realization in practice. In 18 months, there were four videoconferencing consultations. Videoconferencing is only used when considering a thrombolytic treatment. As the thrombolytic treatment depends on several contra-indications written in a guideline, the guideline shape the work practice. In principle, the guideline represents a meaning potential for dialogue and for exploring knowledge in stroke treatment. But, in most cases, the guideline is followed strictly, and thus thrombolysis is not a treatment option in such cases. There is a breakdown in the potential for using videoconferencing, since they only four times have realized the meaning by creating sense and a shared repertoire of knowledge. This includes small turnouts and a lesser strictness to the guideline might lead to more frequently used videoconferencing in acute stroke treatment.**

Keywords-videoconferencing; telestroke; work practice; meaning potential; meaning realized

I. INTRODUCTION

In Norway, a local hospital and a central hospital have both implemented real-time videoconferencing (VC) so that the small local hospital can access specialist knowledge from the large hospital to discuss acute cases in which patients have suffered a stroke [1]. By using VC as a tool, practitioners are able to examine patients in a virtual collaborative process. In acute situations, when time is critical, this collaborative process can shorten decision times and improve treatment outcomes.

Approximately 15,000 people in Norway suffer from strokes each year, constituting the third most frequent reason for death [2]. The stroke incidence is three per 1000 inhabitants [2], estimated at 69 patients per year (1,32 per week) in *this* local hospital. In most cases, strokes are treated with medicament intravenous thrombolytic therapy. Thrombolytic therapy is a treatment used to break up dangerous clots inside the blood vessels. To perform this treatment, the physician injects clot-dissolving medications into a blood vessel. The effect of thrombolytic treatment diminishes over time, while the risk for complications increases [3]. Thrombolytic treatment should be given as soon as possible, but within 4 ½ hours after the symptoms start [2]. As time matters, decisions about diagnosis must be made as soon as possible. Shortening the time to pre-hospital stoke treatment might be possible by remotely assessing patients with stroke prior to their arrival at the hospital through discussions over ambulance computers [4] and through bedside assistance from real-time video smartphones [5]. Once a patient with a suspected stroke reaches the emergency unit, the local hospital might use in-hospital VC to shorten the decision process, and improve the quality of care [6].

Each patient needs to complete a computer tomography (CT), an image digitizing cerebral scanning of the brain, before an exact diagnosis is determined. The professionals have a guideline they follow when patients arrive at the hospital. The decision to start thrombolytic treatment within 4 ½ hours depends on several criteria, or contra-indications, and every case should be considered individually. Giving stroke patients thrombolytic treatment in the acute phase improves their prognosis. The national goal is to give 20 % of the patients thrombolytic treatment within 4 ½ hours after the symptoms' debut. Today, the average in Norway is about 5 % [7].

Many emergency physicians do not use thrombolytic treatment, because they have a sole responsibility for the patient [8]. In the local hospital described here, thrombolytic treatment should be given under the supervision of a specialist. To access specialist competence for a second opinion for supervising thrombolytic treatment over distance, and to save time, VC has been implemented. Implementing VC increases the number of thrombolytic treatments and the patients threatened in the 4 ½ hours window [9]. Therefore, VC can further support the decision about thrombolysis and potentially lead to an increase in the number of thrombolytic treatments given. In September 2010, the VC service was ready to be used, so that the visual sight of the patient could supplement the spoken descriptions, traditionally communicated by telephone. In this way, the physicians and nurses at smaller referring hospitals could communicate with the specialists in the specialist hospital, seeing each other and the patient.

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The paper is organized as follows. Next section gives a background to the paper, by presenting the research question, illuminated and made current by previously research. Section III provides the environment where the VC is situated, and provides a framework for analyzing social interaction. Section IV is methods, describing the research method and how the data is analyzed. Section V is the results, discussed in Section VI. Conclusion and further work are provided in the last section of the paper.

II. BACKGROUND

Using VC in stroke treatment has been referred to as "telestroke". Since the end of 1990s and early 2000s, telestroke networks have been developed. The use of telestroke networks has shown great promise for improving access to expertise and for giving more precise diagnosis. Studies, many of which are connected to funded programs, report outcome, i.e. factors related to successful telestroke interventions, such as levels of satisfaction, acceptance, positive experiences and improved quality of care [10]. Patients treated in hospitals with telestroke networks receive more complete stroke diagnosis and earlier rehabilitation therapy than patients treated in other hospitals [11]. There have been reviews on the motivations for telestroke programs and the barriers to program adoption [12]; the barriers are, i.e., lack of technology support and lack of funding [12]. Research reporting success and barriers to the development of telestroke programs focus on the effectiveness, cost-effectiveness and quality of the technology [8, 10-12]. Little is known about the use of telestroke in daily work practice and what affects the work processes that lead either to success or failure.

Grounded in international findings of satisfaction, positive experiences and improved quality of care using telestroke equipment, as well as our own results on how VC technology *per se* is not the reason for the low frequency use[13], the aim of this work is to explore why VC use is lower than expected. Here, the paper focuses on the work practice of stroke treatment and how the organization of stroke treatment affects VC use in acute care. The objective is to explore the tension between the potential for using VC for collaborative work to increase thrombolytic treatment and for the realization of VC in practice.

III. MATERIALS AND FRAMEWORK

The local hospital examined in this paper has a stroke unit, but no neurologist. Traditionally, the physicians in this local hospital seek a second opinion from the larger specialist hospital over the telephone. The distance between them is about 63 miles or 100 kilometers by airplane over the sea. Using VC instead of a telephone gives the specialist the opportunity to see the patient and the local team when giving advice about treatment. In September 2010, the service was used for the first time, and it is still running.

The VC is located in the local hospital's emergency room (Figure 1). In the specialist hospital, the VC equipment is located in a dedicated room used only for this purpose (Figure 2). When the referring hospital calls up the specialist hospital by telephone and initiates a VC meeting, the specialist immediately moves to this room. During their social interactions, the professionals are able to draw on resources such as their different knowledge and the patient him/herself when discussing the medical problem. The professionals discuss and make sense of the signs and actions that are a part of the collaborative work; i.e., results from the CT, dialogue with the patient, information from the physicians and the nurses.

Social interaction is a difference between meaning potential and meaning realized [14]. The meaning potential in work practice is the way stroke treatment is performed, where the blood test, the CT and the clinical signs and information represent the potential. Through the use of dialogue and VC, the professionals create sense and a shared repertoire of knowledge.

When using VC the professionals meet, medical discussions arise and problems are handled. It is the tension and the gap-closing between the knowledge of the local physicians, their traditional approach to stroke treatment, and their collaboration with the specialist by using VC, which might increase the number of thrombolytic treatments and the patients treated within the hours window, i.e., the meaning realized.

Figure 1. Emergency room at the local hospital

Figure 2. The dedicated room in the specialist hospital

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IV. METHODS

A. Research methods

The VC equipment was introduced to the clinics in September 2010, and it has been studied since. All activity using VC is automatically logged. As a consequence, one can know how many times, when, and for how long the VC equipment has been used. The log data have then been used as a basis for conducting the interviews. As the results will show, the VC equipment logs indicated four total uses.

Thirteen professionals, nurses, physicians and specialists from both hospitals were interviewed, through 12 semi-structured interviews in the autumn of 2011. There were seven informants from the local hospital and six informants from the specialist hospital. In one of the interviews there were two participants. The informants were selected on the basis of their roles: working with stroke patients in the acute phase and/or having participated in VC consultations. Five of them had used the VC equipment. Twelve interviews were conducted face-to-face. One interview was conducted by telephone, since the informant had to postpone the interview appointment when visiting the hospital.

Each interview lasted from 20 minutes to two hours. Those informants introducing the topics of equipment and the workplace while talking affected the length of the interviews, and made them the longest. All interviews were audio recorded, then transcribed. All transcriptions were categorized according to utterances that seemed to be repeated by the practitioners.

Understanding the overall treatment of stroke patients, in both the acute and rehabilitation phases, called for an understanding of the organization of stroke treatment in the hospitals. This included conversations with professionals involved in different stages of the stroke treatment (the laboratory personnel, the stroke unit and CT personnel), but as they were not the ones using the VC equipment in the consultations, they were not included as informants, but as a resource for understanding the treatment of stroke patients.

B. Analysis

All the empirical material was analyzed with emphasis on the collaborative processes and knowledge sharing through medical discussions. It has been important to understand the tension between the use and the non-use of the VC equipment; the patients that could have been discussed by using VC, those patients who have been discussed and why some patients are not discussed.

C. Ethical considerations

The study has been registered and evaluated as a non-report obliged by the North Norwegian Regional Medical Ethics Committee (REK). The personal data are handled according to the personal informative rules in Norway.

V. RESULTS

A. The work practice

The stroke patients arrives the local hospital in the emergency room. The physician on duty meets the patient here and considers the patient condition supported by the nurses. If the patient has symptoms of a stroke, he/she is considered for thrombolytic treatment. The physician evaluates the time limit and other contra-indications for thrombolytic treatment written in the guideline. The patient has blood tests and a CT taken. If the physician and the emergency team want to discuss the patient with a specialist, or if the physician wants to administer thrombolytic treatment, the physician calls up the specialist at the larger hospital while the patient has the blood tests and the CT. This is first done by telephone to let the specialist hospital know that the local hospital want to have a VC. Second, this is done by VC, so that both hospitals are able to both see and hear the patient and the whole team at the local hospital. When the patient has finished the CT, the specialist and the local team wait by the VC to discuss the treatment. This organization prevents lost time by connecting the two hospitals.

Giving thrombolytic treatment depends on several contra-indications; for instance, the time limit is 4 ½ hours, so the onset time must be known, and there are individual criteria such as previous and present medical conditions and medications. Therefore, every patient needs to be considered individually. If the physician evaluates the time limit and the contra-indications in such way that thrombolytic treatment is not an option, the specialist is not connected and the patient is moved to the local medical department and later to the stroke unit for rehabilitation.

B. Stroke patients

During a one-year period, there were reported 12 patients suffering from a stroke in this area [3]. Only two patients were threatened with thrombolysis. It is important that patients are aware of the symptoms of a stroke (informant 4, 5, 10). If the time of onset is not known, the patient cannot receive the treatment. Following quotes represent this:

- "…we can improve our internal routines, but most important is consciousness-raising among the public, to get in touch" informant 4.
- "…the majority are non-relevant (…); they arrive too late" informant 5.
- "…the majority arrive too late (…); they do not reach us in time" informant 10.

Also, every case must be evaluated individually, first in terms of the time of onset and the time limit for thrombolysis, then for other specific circumstances.

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The following utterances illustrate how the physicians (informant 8 and 12) and the specialist (informant 7) reflect the guideline:

- "…one thing we often experience is that patients reach us too late (…) and we might be too strict with the criteria. We might exclude too many small turnouts" informant 8.
- "…we consider it too strict (…) most of the patients are excluded for different reasons" informant 12.
- "The question is if we are too strict. Maybe others have lower limits for giving thrombolytic treatment. It is a clinical judgment. But, we interpret the guidelines very differently from hospital to hospital" informant 7.

As the utterances illustrate, the individual evaluation of the contra-indications, or the guideline, are those cases warranting the potential use of VC.

The contra-indications are not that strict as the time limit, and are available for clinical discussions. These cases, reflecting the guidelines are those where the guideline can be discussed. The guideline are interpreted differently from hospital to hospital (informant 7), and the professionals say they might evaluate them too strictly (informants 8, 12, 7), excluding too many small turnouts (informant 8). This means, that including the small turnouts and a lack of strict adherence to the guideline, could have resulted in some discussions, evaluating and exploring the standardized knowledge in the guideline. More discussions of the guideline, further leads to more frequently used VC consultations.

C. The use of VC

Over the course of 18 months, VC has been used four times to discuss stroke patients. In all four cases, the specialist was connected because the local hospital wanted to offer thrombolytic treatment or to discuss the treatment because the patient was considered a possible candidate for thrombolytic treatment.

TABLE 1. THE USE OF VC AND FREQUENCY OF THROMBOLYSIS

Use of VC		
Patient	***Outcome***	***Thrombolysis***
1	Diagnosis dismissed and changed	No
2	Possible rejection because of previous heart transplant	No
3	Received thrombolytic treatment successfully in the past	Yes
4	Diagnosis dismissed and changed	No

Patient 1-4: September 2010- March 2012. Patient 3-4: March 2011-March 2012.

As Table 1 illustrates, Patients 1 and 4 had their diagnoses dismissed and changed, so no thrombolysis was given. Patient 2 was rejected because of a previous heart transplant, and Patient 3 had received thrombolytic treatment successfully earlier, and then had it again. The following quotes illustrate the treatment outcome:

- "…we had the image, and were able to talk directly to the patient. So it was easier to evaluate the aphasia and the other parameter as well. Because of other symptoms, we did not do thrombolysis" informant 11.
- "I am not sure this will lead to more thrombolysis, but maybe to thrombolysis to those having the correct indication" informant 12.

When VC is used, it is easier to make clinical judgments because the specialist is able to see the patient and the overall situation. The specialist also talks to the patient, which offers more insight into the patient's condition. As Informant 11 and 12 expressed, the treatment is given under more correct indications since VC makes it easier to evaluate all the symptoms. Even though the specialist does not think more patients will have thrombolytic treatment, he says that the treatment decisions are of a higher quality.

VI. DISCUSSION

As giving thrombolytic treatment depends on several factors or contra-indications, the treatment guideline shape the work practice and the use of thrombolytic treatment. If a patient arrives more than 4 ½ hours after symptoms start or the onset time is unknown, he/she is not considered for thrombolytic treatment. There is also guideline for administering thrombolytic treatment, which are discussable and make the evaluation of every patient unique. The guideline represents the meaning potential for exploring knowledge in stroke treatment. But, in most cases, when following the guidelines strictly, thrombolysis is not a treatment option. When thrombolysis is excluded, VC is not connected and stroke treatment is not discussed with specialists using VC. Hence, the guideline limit dialogue and the need for decision support. The work practice, with its routines established in the guideline, makes the use of VC break down.

Before the VC was implemented in 2010, the number of patients with stroke symptoms in this local area was estimated to be 69 patients per year. This local hospital had 12 reported stroke patients in a one-year period resulting in a lower number of candidates for thrombolytic treatment than estimated. By deducting those patients who are identified within 4 ½ hours, only a few patients remain as possible candidates for

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thrombolytic treatment per year. These patients represent the meaning potential for knowledge sharing, discussing thrombolytic treatment and hereby the use of VC. In one year, two patients had thrombolysis. One patient had thrombolytic treatment with no discussion of the patient using VC, as the local team made the decision that it was the correct treatment. The second patient was discussed with the specialists using VC.

Over a period of 18 months, VC has only been used four times. Once, the outcome was thrombolytic treatment. When connecting by VC, the local physicians has evaluated the patient's condition and found thrombolytic treatment to be a possible treatment option. Exchanging knowledge using VC as a tool resulted in thrombolytic treatment on one occasion. After consultation, the stroke diagnosis was dismissed and changed in two cases, and once, thrombolysis was refused since the patient had a heart transplant. This illustrate that the guideline serve as a *guide*, and that collaborative work with the specialist might change and/ or influence the decision. When discussion the patient, the meaning potential was realized, as the professionals created a sense and a shared repertoire of knowledge, by interacting and drawing on each other's resources. After the dialogue, the exchanged knowledge had made such sense that the local physician followed the treatment plans being discussed.

One can assume that several patient cases were the basis for thrombolysis discussions using VC, creating a meaning potential for expanding the knowledge exchange and the use of VC in stroke treatment.

From a retrospect evaluation of the cases, the professionals determined non-thrombolytic treatment to be the correct option. One patient could have been given the treatment, but even though the patient did not receive it, the patient recovered well. This illustrates that the situation has the potential for knowledge sharing, treatment modifications or corrections, and perhaps an increased number of thrombolytic treatments. Over time, discussing cases with may change the way the guideline is used in stroke treatment. The professionals strictly evaluate the use of the guideline and their use differs from hospital to hospital. Using VC gives the professionals access to specialist expertise, and over time realizing the meaning potential by exchanging knowledge so that the guideline can be discussed and the thrombolytic treatment can be used more frequently.

Telestroke research reports on successful telestroke interventions, i.e., satisfaction, acceptance, positive experiences and improved quality of care [6]. Studies reporting barriers explain the obstacle for use, i.e., by the lack of technology supports and the lack of funding. This paper discusses the processes leading to the outcome; VC was only used four times in acute stroke treatment over a period of 18 months. Findings illustrate how work practice, with guideline for treatment, affects the need for a second opinion and the use of VC as a tool for exchanging knowledge. Accordingly, the basis for acute stroke consultations cannot be estimated merely by the number of stroke patients.

Lesson learned, when considering implementing VC, the amount of patients sufficient for the investment needs to be accounted for; i.e. the extent on knowledge sharing and the use of VC consultations is affected by the organization of work practice. There is a tension between the potential for collaboration by using VC as a tool for increasing thrombolytic treatment, and how the traditional way of performing treatment affects the realization of VC in practice. VC represents a tool for potential meaning making. When the patient arrives in the emergency unit, the professionals make decisions affecting how they realize the meaning potential in the situation. Many emergency physicians do not traditionally use thrombolytic treatment, because the rare event of giving thrombolysis and because they have the responsibility solely [4]. By using VC, they can consult specialists and increase the number of thrombolytic treatments supported by specialist competence [5]. Hence, the way the guideline is handled affects the use and the number of thrombolysis as treatment for stroke.

VII. CONCLUSION AND FUTURE WORK

When a stroke patient arrives at the hospital, the blood test, the CT and the clinical signs and information represent the potential for sharing knowledge and creating a shared repertoire of knowledge. Through the use of dialogue and VC, medical discussions arise and problems are handled. The workflow affects how often and if the dialogue using VC and the guideline are used as tools for decision support. The professionals might create a sense and a shared repertoire of knowledge when treatment is discussed and carried out. Hereby, more frequent use of VC consultations can lead to knowledge exchanges and a greater number of thrombolytic treatments made by confident professionals. The specialists are connected on the VC after the physicians have decided giving thrombolysis. Therefore, only a small number of stroke patients are discussed. Including small turnouts and discussions about the guideline might lead to knowledge exchange about several cases. Hereby, videoconferencing consultations will be used more frequently in acute stroke treatment.

It is the tension and the gap-closing between the knowledge of the local physicians, their traditional way of treating stroke, and their collaboration with specialists through the use of VC, which might increase the number of thrombolytic treatments and the patients threatened in the hours window. Changing the work practice, by practicing the knowledge discussed in the VC consultations, realize the meaning potential in acute stroke treatment.

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Even though the VC only has been used four times for discussing acute patients suffering from stroke, these cases are important. The knowledge exchange by the use of VC might have an important influence on the patient's condition and rehabilitation. For future work, it will be interesting exploring the four cases and the processes of knowledge sharing.

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Chronically Ill Citizens and Home Monitoring: "Nothing to talk about"!

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***Abstract*— This paper presents local results from a large EU research study conducted from 2008-2012 (DREAMING). The aim of the study was to evaluate the effects of an ambient assisted living protocol, which may extend the independent life of chronically ill elderly people. Methods: The local findings are based on 10 semi-structured interviews with the involved citizens combined with local results of HADS and SF36. Results: Three main themes have been identified to have a positive influence on quality of life; feeling of safety, empowerment, and acceptance. Conclusions: all the citizens felt a positive influence on at least one of the mentioned themes and thethe technology was well integrated into their daily life.**

Keywords: patient empowerment; health IT; telemedicine; home monitoring, quality of life

I. INTRODUCTION

The current global health care system is under pressure for multiple reasons including aging populations, increased prevalence of chronic diseases, shortage of clinical personnel and increasing expectations from the patients.

To live up to new patient expectations, the health care system must undergo a perceptual change towards increased centralization around the individual citizen – not patient. Hence, there is a need for a different approach in the way we – as a society – think of health care in order to accommodate this new role of the citizen. This new notion will require a change in culture both from staff in the health care sector and from society in general.

This new culture needs to be established upon a set of appropriate values, including respect, solidarity, and involvement towards the individual citizen. Doing so will allow for high standards as regards both professional and organizational quality as well as experienced quality by the individual citizen. We must thereby facilitate a paradigm change from present paternalistic disease management to a more holistic and empathic approach [1].

To enable this change, development of technology can be an important tool, in particular if the technology is created in close cooperation with the users. Experiences show that user-involvement in technological development processes is an effective leverage for organizational and cultural change [2][3].

Part of the challenge associated with the new paradigm can be ascribed to the current fragmented nature of the health care system. There has been a tendency for individual health care providers to focus on isolated optimization of their own work flow (cf. the split into primary and secondary providers). The challenge becomes how to create a better continuity for the citizen in the navigation between the separate providers without sacrificing efficiency and experience for the individual provider [4].

Such a vision involves a change of mindset for all stakeholders in health care, which makes it a rather all-encompassing subject. In some aspects, however, local and regional concrete initiatives can make individual contributions to the greater, global cause relatively independently from each other. In these cases, the question is how to incentivize and facilitate such initiatives within an overall frame while keeping the main goal in sight.

The European Union has a vision about creating a new health care model to help accommodating such needed changes. The path towards this new model involves collaboration between countries, so that countries can work for the same goals by cooperating and sharing knowledge. For most countries there is a need for a collective change of mind-set in creating the new health care model. As a consequence of this, the CIP-ICT-PSP program funded the EU project DREAMING (elDeRly-friEndly Alarm handling and MonitorING) under its objective 2.2 ICT for ageing well [5][6].

II. BACKGROUND

DREAMING was a research project under the auspices of the EU testing a range of welfare technology services in real life pilots in cooperation with public authorities under a randomized control trial. The project tested elderly-friendly alarm and monitoring technology in the homes of chronically ill citizens. The technology applied in DREAMING consisted of medical measuring equipment, environmental monitors, and video conferencing.

With the technology installed in their home, the citizens were able to take their own measurements, e.g. blood pressure or blood sugar, with the dedicated measuring instruments (see Fig. 1). Via Bluetooth, the instruments transmitted the measured value to a hub forwarding it to an internet based portal accessible to the district nurses. For

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each citizen, individual thresholds were set for the different values of relevance. If the measurements differed greatly from this threshold, the nurses received an alarm via SMS or email, depending on the severity of the deviation.

Also connected to the alarm system were the environmental monitors, e.g. fire alarm or gas leak sensor. If the monitors detected some kind of danger or incident out of the ordinary, an alarm was sent to the nurses, who could then take the appropriate action. Finally, a videoconferencing system was installed on the personal TV set of the citizen. This system enabled the citizen to talk to healthcare providers, friends, or family face to face on their own TV. Fig. 1 shows a model illustrating the technologies applied in DREAMING.

The citizens included were at least 65 years old and suffered from diabetes, heart failure, or COPD (Chronic Obstructive Pulmonary Disease). The project was trialed at pilot sites in six European countries: Denmark, Sweden, Germany, Estonia, Italy, and Spain. A total of 284 citizens participated in the trial. Of these 139 were allocated to the intervention group (IG) and 145 were allocated to the control group (CG). In Denmark, the total number was 51, with 26 in the IG and 25 in the CG. Due to drop-outs, the number of participating citizens had been reduced to 11 in the IG and 12 in the CG at the end of the project. The Danish trial site was the island Langeland characterized by its rapidly aging population, remoteness and distances to large hospitals.

Figure 1. Equipment applied in the DREAMING project.

The Danish pilot trial faced a number of technological challenges, see Fig. 2, which were initially handled by the Danish project manager. However, it became clear that a local person from the island with technical knowledge who could establish a close cooperation with the citizens and the district nurses participating in the project would be needed. A retired farmer from the island was hired for this task and both his status as a local and as a senior citizen made it easy for the citizens to relate to him. The fact that he was always available for help and guidance resulted in a smoother trial run and helped both citizens and nurses feel safer about the technology.

The pilot trial ran from the beginning of May 2008, to the end of March 2012. For the purpose of studying health related quality of life (QoL) of the citizens, the validated and internationally accepted questionnaire SF-36 was used. The SF-36 is a multipurpose, short-form health survey consisting of 36 questions. It gives an average of the mental health and physical health components. The citizens in both the IG and the CG filled out the questionnaires at baseline, midpoint, and end of the pilot trial. The SF-36 score ranges from 1 to 100; QoL is deemed higher with increasing score [7]. As a supplement to the SF-36 questionnaire survey, the citizens were screened for anxiety and depression by means of the Hospital Anxiety and Depression Scale (HADS). As this questionnaire has been designed to provide a simple yet reliable tool for use in medical practice, it was deemed appropriate for this study [8]. It was important that the questionnaires were easy to fill out for the citizens and that the result was relatively easy to analyse. The citizens filled out the HADS questionnaires at the same time as the SF-36.

A. Litterature review:

To uncover the existing body of knowledge within the theme of acceptance and QoL in relation to chronically ill citizens and home monitoring, a literature study was carried out. A search on PubMed using the search terms “chronically ill”, “citizen”, “empowerment”, “acceptance”, “home monitoring”, “technology”, and “quality of life/QoL” in different combinations of two – four resulted in 13 relevant articles. Despite their relevance, however, none of the found articles turned out to give accounts of the citizens’ personal experience of living with the technology for a relatively long period of time. In the following, the main trends uncovered by the study will be described and supported by examples.

Several of the articles focused on quantitative results such as cost-effectiveness [9], clinical outcomes [10][11], or both [7]. Others focused on the reliability of the data produced by applying home monitoring in the care for

- Internet access in the homes
- Compatibility Pairing issues between measuring equipment and hub
- Lack of integration to electronic patient records
- Organisational changes (workflow)
- Battery change

Figure 2. Technological challenges.

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chronically ill citizens [12]. Many discussed how to involve and empower patients by employing self-care education [13][14] or interactive online environments [15], e.g. for self-management and self-monitoring [16][17]. In addition, some regarded empowerment as a solution to the problem of noncompliance/non-adherence [18]. It was found that even though telemedicine interventions can increase the feeling of self-efficacy, the citizen's healthcare providers and others related to the intervention play a critical role in engaging them in a new intervention, e.g. involving home monitoring [19]. In most articles touching upon the notion of QoL, this is measured by questionnaire surveys [20].

Many of these studies present hypotheses about the citizens' perception of the technology, but do not directly include the citizens in the study to determine what they really think.

B. *Definitions:*

Home monitoring can be defined as the use of information and communication technology in exchange of information between the patients' home and health professionals. This allows for the clinical staff to respond immediately to alarms from the citizen's home. Home monitoring also empowers citizens to learn and apply expert knowledge and thereby become more responsible for their own health situation [3][21][22].

C. Aim:

The aim of this paper is to present local results regarding acceptance and qualitative of life of the involved citizens from the Danish pilot site: Langeland. The overall question is "how was it to live and cope with the home monitoring in daily life?". The interviews were conducted in addition to the overall design of the project (HADS and SF36) to explore how the citizens' daily life was influenced by the technology.

III. METHODS

Data collection: The interviews were conducted in person in the homes of ten citizens who took part in the DREAMING project. These interviews were conducted as semi-structured research interviews [23]. According to this approach, a research interview can be regarded as a professional version of an everyday conversation where the interaction between the interviewer and interviewee contributes to the construction of knowledge. The purpose of qualitative research interviews of this kind is to understand phenomena from the perspective of the interviewee. In cases where a relative was present, this person took part in the interview. Data were recorded and transcribed, and then content were categorized and analyzed.

Combined with the interviews, the findings include results from two questionnaires: HADS and SF36. The questionnaire survey was conducted in all six European countries. It was analysed for the overall sample, but also for each of the sites separately. In this paper we focus on the Danish results.

Materials: 10 out of eleven citizens (six women and four men) from the rural area in Denmark called Langeland who have lived with the technology for more two years. These citizens represent all the remaining participants in the IG, the CG was not involved in the semi-structures interviews. However, one of the citizens in the IG was not capable for an interview. The age was between 66-82 years at the beginning of the project period. Seven subjects lived alone in their homes and three lived with a relative. Nine lived in their own homes and one lived in sheltered housing.

IV. RESULTS

A. Qualitative interviews:

The interviews revealed three main themes: feeling of safety, empowerment, and acceptance. In the following, the themes will be defined and supported by concrete findings from the study.

Feeling of safety: This can be defined as a feeling of trust and confidence.

A general perception amongst the citizens was that the monitoring equipment increased their feeling of safety. The fact that professionals had an eye in the home and reacted to alarms from the system had a great impact regarding this feeling. As one expressed it: *"The best thing is that someone is keeping an eye on me. It makes me feel safe".* Another subject put it this way: "*It's reassuring, because they call me if the measurements are too high".* Only one citizen didn't feel safer: *"It doesn't make me feel safer, I'm safe enough".* She was one of the participants who had experienced some problems with the equipment. Therefore she did not have a lot of trust in it. In one case, there was a positive effect on the spouse. The wife of the participant said: *"I feel safer now, because he doesn't tell me if his measurements are good or bad. But if the phone rings, then I know".*

Empowerment: In its most general sense, empowerment refers to the ability of people to gain understanding and control over personal, social, economic, and political forces in order to take action to improve their life situations [24].

For nine out of ten, the technology empowered the citizens to different degrees. In general it gave most of them a sense of freedom, because they were less dependent on visits from nurses or visits to GPs. Or freedom because they, to a further extend, could take the measurements themselves.

The technology increased their awareness toward issues related to the disease: *"I'm experiencing that I think more about what I'm doing"* or as another said: *"I'm more aware of when I take my measurements and when I should take the insulin"*.

The technology was no longer only *"a tool to better manage my disease"*, but for two of the participants they found a way of using it for rehabilitation. The video conference system was thereby used to link the community physiotherapist and the citizen and as one expressed it with a smile: "*I have started using videoconference for physiotherapy – I wouldn't get it done, if I had to go somewhere else".* Both staff and citizens have great expectations towards this new way of using it for rehabilitation. The same two citizens and a third also played with the possibility of using the videoconference for communicating with relatives living away: *"I want to use videoconference for talking to my children who live in*

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different parts of Denmark". Furthermore one of the two frequently used Skype for this type of communication; a development that was clearly connected to participating in the DREAMING project.

Acceptance: No sufficient definition of acceptance has been found to be available. We define acceptance as integrating something new, in this case technology and a new way of receiving healthcare services, in your daily life and letting it have a positive influence on it without requiring too much attention.

It was obvious that the technology had become a naturally integrated part of the citizen's daily lives: *"In the beginning we talked about it, now it is just there",* or as another expressed it: *"It has become a habit"* – a habit they did not wish to live without: *"I wouldn't mind keeping it after the project, because it helps me getting around to taking my measurements.* As seen from the quotes in Fig. 3: the citizens had fully accepted the technology and found it better than ordinary care.

Observations from the researchers: having the opportunity to enter the home of ten citizens, who had lived with the technology for a relatively long period of time, we were curious about the physical appearance of the technology. Most had it out in the open on places of convenience for using it, but one had it hidden away – not because of the expression of the technology, but to keep it safe from the grandchildren.

- "There is nothing bad about it"
- "It has become a daily routine"
- "Would recommend it to others"
- "No problem using the technology"
- "I prefer technology over ordinary care"
- "It is nothing out of the ordinary"
- "It has been easy to use"
- "Wants to keep it!
- "It has become a habit"
- "It's a piece of cake"
- "I would miss it"
- "I don't think it is difficult to handle"
- "I like having it"
- "It doesn't make me nervous or anything"

- ***"It is nothing to talk about"***

Figure 3. Citizens about technology

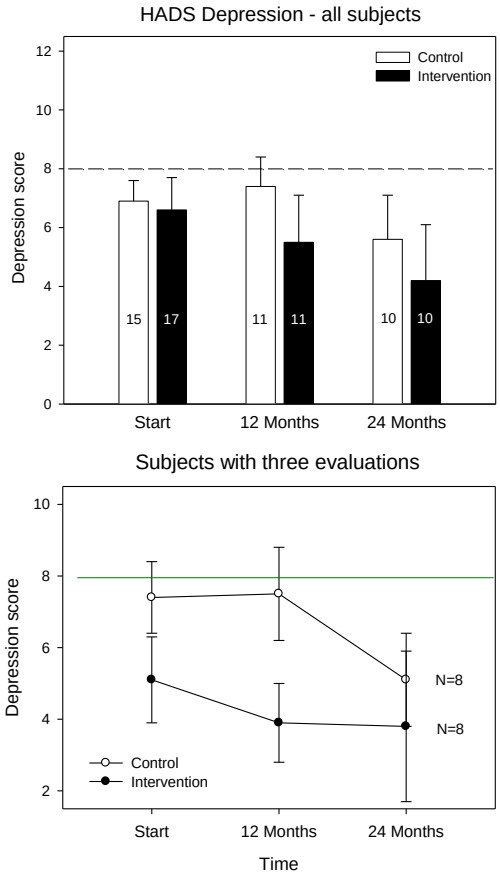

Figure 4. HADS results

Data from the HADS evaluation are shown in Fig. 4. The bar graph shows data for all subjects who took part in any of the assessments. The line graph only depicts the scores for subjects who continuously contributed to all three evaluations. A within subject ANOVA (ANalysis Of VAriance) on these data with time as a repeated measure revealed a main effect of the intervention condition ($F(1,15)=3.74$; $p<0.05$, one-tailed). However, while there was no difference between controls and subjects in the intervention group at the start if all subjects are considered (see bar graph), subjects who continuously took part already differed in the beginning of the study with lower depression scores in the intervention group. This pattern is very similar to the overall result from six study sites. It indicates a higher dropout rate of subjects with high depression scores in the intervention group. In the SF36 there is no group difference ($p > 0.8$) in the physical component score (PCS) which is a measure for overall physical health (Fig. 4, bottom). Both groups show a similar development over time ($F(2,15) = 9.59$, $p< 0.001$), with a slight decrease over the first year and a large increase over the second year. Consistent with this pattern, both the linear trend ($F=4.92$, $p<0.05$) and the quadratic trend ($F=13.70$, $p<0.005$) of the within subject factor time are significant.

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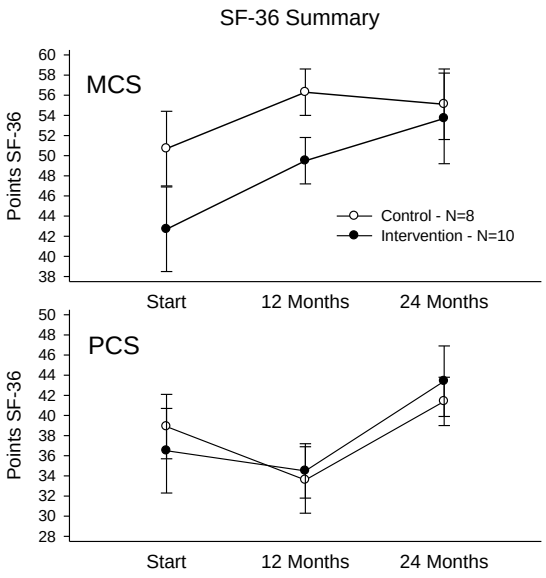

Figure 5. SF-36 results

In the mental component score (MCS) there is a significant development in the control group ($F(2,14)=10.36$, $p<0.005$) as well as in the intervention group ($F(2,18)=4.04$, $p<0.05$), but the group difference is not significant nor is the interaction intervention x time.

V. DISCUSSION

Before interviewing the citizens, we were prejudiced in relation to what we would find. Prejudices like that it was a big issue for the citizens to be involved and use the technology, that it was a challenge for them to handle the technology and that the citizens would discover being a part of a modern and cool group living with technology and that their surroundings would think the same. However, what we found was: "Nothing to talk about"

But it took some time. One big and maybe crucial advantage in the project was the time – all in all four years to prepare, test, and educate citizens including two years of pilot testing in the home of the citizens. To begin with both staff and citizen were hesitant toward this new way of working/new way of handling chronic diseases. A lot of effort was put into addressing the hesitancy by involving all stakeholders in the process. There was time for overcoming technically obstacles – for example getting internet connections to run in the homes of the citizens and the devices to be trustful and functioning. One really important issue related to the positive outcomes was hiring the old local farmer to support and help with small and big issues arising in the process. Speaking the language, being a person the citizens knew kicked in doors that might have been far more difficult to get access to.

In the DREAMING project, the citizens gained more freedom and empowerment, and the health services were provided far more on the terms of the citizens than on those of the system. Part of this was the contribution of the technology to the empowerment of the citizen indirectly in keeping them fit and thereby prevent side effects from the disease. Combined with the increased feeling of safety it can explain the high acceptance in receiving home monitoring. The results from the interviews are supported by the Danish results from the questionnaires (HADS and SF36). Citizens in the intervention group were less depressed than the control group and had a slightly higher quality of life. A review from 2012 [25] including studies from 2007-2012 – 68 studies in all, showed a clear trend towards better behavioral changes of the citizens leading to better empowerment and higher quality of life.

It takes time to turn around habits and start a whole new culture based on change of mindsets for both staff and citizen and maybe many projects do not have the needed time for obtaining positive results?

We are of the conviction that the success experienced in the DREAMING project was linked to the long period of time to run the pilot – it became a habit – a habit that now has turned into daily practice without the citizens' awareness. The involved citizens in DREAMING had a chance to develop along with the technology. It will be interesting to follow further implementation to the community's other chronically ill citizens where this kind of technology and organization is relevant. Will they have to start all over or will they be able to gain from the previous experiences?

It would seem that the elderly chronically ill citizens in general are not resistant towards technology, maybe because the technology has a meaning and a direct purpose (as in the DREAMING project). The future citizens will be more and more used to having technology as a part of their daily life (as using home banking, internet shopping, social media, etc.) and then become more familiar using home technology for handling and improving health issues.

In this case, the technology became leverage for this change and maybe we have started a small revolution in changing a shift in paradigm as addressed in the introduction.

VI. CONCLUSIONS

The overall conclusion is that, having lived with home monitoring technology for more than a year, they had fully accepted it. When interviewing the citizens they looked at us as if we asked how it would be to live with your hoover – good to have but nothing to talk about!

VII. LIMITATIONS

Research involving elderly citizens with a chronic disease can be a challenge in relation to keeping up the number of participants. In the DREAMING project, we began with including 51 citizens and ended up with 23 (control and intervention). The project lasted four years and the citizens were included from the beginning. In such a long period of time, this, often frail, group experiences acute worsening of their condition, are admitted to hospital – do not full recover and some die.

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VIII. PERSPECTIVES

In Langeland the research has turned into daily practice and more communities are on the way of implementing the results. The staff, using the technology, finds new areas where same technology can be used – for instance for young people with diabetes and for rehabilitation. Regarding the citizens, three of the participants were already experimenting or using the technology for new purposes such as rehabilitation or communication with relatives or friends (Skype). Another expressed that he would like to use technology if he should get another kind of disease.

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A Multifunctional Telemedicine System for Pre-hospital Emergency Medical Services

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***Abstract*—The paper presents the design and architecture of a multifunctional telemedicine system for real-time teleconsultation in pre-hospital emergency medical services (EMS). The application of telemedicine has shown to improve patient treatment quality and efficiency in various settings. Still, its use by pre-hospital EMS is lacking. Current technical, normative standards do not provide a sufficient framework in order to design a multifunctional telemedicine system for teleconsultation in pre-hospital EMS. Starting with a use-case driven requirements analysis, a telemedicine system usable in this setting is designed, realized and currently in use for evaluation by selected German EMS departments. This system uses commercial off-the-shelf medical devices, custom devices for communication and an individual system architecture, integrating the heterogeneous components as required by the defined use-cases.**

***Keywords*-telemedicine; teleconsultation; EMS; system architecture;**

I. Introduction

Specialized telemedical applications have shown to improve patient care in different inner-clinical settings and its benefit has already been demonstrated for various pre-clinical uses [1]–[3]. Despite the rapid evolution of personal mobile communication devices with its current manifestation of power-full computing devices like smartphones, tablets or even wearable computing-devices [4], the use of telemedicine in pre-hospital environment is still in its infants.

Research efforts have been undertaken to develop multifunctional telemedicine systems which enable emergency medical service (EMS) teams to perform teleconsultation with remote specialists or more broad treatment facilities like hospitals [5]–[8]. These projects aim at creating pervasive assistance systems using different combinations of audio and video communication, transmission of biomedical data and access to existing medical patient records.

The above systems do only allow teleconsultation from inside the ambulance and the additional devices they introduce do not integrate well into commonly used, existing EMS team equipment. System architectures are proposed which require big parts of the created infrastructure to be classified as a medical device and as such pose a high burden on their realization from a regulatory point of view. Another concern neglected by these approaches is the user role which serves a teleconsultation request and thus guides the EMS team during patient treatment or supports them otherwise.

The German research project TemRas has developed the multifunctional telemedicine systems, described in this paper, which allows on-scene EMS teams to consult a dedicated EMS physician, hereafter called tele-EMS-physician, on duty in a teleconsultation center [9], [10]. This system's novelty is its level of integration into the EMS team's equipment and ease of use, enabling teleconsultation not only inside or close to the ambulance but from every location with suitable mobile network coverage, like inside a patient's home. On August 1st, 2012 the system was taken into service with initially three ambulances connected for teleconsultation in regular EMS missions. After a ramp-up during August, six ambulances from different EMS departments were connected to the system and operational since the beginning of September. Until October 4th, 60 successful teleconsultations have been performed using the presented system.

II. Method

The system's design was created in a mainly linear process with strong user participation and close feedback loops between engineers and users. The original intent of a true iterative, agile development process could not be realized for the whole system, but was instead used to develop the individual user facing software-components. The whole process was agile in that it was not artifact centered and no sign-offs were performed like described by the waterfall-process [11]. Rather, all process activities were focused on the final system being usable for teleconsultation and fulfilling necessary safety requirements. Documents were only generated as basis for further discussion and swapping functionality in and out of development focus was possible during the whole process.

Involved into the system's design process was a team of experienced emergency physicians, most of which had already been working as tele-EMS-physicians during the former project Med-on-@ix [12]. On one hand they are users to the system as tele-EMS-physician, on the other hand they were user representatives for the on-scene EMS personnel. The participating physicians had used the system on-scene during Med-on-@ix evaluation and had regular contact to

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relevant EMS personnel during their work as regular EMS physicians. The system design itself was created by a small team of engineers which also realized most of the currently available prototype; other parts were sourced out to specialized hardware manufacturers.

The emergency physicians defined four main scenarios for the telemedicine system's usage. Together the emergency physicians and engineers described and detailed 21 use-cases as functional requirements descriptions to guide the system's design. These use-cases define which services the system has to provide in order to be usable for the main scenarios and roughly describe their usage and inter-relationship. The use-case's descriptions contain additional non-functional requirements like demands regarding robustness, reliability and data security. Service interface specifications were created in close iterations by the engineers and user facing functionality was created in a mockup-driven process with continuous user involvement. As single service's functionalities were available, users were involved in initial testing and requirements and further design was adjusted according to their feed-back.

Integration and system-tests were performed as early as possible in the process to unveil integration issues, missing necessary and planed unnecessary functionality early on. The early system-tests allowed for a good judgment about the actual relevant functionality for the systems intended scope and allowed the development team to react accordingly.

III. System Design

The multifunctional telemedicine system's design is subject to some project related invariants which had influence on the development process and the overall system design:

- The system was designed and built during the project's first two years and had to be ready for use after that phase in order two allow for its evaluation in regular EMS missions.
- All medical devices used by the system are provided by the associated project partners Philips HealthCare and 3M. Devices from other vendors were not considered for initial integration.

A. Use-Cases and Main Requirements

The defined use-cases can be clustered into three main groups which are further detailed in Figure 1:

- Audio Communication
- Data Transmission
- Common Activities

Besides these main use-cases multiple support use-cases were created to address aspects like user authentication or system administration and are not specific to this telemedicine system.

The prominent notion of audio communication related use-cases is based upon existing experience by the involved system users and user representatives, showing that an easy to use, reliable and robust method for bidirectional voice communication between the tele-EMS-physician and the on-scene ambulance team is the single, most important factor for a successful teleconsultation. Making regular phone calls is necessary for the tele-EMS-physician in order to support the on-scene team in administrative tasks or to contact external specialists like the poison control center. To provide a good usability, the tele-EMS-physician has only a single phone-like interface which integrates handling of internal calls (to the on-scene team) and calls to the public switched telephone network.

All use-cases describing the transmission of case related information between on-scene and the tele-EMS-physician are grouped together in the Data Transmission cluster of use-cases. This contains transmission of continuous real-time or discrete biomedical signals, auscultation streams as well as photo and real-time video transmission. The cardiotocography (CTG) is covered as a special form of biomedical signal transmission; it will only be used to perform a smaller study regarding its usability in pre-hospital EMS and does not have any impact on the current system design.

Common Activities mainly contains use-cases describing the electronic case documentation performed by the tele-EMS-physician and the handling of reports automatically generated from that data. The easiest method of delivering a case report to the receiving hospital, together with the treated patient, is by printing the case's summary report on a printer inside the ambulance. Using fax, a report can be sent to the hospital before the patient arrives. Direct integration with a hospital's information systems is currently outside the described system's scope.

The top four non-functional requirements defined for the system are:

- overall system usability
- security of transmitted data regarding eavesdropping
- data correctness
- robustness of both data transmission and audio communication.

Overall system usability is a very fuzzy formulation. This requirement targets at providing an integrated system experience in order to enable simple workflows during patient treatment. To further concretize this requirement, the system's two main usage locations, on-scene and teleconsultation center, are addressed in separation:

- On-scene the ambulance team's current workflows and carrying pay-load should be influenced as little as possible. The system must seamlessly integrate with the devices used on-scene and be usable for a regular two-person team during potentially stressful patient treatment.
- From the teleconsultation center one tele-EMS-

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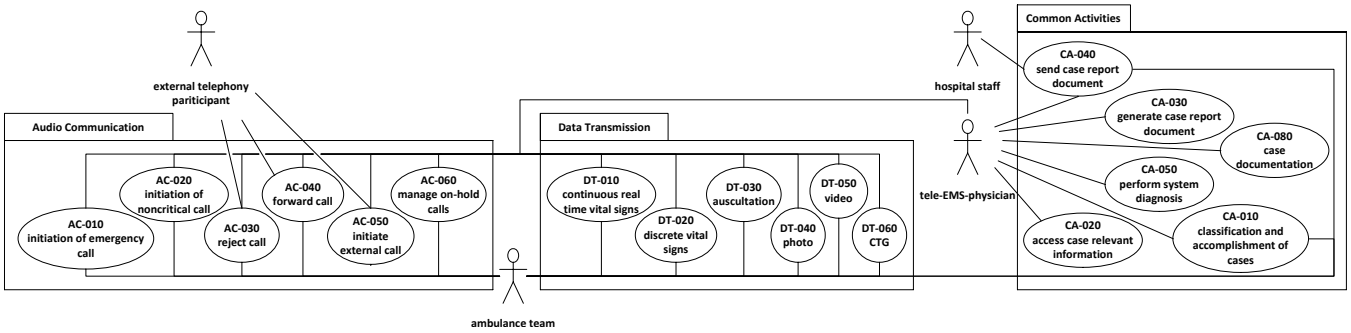

Figure 1. The main use-cases defined for the telemedicine system described in this paper.

physician only interacts with one ambulance team at a given time. All related services must ensure that data only from that team is displayed. The different services must integrate seamlessly into one working environment in order to reduce the burden posed onto the tele-EMS-physician by the system's usage.

Data correctness covers two main concerns:

- Information must not be altered between its acquisition on-scene and presentation thereof to the tele-EMS-physician. If data is transformed in any way it must be ensured that the information it presents is not affected by that transformation.
- It must be ensured that data which is presented to a tele-EMS-physician is at any time associated to the correct ambulance and thus the right patient respective case.

B. System Architecture Overview

Various harmonization and standardization groups have defined different standards and interoperability profiles, a collection of specifications often with accompanying restrictions and definitions, for a multitude of data-interchange and device integration scenarios: Health Level 7 (HL7), Integrating the Health enterprise (IHE), Continua, IEEE 11073 [13]–[15]. The amount of different, sometimes competing, sometimes complementary specifications and usage profiles makes it hard to know where to start when looking for the right design for a system which does not fully fit the existing use-cases. At the same time the harmonization efforts mainly target the hospital or consumer market. A market survey regarding pre-hospital EMS devices shows that by now first manufacturers begin selling telemedicine enabled devices, with each vendor creating an independent, proprietary solution [16], [17].

Based on the use-cases, additional requirements and project constraints, a system architecture was designed. This process started by choosing the devices which compose the on-scene system. This device-centric view onto the system is depicted in figure 2 in which the system is divided into the three locations: consultation center (top), ambulance/in-car (left) and on-scene (right). All data transmission from

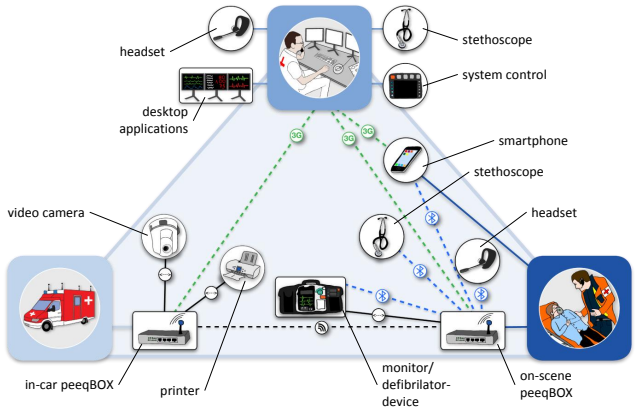

Figure 2. Device-centric view on the telemedicine system's system architecture; adapted from [9].

inside the ambulance and on-scene is relayed to the consultation center via a special data transmission unit (peeqBOX, designed and manufactured for use in this system by P3 Communications GmbH, Aachen, Germany).

The in-car peeqBOX acts as gateway for the Local Area Network (LAN) inside the ambulance, enabling TCP/IP network traffic between this and the consultation center's LAN. The following devices connect directly to the ambulance LAN:

- A network enabled video camera (SNC-RZ50P, Sony, Japan) is mounted at the ambulance's ceiling. It is fully controlled by the tele-EMS-physician who can tilt, pan and zoom its view. The video is streamed using a H.264 video codec, eight frames per second, a Bit rate of 128 kilo Bits per second and an image resolution of 384 times 288 pixel.
- A thermal printer (PocketJet PJ-623, Brother, Japan) with 300 dots per inch using a print server (TL-PS110U, TP-Link, China) for its connection to the network.

The on-scene devices all use Bluetooth to wirelessly connect to the on-scene peeqBOX. This peeqBOX itself is housed inside the right pocket of the monitor-

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Figure 3. An early development prototype of the on-scene peeqBOX fitted inside the right pocket of the monitor/defibrilator-device's bag. The bag's right pocket was later adjust to provide space for patient therapy equipment.

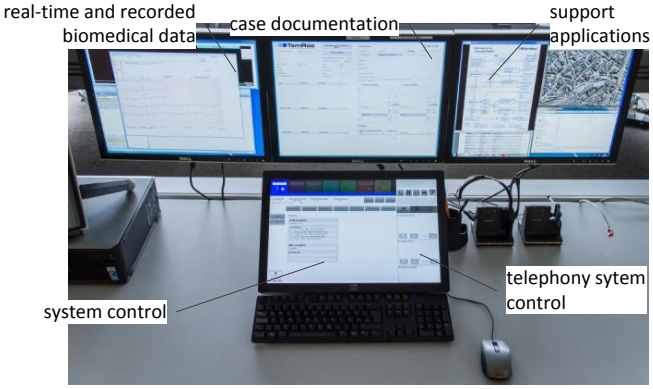

Figure 4. Photography showing a tele-EMS-physician workplace with the three top monitors showing the main applications (besides video) used during a consultation and the lower centered touch-monitor with the system control interface and the integrated telephony system controls to the right. Keyboard and mouse are connected to the desktop computer to interact with its applications on the three top monitors.

ing/defibrillation device, as shown in figure 3. The following devices comprise the on-scene location of the system:

- A monitor/defibrillator-device (HeartStart MRx M3535A, Philips, Netherlands) configured with the options SpO2, NBP, EtCO2, 12-Lead, 12-LTx Bluetooth, Pacing, Q-CPR, Q-CPR Data, 75mm Printer, EventSum Bluetooth, IntelliVue Net and Per Data Tx.
- Two headsets (Plantronics Voyager Pro HD, Plantronics, USA) used by the ambulance team to communicate with the tele-EMS-physician. This communication link is delivered via a regular voice call established by the on-scene peeqBOX using public circuit switched mobile telephony networks.
- A smartphone (HTC Sensation XE, HTC, Taiwan) serving two purposes: In regular operation it is used to take photographs on-scene which are automatically transmitted to the consultation center. In case of the loss of the regular audio connection via the peeqBOX during a case, the ambulance team can directly call the tele-EMS-physician with this phone, increasing the chance for safe termination of a consultation instead of its interruption.
- A stethoscope (3M Littmann electronic stethoscope 3200, 3M, USA); this device's integration is still in its conception phase and is not used by the currently running system.

In the consultation center a tele-EMS-physician's workplace is comprised of the following user-facing devices, as shown in figure 4:

- A wireless headsets (Savi W710/W730, Plantronics, USA); the tele-EMS-physician can choose out of two available models which one to use or switch the headset if the first one runs out of battery power.
- A stethoscope (3M Littmann electronic stethoscope 3200, 3M, USA); this device's integration is still in its conception phase and is not used by the currently running system.
- A desktop computer (OptiPlex 780 DT, Dell, USA with main memory: 4GB; processor: Intel Core 2 Duo E8400, Intel, USA; graphics-card: NVIDIA Quadro NVS 420, NVIDIA, USA) with three monitors (UltraSharp 2007FP, Dell, USA) attached running Microsoft Windows 7 operating system hosting the different applications used by a tele-EMS-physician during consultation.
- A dedicated control computer (OptiPlex 780 USFF, Dell, USA with main memory: 4GB; processor: Intel Core 2 Duo E8400, Intel, USA) with a single touch monitor (Elo 1900L APR, Elo, USA) attached which is used to control the telemedicine system, shows data for system diagnostics and offers an integrated user interface for the telephony system.

C. Device and Service Integration

Classifying the devices by the Continua Alliance's Reference Architecture, the monitoring device and stethoscope are Peripheral Area Network (PAN)- or LAN-devices whereas the on-scene peeqBOX is an Application Hosting Device [14]. All services provided by the tele-EMS-physician relate to WAN-devices. Storage of patient related information could be delegated to a Health Record Device (HRD), but such a service's primary intend of "... offering a broad overview of a person's health status in a central location [18]" is out of the scope of the current system design.

Current state of the art would suggest realizing the connection between said PAN-devices and the on-scene peeqBOX by following IEEE 11073 family of standards [15], [18]. Two current facts prevent this choice:

- Only a subset of the necessary device profiles exist as approved standards: blood pressure monitor and pulse oximeter, whereas basic electrocardiogram (ECG), using 1- to 3-leads, is still in final draft status by ISO [19]–[21]. Communication of 12-lead ECG or stetho-

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scope connection has not been addressed by this family of standards at all. (reason might be focus of use-case)
- None of the devices in question for use supports an open standard for communication. The only way to interface with them is by means of proprietary software provided by the devices vendors.

Instead a common integration approach is used by building a message driven middleware layer following common Enterprise Integration Patterns [22] using individual adapters to control the used third party applications. This middleware layer is comprised of different Java services hosted on a Java application server (Glassfish v3.1.2, Oracle, USA). Messaging is performed via the Advanced Message Queuing Protocol using a single message broker (RabbitMQ v2.7.1, VMware, USA), enabling service adapters to be implemented in different programming languages. The system's user interface presented to a tele-EMS-physician is composed of both preexisting local applications running on the desktop computer and rich web applications specifically implemented for this setting.

The web applications displayed in a special viewer application instead of a regular browser, allowing tight control over them and preventing the user from accidentally navigating away from an application. These viewer applications as well as the other local applications are controlled by an application controller service running on the desktop computer, allowing the middleware services to launch, close or otherwise remote-control them.

All but the system's audio communication functionality uses IP network technology to connect the ambulance (in-car) and on-scene location to the consultation center [23]. This IP network is provided by each of the peeqBOX-devices, simultaneously using multiple third generation mobile telecommunications network links, up to three on-scene and up to five in-car to connect to a special router, called Stationary Communication Unit (SCU), in the consultation center. Additionally the in-car peeqBOX offers a Wireless LAN (IEEE 802.11a) inside and close to the ambulance which is used by the on-scene peeqBOX to relay all its IP network traffic via the in-car peeqBOX and its roof-mounted antennas. All IP network traffic between the peeqBOX-devices and the SCU is distributed among the available mobile network connections and encrypted using AES-265 encryption. This approach enables direct integration of IP network capable services (video-camera, printer) and at the same time ensures a high robustness against the full loss of their network connection.

On top of the IP network each peeqBOX offers a file transfer service using the standard File Transfer Protocol. Via this service files are delivered to ambulance specific inboxes where they are further processed by the middleware layer and handed to consuming services in the consultation center. Access to this file transfer service is offered by additional peeqBOX service adapter:

- The photo adapter queries pictures taken with the smartphone via the Bluetooth File Transfer Profile (Bluetooth FTP), having the smartphone act as server. As soon as the adapter has handed a picture to the file transfer service, it deletes the picture on the smartphone.
- The biomedical signals adapter accepts Bluetooth FTP connections from the monitor/defibrillator-device which uses this method to publish files containing periodic trend data and recorded 12-lead ECGs, both in a proprietary data format.
- System diagnostics data concerning a peeqBOX is collected into a small sized (less than 600 Byte) XML-file every ten seconds and handed to the file transfer service. This data includes: battery level (only on-scene), device temperature, voice and data connection overview, detailed mobile connection link data, headset status, time-stamp and global positioning system (GPS) coordinates.

To enable continuous real-time biomedical signal transmission from on-scene the peeqBOX uses an OSI Layer two network bridge to connect the monitor/defibrillator-device to the clinical network provided by an IntelliVue Information Center (Philips, Netherlands) in the consultation center [23]. The monitor/defibrillator-device's integration will be discussed in more detail in a future publication.

The audio communication between on-scene and a tele-EMS-physician is realized in two stages. The on-scene peeqBOX is used as multi-SIM mobile phone with additional control logic. The user interfaces to this function only by using the single button on its headset, which initiates an emergency call to the consultation center via the best available, circuit switched network. In the consultation center a private branch exchange based on the open-source Asterisk framework answers the call by putting it into a separate conference room. The tele-EMS-physician which accepts such an incoming call is connected to this conference room via a voice over IP client, remote-controlled via the system's middleware layer. Using the touch monitor's telephony interface, the tele-EMS-physician can itself initiate calls either to an on-scene peeqBOX or to an external telephony participant.

IV. Conclusion and Future Work

A multifunctional telemedicine system using commercial off-the-shelf medical devices, which is suitable for use by a regular EMS team, has been presented in this paper. The lack of existing standards for the required integration of medical devices results in an interoperability issue which prevents the creation of open systems and common frameworks or platforms for such a telemedicine system. The current situation requires integrating each device or product line independently. Solving this interoperability issue should therefore be a primary target of future research and regulatory efforts.

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The presented service integration approach using a simple message broker enabled a rapid system implementation and proved suitable for creating an integrated telemedicine system. Its capability for delivering sophisticated, automated workflows, e.g., for advanced reporting or data-exchange with external entities, however is limited. The use of concepts like Enterprise Integration Bus might be a viable option to address this issue and is left for future work.

Integrated information exchange with receiving hospitals or electronic health records is not covered by the scope of the presented research. The IHE and Continua Alliance efforts generally address this concern. Assessing their existing guidelines regarding suitability for this integration use-case remains for future work.

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An Introduction to a Transnational Volunteer Notification System Providing Cardiopulmonary Resuscitation for Victims Suffering a Sudden Cardiac Arrest

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***Abstract*—While it is always desirable in an emergency to get treatment as soon as possible, there are emergencies that need immediate treatment. In case of Sudden Cardiac Arrest an untreated time interval of only a few minutes usually means the victims' death. Given the delay between an incoming emergency call and the arrival of the emergency medical services at the scene, it is necessary to find an alternative way to provide immediate first aid treatment. One approach for this is the implementation of a Volunteer Notification System – involving laypersons and medically trained volunteers into the emergency medical service, by notifying those potential helpers who can arrive at the scene fast enough to provide the urgently needed measures.**

Keywords—Volunteer Notification System; First Responder; Emergency Medical Services; Sudden Cardiac Arrest; Cardiopulmonary Resuscitation; Telemedicine

I. INTRODUCTION

Due to the way today's professional emergency medical services (EMS) are organized, victims in need of urgent medical care are facing a lethal problem. Depending on the type of emergency, the time interval between the incoming emergency call and the arrival of the professional helpers at the scene is simply too long. In Bavaria (Germany) for example, a region with good infrastructure and an advanced medical system, reoccurring studies are made every four years, in order to analyze the effective time interval local EMS need until arriving at the place of incident. The institute for emergency medicine in Munich (INM) states in a recent study that professional EMS in the area of Bavaria require approximately 9 minutes until arriving on scene [2]. Furthermore, the study underlines an ongoing increase in this deficit due to a diversity of reasons. The severity of the time deficit generally correlates with the infrastructure a country can provide, resulting in intensification for less advanced countries and regions. While most emergencies do not involve an immediate life danger for the victim, in case of a Sudden Cardiac Arrest (SCA) the first minutes are of utter importance. Jan Bahr states that as little as three minutes is most likely enough for victims of SCA to suffer permanent brain damage and Karin Grassl describes within her dissertation that the survival rate after five minutes without treatment is practically zero [6, 7]. Victims suffering SCA are in need of urgent medical care that professional EMS alone cannot always sufficiently provide.

A. Structure

The first chapter of this paper describes the medical emergency of a Sudden Cardiac Arrest (SCA) and introduces the basic concept of a Volunteer Notification System (VNS). Starting by identifying and discussing comparable systems, the second chapter focuses on analyzing the technological state-of-the-art of mobile devices and data communication concepts; herby determining the possibilities and restrictions for a VNS approach. The third chapter introduces the current project "EMuRgency". As one focus of the project is the actual implementation of a new VNS, the core components and the corresponding architectural details are being discussed. The fourth and thereby last chapter of this paper introduces the conclusion and shortly discusses a potential generic approach and some optional features.

B. Sudden Cardiac Arrest

The human heart has an electrical conduction system that controls the rate and rhythm of the heartbeat. Problems with this electrical system can cause irregular heartbeats called arrhythmias which can lead to Sudden Cardiac Arrest (SCA) - a condition in which the heart suddenly and unexpectedly stops beating. The hereby resulting loss of blood flow prevents the brain and any other vital organ from getting oxygen. Without immediate treatment, the victim dies within minutes. It's a common misconception that SCA is the same as a heart attack, while in reality, they are quite different. SCA is an "electrical problem" that prevents the heart in its whole from functioning, whereas a heart attack occurs when part of the heart's blood supply is reduced or blocked causing the heart muscle to become injured or die. [1]

C. The basic concept of a Volunteer Notification System

One possible solution for offering faster response treatment is the concept of involving volunteers into EMS by implementing a Volunteer Notification System (VNS). A VNS may be defined as an IT system with the following core functionality: by tracking the location of all registered users, the system will be able to notify exactly those potential

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helpers who are, at the time of the incoming emergency call, geographically close to the place of incident.

This concept of a VNS does not interfere with the local corresponding emergency standard procedures, but can rather be described as an optional add-on to existing EMS; the responsible dispatcher takes the decision if to involve this optional feature. It is important to understand that the potential volunteers are not a replacement for emergency physicians or any professional helper that has been alarmed, but their main purpose is to arrive at the scene fast enough to start Cardiopulmonary Resuscitation (CPR). While there is no exact definition or specification of a VNS yet, it is part of this paper to discuss a potential architecture and distinguish between the core and the optional functionalities of such a system. The technical implementation of an integrated VNS is the focus of the European research project "EMuRgency" which will be described in the chapter three.

II. STATE OF THE ART

A. Existing systems with similar functionality

While a diversity of local approaches to implement notification systems exists already, those approaches generally do not have an academic motivation or background. Therefore, publications on the aspect are still rare and the corresponding projects are opening neither their expertise nor the source codes to the public. The only publically available resources are the corresponding application download, some basic usage documentation and a reference document for the Advanced Programming Interface (API) – which merely offers functionality for providing the systems with data [13].

Based on reviews and the appearance in media all over the USA, the PulsePoint Foundation for example offers one of the most advanced software implementations in the field of emergency notifications at the moment [15]. Formerly known as the "Fire Department App" and developed for iOS only, the new version is available under the name "PulsePoint" for Android and iOS [14, 13]. Even though this application is surely great for offering everyday people a possibility to save lives, based on the available documentation, it is a US-only solution without open interfaces. From an academic point of view, it is regrettable that the achieved competences are not shared, which in combination with non-open source codes makes it is nearly impossible to use the project as a base for a scientific work. Furthermore, the implementation approach is rather static, only allowing two types of mobile devices (Android and iOS) as recipients and no other but US specific regulations, legal circumstances and network characteristics are supported. There are a few smaller projects with less impact and publicity, but the problems stay the same.

Beside the difficulties to communicate and rely on more or less closed projects for information flow and depend on their goodwill, the available solutions are implemented as local solutions that cannot easily be adapted to other countries, regions or new legal environments. Fundamental changes are needed in order to use these systems with other than the original parameters and the underlying model itself does not provide a reasonable extension of functionality without making changes to the actual source code itself.

In summary, the currently available systems lack essential interfaces, public tools for gathering and extracting information, an efficient communication flow and basic concepts for extensibility; therefore it seems inevitable to provide a new approach to the topic rather than upgrading an existing one.

B. Mobile technologies

Advances in mobile technologies and the continuous growing popularity for portable digital devices with internet access in nowadays society offer a great starting point for VNS. Without supplying any special devices, a VNS is able to communicate with a huge variety of volunteers by simple using the existing hardware and infrastructure that people own and use anyway. Modern smartphones for example offer a diversity of features that may be used to aid potential helpers in their mission to arrive on scene as early as possible. Some notable built-in features are real time Internet connections, notification options with vibration and sound, photo and video modes, a variety of sensors to enable situation based functionality like a compass, and the fact that actually any modern mobile device is running an operation system (OS) that supports programmatic solutions for individual software.

Based on the basic definition of a VNS, the core functionality of any VNS is the effective localization of the volunteers. The actual localization of mobile devices within a network is a complex matter, while the reliability of the results generally depends on the corresponding network provider and its infrastructure [12]. Different companies and research groups are working on this topic, offering a variety of Advanced Programming Interfaces (API's) with base functionality to access localization data for different types of devices. One of the most advanced examples is Android's Location API, which is part of the Android software platform, developed by Google in conjunction with the Open Handset Alliance (OHA) [11].

The OHA is a consortium of 86 companies, working on developing and advancing open standards for mobile devices. The consortium, led by Google, includes some of the biggest mobile operators like Telekom and Vodafone, as well as some important manufacturers of mobile devices like Samsung and HTC. As an open-source project, the Android source code is publicly available and can be accessed freely; this reflects in a high user acceptance and fast development progress due to contributions from the open source community. The comScore Incorporation recently published a report on the mobile subscriber market for the second quarter of 2012, by which Android is holding an average of more than 60% market share within the biggest countries of Europe [4]. In a press release from august 2012, the International Data Corporation (IDC) identifies the Android market share at even 68% worldwide and underlines that these numbers are increasing [5]. Both studies are based on device sales in the corresponding regions and therefore reflect the general tendency within the segment of smartphones and other mobile devices with internet access.

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Even though restricting the notification recipients to exclusively smartphones and similar devices running Android is questionable, it seems to be a reasonable decision for rapid prototype development in order to provide an early running system as soon as possible. It must clearly be stated that a limitation of this kind can only be temporary and that a final model of a state-of-the-art VNS has to provide a generic communication approach in order to support a broad variety of different devices. A more detailed discussion on the topic of a possible generic approach will follow in the upcoming sections of this paper.

C. HTML – the language of the World Wide Web

The Hypertext Markup Language (HTML) defines the core language of the World Wide Web (WWW). With the HTML 5 specification becoming the new standard for web interactivity, a lot of features are accessible for programmers to enable client and server technologies to communicate with each other. While a detailed discussion on server push technologies and HTTP requests would clearly exceed the context of this paper, it is important to note that the HTML 5 specification includes full support for so-called WebSockets. WebSockets specify an API as well as a protocol, while the protocol defines the HTTP handshake behavior to switch from an existing HTTP connection to a lower level connection; a so-called WebSocket connection. While a common approach over the last years was to simulate a server push channel over HTTP, a WebSocket connection enables bidirectional communication natively. Referring to the possibilities for the client/server communication within a VNS, the WebSocket approach offers a clean and simple communication concept and enables a generic implementation for any devices complying with the HTML 5 specification. [10]

III. THE EMURGENCY PROJECT

The European research project "EMuRgency" has been started in September 2011. Research facilities from Germany, the Netherlands and Belgium are working together on modeling and implementing an integrated Volunteer Notification System (VNS) to gap the time between an incoming emergency call and the arrival of professional helpers at the scene. The name of the project is a composition of the two words "emergency" and "urgent" and refers to urgent help that is needed in case of SCA. The three upper case letters "EMR" identify the regional base of the project; the "Euregio Maas-Rhein" (Eng. "Meuse-Rhine Euroregion").

A. Definition of the term "volunteers" within a VNS

Before describing the system, its components and the technical details, it needs to be clarified which group of people can actually participate as volunteers within a VNS. A volunteer can be anyone with basic skills in first aid and CPR (Cardiopulmonary Resuscitation) who is willing to help in case of an emergency. It is important to differentiate this definition from the term "first responder" which was defined by US National Highway Transportation Safety Administration as "the first medically trained responder who arrives on scene of an emergency" [3]. While the definition of a first responder includes groups like police officers, firefighters and EMS, it does not include laypersons since those generally do not have medical training. Still, laypersons might be able to provide the needed measures in order to help victims of SCA and thus should be included as potential helpers within a VNS. Within the EMuRgency project, the term "volunteer" is referring to any potential helper, medically trained or not, willing to aid other people in an ongoing emergency.

B. Integration between VNS and professional EMS

Whenever an incident is reported to an emergency dispatch center that might involve SCA, the dispatchers will do what they normally do: send professional help - but optionally also invoke the VNS. It is important to stress that the VNS, at this time of development and based on the way EMS is organized today, is a merely optional feature. This means that the responsible dispatcher may or may not involve the VNS, depending on their analysis of the case and personal motivation. In order for the optional integration to be achieved, the VNS has to provide a user-interface where the dispatcher can initiate a case by forwarding its exact location and some optional information to the system. During SCA, time is of utter importance, so this user-interface has to be as simple and efficient as possible.

Recent interviews were made within the project in order to determine the acceptance and motivation of the dispatchers to integrate a VNS within the general workflow; Even though all the interviewed dispatchers agreed on a potential benefit, it became rather clear that the general acceptance of new systems seems to directly correlate with the extra work that is involved in order to use it. Taking into account the discussed optionality and the still early stage of development within the project, a manual integration will be the starting point towards involving the VNS within the professional EMS workflow. The implementation of an integrated system that gets activated fully automated during a reported emergency is surely desirable, but requires detailed collaboration with the corresponding software providers. Details on this topic are will be addressed in future papers.

C. How to determine the relevant volunteers in an ongoing emergency

As soon as the system receives information on a new emergency, no matter if automated or manually initialized from the dispatcher, the VNS will determine possible volunteers in the closer vicinity of the incident and immediately inform those in walking distance of the ongoing emergency. In order for this to be possible with minimum time effort, the system needs to be "aware" of all potential volunteer locations at the time of the incoming emergency call. This awareness can be achieved by making all connected clients publish their locations to the server in pre-determined time intervals, rather than forcing the server to request all client locations at once not until they are actually needed.

Before notifying any potential helper, a reasonable maximum distance between a volunteer and the incident has

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to be determined. Only volunteers located within the maximum distance will be considered potential helpers in an on-going notification. The distance that an individual person can travel within - let's say - five minutes depends on many different parameters. An older person, for example, might walk slower than a younger person, while some people are simply in a better shape than others, no matter the age. Due to a great variety of individual parameters influencing a proper notification radius, a suitable solution to begin with, is creating a personalized profile setting; giving any registered volunteer the option to define an individual notification distance by configuring the appropriate parameter in their user profile. To maintain a realistic range, the maximum distance a user can set is limited to 1 km at the moment. Within the project, this functionality is implemented by using a public accessible browser based Web Application; accessing the corresponding URL, new users can register and/or edit their profile settings online. From the technical point of view, this Web Application is a frontend for accessing database functionality on the server.

D. Webservices

In order to enable external sources, for example mobile clients or applications from project partners, to access specific functions on the server, a different approach is needed. Specific APIs provide mobile clients the necessary functions in order to communicate with the VNS without having to access a web browser. The same approach can offer project partners an interface for integrating alternative ways of volunteer registration into the main system. Commonly used solutions for offering a limited scope of functionality to external clients are are so called Webservices or more specific, REST based Web APIs [9]. By implementing Webservices, a predefined set of functions will become globally available; different devices will be able to communicate with each other over a given network infrastructure; like for example, the World Wide Web.

E. The messaging architecture

At the time of writing, a running prototype of the VNS is available already. The upcoming section will introduce the used messaging architecture and describe the essential components implemented for the different types of communication.

As long as a client is not involved in an ongoing case, the main communication that occurs between the mobile clients and the server is a client-to-server location publishing that automatically gets invoked in a predefined time interval. While a simple implementation approach for this is a common HTTP POST method, the push communication used to send data from the server to a specific client is an entirely different matter. The World Wide Web (WWW) was originally not intended to support bidirectional communication and therefore does not include the corresponding specifications or protocols. With HTML 5 introducing the WebSocket JavaScript interface, a native solution for bidirectional communication is available. Once a WebSocket connection has been established between client and server, instant data communication becomes possible between both sides without explicitly having to deal with technical differences. Based on this kind of real time connectivity, a variety of different features can be implemented, including chat channels for notified helpers and live camera streaming from the place of incident. A short discussion on optional features in general will follow in the outlook section of this paper.

Even though real time connectivity with WebSockets is a promising approach for implementing specific functionalities, having hundreds or thousands of idle clients permanently connected to the system is definitely not a suitable solution. An increased energy consumption of the mobile clients and a possible server overload due to an increasing number of connected clients are the two main reasons for this. Besides, when not involved in an ongoing emergency, only two types of messages are actually exchanged: firstly the location updates that occur every couple of minutes and are sent from client to server, and secondly the event data that is sent from server to client in order to update the main information view and to display upcoming events, training-courses etc. Since HTTP requests generally include a response-content, the message flow for general information and event data has been implemented as a response to an occurred location update and thus does neither need any special connectivity nor an additional request. It is common practice to restrict HTTP get requests to merely read-only operations and implement any request that modifies data on the server as HTTP post. The main difference between these two types of requests is that within an HTTP get request, the key/value pairs are specified in the URL, whereas in an HTTP post request, the key/value pairs are sent after the headers, as part of the request itself.

Analyzing the base functionalities, there is one type of message that cannot wait for the next "location publish" in order to be sent as a reply from server to client, but instead needs to be send instantly; a new case notification message. This message initiates a new case on the server and alarms any potential helper in walking distance to the emergency; the message needs to arrive on the client with the smallest delay possible. In order to push messages from a server to a mobile client, different cloud messaging solutions are available but generally represent very individual solutions that only work for specific devices or operation systems. The Google Cloud Messaging for Android (GCM) for example is a specific solution to send data from a server to an Android application.

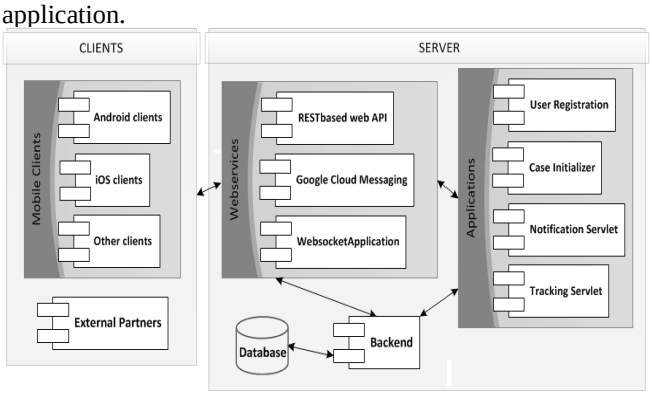

Figure 1: Core components of the EMuRgency VNS

To summarize the messaging architecture at this point of development, HTTP post requests are implemented for client-to-server location updates; the response content of the is then processed in order to send event data from the server back to the client; new cases are initialized by using device specific APIs in order to push notification messages from the server to the mobile clients; and a real time WebSocket communication gets initialized on a new case event for all notified volunteers.

F. An integrated VNS platform

As a scientific project with partners from both technical and sociological research fields, the project is focusing on many more aspects than a simple technical approach for a notification system. Users of the system will be informed on ongoing events or urgent news and since a common interest level of registered people can be implied, communication channels for exchanging know-how and general information are being implemented. A real-time information flow regarding the aspects of first aid and CPR is extending the core notification functionality. While also developing concepts on raising public awareness on SCA, educational content is displayed at frequently used public places; and if in digital form, the streamed content will be enriched or synchronized with data from the VNS. Furthermore, in order to receive substantial scientific results and to determine the potential benefit of a VNS, corresponding reporting and analyzing features are being designed. Open interfaces will supply options for non-project members to change or extend functionalities. Although details on the generic approach and corresponding concepts for an open architecture are not yet fully developed, an integrated VNS platform will combine the different research topics with the diversity of requirements that are to fulfill.

G. Regional differences for involving laypersons into professional EMS

It is important to understand the actual role of an occurring registration and the resulting implications on the system and the user. A newly registered user for example, obviously wants to help, but comparing different countries, potential differences between the way that laypersons are legally allowed to be integrated into EMS, must be considered [16]. Some regions for example might not allow the integration of laypersons in EMS at all; and is a layperson with first aid skills but without corresponding certificates still a layperson? While those questions will not be discussed further within this paper, expert legal advices for different countries are contracted, in order to validate this matter. The direct implication concerning the VNS is that a new user by default will be “unconfirmed” and will not be considered a potential volunteer until “confirmed”; the confirmation process on the other hand is implemented in a separate administrative component, whereas the final details of this component are not yet fully worked out.

H. An overview of the primary components within a VNS

Within the past sections of this paper, the core components of a VNS have been shortly introduced in their corresponding context. Fig. 1 shows an overview of these components while the following paragraph will give some additional information on how they have been implemented.

1) User Registration: Implemented as web application, this component offers base functionality for new users to register to the system; existing profiles can be edited and specific settings can be configured by the user – one example for a user specific setting is the notification radius.

2) Case Initializer: This application constitutes the actual data provider for new emergencies until more automated concepts are available. Intended for dispatchers only, this web application provides the possibility to manually initiate a new case by providing general information on an ongoing emergency and the corresponding unique location, as pair of latitude and longitude. In order to supply a user friendly interface, the location itself is automatically calculated as an approximation for a given address. This component demonstrates the first approach towards supplying the actual notification system with case data and is implemented as a JavaScript application embedded within a servlet..

3) Server-side applications: This component bundles the server-side functionalities of tracking and localizing the volunteers. Furthermore, the Case-Initializer is part of this component in order to provide fastest response times when invoking new emergency events.

4) Backend: The Backend represents the interface for persisting data and provides functions to enable communication between the database and other system components. Moreover, to ensure a consistent data usage within the system, all referenced data models and structures are defined within this component.

5) Webservices: Combining the REST based Web API, Websockets and client specific push technologies like Google Cloud Messaging, this component actually represents an intermediate communication layer; providing predefined functions for external modules and other clients to exchange data with the server.

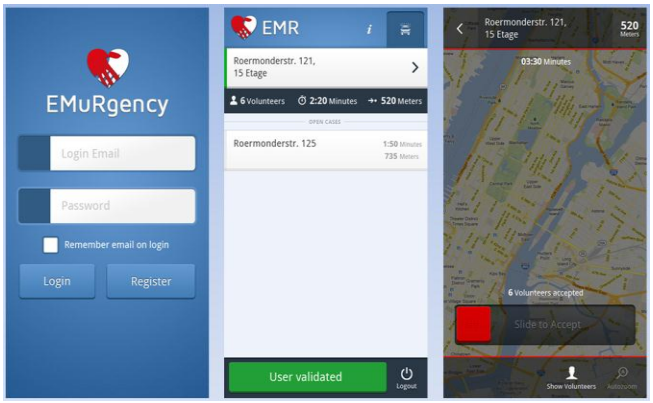

Figure 2: The mobile client application (android version)

IV. CONCLUSION AND OUTLOOK

During the project, sociological and technical aspects are being combined. Country-specific differences in a variety of discussed parameters have been balanced against each other and are being implemented into an integrated VNS platform. Many fundamental difficulties were identified within the past sections of this paper whereas an advanced prototype of the software is available already - Fig. 2 shows screenshots of the android client application. While this prototype implements the essential components introduced in chapter three and enables base notification functionality for nearby volunteers, there are several potentially valuable features being discussed within the project at the moment.

A. Potential future features

The integration of chat channel functionality, enabling direct communication between the dispatcher and all volunteers who accepted a specific case, is one reasonable feature. By using the discussed advantages of a platform independent WebSocket connection, dispatchers will be able to exchange information with volunteers in real-time. Furthermore, status updates and newly received case details can instantly be broadcasted to all relevant receivers.

Another feature is the integration of existing applications or services that provide information on nearby automated external defibrillators (AEDs). Although the time critical aspect of CPR is the main concern for the first volunteer who arrives on scene, it can prove useful for further helpers, to have reliable information on nearby AEDs devices.

There are multiple scenarios in which the use of game design elements (gamification) within a VNS can be used to influence the user behavior; the adoption of a score system for attended courses or participated cases is one example. The general idea of gamification elements is to increase the user acceptance and motivation, whereas a sensible consideration is needed in order not to distract attention from the main topic.

Since modern smartphones and many other portable devices offer build-in functionality for photos and videos, a real-time media streaming from the place of incident is another possible feature with high benefit. The integration of telemedical concepts becomes possible and thereby enables an approach of professional helpers using their expertise to analyze the streamed data, in order to aid the volunteers at the scene with valuable information.

B. Specification of a VNS and future development

Within this paper, the basic concept of a VNS has been described and both essential and optional components have been discussed. Since many parameters are not yet fully determined and legal issues are still being discussed, there is no formal specification of a VNS at this stage of development. Diverse legal aspects still need to be cleared and options for integrating the system into the professional EMS workflow are being negotiated. Maintaining a highly agile programming approach will assure a continuous development and a fast integration of subsystems, adjustments and new requirements.

The research focus for the upcoming two years will be the development and implementation of new concepts to enable a generic integration of heterogeneous environments and devices. Architectural cloud approaches will be analyzed and tested, while the integration of the different partners and their corresponding research topics will form into a complex VNS platform.

ACKNOWLEDGMENT

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Specialist Decision Support for Patients with Ventricular Assist Devices

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***Abstract*—This work presents the Specialist's Decision Support System (SDSS), which is one of the main components of the SensorART platform. SensorART focuses on the management and remote treatment of patients which suffer from heart failure and are treated with ventricular assist devices (VADs). SDSS is a Web-based application that assists specialists on patient's management, offering a plethora of tools for monitoring, designing the best therapy plan, analyzing data, extracting new knowledge and making informative decisions.**

Keywords-Ventricular assist devices; decision support system; web aplications

I. INTRODUCTION

Heart failure (HF) is an inability of the heart to fill with enough blood or pump with enough force or both the human body. It develops over time as the pumping action of the heart grows weaker and can affect the left side and/or the right side of the heart. The most common causes of HF include: high blood pressure (hypertension), coronary heart disease, heart valve disease, and cardiomyopathy. HF is the most increasing cause of death in developed countries; approximately 2% of the adult population suffers from HF, although it mainly affects elderly people (6-10% of people over the age of 65 years will develop HF) [1]. Hence, together with the difficulty of having a sufficient number of donor organs, it is recognized that the VADs will assume an increasingly important role in treating the growing number of patients with advanced HF, not only as bridge to transplant, but also as destination therapy, by considering also the ageing population.

Over the past three decades, technological advancements have led to the development of a series of implantable and external VADs for patients of every age and body size. However, most of these commercial VADs still share a common drawback. They do not provide to the specialists remote monitoring and/or controlling possibilities. The patient must visit the hospital, in order for the specialist to assess his/her condition. Continuous automatic remote monitoring systems and database systems are in the early stage of development with only a few relevant research studies reported [2-5].

SensorART aims to provide a set of technologies for heart assistance, supporting patients with chronic HF, treated at home without renouncing to access high medical expertise, and healthcare specialists keeping under control the performance of cardiovascular implanted VAD by remote control services. This platform moves from the concept of realizing an "upgraded device", thus starting from a VAD that is a mechanical device with the plan of developing an intelligent device.

In general, the SensorART platform consists of five main parts: (i) Sensor component, (ii) Signal Acquisition component, (iii) Hardware Controller, (iv) Remote Control Framework, and (v) Specialist's Decision Support System (SDSS), which is described in this paper. SDSS assists the specialists on deciding the best treatment strategy for a specific patient. It includes: a VAD-heart simulation component that gives to the specialists the possibility of modeling the behavior of a patient before and after VAD implantation, as well as a Decision Support System providing data analysis and projection tools.

II. SDSS PLATFORM

The SensorART SDSS is a Web-based platform that enables specialists with advanced data-driven and expert-knowledge techniques, in order to effectively assess and exploit real patient data (from the Specialist's Monitoring Application), as well as simulated patient data (from the VAD-Heart Simulation Platform) through the following components: (i) Knowledge Discovery, (ii) Monitoring, (iii) Treatment, (iv) Weaning, (v) VAD Suction, and (vi) VAD Speed. The modules menu in the SensorART Web-platform is presented in Fig. 1.

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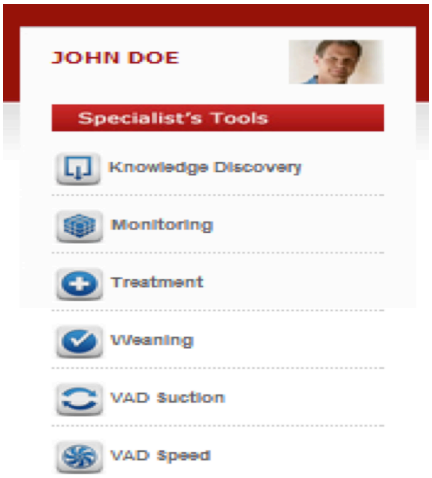

Figure 1. Specialist's Tools menu in the SensorART platform.

A. *Knowledge Discovery*

The knowledge discovery module includes two sub-modules; the association rules tool and the statistics tool.

1) Association Rules Tool: The Association Rules Tool allows the extraction of association rules from the database, enabling thus the extraction of new knowledge from multiple and heterogeneous archived data. The procedure depends on the patients selection, the examined features, the observation period and the support/confidence for the rule mining technique, which is the the *Apriori* algorithm [7]. All the above are defined from the specialist, who: (i) selects some or all patients from the database, (ii) defines the features (and, if needed, corresponding threshold values) to be examined, (iii) sets an observation period and appropriate values for support and confidence. Based on the above selections, associations hidden in the data are derived in the form of "if – then" rules, with the features (variables from the database) and conditions in the "if" and "then" parts defined by the user. The features that can be selected are categorized as: (i) demographic – comorbidities, (ii) heart related, (iii) sensor related, and (iv) laboratory measurements. The outcome of the Association Rule Tool is presented in Fig. 2.

2) Statistics Tool: The statistics tool provides all the necessary tools for the analysis and interpretation of patient data through powerful statistical techniques. These include descriptive statistics (mean, standard deviation, median, variance) along with statistical functions such as hypothesis testing (one Sample and two-Sample *t*-test, pair-sample *t*-test, Welch corrected *t*-test), analysis of variance (ANOVA), nonparametric tests (Kruskal-Wallis ANOVA, Wilcoxon test for one sample and paired Sample) and survival analysis (Kaplan-Meier estimator). A sample for the Kaplan-Meier survival analysis is presented in Fig. 3.

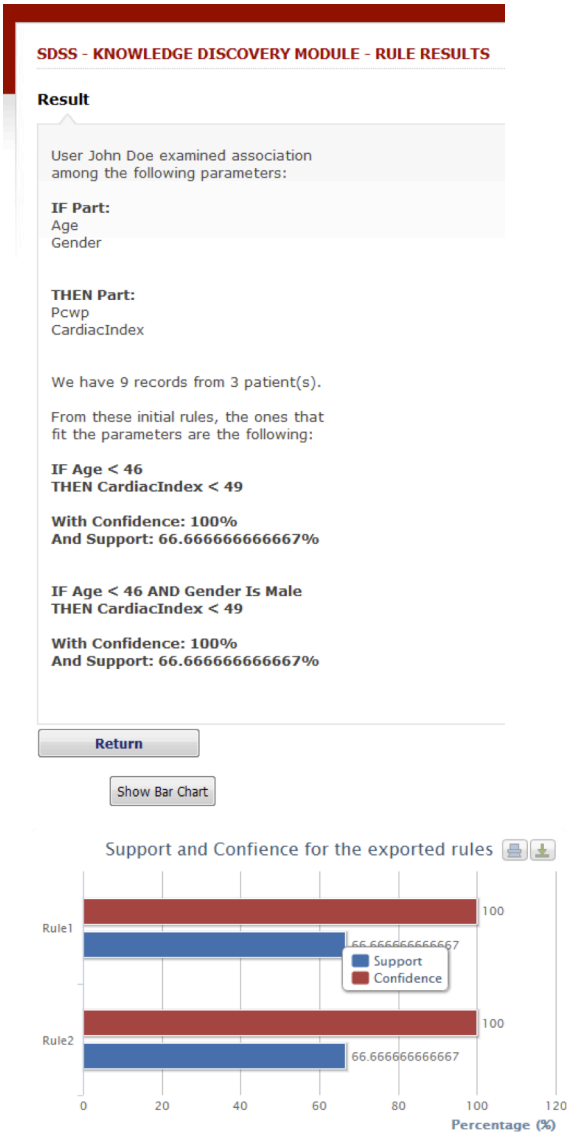

Figure 2. Association Rules Tool outcome.

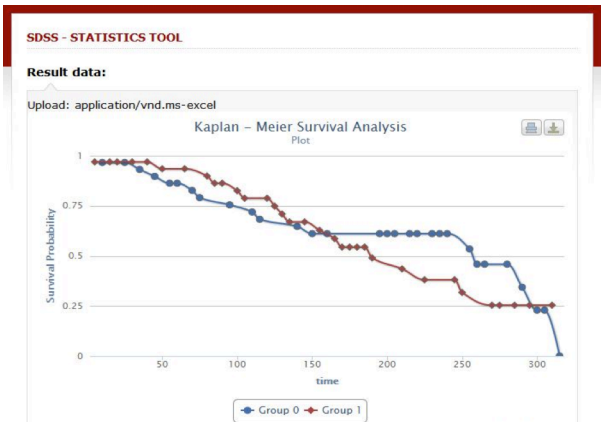

Figure 3. Kaplan-Meier survival analysis from the statistics tool.

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B. Monitoring

The monitoring module provides a graphical tool for examining the day-to-day VAD and patient parameters along with any adverse events that may have occurred. The patient and the parameters that will be included in the graph are selected by the specialist. The features that can be selected are: pump flow/speed/power, pulse index, temperature, systolic and diastolic blood pressure, pulses, weight, INR and drug dosage (warfarin/acenocoumarin), while the adverse events that are recorded include: death, cerebral bleeding, gastrointestinal bleeding, ischemic stroke, transient ischemic attack, ventricular tachycardia and heart failure. A snapshot of the patient and parameters selection along with the graphical result of the monitoring module is presented in Fig. 4.

Furthermore, the Monitoring module is able to provide assessment for future adverse events appearance. The main idea is to analyze the day-to-day data for the last three days and assess the possibility of adverse event appearance in the next day. Subsequently, the functionality is available only if data for the last three days exist. The assessment model has been developed using data from the SensorART database in order to train a decision tree. Currently data from 8 patients, that generate 1026 prototypes have been used for the decision tree induction, however, the model is constantly updated as new data are stored in the database (i.e. retained with larger datasets).

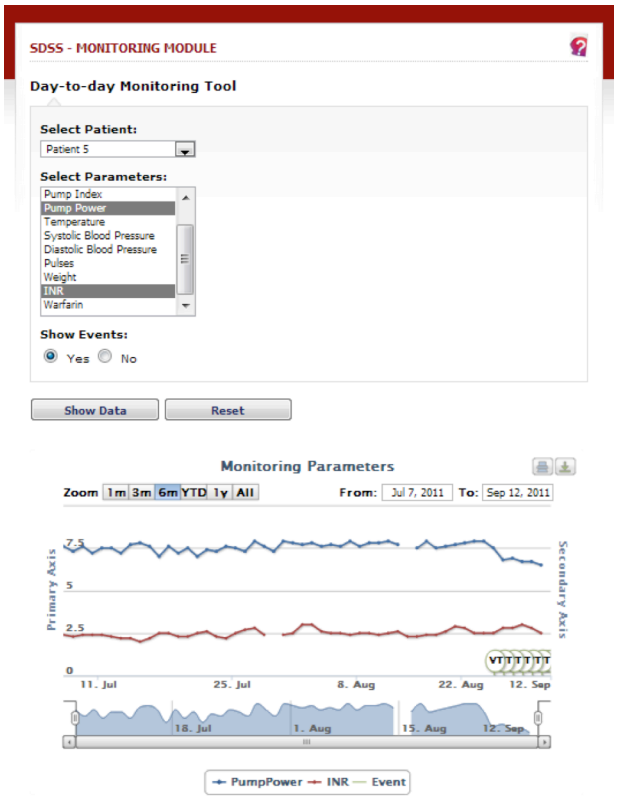

Figure 4. Monitoring module outcome.

C. Treatment

The treatment module can provide risk analysis based on known risk scores, in order to support effective treatment of patients. These include:

- the Heart Failure Survival Score (HFSS),
- the Seattle Heart Failure Model (SHFM),
- the Model for End-Stage Liver Disease (MELD) (due to its potential prediction on survival and need for blood transfusion),
- the Right Ventricular Failure Risk Score (RVFRS) to predict right failure that constitutes a serious complication.

D. Weaning

The Weaning module combines expert knowledge with fuzzy modeling, in order to support the specialists in the selection of patients that may be removed from the VAD therapy. The main idea is to achieve a mixture-of-experts approach, in terms of having multiple models for weaning in the module. These include all state-of-the-art medical knowledge-based models presented in the literature. In addition, the specialist can create and modify additional models (collection of if-then rules), using the build-in model generator. Furthermore, the module incorporates an automated fuzzy model generator [8], aiming on an efficient way of automatically transforming crisp models (either from the literature or user-defined) into fuzzy ones.

The knowledge-based models that have been included from the literature are the ones presented by Santelices et al. [9] and Birks et al. [10]. The user can either view or execute one of the existing models or create a new one, which is subsequently added in the list of existing models and can be also viewed/executed. Also, the user can modify all user-defined models, but not the ones from the literature. A snapshot of the view/execute model screen is presented in Fig. 5.

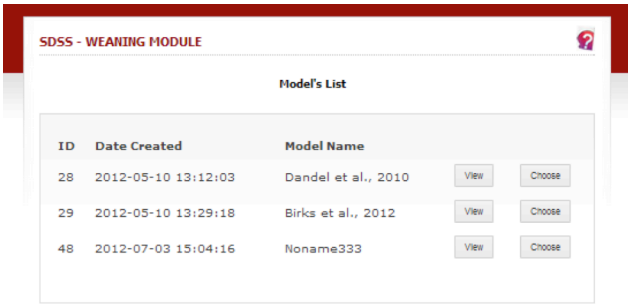

Figure 5. Model selection in the Weaning module.

E. VAD Suction

The VAD suction module provides to the specialists a powerful assistant in their attempt to effectively analyze their simulation sessions from the VAD-Heart Simulation Platform in terms of the suction phenomenon. Used in combination with the VAD-Heart Simulation Platform, it enables specialists to further analyses data from simulation sessions recognizing suction events (Fig. 6).

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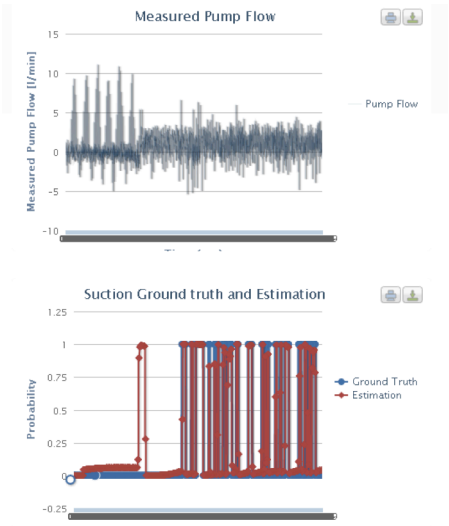

Figure 6. Visual representation of suction module results.

F. *VAD Speed*

The VAD speed module provides to the specialists a powerful assistant in their attempt to effectively plan the treatment strategy for a patient. It proposes adjustments to pump speed settings according to the required cardiac output and pressure perfusion. Used in combination with the VAD-Heart Simulation Platform and VAD suction module, it enables specialists to further analyse data from simulation sessions, identify different pump states and possible issues, as well as draw conclusions regarding the most appropriate pump speed settings.

III. CONLUSION

In this paper, the SDSS platform of the SensorART project is presented and all major tools and functionalities are illustrated. The SDSS has been specifically designed with close collaboration with medical experts, in order to address all major issues and provide all necessary tools for specialists treating VAD patients, in a single platform. In the same context, it includes all medical models and all available medical knowledge regarding VADs and patients with VADs. However, instead of being just a simple collection of medical and technical knowledge, in SDSS these are harmonically merged with computational intelligence, data mining and fuzzy modeling techniques, along with the first specially built database for VAD patients, thus leading to a powerful tool that can support specialists to any decision needed regarding the optimal management of VAD patients.

ACKNOWLEDGMENTS

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Developing eHealth Technology for People With Dementia: Towards a Supportive Decision Tool Facilitating Shared Decision-Making in Dementia

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Abstract— **People with dementia are confronted with many decisions. However, they are often not involved in the process of the decision-making. Shared Decision-Making (SDM) enables involvement of persons with dementia in the decision-making process. In our study, we develop a supportive IT application aiming to facilitate the decision-making process in care networks of people with dementia. A key feature in the development of this SDM tool is the participation of all network members during the design and development process, including the person with dementia.**
In this paper, we give insight into the first phases of this design and development process in which we conducted extensive user studies and translated wishes and needs of network members into user requirements.

Keywords: shared decision-making; decision tool; co-creation; dementia; eHealth

I. INTRODUCTION

Most western countries are currently facing demographic changes that will result in a dramatic increase of the number of people with dementia. Worldwide there are 35.6 million persons with dementia. It is to be expected that this number will be doubled by 2013 and tripled by 2050 [1, 2].

People with dementia are confronted with many decisions in the dementia process regarding daily life and well-being issues. Involving people with dementia in decision-making is not self-evident. They are often ignored [3]. This lack of involvement of people with dementia in decision-making is also noticed in research and design and development processes. Researchers and designers often develop tools *for* people with dementia rather than *with* them. People with dementia belong to one of the most neglected groups in research and development [3, 4].

Adequate care of people with dementia demands involvement of people with dementia in decision-making [5, 6]. In other fields of health care Shared Decision-Making (SDM) has proven its positive results regarding quality of life [7-9]. Moreover, SDM increases satisfaction with decisions and results in better informed patients [10]. Furthermore, SDM increases the autonomy of patients and empowers them [10]. This could also be beneficial to persons with dementia.

One of the supporting tools in SDM are decision aids, paper or IT-based. Thus far, a supportive tool facilitating SDM in dementia is lacking. In our study, we aim at designing, developing, implementing and evaluating such a tool.

Many IT applications have been developed to support people with dementia and their family and formal caregivers [11, 12]. Unfortunately, many IT applications are not used by them because they do not match their needs and capacities [13]. Therefore, in our study, involving network members and inclusion of people with dementia in the development and design process are key features.

In comparison with existing SDM tools that primarily facilitate the patient-clinician relation this involvement of all network members in the SDM process is new. Another new element is the focus on the process of SDM instead of on the decision itself.

In this paper, we describe the first phases of the development process of a supportive SDM IT application.

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We identified user requirements based on user studies to determine the content of this tool.

II. BACKGROUND

The present study is part of a major research program on SDM in care networks of persons with dementia. This program consists of three studies and aims to improve professional care.

SDM is a process of interaction and communication between a patient who wants to be involved and his or her care providers in making health care decisions, taking into account the preferences of the patient and the best available evidence [14]. In clinical practice patients and their clinicians are involved in this medical decision-making process. In our research program, concerning care and well-being related decisions in care networks of people with dementia this means involvement, interaction and communication between people with dementia, informal caregivers and professionals.

The first study of this research program on SDM aims to provide insight into decision-making processes within care networks of people with dementia in order to improve SDM. In this longitudinal study 25 care networks (each consisting of the person with dementia, two informal caregivers and two professional caregivers) are individually interviewed in three measurement cycles with six-month intervals.

In the second study, specific SDM competencies of professional caregivers (e.g. case managers) are developed. Furthermore, best practices of shared decision-making in care networks of dementia will be developed.

The third and present study, developing a supportive IT application that facilitates SDM in care networks of dementia, uses data from the first two studies. Research questions of this third study focus on the requirements for a SDM tool concerning the most suitable content, user-friendly design and effectiveness, and on the requirements for implementation in daily practice.

In the following section we describe the approach for this third study.

III. APPROACH

Although involvement of end users in developing eHealth technologies still is not self-evident, we consider involvement of end users as one of the key factors for developing a user-friendly and usable IT application. Too many IT applications have been developed without ever being used. Another important factor is sustainability in practice. Researchers and developers become more aware of the importance of making their innovations sustainable. Tools and roadmaps are developed to support developers in increasing the structural embedding of IT applications in health care. One example is the eHealth Innovation Matrix (eHix) [15]. Another approach is the ceHRes roadmap. It connects a Human Centered Design with eHealth Business Modeling [16].

Both eHix and the ceHRes roadmap emphasize involvement of stakeholders in all phases of the development. In our research program, a multi-disciplinary consortium consisting of a variety of dementia experts and advocates achieves this. Furthermore, we use a stepwise approach in order to systematically translate user studies (needs and wants) in functional requirements of the tool (figure 1) [17].

We started this study by conducting a systematic review regarding the research question: how are people with dementia involved in the development of supportive IT applications [18]. We were interested in the state of the art regarding this question to discover which implications the results would have for our own development process, especially, in identifying user requirements.

The results of this review show that involvement of people with dementia is not self-evident. Included studies dated from 2003-2010. Researchers and developers differ in how they involve people with dementia, depending on how they value the capacities of people with dementia. In most studies people with dementia were involved in the first phase of the development process. Recently, researchers and developers are more aware of the benefits of involving people with dementia in development processes; it results in more attuned and usable IT applications [18].

A. User studies

In the first developmental phase we explored the needs and wants of all stakeholders. Fifty semi-structured interviews were undertaken with persons with dementia, informal caregivers and professional caregivers to get insight into their experiences in decision-making in dementia. Framework analysis was used to analyze the interviews with AtlasTi software. In addition eight focus groups were conducted, two with persons with dementia, two with informal caregivers, two with professional caregivers and two with experts in the field of dementia. These focus group interviews had a twofold goal. One goal was to double-check the results from the interviews. The second goal was to retrieving additional information about the process of SDM and on the needs and wishes concerning (digital) support. AtlasTi software was used to analyze the focus group transcripts addressing the topics mentioned. Furthermore, an analysis of interactive dementia websites was conducted to identify needs of network members regarding decision-making.

B. User requirements

In a multi-disciplinary user requirement workshop (researchers specialized in older adults, dementia and IT, technicians and developers) we used Affinity

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Diagramming in order to determine user requirements based on the information retrieved in the above described user studies. In addition these user requirements were compared to national dementia standards in order to check whether they match with these standards [19, 20].

C. Functional requirements

In a multi-disciplinary functional requirement workshop (researchers specialized in older adults, dementia and IT, technicians, developers and designers) the user requirements will be translated in functional requirements.

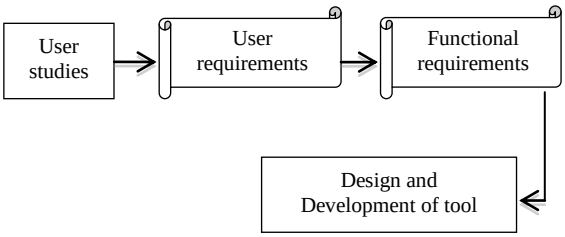

Figure 1 Process from user studies to design and development [17]

D. Experiments

The interface of the supportive SDM IT application will be determined in an iterative, participatory design process. Products of the design and development phases (mock-ups, prototypes) will be the subject of end user focus groups and experiments. Feedback thus obtained informs the next design and development phase in order to improve the content and design of the tool. Special attention will be paid to the adaptability interface of the tool because of the declining cognitive abilities of persons with dementia over time. Experiments will also focus on comparing different ways of implementing the tool in daily practice: network members using the tool individually as a preparation of face-to-face meetings, compared with a shared way using it during such a meeting.

E. Pilot study

When the adapted tool becomes robust enough a pilot study will be conducted to evaluate the usability of the tool in daily practice. Five different care networks of persons with dementia (each care network consist of a person with dementia, two informal caregivers and two professionals) will use the tool for a period of five months. The evaluation focuses on design and content of the tool; interface of the tool; usability of the tool by professionals using SDM; and obstacles and benefits of the use of the tool. Furthermore, the impact of the tool on the care network members, including the person with dementia, and the decisions made will be evaluated.

IV. RESULTS

At this point in time we obtained the results of the user requirements. The interviews with persons with dementia, informal caregivers and professional caregivers gave insight into the issues and decisions network members of people with dementia experience regarding dementia. Important domains are: care, well-being, daily activities, living, mobility and financial and legal matters. Based on the results of these interviews we constructed a persona. This persona served the purpose of aligning the perspectives of the multi-disciplinary project members' view.

Subsequently the results of the interviews, focus groups and analysis of interactive dementia websites were screened for wishes and needs of end users of the tool. This resulted in a selection of more than two hundred relevant items. The principal researcher clustered these items stemming from the data. The selected items and first clustering were peer-reviewed by a second researcher. During the user requirement workshop multi-disciplinary teams checked the clustering and determined the user requirements per cluster. User requirements were discussed until consensus was reached. The user requirements determined concerned the following clusters: participation of the person with dementia, information, role of informal caregivers, role of case manager, role of other professionals, decision history, communication, anticipation, support, self-management and autonomy, and administrative load.

Our check with National dementia care standards learned that the user requirements are in line with these standards.

V. CONCLUSION AND FURTHER WORK

The extensive exploration and translation of the user studies into user requirements created valuable input for the functional requirements process. This study is now midway. The next step is designing and developing the tool, testing it in experiments and improving the tool using the feedback of involved end users, followed by the pilot study and its evaluation.

Developing a tool to facilitate the SDM process in care networks of people with dementia is a real challenge. Involvement of all stakeholders in the design and development process is needed in order to develop a robust IT application. In the current project we aim to involve people with dementia. In the first phases of the development process people with dementia participated successfully.

The participation of people with dementia in this development processes is a *conditio sine qua non* in order

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to get an attuned and user-friendly tool. Researchers, developers and clinicians should be aware of that.

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Impact of Knowledge Transfer Through the Implementation of an Emergency Telemedicine Program in a Brazilian Community Hospital

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***Abstract* — Variation of quality care has been associated with heterogeneous survival rates among emergency and critical care patients. A body of evidence has shown that emergency and ICU physician-led team could deliver a more adequate care and decrease mortality rates and costs. In developing countries there is a shortage of specialists even in metropolitan areas. The main objective of this study is to describe the first Brazilian experience of a real time audio-visual telemedicine program (TM) providing 24/7 emergency and Intensive Care physicians' coverage. Methods: The concept of telemedicine was implemented at two different hospitals in São Paulo; a secondary and public hospital, Hospital Municipal Moyses Deutsch (HMMD), and a tertiary and private hospital, Hospital Israelita Albert Einstein (HIAE). Results: Data were obtained from 100 teleconsultations (85 patients) records over a 4 months period. The majority of the requests originated from ICU (74.1%). Sepsis was the most common reason to access TM (29.4%), followed by stroke (24.7%). TM improved diagnosis in 16.5% and influenced clinical management in 83.5% of the patients. Life-saving TM interventions were stroke thrombolysis in 4 patients and a limb amputation in 1 patient. The majority of patients was discharged with no necessity of referring to another hospital. Conclusion: We conclude that the main contribution of telemedicine-based intervention is to avoid unnecessary transfers and to improve medical decision-making in a real time fashion.**

Keywords-Telemedicine; Emergency care; TeleICU.

I. INTRODUCTION

Brazil is a federative republic that covers 8·5 million km^2 or 47% of the South America continent. With an estimated population of 190,732,694 in 2010, Brazil is the world's fifth most populous country around the world [1]. The Brazilian health system is made up of a complex network of complementary and competitive service providers and purchasers, building a public—private mix that is funded mainly by private institutions. The health system has three subsectors: the public subsector, in which services are funded and provided by the state at the federal, state, and municipal levels, including military health services; the private (for-profit and non-profit) subsector, in which services are funded by public and/or private institutions; and the private health insurance subsector, with different forms of health plans, varying insurance premiums, and tax subsidies. The public and private components of the system are distinct but interconnected [2, 3].

Brazilian "universal" healthcare system is called the Sistema Unico de Saude (Unified Health System, SUS). Most of the population (75%) utilizes almost exclusively this system, which sometimes is unable to offer a qualified health care to all of them. In fact, there is a shortage of doctors and nurses, especially in rural and even in distant metropolitan areas. Many hospitals are also poorly managed, lacking autonomy from state governing boards. And finally, there is a high level of inequality in medical technology and infrastructure, with larger, more affluent municipalities able to provide better technological equipment and medical care [3].

Survival rates for emergency care vary significantly between hospitals, reflecting variations in the quality of care. Many hospitals do not have the facilities and skills to provide effective specialist treatment, 24 hours a day, seven days a week. Evidence shows that emergency and ICU care should be led by experienced consultants with quicker and better decision-making processes, especially in the care of major trauma, sepsis, stroke and acute myocardial infarction [4,5].

Within this scenario comes up seeking to develop options for solving the health problems of critically ill patients, using effective remedies in the quality of care provided. In this context, appears telemedicine as a viable alternative to efficient resolution of such problems. The World Health Organization (WHO) [6] defines telemedicine as "the offering services related to health care, where the distance is a critical factor. Such services are provided by qualified health professionals, using information technology and communication to exchanging knowledge and information valid for diagnosis, prevention and treatment of diseases, and the continuing education of health care providers with health, as well as for scientific research purposes [6]. The Health Department, in order to improve the Public Health System, has decided to create the PROADI - Projeto de

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Apoio ao Desenvolvimento Institucional ao SUS, to improve health services around the country. The PROADI allows some hospitals, classified as "excellent" in terms of quality of care, fund projects, by using philanthropy. In this scenario, the HIAE developed a telemedicine program allowed emergency department and ICU staffs from public hospitals, including the Hospital Moyses Deutsch (HMMD), to receive real-time support from specialist staff in the emergency department and ICU at the Hospital Albert Einstein (HAE).

The HMMD is a 240-beds, medium-complexity, public general hospital, including 60 emergency department beds. An estimated 500,000 people live near to the hospital. Emergency Department receives an annual volume around 200,000 visits. Clinical, pediatrics, surgical, orthopedics, gynecology and obstetrics services are offered. HMMD is located at Jardim Angela district and cover an area with more than 23,125 square, at one of the most deprived areas in São Paulo city that has been considered by the United Nations as one of the most violent urban region in the world.

The objective of this paper is to describe the impact of first Brazilian, real time telemedicine program (TM) providing 24/7 hours/days of an emergency department (ED) and Intensive Care Unit (ICU) coverage. This article is organized as follows: Section 2 presents the methodology and the parameters evaluated. Section 3 shows the most important results. Section 4 deals with discussions. Finally, Section 5 which presents the conclusions and future work.

II. METHODS

In January 2012, the concept of telemedicine (synchronous connection) was implemented between HIAE and HMMD. We implemented a Telemedicine Central Command (TCC) located at HIAE with Endpoint 97 MXP Cisco ® Solution via a dedicated broadband connection of 2 Mb. TCC offers 24/7 coverage provided of ED and ICU consultant and a full range of services and specialties in house, including neurologists, cardiologists and radiologists. We recruited 16 physicians dedicated to TM program with the following characteristics: owning motivation and pro-activity to participate in the project; ICU or ED specialized; ability to transpose the difficulties and propose solutions and mastering all service protocols offering support to applicants.

In the remote hospital (HMMD), a mobile Intern MXP ISDN/IP Cisco ® was introduced. The wireless network was sized to ensure quality signal transmission environment throughout the Emergency department and Intensive Care Unit (ICU). Radiologic and CT scans exams were evaluated using PACS technology.

Inclusion criteria to access Telemedicine were based upon remote ICU or ED physician judgment. Every recruited patient, irrespective of whether transferred or not, was assessed by the Central Command through teleconference with an experienced consultant. Furthermore, we developed 36 clinical protocols that cover broader range of medical entities commonly encountered at the ICU and ED.

Routine data extracted from electronic forms were patient demographics, source of referral, further details of presenting complaint and diagnosis, examinations performed, throughput times, treatment (s) given and discharge categories. Case specific data were collected during teleconsultation. including patient ID; names and grades of staff requesting and providing consultations; presenting complaint; date and time of consultation; type of consultation and images discussed; reason for consultation and query to be resolved; time taken and resources used; nature and impact of any technical problems; diagnosis; referral or treatment advice given.

III. RESULTS

From May to October 2012, a total of 100 patients records from 85 patients were analyzed. Mean age was 48.5 yo, 51 (60%) were male, mean APACHE II SCORE was 22.3; 63 (74.1%) patients were at ICU and 22 (25.9%) were at the ED. The main diagnoses are described in Table 1.

TABLE 1.PATIENTS DIAGNOSES

Diagnoses	n	%
Neurologic *Stroke. Trauma. Syncope.*	27	31.8%
Infection / Sepsis	25	29.4%
Cardiac / Pulmonary *Cardiac Arrest. Infarction. Heart Failure. Heart Block. Pericarditis. Tamponade. Pulmonary Embolism. Lung Cancer.*	20	23.7%
Abdominal *Mesenteric Ischemia. Pancreatitis. Hepatic Failure.*	5	5.9%
Trauma *Abdominal. Thoracic. Hemorrhagic Shock.*	4	4.8%
Others *Coagulopathy. Hyperosmolar Syndrome. Intoxication.*	4	4.8%

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For 14 patients (16.5%), TCC influenced diagnosis conclusion, and for 71 patients (83.5%), TCC contributed to clinical management. In 53 (62.4%) of the consultations, a specialist other than TCC staff were needed to attend specific requests. The external medical specialists consulted are summarized in Table 2.

TABLE 2. SPECIALISTS DEMANDED

Medical Specialist	N	%
Neurology	23	43.4%
Pneumology	6	11.3%
Cardiology	6	11.3%
Infectology	4	7.5%
Gastroenterology	3	5.7%
Cardiac Surgery	2	3.8%
General Surgery	2	3.8%
Hematology	2	3.8%
Others	5	9,5%

Most of the teleconferences occurred in the middle of the day, around 1:30 PM (Table 3). The mean hospital length of stay was 13.6 days, the hospital mortality was 37.6% (32 patients). Regarding patients admitted at the ED (22), 15 (68.2%) were transferred to the ICU, 10 (11.7%) were transferred to a tertiary hospital and 6 of these patients (7.1%) were submitted to major surgical procedures [heart surgery (2), neurosurgery (3) and liver transplantation (1)]. Among all the 85 patients, 36 (42.4%) had an invasive or surgical procedure indicated after TM session.

TABLE 3: TIME OF TM CONSULTATION

Time	Cases
Morning	24
Afternoon	70
Night	6

Table 4 describes the main procedures performed after TM consultation. In 19 (22.4%) patients TM suggested antibacterial-changing scheme.

Among the 4 patients submitted to stroke thrombolysis, the mean time from the onset of the symptoms to the initial of the procedure was 163.2 min, mean NIH Stroke Scale was 14.7 before the thrombolysis and 12.7 at the end of the procedure. There were no cases of bleeding complications after the procedure.

TABLE 4. INVASIVE / SURGICAL PROCEDURES

Diagnosis	n	%
Hemodialysis	17	47,2%
Coronary Angiography	4	11,1%
Stroke Thrombolysis	4	11,1%
Neurosurgery	3	8,3%
Angiography	2	5,5%
Chest Tube Placement	2	5,5%
Cardiac Surgery	2	5,5%
Limb Amputation	1	2,7%
Liver transplantation	1	2,7%

IV. DISCUSSION

Telehealth technologies, which embrace telemedicine, are being used in a wide array of applications and environments, and there is a substantial body of literature advocating their use and general utility [7,8].

Telemedicine has the potential to improve quality of care by allowing clinicians in one “control center” to monitor, consult and even care for and perform procedures on patients in multiple locations.

TM experience in other medical specialties fully applies in the field of emergency medicine (EM) [9,10]. Emergency healthcare is complex but its most important requirement is rapid and correct decision-making on diagnosis and treatment. In addition, this occasionally must be performed in situations other than in a hospital emergency department (ED). Thus in the case of accidents, emergencies, and so on, healthcare is necessary in poor conditions and, most importantly, away from the reference health center, so that distance and time factors get great relevance for the successful diagnosis and treatment of affected patients. In this context, remote teleconsultation by specialists in an emergency situation may be important for rapid, correct and specialized decision making, whether clinical or surgical, on immediate questions such as whether and where to transfer the patient or what therapy should be administered.

Telemedicine may provide medical decision support for remote practitioners with the effect of reducing inter-hospital transfers and improving quality of care. By enabling the transmission of visual information such as X-rays or pictures of injuries to specialists, telemedicine may enable remote practitioners to obtain expert guidance on how to manage a patient locally.

Quality health care to critical patients is complex and requires extensive resource use; the shortage of qualified experienced multidisciplinary teams in some public

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Brazilian Hospitals can negatively affect the outcomes of critical patients. Otherwise, the primary and secondary hospitals need to transfer the critical patients to tertiary centers, which increase the costs of Health System.

Tele-ICU programs can be a solution because they are capable of leveraging the skills of an experienced team of critical care doctors and nurses to ICUs where bedside services are not available and provide a vehicle for broadly applying evidence-based best practice protocols to improve patient safety and outcomes [9]. The experience led us to develop evidence-based protocols but tailored to local constraints such as use of thrombolytics in cases of acute myocardial infarction when angioplasty is not available. We´ve made up to 36 protocols regarding most common ICU and ED issues. These protocols were also used to initiate telemedicine sessions.

Although some patients may still require transfer or referral, particularly in the absence of the necessary on-site facilities or expertise, telemedicine should ensure transfers are appropriate, and made to the right specialist at the right time. It may also ensure that both patients and the receiving unit are adequately prepared for the transfer. Even in cases where a transfer may not be indicated, telemedicine may be used as a medium for 'second opinions' on diagnosis and management, providing reassurance to both the clinician and the patient prior to discharge and potentially improving quality of care. In this case, patients may actually receive an enhanced service, in that they may receive a more senior opinion, other way this would not be feasible.

Advantages related to the implementation of telemedicine in the ED and ICU other than the availability of an experienced team readily accessible, include: to obtaining conducting videoconferencing between stakeholders; quick access to updated sources of information for conducting research together, including development of scientific protocols. Allows patients have access to specialist services including for case discussion and opinion of experts, the viability of training and standardization of procedures and better quality of care, more efficient monitoring of critical patients, as well as monitoring and efficient management of quality indicators of ED and ICU departments.

The benefits also include greater patient safety, reduction in the hospital costs; reduction in the number of hours / ICU nurse / patient-day, reduction in costs for pharmacy, laboratory supplies, therapies and other costs associated with the care of ICU patients. Beyond addition, by promoting the reduction of mean length of stay enables increase in the volume of admissions that result in an increase in revenue institutions. Some authors reported reductions in hospital and ICU length of stay and hospital mortality as well [11].

In Brazil, as in other countries, there is a lack of specialized professionals (including for intensive care), few Brazilian ICUs have specialized physicians 24 hours available. The reasons for this shortage are the high cost of hiring skilled labor and lack of specialized intensive care physicians. Telemedicine programs can help meet this demand by professionals, since they allow access to centers reference in critical care medicine to several distant hospitals, providing this expertise remotely, enabling other professionals, contributing with the reduction of morbidity and mortality. The Hospital Municipal Dr. Moyses Deutsch is a secondary hospital located at a very poor and populated district of São Paulo – Brazil. There is a monthly average of 16000 visits at the ED; many of these are admitted at the hospital with very bad social and health conditions, contributing unfavorably to the patient's outcomes. The clinician's hospital staff is compounded by young general doctors, without specialists like neurologists, neurosurgeons, cardiologists and many others. In this scenario it has been always necessary to transfer many patients to tertiary hospitals to be seen by specialists. Before the implementation of the Telemedicine Program as many as 60 outside evaluations were made each month, mainly for neurologic evaluation. The implementation of the Telemedicine Program reduced unnecessary transfers, during the 6 month period of initial experience; only 11.7% (10 patients) were transferred to other medical centers.

As mentioned before, HIAE provide in house coverage of experienced neurologists available 24/7 hours/days. Through PACS system and radiologist support, TM offered decision making support for stroke thrombolysis. Before the implementation of the TM program, this therapy has never been applied. This is the first Brazilian experience with the implementation of a TM program and the first report of successful stroke thrombolysis guided by telemedicine.

Financial cost also poses both a real and perceived barrier to the application and adoption of telemedicine in developing countries. Equipment, transport, maintenance, and training costs of local staff can be daunting for countries with little income or limited funding for the implementation and maintenance of telemedicine initiatives. Moreover, convincing evidence to support the overall cost-effectiveness of particular telemedicine strategies may be weak, while the economic implications of such strategies in different settings may not yet be known [8,11].

If telehealth is going to move beyond being regarded by many as a tool or a substitute for traditional healthcare delivery, its ability to impact diagnosis, treatment options and patient outcomes must be demonstrated using experimentally rigorous techniques supported by appropriate statistics.

This is a retrospective observational study that analyzed the initial Brazilian experience in the implementation of a Telemedicine Program connecting a secondary medium complex regional public hospital to a tertiary medical center.

The study presented initial encouraging results, the program proved to be useful in helping diagnosis, conducting critical cases and transferring specialized medical knowledge to hospitals with shortage of human and technical resources.

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V. CONCLUSION AND FUTURE WORK

We conclude that the main contribution of telemedicine-based interventions from the tertiary to the secondary hospital is to avoid unnecessary transfers and to improve medical decision-making in real time by an effective expertise transfer. Besides, the implementation of this program allows patients with stroke timely receive thrombolysis guided by telemedicine. Finally, a prospective clinical trial will be running to analyze the impact of TM program on patient outcomes, including hospital length of stay, sequelae, and hospital mortality. From these data, we could spread this technology in different areas around the country.

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Disrupting the market for workplace health: The case of OfficePhysio

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***Abstract*— Today's societies face increasing health care costs due to a growing world population, an aging society, and rising prices for health care. A new breed of health care entrepreneurs tries to conceive new ways to deliver health care. One area in which entrepreneurial ventures seek to revolutionize today's health care is workplace health, providing electronic solutions over the internet. This study sets out to explore whether and how an eWorkplaceHealth program can disrupt the market. The findings—based on an explorative single case study—suggest that eWorkplaceHealth is a disruptive business model that may have already 'overshot' the product performance of traditional workplace health.**

Keywords: eHealth, business models, disruptive innovation, workplace health

I. INTRODUCTION

Today's societies face increasing health care costs due to a growing world population, an aging society, and rising prices for health care. A new breed of health care entrepreneurs tries to conceive new ways to deliver health care. One area in which entrepreneurial ventures seek to revolutionize today's health care is workplace health, providing electronic solutions over the internet. This study sets out to explore whether and how an eWorkplaceHealth program can disrupt the market. The findings—although based on a single case study—suggest that eWorkplaceHealth is a disruptive business model that may have already 'overshot' the product performance of traditional workplace health.

II. DISRUPTIVE BUSINESS MODELS

Health care has been a prominent example of disruptive innovation [1]. However, eHealth services are a recent phenomenon that emerged with the rise of the internet. These services differentiate themselves from traditional health services in that they create and capture value in significantly different ways [2]. Hitherto scholars have examined how eHealth business models can be modeled and tested a priori [3], studied the opportunities for developing countries [4] or investigated how privacy concerns are accounted for [5]. However, to the knowledge of the author, few have examined the disruptiveness of eHealth services compared to traditional ways of workplace health. Thus, in the following I briefly review the literature on business models and business model innovation and juxtapose traditional modes of workplace health with an eWorkplaceHealth service to determine its disruptiveness.

Literature on business models and business model innovation is relatively young and emerged in liaison with the dot.com era in the 1990s [2], [6]. In that period, new means of communication allowed making available and transacting information in an unprecedented speed, which gave rise to new forms of businesses, blurring the boundaries of industries [7], [8].

Due to its interdisciplinary nature [2], it is difficult to pinpoint a definition for business models or even what business models are. In fact, business models neither fit economic theory, nor organizational theory [2]. Foundations of the construct can be found in business strategy [9], building upon frameworks such as the value chain, resource-based theory, strategic networks, and transaction cost economics [9]. Due to its nascent state no uniform definition has emerged [6], [9], [10].

One area of business model research targets 'e-commerce' which is concerned with describing emerging businesses due the internet. In other words, scholars seek to understand how emerging telecommunication practices enable novel ways of creating value. Recent findings suggests that the internet enabled new sources of value creation, that is it creates efficiencies, complementarities, novel approaches and lock-in situations [11]. Using the business model as an analysis framework allows to clearly illustrating the transactions, its governance, content and structure. Thus, business models are a way of describing emerging phenomenon of e-businesses and their sources of value.

Recently, scholars found that business model innovation holds the promise to create a competitive advantage and even disrupt industries [12]. Johnson et al. [13] point to business model innovation being a source of competitive advantage and emphasize its game-changing character. Similarly for Nidumolu et al. [14] business model innovation refers to "find[ing] novel ways of delivering and capturing value, which will change the basis of competition." Mitchell and Coles [12] distinguish two types of altering existing business models: business model improvement (incremental change) and business model innovation (disruptive change). Four out of the seven dimensions of a business model—that is the

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who, what, when, why, where, how and how much of delivering value to customers of the existing business model—need to change to constitute disruptive change [12]. Incremental change refers to changing less than four dimensions. I apply this framework to determine whether workplace health delivered electronically is a disruptive business model.

III. TRADITIONAL WORKPLACE HEALTH VS. EWORKPLACEHEALTH

One area in which entrepreneurial ventures seek to revolutionize today's health care is workplace health. Many jobs today require largely monotonous work behind the computer which is in fact counter the human nature. Typical workplace related health problems are for instance the burnout syndrome or back related problems. Particularly the latter causes significant harm to employees and costs for employers. Until today, employees would mostly only go to the doctor or physiotherapist when problems arise, i.e. when it is too late. In Germany, for instance, more than 23% of all sick days are due to back related problems. However, simple interventions at the workplace—such as brief exercises and minor behavioural changes—can prevent problems, alleviate existing computer work related problems, and improve the health and motivation of employees in general. Consequently also the costs of companies can be reduced. Traditionally these interventions were provided by physiotherapists that would come into office places, educate employees about ergonomics at the workplace and conduct exercises together. The problem is that this way of intervention is time intensive, difficult to offer to the entire workforce and also requires facilities that not all companies might be able to provide.

Recently, a new way of providing workplace health has been adopted by companies which has the potential to disrupt the prevalent practice of companies, i.e. inviting physiotherapists to their premises [15]. So called eWorkplaceHealth has been pioneered by a few companies [16]. New information and communication technologies such as video over the internet, communities and interaction enabled companies to design new customized ways of delivering workplace health. Because these services are online based, users benefit from personalized programmes and the flexibility to do exercises whenever it suits them. Also employers profit because every additional user only causes marginal additional costs.

Table 1 juxtaposes traditional workplace health services with eWorkplaceHealth services on the aforementioned seven dimensions of business models [12]. It shows that all dimensions are altered by eWorkplaceHealth services. Instead of selected employees, all employees can be reached. Whereas physiotherapist would largely focus on exercises or alleviate pain, eWorplaceHealth besides providing exercises and (limited) possibilities to heal minor health issues (e.g. stiff neck) adds an educational component that gradually creates knowledge and awareness. The why is the only dimension that is somewhat similar. Both approaches intend to build workplace health competences (e.g. how to sit properly). However, eWorkplaceHealth extends this for instance to related topics such as concentration, breathing or behavioural patterns, i.e. is more comprehensive. One of the significant advantages is that eWorkplaceHealth can be conducted anywhere and is not fixed to a certain place. This is due to the fact that it is provided over the internet on any device (mostly PC, but also tablet PCs or smart phones). Last, the price point is significantly lower than traditional approaches as each additional user only causes marginal costs.

TABLE I. DISRUPTIVENESS OF EWORKPLACEHEALTH

Business model dimensions	Traditional workplace health	eWorkplaceHealth
Who	Selected employees	All employees
What	Dispersed: various separated interventions, e.g. back school, instructions, gym	All-inclusive: information, exercises, guidance to healing
When	Fixed: set times or after work	Flexible: whenever an employee has time
Why	To conduct exercises, alleviate problems, partially build workplace health competences	To build comprehensive workplace health competences, mobilize, motivate, support healing and inform
Where	Fixed: dedicated places, e.g. community room or gym	Anywhere: at the workplace, but also at home or in the hotel
How	Personal: delivered by an instructor	Virtual: delivered by online videos, descriptions and eLearning tools
How much	Expensive: per hour rate	Inexpensive: small fee per employee per month

Consequently, eWorkplaceHealth appears to have the character of a disruptive business model. In order to understand whether eWorkplaceHealth can disrupt the industry, first it needs to be explored whether users perceive benefits of these services. Therefore I conducted an explorative case study. In the following sections I describe the methodology, report the findings and discuss the implications.

IV. METHOD AND CASE SELECTION

In order to inform the overarching research question: *Whether and how can eWorkplaceHealth services disrupt the industry of traditional workplace health?* I conducted a single explorative case study to evaluate how users perceive the benefits of these services. Single case studies suffer from low external validity [17]. However, they may enable

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multiple levels of analysis [18]. This study intends to explore the phenomenon and is intended to be extended subsequently. In order to gain insights in the application at one organization, I selected a government agency that implemented an eWorkplaceHealth service.

The case organization that implemented the eWorkplaceHealth program named OfficePhysio[1] is a state agency in Hannover, Germany. This agency provides already different traditional workplace health services such as that they have a group that regularly does exercises together and they conduct breaks during the work time in which interested employees actively relax. In order to verify whether the organization would introduce OfficePhysio for all employees as an alternative to traditional means, it conducted a test for a period of four weeks with a small group. A questionnaire to inquire the effectiveness was circulated afterward. The data of this test period was available for this research. The organization has about 300 employees. The test was conducted by 20 employees. Twelve users filled out the questionnaire.

OfficePhysio (see screenshots in Fig. 1 in the appendix) is developed—based on medical studies and in collaboration with certified experts—as an eWorkplaceHealth service which provides different modules, that is an eLearning module which gradually educates users about all workplace related health issues and its solutions, an eMoving module which provides video tutorials for exercises that targeted different problem areas, such as shoulder-neck, lower back, but also eyes, and RSI (so called mouse arm). In addition, an eHealing module provides practices via online tutorials to treat minor health problems such as a stiff neck. Different customized emails remind users about doing their exercises, inform users with workplace related health knowledge and give small tasks that users can do as 'homework'. It takes five to ten minutes a day to conduct an exercise and read the information.

V. FINDINGS

In the following I present the results as they have emerged from the data (see Table 2). First, 75% of the sample had workplace health related problems. The most reported problems were shoulder-neck problems, followed by eye fatigue. Some also just mentioned general back problems. The users tested the program for four weeks and 92% were very positive about the usability. Just 8% regarded the program as ok, none as mediocre. Interestingly all of the participants found the program motivating. Yet, despite the program being motivating, only 25% managed to do their exercises when they were reminded by email. However, the strength of the programme is that the reminder email remains in the inbox and can be deleted once the user has done the respective task or exercises—which also underlines the flexibility the programme provides, because in daily working life often unexpected tasks need to be done which are of higher priority.

TABLE II. RESULTS OF THE QUESTIONNAIRE

Question	Result
Did you have workplace health related problems?	Yes: 75% No: 25%
Usability of the programme	Good: 92% Ok: 8% Mediocre: 0%
Is the programme motivating?	Yes: 100% No: 0%
Do you conduct your exercises when you receive your reminder email?	Yes: 25% Partially: 17% No: 58%
Were you disturbed by your colleagues?	Yes: 33% No: 58% N/A: 8%
Would you permanently use the programme?	Yes: 67% No: 33%
Were your workplace related health problems alleviated?	Yes: 50% No: 25% N/A: 25%
Would you recommend the programme?	Yes: 92% No: 8%

Another challenge of these programs is that for some modules, such as exercises at the workplace, users might be embarrassed. However, only 33% felt disturbed by their colleagues. Moreover, 67% answered that they would permanently use the eWorkplaceHealth program. With regard to the (subjective) health results, 50% said that their problems were alleviated and only 25% felt no difference. Finally, 92% would recommend the program to others.

Furthermore, an analysis of the individual respondent results reveals that two of the respondents that had not problems would not continue to use the program permanently. Despite the small number it might be an indication that prevention is not as popular and that only if problems are present, users are willing to engage which is in line with previous research [16]. What is more, those that had no back problems were also less motivated to conduct the exercises in a timely manner. Last, all of those that had problems would recommend the eWorkplaceHealth program to others.

Open questions with regard to how such a program could be improved showed that some users would like to have more variety of exercises (the program provides 65 video tutorials). Moreover, some respondents would like get the same video tutorials as their colleagues in the same room so that they can conduct the exercises together in a team which might be a solution to the fact that users might feel disturbed or embarrassed by other colleagues. 50% of the respondents that felt disturbed/embarrassed requested to have the same exercises at the same time. One respondent suggested improving the written instructions (the video tutorials are without sound to avoid disturbing other colleagues).

In summary, the findings indicate that users are very positive about the eWorkplaceHealth program. Most that had problems felt better after the test period. What is more all

[1] The author of this paper is affiliated to OfficePhysio as a co-initiator.

respondents felt motivated which is in line with results of studies on web-based dietary that showed that the retention was significantly higher than for instance paper based interventions [19]. Also, almost all would recommend the program. Challenges prevail with regard to being embarrassed in front of colleagues.

VI. DISCUSSION AND CONCLUSION

This paper set out to understand whether and how eWorkplaceHealth services can disrupt traditional businesses of providing workplace health. This study conceptually developed that eWorkplaceHealth programmes create new efficiencies and enable new approaches to providing health services [20]. Because eWorkplaceHealth programmes reach all employees and seem to be effective and motivating, they can have a game changing character for the industry [13]. Due to its novel approaches on all dimensions compared to the traditional business model it can possibly disrupt the industry [12].

Interestingly, our study suggests that eWorkplaceHealth—due to its flexibility, low price point but most importantly comprehensiveness and effectiveness—appears to be superior to traditional practices on most dimensions. In that sense eWorkplaceHealth appears to 'overshoot' the product performance of traditional practices soon or even immediately (see Figure 1 below). This suggests that some disruptive innovation could overshoot the market right away, a phenomenon that needs further research but could tentatively be called 'born overshooter'—similar to born globals in the international business literature. These findings are in contrast to findings in health education that suggest that video or eLearning services are inferior [21]. However, although eWorkplaceHealth has an educational element, it has different requirements and different targets.

Despite the limitation of the small sample size and single case study, this exploratory study indicates that eWorkplaceHealth is accepted by users, improved (perceived) health conditions and was motivating. Thus, the conceptual and empirical results on eWorkplaceHealth illustrate that these programmes could disrupt the industry. What would accelerate the process would be more variety in the video tutorials and simultaneous exercises in offices—yet this needs to be validated in further research. Thus, eWorkplaceHealth may have the potential to disrupt the industry of traditional workplace health. Furthermore, eWorkplaceHealth programs can be a means of large organizations to provide workplace health support to all their employees. In order to avoid the innovator's dilemma [15], traditional workplace health provider could adopt a strategy in which they offer eWorkplaceHealth as a complementary service.

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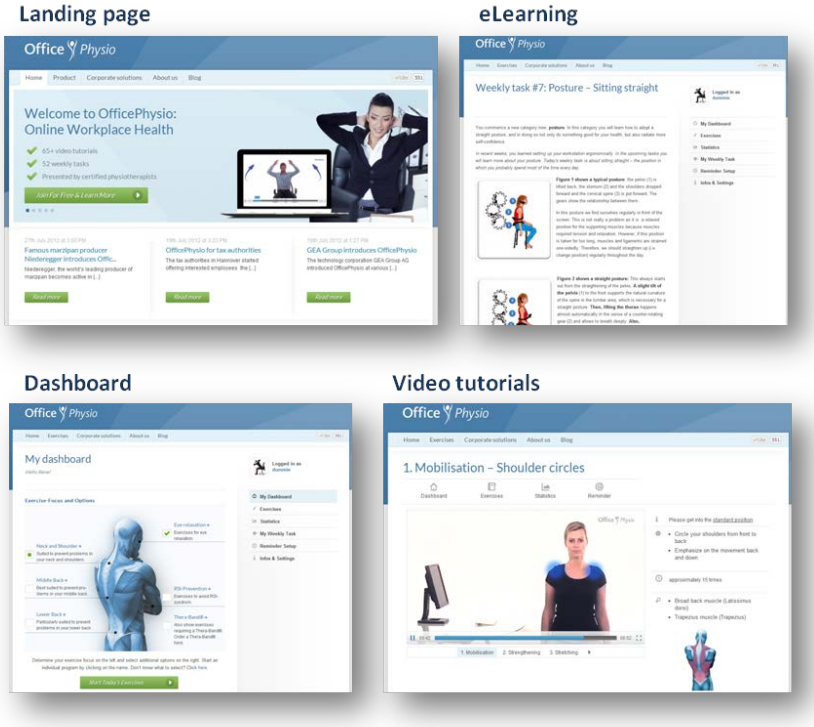

Figure 1. Screenshots of the eWorkplaceHealth program OfficePhysio (Top left: startpage; top right: health information email; bottom left: dashboard including customization; bottom right: video exercise)

E-Health System Development based on End User Centered Design

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***Abstract*—Legal and ethical aspects need to be taken into consideration during the development of an e-Health system, especially if this system monitors and assists elderly people. Furthermore, privacy and psychological aspects as well as the end user requirements are essential, since developing Ambient Assisted Living technology without integrating the end user results in products or functions which are not desired by the end user. Not considering the end user requirements (e.g., privacy concerns, desired functions) leads to the issue of less acceptance for new technology, since no benefit for the end user can be provided. In order to respect the end user's needs from the very beginning of a project, the integration of the end user throughout the whole project is seen as a key factor. This includes the analysis of the user requirements and regular feedback loops during the project. An example of the user centered design during the development of an e-Health system within the AAL-JP project *fearless* is presented in this paper.**

***Keywords*-end user integration; ambient assisted living; fall detection;**

I. INTRODUCTION

Fear of falling is a common problem for elderly and lead to reduced activities, even if the elderly did not fall [1]. Furthermore, falls are considered to be a great risk for elderly since the mortality of fallers is higher compared to other elderly and elderly may lie on the floor for hours [2].

This motivates the introduction of an event detection system which is able to detect falls automatically. The aim of the AAL project *fearless*[1] ("Fear Elimination As Resolution of Elderly's Substantial Sorrows") is the reduction of elderly's fears by providing alarms if unusual events (e.g., falls or fire) are detected. An all-in-one e-Health system is developed, focusing on fall detection at the beginning but offering a high degree of adaptability and standardized interfaces to be able to integrate other systems (e.g., alarm systems) at a later stage.

A main problem when developing AAL technologies is the proper integration of end user during the development process and the evaluation of the system. Despite this fact, developed approaches are tested under laboratory settings only (e.g., [3]–[7]), thus yielding in promising results. But to verify these results, field tests with elderly have to be conducted and their feedback need to be integrated into the development process. The contribution of this paper is to present a user centered development of an e-Health system and the end user integration strategy evolved in the *fearless* project.

The rest of this document is structured as follows: Section 2 gives an overview of the technical system methodology, whereas Section 3 discusses the user centered design process. Finally, a conclusion is drawn in Section 4.

II. METHODOLOGY

The structure of the *fearless* system is depicted in Figure 1, showing all relevant interfaces and involved end user. The proposed e-Health system consists of sensor units (Xtion Pro + small PC for data processing) installed at the elderly's house or flat. The system is adaptable, hence standardized interfaces to third parties are provided (e.g., alarm system, gas detector). Unusual events (e.g., falls) are detected automatically and alarms are sent to the telematics platform. This platform enables elderly, relatives and care taker to access the alarm events. Furthermore, the telematics platform offers interfaces to different standardized electronic health record systems (e.g., ELGA in Austria) to include health professionals.

Autonomous sensors detecting falls automatically are needed, since it is important to reduce the cognitive load on the user, especially when dealing with dementia [8]. The use of computer vision is feasible, since it can overcome the limitations of other sensor types [9] and no devices need to be worn. Zweng et al. [7] show that the accuracy of their fall detection approach is higher compared to 2D cameras when using a calibrated camera setup and a 3D reconstruction of a person. Hence, we propose to use a Kinect / Xtion pro, since 3D information is available for distances up to ten meters without the need for a calibrated camera setup. However, the SDK is optimized for a range from 0.8 to 3.5 meters and thus not all features provided by the SDK can be used for higher distances (e.g., NITE). Moreover, the scene can be analyzed in more detail (e.g., estimation of the ground plane) in comparison to standard cameras.

However, the use of computer vision raise privacy issues. Due to this facts, the Kinect respectively the Xtion Pro

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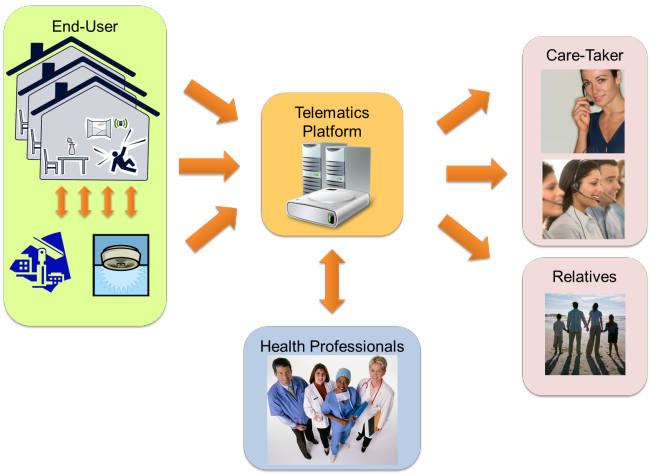

Figure 1. *fearless* e-Health system

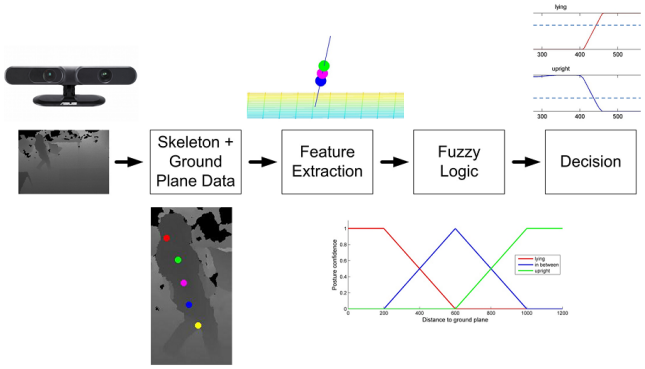

Figure 3. Technical Workflow

sensor is used, since depth data can be used to detect falls (e.g., [4], [5]). Using depth data respects the privacy of elderly, since neither the person nor the surrounding can be identified from depth images. A depth image only visualizes the position and the distance to the sensor. Figure 2 (left) shows an example of a depth image illustrating a person, tables and a mat lying on the floor. This visualization illustrates the distances of subjects and objects to the sensor. The brighter the color in the depth image, the more far away the person or object is. On the other hand, the darker the object is, the closer to the sensor it is. Furthermore, black indicates that there is no data available (e.g., due to sunlight or reflections). In contrast, the corresponding RGB image is shown in Figure 2 (right), representing the same scene.

The workflow of our approach is depicted in Figure 3: starting with a depth image, the skeleton and ground plane data is extracted by the use of OpenNI [10]. The skeleton joints of the shoulder, spine and the center of the hip are extracted and analyzed using fuzzy logic. Based on the results of the fuzzy logic, a decision is made if the person is in an upright position or lying on the floor. Since only the skeleton joints are used, the privacy of the elderly is respected due to the use of an anonymous and abstract visualization only using lines and dots. An example of this

Figure 2. Depth image (left) and corresponding RGB image (right)

visualization is shown in Figure 4: the dots are representing the upper part of the body, whereas the line represents the major body orientation and the ground floor. In case of an alarm, the alarm including this abstract visualization is sent to the telematics platform, depicted in Figure 1. Moreover, the alarm is stored and forwarded to the appropriate care taker organization or relative by using this platform.

To be able to meet the required end user demands, the following criteria need to be fulfilled:

- **False Alarm Rate:** false alarms (false positives, FP) are events, where the system reports a fall, although the person does not fall. Since each fall event is monitored by a care giver organization or a relative, FP result in time and cost consuming actions. On the other hand, false negatives (FN) are events, where the person falls down but the system does not detect the event. The drawback of FN is that the system misses the fall and thus no help can be provided. In summary, the number of FP and FN need to stay below a threshold (e.g., the number of FP and FN when using a panic button), otherwise the system will not be successful. To reduce the number of FP and FN, the verification of an alarm by a call center agent or relative, before taking counter-measures, is proposed by sending additional verification illustrations. These illustrations, depicted in Figure 4, show abstract visualizations of a person representing the upper body of the person by three dots (shoulder, spine, hip) and a line as well as the position of this person with respect to the ground floor. Due to this representation, the illustration is even more anonymized than when using depth images, although the relevant information (person is in an upright position vs. person is lying on the floor) is still obtained.
- **Security and Privacy:** Ensuring high security and privacy standards are essential for a successful e-Health system. Hence, only abstract and anonymized illustrations are accessible, shown in Figure 4. Furthermore, all connections of the *fearless* system are encrypted

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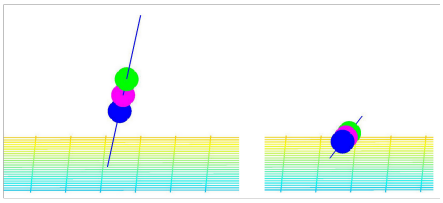

Figure 4. Verification image of a person (a) being in an upright position (left) and (b) lying on the floor (right). The upper body of a person is represented by only three dotes and one line.

using the AES-256 encryption standard. To ensure privacy by design, it is not possible to view a camera picture, since no (RGB) camera is used. Moreover, the system does not look like a standard camera and thus no stigmatization takes place since the sensor can be integrated into the flat or house.

- **Affordability:** Technology for elderly need to be affordable, hence the system is built of low-cost standard components to ensure to meet the end user requirements. Similar to the panic button, elderly will be able to rent the system and thus covering the hardware as well as personal costs.
- **Adaptability:** To be able to provide an all-in-one solution, interfaces to other systems (e.g., alarm systems, smoke detectors) are provided. Hence, the system can be personalized according to the end user's needs and a single safety and security system can be provided.
- **Control belief:** This end user requirement is fulfilled by providing access to all information gathered by the system via the use of the telematics platform. This platform acts as central point of information and all alarms are sent to this platform. Elderly, their relatives and care taker organizations have access to this platform. This solution fulfills the requirement of empowering elderly to have control over their data, although conflicts arise since elderly perceive the use of the Internet as costly and difficult [11].

III. End User Centered Design

The *fearless* consortium brings together ten interdisciplinary partners from Austria, Germany, Spain and Italy. To be able to integrate end user, two caregiver organizations are responsible for the recruitment of the test persons. Technical partners are responsible for developing fall and fire detection algorithms, but also for providing the telematics platform. Since the aim of the *fearless* project is the reduction of the fears for elderly living in their own homes, the impact of this assistive technology and its relation to fears is analyzed by psychologists. Business experts are responsible that the research within this project results in a technology which is affordable for elderly, whereas medical experts monitor the health status of the elderly throughout the project.

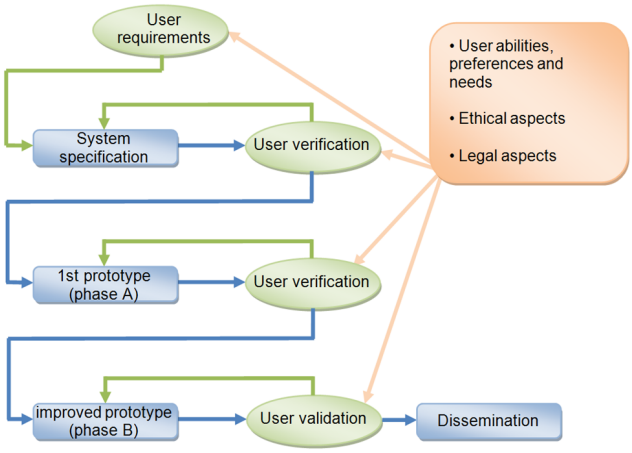

Figure 5. End user are integrated throughout the whole project duration

Figure 5 illustrates the integration of the end user within the *fearless* project: at the beginning of the project, a user need analysis is conducted to assess the needs and fears of end users are by theoretical derivations from existing psychological models and theories and semi-structured interviews. According to the user requirements, an initially defined system specification is continuously evaluated by end users and redefined through regular feedback loops. Field pilots in combination with semi-structured interviews are conducted to ensure that the system is developed according to the end user needs. Since end user provide regular feedback, the technical specification of the *fearless* system is adapted throughout the project.

During the field pilots the *fearless* system is installed in elderly's flats in Austria, Germany, Italy and Spain. The field pilots consist of two different phases: during phase one, the first prototype of the fall detection system is installed in four flats (one flat in each country) to obtain first results of the system. Due to these results the prototype is enhanced before phase two with 30-40 installations will be conducted. The aim of the field pilots is not only to test the fall detection system itself, but also to assess technological and psychological aspects (e.g., enhanced mobility) as well as integrating care taker organizations and relatives throughout the project. The mobility aspect is evaluated during the field pilots by the use of step counter: if elderly have less fears, they do not avoid activities and are thus more mobile. Furthermore, also the ethical comissions are involved during the field pilots to verify the feasability of the *fearless* system from a legal and ethical point of view.

The project benefits from the different interdisciplinary perspectives, from which the results of the field pilots are analyzed. From a technical point of view, the fall detection algorithm [5] is tested under real settings and is adapted to the end user's needs while overcoming the lack of realism when performing falls in the laboratory. Furthermore, the

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overall system including its interfaces as well as the feasibility of the system setup is evaluated. From an organizational point of view, end user organizations are able to integrate the system into their workflow and provide feedback to adapt the system to their needs. Elderly are involved to provide essential feedback to the technical partners. Additionally, we assume to reduce their fears by providing safety while using our system. Since the field pilots are conducted with medical and psychological support, changes and benefits for elderly can be determined and these assumptions can be verified.

In summary, the following end user are involved during the project:

- **Elderly and relatives** are involved during the end user requirement analysis and during the field pilots. Elderly install the system in their flats during the field pilots, whereas their relatives can receive the alarms if unusual events are detected.
- **Care taker** are involved during the end user requirement analysis and are fully integrated during the field pilots. Hence, the care taker's call center is integrated and alarms are forwarded to the appropriate call center. Thus allows to verify the feasibility of the overall workflow in case of an alarm.
- **Health professionals** provide medical guidance and assistance throughout the project.
- **Electricians** are involved during dissemination activities since elderly contact their already well-known electricians around their corner and thus electricians need to be aware of new technologies such as e-Health systems.

IV. Conclusion and Future Work

This paper presented an overview of the user centered development of an e-Health system and the end user integration within the *fearless* project. Since AAL technologies are tested under laboratory settings, tests with elderly are missing. Hence we focus on field pilots and regular end user feedback loops. To enhance the acceptance of such technologies, end user need to be integrated even during early project phases. The integration should not only focus on primary end user (elderly), but also on secondary end user (e.g., caregiver organizations, relatives) since these people are also confronted with the use of AAL technologies. In order to achieve this, all relevant stakeholders are included and the end user feedback is received from all stakeholders, establishing an interdisciplinary view. Due to the feedback, adaptions and improvements of the system are developed (e.g., integration of a power switch to ensure the end user's control belief).

Future work deals with the improvement of the system according to the end users feedback gathered during the field pilots. The improvement of the system includes further technical devlopement and the development of additional features, but also design issues might be adressed by the end users. Furthermore, the workflow for the end user integration (i.e., relatives and call center) will be analyzed and optimized as well as the feasibility of the verification images to distinguish between true and false positives.

Acknowledgment

The authors want to thank the whole *fearless* project team, since techniques and ideas of many researchers involved are used.

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Critical Success Factors for eHealthcare

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***Abstract*—As healthcare enterprises move towards a sustainable healthcare delivery model, an ehealthcare strategy is being adopted. In this study, the critical success factors for an ehealthcare strategy were identified. Their relative importance was determined based on increasing access to healthcare and reducing its cost. To succeed in ehealthcare initiatives the necessary factors are appropriate government policies, literacy levels, and telecommunications and power infrastructure. The focus should not be on technology; instead, factors such as healthcare provider and consumer mindsets should be addressed to increase the acceptance of ehealthcare services.**

Keywords-ehealthcare; critical success factors; efficiency; AHP; ISM.

I. INTRODUCTION

In the developing world, ehealthcare is often proposed as a solution to certain healthcare problems – accessing the rural population and trying to bridge the huge gap between the demand and supply of healthcare services. In the Indian context it is important to understand the healthcare and demographic scenario. There are huge differences between urban and rural India in terms of quality of available healthcare. Approximately 70% of the Indian population lives in rural areas whereas approximately 90% of the secondary and tertiary healthcare services are located in urban areas. The primary healthcare facilities in rural areas are also inadequate.

Ehealthcare exists as fragmented efforts by various Ministries of the Government of India (GOI) and a few corporate hospitals to address the challenge of providing healthcare to over 1 billion people. The Department of Information Technology (DIT), Ministry of Communication and IT (MCIT), GOI has setup about 75 nodes in collaboration with various State Governments for applications such as tropical diseases, cancer care and consulting specialists from remote areas. Another DIT project is the setting up of Common Service Centers (CSC) – about 100,000 nodes, in rural areas. These are envisaged as serving as a front-end for government services of which ehealthcare is one of the services to be provided [9][10]. The Indian Space Research Organization (ISRO) has an ehealthcare network consisting of 225 hospitals – 185 in rural areas connected to 40 super specialty hospitals. The Village Resource Center (VRC) is a project of ISRO along the lines of the CSCs to provide services including ehealthcare services. The Ministry of Health and Family Welfare (MoH&FW), GOI implemented an Integrated Disease Surveillance Program that connects district hospitals with medical colleges of that state. Tele-opthalmology projects and a national cancer network are additional projects that have been funded [9][10].

Policy initiatives by different ministries of the GOI include those by the DIT of the MCIT: standardization of ehealthcare systems, hardware, software, security and privacy issues to enable planning and implementation of ehealthcare networks. A project called the "The Framework for Information Technology Infrastructure for Health (ITIH)" to address the information needs of various stakeholders has been undertaken. A National Task Force on Telemedicine was set up in 2005 by the Ministry of Health and Family Welfare (MOH&FW), GOI and a part of their mandate is to evaluate all players and projects in ehealthcare in India, define standards of electronic medical records, work on different modes of ehealthcare networks in the country and develop a national policy for ehealthcare for the 11th Five Year Plan [9][10].

A review of literature showed that improvements in healthcare delivery are achieved by ehealthcare in terms of improved access and quality, and reduced costs [2][3]. The challenges to the advancement of ehealth that remain are issues relating to confidentiality, reimbursement, and legal and ethical considerations.

When considering costs the literature shows that health outcomes improved at lower costs with ehealth as compared to traditional home visits by healthcare professionals [4][5]. Though there are initial set up costs, studies indicate overall lower costs due to better triage as a result of ehealthcare, reduced length of hospital stay, and reduced travel costs [6][7]. Costs, however, are incurred by the healthcare provider whereas savings benefit the payer, so these savings need to be realized by both [8].

With limited resources it is important to ensure the success of new and sustainable ways of healthcare delivery [1]. There exist frameworks for the introduction of ehealth technologies based on standard models for technology development and introduction [19]. Factors that would ensure the success of technology innovation and diffusion have, however, not been studied in detail, and neither has their importance been ranked [18].

Based on a literature survey, we identified ten critical success factors (CSF) that influence the efficiency of ehealthcare in terms of their impact on increasing access and

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reducing the cost of healthcare delivery. The relative importance of these factors was determined as well as the relationships among them.

In the following sections, the critical success factors are identified and ranked in their order of importance. No evaluation has, however, been done in terms of cost-benefit analysis of ehealthcare or its impact on public health.

II. METHODS

A search of peer-reviewed literature databases such as MEDLINE, PUBMed, academic journals, conference proceedings, and Google Scholar was done. Websites of the World Health Organization (WHO) [21] and GOI [22] were also searched. Search terms such as "ehealth", "ehealthcare", "telemedicine" and synonyms were used. Abstracts of articles were used to identify relevant articles. The 'snowball' method [23] was used to further identify articles from the reference lists of these articles. Ten CSF for ehealthcare were identified:

A. Critical Success Factors

The ten CSF and their relevance to ehealthcare are listed below.

- Data warehousing and data mining - appropriate data warehousing and data mining techniques are important, as online patient record storage and retrieval of relevant data for medical decision making is an indispensable component of any ehealthcare paradigm [9]. Health information needs to be integrated with technology, which has been done in the West but not in India.
- Expert systems - decision support systems for diagnoses as well as for demographic analysis for public health programs are extensively applied in the delivery of ehealthcare [9].
- Data access control - the healthcare sector in the West has stringent requirements for data security and controlling access to confidential patient data. In the United States the Health Insurance Portability and Accountability Act (HIPAA) was passed for improved patient privacy and data security. Interoperability standards need to be in place along with data security [2]. In India, however, laws and standards for protecting a patient's electronic healthcare record are still in their infancy.
- Biomedical engineering technology - appropriate biomedical engineering technology is necessary to support ehealthcare applications. Technical support is necessary throughout installation and needs to be ongoing for all stakeholders along with user-friendly technology. Quality of service needs to be ensured, e.g., low down-time. Diffusion of ehealthcare technology needs initial champions as in the introduction of any other technology [2][11]. A study on the intention to use wireless technology for healthcare in India showed that technology factors are important along with financially viability [9][12].
- Telecommunications and power infrastructure - reliable networks will be of prime importance as ehealthcare activities increase [11]. This is very important in India where uninterrupted power supply is yet to be realized in most parts of the country. This will need to be coupled with a high-bandwidth, zero-downtime telecommunications network to support ehealthcare delivery. A study on the intention to use wireless technology for healthcare in India showed that communications factors are important [9][12].
- Government policies - international studies have shown that policy and legislation are important for ehealthcare success [2]. Indian studies also show that licensing, ethical, and legal issues need to be addressed to promote integration of IT tools to facilitate ehealthcare [9][10]. Government policies concerning healthcare, education, infrastructure, technology, insurance, and legal issues all have a bearing on the success of ehealthcare in India.
- Healthcare insurance - financing is an important factor as insurance companies need to have tariffs in place for this new mode of healthcare delivery [2]. Health insurance is another sector where the entry of third party administrators and private players is set to change the way healthcare coverage is provided in India.
- Literacy levels - a literate population with a minimum level of computer awareness is essential for the success of ehealthcare. Technology is useless when faced with ignorance and an inability to use it appropriately and effectively. As of figures reported in 2008 only 65.38% of India's population is literate with only 2% being well-versed in English [9].
- Consumer mindset - a literature review on the effect of ehealthcare on doctor-patient communication showed that ehealthcare was favored in approximately 80% of the studies [13]. In India some studies show an acceptance of technology as a result of reduction in travel costs and time, whereas other studies report a lack of confidence on the part of patients in ehealthcare [9].
- Healthcare provider mindset - user acceptance is a very important factor and the involvement of healthcare professionals is essential from the design phase itself [2][14]. Ehealthcare facilities need to be available in the doctors' offices, training needs to be provided as well as monetary compensation for providing ehealthcare services for user acceptance [11][15]. Possible reasons for physicians being reluctant include being too busy, a perceived loss of control, a lack of conviction in its potential, and not being conversant with ehealthcare [7][9]. An Indian study showed that ehealthcare's clinical usefulness influenced its adoption along with the administrative factors involved [12]. To be able to fully utilize the potential of ehealthcare, healthcare providers will have to be responsive and committed to ehealthcare [2][11].

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As various studies have shown training and organizational support is essential for adoption along with a change agent who is in a position to affect strategy and decision making [16]. Ehealthcare needs to fit into existing work protocols and not function as an add-on. Effective change management will be necessary to overcome resistance to adapting to new ways of delivering healthcare.

The above 10 critical success factors were assessed in terms of their impact on increasing access to and reducing the cost of healthcare delivery.

B. Analytic Hierarchy Process

Analytic Hierarchy Process (AHP) was used to determine the relative importance of the CSF that influences the efficiency of ehealthcare [17]. AHP is a multi-criteria decision making technique that allows relative ranking of both qualitative as well as quantitative information. The information is separated into a hierarchy of alternatives and criteria. The alternatives, i.e., independent variables, are the ten success factors. The objective, i.e., dependent variable, is efficiency of ehealthcare. The criteria, i.e., mediating variables, against which the alternatives are ranked are increasing access to healthcare services and reducing cost associated with healthcare delivery. Based on this objective, two criteria and ten alternatives, a vector ranking the ten CSF was obtained from a group AHP performed on the inputs provided by individual healthcare providers. A Microsoft Excel spreadsheet was programmed to compute the group AHP rank vector. The ranking in this vector denotes the perceived importance of the CSF.

C. Interpretive Structural Modeling

Interpretive Structural Modeling (ISM) was used to determine the relationships between the CSF that influence efficiency of ehealthcare and establish the strategic drivers necessary for success (Sage, 1977) [20]. The ten CSF were assessed with respect to each factor having an impact on another factor. These CSF were used to develop a group ISM based on the inputs provided by the same individual respondents. To develop a group ISM, the majority answer was taken for each question from the individual answers provided by the respondents. ISM software was used to perform the ISM calculations. The ISM directed graph, or digraph, shows whether a factor has an impact on another factor and determines the strategic drivers.

D. Data Collection

An exploratory study was carried out with data gathered using a survey instrument tailored for AHP and ISM and consisting of two sets of questionnaires. The questionnaires were administered to a convenience sample of thirty-one healthcare providers, out of which eighteen responded. These respondents were from the National Capital Territory of Delhi. Eleven of these respondents were doctors from a large government teaching hospital, four were doctors in private practice, one was an ehealthcare manager for a large private chain of hospitals, and two responses were obtained from academics specializing in information technology and healthcare management.

III. RESULTS AND DISCUSSION

The results from both AHP and ISM are presented in the following sections:

A. AHP

An AHP computation was performed on the collective set of inputs obtained from all the respondents. The results, in terms of ranking of the criteria and the CSF, with their relative weights indicating decreasing importance, are given in Tables I, II and III.

Healthcare providers, as a group, perceived increasing access to be more important than reducing cost for increasing the efficiency of ehealthcare as shown in Table I. Keeping in mind the large population of India that is currently under-served in terms of basic healthcare services, any initiative that attempts to provide healthcare services should increase access to the services.

Table II shows the ranks of the CSF with respect to the two performance assessment criteria – increasing access and reducing cost. Healthcare providers rank literacy levels as the most important factor influencing access. Consumer and healthcare provider mindsets along with telecom and power infrastructure follow in close succession as to their importance in increasing access. Without a literate population it is not possible to fully utilize ehealthcare services. The mindsets of people as well as the basic infrastructure issues are important for accessing a larger number of people.

With respect to reducing cost, literacy levels are once again considered the most important factor, with telecom and power infrastructure a close second, and government policies in third place. For ehealthcare to service the country a literate population is desirable. When dealing with an illiterate population greater costs are incurred and this is reflected in ranking literacy levels as the number one factor affecting the cost of ehealthcare. The infrastructure costs also have a bearing on ehealthcare costs and hence they are in second place. Government policies, in third place, also have an impact on the cost of ehealthcare.

In the combined ranking shown in Table III, literacy levels are considered the most important factor influencing the efficiency of ehealthcare. The telecom and power infrastructure is ranked second with consumer and healthcare provider mindsets a close third and fourth. A literate population is a prerequisite for effective ehealthcare delivery both in terms of increasing access and reducing cost. Without telecom and power any ehealthcare initiative will not function properly. The mindsets of both the healthcare providers and consumers are also important for ehealthcare to gain acceptance as a means of giving and receiving healthcare services. The technology aspects of the business such as appropriate IT and biomedical engineering

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technology are ranked the lowest in their impact on ehealthcare.

TABLE I. AHP RANKS OF CRITERIA

Criteria	Relative weights
Increasing access	0.5778
Reducing cost	0.4222

TABLE II. AHP RANKS WITH RESPECT TO CRITERIA

CSF with respect to increasing access	Relative weights	CSF with respect to reducing cost	Relative weights
Literacy levels	0.1951	Literacy levels	0.1644
Consumer mindset	0.1298	Telecom / power infrastructure	0.1537
Healthcare provider mindset	0.1274	Government policies	0.1337
Telecom / power infrastructure	0.1262	Consumer mindset	0.1070
Government policies	0.1042	Healthcare provider mindset	0.1055
Expert systems	0.0703	Healthcare insurance	0.0887
Data access control	0.0665	Data warehousing / data mining	0.0877
Healthcare insurance	0.0644	Expert systems	0.0679
Data warehousing / data mining	0.0632	Biomedical engineering technology	0.0536
Biomedical engineering technology	0.0531	Data access control	0.0378

TABLE III. COMBINED AHP RANKS

CSF	Relative weights
Literacy levels	0.1821
Telecom / power infrastructure	0.1378
Consumer mindset	0.1201
Healthcare provider mindset	0.1181
Government policies	0.1167
Healthcare insurance	0.0747
Data warehousing / data mining	0.0736
Expert systems	0.0693
Data access control	0.0544
Biomedical engineering technology	0.0533

B. ISM

A group ISM was developed from the inputs obtained from all the respondents and is shown in Fig. 1. Government policies are the most important strategic driver having an impact on the other factors as can be seen in Fig. 1. Relevant government policies need to be in place to accelerate the pace of infrastructure development in the country without which ehealthcare cannot hope to achieve any measure of success. Government policies also have a direct impact on the literacy levels in the country that will, in turn, drive changing consumer mindsets.

The telecom and power infrastructure in the country is the second most important strategic driver for ehealthcare initiatives. With an adequate infrastructure in place the healthcare provider mindset will be influenced positively in favor of ehealthcare as a successful delivery mechanism. The information and biomedical engineering technologies are not as critical in ehealthcare delivery.

The results from both tools show that non-technology issues such as government policies, telecom and power infrastructure, and literacy levels in the country are more important than technology issues.

IV. CONCLUSION

We sought to evaluate the ten CSF that influence the efficiency of ehealthcare delivery. AHP was used to rank the CSF and ISM to determine the strategic drivers. Increasing access and reducing cost were the criteria used. To succeed in ehealthcare initiatives the CSF that need to be in place are appropriate government policies, literacy levels, and telecommunications and power infrastructure in the country. The focus should not be on the IT tools and biomedical engineering technology as is most often the case. Instead the non-technology factors such as healthcare provider and consumer mindsets should be addressed to increase acceptance of, and enhance the efficiency of, ehealthcare services.

ACKNOWLEDGMENT

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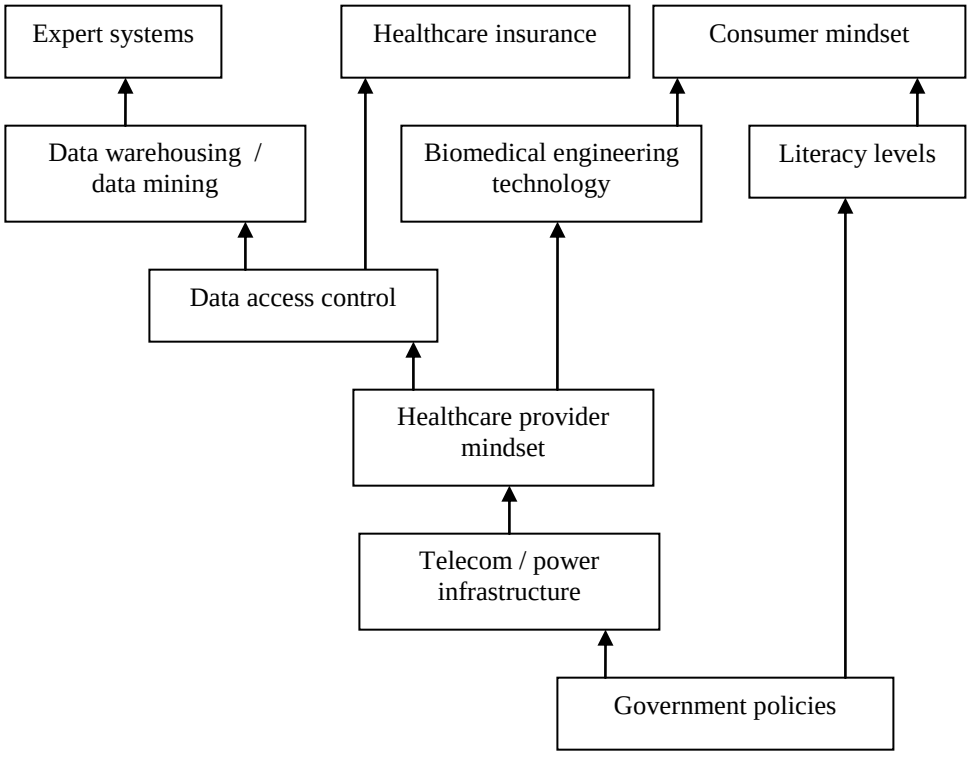

Figure 1. Group ISM digraph

Developing evidence guidelines for eHealth Small and Medium-sized Enterprises

Towards feasible yet convincing evidence

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***Abstract*—eHealth applications hold many promises, for instance to improve the quality of health care, to increase its accessibility, or to reduce the cost. Yet, many eHealth innovations never reach the stage where they get embedded into routine health care. This is due in part to a lack of evidence that these innovations indeed deliver what they promise. For small and medium-sized enterprises (SMEs) in particular, collecting convincing evidence for eHealth innovations proves to be a challenge as the available time, resources and expertise to do so are often limited. In response to this challenge, the research group *ICT Innovation in Health Care* initiated the project *Successful Entrepreneurship in eHealth*. The project is a cooperation between 24 parties in The Netherlands: eHealth SMEs, health care providers, patient organizations, health insurance companies, and national health care authorities. Its aim is to speed up eHealth innovation by providing eHealth SMEs with guidelines for collecting feasible yet convincing evidence. In this paper the project's approach is introduced and some preliminary results and lessons learnt are discussed.**

Keywords: eHealth; innovation; evidence; guidelines; SME

I. INTRODUCTION

Getting an eHealth innovation embedded into routine health care often turns out to be a challenge. Several causes can be identified, including a narrow focus on technological aspects of the innovation, too little involvement from key stakeholders during design and implementation, or lack of a good underlying business model [1]. The research group *ICT Innovation in Health Care* at Windesheim University of Applied Sciences (Zwolle, The Netherlands) has dedicated itself to study these issues and to support small and medium-sized enterprises (SMEs; in The Netherlands defined as companies with up to 250 employees) in overcoming them. For instance, the research group recently published the first version of the eHealth Innovation Matrix [2]; an online assessment and library that offers eHealth SMEs (i.e., SMEs offering eHealth products and services to health care providers and the public) guidance in developing and evaluating a business model for their eHealth innovations.

A. Collecting evidence for eHealth innovations

In a recent series of workshops organized for eHealth SMEs and health care parties, an inventory was made of the problems encountered when getting eHealth innovations embedded in routine health care. Among the list of problems, collecting *evidence* for an innovation came out first. To get their innovation accepted by patients and care providers, reimbursed by health insurance companies, endorsed by patient organizations, or approved by national health care authorities, innovators often need to show evidence for the innovation's effectiveness, for instance to increase treatment quality or reduce the cost of delivering health care.

For a typical eHealth SME it is often unclear what kind of evidence is expected and by whom, and according to which standards this evidence should be collected. In other cases, the standard may be clear (e.g., a randomized controlled trial) yet practically unfeasible for an SME due to a lack of available time, (financial) resources, or expertise. To complicate matters further, care providers, insurance companies and care authorities offer no clear guidelines for eHealth innovators. They recognize that this discourages eHealth adoption and that it impedes innovation within the Dutch care system [3].

B. Towards feasible yet convincing evidence

At the beginning of 2012 the project *Successful Entrepreneurship in eHealth* (SEE) was initiated by the research group to address these challenges. The project constitutes a cooperation between 24 eHealth SMEs, health care providers, patient organizations, health insurance companies, and national health care authorities in The Netherlands. The project's aim is to establish guidelines for collecting evidence in such a way that (i) it is practically feasible for eHealth SME's to do so and (ii) the resulting evidence is acceptable and potentially convincing for care providers, health insurers, or care authorities. Hence the project's motto: *towards feasible yet convincing evidence*.

To achieve its aim, the project will address the following research questions:

1. What kinds of evidence for eHealth innovations are generally recognized? Are there any commonly accepted evaluation frameworks?
2. What are relevant outcome indicators and methods to collect specific kinds of evidence? How do these compare in terms of methodological quality and practical feasibility?

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3. Which parties in the Dutch care system (patients, care providers, health insurance companies, national care authorities, others) will need to be convinced of the effectiveness of an eHealth innovation before it can be embedded into routine practice?
4. How do these parties value the kinds of evidence mentioned earlier? What typically constitutes "convincing evidence" for these parties?

By generating answers to these questions the project will offer guidance to eHealth SMEs: which parties will need to be convinced of the effectiveness of an innovation, what evidence will be required, and how to collect this evidence in a feasible yet acceptable way.

II. APPROACH

The project is structured into four phases which are briefly outlined in this paragraph.

A. Inventory

During this phase an inventory is made of generally recognized types of evidence. This is done by means of a literature review, interviews with health care experts in The Netherlands, and workshops with representatives of Dutch health care providers, insurers, patient organizations, and national health care authorities. Questions to be answered include: Which parties are involved when getting an eHealth innovation embedded in routine health care? What kind of evidence is generally needed, and how should it be collected? How do parties value various kinds of evidence? What criteria are typically used? The results will include:

- An initial overview of commonly required types of evidence, possibly clustered into themes or categorized by type of eHealth application;
- A series of fact sheets, one for each type of evidence, containing purpose, relevance for various parties, methods, criteria, and practical feasibility.

B. Case studies

Whereas the analysis during the Inventory is top-down, the analysis during the case studies is deliberately bottom-up – to involve the SMEs and to enrich the analysis with examples of concrete situations, dilemmas and obstacles encountered. Cases from the participating eHealth SMEs will be selected for a detailed study by means of analysis of available documentation, workshops with experts, and in-depth, semi-structured interviews. Questions to be answered include: How are SMEs trying to get their innovations embedded into routine care? Which stakeholders do they identify and involve? What kinds of evidence do these stakeholders require? What evidence did the SMEs collect so far, and in what ways? How did stakeholders evaluate the evidence, against what criteria? The results will include:

- Detailed, in-depth descriptions of successful and unsuccessful strategies followed by SMEs to get their eHealth innovations embedded in routine health care;
- Specific examples of evidence that was required, whether and how it was collected and, if applicable, how it was evaluated by health care providers, insurers, patient organizations, or national health care authorities.

C. Guidelines and best practices

In this phase, the case studies will serve as input to a series of workshops with health care experts and representatives of health care providers, insurers, patient organizations, and national health care authorities. Learning lessons from these specific examples, and building on the results of the Inventory, best practices for embedding eHealth innovations in routine health care will be identified. Furthermore, guidelines will be developed for collecting and evaluating the required evidence. Best practices and guidelines will then be combined into a systematic approach for collecting and evaluating evidence for eHealth innovations. To validate the newly developed systematic approach it will be applied and evaluated in a second series of case studies. Thus, the results of this phase will include:

- An initial, systematic approach for collecting and evaluating evidence as required for getting an eHealth innovation embedded in routine health care;
- Validation of the systematic approach, including an inventory of practical issues and points for improvement.
- A revised, final systematic approach.

D. Consolidation and tool development

In this final project phase, the systematic approach described above will be consolidated in a web-based tool and documented in a handbook:

- The web-based tool will offer eHealth SMEs guidance in planning and implementing evidence collection for their eHealth innovation;
- The handbook will document the various types of evidence for eHealth innovations, including methods for collecting evidence and criteria for evaluating it.

III. PRELIMINARY RESULTS

The project *Successful Entrepreneurship in eHealth* started at the beginning of 2012 and will conclude at the end of 2013. At the time of writing, the first project phase, Inventory, is nearing completion while the second phase, the case studies, has just been started with the first in-depth interviews. This paragraph highlights some preliminary results and lessons learnt.

A. No generally accepted standards for collecting evidence

During the literature study several articles and reports offering proposals for evaluation frameworks were found, with guidelines for the evaluation of eHealth applications, lists of outcome indicators, and descriptions of methods to collect evidence [e.g., 4, 5]. However, the general consensus in the literature is that there are currently no commonly accepted standards for collecting evidence for eHealth applications [6, 7]. The assumptions, methods, and study designs of experimental science may altogether be less suited for application in the socio-political context in which eHealth evaluations usually take place, and alternative approaches

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that view evaluation as social practice rather than scientific testing need to be considered [8]. Moreover, the tendency to focus on "hard" evidence provided by randomized controlled trials (RCTs) may result in disregard for the interests and experiences of the individual patient [9]. Some researchers therefore argue for a contextualized approach in which all relevant stakeholders are actively involved in the definition of the outcome indicators that will be used for evaluation [10, 11].

B. Stakeholders recognize three themes for evidence

During the interviews with health care experts and the workshop with representatives from health care providers, insurers, patient organizations, and national health care authorities, three dominant themes were recognized by the participants within the larger concept of evidence: *effectiveness* ("did health care get any better?"), *cost efficiency* ("did it get any cheaper?") and *labor savings* ("did it get any less labor intensive?"). Below we briefly describe each theme, including a few relevant issues mentioned by the participants.

1) Effectiveness

This kind of evidence relates to clinical effectiveness, quality of care, safety, accessibility, timeliness, and patient satisfaction. However, eHealth's primary purpose may not always be patient recovery; frequently, eHealth is directed at retaining autonomy, strengthening the involvement from relatives, maintaining social participation, or improving a patient's wellbeing. Although these aspects are hard to measure, they are important from the patient's perspective and also valued by care professionals and society as a whole.

2) Cost efficiency

This includes evidence with regard to cost savings, cost control, and efficiency in terms of time, money, and other resources. eHealth applications have traditionally been considered as a promising way to reduce the cost of delivering health care. With the growing emphasis on budget control in health care, evidence for eHealth's cost efficiency is becoming increasingly relevant for decision makers. The current Dutch health care policy, for instance, is directed at stimulating cost-efficient eHealth applications that are replacing (instead of supplementing) traditional forms of care [3].

3) Labor savings

This relates to evidence that the same number of patients can be treated with the same quality, but with fewer hours worked by health care professionals. Although labor savings might be considered a special case of cost efficiency, the predicted labor shortage in the Dutch health care system justifies this kind of evidence to be considered separately. Labor savings also occur when an eHealth application reduces the complexity of a particular task, allowing highly schooled professionals to delegate part of their work to less skilled staff.

Various indicators and methods relating to the above types of evidence have been identified during the interviews and workshop and also from the literature. They are currently being complied into three sets of fact sheets, i.e., one set for each theme.

C. How stakeholders value evidence

From the interviews and workshop it has become clear that "heavy" forms of evidence (obtained using, e.g., randomized controlled trials) are certainly not always necessary to facilitate the uptake of eHealth applications. The participants agreed that RCTs are not always useful, necessary or practically feasible. Furthermore, care providers and health care insurers indicated that they will still rely on their own patient data to support any decisions they make about embedding eHealth applications.

National care authorities, on the other hand, hold the view that eHealth applications typically only change the way in which health care is being delivered. As long as there are no indications that clinical effectiveness is at stake, and within the limits defined by the health care system, care providers and health care insurers are free to negotiate and decide about the use (and reimbursement) of eHealth applications.

D. "Innovation routes" for embedding eHealth innovations

One topic which arose very prominently during the workshops, is that it is not straightforward which path an SME should follow within the care system to get an eHealth innovation embedded into routine care. In part this is due to the wide variety of applications that fall under the common denominator of eHealth, but it is also due to the complexity of the Dutch care system, which is highly regulated and in which various authorities and other parties each play a distinct role. From a myriad of options an SME should consider very carefully which "innovation route" to follow, as the chosen route will determine which stakeholders to address and involve. Stakeholders will have their own roles, responsibilities and interests, and hence will need their own arguments to get convinced of an eHealth application's added value. It is, therefore, the chosen innovation route that determines the context in which evidence will be collected and the purpose for which it is collected.

IV. CONCLUDING REMARKS

Returning to the project's slogan, *towards feasible yet convincing evidence*, it has become clear that it is absolutely essential to consider the purpose for which the evidence will be used. Any collected evidence effectively constitutes the foundation beneath a business model in which all relevant stakeholders and their interests have been accounted for. Although this conclusion may perhaps be obvious, the first case study interviews with SMEs indicate that they do not always realize this or act accordingly. SMEs should therefore identify and involve stakeholders as early as possible, and preferably define and collect any required evidence in a cooperative effort together with all relevant stakeholders.

The preliminary results clearly point out that eHealth SMEs require a "map" – not just to find the most promising innovation routes within the Dutch care system, but also to identify relevant stakeholders and their interests. Creating such a map, and embedding the evidence fact sheets within

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it, will provide SMEs with essential information they need to collect convincing evidence in a feasible way. In the coming months, this will therefore be the project's highest priority.

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What Seniors Want in a Mobile Help-on-Demand Service

A user needs analysis in the MobileSage project

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***Abstract*— Ambient assisted living can greatly assist seniors in pursuing an active and healthy lifestyle. MobileSage is an Ambient Assisted Living Joint Programme supported project that develops a cloud enabled smartphone based help-on-demand service for seniors providing appropriate "just-in-time" assistance through an individualized adaptive and multimodal user interface. This paper details the results from a user needs analysis conducted with seniors to help determine the design of MobileSage. Six focus groups in three countries were held to illicit the information. The user input is structured under the following themes: Multimodality: Input & Output; Navigation (wayfinding); Personalization; Help material – content; Help-on-demand; and Privacy, trust and security concerns. The MobileSage system will have its first iteration of user testing late Fall 2012.**

Keywords: user needs analysis; Help-on-demand; seniors; smartphone; multimodality; ambient assisted living.

I. INTRODUCTION

In the modern self-service and technology-saturated society, we find ourselves increasingly in situations in which we need access to information and perhaps assistance to be able to cope and manage successfully. It may be when adopting Internet banking, when using a ticket vending machine, when using an automated supermarket checkout system, or when checking in electronically at the airport. We may also need assistance when having acquired electronic domestic appliances that for various reasons have deficient or inappropriate operating instructions and manuals, e.g., being overly technical, or using a minute font size etc.

The information and assistance needs to be presented in a manner that the user prefers and finds accessible and easy to use. It also needs to be available when required and arrive in a timely fashion. Given their somewhat slower uptake of technology, seniors especially may benefit greatly from having access to user-friendly low threshold information and assistance services. This may assist seniors in pursuing active and healthy lifestyles, and is in accordance with an active ageing paradigm.

The MobileSage (MS) R&D-project develops such a help-on-demand (HOD) service for seniors. MS is partly funded by the European Commission through the Ambient Assisted Living Joint Programme (REF. AAL-2010-3-050). The participating countries are Norway, Spain, Romania and the UK.

MS involves the development of a cloud enabled smartphone based HOD service for seniors providing appropriate "just-in-time" assistance through an individualized adaptive and multimodal user interface. The front end consists of an application (app) installed on an Android phone. Advanced software on a server including a database populated with the HOD media in the form of text and multimedia files comprise the back end of the system. The content in the database is generated through a Content Management System (CMS). An overview of the MS architecture is provided in Figure 1.

The system can be applied to an abundance of situations and contexts in which seniors require assistance to conduct everyday tasks. Two brief examples will suffice.

Mr. Tweed is faced with a ticket machine when wanting to catch the train to his granddaughter. He is unsure on how to operate the machine. He sees that the ticket machine is MS enabled. He starts up the MS app on his smartphone (Figure 2), and brings the phone in close proximity to the ticket machine. The Near Field Communication (NFC) reader on the phone scans the NFC tag on the machine, and the unique code helps identify the ticket machine. The machines ID is used when the MS app contacts the MS server, and downloads the appropriate support material to the smartphone. Mr. Tweed's MS profile indicates that he prefers video instructions, and a brief video on how to use the ticket machine is shown on the smartphone.

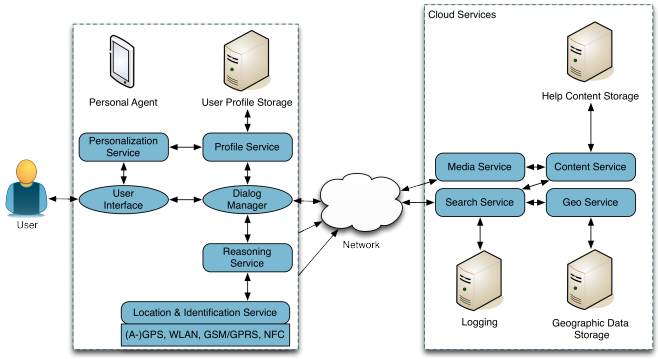

Figure 1. The MobileSage architecture.

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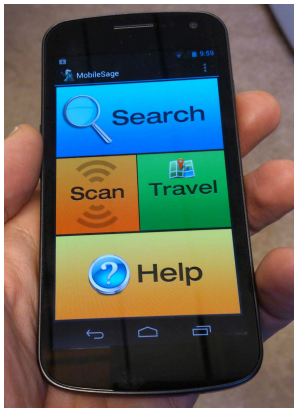

Figure 2. The MobileSage smartphone application.

Mrs. Wool has just bought a new blood pressure monitor, but is unable to use it as the instructions are in very small print, and Mrs. Wool has poor vision. By reading a Quick Response (QR) code, the MS app provides Mrs. Wool with a simple instruction manual in large print text retrieved from the MS server.

To ensure that the MS service is in accordance with the needs and wishes of real seniors, a thorough user needs analysis was conducted. In this paper the methods used and findings from this user needs analysis are summarized and discussed. A brief conclusion is provided along with a description of further planned work.

II. RELATED WORKS

The MobileSage project encompasses a plethora of technologies and domains including Help on Demand & Assistance "just-in-time", Multimodality, Adaptive and adaptable user interfaces, Context & location sensitive services, Reasoning agents and Profiles & personalization. Given the breadth of topics, a comprehensive summary of related works is not possible. A selection of relevant works is mentioned primarily limited to larger European R&D activities.

In the ongoing APSIS4ALL-project [1] the focus is on using the mobile phone in personalizing interaction with Public Digital Terminals (PDT) such as cash dispensing machines and ticket vending machines. Key elements covered in [1] are digital interaction with the mobile phone, profiles and personalization, adaptive user interfaces and multimodality. The end users targeted are people with disabilities, the elderly and novice Information and Communication Technology (ICT) users.

The completed ASK-IT project [2] had a similar scope as MS in terms of providing real-time information and being of assistance, but dealt primarily with travelling although work and leisure contexts were also addressed. The WayFiS, Mediate and Access2all projects [3, 4, 5] all deal with accessibility and transport or travelling. They share some attributes with MS, be it in a more domain specific manner. Similarly, [6] is concerned with context-based adaptation of ubiquitous web applications focusing on tourism and travel.

Soprano [7] had a similar scope to MS, but was more centred on independent living and a smart home environment. OASIS [8] also includes many elements of MS, but is a much larger project encompassing a wider number of topics. It is further preoccupied with architecture and platform development. INHOME [9] is also concerned with an architecture platform and ways of providing intelligent ICT based services for assisting independent living of elderly people in the home environment.

The ongoing MyUI-project [10] focuses on the mainstreaming of accessible and highly individualized ICT products. As with MS the need for adaptive personalized interfaces is of paramount importance. This was also a key feature of the Diadem project [11], which focused primarily on web interfaces.

Other scientific undertakings are narrower in scope and touch on certain elements in MS. In terms of user interface research SNAPI [12] and GoldUI [13] are of interest, whereas the HAPTIMAP project [14] is interesting in terms of multimodality and mobile location based services. Mapped [15] and HMFM [16] deal with multimodality and also cover similar ideas as MS. There are also a number of other major and more general international R&D activities that touches upon topics covered in MS [17, 18, 19].

Thorough user needs analysis were important parts of many of the projects mentioned above as well, but for reasons of brevity we cannot elaborate on these. We will draw the attention to one piece of academic work that did focus entirely on user needs in the related topic of location aware mobile services [20]. The author presents user needs separated in five main themes, which are not too dissimilar to the topics chosen in MS.

A review of current ongoing and past projects and initiatives shows that although there are a number of activities that touches upon similar topics, no other project is identical. Thus, MS is as such unique and innovative in its scope. It complements a number of other relevant R&D activities, and adds new knowledge and technology in a number of areas.

III. METHOD AND DESCRIPTION OF PARTICIPANTS

A. Method

We used a qualitative approach utilizing focus groups to elicit the information for the user needs analysis. Six focus groups were conducted, with two groups each in Spain, Norway, and Romania. There were some local variations in the inclusion criteria between the groups, but key criteria were actual mobile phone ownership and being a senior. The informants also completed a short questionnaire regarding demographics, mobile phone ownership and usage. The groups varied in size from four to eight persons. Each group was presented with two scenarios in which MS was used – one involving travel and the other use of a domestic appliance with some variation in scenarios used in each

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country. The scenarios were discussed based on a theme guide.

The required ethical issues were covered, especially through the informed consent form signed by each focus group participant, and the provisions related to personal data protection.

Transcripts were made from the recordings, and based on these summary reports for each group was made on a national level. A qualitative thematic meta-summary for the whole project based on the national reports was made.

B. Description of the participants

In total 39 informants took part. The vast majority was 60 years or older. In total the material comprised a wide variety of users in terms of functional capacity and impairments potentially impeding on ICT usage. It includes both the "average healthy" senior and persons with specific health issues including sensory impairments and mild cognitive impairments. The participants are described in Table I.

The groups are heterogeneous in terms of the type of mobile they use, and the types of functionality and services they utilize. It appears that the group in total comprises both advanced and basic mobile phone users, as well as the average senior mobile phone user. An overview of their mobile phone ownership and usage pattern is provided in Table II.

TABLE I. CHARACTERISTICS OF THE INFORMANTS.

Country:	Total #:	Gender (f/m):	Age range:	Comments:
Norway	12	5/7	48-81	Two groups of six in each. One group consisted of persons born outside of Norway.
Spain	11	8/3	62-75	Two groups.
Romania	16	11/5	67-86	One group consisted of persons with mild sensory impairment, the other group of persons with mild cognitive impairment.
TOTAL	39	24/15	48-86	

TABLE II. MOBILE PHONE OWNERSHIP AND USAGE PATTERN.

Country:	Type of mobile:	Usage pattern:	Comments:
Norway	Almost 1/2 had smartphones,. Majority used basic phone functions.	2/3 used calling, texting, MMS and photos. Some used e-mail and apps.	The group of persons not born in Norway had more basic phones, and used mainly basic functions, compared to the other group.
Spain	9 had basic phones and 2 had smart phones.	Calling, texting, MMS, photos and calendar, apps	Use of MMS, photos and calendar quite common. Few advanced functions.
Romania	All had standard basic phones.	All for talking and 50% for texting	Only one used phone for other things than talking and texting None used computers.

IV. RESULTS

A thematic summary of the findings from the focus groups is provided below. The themes reflect the main issues covered in MobileSage, and formed the basis for the scenarios and theme guides used in the focus groups. The themes are Multimodality: Input & Output; Navigation (wayfinding); Personalization; Help material – content; Help-on-demand; and Privacy, trust and security concerns.

A. Multimodality

In general this relates to the provision of output in various modalities, adapted to the user's needs and preferences, e.g., text, video, audio etc., as well as different ways of operating the device, e.g., touch, voice, physical keyboard input etc.

The interest in voice input varied from enthusiasm to seemingly polite interest; some did not prefer voice input at all compared to keyboard or -pad input. It was pointed out in several of the groups that voice input would be both easier and faster compared to keyboard usage, and it would be especially beneficial for persons with visual or movement disorders. The problems using on-screen touch keyboards were mentioned.

Several of the informants had had first-hand negative experiences using voice input. Their experience was that voice input was difficult to use because of poor speech recognition software. The need for a high quality voice input feature was mentioned as a prerequisite for implementation. It was also pointed out by several participants that a voice input feature must be context sensitive, i.e. must only receive and process input and execute something when intended to by the user to avoid unintentional execution of commands and actions.

There was almost universal interest in multimodal output, with few exceptions. Audio output such as text-to-speech is viewed as an important adjunct to visual text output in many situations, and especially for persons with visual impairments. There are also certain situations in which audio output is preferable to visual, e.g., when driving. Several informants mentioned that it is important to facilitate connectivity between the phone and hearing aids to ensure that the audio is available for users of hearing aids and other assistive hearing devices.

It was raised, though, by a number of participants, that audio output is not suitable in all contexts and for all information due to reason of privacy and safety. Although, many were positive to having text messages read aloud, some were reserved about this due to the potential private nature of the content.

The use of video for demonstrations and tutorials was universally applauded. It was also pointed out that audio equivalents must be available to ensure that those with visual impairments do not miss out. It was highlighted that the video sequences must not be too long, and needed to provide step-by-step instructions to avoid information overload.

Overall there was a genuine interest in multimodal solutions. Some had concerns for their usage in certain situations, and it was argued by some that it must be very easy to switch between the different modalities. Few had

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much experience with vibration/haptics as a modality. It was also mentioned that it was essential to have fall back modalities available if required due, for instance, to changes in environmental conditions, e.g., persistent loud noise which means that voice output need to have a visual alternative. Having a large screen was deemed important.

B. Navigation (wayfinding)

In general this was related to provision of support for both in- and outdoor navigation, but also to automatic detection of objects and the provision of location aware information.

All groups were interested in using a mobile phone as a device for in- and outdoor navigation. Voice navigation was especially appealing. A handful of the Norwegian respondents reported to have first hand experience with using the phone as a navigation device. In addition to getting assistance with findings one's way, it would also make them feel safe. Possible uses for indoor navigation could be to find one's way around shopping centres, as well as locating exhibits in museums and the like. Some concern was raised, however, with the cost of using map-based services in terms of downloading data over cellular networks.

There were some who raised the issues that a mobile phone screen is small for maps, and that it only shows a small area of the map. This could cause problems, especially for getting an overview of an area. Another point was that mobile maps are sometimes not up to date, and that this could cause problems. Further, some pointed that that they did not want to get too dependent on the phone for navigation purposes, and preferred paper maps.

It was mentioned that automatic detection of objects in one's surroundings could be useful – especially to regain one's bearings if lost. Many liked the idea of automatic location aware information, whereas others wanted manual settings for this. The access to a variety of Points of Interest (POI) for both tourist and practical purposes was mentioned as desirable. The possibility of being able to locate other persons through the phone was also mentioned in a couple of the groups, especially in the context of persons who were vulnerable, e.g., those with mild memory impairments.

C. Personalization

This is to be understood as the provision of support that is adapted to the specific, personal needs and preferences of the individual user. This theme is closely related to multimodality.

By and large there was universal agreement that a phone that can be personalized to individual needs was very positive and very useful. It was pointed out that not only must the in- and output be able to be personalized, but also the functionality and complexity of the device and services. It was for instance said that functionality not required by a certain person, should be hidden in the menus so it would not complicate or confuse the user. It should also be possible to change the complexity level to individual needs. This was especially important for persons with cognitive and memory issues. It is vital that the most important functions and controls are easily and readily accessible – including an emergency button to alert others in potentially dangerous or vulnerable situations.

It was also pointed out that a person's needs may change over time, and that this was important to take into account in a flexible set up. Suitable translations in terms of language are a must, and it was also mentioned that multiple languages should be available if this was preferred.

There was also a concern about who should assist the user with making changes to the set up of the smartphone when required. This is a pertinent point that needs addressing. Personalization also raised concerns from a privacy and security perspective. This was because personalization could mean that information about personal characteristics and potential vulnerabilities such as cognitive or visual challenges would be stored on the phone.

D. Help material – content

This pertains to the type of content provided as help material. Various types of content were suggested, such as:

- Maps and directions for orientation and navigation – both in- and outdoors.
- Travel information, and points of interest, including sights and services like ATMs.
- Tourist information about services and practical information including emergency information.
- Manuals, demos and tutorials – preferably step-by-step guides on for instance self-service machines, domestic appliances, recipes etc.

The modality and delivery should be personalized. Suitable modalities were video, audio and text. Adequate help materials – and access to training in using the equipment – were also emphasized.

E. Help-on-demand

Pertaining to provision of help "just-in-time", when needed. Many in the groups were positive to automaticity in the timing of help or assistance when needed. It was, however pointed out that for some persons and in certain situations this would not be appropriate. It could be distressing and disturbing. For others, like persons with cognitive challenges, help "just-in-time" would be very advantageous in a number of situations and for a number of reasons. Though, it is essential that a manual override is available, and that one has a choice in switching the type of mode on and off.

F. Privacy, trust and security concerns

This theme deals with issues pertaining to privacy, trust and security that MobileSage may evoke. These issues were raised in all groups, and seemed to be important for all. It was essential to trust the services and the information that was provided. The trustworthiness in the content would partially depend on who the content contributors were, and who were allowed to provide content. The ability to switch different services on and off depending on how much trust the user may place in one or another service, was framed as a possibility.

Privacy was a prime concern, and the protection of personal sensitive information such as health-related data

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was raised by many informants as a very serious concern. Of particular concern were the potential consequences of losing the device. The use of PIN codes and content protecting was suggested. The problem of having to remember (and possibly forgetting) the PIN was also raised as an issue. Privacy issues around logging of, for instance geographical and activity information were also forwarded as an issue that needed to be addressed. As well as the use of tracking of oneself or other people.

The issue of becoming overly dependent on the phone for vital functions and assistance was also raised as a safety concern. What would one do if there were no mobile coverage, or the battery went flat etc.? The need for the user to be in control and be informed about the various aspects pertaining to security, privacy and safety was suggested as being of paramount importance.

G. *Miscellaneous issues raised*

Below are a number of miscellaneous issues that emerged in the focus groups mentioned. They are all thought to have significance for the development of MS app. The cost of device/service was mentioned by a number of informants as an important issue. It cannot be too costly, as this will place it beyond the reach on many potential users, as well as being discriminatory.

It was also emphasized that smartphones should have physical buttons to assist operation. They should be large. The screen should also be sufficiently large to make it easy to see the content and easy to operate the device. Adequate training in use of the system is for many of utmost importance. Further, motivation to use MS was forwarded as a key issue for success. It was suggested that if the design provides an easy to use interface that makes it easy to navigate and operate MS, the motivation to use the device would hopefully be higher.

V. BRIEF DISCUSSION

We will in this section briefly discuss some of the results, as well as scrutinize the method used. The groups appeared to be positive to the MS system. Many seemed to realize that it could be of real help to them. This was interesting as few seniors own smartphones [21], with subsequent low usage of the types of services that smartphones can offer. Some research indicates that seniors are getting increasingly interested in smartphones and that the adoption rate is on the increase [22]. A survey into types of different mobile services showed that many seniors are interested in using services similar to those offered in MS [22].

Voice input was one of the major talking points in terms of input modality. Touch was also mentioned, but too a much smaller extent. This is interesting given that the use of voice as an input modality is really in its infancy in terms of mobile phones. The introduction of Siri on the iOS platform and similar attempts on Android phones may of course in time change all that. We would have thought that using touch as an input method given its ubiquitousness in the smartphone world would be something the informants would like to discuss to a larger extent. This may be because few of the participants had phones with a touch based user interface. It may well also be that the theme guide specifically mentioned voice input as a modality, and that the groups became preoccupied with this as a result.

It was raised that a touch user interface was problematic for some, and the need for physical buttons was also highlighted. Physical buttons are increasingly omitted from smartphones. This trend goes against the wishes of the focus groups. Touch only user interfaces with few or no physical buttons may be difficult to use for a number of groups, amongst them people with motor disabilities like hand tremors, as well as people with visual problems.

The wish for simple and easy to understand user interfaces with little complexity is one of the key messages from the focus groups. This echoes previous research, that seniors would like little complexity in their mobiles [23]. Attempts to accommodate this in smartphones are also seen elsewhere. Doro [24] has for instance recently launched a senior friendly user interface on an Android based device.

It was also suggested by the informants that it should be possible to increase and decrease the complexity of the MS system depending on personal needs. This could be especially useful for persons with cognitive issues. Fraunhofer Portugal [25] offers this feature in a tracking and navigation app for persons with dementia.

It is noteworthy to observe the focus that the informants had on security and privacy in terms of the MS system. As it came out from the discussions, despite their low smartphone ownership many of the informants are well aware of various privacy and security risks when using smartphones. This echoes findings from other user studies with actual smartphone users [26]. It is also interesting to note that multimodality, e.g., using audio to have information read out, was perceived as a security or privacy risk too.

The wide variety of HOD content mentioned by the informants covered many types of domains and activities. The majority of content did however focus on travel and tourism. This may be explained by the emphasis made on the first scenario that is a travel scenario. This may have influenced their answers and discussions. The MS system can offer HOD in virtually all contexts and settings, but this did perhaps not become evident amongst all the participants.

The issue of cost was raised. The costs are related to the cost of a smartphone as well as whatever the cost (if any) the MS system will be to the consumer. This is a very important issue, especially as we currently are having a financial crisis in many European countries. It is also an important factor that many seniors are on low incomes. It should be pointed out that the MS service can be used with relatively cheap smartphones. However, one may not be able to access all features such as NFC. NFC is usually only incorporated in the more expensive high-end phones, but is increasingly found in less more affordable handsets.

There are a number of methodological issues that may have influenced the results. Firstly, using a qualitative approach one is always open to different biases and interpretive issues. We have tried to be as open, objective and transparent as possible to combat this, but the results will always be a matter of the subjective influence by the researchers.

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The informants were very heterogeneous in terms of ICT and mobile phone experience, nationality, and functional capacity, to mention but a few characteristics. This may be viewed as a methodological weakness, i.e. the generalizations made in the results section only apply to some or certain of the participants or sub-groups. We choose to look at it as strength, however. By getting input from a group with a wide variety of user requirements, we were able to collect a wide range of user needs. As the potential users of MS possess an equally wide range of user needs, this may prove an asset rather than a liability. One should bear in mind, however, that there were very few participants in Spain and Romania that had smartphone experience. This fact will more than likely to have a bearing on the results, and needs to be taken into account when interpreting the results.

VI. BRIEF CONCLUSION AND FUTURE WORK

The focus groups provided a wealth of useful and relevant information. It shows a breadth in both user needs and requirements, as well as in the different users' familiarity with ICT and mobile technology. Further, it confirms many of the assumptions underpinning the MS project, as well as adding important commentary and input which will be invaluable when implementing MS.

Ideally all products and services should be designed in a manner that follows the principles of universal design, so that everyone can use or access them. This may be the case in a remote future. Meanwhile, there is a need for systems like MS. This need is likely to persist for a long time to come.

The MS project is conducting user testing of the first prototypes of the HOD and CMS in late Fall 2012. Several additional iterations are planned. The projects concludes in 2013

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Evaluation of e-Health by PSM (Propensity Score Matching) Method

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***Abstract*— The authors have been conducting successive estimations on the effect of e-Health on medical expenditures and outpatient treatment days for chronic diseases using survey data from Nishi-aizu Town, Fukushima Prefecture, Japan. The reason why this town was chosen is that it has been implementing e-Health more than 15 years and is one of the most successful examples. This paper uses several other outcome variables such as medical expenditures and treatment days of outpatient and inpatient, and compares those outcomes among two groups such as 199 treatment (users) of e-Health and 209 control (non-users) selected from residents. In this paper, the propensity score matching (PSM) method, a rigorous analytical method is used to overcome sample selection bias which is contained in data in the process which samples were selected. PSM is a method to choose subjects from two groups with exact similar characteristics except for their use or non-use of e-Health. After eliminating biases, the effect of e-Health on medical expenditures and treatment days was estimated. To obtain robust results, two different matching methods were applied, that is, caliper matching, and Epanechnikov kernel matching. The results demonstrated that the treatment group has lower medical expenditures for chronic diseases than the control group. Using other outcomes enables international comparison of e-Health projects with the same standard. Such comparisons are also presented.**

Key words-e-Health, propensity score matching; sample selection bias; inpatient; outpatient; medical expenditure.

I. INTRODUCTION

The most common method of evaluating the effectiveness of a new drug or clinical intervention is the Randomized Control Trial (RCT), in which subjects are randomly selected and categorized into a treatment and a control group, and the effect is compared between two groups. The most serious problem of RCTs is avoiding bias between the two groups, which is referred to as sample selection bias. Samples are required to be selected randomly without bias and must be as similar as possible between the two groups to obtain an unbiased evaluation. Such unbiased sampling is not always achieved, since there are actually many ways in which the material diverges with regard to users and sample subjects. A suitable method of matching the two groups to obviate such bias is therefore required. Traditional ways of coping with this problem include the matched sampling method or matched-pairs analysis. This method selects subjects in the control group to ensure similar criteria, such as age, sex, or health status, to subjects in the treatment group. In the field of telemedicine, matched each of their treatment subjects with four control subjects having similar demographics and morbidity status ([1] for example). Ambiguity with this method remains, however: what multiple of each treatment subject is sufficient to eliminate bias, and by what degree is bias is actually reduced? Moreover, sampling becomes more difficult with an increase in the criteria; and if the number of criteria must remain small, selection bias will remain.

A more rigorous method of overcoming selection bias is the propensity score matching (PSM) method, which enables the inclusion of as many criteria as necessary. A propensity score related to biased characteristics is first calculated for each individual, and then outcome variables, such as medical expenditures, are compared for individuals whose scores are close. One treatment subject is matched to one control subject who has similar characteristics, reducing sample selection bias. Moreover, the actual decrease in bias after matching can be calculated.

PSM use in medical research has been long and varied. Among studies of clinical interventions, for example, [2] examined the association of ambulatory visits to cardiologists, internists, and family practitioners after discharge for myocardial infarction and mortality. Using PSM to adjust for the demographic, clinical, and hospital characteristics of patients, they successfully ranked treatments among matched patients in terms of a reduction in morality. [3] analyzed whether aspirin is associated with a mortality benefit in patients with coronary disease. While simple univariate analysis found no association between aspirin use and mortality, adjustment by PSM for age, sex, and other characteristics, including risk factors, other medications, and coronary disease did identify a decrease in mortality with aspirin. In drug evaluation, [4] compared conventional and atypical antipsychotic medication for mortality among elderly patients, and used propensity-score adjustments to conclude that the former increased the risk of death.

Our previous paper ([5]) used the PSM method to estimate the effect of e-Health on outpatient medical expenditures and days for treatment and demonstrated that for chronic diseases, e-Health successfully improves these outcomes of its users in comparison with non-users. [5] examined, however, above two outcome variables related to all and chronic diseases, and there are other outcomes we have to compare. The aim of this paper is to expand the previous analysis in such a way that patients are categorized in more detail, that is, we compare medical expenditures and treatment days of inpatient and

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outpatient, and so on. Accordingly, this paper can highlight clearly the robustness of the results of our successive estimations, that is, telecare or e-Health has effects on chronic diseases, not necessarily all diseases.

Although treatment-effects studies have been widely used in medicine, only a few studies have examined the effects of telemedicine using PSM. One example is the study of Care Coordination/Home Telehealth (CCHT) conducted by the Veterans Health Administration (VHA) by [6], albeit that their analytical methods of PSM and estimation were less rigorous than those of the present study, with outcome variables restricted to hospital admission and days of hospitalization. To our knowledge, no other study has evaluated the effect of e-Health on medical expenditures using PSM.

II. EHEALTH SYSTEM OF NISHI-AIZU TOWN

A. About Town

Nishi-aizu Town is located in the Northwest corner of Fukushima Prefecture, and is been an important point of transit to reach Niigata Prefecture and Aizu-wakamatsu, a nearby major city. The center of town is in a basin but the main area is surrounded by mountains, which cover 86% of the prefecture's area. The climate is severe in winter and summer, with lots of snow. The population is about 8,000; there are 3,000 households, and the percentage of the elderly (≥ 65 years) was 41.0% in 2010. The main industry is agriculture, and rice is the main product.

B. Health and Medical Situation

As stated earlier, severe winter, especially heavy snow causes elderly people to lack physical exercise. In addition, due to a traditional diet of salty and protein-poor food, the town's death rate was 1.7 times higher than the national average during 1983-87, partly due to high rates of stomach cancer. The number of bedridden elderly people suffering from osteoporosis or arthritis is higher than the national average. In order to cope with these situations, the town office took initiative to establish a "total care system," which is referred to as the "Challenge to 100 Years Old," by unifying health, medical and welfare services. As a part of this project, e-Health was introduced in 1993.

In the town, there are three public clinics, named Nishi-aizu, Murooka and Shingo, which are operated by the National Insurance System, and two private clinics. The total number of medical doctors is four. One full-time physician is employed in the Murooka clinic, while the Shingo clinic has a part-time doctor dispatched from the other two clinics. There are private doctors, a surgeon and a neurologist, but both are more than 70 years old.

C. Introduction of e-Health

In order to prevent chronic diseases such as cerebral infarction and stroke, the town office introduced e-Health in 1994 which is Japan's longest-running e-Health. 300 peripheral devices called "*Urara,*" manufactured by Nasa Corporation, were provided to residents who have symptoms of the above diseases. Each terminal is connected a host computer via PSTN (Public Switched Telephone Network), and health-related data of users, such as blood pressure, pulse, ECG, blood oxygen, weight and temperature are transmitted to a host computer. In 1996 and 1997, an additional 50 terminals each were purchased. These terminals use the CATV network for transmitting data. All costs of operating the system are paid by the town. In 2010, new peripheral device called "*Kouri,*" was introduced in accordance with the network renovation of CATV for optical fiber. Currently all network were transformed to optical fiber.

D. Operation of the e-Health System

The section in charge of e-Health is the town office's Department of Health and Welfare, which consists of seven public health nurses which represents a much larger ratio than in other towns. They check the above health data transmitted by users and if these nurses observe unusual data, they ask medical doctors in clinics to see the patient in question. The health data of each user are summarized in a "Monthly Report," which is sent to a physician in charge. After a public health nurse adds their comments, the report is sent to the user. When the user sees a doctor, he/she is asked to bring the report with him/her.

e-Health is being operated as a part of the town's "Project for Promoting Total Care," and its essence lies in the close collaboration of health, medical and welfare activities. One important example of this collaboration are "Regional Care Meetings," which consist of doctors, nurses, public health nurses, staff of the town office, helpers of elderly people, and living advisers. The total number of participants in each meeting is over 20. Problems and treatments regarding a particular user, such as medical examinations, health advice, and care are discussed in detail. The health data of e-Health plays a role in this meeting. In Nishi-aizu Town, many such examples of exchanging information on residents can be found in the town office.

In addition, the town office organizes users' meetings five times a year in order to enhance motivation to use e-Health, and users exchange their experiences with using the system. These activities promote usage of the system. The introduction of e-Health is not the sole factor promoting regional healthcare; rather, it should establish a framework for the system to assist all related sections and personnel.

III. MATERIALS AND METHODS

A. Selection of sample and data characteristics

The data used in this paper were reported in our previous study ([8]). From a total of 523 users and 3,528 non-users in Nishi-aizu Town, 199 and 209 individuals were selected for each group through a questionnaire survey which asked about individual characteristics and use of e-Health. Healthcare receipts for five years (2002 to 2006) were obtained from the National Health Insurance system and checked. The small number of users meant that the sampling was necessarily biased, as detailed in Table I, which expresses biases by the difference between the averages of the two groups, and uses t-values to indicate the degree of bias for individual variables. Significant biases were identified in "chronic diseases," "age," "number of family" "income," "heart disease," "high blood pressure," "strokes", "ophthalmic diseases," "anal diseases",

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and in subjective belief in the value of e-Health on health status, termed "Effects 1-4."

The number of positive replies to the questionnaire item asking whether the subject had chronic diseases or not was substantially higher for the user than the non-user group. Substantial corresponding bias was also seen with regard to the presence of heart disease, high blood pressure, and strokes, and with regard to the number of users treated for these conditions during the sample period. A question on subjective belief in the value of e-Health on health status with respect to four effects showed that users tended to have higher health consciousness than non-users, which is consistent with anecdotal impressions expressed by the town's public nurses who manage the system.

B. Propensity Score Matching

PSM was initially proposed by [9], [10] [11] and developed by [12]. The procedure is as follows:

(1) First, subjects in the user (treatment) and non-user (control) groups are individually matched with one another so that their propensity scores as calculated according to their attributes become closer. The score is calculated by a probit analysis, which is interpreted as the predicted probability of a probit estimation. The model consists of the user dummy as a dependent variable, while independent variables are those that have a sample selection bias, as shown in Table I.

TABLE I TEST OF SELECTION BIASES

Variable	Non-user	User	t value	
Chronic diseases	0.388	0.466	-3.46	***
Sex	0.568	0.546	0.98	
Age	68.894	71.629	-6.80	***
Education	1.579	1.571	0.21	
Employment	0.532	0.520	0.53	
Number of family members	2.401	2.945	-6.29	***
Income	3.274	2.961	2.61	***
Heart diseases	0.064	0.144	-6.03	***
High blood pressure	0.367	0.469	-4.61	***
Diabetes	0.081	0.087	-0.48	
Stroke	0.045	0.059	-1.45	*
Respiratory diseases	0.129	0.116	0.92	
Cancer	0.068	0.078	-0.86	
Gastropathy	0.157	0.164	-0.40	
Lumbago, Arthritis	0.147	0.159	-0.71	
Ophthalmic diseases	0.211	0.297	-4.43	***
Kidney diseases	0.029	0.021	1.16	
Anal diseases	0.014	0.005	1.95	**
Effect 1: reduced anxiety in day-to-day life	0.962	1.076	-3.15	***
Effect 2: stabilization of illness	0.824	0.977	-5.00	***
Effect 3: enhancement of health consciousness	0.911	0.980	-2.19	**
Effect 4: decrease in medical expenditures	1.026	1.361	-7.75	***
Year 2002	0.243	0.135	5.97	***
Year 2003	0.206	0.191	0.84	
Year 2004	0.206	0.191	0.84	
Year 2005	0.175	0.238	-3.47	***
Year 2006	0.170	0.245	-4.15	***

Note 1: N = 2040 (users = 995, non-users = 1045).
Note 2: Testing was one-tailed.
Note 3: ***, **, and * indicate a significance level of 1%, 5%, and 10%, respectively.

(2) Second, subjects in the treatment and control groups are matched based on propensity score. There are several ways of matching - caliper matching is generally considered better than others, such as nearest neighbor matching, since it can exclude 'bad' matches ([7]). This paper utilizes caliper matching, in which a value for the maximum distance of predefined propensity scores is fixed at 0.0001, which the PSM literature describes as sufficiently small. The suitability of the matching can be examined by a balancing test, in which the explanatory variables listed above in the treatment and control groups are compared by a t-test - when a treatment does not meet its best-matched control, re-sampling by the bootstrapping method with 1000 replications is conducted. If there is no statistically significant difference, the matching is concluded.

(3) Finally, the effect of e-Health on outcome variables, which in this paper are medical expenditures and number of days required for treatment, is examined based on matched samples by a t-test (standard error estimation).

IV. RESULTS

Summary statistics for outcome variables, namely medical expenditures and days for treatment, are summarized in Table II.

A. Bias control

PSM thus calculates a propensity score by a probit model in which the dependent variable is the user dummy variable, while independent variables are selected based on whether they contain a selection bias. Whether matching based on the propensity score works is examined by a balancing test is shown in Table III. The column named "% of bias" indicates the percentages of bias contained before and after matching for each variable. For example, "age" has 28.3% bias before matching, which is reduced to 4.4% after matching. Similarly, the column "% of reduced bias" shows the percentage of bias actually reduced by PSM, or 81.9% for age. The reduction in

TABLE II SUMMARY STATISTICS FOR OUTCOME VARIABLES

Variable	Mean	Std. Dev.	Min	Max
Medical expenditure (Outpatient + Inpatient)	20833.30	35027.02	0	469632
Medical expenditure (Outpatient)	16997.22	25083.83	0	469632
Medical expenditure (Inpatient)	3987.99	19277.99	0	242481
Treatment days (Outpatient + Inpatient)	16.32	19.59	0	181
Treatment days (Outpatient)	14.75	15.86	0	144
Treatment days (Inpatient)	1.50	9.06	0	178
Medical expenditure (chronic diseases)	6836.33	10266.33	0	76573
Treatment days (chronic diseases)	6.09	8.37	0	85
Medical expenditure (non chronic diseases)	10160.90	22685.98	0	469632
Treatment days (non chronic diseases)	8.66	12.88	0	144

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TABLE III RESULT OF BALANCING TEST

Variables	Treatment	Control	% of bias (Before → After)	% of reduced bias	t-value
Chronic disease	0.466	0.486	15.6 → -4.1	73.8	-0.81
Age	71.629	72.124	28.3 → 4.4	81.9	-1.13
Number of family members	2.945	2.860	26.3 → 4.5	84.4	0.87
Income	2.961	2.968	6.5 → -2	97.5	-0.06
Heart diseases	0.144	0.131	-9.3 → 1.8	83.0	0.79
High blood pressure	0.469	0.466	54.2 → -2.1	96.6	0.14
Stroke	0.059	0.063	30.9 → -1.9	69.5	-0.37
Ophthalmic diseases	0.297	0.275	15.5 → -0.1	74.8	0.97
Anal diseases	0.005	0.003	15.6 → -4.1	80.7	0.55
Effect 1: reduced anxiety in day-to-day life	2.443	2.448	28.3 → 4.4	99.3	-0.08
Effect 2: stabilization of illness	2.548	2.573	26.3 → 4.5	96.2	-0.50
Effect 3: enhancement of health consciousness	2.650	2.635	6.5 → -2	98.1	0.35
Effect 4: decrease in medical expenditures	1.842	1.866	-9.3 → 1.8	93.8	-0.41
Year 2002	0.135	0.136	54.2 → -2.1	99.2	-0.05
Year 2005	0.238	0.238	30.9 → -1.9	99.3	-0.02
Year 2006	0.245	0.254	15.5 → -0.1	88.7	-0.39

Note 1: ***, **, and * indicate a significance level of 1%, 5%, and 10%, respectively.

TABLE IV RESULT OF ESTIMATION BASED ON PSM

	Outcome variables	Matching	Treatment	Control	Difference	S. E.	t value	
(1)	Medical expenditure (Outpatient + Inpatient)	Before	24090.52	18679.51	5411.02	1580.16	3.42	***
		After[a]	19598.07	29947.71	-10349.64	6475.68	-1.60	
		After[b]	24090.52	27385.88	-3295.36	3004.00	-1.10	
(2)	Medical expenditure (Outpatient)	Before	19448.53	15376.33	4072.21	1131.26	3.60	***
		After[a]	19448.53	21898.47	-2449.94	2024.69	-1.21	
		After[b]	16417.11	21692.92	-5275.81	4862.42	-1.09	
(3)	Medical expenditure (Inpatient)	Before	4835.41	3427.64	1407.78	871.62	1.62	*
		After[a]	3282.38	8462.42	-5180.05	2647.19	-1.96	**
		After[b]	4835.41	5606.38	-770.96	1092.70	-0.71	
(4)	Treatment days (Outpatient + Inpatient)	Before	18.39	14.95	3.43	0.88	3.89	***
		After[a]	15.42	23.09	-7.67	3.43	-2.24	**
		After[b]	18.39	20.33	-1.94	1.28	-1.51	
(5)	Treatment days (Outpatient)	Before	16.69	13.46	3.23	0.71	4.53	***
		After[a]	14.14	18.46	-4.32	2.75	-1.57	
		After[b]	16.69	18.04	-1.35	0.88	-1.52	
(6)	Treatment days (Inpatient)	Before	1.60	1.44	0.16	0.41	0.39	
		After[a]	1.17	4.47	-3.31	1.65	-2.00	**
		After[b]	1.60	2.23	-0.63	0.52	-1.22	
(7)	Medical expenditure (Outpatient, chronic diseases)	Before	6888.44	6801.86	86.58	464.47	0.19	
		After[a]	6888.44	9442.27	-2553.82	582.83	-4.38	***
		After[b]	5410.49	9404.12	-3993.63	1781.31	-2.24	**
(8)	Treatment days (Outpatient, chronic diseases)	Before	6.03	6.13	-0.10	0.38	-0.26	
		After[a]	6.03	8.63	-2.60	0.48	-5.47	***
		After[b]	4.80	8.78	-3.97	1.55	-2.56	**
(9)	Medical expenditure (Outpatient, non-chronic diseases)	Before	12560.09	8574.46	3985.63	1022.56	3.90	***
		After[a]	11006.62	12288.79	-1282.17	2662.46	-0.48	
		After[b]	12560.09	12487.07	73.02	1285.91	0.06	
(10)	Treatment days (Outpatient, non-chronic diseases)	Before	10.66	7.33	3.33	0.58	5.76	***
		After[a]	9.34	9.69	-0.35	2.27	-0.15	
		After[b]	10.66	9.40	1.26	0.82	1.54	

Note 1: ***, **, and * indicate a significance level of 1%, 5%, and 10%, respectively.
Note 2: Cases (1)-(6) are related to all diseases, whereas cases (7)-(10) are chronic diseases.
Note 3: Matching methods are based as follows.
After[a]: Epanechnikov kernel matching
After[b]: Caliper (0.0001) matching.
Note 4: Standard errors of caliper matching are based on the bootstrapping of 1000 replications.
Note 5: Medical expenditure was reduced after matching, as indicated in the column "Difference," and this is measured by "points" of the National Health Insurance system. One point is equivalent to JPY10 (US$0.13).

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sample selection bias is thus successful, since no statistically significant variable remains after matching in terms of t-values. In particular, biases related to subjective belief in the value of e-Health on health status shown by "Effects 1-4" are also substantially reduced.

B. Effect of e-Health on medical expenditures and days of treatment for outpatient and inpatient.

This paper uses two outcomes such as medical expenditures and days of treatment, but categorizes patients in different ways, namely, outpatient, inpatient, and outpatient + inpatient. As a result, 10 cases are analyzed, which are listed in Table IV. Our previous paper [5] examined only two cases; (7) and (8), which are related to chronic diseases, the main targets for Nishi-aizu's e-Health system. Cases (1)-(6) are related to all diseases for comparison with chronic diseases.

In Table IV, the rows named "before" and "after" indicate estimations before and after matching. Two methods of PSM matching are examined, Epanechnikov kernel matching and caliper (0.0001) matching. Table IV shows that both outpatient medical expenditures (7) and outpatient days of treatment (8) for chronic diseases did not significantly differ between users and non-users of telecare before matching, whereas after matching two matching methods showed a significantly negative difference ($p<0.05$), implying that e-Health has an effect on outpatients medical expenditures and days of treatment for chronic diseases. The column "difference" indicates the decrease in the amount of expenditure and number of treatment days. Caliper matching provided the greatest effect, namely JPY 39,936 (US$ 499.20) and 3.97 days per year per user, while Epanechnikov kernel matching produced the smallest, at JPY 25,538 (US$319.23) and 2.60 days.

The above results are already presented in [5], but this analysis shows new results regarding (3), (4) and (6), that is, users have significantly smaller inpatient medical expenditure (3), treatment days (outpatient + inpatient) (4), and inpatient treatment days (6) than those of non-users ($p<0.05$). The amounts of difference are JPY 51,801 (3), 7.67 days (4), and 3.31 days (6), respectively. It should be noted that these results hold only in terms of Epanechnikov kernel matching, and then these do not satisfy robustness. As for the other cases such as (1), (2), (5), (9), and (10), this analysis does not provide any significant results, and further examination is necessary.

The estimation in this paper shows that even if other outcomes are taken as dependent variables, telecare of this town has effect on the reduction of outpatient medical expenditures and days of treatment of chronic diseases.

IV. DISCUSSION

Cases (7) and (8) in Table IV thus demonstrates that e-Health does not contribute to a reduction in medical expenditures for all diseases, but only for chronic diseases ([5] [13] [14] and [15] have the same result), since users' expenditures for chronic diseases are larger than those of non-users before matching, but significantly smaller after matching.

The estimation results related to cases (4) and (6) for days of treatment, which are statistically significant with Epanechnikov kernel matching, can be used for some interesting international comparisons. Regarding the research results with the Kent Development Pilot in the UK and the CCHT project of the VHA in the US, the former studied the effect of telehealth on the number of inpatient days, general practices (GP), acute care, and others by experimental observation with statistical analysis ([15]). This study compared outcomes at baseline and six month with a focus on patients with COPD, heart disease, and diabetes. The authors concluded that telecare use resulted in a decrease in the number of home visits and GP surgery per participant, Accident and Emergency (A&E) visit of 0.5days, and inpatient treatment days of 1.5days. The latter reported in the same manner as the Kent study, that is, the number of inpatient treatment days was reduced by 25%, and the number of hospital admission by 19% ([16]). Thus other results of international projects were estimated mainly in terms of inpatient treatment days, not expenditures, and all diseases, not only chronic diseases. This paper is aimed to obtain the results which can compare in the same manner. According to our results, the Nishi-aizu project has larger reduction of inpatient treatment days than the Kent project (3.3 vs. 1.5 days). On the other hand, the reduction of bed days of this paper is calculated as approximately 16.12%, which is smaller than that of the VHA project (25%).

Table V also compares the effects obtained by the other estimation methods, such as simple OLS ([13]) and system GMM ([8]), used in our previous papers. The effects of e-Health are underestimated when sample selection biases are not controlled.

TABLE V COMPARISON OF RESULTS USING ALTERNATIVE ESTIMATION METHODS

	OLS[1]	**system GMM[2]**	**PSM**
Medical expenditures for chronic diseases	JPY 15,302 (US$ 191.28)	-	JPY 25,538-39,936 (US$ 319.23-499.20)
Days of treatment for chronic diseases	1.6 days	2.0 days	2.6-4.0 days

Note 1: Akematsu and Tsuji [13]
Note 2: Minetaki, Akematsu, and Tsuji [8]

Although PSM offers major benefits in the evaluation of e-Health projects, it has its own limitations. First, it requires a large number of samples, and several previous studies have in fact used samples in the several tens of thousands range. Second, its results are not always robust, which is why our present paper examines two matching methods. These limitations have been described (see [9] and [12] for example), but one limitation specific to e-Health has not. In this paper, PSM successfully demonstrated that the user group had less medical expenditures than the non-user group under the condition that all subjects were closely similar except in their use of e-Health. Our previous study [13] [14] and [17] concluded that these results were due to the difference in

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health consciousness between the groups. By checking heath data transmitted by the e-Health system and receive health consultation from town's public nurses, users became more concerned with health and had an incentive to change their behavior to be more health-conscious. These findings are not consistent with those of the present analysis, however, which found different expenditures despite a closely similar degree of health consciousness, which could only be due to e-Health use. PSM thus provides little explanation of why and how e-Health leads to these results, and identification of these mechanisms requires the use of other empirical methods together with PSM.

V. CONCLUSION

By using PSM, this paper successfully controls biases due to the way to collect the sample (sample selection bias) and provides a rigorous demonstration of the effect of an e-Health implementation in a small Japanese town in reducing the number of treatment days as well as medical expenditures. Moreover, this paper uses some other outcomes as dependent variables and their estimation results enable to compare with the outcomes of e-Health projects in the UK and US which have the similar peripheral device and system. According to our in-depth surveys of these projects, there are similarities and differences in these projects, but a common success factor lies in the enthusiasm of nurses, public or visiting nurses who participate in these projects to maintain health of the residents in the community. Further detailed study is required for factors of differences.

Let us discuss on the economic foundation of the project. Nishi-aizu Town does not charge any fee to users. Other projects in the most of counties are the same. Neither this program nor those referenced in the UK and US charge user fees; rather, all are subsidized by the central as well as local government, as indeed are the UK demonstration programs, since they are national pilot projects. However, the ongoing sustainability of e-Health requires a new financial framework. [17] conducted a cost/benefit analysis of Nishi-aizu's e-Health and calculated a B/C (cost-benefit) ratio which was 0.25. The initial costs of the implementation, such as for host computers and peripheral devices, were borne by the central government, however, excluding them form analysis gave a B/C ratio for Town which bore only operational costs, which is 0.91. But this is not sustainable. One possibility for promoting e-Health is reimbursement using public medical insurance. The amount of reimbursement is based on economic effect of e-Health and must be obtained rigorous analysis. Most of countries are not recognized reimbursement for e-Health, which reason is simple; e-Health is not diagnosis but prevention of diseases. The simple e-Health system does reduce medical expenditures of users. The present paper provides important support for the development of evidence-based policies for the diffusion of e-Health.

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APPLYING the STOF BUSINESS MODEL FRAMEWORK in EHEALTH INNOVATIONS

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***Abstract*— eHealth solutions create opportunities for improving efficiency and quality in health care. Still many eHealth innovations never get beyond the project phase. A business model approach can help eHealth entrepreneurs and innovators to bridge the gap between Buzz (ICT as a promise for better care) and Business (viable eHealth services and business models). The research group ICT Innovation in Health Care developed a business model approach based on three components: the STOF business model framework, the innovation process and relevant success factors for eHealth innovations. This resulted in the development of an online eHealth innovation Matrix (eHix). The approach is illustrated by an actual eHealth case.**

Keywords- business models; innovation; guidelines; success factors

I. INTRODUCTION

The research described in this paper focuses on how to embed eHealth innovations in routine care. Nowadays there is still a discrepancy between the opportunities offered by innovative eHealth applications and the reality of routine health care. 'End-of-project' all too often means 'end of innovation'. This has also been observed by others [1] and although plenty of suggestions have been made for improvement, a comprehensive approach which supports innovators in bridging the gap between project and routine practice is still lacking.

IT-related business model innovations have become key factors in achieving structural innovation in healthcare [2]. A business model approach can therefore be used as an instrument to bridge the gap of innovative eHealth ideas to successful IT-based care services. The approach described in this paper is a combination of business model design, the phases in the innovation process and generic and eHealth specific success factors. These three components combined result in what we have called the *eHealth innovation Matrix* (eHix).

By combining the phases in the innovation process with a business model approach (based on the STOF Framework [3,4]) the future challenge of embedding the innovation in routine care gets attention throughout the various activities.

Success factors play an important role in business model design [3]. Success factors (SFs) can be described as "the key areas where things must be right for the business model to flourish" [4]. The success factors indicate to what extent a business model is capable of creating value for customers and capturing value by the network of stakeholders.

Well-known and lesser known success factors for eHealth innovation receive a better place in the innovation process by linking them with the correct phase and the right business model domain, thus avoiding pitfalls and underestimation of non-technical requirements.

The eHix is a combination of the STOF framework (Section II) and the phases in the innovation process (Section III). When combined, a matrix model (Section IV) is created that can be used to allocate the SFs (Section V) which are extracted from generic, market specific and case specific studies.

A case study called DiMove will be used to illustrate the added value of eHix. DiMove is a Real time Medication Monitoring (RTTM) service for patients with epilepsy.

II. STOF FRAMEWORK

The basis for the development of the methodology is to consider eHealth innovation as a service innovation rather than technological development. For successful implementation of eHealth services a healthy business model is required. We therefore use a business model approach. A business model is essentially a description of how organizations offer innovative services in an economically viable way. There are several business model frameworks available [5]; of these we used the STOF framework.

The STOF framework [3,4] describes a business model in terms of four interrelated domains, i.e. the service domain, technology domain, organisation domain and finance domain.

The service domain gives a description of the service offering, its value proposition and the market segment at which the offering is targeted. The Technology domain gives a description of the technical functionality required to realize the service offering. A description of the structure of the multi-actor value network required to create and provide the service offering and describe the focal firm's position within the value network can be found in the Organization domain. The Finance domain describes the way a value network

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intends to generate revenues from a particular service offering and of the way risk, investments and revenues are divided among the various actors in a value network.

Figure 1 shows the perspectives and examples from the four business model domains. For example, data streams transferred over networks and the end-user applications and devices co-determine the required functionality in the technology domain.

Domain	Perspective	Example
Service	Value proposition Target group	Customer or End-user Market Segments Rate and Effort
Technology	Functionality required	Devices Applications Data
Organization	Structure of value network	Actors Roles Interactions
Finance	Cost structure Profit potential	Revenues Pricing Perfomance indicators

Figure 1. Business model domains, perspectives and examples

III. INNOVATION PHASES

There are many models in use to describe the innovation process [1, 6, 7]. We have chosen a model which is based on the innovation phases of Cooper [7] and which uses five innovation phases, each with its own goals and approaches, i.e.: inventory phase, design & development phase, experimental phase, pilot phase and implementation phase. The innovation process begins with the inventory phase. The purpose in this phase is to make an inventory of the needs and conditions of the users for whom the new service will be created. The next phase, design and development, focuses on thinking about the business model and how the technology will be designed and developed. This is followed by the experimental phase in which some users try out the new application, often in laboratory setup. Subsequently, in the pilot phase, more users will be involved to work with the new service in their daily practice. When successful, the process ends with the implementation phase. Figure 2 shows the five innovation phases and examples.

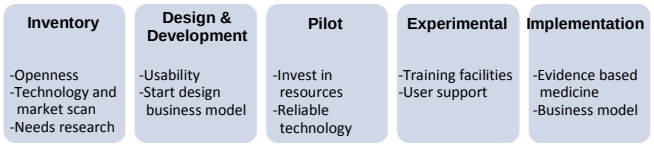

Figure 2. Innovation phases and examples

IV. MATRIX MODEL

The five innovation phases can be combined with the four business model domains to form a matrix with 20 cells, the eHealth innovation matrix (Figure 3). The matrix allows to allocate distinctive SFs to each cell. A cell describes the essential steps and choices in the innovation process for a specific area within the business model in a specific phase and can therefore be matched with success factors for eHealth innovations. These SFs will be identified in the next step to complete the eHix innovation matrix.

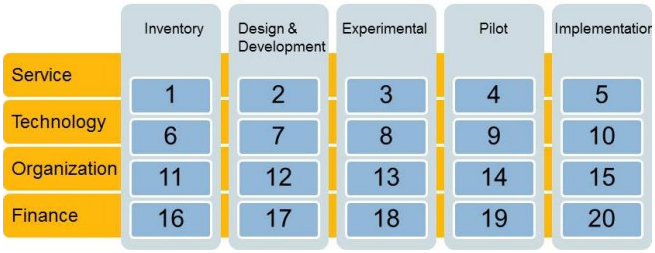

Figure 3. Combining business model domains with the innovation phases

V. SUCCESS FACTORS FOR EHEALTH INNOVATIONS

The third and final step of the approach is the identification of possible success factors for eHealth service innovations. The success factors can be divided into three groups, Generic Success factors, Industry and market specific success factors and Case specific success factors [8].

A. *Generic Success Factors*

A number of generic success factors need to be satisfied by any business model for it to be viable. For example, does the business model create value for the customers and does it create value for the (business) actors? A business model that obviously creates value for the customer does not necessarily create value for other actors participating in the business model and therefore may not always be viable.

One of the most important SFs is the “match to customer needs” [9]. In different studies this SF correlates strong with the actual success of the innovation. For eHealth applications, customers may include patients, doctors, medical specialists, caregivers, or health insurance companies. It is therefore important to determine who the customers are and their interests and requirements. Urban and Hauser added one success factor that emerged in several studies, ”time to market”. This SF is especially important in industries where the lifecycles are short and frequent innovation must fit a moving window of technology or market performance [10]. This SF applies to eHealth services as well, as these services are usually based on the products of the fast moving ICT industry.

B. *Industry and market specific success factors*

The industry and market in which a business model and innovative concept is deployed, i.e. the business context, often comes with its own success factors as well. For example the care market requires new care solutions to be ‘evidence based’, i.e. with clinically proven value, before they are admitted to the care market.

An expert meeting can be an efficient instrument for gathering Industry and market specific SFs. To this end, one typically invites different stakeholders and experts such as actors involved in the business model, researchers, market specialists, end-users representatives, financial experts, innovation specialists or technology experts. A recent expert

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meeting organized by our research group delivered the SFs shown in Table 1.

TABLE 1. SUCCESS FACTORS DELIVERED BY EXPERT MEETING

	Success factors
Service	Strengthening primary care
	Involve patients
	Lifecycle management
	Patient central
	Keep it simple
Technology	Proven technology
Organizational	Direct contact with customers
	Avoid network complexity
Financial	Avoid application for grant before structural plan is created
	pricing strategy: dirty cheap in beginning

C. *Case specific success factors*

Finally the specific case at hand may come with its own success factors. The innovation in itself may entail specific SFs due to for example the use of a specific technology. Specifically the issues regarding the adoption of the technology, the technological developments and the reliability of the chosen technology should be addressed. Case specific factors can also be more specified versions of generic or industry specific success factors. We will discuss examples of case specific SFs in the next section, where we apply the eHix in the specific case of real-time medication monitoring for epilepsy patients.

Now each combination of a business domain and a innovation phase can be coupled with SF's, completing the eHix.

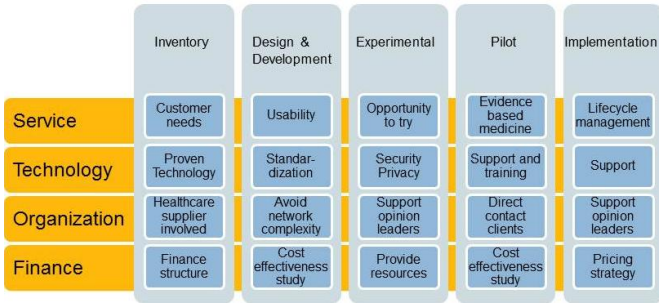

Figure 4. eHix with success factors

VI. THE DIMOVE CASE

This section illustrates the method explained earlier in this paper by a specific practical case. First we provide a description of the DiMove case. This case has gone through all innovation phases and is now in the implementation phase. Then we provide the designed business model based on the STOF framework and match the business model design with the earlier mentioned success factors. The last section contains an enumeration of the most important "lesson learned" based on this case study.

A. *The DiMove service*

DiMove [11,12] is an eHealth solution for assisting patients with epilepsy in taking their medication. For patients with epilepsy it is important to take the medication at regularly set times. A Dutch study into the medication use of people with epilepsy found an adherence of 65% [13]. Some patients frequently forget taking the medication at the correct time, which can lead to the occurrence of more epileptic seizures. DiMove uses a smart medicine box in combination with a web application (Real time Medication Monitoring, or RTTM) [15]. The medicine box will send a message to a server when the box is opened. The messages are wirelessly transmitted by GPRS or SMS. A message contains information about the time of opening, an identification of the user, an identification of the drug if the patient uses different types of drugs, and any other desired information. The RTMM works wherever there is a connection with a GSM network. Approximately 20 seconds after opening the box, the information is processed, stored and available in the DiMove application. The details of that message are stored in a central database and are accessible via a secure Internet account. When the patient forgets to take his or her medication he or she will receive a text message as a reminder to take the medication.

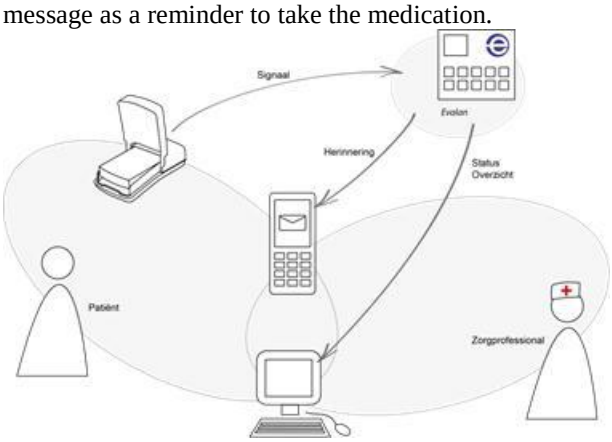

Figure 5. RTMM concept

B. *The DiMOVE business model*

1) *Service domain*

This part of the STOF Frameworks describes the service offering, the value proposition and the possible market segments of the DiMove service. DiMove is offered as a support program for epilepsy patients. The patient uses the RTMM device for real time monitoring of medication use. The DiMove Support Program includes a web-based user interface that provides overviews of medication use and seizure history, an electronic diary to record seizures, and distribution of regular summary reports to monitor use of the DiMove program. The application also supports sending questions to patients and for patients to send answers back to health care professionals.

The program starts with a consultation during which the epilepsy patient receives instructions about the DiMove Support Program. A dedicated health care professional monitors the patients that use the program. The customers who will actually pay for the DiMove service are *specialized clinics for treating patients with epilepsy.* They can use DiMove as a service for some of their patients. The

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DiMove service also provides extra information for their medical specialists. So the users of the service are the *patients* and the *specialists*.

DiMove assumes that patients who got acquainted with RTMM during their treatment in an epilepsy clinic may also want to continue their subscription once hospital treatment has ended. In the Netherlands there are 120.000 epilepsy patients [15]. The potential target market for DiMove is 10.000 patients, as patients have to be able to operate the DiMove technology (mobile phone and web application). It is easy to see that the concept is also suitable for many other users of medical drugs (in solid form) with a chronic illness. This could considerably increase the market potential of DiMove. The value proposition for the patient is *medication adherence*.

For the medical professional the service provides more *detailed information* about the use of the medication by the patient and the possible effects of the medication based on adjustments in the medication. Health organizations can *improve the effectiveness* of their treatments and create competitive advantage compared to other health organizations. The value proposition for parents of a child with epilepsy is an *enhanced sense of security* because the child is less likely to forget to take medication. The parents can receive a text message as well, if they want.

2) Technology domain

The technology domain contains a description of the technical functionality required to realize the service offering. Some relevant variables in this domain are: the technical architecture, network accessibility, needed devices and applications.

DiMove's *technical functionality* consists of five main components:

1. a standard cell phone that is able to receive and display text messages;
2. a medicine box that is able to send a signal to a server when it is opened;
3. a web application that is accessible for the patient, caretaker and medical professional,
4. a server where the data is stored,
5. the mobile internet connecting the box, the application and the server.

The technology used in the DiMove service is *proven* and *relatively simple* and therefore reliable. Reliability is important because the service intends to deliver complete and accurate information about the use of medication. The messages sent by the RTMM device are wirelessly transmitted by GPRS or SMS. SMS has proven to be a reliable communication service. Another advantage compared to, for example, using a 3G network, is that the client can use a standard telephone instead of a smartphone. Almost every cellphone is able to send and receive SMS. In most cases the client already has a cellphone and doesn't need (or want) to buy an expensive smartphone with mobile internet subscription.

3) Organization domain

This part of the business model contains a description of the different actors in the network needed to deliver the eHealth service and the position of these actors in the value network.

Actors: Evalan is the supplier of the hardware and the developer of the DiMove concept. Evalan is also responsible for the marketing, sales and technical support. SEIN is a specialized clinic in the Netherlands for epilepsy treatments. SEIN is the paying customer for Dimove and provides the DiMove support program to its patients. SEIN is also responsible for the development of the medical protocol for the support program. Other actors of interest are the pharmaceutical industry (for instance by offering a package deal, DiMove in combination with the medication), insurance companies (extra service for their customers with epilepsy) and the NVN (Dutch Society for Neurologists). The NVN determine the standard treatment for epilepsy patients in the Netherlands. If the NVN would decide to include the DiMove concept in the standard treatment for epilepsy, all care providers would have to make use of DiMove.

Actors' strategic interests: For SEIN and other epilepsy clinics the strategic interest is mainly providing extra service to their clients and getting more detailed information about their patients to improve their treatments. Evalan is trying to get a solid market position in the Dutch health market and a stable starting point for further development of the DiMove concept. Our research group at Windesheim is studying how to design and implement eHealth solutions like DiMove and aims to spread this knowledge towards other projects and publications.

Organizational Arrangements: The cooperation between the partners is specified by a term sheet. This term sheet summarizes the main commercial terms and conditions of the Collaboration Agreement for the development, testing, and commercial exploitation of the DiMove Program. SEIN is responsible for the training and guiding of the healthcare professionals and is supporting the marketing of the DiMove service. Evalan Is accountable for the sales and marketing of the DiMove concept and responsible for further development of the DiMove service and the technical support during the exploitation.

4) Financial domain

The financial domain describes the way the service intends to generate revenues and the way risk, revenues and investments are divided among the various actors in network. *Revenues*: The revenue model at this moment is a subscription, based on a monthly fee per medicine box. *Financial arrangements*: There are also arrangements about how to divide the revenues among the initial DiMove partners. For a period of seven years each partner receives a development fee as a percentage of the sales revenues.

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C. The success factors for DiMove

In section V three levels for finding success factors were described. Table 2 contains some of the success factors for each of these levels that are relevant for DiMove. The next paragraphs describe the success factors for DiMove for each level.

1) Generic success factors

Table 2 shows three important generic success factor for DiMove. *Understanding of the potential target group(s)* is a success factor mentioned in many studies [4, 8]. Much is known already about DiMove's target group, namely epileptic patients. The same applies for a *clear value proposition*. DiMove has a clear value proposition for the different users (doctors and patients), namely improved medication adherence.

The business model variable *Actors* has a positive effect on the success factors "Understanding potential target group" and "Contribution to improvement of quality of care". The current partners in the DiMove development know the target group very well. One of the largest specialized epilepsy clinics in the Netherlands is involved in this project. They have considerable experience with treating epilepsy patients and have the necessary expertise to provide evidence that the DiMove support program indeed improves the quality of care.

Little research has been done to identify other potential target groups. So it is recommended to investigate possible other target groups to increase the market potential and make the business model more viable.

2) Industry specific success factors

The contribution of eHealth solutions towards improvement of quality and efficiency in healthcare is a considered an important success factor. The ability to reduce the costs of health care after implementation of the innovation is also a strong success factor. The costs of health care continue to increase due to aging of the Dutch population. There is considerable political interest to reduce the costs and improve the efficiency in health care at this moment. Cost effectiveness was an issue in this case, although a proper cost effectiveness study has not been performed for this specific target group. In this case DiMove is not a new treatment but an instrument for the medical specialists and the client to improve the effectiveness of the standard treatment. During the design of DiMove SEIN conducted a pilot including 48 patients. The preliminary results showed improvements in medication adherence and experienced quality of life, and a decreasing frequency of epileptically seizures.

Another important success factor in health care is the opinion of health care professionals, especially medical specialists. The neurologists of SEIN are part of the NVN (Dutch Society for Neurologists). SEIN is enthusiastic about the potential of DiMove and they are lobbying to include DiMove in the Standard Treatment for epilepsy. When this succeeds the DiMove service is eligible for reimbursement by health insurance companies. This can increase the market potential of DiMove because health care organizations like SEIN can use the service for their customers and get reimbursement from the insurance companies. Now SEIN is paying for the service using their own financial resources.

3) Case specfic success factors

In the DiMove case the specific success factors were discovered by conducting a business model workshop with the different project members of the DiMove project. The participants consisted of a professor of eHealth innovation, a technology specialist, a supplier of hardware and software, a manager of an epilepsy clinic, and a health innovation broker. The goal of the workshop was finding a viable business model for DiMove, but the results of this workshop also contained some case specific success factors for DiMove. The three most relevant case specific success factors are listed in Table 2.

TABLE 2 SUCCESS FACTORS DIMOVE

	Success factors for DiMove
Generic SFs	Understanding of potential target market(s) or target group(s)
	Clear value proposition(s)
	Creating a team with knowledge and experience
Industry specific SFs	Contribution to improvement and efficiency in health care
	Support of opinion leaders
	Support and training facilities
Case specific SFs	Proven technology
	Market situation
	Technology adoption among target group and health professionals

For DiMove the *market situation* is important. In the Netherlands the concept is unique, but there are some international initiatives that can compete with the DiMove concept using different approaches. These initiatives are from two multinationals with the capabilities and resources to introduce their concepts on the Dutch market fast. DiMove is tailored towards epilepsy patients, a relatively small niche market. This creates a knowledge lead for DiMove, and because the market size for this niche is small, it is probably less interesting for big multinationals. To keep track of competitors is an important case specific success factor for DiMove. Another success is *adoption by the target group*, patients and health professionals, and being able to understand and use the DiMove technology. Pilots concluded that the target group is enthusiastic about using DiMove. Having the support of the medical staff and especially the treating doctor was found to be important.

VII. LESSONS LEARNED AND FURTHER RESEARCH

A. Lessons learned

A workshop based on the eHix with the different actors involved in the development of DiMove resulted in the

awareness of possible other target groups for the service. For example home care organizations could be an interesting target market for a concept like DiMove. These organizations deliver care to patients who often need to take many different kinds of medication. The workshop also created a broader perspective on the impact of the service for different stakeholders like the pharmaceutical industry, caregivers like parents and relatives, and insurance companies. This actually lead to initiative to start the lobby with the NVN (Dutch Society for Neurologists) mentioned earlier. In an evaluation session the owner of Evalan, the entrepreneur behind DiMove, stated that one of the most important success factors for implementing eHealth services like DiMove is the need to have a health care supplier acting as a partner during the development of the eHealth service. The support of opinion leaders, for instance the medical specialists, was also mentioned by him to be an important success factor.

This case study doesn't validate the effects of the mentioned success factors. Therefore more evidence about the contribution of the success factors to an actual successful market introduction of health services like DiMove is needed. For instance, a retrospective approach might be used to establish the effects of the mentioned success factors in a range of different cases, including the further development of DiMove.

B. Further research

In the previous paragraphs we identified the success factors that are relevant for services like DiMove. This actually represents only one dimension of the eHix. The other dimension are the five innovation phases. The current version of the eHix (www.ehix.nl) offers two functionalities: the eHix Scan and a Tools Library. The instruments in the Tools Library are grouped by cell and consist of templates, checklists, approaches, examples and references with which the required steps in the innovation process can be followed as closely as possible.

The eHix Scan consists of a questionnaire with which entrepreneurs and project owners can establish the status of their project and the designed business model. The scan's questions are connected to the cells of the eHix matrix. After completing the questionnaire, the results show the status of the project by color coding the cells in the eHix matrix. Red cells need attention, and the tools in these cells provide the project owner with some instruments or templates to improve the status of the project. Green cells, on the other hand, indicate that the most important factors are taken into account. In January 2013 the development of a new version of the eHix starts. This version will integrate the mapping of the success factors for eHealth services to the cells of the matrix model, as presented in this publication. The questionnaire of the eHix scan will then be based on the success factors instead of deliverables like a project plan or business plan. The online toolbox will be targeted more specifically to eHealth entrepreneurs, helping them to design robust and viable business models for their eHealth innovations.

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Multi-Factor Authentication in Telemedicine Systems

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***Abstract*—Telemedicine systems require authentication services that are strong enough to ensure data confidentiality and privacy, and flexible to meet the needs of health professionals and patients. The focus of this work is the authentication process. We propose an authentication service for telemedicine technologies based on web services. This service makes use of scalable authentication methods based on two-factor authentication mechanisms. Its main characteristics are: flexibility of configuration for the authentication mechanisms, as well as the use of a robust system for recording events. In this paper we deal with the engineering requirements of the security system and the details of its implementation. We also discuss the efficacy and ease of use of different authentication methods.**

Keywords-Multi-factor Authentication; Telemedicine

I. INTRODUCTION

The increasing development in technology has enabled the use of electronic media for communication and the execution of services. In this context, information systems present viable solutions too many types of problems, including social ones. Similarly, telemedicine and e-health environments facilitate access to health services to people redas well as they simplify the use of technology by health care professionals [1].

However, this growth does not only bring benefits, it also exposes the fragility that many systems have in relation to information security. The authentication process, for example, can be responsible for many of the vulnerabilities and errors if it is not properly applied. Today, we still see a scenario where most systems use a login and password model-based authentication. This tends to be weak, given the current technological advances and capabilities of intruders. One of the main vulnerabilities of this model is identity theft, which may occur by the guessing or the stealing of a user's credentials. These types of attacks are fairly common since users are usually not aware of the existing threats.

The risk of such threats increases when the information in the system is private and the authentication model is weak. Given the sensitivity of the information in telemedicine systems, identity theft cannot only cause information leakages, but can also lead to serious or damaging circumstances that can harm the doctor/patient relationship. Thus, the use of a more efficient authentication with stronger methods becomes a way to increase the overall security. An important issue is that these methods must not make the access of health record and patient care more difficult.

Moreover, strong authentication methods are commonly related with the use of specific cryptographic devices [1][2][3][4][5]. Such devices are linked to specialized hardware to allow their use. These types of devices have low interoperability. In other words, they have a high impact on mobility and usability of a web system. Within the virtual environment of telemedicine there is still another problem: a doctor should be able to access medical systems from anywhere at any time because any impediment by the system can mean a life-threatening situation. Thus, the authentication model should be strong enough to guarantee security, but should not rely on devices that affect mobility and usability for the sake of efficiency.

This paper proposes a new authentication model that uses modular and flexible methods with a two-factor authentication as a secure web service. The proposal is based on the real needs of the Santa Catarina Integrated Telemedicine and Telehealth System (STT/SC, in Portuguese), a project of the Federal University of Santa Catarina (UFSC, in Portuguese) in partnership with the Santa Catarina State Health Office (SES/SC, in Portuguese). Within the proposal, the STT/SC integrates various methods of the two-factor authentication based on the possession of auxiliary devices, such as a cellphone, or physical presence in a particular geographical location by using land-line systems. An important feature in our proposed system is the flexibility of the authentication process by using a list of acceptable mechanisms.

The remainder of this paper is organized as follows: a brief discussion about the Integrated Telemedicine and Telehealth System is presented in Section II. Section III has an inventory of related work with an analysis of the adequacy of each work in regard to the subject. Sections IV and V describe the construction stages of the proposed model, from inception to completion. The implementation of the model is presented in Section VI. The authentication methods used in this work are presented in Section VII. Technical analysis of the authentication methods and the proposed model are

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presented in Section VIII. Finally, Section IX contains the conclusion and suggestions for future work.

II. Integrated Telemedicine and Telehealth System

The increase of information technology development in recent years has enhanced virtualization of various types of services. Among these types, the ones that deserve special attention are telematic environments. Telematic environments present viable solutions to many types of problems, including social ones like public health, citizenship, etc. [1]

As part of solutions to social problems The Catarinense Telemedicine Network (acronym for RCTM, in Portuguese) [6] is an example. Aiming to facilitate the access to tests of medium and high complexity in the country side, UFSC and SES/SC conceived the RCTM.

The main purpose of the RCTM was to extend the the availability of medical equipment such as electrocardiograms, computer tomography and magnetic resonance to smaller cities. A pilot project was created in 2005, which began by connecting two cities in the interior of Santa Catarina with the state capital, Florianópolis [7].

The STT/SC is a virtual environment to support medicine, which aims to facilitate access to specific health services to people who could not have them in the conventional way. The main problems people face are physical disabilities, geographical distance, and financial difficulties. [8]. The STT/SC makes available over the web, images, signals and medical reports generated from accredited health institutions distributed throughout the state of Santa Catarina - Brazil. Currently, the system has an average of 50,000 examinations per month and has more than 2.5 million examinations and images stored since 2005.

While all this growth brought benefits, it also exposed weaknesses that the model has in relation to information security. The high sensitivity of the information may raise the risk of exposing them to attacks, damage, or compromise. Fraud and forgeries on medical diagnoses and altered entries are serious threats, as they can put people's lives in danger.

Identity theft is a common attack in this type of system. It is closely linked to the authentication process. For example, if the authentication process is weak and allow the use of short passwords, the chances of such an attack increases. Therefore, the adoption of a more efficient and stronger authentication system is a simple way to increase the overall security.

III. Related Work

Security in medical systems has gained the attention of governments, healthcare providers, research centers and, consequently, has been a recurring theme in the publications. Most proposals to the authentication process use a second factor of authentication and can be separated into two major groups: those based on digital certificates, and those based on biometrics.

Martínez et al. [1] propose an interoperable security design capable of providing secure authentication and authorization based on digital certificates. The proposal comes from a study of business models for applications of e-government and e-health, which often have the same needs when it comes to security. The model is based on authentication and authorization web services to ensure interoperability between different systems, and it uses digital certificates to ensure the user's identity.

With similar goals, Ahn and Shin [2] proposed a framework for authentication based on cryptographic tokens that aims to provide more security to protect the data of this type of system. The focus of this work is the design of a framework that is able to strongly authenticate a user in different ways (through the use of signatures, passwords or biometrics) and secure access to its data. In this model there is an effort to abstract the different technologies of smart tokens from the authentication layer, allowing the interoperability between several different services related to e-health systems.

Still following the same line, Al-Nayadi and Abawajy [3] propose the design and implementation of an architecture for authentication and authorization also based on digital certificates that aims to integrate different e-health systems maintained by various institutions in order to centralize patient's data. This model is based on the fact that each system has an Identity Certification Authority (ICA) that distributes and signs certificates of its users. Each ICA in the network trusts in the others and performs authentication to remote systems through verification of a certificate. The authorization is based on the attributes of each certificate.

With a different approach, Han et al. [4] proposes a framework for authentication and authorization based on fingerprints. The framework is intended to enhance the authorization of e-health services and to ensure access for their users. Authentication is based on fingerprints with a Personal Identification Number (PIN).

In a line similar of Han et al. [4], Garson and Adams [5] propose a system design for e-hospital security and privacy. Their work presented an authentication model based on fingerprint and RFID. In addition to user authentication, the proposal prevents data from leaving the hospital by blocking user authentication from outside the building. Not only concerned with the authentication process, the authors also present a new encryption method that seeks to prevent the system from theft, loss and copies of documents.

The papers presented above show a concern for interoperability between systems, and are mostly based on digital certificates. In such models is necessary to have smart card readers to perform basic operations. Such readers have low interoperability and make the use of the system in mobile devices more difficult. Therefore, the use of readers affects

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one of the main characteristics of a web system: mobility.

One alternative for solving the problem with the readers is to use the software certificate (also cited in the presented works) which allows the model to be interoperable and mobile, but also reduces the level of security that can be provided. Depending on the way which the certificates are stored, the required effort to attack the model is similar to attack a model that uses a simple password.

Other papers presented follow a line using biometrics as the second factor of authentication. The reading of a fingerprint is made by a specific hardware, which has the same problems of the smart card readers. Moreover, they often don't have compatibility with each other. In practice, this approach is even worse than the model based on digital certificates, since the user (patient/doctor) is forced to use a computer that meets all the installation requirements of the reader. Furthermore, this is a technique that has false positives and negatives rates higher than acceptable.

Our proposal is based on the strengths of the papers presented, and seeks to correct the problems identified and provides a better adaptation to the telemedicine systems. To achieve the goals of creating a new two-factor authentication process, we did an examination of requirements using the STT/SC as a case study. The process of construction of our proposal is presented in the following sections.

IV. Case study and requirements

To better understand the requirements of an authentication model looking at the medical context, we conducted a study about the use of this type of system using the STT/SC. Actual usage scenarios showed us that there are cases where users (usually medical specialists that provide reports) need to access the system from a computer outside the hospital, for example, when they are traveling. Thus, the first requirement is to maintain the mobility of the web system. The authentication service has to cope with that.

It is assumed that such a system should not block the work of a doctor, because this may put patients live at risk. Therefore, a user should be able to access the telemedicine system from any computer, tablet or mobile phone, since it has an Internet connection. Because of this requirement, the adoption of authentication methods that require cryptographic hardware, and that need specific readers, such as smart cards and biometrics, is unfeasible.

Moreover, it was noticed that there were cases where access to the system was urgent, and in these cases, the user should not have their access prevented. So in the same way that the device used to access the system cannot be limiting, the devices that are used as second factor of authentication should also not restrict access. And this is the second requirement of authentication model: flexibility.

Cryptographic tokens are very specific devices and can be easily lost or forgotten. Thus, we avoid the use of specific hardware and try to replace them with other devices of daily use, like cell phones, which normally are carried by users. Furthermore, the flexibility of the services requirements also requires a user to be able to access the system even when they are not in possession of any device required. The model should provide this kind of situation and offer alternatives.

V. Proposal

Besides the requirements presented in the previous section, we must also take into account requirements common to the authentication models. For that, we built the first prototype. This was a dedicated library responsible only for the authentication process and to make available a set of authentication methods, allowing the system to decide the way that these methods will be used. In order to allow STT/SC to decide witch method use to authenticate the users, the library had to be written in PHP [9], same programming language of STT/SC.

All authentication methods involved in this model are used as a second factor of authentication, i.e., in our proposal the user authenticates exactly the same way they do today and, in a second step, gives some information to prove that he has possession of certain unique device. The authentication methods used were selected in such a way that they would not change the characteristic of mobility of STT/SC. This was done using common devices, such as smartphones and landlines instead of specific cryptographic tokens. Furthermore, we do not use methods of authentication that depend on token readers, such as those based on smart cards and biometrics.

But even in this scenario, we cannot assume that all users of the system have the required device during authentication. To meet the requirement of flexibility, it was necessary to provide the possibility of changing the authentication method to an alternative (that depends on another type of device), which is also provided by the library. Therefore, the model preserves the characteristics of mobility and flexibility of the system, while it does not prevent access to its users as provided in the requirements.

The scenario presented above meets the requirements and fits well in cases where the user is not with his smartphone, or it is out of battery. However, it's not well suited to cases where the user makes constant access to the system but does not have such a device. This implies that one more process is needed to change the authentication method for each access attempt. To avoid frustrated users who might try to bypass the authentication process, a new model was proposed.

A new strategy was then conceived: each user has a list of authentication methods that are enabled. Thus, the user keeps disabled methods that uses devices which he does not have, and prevents cases as described previously. With the inclusion of user's data and the different combinations of authentication methods that the system may possess, this new model began to store a much larger amount of information. No longer behaving like a library, it became

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an authentication service. Now has its own context and independence from the system that uses it.

VI. Implementation

The proposed model was implemented as a secure authentication web service using the standard remote procedure call (RPC). In this implementation, we used the XML-RPC, which is a simple pattern of RPC that allows communication between systems of different architectures and languages. This is possible because the communication is done via HTTPS and the encoding of calls is done with XML, two standards quite solid and disseminated.

Since the goal of the service is only to authenticate users, we opted for a simpler protocol. Thus, we have avoided transforming the authentication (which only carries the credentials of a user) into a complex and long procedure.

The use of a mutually authenticated HTTPS was necessary to prevent the user's credentials transit in unprotected networks upon communication between the STT/SC and the web service.

The web service has an interface that centralizes all authentication methods available, called Authenticator. Each call to one of the methods of the Authenticator is actually the process of authenticating a user. The data of these users are maintained by the web service in a local database. Thus, it was necessary to introduce an administrative interface to the service for the maintenance of users. This interface is called ServiceManager and it takes care of all the maintenance of data related to users. These include the maintenance of lists of authentication methods enabled for each user and the system authentication policy.

The policy is a form of combining the authentication methods and its level of priority. In other words, a user will authenticate with the method that the system considers the most priority. The list of enabled authentication methods defines which methods the user can use, i.e., if a user does not have a smartphone, then all authentication methods that rely on such a device are disabled.

With this approach it was possible to automate the change of the authentication method. The web service uses the policy and the list of enabled methods of the user, and with this information it mounts a third list with the intersection of both, ordered in the same way that the policy. It is still possible to analyze if the methods that depend on the internet are online, avoiding attempts that would result in failure.

The Figure 1 describes an authentication process in the telemedicine system integrated with the authentication service. In the first step, the user gives his credentials to the system. In the second step, the system pass the credentials to the authentication service, so that can verify it (step 3). If the verification succeeds the authentication service combines the list of enabled methods of the user and the policy to make a third list with the intersection of both (step 4). In other words, the third list contains the methods that the user is able to use (the user has the required device) and the system supports, sorted by the priority of the policy. In the step 5, the authentication service requires to the telemedicine system to use the priority method, in this case Phone call. In the step 6, the system requires to the user to use the Phone call method. In the step 7, the user makes the call, concluding the authentication process. In this case the system avoided two methods that user cannot use to authenticate himself because he does not have the required devices.

In this approach, the change of the authentication method is a sporadic process, where the user says he is not in possession of any of the requested devices and bypasses the second check. Such cases are provisioned in the service, since flexibility is a requirement, but are recorded in a database of logs and accounted for by user. These data are available to the system, so it can use the records in the way it wants, the system can allow a specific number of bypasses, or even block access to a user if it detects a possible attack.

In this new model, the only actor existent is the telemedicine system. This emphasizes the separation between the layers of authentication and authorization. The service does not worry about which user is performing the operation, since it has been authorized by the STT/SC. Each of the three specific requirements has been addressed in this model. Mobility and flexibility are characteristics inherited from the first model and the impact on usability is reduced by automating the change of authentication methods.

VII. Authentication Methods

The methods used in this work are all authentication factors based on something the user possesses. According to Cheng [10] in multi-factor authentication system, each factor must be in possession only of the user and an attacker should not be able to access it easily.

Our proposal tries to use personal devices, which are usually carried all the time by users, thus making any attempted attack easily noticeable. We avoid the use of specific cryptographic tokens because they are not common objects for users of medical systems, and they usually have low interoperability, besides that, they are very expensive. There are three methods chosen to be developed in this research: One-Time Password, SMS and phone calls.

As it's name suggests One-Time Passwords [11] are passwords that are used only once, generated from a previously shared seed. According to Haller et al. [11], the process of generating OTPs should have two entities: a generator and a validation server. The generator is usually a device of personal use, in this work we use a smartphone with an application developed based on Google Authenticator to generate passwords [12].

The SMS (Short Message Service) based method is an Out of band authentication method. According to FFIEC [13] an Out of band, authentication can be defined as an

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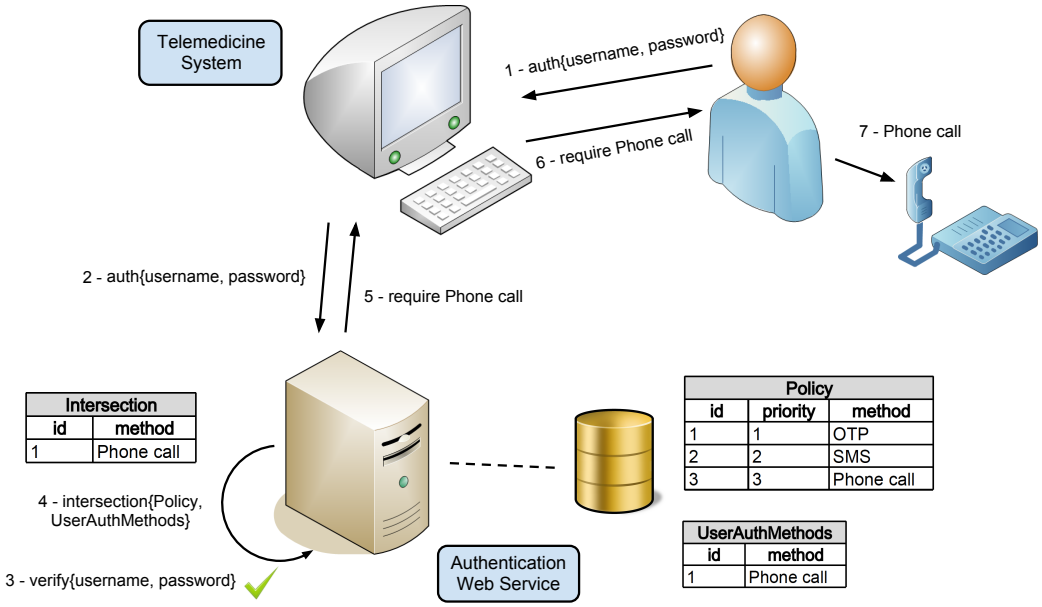

Figure 1: Authentication Service

authentication technique that allows the identity of the user who originated the transaction to be verified through another channel from the one used to start the operation. This method consists in sending a random alphanumeric password via SMS to the user's cellphone. When the user receives the password it is used as a second factor of authentication to prove the possession of the phone line (cellphone).

The phone calls based authentication method is also Out of band and consists of recording the caller ID of a call made by the user to one of the allowed phones in the telemedicine system. The allowed phones are VoIP phones that run a script that gets the caller ID when a call is received and ends it. The script also records via the web service authentication the obtained caller ID. When the web service receives an ID it identifies the user who owns that number and records the time of the call. To authenticate, the user enters his username and password (first factor) and in a second stage informs that already made the call. The service verifies that the information is true and checks whether the operation has not expired. The expiration time of a call and the allowed class of the phone (fixed or mobile) is defined by the telemedicine system. The fact that the user has executed a call to one of authorized numbers is a proof of possession of the second factor, in this case access to a cellphone or landline.

VIII. Analysis

This session presents an analysis on security and usability of each authentication method. The analysis is based on their characteristics, as well as other general analysis of the proposed model.

The technical analysis of the authentication methods is based on the Eletronic Authentication Guideline [14] of NIST - USA (National Institute of Standards and Technology). The guideline contains recomendation for remote authentication over open networks, like internet. The technical guidance supplements OMB guidance, that defines four levels of assurance (Level 1 to 4) in terms of the consequences of the authentication errors and misuse of credentials. The NIST guidance specific technical requirements for each of the four levels of assurance in five areas. In this analysis we consider only the area of tokens.

A. Analysis of authentication methods

In our proposal, One-Time Passwords uses smartphones as passwords generators. Because they are personal devices, users already are familiar with their interfaces and their forms of interaction. Because of that, this model does not cause a great impact on the usability of STT/SC. It does not require a user to interact with unknown cryptographic devices, which are difficult to use sometimes.

One-Time Passwords are quite common and well accepted in banking environments. Similarly to these environments, operations in medical systems can also be considered of high risk. Thus, the use of OTP in a system like that is justified.

According to FFIEC [13] passwords generators are secure for the time-sensitive nature or synchronized authentication. Also according to FFIEC [13], randomness, unpredictability, and uniqueness of the OTPs substantially increase the difficulty of an attacker to obtain a password. Moreover, the process of generating an OTP is offline and cyber attacks

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could only be realized when the password is already used. Whereas after its use, OTPs are invalidated, the chances of success of such an attack are quite low.

The attack by guessing also has a very small chance of success too. According to M'Raihi et al. 2005 [15] the probability of success of a guessing is:

$$Sec = \frac{s.v}{10^{Digit}}$$

The probability is a function of size s of the window provided by resynchronization method, the quantity v of attempts that an attacker can do before being blocked and the amount of digits that the OTP has.

Because smartphones are of a very personal nature, physical attacks like theft would be easily perceived. Unlike cyber attacks, robberies and thieves of physical devices are not usually discrete and the user knowing the attack and its consequences, may take appropriate action to mitigate it, such as cancellation or temporary blocking his account.

Smartphones are sophisticated and expensive equipment. Thus, the SMS authentication is an alternative that is more far-reaching, in regards to smartphones. According to ANATEL (Brazilian Agency of Telecommunications) [16] the amount of mobile accounts in May 2012 in Brazil is more than 254 million, a sum greater than the population which according to the population census of 2010 [17] is about 190 million. And one of the advantages of this model is the fact that most users already have cellphone and already are familiar with the SMS system too.

According to Alzomai et al. [18] the main advantage of using an SMS-based model is that the messages are sent through the mobile phone network, which is separate and independent from the internet. According to Jøsang et al. 2007 [19] security schemes like this are based on the assumption that it is difficult for an attacker to steal a user's cellphone or to attack the mobile network. The chances of success of an attack by guessing are similar to those in previous model since the characteristic of randomness is also present in this model.

However, the SMS model has a high cost for the STT/SC. Each authentication requires sending a message and, the cost of maintaining the model increases with the number of accesses. As an alternative to this high cost was presented the third model, based on caller ID.

The model based on caller ID has the same features of the SMS model: it uses devices that users already have and know; it uses an independent network and the security level is also similar. The advantage of this model over SMS is that it's free for the STT/SC and can also be a free method for users, depending on the contract plan with the carrier.

B. Analysis of the Model

The security level of the model is very tied to the level of security provided by each of the methods that the STT/SC uses. According to the technical guidance of NIST, basic OTP generators can be considered a Single-factor OTP device. These types of device can reach 2 in the level of assurance. Because our application uses a password to block access to the OTP generator, it can be considered a Multi-factor OTP device – since the password is something that the user knows, and the OTP proves that the user has the generator device – reaching 3 in the level of assurance.

The SMS-based method can be considered an Out of band token, it means that is uniquely addressable and supports communication over a channel that is separate from the primary channel for authentication. According to the technical guidance of NIST, these types of tokens can reach 2 in the level of assurance. Likely the OTP device, this token can reach the level 3, but only in cases where the user becomes aware of the existents threats and configures his cellphone to use some kind of password to block it.

The caller ID based method does not fit the tokens classification of NIST because it does not use any password in the process. Despite that, it can be also considered an Out of band token because of its similarity with the SMS-based method, and reach a level of security close to the provided by the level of assurance 2.

However, the methods presented are only one of the factors used in the authentication process. According to Di Pietro et al. [20], an attacker who successfully break some of the methods presented, still would not have access to the STT/SC without knowing the user's login credentials. Furthermore, our proposal gives the system the freedom to define how to use the methods, so that it can use more than one at a time, increasing the difficulty of an attack.

The authentication process is completely separated from the business rules of STT/SC. This means that the web service can be used in security critical areas of the system, not just the login. By increasing the number of factors used in an authentication or the amount of sessions that require authentication, it increases the level of security. Of course, overuse may lose usability. According to Alzomai et al. [18], when users encounter frustrating security tasks, they tend to avoid them or ignore them. Thus the flexibility of the model is shown as an important feature because it allows the system to define where and how it wants to use the web service.

IX. Conclusion and Future Work

This paper presented a new authentication model based on secure web service. This model is geared to the security needs of STT/SC, which contains high sensitive information. In order to fit the main requirements of this type of system, the model uses multi-factor authentication. It also provides a set of authentication methods that can be combined to provide greater flexibility and reliability to the process.

Our model operates as a web service and therefore does not imposes some technological limitations, such as the implementation language. It also does not require the use of specific cryptographic tokens. For that it can be easily

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integrated into various systems. Its high interoperability and its efficiency could be demonstrated by a prototype of the service. The proposal is fully implemented and integrated into a telemedicine system in operation in all the cities of the state of Santa Catarina and used by more than 6,000 users (doctors, nurses and technicians).

Our analysis shows that, the proposed model fits well to telemedicine systems. It provides flexibility and can be molded in order to meet the needs of such systems. In this analysis, we included the main features of STT/SC, which are flexible enough to avoid interposition between the system and the doctor-patient relationship. Its high interoperability and system event log robustness is also demonstrated.

Besisdes that, our analysis also demonstrates a increase in the security of the authentication process of the STT/SC. That can be demonstrated by the levels of assurance, which reaches 1 when the system uses only the simple password based method, and reaches up to 3 with our proposal.

The analysis also demonstrated that the model covers the major attacks involving the authentication process. In our model we can provide authentication properties not present in most other models, such as guaranteeing geographical authentication, based on the use of landline system.

In order to improve the authentication service offered it is suggested to add new authentication methods. Our next steps in improvement of authentication mechanisms are the inclusion of an identity based encryption to allow authentication of users not registered in the system. We also plan the implementation of a system for sending one-time password (OTP) via dial tones, which makes the OTP method even more affordable.

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Patient-Buddy-Build: Customized Mobile Monitoring for Patients with Chronic Diseases

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***Abstract*—This work consists of developing a tool for generating mobile apps containing a questionnaire tailored to the distance monitoring of patients with chronic diseases. The customization is based on parameters and formal descriptions such as patient preferences, type of chronic disease, monitoring process required by the doctor, prescribed medication and information about the context (i.e. environment) of the patient, that are to be obtained from sensors. The questionnaire generated from this data should be completed by the patient with his/her condition and possible symptoms. These pieces of informations will be sent by the mobile app together with the data from the sensors to the responsible physician. The medical treatment and the kind of chronic disease will define the set of information to be collected. It should be stressed that the goal is not to support automatic diagnosis, but only to provide means for physicians to obtain updated information about their patients, so as to allow remote monitoring of patients.**

Keywords - mobile health; patient monitoring; ontologies; expert system; context-aware application.

I. INTRODUCTION

From the 90's until now, we can see a huge growth in the development of technologies for cellular mobile communication. The popularization of these technologies has enabled access to remote information anytime and anywhere, opening a wide range of new applications and services to users.

The number of mobile devices like smartphones grows increasingly in Brazil. According to data released by IDC, a consultancy firm specialized in technology and telecommunications market, approximately 15,4 million units of these devices have been sold in Brazil in 2012 [2].

In parallel, the coverage of mobile network also increases continuously; by the end of 2012, Brazil should have 124 million mobile broadband access points. It is expected that in the near future even low income people will have smart phones and access to mobile broadband in cities, as well as in many rural areas.

Hence, in this scenario there is an increasing urge of mobile application development for every field, including health care.

Mobile Health characterizes the practice of medicine and healthcare through mobile devices [3]. This area grows every day, and more and more hospitals and healthcare professionals are adopting to mobile technology.

The health application for mobile phones and mobile devices are expanding and changing the way of how and where medical care is done. Actively engaging patients and health professionals using sensor-rich mobile devices can help to monitor, prevent and treat diseases [4]. Furthermore, patients that have difficulties to go to a hospital or their doctors, either because they live far away or do not have sufficient funds, may benefit from a more convenient, cheaper and yet effective medical care.

This work addresses the monitoring of patients with chronic diseases mainly because of the following [1]:

- A characteristic of an aging population.
- Involves high cost treatment.
- May include high risk patients.

The remote monitoring of these patients can help to prevent their health conditions from worsening and avoid health crises. [5].

II. OBJECTIVE

The main objective of this work is to develop Patient-Buddy-Build (PBB), a prototype tool for generating mobile applications containing a customized questionnaire for remote monitoring of patients with chronic diseases.

The purpose is not to develop a complete and readily usable mobile application, but to use it as a proof of concept of the proposed technique of automatic generation of mobile questionnaires from formal descriptions (including patient and doctor preferences, symptoms of disease, treatment method, etc) and to identify benefits and limitations, of the approach. In particular, this work has its focus in:

- Representation of medical knowledge and context information using ontologies [6].
- Generation of customized questionnaires using a knowledge base that contains information about the patient, available mobile sensor data, the disease and the monitoring process. The idea is that the information obtained from the questionnaires (filled out by patients) and the information provided by the sensors (such as GPS), are suitable for remote monitoring of the patient by doctors.

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The remainder of the paper is organized as follows: Section **III** describes the overall project, introduces the cooperation partners and explains what methodology is being used in this project. In Section **IV**, we describe about the current developed prototype. Section **V** gives an overview of our proposal for the final prototype and the technique of automatic generation of questionnaires for remote monitoring of patients with chronic disease. And finally, in Section **VI**, we draw some conclusions about the project.

III. METHODOLOGY

This work is being developed within the scope of the MobileHealthNet project [7], a joint effort of the Distributed Systems Lab at UFMA [8] and the Laboratory for Advanced Collaboration at PUC-Rio [9], with support from the University Hospital (HUUFMA) of UFMA (Federal university of Maranhão). In particular, the development of the Patient-Buddy-Build (PBB) is being supported by two units of the HUUFMA: The Assistance Program to Asthmatic Patients (PAPA) and the "Casa da Dor", which specializes in treating patients suffering with chronic pain. The PBB relies on the MobileHealthNet communication middleware which has authentication and cryptographic mechanisms already implemented in it. Therefore issues regarding security will not be discussed in the paper.

The overall methodology for development of the Patient-Buddy-Build (PBB) consists of the analysis and evaluation of the results obtained from the process described below:

1. Meetings with doctors involved in the project to survey requirements regarding the monitoring of patients with chronic disease.

2. Development of a first prototype to gain more involvement with doctors, giving them a more concrete example and thus helping them to better understand how to contribute.

3. Proposal for a model with a high level language for describing processes for monitoring of patients to be discussed and refined with doctors.

IV. THE FIRST PROTOTYPE

According to number *2* (described in the previous section), a prototype was developed to give the doctors a better understanding of the tool, and to improve our familiarity with the Android platform and the communication middleware that will be used in the project. Fig. 1 shows an overview of the prototype's components:

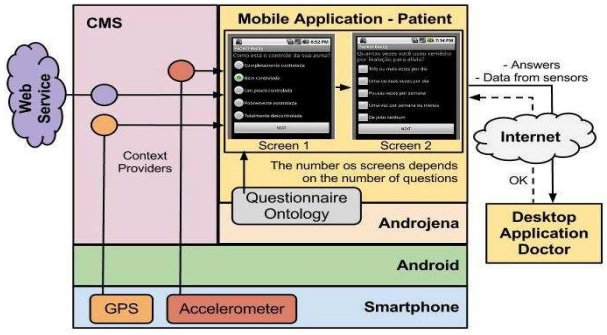

Figure 1. The first prototype.

In this first prototype a group of symptoms is associated with a questionnaire. So, depending on the symptoms that the patient has, a different questionnaire will be generated. The specialist defines the questionnaires, the group of symptoms and relates them to each other. All this information is defined through an ontology persisted in the mobile phone. This ontology defines as well how to answer each question (ex.: using a text box or preset options).

A location provider was created that informs the geographical position of the user. An address provider, that given a latitude and longitude, informs the address that the user is located. And a provider that, given an address, gathers current weather information in the region. Since we are working with chronic diseases like asthma, weather information can be very useful to better monitoring the patient.

Asthmatic patients are more susceptible to climate change. Their health condition can get worse if, for example, the weather gets too hot or too cold. For this reason was created a context provider that informs the application about the climatic conditions.

The patient executes the application and answers a questionnaire. At the end of it, the answers and the information collected by the context providers are sent to the doctor's application that shows the information received on screen.

V. THE FINAL PROTOTYPE

We will develop a framework for generation of mobile applications, where each one will be responsible for monitoring a patient. The monitoring will be done by collecting information from the environment and in response to questionnaires generated automatically. The idea is that these questionnaires can be answered in a quick and practical way, without excessive input text and prevalence of multiple choice answers. The information collected is sent to the doctor, so he can make an assessment of the patient's condition. We also will develop a notification system where the doctor can, for example, notify the patient to attend the hospital for a change in treatment or further analysis.

A. The organization of the knowledge base

Here we will talk about the organization of the knowledge base [10] that will be used to generate the questionnaire and for aiding the patient monitoring. It is divided into four ontologies described below:

1) Disease Ontology: Contains disease data relevant to the application as it relates to the monitoring of patients with chronic disease. Information like symptoms, disease's name and description.

2) Questionnaire Ontology: This ontology describes information concerning the questionnaire. Question types, e.g., font size to be used, text color, etc. The type of answer

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that will be allowed, for example, multiple choice, text box or by using the accelerometer provided by the smartphone.

3) Environment Ontology: Describes what context data will be captured from the environment. These data can be captured through sensors or web services. Depending on the mobile device used, it may have different sensors that can be configured to use the application. Examples: GPS (Global Positioning System), to determine location and accelerometer can be used as another way to answer questions with "yes" or "no" as possible answers. The context data will be modeled as described here [11].

4) Control Ontology: It defines the disease states in which the patient may be during monitoring. In Fig. 2 they are named as: Healthy, Pre-critic and Critic. This ontology describes how the knowledge from all the other ontologies will be applied to monitor the patient.

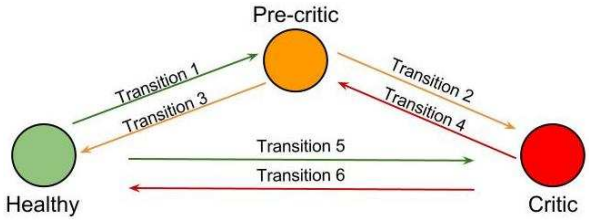

Figure 2. Control Ontology.

Each of these states has a set of rules that define whether a patient is in that state or not. Transitions have a source state and a target state; they also have a set of rules that define what is needed to go from the origin state to the target state. When a questionnaire is generated it will direct the questions to extract information to help identify if the patient's state has changed or not.

Furthermore, this ontology also defines the frequency of the formulation of questionnaires and the factors that may trigger it. The user can set, for example that if the climate is favorable to a worsening of the patient, the frequency of the questionnaire generation should be increased.

B. *An overview of the process for generating the questionnaire*

Fig. 3 presents more detailed information about the transition 1, also presented in Fig. 2.

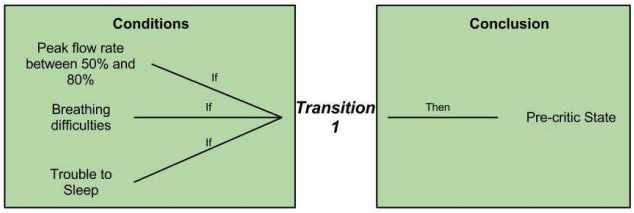

Figure 3. Transition 1.

The transitions are divided into two parts: the conditions and the conclusion. In transition 1 illustrated in fig. 3, the conditions are *breathing difficulties*, *peak flow rate between 50%-80%* and *trouble to sleep*; and the conclusion is the pre-critic state. This means that when all the conditions are true, the conclusion also will be.

The generation of the questionnaire is done while the questions are being answered by the patient. During this process, the PBB knows the last state in which the patient was classified. The first classification is given at the moment that the application is created, by the doctor.

Here is an overview of the algorithm for generating the questionnaire:

1) The program will visit each of the transitions that have the current state of the patient as the source state.

2) For each of these transitions, the program will check if the conditions are true. If they are, the patient may have his state changed.

The generation of the questionnaire is obtained through this process of verifying the conditions of the transition. For example, the transition 1 presented in Fig. 3, that has the conditions: *breathing difficulties*, *peak flow rate between 50%-80%* and *trouble to sleep*, for its verification will be raised two questions. One trying to find out if the patient has *trouble to sleep* and another asking if he has *breathing difficulties*. The verification of the condition: *peak flow rate between 50%-80%* can be done automatically through a sensor.

3) In case for all transitions, neither condition is satisfied, it is inferred that the patient is still in the same state. If all conditions of any transition are true, it is inferred that the patient is in the target state of that transition. If none of the transitions has its entire set of conditions satisfied, the program searches through the transitions with greater similarity with the patient's acquired data and it defines the new state of the patient as being the target state of this transition. The proposed calculation of similarity will be made for each condition as follows:

- *Set A*: Set of the conditions of the transition.
- *Set B*: Set of conditions (information) acquired from the patient.
- *Result Set*: *Set A – Set B*, if Set A has a greater number of elements, or *Set B – Set A*, otherwise.

The minus sign used is the set-difference operation. The transition with the *Result Set* that has fewer elements is chosen. We now calculate the percentage of satisfied conditions that this transition has. At least 70% of the conditions of the transition should be satisfied; otherwise the state of the patient remains unchanged.

4) In this step the program now has infered a new state for the patient. It is checked all the conditions listed in the

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chosen state not yet verified with the patient. And here ends the cycle of questions.

5) The doctor will receive a report with the collected data. This report contains a brief explanation of how the diagnostic process was preformed by the application. The report will say which state (eg healthy, pre-critic or critical) the patient was in at the beginning of the questionnaire's generation. It will also tell when and why the program was seeking evidence of a possible transition to another state, aiming to indicate what steps were taken by the diagnostic process done.

It is important to understand that the goal of the process of generation of the questions is to gather information from the patient, so that the doctor can make a diagnosis and define what state the patient is. The application only suggests a state and it will not conclude anything alone. After the doctor's evaluation of the information collected by the application, he can send a notification to the patient, for example, asking him to attend the hospital.

The existence of these states aims to guide the application in the process of collecting data about the patient. They define which data the application will worry about monitoring. The application will behave according to the information described in the control ontology. Through it, the doctor can set the way he considers most appropriate to monitor his patient.

It is also possible for the doctor to disable the automatic generation of the questionnaire and manually enter a questionnaire. The rehabilitation of the generation can be made each time the doctor receives the report with the patient's data. One should note that at the time the automatic generation is turned off; all data collected through the questions have no meaning for the application and will only be persisted in text form.

VI. CONCLUSION AND FUTURE WORK

Remote monitoring enhances the contact between doctor and patient, providing them with an additional form of communication that both may decide how best to take advantage.

Several papers contained in the literature focus on monitoring patients. This work has some different approaches:

- The use of ontologies for knowledge representation.
- A proposal to separate the monitoring process of the patient from the application.
- The concept that the same system can be used for a variety of chronic disease from a change in the ontologies.
- The possibility of defining which context data will be captured from the environment.

One of the possibilities of future work is to develop new ways for the physician to insert information in the ontologies. At this stage of the work, the doctor needs a specialist in ontologies to write his or her form of monitoring their patients.

Another possibility is in the form that we represent the monitoring process dictated by the doctor. Now, it is all represented by an ontology, we could try to use first order logic, like description logic, to express the rules of the monitoring process. Using logic, the program will have much more information about the monitoring process and will have much more capability of inferring new information.

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ePatient and eNurses Tools Based on Tactile Interfaces Applications for Nursing Home Residents and Nurse Team Support

Extension to Ambient-Assisted Living Semiotic Command Interfaces

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Abstract—**This article shows what usage can be made of touch screens to monitor elderly activities and health parameters. The system is based upon a classical 10-inch tablet on which a portal allows to access several activities for communications, cerebral activities through games, electronic mailbox, and multimedia applications. Statistical results can be used by the medical team to follow the mental and medical state of the resident, and to adapt the daily activities. The graphic interface and the game types are derived using a semiotic approach taking into account the biography of the person through the memory of gesture.**

Keywords-Touch screen interface; semiotic approach; cerebral training; health statistics; nurse team support

I. INTRODUCTION AND CONTEXT

Surveys shows that only between 6% and 15% of people over 70 years use touch interfaces, against 83% for those under 35. The main cause is a lack of information leading to a lack of interest, the fear of not being able to use it because of missing skills or health problems, or a wrong idea on the cost of equipment. However, another French survey shows that, if the mobile phone is the tactile object most commonly owned today, the most wanted tactile devices are equipments for elderly and disabled people (71%) before classical comfort home automation [1].

To improve tactile interfaces design and usage, it is important to take into account the memory of gestures, especially for people with reduced autonomy because the gesture used to interact with the interface is not always obvious. This implies that the functional signs (icons, buttons) and gestural modes of interaction (gestures required for a particular action) are fully embedded in their memories of daily practices. Because each handicap situation is unique, customable, adaptable and updatable interfaces based on physical and mental skills of each user must be designed. To help disabled people to take possession of the interface and to reactivate their memory of gestures, several parameters must be taken into account: the continuous aspect of the gesture (to increase the sense of proximity to the object), a maximum contextual speed response with a minimum delay in the resulting action, the accuracy of the response to the gesture, the adequate feedback and acknowledgment of the interface. Depending on the level of autonomy and the ability of the person, the adequate interface can generate an effect of continuity between the user and his environment, an effect of harmony between his body and the interface. The interface is then experienced as an extension of the body of the user. This can be done using the semiotic approach. We first define semiotics for ICT and health, and then describe our touch screen demonstrator for people with loss of autonomy using this approach. We further extend the concept for the monitoring of home automation equipments.

II. SEMIOTICS OF THE INFORMATION AND COMMUNICATION TECHNOLOGIES (ICT) & HEALTH

In his *Cours de linguistique générale*, De Saussure wished to elaborate a science, which could study the "life of signs within the social life [2]". Semiotics actually describes texts, images, objects, spaces, etc

Semiotics of ICT includes two main themes: (i) the multimedia, multimodal and hypertextual context and graphical and (ii) material interfaces; we can quote the work carried out by the University of Limoges in both areas [3-7]. In both instances, the semiotician examines how a text or an object which is intended to support interaction with a digital service and/or device is perceived. What understanding of service is suggested to the user by a text, or an object? On what mode(s) of perception should a digital support service, for a specific health need, be based? Finally, the semiotician raises the question of understanding both the sensory and cognitive appropriation of the meaning (of the text or object and the support it provides). To globally sum up, semiotics will be the innovative tool to efficiently optimize the parameters that lead to the best appropriation of the technologies by the end-user and to the best assessment of the associated impacts, for the end-users, the medical actors with a feedback to the policy makers.

Semiotics of ICT in the field of health is focused on the way that the user, with the current skills and the gestural and cultural experiences he developed in the course of the practices of his everyday life, perceives digital objects that are intended to help him. In this particular case, it is not only a question of questioning the relevance for a given user (the shape, the size, the colour of an interface), but also of questioning the efficacy of the mode of gestural interaction that the device proposes.

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How to facilitate an effective interaction with an object/device based on the user perception? This is this question that we will answer.

Thus, appropriation of ICT objects under a semiotic approach will carry out the following topics:

- Social, organizational, ethical and legal aspects;
- Efficacy and effectiveness of technologies;
- Better understanding of their use.

III. TOUCHSCREEN TABLETS FOR PEOPLE WITH LOSS OF AUTONOMY IN HOSPITAL

An experiment has been carried out in a nursing home (EHPAD in French), in Ajain, (department of Creuse). This structure hosts more than 200 residents and an important medical and nursing staff including a psychologist.

A. ICT architecture and targets

Figure 1 shows the ICT network structure that has been set up in the EHPAD.

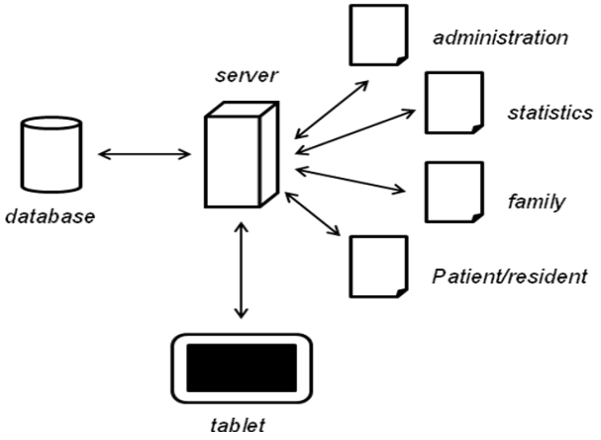

Figure 1. ICT network architecture

Such architecture has been designed to create and manage:

- A database system;
- An administration interface (account management, contents development…) for the EHPAD staff;
- A statistic interface which allows a real-time resident follow-up by the EHPAD staff;
- A family interface which permits to communicate with the family;
- A resident interface (portal) designed according to a semiotic approach.

Figure 2 shows the main portal screen.

B. The applied procedure

The different icons and related pages have been defined in a collaborative work between the residents, the psychologist and the semiotician.

It is important to note the presence of games (*Jeux*). It is recognized that people regularly in stimulating their mental activities (reading, learning, playing memory games, etc.) delay the effects of age [8]. Games for each specific cognitive domain have been developed always guided by a semiotic approach: memory, attention, executive and visuospatial functions, competition aspect…

Figure 2. Resident personal interface main page

Through the statistic interface, the EHPAD staff can evaluate the progression of the resident: date, time per game, number and levels of errors… and proposes feedback solutions. Figure 3 shows the graphical evaluation of the resident results for a game consisting in reconstituting words from pieces. Green and blue bars compare the time taken by the resident and the average time of all the participants (vertical axis) depending on the difficulty level (horizontal axis from 1 to 9). Red and orange bars compare the number of error of the resident to the average errors of all the participants.

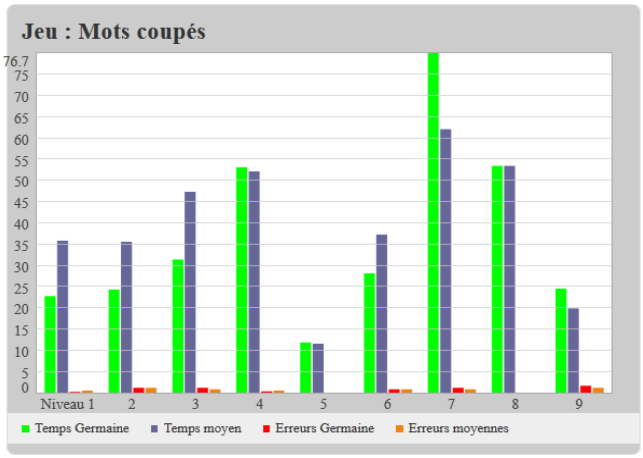

Figure 3. Statistical results

C. Studied sample and major results

Nine residents participated to 16 individual sessions over 7 weeks. The residents were from 74 to 86 years old and suffered from different pathologies: Alzheimer (weak) and Parkinson diseases, cognitive disabilities, depressive syndrome, various disorientations, etc.

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From a technological point of view, the graphic chart, navigation system, games scenarios and interactivity have been validated. A touch pen is often preferred to the finger touch.

From a human point of view, all residents showed enthusiasm:

- Always voluntary. No refusal.
- They directly go to the games screen after switching on the table.
- An efficient signage has facilitated learning (contribution of the semiotic approach).
- They absolutely want to finish the game with the pride of success.

This shows that these experiments have provided a "well-being" to the residents and facilitated the work of the EHPAD staff.

IV. APPLICATION OF THE TOUCH SCREEN TABLET FOR THE MONITORING OF HOME AUTOMATION EQUIPMENTS BY THE RESIDENTS IN THEIR PRIVATE APARTMENT

A. Description of the prototype

The prototype is presented in figure 4 and consists in a touch screen associated with radiofrequency modules.

The low cost and low consumption ZigBee radiofrequency link has been chosen for the monitoring of equipments In addition, it is open source and nowadays becomes a standard.

A synthesis image has been designed using an open source graphic software. The image reproduces in detail the apartment rooms. The resident is able to recognize all his furniture, light switches, windows… and to identify himself to his daily environment as illustrated in figure 5. This allows a better appropriation of the touch screen icons by the resident.

B. Operating mode and improvements

Touching an icon simply activates the corresponding equipment. The result of each action is immediately fedback on the screen: lights are switched on or off, shutters are opened or not, etc.

If the resident uses the classical equipment, the action result is also fedback to the tablet graphical environment.

At the next step, ZigBee modules will be miniaturized and embedded into the touch screen device and equipments. A 3D photo of the apartment taken with a fish eye camera will give a more realistic image of the housing environment.

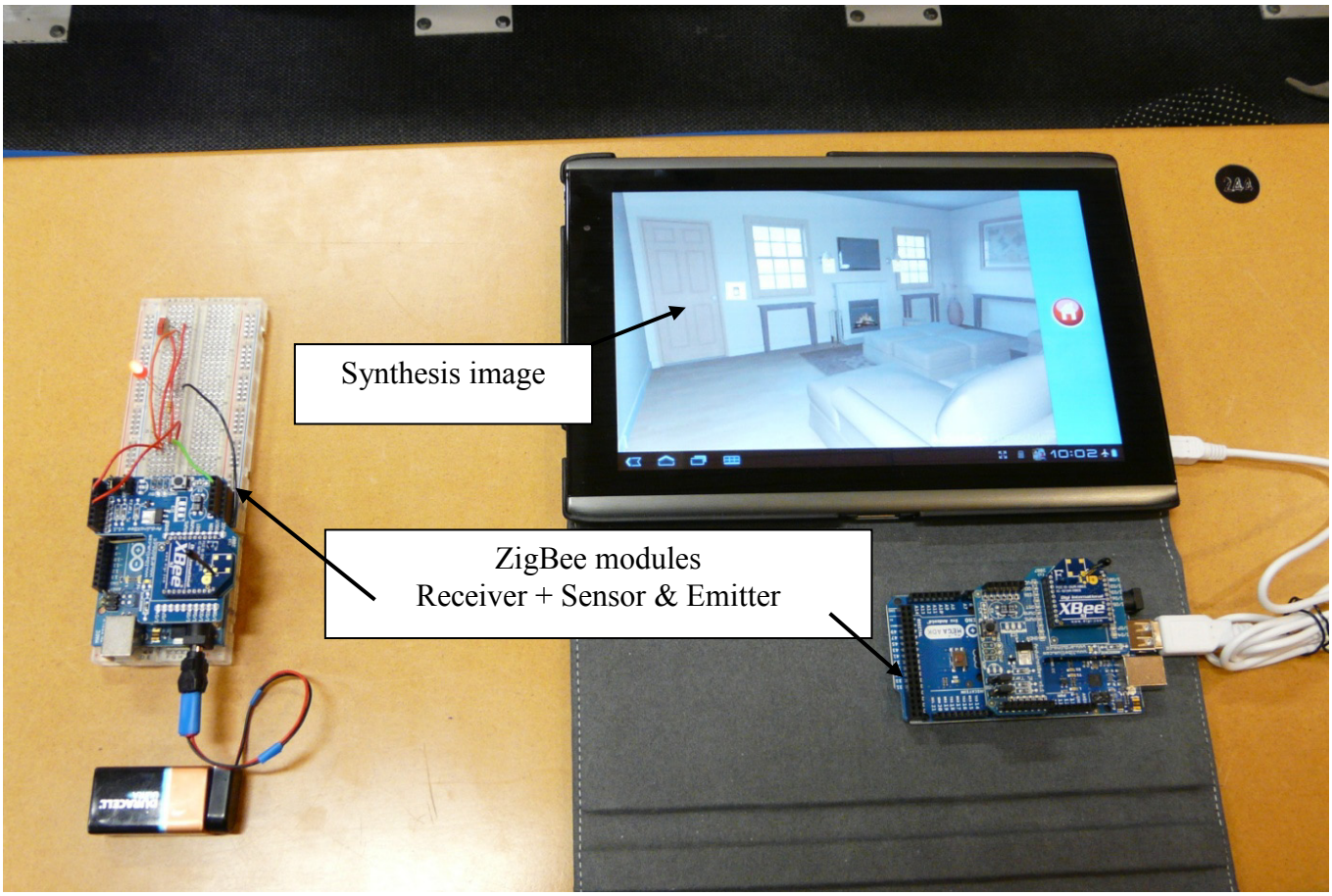

Figure 4. Prototype touchscreen with ZigBee modules

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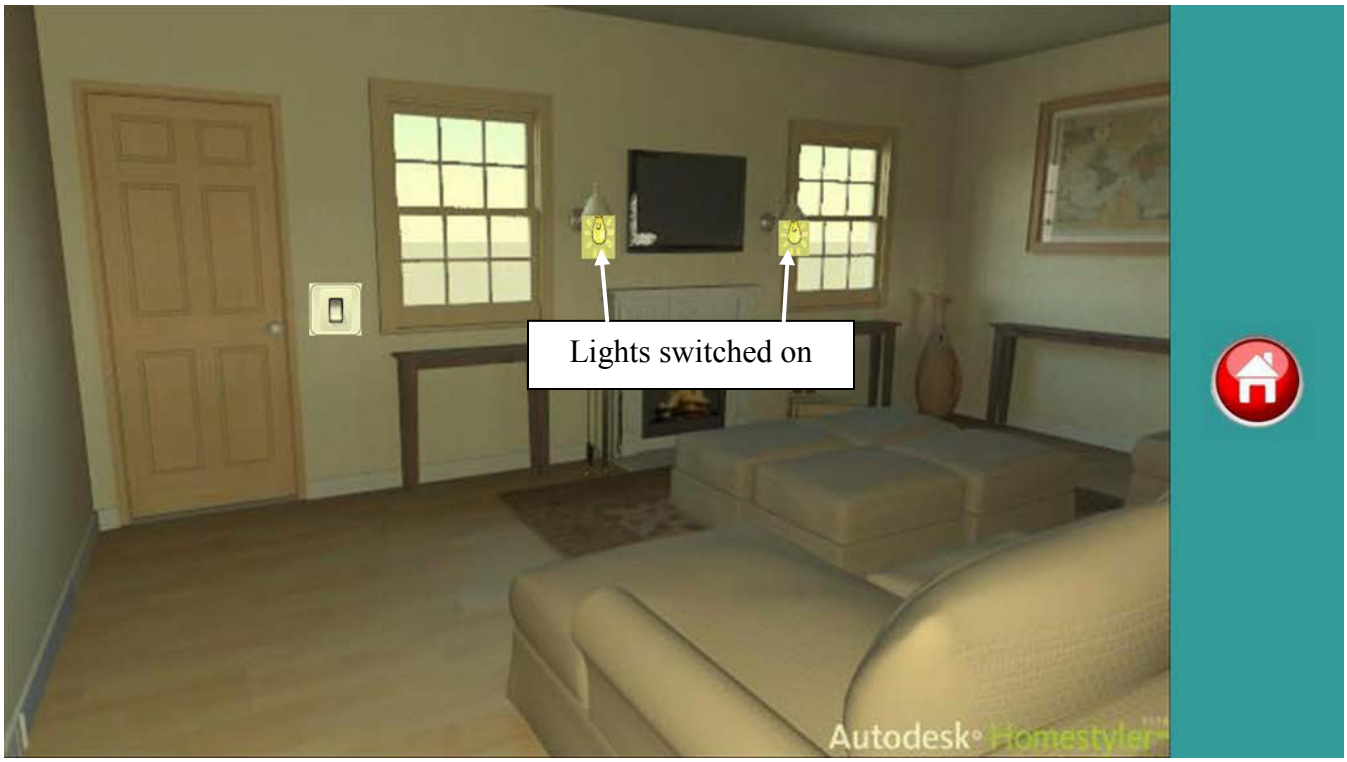

Figure 5. Detailed synthesis image

V. CONCLUSION AND FUTURE WORK

In this article, we show what usage can be made of touch screens to monitor elderly activities and health parameters. Our experimentation is based upon a classical 10-inch tablet on which a portal allows to access several activities. The originality of the interface, at this step, is that the graphic interface and the game types are derived using a semiotic approach taking into account the biography of the person through the memory of gesture.

Next step will focus on the design itself of the graphic interface, to integrate home automation application using the same approach. This command interface will be based upon the use of 3D-picture of the housing environment of the person.

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[8] See for example the Nun study from the University of Minnesota, www.healthstudies.umn.edu/nunstudy.

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Stress at Work: Developing a Stress Management Program in a Web-Based Setting

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***Abstract*—Stress among employees is a public health issue in modern working life in developed countries. A lack of balance between job and demands in private life, and stressful situations in work life let people experience high levels of stress. Long-term sick leave and ill-health can be a consequence of high stress exposure during a long period of time. The objective of this interdisciplinary ongoing research program is to develop a platform providing multiple help online with evidence-based measures in a stress management program. The program is aimed to prevent stress-related dysfunctions and promote wellbeing and lower levels of stress among salaried employees in white collar jobs. The platform includes a web based system for asking experts, communities for peers and different health promotion measures which will be further described.**

Keywords-white collar workers; learning; relaxation exercise; coping; interdisciplinary research

I. INTRODUCTION

Stress is a public health issue in modern working life in developed countries. During the past years there have been substantial efforts on advancing information technology for effective health applications. These could be proactive, preventive and intervention measures to improve work life balance and occupational stress in the western economies. To address the challenge of health and wellbeing we need to include web-based empowering of patients and healthy individuals to enable them to play a substantial role in their own health and health promotion measures and increase knowledge for decision support.

This paper describes the development of an evidence-based online stress intervention which is still work-in-progress. It introduces a web-based stress management system that applies a holistic and communicative approach to prevention and intervention of negative stress exposures and reactions among white collar workers in a Swedish setting. The system is based on group interaction, information sharing, and integration of actors' knowledge.

II. STRESS AND STRESS MANAGEMENT

The concept of stress is complex, and can either be seen as an exposure, a stressor, acting on the human body and mind, or an effect, a stress response, of an event or thought in an individual. Stress reactions include physiological as well as psychological components. It is about how we perceive demands and what ability we have to cope with them. Stress among employees is a public health issue in modern work life. Intense lifestyles, with high demands in job and in private life, let people experience high levels of stress. Long-term sickness and absence from work can be a consequence of high stress exposure [1].

Stressors in occupational work, such as a frustrating work situation, locked-in positions, over commitment in work performance and work-family imbalance are often major causes of psychological and physiological strain. Overcommitted co-workers suffer from inappropriate perceptions of demands and not enough coping resources. It could be misconceptions preventing co-workers from properly estimate cost–gain relations and to set limits. Studies have shown that stress related dysfunctions are associated with a state of fatigue, sleep problems, lack of recovery, and also long term sickness absence [2] [3] [4] [5]. It is well-known that preventive measures and early interventions are beneficial in order to prevent people from stress-related dysfunctions, and risk of later illness and sickness absence.

III. THE WEB-BASED STRESS INTERVENTION

The Internet can serve as an interactive medium for information and communication, with accessibility and interactivity for almost everyone in the western world. It can include numerous of users, and gives users new knowledge and information as well as opportunities to communicate. It challenges traditional one-way information in health information, and can be used in developing interactive environments. Its main principles are in line with and suitable in health education and empowering processes. However, the function for many years was information search and retrieval, but the technology now makes it possible to use interactive applications. This makes it possible to integrate applications for shared experiences, recognition and support among users, which is characteristic of the web 2.0. To let users be not only consumers, but also producers and contribute to content is a valuable development [6]. Electronically accessed health services, such as web based communities for peer level support, and ask-the expert systems for more extensive medical information, offer answers and support. A benefit for

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the user could be reached if these two different health venues could be integrated [7].

The objective of this interdisciplinary research program is to develop a platform giving multiple help online with implemented evidence-based measures in a stress management program which is aimed to prevent stress-related dysfunctions and promote wellbeing and low levels of stress levels among salaried employees in white collar jobs. The platform includes a web based systems for asking experts, communities for peers and intervention programs offering health promotion measures.

IV. DESIGN AND MODEL

This new program is based on the bio-psychosocial model stating that biological, psychological and social factors are equally important in the development of disease or to promote and maintain good health and prevent ill health. The model is based in that health is a combination of biological, psychological, and social factors rather than solely biological or biomedical [8] [9]. In this project he model should be seen as a general framework to implementation and intervention of stress related exposures and reactions.

The core element of the intervention is a learning process in which the participants learn to approach solvable problems and issues connected to promotion, prevention or reduction of stress. The project will be an ongoing process with the multiple help system on line that is set up and designed in the project. The system is a combination of self-help, groups, support and expert help online. Thus the program aims to enable people to gain better control over health determinants. Health promootion in work life is the combined efforts of employers, employees and society to improve the health and well-being of people at work. In this study the focus is on promoting active participation and encouraging personal development.

The base of all intervention measures in this project is the empowering processes of the individuals. The educational approach to health promotion is concerned to enabling people to make informed choices, which is well in line with the design of this study. The promotive and preventive approach targets behavior changes in individuals, such as: internal locus of control as a key factor in efforts to create empowered environments and empowered individuals [10] [11].

V. THE INTERVENTION PROGRAM

People who will be included in the project are more or less exposed to stress, which has to be considered when designing the web based system. Relaxation exercises, access to relevant information and interaction with other users and health professionals, helpful on-demand for upcoming stressful situations as well as long-term strategies for learning a new behavior and coping with stressful situations are parts of the system. The aim is to let the users become more empowered in their daily lives.

The techniques used in the stress management system are utilized in cognitive therapy, stress management and in body-oriented therapies. Relaxation exercises can ease stress reactions and prevent more chronic stress related dysfunctions. The exercises include techniques for improving breathing, relaxation, body awareness, sleep, cognitive reframing, emotional control, self-efficacy and self-esteem.

The relaxation exercises, such as 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 body relaxation [12]. This 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 [13]. Cognitive-behavioural skills were found to be 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 [13] [14]. 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 [15] [16]. 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 [15] [16] [17]. It has been found that there could be a lowering of blood pressure during deep breathing [18], which is interesting to consider in stress management.

Figure 1. Components of the Web-Based Stress Management System.

Work coaching and counseling in stress management are a relatively new, but an increasingly sought after method for helping people to improve, develop, learn new skills, find personal resources, achieve aims and manage life change and personal challenges such as work-related stress and achieving work life balance. Occupational coaching might be effective for situations, whether in personal life, career, corporate or business life [19] [20]. It is well established among business and management executives, but has not been used much on a individual level among gainfully working men and women in the general population [21].

These work oriented programs have not been scientifically evaluated regarding primary or secondary prevention for stress related disorders or as a health promotion measure for gainfully working people. We will include these measures in the web program to evaluate both the general design and also how they can be implemented on the Internet as a dynamic

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tool in the communication process. There will also be an approach to focus the work-family balance.

VI. MEASUREMENTS AND OUTCOMES

There are different theoretical models including the stress concept. The demand-control-social support model is one of them. It a multidimensional model that examines the relationship between a person and the environment with particular focus of the interaction in employment settings. This model utilizes three dimensions which focus which can explain the development of stress reactions in working people. The individual, which is central in this model, has her or his perceptions of work experience. Factors connected to the psychosocial work environment, such as demand, control, and support are the core components of the model [22].

In this program electronically accessed health services, means stress management, which may offer the advantages of both expert knowledge as well as a social network where collaborative learning by means of social support is provided, and as understood to be a social network's provision of psychological and material resources intended to increase the individual's ability to cope with stress [23]. All the involved actors can benefit and the possibility of cross-fertilization to take place [7].

VII. CONCLUSIONS AND FUTURE WORK

Stress among working people is a public health issue. In order to outline preventive and intervention measures for stress reduction, information technology for effective health applications should be developed and implemented. This paper describes how a web-based system for stress management has been developed entailing self-help through information access and exercises, and also support and guidance from peers and medical professionals. The platform is ready for use and to be implemented.

The web-based stress management system presented in this paper has resulted from previous research studies of web-based solutions for learning new lifestyles, stress management and clinical trials. The next step is to make the system available to a group of employees who experience stressful lives. The focus will be on white-collar workers: office workers and in middle management positions. To evaluate the implementation stress levels will be measured using established questionnaires. levels will be measured using established questionnaires. In addition, there will be observations of systems usage and content and discourse analyses of the web-based communication [24] [25.

We will complement the web-based system by a mobile application. To add new technical features will be useful to increase the system flexibility for the users. This would make it easier for the users to get help in their everyday lives, whenever and wherever they need support from peers, experts and information contents.

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Mobile Real-time Analysis of Patient Data for Advanced Decision Support in Personalized Medicine

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***Abstract*—Personalized medicine aims to treat patients specifically with respect to their individual dispositions. For that, researchers and physicians require a holistic view on all relevant patient specifics when making treatment decisions. We present our findings of applying in-memory database technology to enable real-time analysis of individual patient and cohort data. In this contribution, we describes the mobile application "Oncolyzer" that provides a holistic view on individual patient data and enables flexible analysis of cohort data on mobile devices. It opens flexible access to relevant patient data on the hospital campus when time-critical treatment decisions need to be made.**

Keywords-Clinical Decision Support; Personalized Medicine; In-Memory Database Technology; Real-Time Analysis; Business Processes

I. Introduction

The amount of data acquired during patient's medical treatments is immense. For example, data of tissue analyses, medical imaging, and haemograms, etc. add up to terabytes of medical data depending on the specific diagnostic approach [1]. In future, we expect the level of detail of therapy data to increase continuously.

Personalized medicine aims at treating patients specifically based on their individual dispositions, e.g. genetic or environmental factors [2]. Thus, we consider the detailed acquisition of medical data as the foundation for personalized therapy decisions. The more fine-grained data are available, the more specific are the gained insights, but the complexity of data processing rises, too.

Modern Hospital Information Systems (HIS) consist of various data sources. Combining data from distributed sources is one of the challenges of Computerized Clinical Decision Support (CCDS) systems. Business Warehouses (BW) or Business Intelligence (BI) systems incorporate specifically prepared business reports in a central system. However, these reports do not allow a free combination of all available attributes.

In the given work, we present our findings of applying in-memory database (IMDB) technology for analysis of clinical data during treatment of patients suffering from cancer diseases. Based on the feedback of physicians and researchers, we designed a software system and a specific mobile application as depicted in Figure 1.

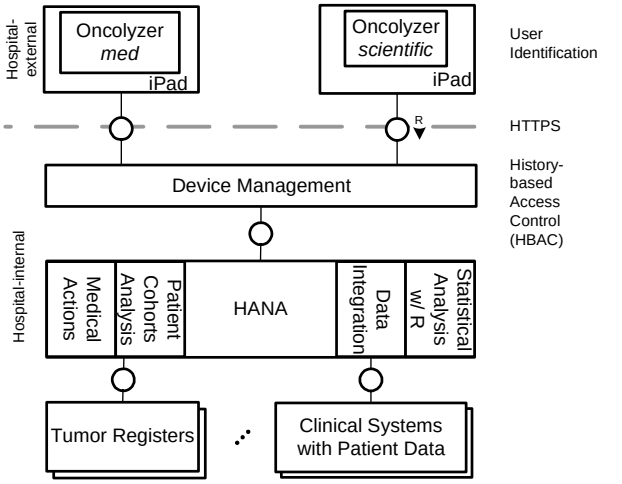

Figure 1. Oncolyzer system architecture: Data from clinical systems is combined and analyzed by the IMDB. The results are accessible by the iPad application.

The rest of the paper is structured as follows: In Section II our work is set in context of related work. We define requirements for clinical IT systems used in context of personalized therapy in Section III and outline the applicability of IMDB technology in Section IV. Our research prototype Oncolyzer, which is specifically designed for individualized therapy of cancer patients, is presented in Section V. In Section VI, we define innovative business processes that become possible due to the use of IMDB technology for real-time analysis of patient data. We discuss our research results in Section VII and conclude our work with an outlook in Section VIII.

II. Related Work

Requirements engineering for software systems is well defined, e.g. by the International Standards Organization (ISO) [3]. However, requirements for clinical soft-

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ware are only rarely differentiated by existing standards. Coble et al. [4] outline their experiences during designing, prototyping, and testing of clinical software for workstations in the 1990s. We followed the design thinking approach for software engineering of Plattner et al. [5], which builds on viability, feasibility, and desirability of the desired software. In consensus with Coble et al., this approach requires the early and regular involvement of future users of the developed software system, i.e. physicians and medical researchers in our case.

Coble et al. focused on the development for fixed workstations. Our user interviews showed that physicians and researchers do not work at dedicated offices only. In contrast, they have frequently changing working locations, e.g. emergency room, surgery room, intensive care station, etc. As a result, we emphasized the mobility aspect during requirements engineering.

Wright et al. [6] propose the use of Web 2.0 techniques for building CCDS systems, e.g. Wikis for knowledge management or private online forums. They elaborate on the value of online CCDS, but they also discuss various concern for a clinical wide use of Web 2.0 CCDS, such as costs for knowledge management and liability for correct data. We agree that online CCDS can improve clinical knowledge management. However, we also see a need for having the accumulated knowledge at hand at any time. Thus, we focus on converging clinical knowledge from private online sources and the required mobility aspects of physicians and researchers.

Based on our conducted feedback loops, we focused on the selected application perspectives summarized in Table I. A detailed description of design decisions and these perspectives is elaborated in Section V.

Table I. Application perspectives and corresponding user groups Physicians (P) and Researchers (R).

Perspective	Group	Sect.
Holistic Patient View	P, R	V-A
Search in Structured and Unstructured Data	P	V-B
Real-time Analysis of Patient Cohorts	R	V-C

III. Requirements

In the following, we define specific requirements for designing clinical software systems. They reflect a selected subset of requirements from the software engineering catalog as defined for product quality in ISO/IEC 9126-1 and specifically revised in context of our work [3].

- **Ease of Use:** Clinical software artifacts must be usable by untrained users, i.e. its user interface (UI) should combine ease of use and functionality.
- **Response Time**: The response time of clinical applications must not exceed an empirical threshold of approx. two second [7]. Our user interviews showed that otherwise the latency outperforms any benefits resulting in the application not being used.
- **Reliability:** Clinical software must be available without unplanned interruptions or malfunctions due to its life-critical purpose.
- **Productivity:** Users of a clinical software solution should be more efficient than performing manual processing steps or using alternative tools.
- **Scalability:** The system behavior of the designed software must not be affected by the number of concurrent users. Extending existing hardware resources, e.g. number of database servers, should result in a linearly increasing capacity.
- **Data Security:** Clinical data are sensitive and must be accessible by authorized personnel only. Intended or unintended exposure of these data must be addressed during the design of clinical software.

IV. In-memory Technology Building Blocks

We refer to IMDB technology as a toolbox of artifacts to enable processing of enterprise data in real-time in the main memory of server systems. IMDB technology enables CCDS in an interactive way without keeping redundant or pre-aggregated data, which is commonly used in BW or BI systems to improve response times for certain long-running reports [8]. In the following, we outline selected building blocks of the IMDB technology enabling real-time analysis of clinical data.

A. Combined Column and Row Store

Historically, separate database systems for processing of analytical and transactional data evolved. The former store and process data in a row-oriented format, i.e. attributes of one record are stored side by side, while analytical database systems are optimized to scan selected attributes of huge data sets rapidly, e.g. by maintaining pre-aggregated totals. Combining column and row stores improves data access for analytical queries while keeping transactional response times fast.

B. Insert-only

Insert-only defines how newly inserted data are managed. Traditional database systems support four operations for data manipulations, i.e. insert, select, delete, and update of data. The latter two are considered as destructive operations since original data are no longer available after its execution [9, Section 7.1]. In other words, it is neither possible to detect nor to reconstruct the complete history of values for a certain attribute after its execution since only the latest value is permanently stored. This violates legal regulations to permanently store clinical data. Insert-only tables store the complete history of value changes and the latest value for a certain attribute [8]. Insert-only enables tracing

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Table II. Comparison of patient database table (top) and its compressed, horizontally three-partitioned pendant with corresponding dictionary (bottom).

Rec.	PatID	Loc.	ICD
1	091487	Colon	C18.4
2	357982	Larynx	C32.0
3	123498	Lip	C00.9
4	998711	Colon	C18.7
5	215678	Rectum	C20.9
6	647912	Rectum	C20.9
7	167898	Mama	C50.9

=

	Rec.	PatID	Loc.	ICD
I	3	123498	2	C00.9
	1	091487	4	C18.4
	4	998711	4	C18.7
II	5	215678	3	C20.9
	6	647912	3	C20.9
	2	357982	1	C32.0
III	7	167898	5	C50.9

+

Val.ID	Value
1	Larynx
2	Lip
3	Rectum
4	Colon
5	Mama

of decisions within the treatment process, e.g. to retrospectively perform analysis when certain treatments were initiated.

C. Lightweight Compression

Lightweight compression refers to a data storage representation, which consumes less space than its original pendant [8]. Due to the fixed data type per attribute, the data domain is within a given interval, e.g. integer values. The given data type defines the max. required data domain for a compressed format. A columnar storage layout supports lightweight compression techniques, such as run-length encoding, dictionary encoding, and differencing [10]. Table II depicts an excerpt of the patient table that is compressed using dictionary encoding.

D. Partitioning

We distinguish vertical and horizontal partitioning [11]. The former refers to the arrangement of individual database columns, which is achieved by splitting columns of one database table in two or more sets of columns. Each of the sets can be distributed on individual database servers [12]. The latter addresses long database tables and its division into smaller chunks of data [8]. Splitting data into equivalently long horizontal partitions supports parallel search operations and improves scalability. For example, a Kaplan Meier analysis requires a full scan of the patient table as depicted in Table II to identify patient records having the identical International Code of Disease (ICD). With a single partition, a single thread needs to access all patient records to check the ICD predicate. The example depicts the major code of the ICD as partition criteria. Thus, the three partitions can be processed in parallel.

E. Multi-core and Parallelization

Parallelization can be applied to various locations within the application stack of software systems. Let us consider the HIS as an enterprise system that needs to serve requests of different users from various departments at the same point in time. Processing multiple queries can be handled by multi-threaded applications, i.e. they do not stall when dealing with more than one query at a time. Operating systems threads are a software abstraction that need to be mapped to physically available hardware resources [13, Chapter 2]. A Central Processing Unit (CPU) core is comparable to a single worker on a construction area. If each query can be mapped to a single core, the system's response time is optimal. If the workload exceeds physical capacities of a single system, the work load can be distributed to multiple servers or blades to achieve optimal processing behavior. From the database point of view, data partitioning supports parallelization since multiple CPU cores on multiple servers can process individual partitions in parallel [14, Chapter 6].

F. Active and Passive Data Store

We distinguish active and passive data stores. The former are accessed frequently and updated regularly, e.g. patient records of patients in the emergency room or on the intensive care unit. Passive data are neither updated nor accessed regularly, i.e. they are mainly used for analytical and statistical purposes or in exceptional circumstances, where specific investigations require them. For example, data stored about patients that have left the hospital and have been invoiced can be considered as passive data. The separation of active and passive data is a special implementation of data partitioning that establishes a memory hierarchy, e.g. fast main memory, solid state disks, hard disks, tapes, etc. [8].

V. Research Prototype

In the following, we share details about our research prototype and its application perspectives as summarized in Table I. The system architecture and its integration within the HIS is modeled in Figure 1. The key component of the architecture is the IMDB HANA that enables real-time statistical analysis of patient cohort data, medical actions, and data from further clinical systems. The mobile devices are connected via a device management layer to the database management system, which combines data from clinical data sources, such as tumor registers or HIS.

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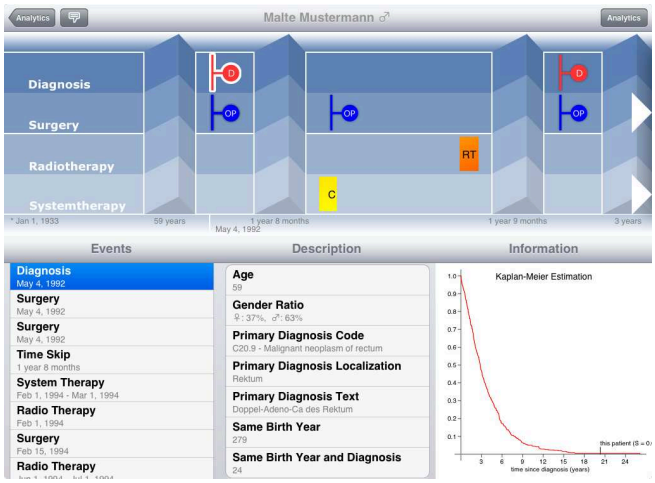

Figure 2. The holistic patient view consists top-down of name and gender details, interactive treatment history combining all relevant treatment information on a single screen as well as a tabular view. The latter contains from left to right details for treatment events, analytical results, and a graphical evaluation of patients with the same primary diagnosis using the Kaplan Meier analysis.

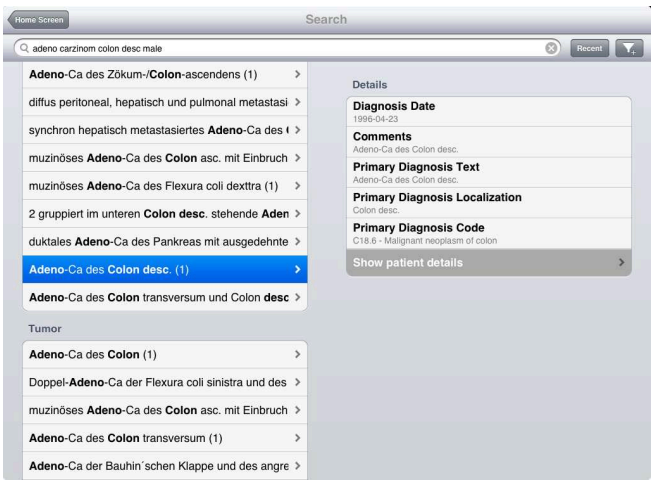

Figure 3. Result set of the search query for "adeno carzinom colon desc male". The search term "carzinoma" is identified by the fuzzy search as equivalent for "carcinoma" and is also substituted by its abbreviation "ca". The result set is also filtered using the value "male" obtained from a search in the structured attribute "gender".

A. Holistic Patient View

The holistic patient view as depicted in Figure 2 combines patient specific data from various clinical databases. For example, the complete treatment history consisting of diagnoses, surgeries as well as radio and system therapies are combined and visualized as a graphical timeline. The IMDB technology performs real-time analysis to identify similarities in the data of the selected patient and data of hundreds or thousands or even hundreds of thousands similar patients. For example, results for patients with the same year of birth, with the same primary diagnosis, or gender ratio are transparently calculated for any selected patient. This environmentally derived information can significantly help to identify sources of diseases, e.g. to identify the connection between TP53 gene mutations and urinary bladder cancer after the nuclear plant catastrophe in Chernobyl in 1986 [15].

The incorporated IMDB is hosted by the central IT department running on multiple high-end servers. In contrast to data warehouse systems, which store pre-aggregated totals to improve long-running queries, IMDB technology performs all calculations on the fly. In other words, once a new patient record has been added to the database, it can be accessed immediately via the Oncolyzer. The new record directly influences calculations and analysis results, e.g. Kaplan Meier analysis.

B. Search in Structured and Unstructured Data

We are convinced that diagnostic reports contain valuable information, although they consist of less standardized free-text documents. As a result, it is hard to access relevant details, e.g. to determine `subscribed drug = Vincristin`. The Oncolyzer is equipped with a combined search for structured and unstructured data, which is supported by the underlying IMDB technology. The application perspective consists of a search box following the Google-like UI. Patient documents from different systems, e.g. diagnosis reports, preliminary diseases, death causes, etc., are searched for the terms entered as depicted in Figure 3.

In addition to an exact match search, fuzzy search also detects similar search terms, e.g. in case of typos [16]. Our research showed that fuzzy search is valuable in clinical contexts as medical terms can be documented in either Latin, English or German or their abbreviations. Fuzzy search accepts a specific degree of fuzziness in the search term, i.e. the result set contains more relevant search results than an exact search for terms.

We further integrated a synonym search, which returns documents that contain synonyms instead of the searched terms. For instance, the abbreviation "ca." is synonymously used for "circa", but it refers to "carcinoma" in clinical documents. A clinical classifications was added to the synonym table, e.g. the ICD and the corresponding tumor location [17]. Thus, a search for the tumor location "rectum" also returns results containing the ICD code "C20".

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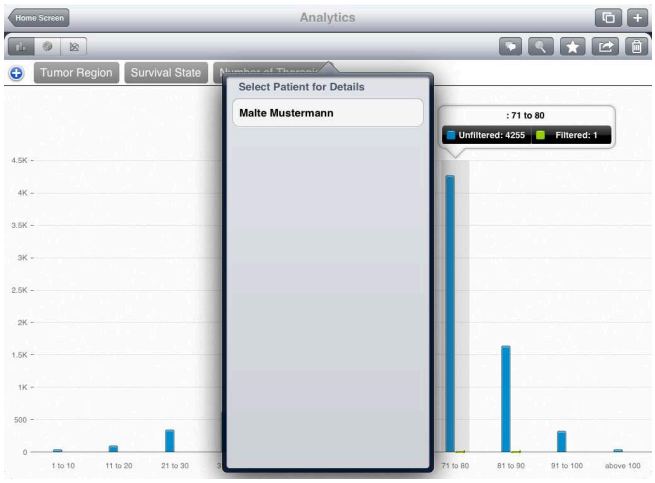

Figure 4. Real-time analysis of patient cohorts: Filters for tumor region, survival state, and number of therapies were applied and a patient in the age group "70 to 80" with the alias "Malte Mustermann" was identified.

Furthermore, stop words for structured search are derived from all values stored as structured attributes. A subsequent search for each stop word is performed in the database table containing the structured attribute. For example, a search for "male adeno ca" is expanded to a combined search for patients having the value "m(ale)" in structured attribute "gender" and associated documents with indications for an adeno-carcinoma.

The combination of search in structured and unstructured data leads to more accurate result set than traditional search tools, e.g. exact match search.

C. Real-time Analysis of Patient Cohorts

Researchers are able to perform individual real-time analysis on patient data on their mobile devices. The analytical view of our Oncolyzer provides the graphical UI for visualization of results of complex analytical queries that are executed by the IMDB system. Thus, researchers are able to identify relevant correlations with external factors, e.g. to prevent recurrences or to form patient cohorts. The quantity of patients that fulfill specific preconditions can be determined by using individual criteria for filtering, such as the patient's age, the gender, kind of tumor, or its localization as depicted in Figure 4. The results are interactively visualized using individual chart types, such as bar, pie or line charts. Clicking on a fragment of the chart shows the list of concrete patients. All patients are linked to their holistic patient view, which connects analysis of cohorts and specific patients.

VI. Innovative Business Processes

In the following, we outline business processes that build on our research prototype. They describe a completely new way of exploring treatment-relevant information. We focus on the involved business entities and their actions. Table III classifies processes, involved entities, and required application perspectives.

Table III. Classification of innovative business processes and affected user groups (P = Physicians, R = Researchers, B = Business managers), category (N = New, E = Extended), application perspective (S = Search view, H = Holistic patient view, A = Analytical view), and corresponding section within this document.

Business Process	Group	Cat.	App.	Section
Evidence-based Treatment	P, R	E	H	VI-A
Building Research Hypotheses	R	N	A, H	VI-B
Pharmaceutical Feedback Loop	R	N	A	VI-C
Federal Bureau of Statistics	P, R	N	A	VI-D
Health Insurance Companies	B	N	A	VI-E
Tumor Board	P, R	E	A, H	VI-F

A. Evidence-based Treatment

Evidence-based treatment decisions are either directly taken by physicians or supported by researchers, such as biologists. It requires the retrieval of all available patient data and the summary of treatment relevant details in the UI [2]. We designed the holistic patient view as described in Section V-A to combine clinical data. In addition to patient specific data, it also contains results of specific analysis results of data of patients with similar indications or primary diagnoses.

B. Building Research Hypotheses

Clinical researchers require flexible ways to test hypotheses and correlations between certain aspects of patient data. BW or BI systems enable the analysis of patient cohorts in a fast way, but involve complex administrative operations for data preparation before accessing results. After patient data is Extracted, Transformed, and Loaded (ETL) into the BI system [18], they are optimized for predefined queries, i.e. expected correlations need to be included in the reports. We introduce a completely new way of analyzing patient data while bypassing ETL processes. We keep all relevant patient data in the main memory in a columnar format without the need to load and prepare data, e.g. from disks, before starting their analysis. As a result, data is accessed at main memory latency time, i.e. 10 ns, instead of about 100 ms required for hard disk access [8]. The analytical view as described in Section V-C is designed for interactive exploration and analysis of patient data. Analyses are processed by the IMDB while the mobile application is connected as remote UI and input device. Researchers can access the holistic patient view for each patient of the result set to retrieve patient-specific details depending on their granted access.

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C. Pharmaceutical Feedback Loop

New pharmaceutical products require to pass clinical trials before being approved for regular use [19]. Pharmaceutical manufacturers require patients with very specific indications to participate in clinical trials. Pharmaceutical researchers can analyze patient cohorts in a similar way like clinical researchers using the analytical view. Their access is restricted to anonymized cohort data only, i.e. they are prohibited to access personal details of the holistic view. If a certain number of patients with similar indication is required, but not present, they can use bookmarks to get notifications once relevant patients are present. Instead of performing these analyses multiple times, a push notification automatically indicates new relevant patients. If the patient should be recruited, the pharmaceutical researcher contacts the hospital and the patient is informed by her/his physician. Only if the patient agrees, the contact with the pharmaceutical researcher can be established.

D. Federal Bureau of Statistics

Statistical analyses of cancer diseases are regularly conducted to supervise influencing factors, such as compliance of treatments with clinical guidelines, rate of new or recurrent cases, and an analysis of regional accumulations [20]. The primary step is to obtain relevant data from nationwide hospitals. In Germany, there are clinical tumor registers that contain well documented data about all recent cancer cases. A widely used documentation system is the Giessener Tumor Documentation System (GTDS) that provides interactive tools for documentation, verification, and export of analysis data [21]. In future, we expect the following trends to come up:

- The level of detail and therefore the size of the documented data will increase and
- Consolidated nationwide tumor registers will offer new sources of information, e.g. for research [22].

Combining data from nation-wide tumor registers improves the quantity of available data for evidence-based treatment decisions. We implemented a Kaplan Meier analysis that visualizes fractions of patient cohorts and their survival time after first diagnosis [23, Chapter 9]. It is based on patient cohorts with the same ICD of a single hospital. The outlined business process describes a completely new way to combine data from decentralized tumor registers. In future, the basis for these analyses will include data from national and worldwide tumor registers. Thus, the quality of data used for personalized treatment is improved by combining national and international data sources.

Our contributions prove that IMDB technology can be used to bridge individual data formats without the need of data transformation. Therefore, we make use of database views, i.e. a defined transformation rule that is processed, when the underlying data item is accessed [8]. As a result, views are a transparent way to expose a homogenous data format while original data remains unchanged. On the one hand, views require a portion of designated processing time of the CPU. On the other hand, the use of views reduce the time for integration of new data, i.e. required transformations are eliminated. This is beneficial, if you access only a small portion of data and instant transformations are performed (e.g. 100 relevant patients) while traditional ETL processes need to transform the full data (e.g. of 100k patients).

Exposing analytical access to patient data supports employees of the Federal Bureau of Statistics to create national cancer reports. IMDB technology can reduce the integration effort for combining patient data from clinical tumor registers of different vendors. Furthermore, it enables interactive data exploration to trace any kind of statistical anomalies and to determine their natures. Nowadays, tracing anomalies in the reported data is a time-consuming task since experts of the statistics bureau, of the clinic and the physician who have treated a specific patient, need to be involved. As a result, the release cycles of cancer reports can be reduced, for comparison, the German cancer report 2007/2008 was released in 2012 [20].

E. Health Insurance Companies

Health insurance companies are interested in optimizing the overall time of hospital stays. However, the duration of a specific stay depends on various factors, such as age of the patient, stage of cancer, etc. Periodically, health insurance companies negotiate fixed rates for treatments of specific disease types with hospitals [24]. The rates are aligned with the average national costs for treatment of the specific disease. However, hospitals specialized for the treatment of certain disease types argue that they receive more complex cases compared to small, regional hospitals. As a result, hospitals are also interested in providing in-house analysis of certain disease types to negotiate more adequate rates. Latest analyses of treated patient cohorts suffering from a specific disease type forms the basis for the negotiating process. In addition, it enables a more transparent and holistic view on the treatment process, e.g. to match specific thresholds for the duration of a hospital stay.

F. Tumor Board

In the course of cancer treatments, each individual case is discussed by dedicated experts. They develop a specific treatment plan, discuss alternatives, and regularly evaluate the performance of the chosen therapy, which requires all relevant data of the discussed patient [25]. All decisions of the tumor board need to

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be documented and communicated, e.g. new treatment decisions to anybody involved in the treatment process.

The holistic patient view of our research prototype provides the tumor board with all relevant patient data. We also added notes for patients and analysis results. Notes can be used to ensure that all treatment relevant decisions of the board are immediately documented and all involved personnel are automatically informed when accessing the patient's data.

VII. Discussion

In the following, we discuss how our work respects the requirements for medical software defined in Section III.

We found that tools for physicians need to match strict response time requirements. Due to the possibility of unexpected events, such as emergencies, long-running surgeries, etc., they need to have access to patient data at any time and location. Physicians frequently change their working locations within the hospital instead of waiting for patients in their office. Thus, there is a need for mobile access to patient data compared in contrast to desktop computers.

We address the response time requirements by applying IMDB technology for data analysis, specific UI design for accessing relevant data, and an optimized data exchange to minimize the amount of exchanged data between servers and mobile device.

Our prototype is designed for use on mobile tablet devices. The mobility requirement forced us to focus on the ease of use, e.g. due to size restrictions of mobile displays. Firstly, we restricted the number of application perspectives to a login, text search, real-time analysis, and the holistic patient screen. During our design evaluation sessions, we constantly received feedback from physician and researcher user groups. We identified that each user group has specific requirements. As a result, we designed the search screen for physicians and the analytical screen for researchers specifically. Both screens consist of a limited number of UI controls. The search screen consists of a search field and a selector for data sources. The analytical screen starts with a selector of primary filter criteria and stored bookmarks.

In comparison, the holistic patient screen is optimized for all user groups. The specifically designed interactive time slider combines patient data from all hospital stays and supports access to huge sets of patient data on a limited screen. The latter enables a detailed drill-down once a certain data entry is selected.

We were able to build an interactive mobile application by exchanging a minimum of patient data to initialize screens. Once the user is drilling-down to a specific data item, detailed data are asynchronously loaded to update the displayed content using asynchronous Ajax calls and JavaScript Object Notation as data exchange format [26], [27]. Thus, the ease of use and the response time behavior of the application are addressed without affecting the quality of available data.

The data quality aspects also depends on the reliability of the application. For that, the Oncolyzer is designed as remote UI only while business logic and complex analysis are processed in the IMDB system. For example, if the battery of the mobile device drains, physicians can switch to any other device, log-on, and access their data. The IMDB system is operated by skilled personnel in the IT department of the hospital. For scaling, new servers are added to the database landscape and data portions are updated without interrupting database operations.

New releases of the Oncolyzer are automatically deployed via device management tools, such as Afaria [28]. The Sybase Unwired Platform (SUP) is used to process user authorizations, perform necessary data transformations, and manage incidents, e.g. when an iPad device gets lost. To prevent unintended data exposure, patient data are never stored on the mobile device. If the application is suspended or closed displayed data are cleared. Unintended access is prevented by built-in locking features of the incorporated devices, e.g. password protection. Access to sensitive patient data is controlled by transparent security extensions of the History-Based Access Control (HBAC) [29]. HBAC logs all user queries, analyzes them for taking access decisions, adapts access rights, and filters the result set accordingly.

The Oncolyzer is designed for very specific use-cases in which the productivity of physicians and researchers was increased, i.e. they access patient data using our application in a unified way. The selected software development process Scrum supported us in releasing new working prototypes at the end of each week, receiving feedback at the beginning of the week, and integrating new features during the remaining time [30]. The tight interaction with future application users helped to validate the results of our development sprints every week.

VIII. Conclusion and Outlook

Treatment of cancer disease is a complex process, which involves different actors contributing their individual piece of information to a complete picture. In context of personalized treatment, we expect the amount of available data per patient to increase further, e.g. by integration of data from worldwide research institutes. We outlined IT challenges in context of personalized treatment and defined requirement for clinical software applications, e.g. strict response time of less than two seconds. To prove the feasibility of our vision, we applied IMDB technology for addressing real-time analysis of clinical data. With regular user feedback, we were able to design a CCDS as mobile application for iPad and Android devices: The Oncolyzer is specifically developed

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for physicians and medical researchers. We discussed innovative business processes that become possible by integrating the Oncolyzer in the clinical context, e.g. involved industry partners benefit from anonymized analysis results as well as experts in tumor boards.

The given work is an initial move towards taking individualized treatment decisions in the course of systems biology. Our research results depict how to bridge the gap between clinical data in HIS and end users, who require access anywhere at any time.

IX. Acknowledgements

The given work combines the results of the research areas software engineering and translational research on tumor diseases. It is built on the collocation between the Hasso Plattner Institute in Potsdam and the Charité – Universitätsmedizin Berlin. Our results were honored with the 2012 Innovation Award of the German Capital Region. We thank all colleagues, researchers, and partners that were involved in requirements engineering, design, implementation, and evaluation to make this vision come true.

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Towards an Architecture for a Game Achievement Based System to Analyze Human Health Comparative Behavior

Analysis of People's Behavior Regarding Sharing Their Health Data and Proposing a Health Achievement Service Known From Computer Games

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***Abstract*—Nowadays a few concepts of games and game design are used in different non-entertainment domains (this is also called gamification). Part of this gamification is also emerging in the health sector. This work-in-progress paper tries to define a methodology and an architecture how an achievement based service in healthcare can be designed, analyzed and implemented. This service uses patient data from different sources (e.g., from a patient's personal health record) to share anonymized health related information/achievements with other people. Thus, it might build up a comparative behavior between patients and motivate them to increase the usage of a personal health record.**

Keywords - electronic health record; patient empowerment; achievements; medical informatics.

I. INTRODUCTION

Noncommunicable diseases, e.g., cardiovascular diseases, cancer, chronic respiratory diseases, diabetes, are leading causes of death and found to be rooted in unhealthy behavior [16]. People are facing day-to-day negative stress and put themselves at risk largely due to tobacco use, alcohol consumption, physical inactivity as well as unhealthy diets resulting in overweight and obesity [16]. A change of behavior, however necessary, is relatively unlikely to occur. While short-term behavioral changes may be accomplished rather easily, it is the long-term change that is of interest to affect one's health and well-being. Hence, motivational factors are paramount to be proposed and further focused on. One way to tackle this problem might be gamification of which several definitions are available. Deterding et al. [17] declared it as "the use of game design elements in non-game contexts." Gamification concepts are on the rise, invading not only the health sector, but a magnitude of disciplines and markets [18].

While electronic health records (EHR), respectively personal health records (PHR), are a much debated issue [9][15], their implementation and adoption leverages tracking and analysis of continuous patient data, thus, treatment progress.

Nonetheless, as of today, "gamifying" PHRs, in contrast to the adoption of rewarding concepts in online social networks [6][8][19] or wikis [7], has not been the center of attention.

This work-in-progress paper aims at identifying and evaluating reasonable motivational factors to be incorporated into EHRs/PHRs, respectively, health related information sharing platforms, in general, and proposes a methodology as well as an architecture in an effort to introduce change in behavior and mind upon encouraging a healthier lifestyle among people by means of an achievement based service.

The basic idea of this is to analyze, design and develop a prototype application which allows to gather information from different sources (e.g., a PHR) and to change the entered values into an achievement which can be displayed in a desired social network. An achievement system is a reward system, where players can complete goals and earn achievements for it, which are visible to others [6]. In case of this work those achievements do not contain any personal health data, but just display the activity itself. E.g., if someone enters the blood pressure, an achievement will be generated and displayed which shows that the user entered the blood pressure, but does not reveal the specific values. This system should then be evaluated to determine if such health achievements could be used to increase the usage of PHRs and to motivate other people to use it by communicating health activities.

The remainder of this work-in-progress paper is structured as follows. Section II gives an overview on current and related research subject to gamification and the health sector. Section III outlines methodology to gather information for developing an achievement based service. Section IV describes the basic architecture of such a system and Section V covers the conclusion and future work.

II. RELATED WORK

There are a few studies on EHR/PHR, in particular aspects like security, privacy and acceptance (like in

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[9][15]). The association thereof, with concepts traditionally known from the gaming industry and psychological discipline, i.e. social rewards/achievement systems, is scarce, if at all present in research. Here, we give an overview on what has been the recent center of attention.
Utilizing EHRs, or at least parts thereof, is subject to a certain extent of skepticism. Upon editing or entering data into EHRs results to be found were of neither positive nor negative connotation [1][15].

From a psychological point of view several theories for changing human behavior are existent. The Transtheoretical Model (TTM), Health Belief Model (HBM), Social Cognitive Theory (SCT), and the Theory of Reasoned Action/Planned Behavior are among the most common ones [23]. TTM delineates six stages [24], namely, precontemplation, contemplation, preparation, action, maintenance and termination, whereas adherence does not occur in a linear fashion [23]. SCT [21], on the other hand, relies on a construct called "triadic reciprocity" [23]. The individual, one's environment and one's behavior are all influencing, thus, affecting each other either way. Moreover, key concepts associated with this triadic cycle involve – to name just a few - behavioral capacity, expectations and reinforcement. The latter centers on achieving higher motivation to perform or change certain behavior by means of rewards and incentives [23]. Adding up further to that line, a sole intention is likely not enough to induce behavior change [22]. Hence, research on bridging mechanisms like certain motivators is yielded necessary. This is where the proposed achievement architecture in here comes into play.

Assuming that people are lacking some sort of motivation to update their health status, certain incentives as in gamification aspects could play a key role in raising people's interest and awareness. This becomes especially important since we put ourselves at risk to various diseases by engaging in unhealthy lifestyles. Several frameworks have already been established in an effort to empower individuals upon recording health activities as well as deliver them with an overview on their general lifestyle. There are a lot of applications allowing earning some sort of reward for reaching a goal, but those applications are not connected to each other and the earned goals are not always displayed in a social community. Apart from utilizing specific software to recover one's own data [3], approaches range from implementing wellness journals promoting mobile interaction [4], to the development of hardware devices, e.g., heart rate belts, body area networks (BAN), aiming at leveraging measurement and sharing of data with social networks [12].

Initial approaches have been undertaken to become familiar with people's reasoning as to why information and communication technologies and designated eHealth platforms are used in order to introduce behavioral change [5]. The underlying model could serve as a basis on designing the proposed survey in this paper.

A community dealing with amyotrophic lateral sclerosis (ALS) indicated that patients suffering from this neurodegenerative disease are more likely to communicate and share their own experience and health related information via support of peers [14]. Here, the underlying idea was not to hide or disguise one's health data, but rather, be open about it in an effort to share experience and help others coping [14]. A study [13] even points out that linking PHRs with social networks is increasingly becoming more important for patients. Hence, the proposed idea is likely to be of benefit to users struggling with one's health and well-being.

Achievements in video games are seen rather critically when it comes to user benefits [10]. Needless to say, that research solely carried out in theory provides only a limited indication for the success of this approach. Therefore, putting gamification to practice is favored. By means of utilizing WiFi or GPS signals, a client/server software architecture succeeded in transforming gamified aspects into real-life achievements, such as 'user has been to Paris once' [2].

Comparing the effects of using a photo-sharing environment that is associated with an incentive based service was the primary intention in [6]. Subject to this study, users did not report designated interest regardless of whether the achievement service had been provided to them or not [6]. A service for a wiki system to reward users with a ranking based on wiki-activity proposed several methods of bringing achievements to the people [7]. However their work was reported to be at an initial stage, still, which is why additional research to succeed in raising motivation was proposed.

In a study [20] a mobile application was developed to define and enter goals. When those goals are reached users are rewarded with trophies and ribbons, which can be displayed on facebook. After a test just three people (out of 23) did find the trophies and ribbons motivating.

In [8], a movie-rating community gives movie recommendations to members based on numerical ratings and reviews. Authors designated higher participation within the community upon assigning specific goals, whereas unspecific goals reflected quite the contrary. Interestingly, establishing group goals has shown to be of higher efficacy regarding individual movie ratings than no goal assignment at all [8].

Bearing in mind aforementioned research about social rewarding, achievement systems and services are suggested to succeed in raising awareness as well as motivating people towards higher contribution and sharing of health related data.

III. METHODS

The proposed methodology for an achievement based service can be found in Figure 1 (the numbers represent the order of the methodology, while the arrows indicate the dependency) and consists of the following steps. First, a literature research is conducted to get an overview of the

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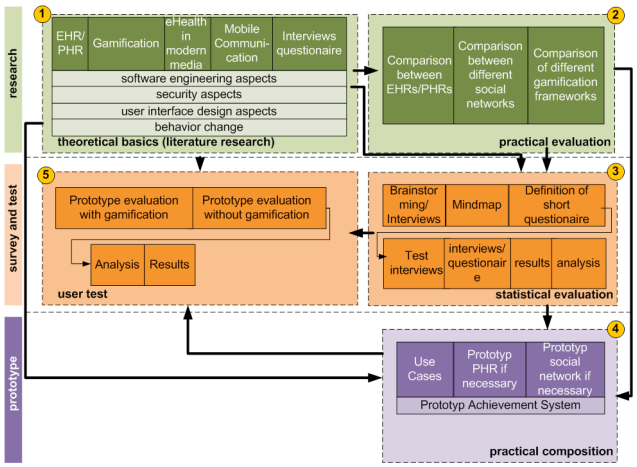

Figure 1. Methodology

current state of the art regarding needed topics. Topics besides general aspects (user interface design, security, software engineering and psychological aspects for behavior change) are gamification, eHealth in modern media, mobile communication, EHRs, PHRs and theoretical basics about interviews and questionnaires. Subsequently, a practical evaluation is carried out to compare different gamification frameworks which might be used to set up the prototype as well as a comparison between different PHRs and social networks to include in the prototype setting. This step is done to find out if there are services or applications that might be usable in the prototype setting. If no satisfactory result is found, the needed components will be newly implemented.

To explore people's visions and desires for such a system a few initial interviews will be conducted. In combination with brainstorming a mindmap will be drawn. Based on this a short questionnaire will be constructed to get sociodemographic data and to assign the interview partners to gaming categories (e.g., if someone plays games and is open to achievements). This should include the reference to the Bartle Type of Gamers [11]. Afterwards the interviews and the short questionnaire will be conducted and the results will be analyzed. As a consequence use cases will be drawn which will end up in designing and implementing an achievement system prototype (as well as a PHR and social network prototype if needed). After the implementation of the prototype, a few users (20 to 40 people) should test the system with the gamification service over a given period of time (about 2 months). The users should all have a positive attitude towards rewarding systems and achievements (which will be determined with the interviews and questionnaires) and should be between the age of 18 and 40. The users should be split up into two groups – for one group achievements will be generated and displayed but not for the other group. The reason for doing so is to uncover if there is a difference in the usage of such a system when a gamification service is present or not (which will be concluded in the results and analysis).

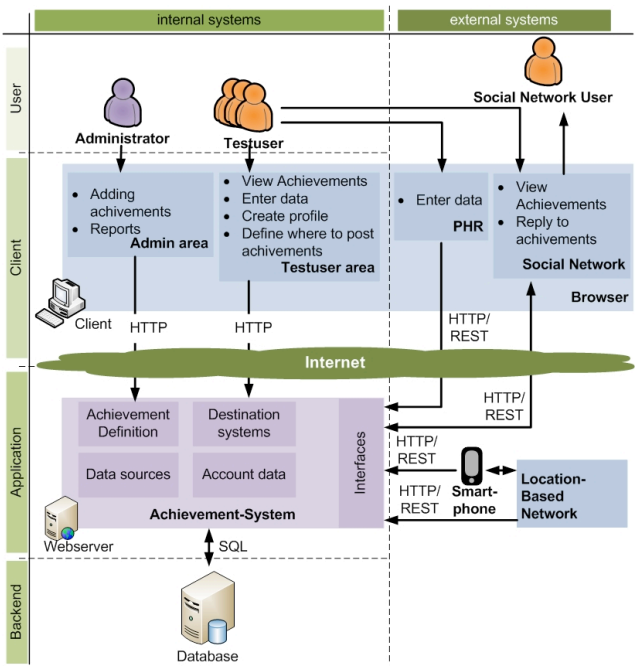

Figure 2. Architecture

IV. RESULTS

Based on the results from the interviews a final architecture will be postulated. However, a few basic requirements will be defined before. The architecture should be able to handle the definition, display and altering of achievements. It should be possible to have different views for different user groups (e.g., the administrator has the possibility to define new achievements), so each user can define where his achievements will be displayed. It should also be enabled to define a source for the health related data (e.g., PHR) as well as needed authentication to retrieve data from there. Moreover, including location based services, e.g., to get an achievement for checking in into a fitness center, is considered.

The basic idea of this architecture (see Figure 2) will consist of an internal system (the achievement service and all required components) and an external system, which will include all systems where data will be imported from or displayed to externally. The architecture is divided into a server and a client part. On the client side a user can access the prototype, a web application, with a browser. The data is transferred through the Internet with HTTP/REST and stored in an SQL Database. In summary the architecture relies on the following tiers:

- Client: Through the frontend the test users and the administrator can access the application with a graphical user interface (GUI). It will hold an admin area to define and add achievements as well as the possibility to display reports (which user has added information and which achievements have been

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reached, to use for the final evaluation) and a test user area (where the test users can view achievements, create and edit their profiles and to define where reached achievements will be displayed or posted).

- Application: Holds the application itself and acts as a communication layer between the achievement system and external systems (PHR, social networks and location based services).
- Backend: the backend will consist of the database to store the data.

V. CONCLUSION AND FUTURE WORK

This work presented a novel approach upon delivering insights into how and why people share their health related data with others. By means of a centralized achievement system an architecture and a methodology for the definition, development and analysis for such a system was given. Currently the evaluation is ongoing as well as the implementation of the basic requirements for the prototype of the achievement system in order to be tested afterwards.

Future work besides finalizing and evaluating the system includes an integration of such a system into the rehabilitation process for stroke patients using a serious game. People going through a rehabilitation therapy often experience a lack of motivation. By including an achievement system into such an online community, patients might be motivated and feel connected. That, in turn, might help them through their rehabilitation process and to achieve better results. Also, an evaluation should be conducted, finding out, if this approach might help people with their rehabilitation.

Being in good health and even more preventing illness is of utmost importance for each one of us. Hence, researching on it and support maintaining our health are worthwhile pursuing.

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Web-based Lifestyle Management for Chronic Kidney Disease Patients in a Clinical Setting

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***Abstract*—Maintaining a proper lifestyle is important for chronic kidney disease patients. This study investigates whether an online lifestyle diary supplementary to the support received in the outpatient clinic can help patients to get to such a lifestyle. A total of 33 participants expressed their willingness to participate in the study. However, 11 of them did not start actually. The remaining 22 participants used an online lifestyle diary. They received limited support regarding practical issues and feedback on lifestyle issues only when they asked explicitly. Questionnaires were used to determine the change in self-efficacy and self-management with regard to lifestyle after four months. Only five participants used the website successfully. They had already developed a good self-efficacy and self-management. A disappointingly large group hardly used the website. The effectiveness of using the website regarding self-efficacy and self-management was therefore limited in this particular situation. Insights of the outpatient clinic's caregivers and information from the participants partly clarify the factors involved in lifestyle management and coaching. Motivation of the participant appears to be an important factor as well as setting realistic goals. If a patient were to receive feedback on lifestyle issues regularly while working with the website, more satisfactory results might be obtained. Finally, the participant's (computer) skills and practical support played an important role. Taking these factors into account, the already comprehensive task of lifestyle coaching would be extended with specific new tasks, requiring the necessary skills and motivation of the caregiver.**

Keywords-chronic kidney disease; healthy lifestyle; online lifestyle diary; self-efficay; self-management; intervention.

I. INTRODUCTION

It has been estimated that among adults the prevalence of chronic renal failure, varying from mild renal insufficiency to end-stage renal disease, is between ten and eleven percent [1]. Since age plays an important role in the development of renal insufficiency, with an aging population the prevalence of chronic renal disease will only increase.

It has been recognized that for many patients maintaining a proper lifestyle helps to reduce the deterioration of the renal function [2, 3]. Besides taking the prescribed medication, regular exercise, smoking cessation and maintaining a healthy weight, a specific kidney failure diet is an important part of the treatment plan [4]. The recommended diet may change over time if the kidney disease deteriorates.

The Isala klinieken in Zwolle is one of the Dutch hospitals with an outpatient clinic for chronic kidney disease (CKD) patients. Often these patients need to adapt their lifestyle. A multidisciplinary team which consists of nephrologists, dieticians and nurse practitioners supports the patient in achieving the necessary behavioural. Interventions made by the team aim at increasing the self-efficacy and the self-management of the patient. For the caregivers in Zwolle motivational interviewing [5] is the preferred conversation style when they talk with patients about lifestyle.

Obviously the treatment varies from patient to patient, as does the number of visits to the clinic. Typically a patient will have two conversations per year with a nurse practitioner about issues concerning lifestyle, self-efficacy and self-management beside treatment by a nephrologist and advice from a dietician. The nurse practitioners found the time between two such conversations too long for their patients. Opportunities to support them better between visits in the outpatient clinic were therefore investigated. This led to the question whether a web-based tool, supplementary to the support from the outpatient clinic, could help patients to maintain a proper lifestyle [6, 7].

The results of a randomized controlled trial by Chen et al. [8] indicate that a standardized self-management support programme may play a significant role in reducing CKD progression and morbidity of late-stage CKD patients. Jansen et al. present an intervention programme for patients with end-stage renal disease and their partners [9]. Their findings show that an approach in which cognitive, emotional, behavioural, and contextual aspects are integrated is promising.

However, a study by Elzen et al. [10] did not yield any evidence for the effectiveness of the well-known Chronic Disease Self-Management Program (CDSMP) on self-efficacy, self-management behaviour or health status of older patients in the Netherlands. The authors presume a ceiling effect, pointing out that in the Netherlands chronically ill patients do not usually only see a physician, but also a specialized nurse who gives them a lot of information about various aspects of self-management. Blanson Henkemans et al. recognize that self-management has become common practice [11]. They advocate a longitudinal empirical study

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to investigate whether self-management will lead to labour savings.

Self-management programmes may be complemented by web-base lifestyle tools. Wyatt et al. evaluated the effectiveness of an Internet-based 12-week programme in supporting weight loss [12]. They found that this programme could, among others, successfully produce meaningful weight loss. Dilorio et al. report the results of a research study evaluating a web-based epilepsy self-management intervention [13]. The study findings show that this programme can be an effective means to encourage self-management. Araújo et al. compared the feasibility and clinical outcomes of a standard paper-based asthma self-management strategy with web-based strategies [14]. They concluded that web-based management was feasible, safe, and preferred by patients. They found that short-term outcomes were at least as good. Bromberg et al. studied a web-based intervention to improve migraine coping and self-management [15]. They concluded that this intervention may be a useful behavioural adjunct to a comprehensive medical approach to managing migraine. Blanson Henkemans et al. enhanced an online lifestyle diary with a persuasive computer assistant (an animated iCat) [16]. They concluded that this approach is likely to support motivated overweight people and individuals with lifestyle-related diseases to get a better insight into their self-management and adhere to it.

However, some studies report poorer results. Kerr et al. studied web-based interventions for heart disease self-management [17]. This study showed that the intervention did not result in a large number or all types of patients with coronary heart disease using the intervention for self-management support. Verheijden et al. investigated rates and determinants of repeat participation in a web-based health behaviour change programme [18]. They found that behavioural intervention programmes may reach those who need them the least. Kelders et al. investigated the users and effect of a web-based intervention aimed at healthy dietary and physical activity behaviour [19]. They found that respondents did not use the application as intended and that users were healthier and more knowledgeable about healthy behaviour than non-users. Nijland et al. explored the factors that influence the initial and long-term use of a web-based application for supporting the self-care of patients with type 2 diabetes [20]. This study also mentions a ceiling effect. Moreover, usage of the application was hindered by low enrolment and increasing non-usage.

None of these studies deals with web-based lifestyle management for chronic kidney disease patients. The present paper therefore discusses the introduction of a web-based lifestyle diary supplementary to the care CKD patients receive in Isala's outpatient clinic. A pilot was carried out to determine the effectiveness with regard to self-efficacy and self-management of using an online lifestyle diary.

The paper is structured as follows. Section II discusses the preparatory steps taken before the pilot started, followed by a description of the applied method in Section III. Section IV gives an overview of the results of the pilot followed by a discussion in Section V. Section VI concludes the paper.

II. PREPARATORY STEPS

Based on the results of interviews conducted with caregivers at Isala's outpatient clinic, an Internet search was carried out in order to select a lifestyle management website for CKD patients. Eleven candidate software tools were identified. Of these candidates dieetinzicht.nl [16] was considered the most promising application.

To verify whether the selected website was suitable for supporting lifestyle management for CKD patients a user experiment was conducted involving six participants who all had undergone a successful kidney transplant. After a week they completed a questionnaire in which their experiences were recorded. Further information was collected in a focus-group meeting.

The participants held the opinion that the website they had used should not be seen as a replacement of the contact with caregivers but that the website would contribute to the lifestyle management of patients with CKD. Moreover, they indicated that patients should be sufficiently skilled in using a computer.

June 2011 Bonstato B.V. launched mijnnierinzicht.nl, a new website based on dieetinzicht.nl [21]. This new website has been developed with support of the Dutch Kidney Foundation ("de Nierstichting") and augmented the original website, among other things, with a communication module and the possibility to record data about daily exercise as well as smoking habits. The website mijnnierinzicht.nl contained all functionality required for the pilot. Moreover, it offers extensive support for maintaining a proper diet. By accurately entering data about consumed meals in a diary, comprehensive information can be obtained about nutrition components such as minerals and vitamins in the CKD patient's diet. For this purpose mijnnierinzicht.nl contains a database with information about a large number of products. Most of the aforementioned studies did not report such an elaborate functionality.

To check the materials developed for the pilot, such as a Quick Start Guide, and the intended procedure, a pre-pilot was conducted. For this pre-pilot seven patients were invited who had dialysis. They used the website for one to two weeks. Five participants completed the pre-pilot, the two others stopped due to personal circumstances. The pre-pilot only led to minor adjustments in the tested materials. One of the participants was particularly confident: *"This can hardly go wrong, even for the elderly and people who are not used to working with a computer the manual is very clear."* Some participants were positive about mijnnierinzicht.nl ("*a beautiful site which certainly has added value*"), although another participant warns that the site is too time-consuming in proportion to the benefits.

III. METHOD

Participants in the pilot were selected from Isala's outpatient clinic for patients with chronic renal insufficiency. None of them had dialysis. Moreover, they should be able to use a web browser and e-mail and speak Dutch. Depression or cognitive complaints could be a reason for exclusion. Patients who were considered to be potentially successful

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users of the website were invited for the pilot in a telephone call some days before their next visit to the clinic. If they were willing to participate, they were sent a two-page sheet containing information about the pilot.

At the next visit to the clinic the participants filled in an informed consent as well as the first of two questionnaires. This questionnaire contained seven questions dealing with self-efficacy related to lifestyle. Five questions dealing with self-management completed this questionnaire.

The participants also received a Quick Start Guide, both in print and on a USB-stick. This 33-page guide informed them how to enter data with respect to diet, activities (sport, leisure) and smoking habits. It also showed how users could get insight into their lifestyle, using the various tables and graphs of mijnnierinzicht.nl. Moreover, a chapter dealing with the communication module was added. The participants were free to decide how often and when they wanted to use the website and for what purposes.

The participants were asked to use the website for four months. After a week they received an e-mail asking them whether they had actually started. Help was offered if needed. During the pilot, participants were invited to ask for assistance or to ask for feedback through the communication module of the website. Obviously, if they contacted the clinic in the usual way such as by e-mail or telephone, they were answered equally. Each month the participants received an e-mail in which they were invited to attend an informal consultation hour where they could also receive help if they encountered any practical difficulties in working with the website. In this e-mail participants were asked to report how many times they had used the website in the past month. The e-mail also contained a newsletter informing the participants about the progress of the project. Each newsletter contained an interview with somebody who was involved in the project.

Two types of support should be distinguished: help with practical issues such as creating an account for the website and support regarding lifestyle. As all sorts of tasks are done nowadays using the Internet, such as buying books and completing tax forms, it was expected that most participants would be able to use the online diary independently with the help of the Quick Start Guide. Only when the patient took the initiative to contact the caregiver, for instance via the communication module of the website, lifestyle-related advice was given. This study looked into the effects of using the website separate from the usual treatment on self-efficacy, self-management and lifestyle.

After a period of four months the second of two questionnaires was sent to the participants. This second questionnaire repeated the questions of the first so that changes in self-efficacy and self management could be determined. Moreover, questions were added asking whether the website had helped to achieve a proper diet, a healthy weight, sufficient exercise and smoking cessation. It was also asked whether using the website was time-consuming and difficult to use. Participants also reported about the added value of the website and it's communication module to the visits at the clinic. A question was added asking about the frequency of use of the website. The second questionnaire allowed the participants to add explanations to their answers.

If the second questionnaire was not received in due time, the participant was contacted by telephone, or e-mail or reminded orally at their next visit in the clinic. In order not to damage the trust between clinic staff and patients, participants had to be treated with gentle insistence.

Finally, the researchers discussed the results with the participating caregivers of the outpatient clinic in a focus group meeting.

IV. RESULTS

A total of 33 participants expressed their willingness to participate in the pilot. However, eleven of them did not actually start. They did not hand in an informed consent nor the first questionnaire (Group I). From seventeen participants an informed consent and a first questionnaire were received, but this group hardly used the website (Group II). Five participants used the website often enough to be meaningful for them, as described below (Group III). Table I summarizes the main results of the three groups. Age only seems to play a role in actually starting. The numbers for self-efficacy and self-management are rated on a scale from 1 to 5, with 5 representing a high self-efficacy and high self-management. The figures in Table I should be treated with caution because of the small number of participants. The table suggests that the participants in Group III had already developed a better self-efficacy and self-management than the members of Group II. No significant differences were found between the first and the second questionnaire with respect to self-efficacy. On average, only self-management regarding nutrition changed: the five participants on average scored 0.8 points higher. Next the response rates of the e-mails sent to the participants are included in the table. Again, Group III shows better results. Finally, the table shows the reasons why the participants in Group I and II did not use the website successfully. They informed the research team about these reasons responding to the monthly e-mails or through other contacts such as visits to the clinic.

TABLE I. MAIN RESULTS OF THE PILOT

Group	I	II	III
group size	11	17	5
male / female	8/3	13/4	4/1
age (av.)	59.8	55.2	55.6
number of smokers	N.A.	2	0
self-efficacy (av.) before pilot	N.A.	3.7	4.5
self-efficacy (av.) after pilot	N.A.	N.A.	4.4
self-management (av.) before pilot	N.A.	3.4	4.2
self-management (av.) after pilot	N.A.	N.A.	4.4
response month 1	N.A.	41 %	60 %
response month 2	N.A.	24 %	100 %
response month 3	N.A.	29 %	60 %
response month 4	N.A.	35 %	80 %
too busy or lack of motivation	3	2	N.A.
technical problems	1	3	N.A.
lack of (computer) skills	4	8	N.A.
unknown or other reasons	3	4	N.A.

The technical problems mentioned in the table include not having Internet at home. Among the reasons referred to

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in the bottom row of the table there was a case of severe illness. To mention another example, one participant refused to create an account because of bad experiences with other organizations. In more than half of the cases participants stopped due to technical problems or lack of skills.

One of the five participants in Group III had developed his own Excel application to store information for lifestyle management concentrating on sodium, potassium and protein. He has been using it for a long time. He entered data in mijnnierinzicht.nl for 25 consecutive days and after that with decreasing intensity until he found confirmation from the website that his lifestyle was indeed healthy. He felt that the website might be difficult to use for elderly patients but considered the website very useful for patients who had just learned that they suffered from renal insufficiency.

A second participant used mijnnierinzicht.nl to learn about the components in his nutrition, for which he considered the website very valuable. Once he had detected a recurrent pattern he stopped with the intention to use the website again if necessary. At some point the laboratory results of this participant showed a high sodium level in his urine. The website helped to find out that this was caused by the medicines he used and not his diet.

A third participant of these five used the website to get to a proper diet and a healthy weight. Once he had reached his goals he decided to use the website less intensively. A fourth participant benefitted from the website to reach a healthy weight and a sensible diet with respect to potassium and sodium. The last of five participants used the website to get to a proper diet.

All five participants reported that they had experienced no difficulty using the website. Four of them felt that it took little time to enter the necessary data while a fifth participant answered neutral. It should be noted that the participants filled in the second questionnaire after having spent time using the website. A participant who reported that entering the data took little time mentioned in an e-mail a few weeks after he had started that working with the website was time-consuming.

With respect to the question whether the website was useful in addition to the conversation in the clinic about lifestyle the picture was unclear. The same goes for the question whether the communication module of the website was helpful in maintaining a healthy lifestyle. Opinions among the participants were divided with respect to both questions.

During the focus-group meeting the caregivers recognized the potential value of the website for their patients. Moreover, they realized that they could gain more detailed information faster. The caregivers discerned a number of factors which may influence the successful use of an online lifestyle diary. Apart from the patient's motivation and skills and the question whether the patient can spend enough time when being introduced to the website is of importance. If a patient is just starting to realize the consequences of his or her disease, it may be sensible to postpone the use of the website for some time. Considering the high number of patients who hardly used the website, the caregivers discussed the possibility to integrate the online lifestyle diary in the existing coaching process. Although they expected an improvement of care if feedback was given more actively, it remained unclear whether this would lead to more efficiency.

V. DISCUSSION

The aim of this study was to determine the effectiveness with regard to self-efficacy and self-management of using an online lifestyle diary. CKD patients were asked to use the diary supplementary to the care they received from the outpatient clinic. Participants in the study worked with this online diary independently, which meant that they did not receive active coaching aimed at goal setting when using the website, nor did they receive any guidelines regarding the duration or frequency of use of the online diary. The help offered was mainly concerned with practical use of the website. Regarding lifestyle issues the participants were not supported actively while working with the website. However, they were invited to ask questions about their lifestyle, preferably using the communication module of the online diary.

Apparently, for a minority of the participants this was sufficient. In view of the results from Table I it is not surprising that an overall improvement could hardly be observed, comparable to the ceiling effect mentioned before [10, 20], with an exception for self-management regarding nutrition. These participants were motivated to change their lifestyle if necessary and were able to set realistic goals. The higher response rate of the monthly e-mails also illustrates the motivation of this group.

Despite their willingness to participate in the present study a large majority of the participants did not use the website successfully for reasons mentioned in Table I. Such results were disappointing. Some of the aforementioned studies have reported comparable results [17-20].

Insights of the caregivers, the positive results observed and the reasons why participants hardly used the website help to understand web-based lifestyle management better. It should be noted that the reasons for the poor results are multifactorial and that the findings of the present study do not clarify the relations between the various factors involved. It is possible, however, to mention a number of important factors.

A. Motivation

Caregivers noticed that patients may wish to carry on with their life and be reluctant to spend time on detailed lifestyle management tasks, despite their chronic disease. Not all patients who want to take up such tasks may find the idea of working with a computer very attractive. The routine of regularly entering data into the online diary over a prolonged period of time requires concentration and time. When advising a patient to use an online lifestyle diary, one should take into account the patient's stage of change discerned in motivational interviewing and verify whether the patient is sufficiently motivated to change their lifestyle and use the website, taking into account socially desirable responses. Can he or she find the discipline to use the website long enough? Internal and external motivation

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factors should be discerned. Conversations with participants suggest that in the present study some of them may have been motivated extrinsically because they were prepared to help researchers when kindly asked. Obviously this motivation differs from an intrinsic motivation to improve one's their lifestyle.

B. Realistic goals

Participants using the website successfully did so for a specific purpose and during a sufficiently long but limited period of time. They tended to use the website when special events occurred or when they felt the need to obtain conformation about their lifestyle. This shows, in accordance with the findings of behavioural psychology [22], the importance of setting specific and attainable goals. If the caregiver should, contrary to the approach taken in this study, choose to coach patients in setting goals for working with the website, it might be expected that patients gain more from it. In such an integrated approach (i.e. integration of using the online lifestyle diary in the existing coaching process) the caregiver will discuss goals with the patient, taking into account, among other things, the illness perception of the patient and the necessary change in lifestyle. Moreover, the caregiver will advise about the period of time and frequency of using the diary.

C. Feedback and coaching

A further step in integrating the usual coaching and the online lifestyle diary would be taken if the caregiver should look actively into the information entered by the patient in order to give feedback. It may be expected that patients will be encouraged to improve their lifestyle with the help of the website if they receive feedback regularly: Nijland et al. remark that in their study personalized feedback appeared to be one of the most promising features for long-term usage of the application [20]. Initially this feedback can be given more often. Later on, as the patient is sufficiently empowered, the time between two contacts may be longer. To avoid surprises it should be agreed beforehand when messages will be received. Depending on the nature of the feedback a response may be given in writing, over the telephone or face to face.

D. Skills and practical support

Obviously, for web-based lifestyle management patients should have easy access to a computer and the Internet. Moreover, the patient must be sufficiently skilled in using a computer. Even with an increasing number of people who use a computer regularly this remains an issue as entering detailed information in an online diary requires skills that differ from ordinary tasks. Help with technical problems and training must be separated clearly from feedback on lifestyle topics. For example, one of the participants in this study faced problems creating an account because he was not aware that a username should not contain a space. Preferably, such practical problems should not be dealt with by caregivers (although they did so in a number of cases) but, for instance, by a helpdesk.

Summarizing, it is clear that web-based lifestyle management can be a complicated and elaborate task for CKD patients. Advising when and how to use the website caregivers should weigh each patient's unique situation. The present study shows, however, that it can be difficult to assess a patient's skills and motivation properly, demonstrating the need for improved assessment tools and techniques.

E. Further considerations

A changed approach to patients who work with the website as described above may also affect the daily work of caregivers. Apart from logistic matters such as reserving time slots to give patients feedback via the communication module of the website, the necessary infrastructure must be realized. For instance, integration of the data for the online diary tool with the patient's Electronic Health Record is expedient. It remains unclear whether the care improved through the website will be more time-consuming or not.

Some of the factors mentioned above can be found also in the usual coaching. The importance of setting realistic goals, for instance, is widely accepted. However, web-based lifestyle management adds new aspects to the caregiver's already extensive task of lifestyle coaching. Apart from assessing the patient's skills and motivation for online lifestyle management, new opportunities and challenges emerge when care is given through online feedback. What applies to patients equally applies to caregivers: they should be sufficiently motivated for online lifestyle coaching and may need to acquire new skills for that.

Moreover, in order to be successful web-based lifestyle management needs to be facilitated sufficiently. The user-friendliness of the online diary should be improved. To mention two examples, navigation must be intuitive and the database for nutrition products should be as complete as possible and more easily accessible. Finally, the website used in this study can be used without cost until 2016. However, given the tendency in the Netherlands to implement e-health only as a substitution of the usual care [23] an extensive financial analysis is necessary for online lifestyle coaching.

VI. CONCLUSION AND FURTHER RESEARCH

In this small-scale qualitative study an online lifestyle diary was introduced while participants were helped mainly with practical issues only. With this approach only a small group of users used the online diary successfully. It follows that the effectiveness of using the website with regard to self-efficacy and self-management was limited in this particular situation. Web-based lifestyle management appears to be a complicated and elaborate task for patients, requiring motivation and skills. Lifestyle coaching with an online diary, integrating the website into usual care, likewise requires motivation and skills.

To reach the full potential of web-based lifestyle management and coaching a number of issues must be addressed. The concept of online lifestyle coaching needs to be developed further exploring questions such as how a caregiver can appropriately assess a patient's skills and motivation, how to estimate which support will be necessary

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and how the intensity of online lifestyle coaching should change over time. Further development of web-based lifestyle management and coaching needs to be rooted in behavioural theory, applying an adequate psychological model, and needs to clarify the relations between the various factors involved. Finally, technology can still be improved, including usability of the website.

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Recognizing Physical Activities Using the Axivity Device

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***Abstract*— Physical activity is a major part of a user's context for wearable computing applications. The system should be able to acquire the user's physical activities by using body worn sensors. We want to develop a personal activity recognition system that is practical, reliable, and can be used for health-care related applications. We propose to use the axivity device [1] which is a ready-made, light weight, small and easy to use device for identifying basic physical activities like lying, sitting, walking, standing, cycling, running, ascending and descending stairs using decision tree classifier. In this paper, we present an approach to build a system that exhibits this property and provides evidence based on data for 8 different activities collected from 12 different subjects. Our results indicate that the system has an accuracy rate of approximately 92%.**

Keywords-component; Physical activities; accelerometer sensor; classifier.

I. INTRODUCTION

Human activity recognition by using body worn sensors has received attention in recent years. Activity recognition systems in health care support especially in elder care, long-term health/fitness monitoring, and assisting those with cognitive disorders [1, 2, 3] has been demanded. Therefore, recognizing human physical activities with body worn sensors is not a new research field; much research has already been done in this area. We can identify users' physical movements using a body movement suit [2]. We also have other research projects where researchers identify the users' physical activities using some sensors like [3, 4, 5, 6, 7 and 8].

In some diseases like diabetes, heart problems, mentally disabled persons, elder patients are required to perform some physical activities in order to make them physically fit. Similarly, in some cases patients need to be monitored by nurses which is very time consuming and expensive.

Modern day lifestyle has lead to various physical and mental diseases such as diabetes, depression and heart diseases as well. According to the World Health Organization, there are at least 1.9 million people dying as a result of physical inactivity annually [10].

Although, people are aware of the importance of exercise there is a lack of motivation due to their busy schedules. People need to be forced and reminded about physical activities. Probably automatic and personal reminders can be very helpful if it can monitor one's physical activities and persuade people to perform them regularly.

Activity recognition technology can tackle this problem as it is able to monitor an individual's physical activities and their duration in order to estimate how much calories are being consumed on a daily basis. Those systems can also provide recommendations when they fail to complete enough exercise and it also encourages people to conduct more activities [12, 13 and 14].

In some cases, especially in heart diseases, physical activities are also required along with the physiological information for doctors in order to examine their patient's conditions when he is away from the doctor's clinic [19].

We want to develop a physical activity recognition system using a minimum amount of sensors which should be able to identify the basic activities like lying, walking, running, sitting, standing, cycling, ascending and descending stairs.

In our research we want to prove that it is possible to identify the aforementioned activities for a specific user by using a 3D accelerometer. In next chapter, "related work" will be discussed, "hypothesis and research question" will be discussed in the 3rd chapter, "experimental methodology" will be discussed in the 4th chapter, "evaluation" will be discussed in the 5th chapter and "conclusion and future work" will be in the last.

II. RELATED WORK

There are several ways to recognize a person's daily activities. One way is using cameras to visually detect people's motion [15, 16].

The drawback of this solution is that a large number of cameras would be required in order to monitor a moving person. This system would also need to be designed to compute information from each camera and deal with other factors such as light, distance and angle, which make the system impractical.

Researchers have identified various physical activities using wearable sensors like sitting[3,6,7,8], standing [3,6,7,8], lying [6], walking [3,4,5,6,7,8], climbing stairs [3,4,6,7,8], running [5,7,8], cycling [5,8], strength training [8] etc. However for their recognition system they have used more than one sensor. For example, some researchers identified around 20 activities using 5 sensor boards. They identified walking, walking carrying items, sitting & relaxing, working on computer, standing still, eating or drinking, watching TV, reading, running, bicycling, stretching, strength-training, scrubbing, vacuuming, folding laundry, lying down & relaxing, brushing teeth, climbing

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stairs, Riding elevator and Riding escalator using Decision Table, IBL, C4.5 and Naive Bayes algorithms. They placed sensors on the limb positions and on the right hip [8]. Similarly researchers identified 12 activities using 3 sensor boards, they identified sitting, standing, walking, walking up stairs, walking down stairs, riding elevator down, riding elevator up, brushing Teeth[3], researchers identified 3 activities; walking, climbing stairs and descending stairs using 9 tilt switches using K-means clustering and brute force algorithms, these sensors were worn just above the right knee [4].

In our work, we want to use only one 3D accelerometer sensor in order to identify a few activities. A few of these physical activities (lying, sitting, walking, running) have already been identified by using a single device [9] but in our research we want to identify more physical activities by using a single wearable 3D accelerometer sensor and we also want to use different locations on a person's back, as opposed to the approach presented in paper [9] where the focus was only on the lower part of a person's backbone.

III. HYPOTHESIS AND RESEARCH QUESTION

The acceleration measured by a 3 axis accelerometer (X,Y,Z) at a specific point (backbone), indicates which activity the person is performing (lying, sitting, walking, standing, cycling, running, ascending and descending stairs), using classifier algorithms (J48, AODE).

In this paper, we investigate some practical aspects of creating an automatic, personal activity recognition system. Through our experiments, we want to find the answers of the following questions:

• Is it possible to identify which activity the person is performing (lying, sitting, walking, running, standing, cycling, ascending and descending stairs) by using a 3D wearable accelerometer sensor on participants' backbone?

• Which particular location on a person's backbone is better for identifying these activities?

IV. EXPERIMENTAL METHODOLOGY

We used AX3 data logger [1] in order to identify physical activities (as shown in Figure: 1).

Figure 1: Axivity device

It was worn on the participants' backbone and they wore it on three different locations of their backbone; lower, middle and upper part respectively (as shown in Figure: 2). Participants were required to perform each activity for two minutes; one minute was meant for training data and other minute was for test data.

The AX3 data logger contains 3-axis of accelerometer with flash memory and clock. This device is small and easy to use, its dimensions are 6x21.5x31.5 mm and its weight is 9 grams.

The device comes with pre-installed software with the possibility to configure its settings. For example, we can configure sample rate, gravity etc. It continuously logs contextual information (time; hh:mm:ss and axis; X, Y, Z) to its internal memory. We can also set the duration for logging this information. There is also a possibility to export the logged data from the device to a computer in CSV format.

In order to attach this device on the participants' back, we used sticky tape which was directly placed on the skin. We logged continuous data with 8G and the sample rate was 100 Hz.

We implemented an application for 'Pocket PC' where we can state the starting and ending time for each physical activity during experiments. This application generates text files with this information for each physical activity for both training data and test data. It also stores the participants' personal information i.e. age, gender, height and weight. We implemented another application in Java for analysis; we used WEKA APIs [17] in order to use machine learning algorithms. This application requires three input files: both training and test data from 'Pocket PC' as well as the CSV file from the axivity device. Firstly, it filters needed data from the CSV file based on the time stamp from the files from the 'Pocket PC for each physical activity and generates training and test data files in ARFF format. Later, it applies J48 and AODE algorithms on training data for generating models from both machine learning algorithms. After-wards these models take data as an input in order to predict their values and compared with ground truth.

We recruited 12 testers (7 males, 5 females) for our experiment setup. The range of participants' age was from 20 to 30 and ranged in BMI (body mass index) [10] from 18.7 to 28.7 (mean 23.1, SD 2.98). They performed each physical activity (Lying, Sitting, Standing, Walking, Running, Cycling, Ascending and Descending stairs) twice. Two of our testers could not participate in 'Cycling' activity. Participants' were continuously observed during experiments.

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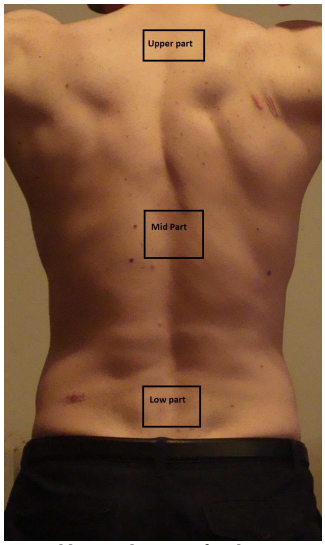

Figure 2: Backbone's location for the axivity device

V. EVALUATION

At the end we collected data from 12 participants and each participant performed eight different physical activities (except two participants who performed only seven), each physical activity contains a data of two minutes with a sample rate of 100Hz which implies we gathered (100X60X2X8) 96,000 instances for each data-set except two where we managed only 84,000 instances. We divided each data-set into two parts; one part was for training data and other was for test data. We generated a model from training data and then applied it to test data in order to predict the values. We got 100 values(X, Y, Z) from the axivity device for each second because the sample rate was set to 100 Hz and we also got 100 predictions for each second. We wanted to have a single prediction for each second, therefore the activity with the maximum number of instances per second was chosen. This resulted in a single value for each second, instead of the 100 values that are received from the axivity device every second, leading to a much easier analysis of the experiment. After-wards these single values were compared with the ground truth of the physical activity to realize the accuracy of our test.

TABLE I. PREDICTED RESULTS FROM BACKBONE'S LOWER PART

	Min	**Max**	**Avg**	**SD**
	J48	***(J48)***	***(J48)***	***(J48)***
	AODE	***(AODE)***	***(AODE)***	***(AODE)***
Lying	56.67	100	95.14	12.58
	93.33	100	99.31	1.94
Walking	100	100	100	0
	88.33	100	98.75	3.34
Running	81.67	100	97.3	5.6
	90.91	100	98.97	2.71
Sitting	65	100	96.14	9.93
	73.33	100	96.97	7.58
Standing	88.33	100	98.06	3.95
	86.67	100	97.51	4.52
Cycling	83.33	100	97	5.26
	80	100	96.5	6.16
Ascending stairs	0	98.33	84.4	27.62
	0	100	84.63	27.66
Descending stairs	18.33	100	82.15	21.65
	11.67	100	80.89	23.78

Our results (Table 1) show that placement of the axivity device on the lower part of the backbone was able to predict all physical activities with the accuracy of more than 80%. Lying, Walking, Sitting, Standing and Cycling activities were predicted with the accuracy of more than 95%. Walking activity was predicted 100% by J48 classifier.

TABLE II. PREDICTED RESULTS FROM BACKBONE'S MIDDLE PART

	Min	**Max**	**Avg**	**SD**
	(J48)	***(J48)***	***(J48)***	***(J48)***
	(AODE)	***(AODE)***	***(AODE)***	***(AODE)***
Lying	40	100	92.08	17.82
	93.33	100	99.16	1.94
Walking	96.67	100	99.58	1.04
	95.33	100	99.06	1.59
Running	91.38	100	98.84	2.81
	93.1	100	98.56	2.44
Sitting	46.67	100	90	18.33
	46.67	100	90	18.35
Standing	30	100	85.83	21.76
	35	100	86.66	20.65

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Cycling	81.67	100	97.83	5.8
	76.67	100	96.83	7.3
Ascending stairs	6.67	98.33	80.7	24.32
	23.33	100	83.05	21.12
Descending stairs	73.33	100	84.75	13.5
	63.33	100	88.35	10.42

Our results (Table 2) show that placement of the axivity device on the middle part of the backbone was able to predict all physical activities with the accuracy of more than 80%. Walking activity was predicted 99% by J48 and AODE classifiers.

TABLE III. PREDICTED RESULTS FROM BACKBONE'S UPPER PART

	Min	**Max**	**Avg**	**SD**
	J48	**J48**	**J48**	**J48**
	AODE	**AODE**	**AODE**	**AODE**
Lying	60.67	100	95.75	11.23
	96.67	100	99.72	0.96
Walking	48.33	100	92.78	15.1
	61.67	100	94.58	11.42
Running	93.1	100	97.9	3.45
	90	100	98.04	3.26
Sitting	1.67	100	80.7	37.59
	0	100	78.2	37.57
Standing	58.33	100	92.08	12.6
	61.67	100	90.97	12.15
Cycling	96.67	100	99.33	1.17
	95	100	99.17	1.62
Ascending stairs	15	100	80.03	24.37
	21.67	100	81.23	22.54
Descending stairs	43.1	93.33	75.95	20.34
	40	100	83.68	17.34

Our results (Table 3) show that placement of the axivity device on the upper part of the backbone was able to predict all physical activities with the accuracy of more than 75%. Cycling activity was predicted 99% by J48 and AODE classifiers.

TABLE IV. COMPARISON WITH ALL BACKBONE'S LOCATIONS

	Low	**Mid**	**Up**
	J48	**(J48)**	**(J48)**
	AODE	**(AODE)**	**(AODE)**
Lying	95.14	92.08	95.75
	99.31	99.16	99.72
Walking	100	99.58	92.78
	98.75	99.06	94.58
Running	97.3	98.84	97.9
	98.97	98.56	98.04
Sitting	96.14	90	80.7
	96.97	90	78.2
Standing	98.06	85.83	92.08
	97.51	86.66	90.97
Cycling	97	97.83	99.33
	96.5	96.83	99.17
Ascending stairs	84.4	80.7	80.03
	84.63	83.05	81.23
Descending stairs	82.15	84.75	75.95
	80.89	88.35	83.68

Our results (Table 4) show that "laying" activity was predicted with an accuracy of 99% by the AODE classifier from all locations, "Walking" was predicted with more than an accuracy of 98% from lower and middle parts of backbone, "running" was predicted with more than an accuracy of 97% from all locations, "sitting" was predicted with an accuracy of 96% from lower backbone, "cycling" activity was predicted with more than an accuracy of 96% from all locations, "ascending stairs" activity was predicted in the range of 80% to 85% by J48 and AODE classifiers from all locations and "descending stairs" activity was predicted in the range of 84% to 89% by J48 and AODE classifiers from middle part of backbone.

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TABLE V. BACKBONE'S LOCATION-WISE PERFORMANCE

	Min	**Max**	**Avg**	**SD**
	J48	***J48***	***J48***	***J48***
	AODE	***AODE***	***AODE***	***AODE***
Low_backbone	82.15	100	93.77	6.66
	0	99.31	94.19	7.19
Mid_backbone	80.7	99.58	91.2	7.13
	83.05	99.16	92.71	6.43
Up_backbone	75.95	95.75	89.32	9.06
	81.23	99.72	90.7	8.6

Our results (Table 5) show that our system was able to predict physical activities with better accuracy rate (in terms of average) if acceleration data is coming from lower part of the backbone.

VI. CONCLUSISION AND FUTURE WORK

Our system is able to recognize a high percentage of the physical activities with the help of the decision tree and AODE classifiers. Results have shown that one 3D accelerometer sensor is enough for identifying a few physical activities (sitting, standing lying, walking, running, cycling, ascending and descending stairs). For every user, the system needs to be trained with the sensor data so that it would be able to predict the physical activities using the axivity device. This prototype is only a "proof of concept" and our results show that a single 3D accelerometer sensor can identify the above mentioned physical activities independent of BMI (body mass index) and age group. The accelerometer sensor has to be fixed properly on the backbone of the tester in order to predict the tester's movements successfully. To conclude our discussion we can safely lay claim to being able to identify the aforementioned physical activities by using a 3D wearable accelerometer sensor and our results show that lower part of the backbone can be a good location for the wearable 3D accelerometer sensor.

We will put the accelerometer sensor on other parts of the body in order to identify some other physical activities and we will use it for online machine learning.

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A Common Platform for AAL Services and a Common Future – The universAAL Project

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***Abstract* -- universAAL is a European project set in motion to push and aid the market for AAL services and products. Its main objective is to make it technically possible and economically affordable to develop AAL services by providing a common, open, European platform, which sets up a market for buyers, sellers and users to meet and by supplying tools, a reference architecture and software components which aid the developing process. Simultaneously, a community is being established to foster interest and to gain widespread adoption of the universAAL platform.**

Keywords – AAL; platform; interoperability.

I. INTRODUCTION

The demographic challenges are rising as the European population ages. More support is and will be needed with fewer hands to cater for these needs. A large EU project has been established to make new Ambient Assisted Living (AAL) services technically feasible and economically viable to develop [1].

The potential benefits of AAL solutions have already been clearly recognized with a huge market potential, while societal trends indicate that they will be attractive to a large and increasing number of people. This potential has not yet been fulfilled and uptake and implementation of AAL solutions have so far been limited because it requires large resources to be committed. The few products and services made available on the market are often standalone solutions and not interoperable and have, therefore, had limited success.

With these challenges in mind, the universAAl project was initiated in order to standardize the approach to developing AAL solutions.

There have previously been several other funding initiatives within the EU to create a platform, services among others. However, this is the first to gather and group all the needs from within the AAL community under one single project [2]. universAAL is built upon previous EU funded projects, such as PERSONA, AMIGO, MPOWER, SOPRANO, OASIS, VAALID, GENESYS [3]

The project has 19 partners from allover Europe with the aim of developing an open, common European IT platform for AAL solutions and services.

II. OBJECTIVES

Facts about universAAL:

Full Name:	UNIVERsal open platform and reference Specification for Ambient Assisted Living
Start date:	01.02.2010
Duration:	48 months
Budget:	13.980.164 €

The main objective [4] for the project is to make it technically feasible and financially viable to develop, design and launch new and innovative AAL solutions. Part of this strategy entails the development of a full suite of software components which can compose an environment for developing and running AAL applications for companies, private individuals, institutions etc. This will be done through the establishment of e.g. the universAAL developer depot and the uStore. In addition, the project aims at gaining widespread adoption and acceptance of the platform and to expand the number of companies which develop AAL solutions.

An overall goal for the project**,** and especially the platform, is that companies and other actors can use it for free, for incorporating into intelligent systems for e.g. elderly homes, care facilities, hospitals and hereby boost the market for AAL by opening up for more digital services.

III. THE PLATFORM

The platform will be produced by a mixture of new developments and consolidation of state-of-the-art results from existing initiatives and entails 3 main parts, as seen on the Figure 1 below: runtime support, development support, and community support.

Runtime support is a software environment which offers core output and services within AAL, making it easy to construct applications such as fall detection, alarms, GPS (global positioning system) detectors, etc.

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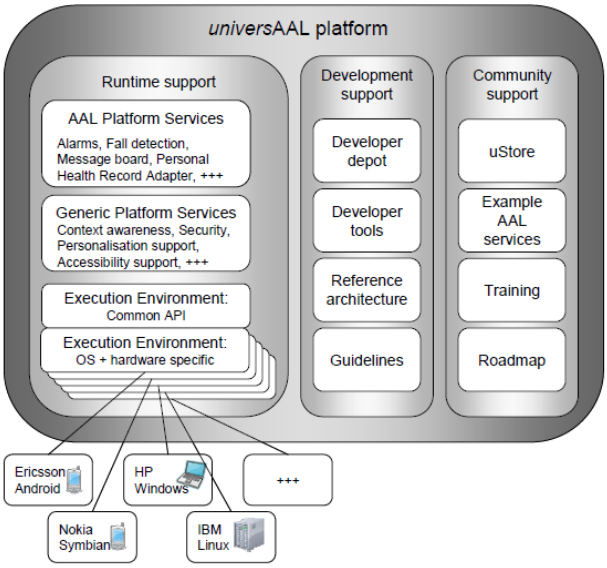

Figure 1. universAAL platform

Development support includes documentation, tools, and an online depot of several development resources such as software components, which are open and should make the integration and development of AAL services and applications easier.

Community support includes training and an online one-stop-shop which offers easy access to services and applications.

The online one-stop-shop is called uStore and functions as the market place where suppliers can offer their services (both hardware and software and human resources) so that others can find them. In addition, this platform supports the use of several existing platforms and allows interoperability with existing systems and domains.

IV. THE UNIVERSAAL NOVELTIES

The universAAL project presents some novelties with respect to other AAL platforms. We distinguish between the technological and academic aspects.
The Technological Aspect: universAAL has been designed and implemented by following a 3-level approach:

- Reference model (RM): the consortium fist concentrated on the definition of the common understanding of the AAL domain. The reference model defines the relevant concepts and relationships among them.
- Reference architecture (RA): this architecture provides a high-level structure of the universAAL components. The RA has been designed in order to be independent from the enabling technologies and protocols. The RA defines the role of the components of the universAAL project and the functionalities that are provided.
- Concrete architecture (CA): the CA is a concrete implementation of the universAAL platform inspired from the RA. The universAAL consortium has released the official CA in order to demonstrate the real benefits of the universAAL platform.

The benefit of this approach is the design of a unified AAL platform that takes advantage from a high-level modeling independently from specific technologies.

V. THE ACADEMIC ASPECT

The project comprises the runtime, the development tools and the community support. This makes universAAL a useful toolkit for academic lecturers and seminars. Students interested in developing new AAL service, are supported by the universAAL tools (a notable example is the universAAL AAL Studio). Such tools allow following the developers during all the steps: designing, coding, testing and integration by reducing the learning curve of the universAAL platform.

VI. THE COMMUNITY

As part of the strategy of achieving the above mentioned objectives and to gain a widespread implementation and adoption of the universAAL platform, universAAL has started AALOA – an AAL Open Association together with other projects – see figure 2. The idea with AALOA is to create a non-profit organization open to individuals, institutions, and industry. It provides a meeting point for the industry and academia and will be able to catalyze interests and efforts around AAL, promoting standardization and identify key areas of interest. AALOA works independently from the universAAL project.

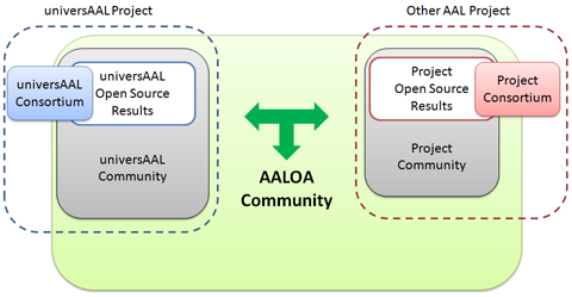

Figure 2. AALOA overview

In connection with the Open Association AALOA, an annual AAL competition has been created and is called EvAAL (Evaluating AAL Systems through competitive benchmarking). The competition has been established to foster interest from the research and development environments within the many disciplines of AAL and to develop new metric systems to measure, test and evaluate AAL systems.

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VII. WHAT UNIVERSAAL SOLVES

universAAL has brought experts, end users, and developers together to address the growing need for a common reference architecture within AAL applications as well as creating a virtual meeting point for developers and users, initiating a common standard to heighten the quality as well as interoperability with the health care sector.

In short, this project has the goal of initiating and boosting the market for AAL as well as creating a common standard so that interoperability can be secured and costs will decrease.

It is the vision of the project partners that it should be simple for users to download and setup AAL services as it is to download and install software application on modern operating systems.

VIII. THE DEVELOPMENT OF THE PROJECT TO DATE

While the goal of the project is to have all the above mentioned objectives ready by the end of the project period, with around 1 years left of the project, it has at this point already released first versions of uStore, the market place in which it is possible to search for and download applications (but not yet to install it), and developer depot which will be further enhanced during the project period. The middleware is under construction, some of it ready**,** while AALOA has been created and has already hosted 2 successful EvAAL events.

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Validation of a Telemonitoring System for Sleep Apnea Treatment

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***Abstract*—Patient's compliance is crucial for the effectiveness of continuous positive airway pressure (CPAP) treatment of obstructive sleep apnea (OSA), but many patients withdraw it due to its side effects. Air Liquide developed NOWAPI, a novel telemedicine system, which provides the CPAP treatment remote monitoring of the patient at home and is designed to be compatible with all CPAP devices under clinical use. The aim of this study was to validate NOWAPI in a bench test simulating OSA patients. First, the influence of NOWAPI sensor unit geometry to the CPAP treatment was assessed. Then, NOWAPI's performance in correctly detecting the treatment duration and the residual events was tested. Recorded data were wirelessly sent to a secure server by NOWAPI, then downloaded and analyzed. NOWAPI sensor unit connection to the setting did not influence the CPAP treatment. The difference between the treatment duration estimated by the device and actual values was never higher than 3 min over the 4-hour test. The difference between the apnea-hypopnea index (AHI) estimated by NOWAPI and the actual values was not significantly different from the one between the AHI estimated by the CPAP machines and the actual values (p=0.171). NOWAPI showed an excellent performance in this bench test and could be a valuable tool for telemonitoring the treatment of OSA.**

Keywords: telemedicine; eHealth; home monitoring; sleep apnea; CPAP.

I. INTRODUCTION

Obstructive sleep apnea (OSA) is a very prevalent disease mainly associated with daytime sleepiness and deterioration of quality of life and is suffered by 2% to 4% of middle-aged adults [1]. OSA entails repetitive partial or total occlusion of the upper airway, which results in significant levels of sleep disturbance and snoring. However, the seriousness of untreated OSA is stressed by its significant consequences, including depression, ischemic heart disease, stroke, hypertension and significantly increased risk of motor vehicle crashes [2;3].

The treatment of choice for OSA is continuous positive airway pressure (CPAP) applied through a nasal mask during sleep. This constant pressure is transmitted to the pharyngeal area, thereby avoiding upper airway obstruction [4]. Despite the documented clinical efficacy of CPAP, up to 50% of patients suspend or underuse CPAP treatment, mainly due to its discomforting side effects, such as pressure intolerance, claustrophobic reaction to the mask, mask displacement, and machine noise [5;6]. Many of these problems could be easily solved by a closer follow-up, especially during the first weeks, but busy sleep centers have difficulties in giving such support.

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If patients do not use CPAP for the recommended minimum of 4 hours per night, clinical outcomes are compromised [7], demonstrating that adherence optimization is a critical aspect of patient management.

Several studies confirmed that treatment compliance could be significantly improved by comprehensive support programmes and timely interventions by health professionals [8]. In recent times, it has been recognized that telemedicine could have a valuable role in improving CPAP therapy adherence [9]. In fact, telemedicine has been used in various studies to promote and reinforce CPAP treatment. In most of them a cognitive behavioural intervention was applied to OSA patients at home, by telephone [6], the Internet [10] and videoconference [11]. Despite mixed results were achieved in terms of significant improvement of CPAP compliance, the potential of telemedicine to be integrated into the care of OSA patients was confirmed.

Two recent randomized studies [12;13] combined elements of psychoeducational interventions together with technological innovation. Usual care was compared to a wireless telemonitoring of CPAP compliance and efficacy data, which physicians were able to daily monitor through a secure web browser and thus contact the patient if needed. Both studies resulted in higher CPAP adherence and improved OSA outcomes and demonstrated that continuous monitoring of patient's compliance could be useful to early detect underuse and to properly address possible problems.

Some existing CPAP and APAP (Automatic Positive Airway Pressure) devices monitor patient's compliance by using different algorithms, but only few of them offer continuous remote monitoring. Air Liquide developed NOWAPI, a telemonitoring system designed to be compatible with all commercially available CPAP/APAP devices. The aim of this study was to validate this new monitoring system in a bench test.

II. METHODS

A. System Description

NOWAPI system has been designed to remotely monitor the CPAP or APAP treatment of patients with sleep apnea at home. The system overview is depicted in Fig. 1. NOWAPI comprises a small sensor unit (15x4x7 cm) powered by a rechargeable battery, which contains a pressure and flow sensing module, a specifically developed detection software for the analysis of the measured signals and detection the breathing events, a GPRS communication module, which enables data transmission to a server, and a clinical interface,

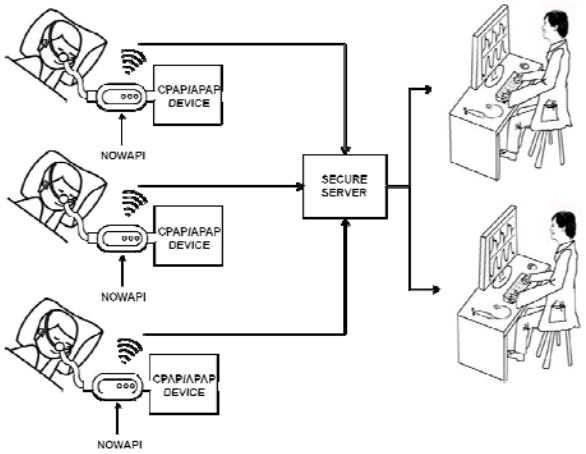

Figure 1. NOWAPI system data flow.

which enables the physician to visualize and properly evaluate the data downloaded from the server. The NOWAPI sensors unit is connected between the CPAP/APAP device outlet and the patient's tubing. During the patient's CPAP/APAP treatment, the system detects the pressure and flow signals which characterize the patient's breathing and estimates the treatment use rate and some important parameters to assess the effectiveness of the therapy, such as the number of apneas, hypopneas, flow limitations, snoring periods, and average breathing flow and nasal pressure. The system stores all data in 2 different files, a detailed file with a sampling rate of 25 Hz and a synthetic file where data are recorded as mean values over 15–minute consecutive periods. The latter file is sent by the GPRS module integrated into the device to a secure server then available to be downloaded and analyzed.

Furthermore, a led in the sensors unit turns red if the treatment duration is less than the minimum standard of 4 hours/night, giving an immediate useful feedback to the patient about his/her treatment compliance.

B. Patterns of disturbed breathing

NOWAPI was tested with 2 different sets of simulated breathing patterns. In the first phase, a series of 20 waveforms consisting of the successive repetition of apneic or hypopneic events or persistent flow limitation [14;15] was used.

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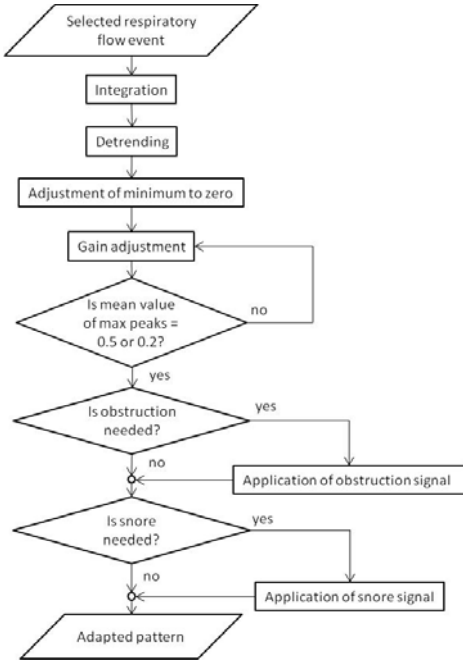

Figure 2. Block diagram of the algorithm implemented to obtain the breathing patterns simulating patients with OSA.

In the second phase, the system performance was tested in 30 different test scenarios especially developed for this study, simulating 30 sleep periods of OSA patients under CPAP treatment, lasting 4 hours each. These simulated breathings consisted of realistic airflow patterns built from a library of actual events (e.g. normal breathing, apneas, hypopneas, flow limitations) selected from real OSA patients' polysomnographic recordings. The selected events were exported by using the polygraph software with a sampling frequency of 64 Hz. Then, each event was properly elaborated by an algorithm implemented for this study. The block diagram describing the algorithm, developed by using Matlab computing tool, is shown in Fig. 2. First, the flow event was integrated to obtain the volume signal. Then, the signal was detrended and adjusted in order to have the minimum signal point at zero. Then, to reproduce the typical tidal volumes for normal breathing (0.5 l approx) and hypopnea (0.2 l approx), the signal gain was iteratively adjusted until the mean value of the signal peaks was 0.5 in the case of normal breathing and 0.2 in the case of hypopnea. Subsequently, the obstruction signal controlling the test bench valve was added to obstructive events. Moreover, a snore signal was added where requested. Then, the processed events were assembled to obtain the 30 4-hour simulated breathing patterns (Fig. 3).

C. Measurement Setup and Protocol

NOWAPI sensors unit was plugged between the CPAP/APAP device (or its humidifier) outlet and a model simulating an OSA patient [14;15], as shown in Fig. 4. This computer-driven model comprises a flow generator and an obstruction valve which allows the simulation of obstructive events. Other two valves (the leak and the exhalation valves) allow the simulation of leaks and mouth breathing and a loudspeaker simulates snoring. The test bench is equipped with two sensors, which record pressure and flow signals. A calibrated leak (EP on Fig. 4) simulates the mask leak.

This validation study comprised two phases in which the same test setting (Fig. 4) was employed.

1) First Test Phase

The aim of the first test phase was to verify that the NOWAPI sensors unit connected between a CPAP/APAP machine and the conventional tubing connected to the patient did not modify the normal performance of the CPAP/APAP machine. Two commercially available CPAP/APAP devices (S9 AutoSet, Resmed and Remstar Auto, Respironics) were subjected to a set of 20 breathing patterns described elsewhere [14;15] with 2 alternative settings: with or without their Comfort Mode (CPR) activated and with or without NOWAPI sensors unit connected to the test setting. The responses obtained in the 4 different experimental conditions were compared and evaluated.

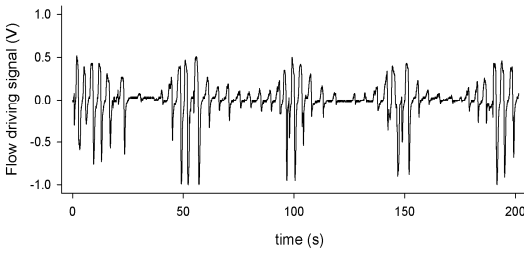

Figure 3. Fragment of a pattern of disturbed breathing which simulated an OSA patient's sleep periods of treatment.

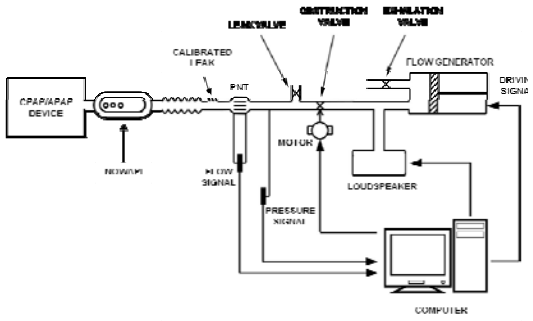

Figure 4. Scheme of the test setting.

2) Second Test Phase

In the second test phase, NOWAPI was subjected to the 30 patterns especially implemented for this study, which simulated 30 sleep periods of OSA patients under CPAP treatment. The aim of this phase was the assessment of NOWAPI's performance in correctly detecting the treatment duration and the residual disturbed-breathing events.

In order to assess the effect of water condensation into the tubing on the measurements, usually caused by patient's breathing, three of the tests were performed with the APAP device humidifier turned on. To guarantee realistic water condensation, humidifier was set to maximum level and the APAP device tubing was immersed in ice.

The simulated patients were treated with 3 different currently available devices for APAP treatment: S9 Autoset (Resmed), Remstar Auto (Respironics) and Goodknight 420E (Sefam). Each APAP device was connected to the monitoring device with its own tubing. A Whisper Swivel valve (Respironics) was used as exhalation port for all devices.

Each 4-hour test was preceded and followed by a 30-minute period during which the NOWAPI device was functioning but not subjected to either APAP device pressure or patient simulator's breathing. This was to ensure test two epochs in which no treatment time and no events should have been detected.

The synthetic files for each of the 30 tests, containing the data recorded as mean values over 15–minute consecutive periods, were sent via GPRS to the Air Liquide secure server and then downloaded for analysis. In this study, treatment duration and respiratory events, measured as apnea-hypopnea index (AHI), detected by NOWAPI were considered for analysis and compared to the ones detected by the CPAP/APAP devices and to the actual simulated patterns generated by the bench.

III. RESULTS

The results of first test phase are summarized in Table I. The absolute differences between the two test settings with and without the NOWAPI sensor unit in the circuit of the following parameters were calculated: the time taken by the CPAP/APAP machine to reach the pressure of 10 cmH_2O (T_{10}) and the maximum pressure applied by the machine (P_{max}). The minor differences founded between the two test conditions are imputable to the intrinsic variability.

TABLE I. RESULTS OF THE FIRST TEST PHASE

CPAP/APAP machine	**Absolute difference with NOWAPI/without NOWAPI (mean±SD)**	
	T_{10} (min)	***P_{max} (cmH_2O)***
S9 Autoset with CPR[a]	0.40±0.43	0.50±0.77
S9 Autoset without CPR	0.19±0.29	0.11±0.14
Remstar Auto with CPR	1.23±0.98	0.78±1.54
Remstar Auto without CPR	1.50±1.75	1.26±1.41

a. CPR = Comfort Mode.

In the second test phase, all data sent to the server via GPRS were successfully received and analyzed. The percentage difference between the treatment duration estimated by NOWAPI and actual values was never higher than 1.25% (3 min) and never lower than -0.42% (-1 min).

The difference in absolute values between the AHI estimated by NOWAPI and the actual values, 0.9±1.6 events/hour (mean±SD), was not significantly different from the difference in absolute value between the AHI estimated by the CPAP/APAP machines and the actual values, 0.9±1.0 events/hour (p=0.171, the normality condition was achieved). This good agreement was confirmed by Bland-Altman analysis of AHI values estimated by NOWAPI in

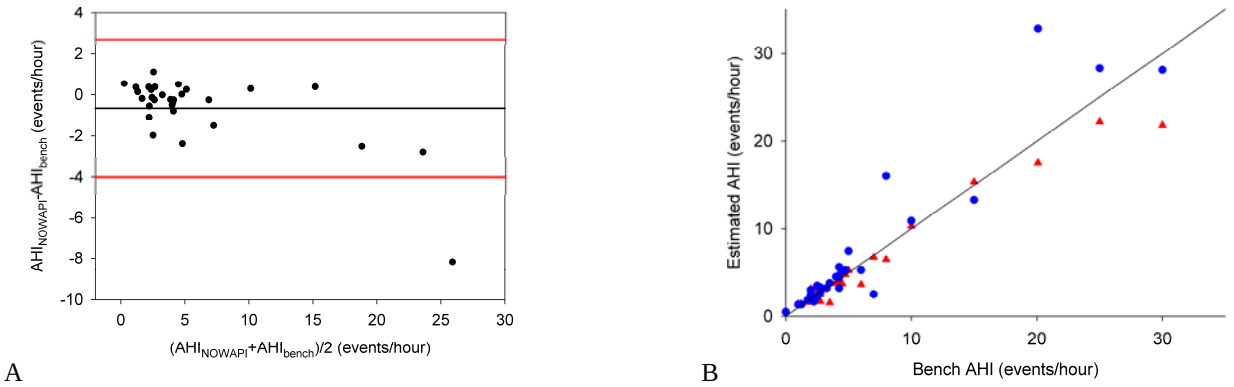

Figure 5. (A) Bland-Altman analysis of AHI values estimated by NOWAPI in each test versus the actual ones; (B) AHI values estimated by NOWAPI (red triangles) and the PAP machines (blue circles) versus the bench ones for each test.

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each test versus the actual ones (Fig. 5A). Also, AHI values estimated by NOWAPI showed a very good correlation with the actual values (R^2=0.97), slightly better than the ones estimated by PAP machines (R^2=0.88) (Fig. 5B).

IV. DISCUSSION

NOWAPI is a novel telemedicine system which provides remote monitoring of CPAP/APAP treatment of OSA patients at home. It detects critical parameters to evaluate the patient's adherence (treatment duration), and the effectiveness of the treatment (residual respiratory events) and sends them via GPRS to a secure server. In this way the data can be easily downloaded and revised by the physician or the health professional providing CPAP, who can perform a closer patient's monitoring and timely intervene to improve his/her treatment compliance.

Few systems in the market provide this kind of remote treatment monitoring, which is usually integrated in the CPAP/APAP devices and implemented with a different algorithm for each manufacturer. Since NOWAPI is a stand-alone system, it can be compatible with all the commercially available CPAP/APAP devices currently in clinical use. This fact would make it easy to remotely monitoring any patient, regardless of the specific CPAP device he/she uses.

In this study, NOWAPI system was evaluated in a bench. In a first test phase, two different CPAP/APAP machines were subjected to a previously validated set of disturbed breathing patterns [14;15] with or without NOWAPI device connected between the CPAP/APAP and the bench. The results of this phase demonstrated that the geometry of NOWAPI does not influence the CPAP treatment.

In the second test phase, NOWAPI was subjected to 30 different breathing patterns especially built for this study by assembling real respiratory flow signals recorded during polysomnography in OSA patients. The telemedicine system successfully sent the recorded data to the central server and showed an excellent performance in estimating the CPAP treatment duration and in detecting residual respiratory events.

A bench test is a useful tool to validate new systems such as NOWAPI, because it allows the comparison of different devices response when they are subjected to exactly the same patterns of disturbed breathing, which is not possible in patients, due to the biological variability in their disturbed breathing patterns [13]. Actually, bench tests and clinical studies are both useful and should be considered complementary when evaluating a specific system [14]. Subjecting NOWAPI to reference breathing patterns at the bench was a first step for evaluating the performance of the hardware/software implemented in the system.

V. CONCLUSION AND FUTURE WORK

NOWAPI showed good compatibility with the CPAP machines and an excellent performance in estimating the duration of the CPAP treatment and in detecting residual respiratory events in simulated OSAS patients. The results of this study demonstrated that NOWAPI system could be a valuable tool for telemonitoring the treatment of obstructive sleep apnea.

The results of the study will be verified in a clinical trial on patients in the clinical routine.

ACKNOWLEDGMENT

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Real Time Medication Monitoring with customized SMS reminders for people with refractory epilepsy

Will medication adherence levels improve when patients receive customized SMS reminders?

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***Abstract*— A high level of medication adherence is important for people with refractory epilepsy. For most people, however, it is difficult to have their medication intakes as prescribed every day. In this study we investigated if Real Time Medication Monitoring (RTMM) with customized SMS-reminding had an effect on the adherence level of people with epilepsy. We found a higher adherence level for people receiving these customized SMS reminders, compared to monitored patients not receiving reminders. Additionally, they also feel more adherent, their seizure frequency or severity decreases and they experience a better overall health.**

Keywords: medication adherence; epilepsy; medication monitoring; medication reminders; SMS.

I. INTRODUCTION

Epilepsy is a disorder of recurrent unprovoked seizures. the prevalence of epilepsy in Europe is 0.007%, but in people with an intellectual disability the prevalence is about 30% [1]. Although it is a disturbance of brain function, epilepsy can be categorized as a chronic disease. Most people with epilepsy need to take daily medication over an extended period of time.

Although medication does not cure epilepsy, in about 70% of the people with epilepsy seizures disappear with medical treatment. For the remaining 30% seizures continue to exist. Continuing seizures are seen more often in persons with lower cognitive ability. The regularity of medication intake is important in epilepsy treatment since omission of one or more doses can provoke seizures [2]. The severity of these seizures, sometimes after a long period of seizure freeness, can be higher, sometimes resulting in a status epilepticus or even sudden unidentified death in epilepsy (SUDEP) [3]. For most people it is difficult to have their medication intakes as prescribed every day. In a Dutch questionnaire study into the medication use of people with epilepsy an adherence of 65% was found [4].

Especially persons with below-average cognitive ability and patients in puberty are groups who need extra support in medication adherence.

Several earlier studies evaluated SMS reminders showing positive results on adherence [5-10]. In these studies, however, SMS reminders were sent regardless of whether the patient had taken the medication or not. Such automated daily reminders may cause habituation resulting in a loss of effectiveness [8]. Hence, in our study we aim to avoid habituation by using a Real Time Medication Monitoring service with customized SMS-reminding: patients are only reminded when they have forgotten to take their medication.

To our knowledge our study is the first to evaluate a Real Time Medication Monitoring service with customized SMS-reminding to support people with refractory epilepsy in their medication use. The main aim of this study is to evaluate the effect of this service on the adherence to anti-epileptic medication in patients with refractory epilepsy. We focus on the aspect of adherence that refers to how well patients follow their prescribed regimen [11]. Furthermore we are interested in secondary effects of the improved medication adherence: do patients experience a change in seizure frequency or severity and in quality of life?

II. METHODS

A. The RTMM-service

The RTMM service is based on an electronic dispenser (see Figure 1). The dispenser sends a brief message to a central server each time it is opened. The message is sent wirelessly, through the GSM network via GPRS, to a central server. This message contains information about the date and time of the dispenser opening. The electronic dispenser works in nearly every country in the world at locations where mobile phones have network coverage.

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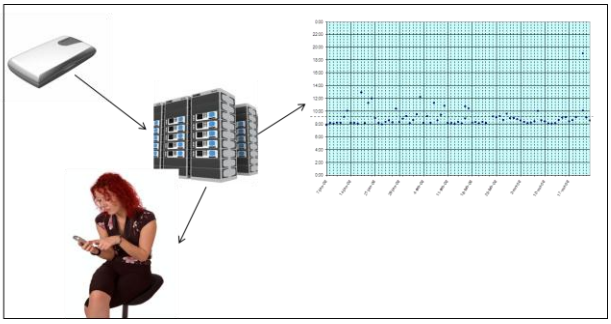

Figure 1. The RTMM service with customized SMS reminders

Patients were instructed when receiving the dispenser and chose one up to four time intervals within which they had to take their medication. This was according to their prescribed number of daily doses. The medication was placed in the dispenser by the patients themselves. An SMS reminder would be sent if they had not opened their medication dispenser within the agreed time interval. The content of the reminder was: "Have you taken your medication yet? Please take your medication as prescribed by your health care provider".

B. *Illustration of data registered with RTMM*

Figure 2 shows an example of data as collected by the RTMM service. The horizontal axis displays the days of the monitored month, the vertical axis displays the 24 hours of each day. Each opening of the medication dispenser is plotted by one dot in the diagram. The shaded segments represent the agreed time periods for medication intake. In this example the patient follows a medication regimen of four daily doses. The RTMM data reveals quite a regular pattern of medication use for this patient.

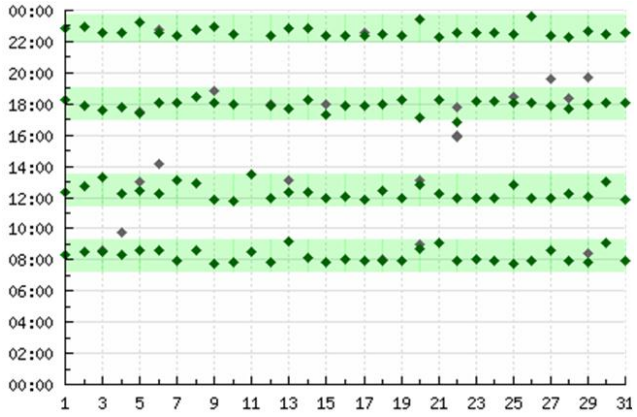

Figure 2. Example of medication intake data as registered with RTMM

C. *Study design*

The study described here is an observational cohort study of data collected during a period of at least two months during which participants (n=28) used RTMM with the intervention of SMS reminders.

The use of an electronic monitoring device may already contribute to a higher adherence because of patients' awareness of being monitored [12]. To find the exclusive effect of the SMS-reminding function in this device, a subset of the included participants (n=18) were electronically monitored with RTMM without the SMS reminders, for at least 6 weeks (see Figure 3). This control period (t_0–t_1) was prior to the intervention period with the SMS reminder service (t_1-t_2).

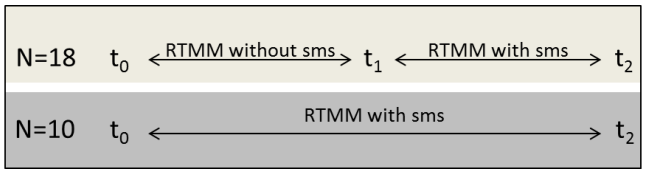

Figure 3. Included participants per type of intervention

D. *Participants*

Inclusion criteria for participants were: (1) having a clinically definite diagnosis of epilepsy; (2) having at least one epileptic seizure per week; (3) being able to present a precise documentation (diary) of all seizures during half a year prior to the start of the study; (4) aged 15 years or older; (5) independently taking and managing medication; (6) having access to and being able to use a computer and internet; (7) owning and being able to use a mobile phone. Besides these inclusion criteria there was one exclusion criterion: 'playing' with the device: opening and closing it for non-medication purposes for multiple times a day during a week. These criteria are elaborated upon in the research protocol [13].

Participants were recruited from the outpatient clinic of the tertiary epilepsy clinic in Zwolle. They responded to posters in the waiting rooms with a call for volunteers. Or they were asked by their neurologist, nurse practitioner or other paramedical co-worker of the clinic. The inclusion of the participants was performed by one of the investigators explaining the study and the participant's role. If the person with epilepsy agreed to participate and met the inclusion criteria an informed consent was signed by both the participant and investigator. Ultimately, 28 persons with epilepsy participated in the study.

E. *Outcome measures*

The first two outcome measures were calculated from data registered with the RTMM service during the intervention period.

(1) *Correct intakes:* the proportion of doses taken within agreed and predefined standardized time intervals. This measure is to assess the precision with which the patients adhere to the prescribed regimen.
(2) *Missed doses:* the proportion of doses not taken, calculated by dividing the total number of missed doses by the total number of prescribed doses during the intervention period. This measure is to assess whether the appropriate number of doses was taken each day.

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The following outcome measures concern patients' experiences which were assessed with written questionnaires handed out to each patient both pre-test (t_0) and post-test (t_2). The following aspects were measured:

(3) *Patients' judgment on their medication adherence.* Patients were asked to compare their adherence to medication use with and without the support of RTMM with SMS reminders.
(4) *Seizure frequency.* Patients were asked for their seizure frequency in the prior six weeks based on their paper diaries. The paper diaries were also handed in and answers were checked by the investigators.
(5) *Experienced effects on seizures after RTMM intervention.* Patients were asked to indicate if and how their seizures differed after the intervention period.
(6) *Quality of live.* The health-related Quality-of-Live questionnaire, with 31-items (QOLIE-31) by Cramer et al. [14] was used to assess the quality of live. This validated questionnaire covers both general and epilepsy-specific domains. Cross-cultural translations were made for nine languages among which Dutch.
(7) *Satisfaction with the RTMM service.* Patients were asked for their experience with the SMS reminder service on two aspects: convenience of total service, and ease of use of the medication dispenser.

III. RESULTS

A. Characteristics of Study Participants

In total 48 persons with epilepsy received the dispenser and the corresponding instructions. Eleven persons did not use it at all or only during a few days. Five persons used it only during 1-4 weeks and four only during the period without SMS reminders (control period). These 20 persons were classified as "drop outs". Their reasons for dropping out varied from the design of the dispenser to privacy concerns.

Ultimately, 28 persons with epilepsy participated in this study. The characteristics of both participants and drop outs are shown in Table I. There are no differences between both groups for gender, age, educational level, living situation, and seizure frequency. The groups differ in their daytime activities: participants had more regular daily activities, like work or school, than the drop outs (71.4% vs. 30%, p=0.014). Furthermore, the severity of epilepsy differed between both groups. In total 35% of the drop outs had severe tonic-clonic seizures compared to 14.2% of the participants (p=0.041).

TABLE I. CHARACTERISTICS PARTICIPANTS AND DROP OUTS

	Characteristics Participants and Drop Outs			
	Total	***Participants***	***Drop Outs***	***p-Value***
Number	48	28	20	
Male, n (%)	25 (52.1)	13 (46.4)	12 (60.0)	p = 0,359
Age, mean (min-max)	33.7 (15-62)	25.5 (15-61)	34.0 (15-62)	p = 0,242
Educational level medium or lower, n (%)	35 (72.9)	20 (71.4)	15 (75)	p = 0,516
Regular daily activities (occupation/school, n (%)	26 (54.2)	20 (71.4)	6 (30)	p = 0,014
Living alone, n (%)	9 (18.8)	4 (14.3)	5 (25)	p = 0,549
Seizure frequency per week				p = 0.654
1 seizure, n (%)	14 (29.2%)	8 (28.6%)	6 (30%)	
2-4 seizure, n (%)	16 (33.3%)	9 (32.1%)	7 (35%)	
4-6 seizures, n (%)	5 (10.4%)	2 (7.1%)	3 (15%)	
7 or more seizures, n (%)	13 (27.1%)	9 (32.1%)	4 (20%)	
Type of seizures				*p = 0.041*
Simple Partial	2 (4.2%)	2 (7.1%)	-	
Complex Partial	35 (72.9%)	22 (78.6%)	13 (65%)	
Tonic Clonic	11 (23.0%)	4 (14.2%)	7 (35%)	

As indicated, participants (n=18) were included in a control group using RTMM without SMS reminders in advance of using it with SMS reminders. Table II shows the number of included patients, the lengths of the study periods and the type of intervention (with/without SMS) they received during these study periods.

TABLE II. PARTICIPANTS PER TYPE OF INTERVENTION AND LENGTH OF STUDY PERIOD

Participants per type of intervention and length of study period			
	Study period	***Median days (min-max)***	***Type of RTMM service***
N=18	t_0–t_1	120 (30-120)	without SMS reminders
	t_1–t_2	225 (120-360)	with SMS reminders
N=10	t_0–t_2	360 (60-360)	with SMS reminders

B. Differences in Adherence

Table III shows the differences in adherence for the control group (N=18) between the RTMM service without SMS reminders and the same service with SMS reminders. While receiving SMS reminders participants had a significantly higher percentage of correct medication intakes (p=0.003). These participants also had an almost significant lower percentage of missed doses (p=0.058).

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TABLE III. DIFFERENCES IN ADHERENCE DURING THE USE OF RTMM WITH AND WITHOUT SMS REMINDER SERVICE

Differences in adherence during the use of RTMM with and without SMS reminder service			
n=18	***Without SMS*** ***(t_0-t_1)***	***With SMS*** ***(t_1-t_2)***	Related-Samples Wilcoxon Signed Rank Test
% Correct intake median (min-max)	68.47 (31.11-102.50)	82.85 (30.83-98.89)	p=0.003
% Missed doses median (min-max)	17.92 (1.67-44.44)	7.11 (1.11-49.21)	p=0.058

In addition to the above control group, ten participants received SMS reminders from the start of their inclusion (t_0-t_2). In these ten participants the median percentage of correct intakes was 88.06% (34.58-97.92). The median percentage of missed doses was in these ten participants 9.17 (1.88-44.17). Both percentages did not differ significantly from the control group when receiving SMS reminders (t_1-t_2).

C. Experienced Adherence

In the post-test questionnaire a majority of the participants (57.1%) indicated they experienced an improved adherence due to the RTMM service with SMS reminders (Table IV).

TABLE IV. ADHERENCE AS EXPERIENCED BY PARTICIPANTS

Experienced Adherence	
Do you consider yourself more adherent with the use of RTMM?	
	N=28
Yes, n (%)	16 (57.1)
No, n (%)	6 (21.4)
No Answer, n (%)	6 (21.4)

D. Seizure Frequency

Both pre-test (t_0) and post-test (t_2) participants rated their seizure frequency based on their paper diaries. Results are presented in Figure 4.

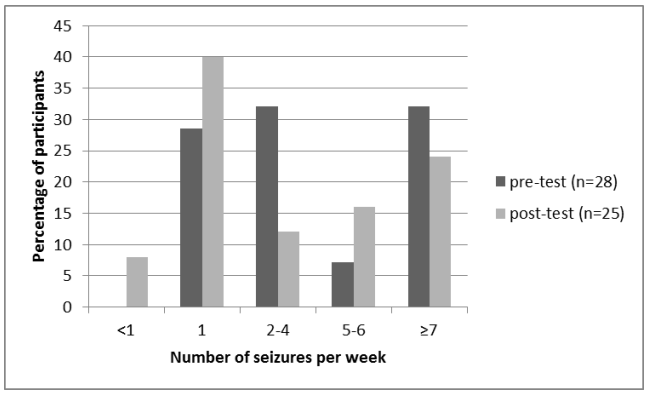

Figure 4. Number of seizures per week

Although these results were not statistically significant, a trend is visible: participants seem to have less seizures during the use of RTMM with SMS reminders than before this use.

E. Experienced effects on seizures

In the post-test questionnaire participants were asked about the effect of the RTMM service with SMS reminders on their seizures (Table V). A decrease of seizure frequency was mentioned by seven participants (25%). No change in seizure frequency but a decrease in seizure severity was mentioned by 16 participants (57.1%).

TABLE V. EFFECTS ON SEIZURES AS EXPERIENCED BY PATIENTS

Experienced effects on seizures	
Do you experience a decrease in seizures due to the use of the RTMM service?	
	N=28
Yes, n (%)	7 (25.0)
No, but less severe, n (%)	16 (57.1)
No, n (%)	2 (7.1)
No Answer, n (%)	3 (10.7)

F. Quality of Live

The Quality of Life in Epilepsy questionnaire (QOLIE-31) was distributed three times during the study (Table VI). A comparison for the control group between QOLIE(0) and QOLIE(1) indicated no significant differences in Total Score, nor in the six different dimensions (Seizure Worry, Emotional Well-being, Energy-fatigue, Cognitive functioning, Medication effects, Social functioning).

TABLE VI. DISTRIBUTION OF QOLIE-31 DURING THE STUDY

Distribution of QOLIE-31 during the study			
	t_0 ***(pre-test)***	***t_1***	***t_s*** ***(post-test)***
Control group N=18	QOLIE(0) at start of RTMM without SMS	QOLIE(1) at start of RTMM with SMS	QOLIE(2)
N=10	QOLIE(0) at start of RTMM with SMS	-	QOLIE(2)

Comparing QOLIE(0) with QOLIE(2) for all 28 participants indicated no significant changes except for the scores on the Visual Analog Scale (VAS) about the overall health (Table VII). Participants experienced a higher overall health at the end of the study. This difference was significant.

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TABLE VII. OVERALL HEALTH AS EXPERIENCED BY PARTICIPANTS

	Experienced Overall Health		
	t_0 (pre-test) (n=28)	t_2 (post-test) (n=28)	p-Value
Mean health score on a Visual Analogue Scale from 0-100 points	59.8	65.7	p = 0,049

G. Satisfaction with the RTMM service

At the end of the study participants filled out a questionnaire about their experiences in this study and their satisfaction with the RTMM service (Table VIII). The questions about the use of the dispenser showed in general results fitting to moderate satisfaction. Most people thought the device helped them in medication use resulting in a better compliance. They were satisfied with the reminders by SMS. Half of the participants were satisfied with the design of the medication box.

TABLE VIII. SATISFACTION WITH THE RTMM SERVICE

Satisfaction with the RTMM service	
	N=28
Did you experience the SMS reminder service as pleasant?	
Yes, n (%)	18 (64.3)
Neutral, n (%)	4 (14.3)
No, n (%)	2 (7.2)
No Answer, n (%)	4 (14.3)
Did you experience the medication box as easy to use?	
Yes, n (%)	13 (46.4)
Neutral, n (%)	5 (17.9)
No, n (%)	7 (25.0)
No Answer, n (%)	3 (10.7)

IV. CONCLUSION AND FUTURE WORK

People with refractory epilepsy using Real Time Medication Monitoring (RTMM) with customized SMS-reminding to support their medication use, have a higher adherence level than patients who do not receive SMS-reminding. Additionally, they also feel more adherent, their seizure frequency or severity decreases and they experience a better overall health. Overall, patients' experiences with the RTMM system are positive.

Since other patient groups have adherence difficulties as well, the RTMM service with customized SMS-reminding may provide opportunities for increasing adherence for other chronic diseases.

A. Discussion

Our findings are in line with the results from the single previous study we found evaluating the effect of RTMM with customized SMS reminders on adherence [15]. Similar to our results, Vervloet et al. found increased adherence levels for participants receiving SMS reminders compared to participants who were only monitored with RTMM. Vervloet's study concerned type 2 diabetes patients. What we added to this study was not only the effect on adherence for a different group of patients, but also the effect on the health of these patients, be it subjective. Where Vervloet did not collect clinical data (i.e. blood glucose levels) or subjective data on health conditions, we collected data on the experienced epileptic seizures and quality of life.

Participants in our study experience less seizures or less severe seizures and an increase in overall health. The latter is likely to stem from the decreased number or severity of seizures, but may also (partly) be the effect of a feeling of reassurance participants get from the SMS reminders: they do not have to worry to forget a dose since they will receive a reminder by SMS. We did not investigate whether this reassurance was one of the effects of the RTMM service with customized SMS reminders.

A common critique of RTMM is that opening the medication dispenser is not a confirmation of the actual ingestion of the medication. However, the validity of electronic monitoring devices is confirmed by studies comparing drug assays with medication intake behaviour measured through electronic dispensers [16-18].

B. Limitations

This study was performed in a small sample of people with refractory epilepsy, in an epilepsy clinic. This limitation influences the statistical significance of results and it prevented us from analysing results of subgroups within the total group of participants.

A second limitation of the study concerns the chosen inclusion criterion of having at least one seizure per week. This resulted in participants with high seizure frequencies. We selected this group expecting they would benefit most from RTMM with customized SMS reminders. Future research should also include participants with lower seizure frequencies.

C. Future Work

Due to the positive results of the above study the RTMM service with customized SMS-reminding is now structurally embedded in the involved epilepsy clinic. It is offered to a broader group of persons with epilepsy than based on the above inclusion criteria. Young people, mentally disabled people and persons with lower seizure frequencies are using the service and will be monitored. This offers the authors the opportunity to build on the above study with new data concerning longer term effects of a larger sample of participants from different subgroups.

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The authors strongly recommend for future studies to investigate the differences in adherence effects between customized and non-customized SMS reminders. The latter have become available by freely downloadable apps running on smartphones. As indicated in the Introduction, daily sent reminders may cause habituation leading to lower effectiveness. Future studies should include a control group monitored by RTMM but receiving non-customized SMS reminders.

Future research is also recommended to further investigate the impact of RTMM and SMS reminders on seizure frequency and severity. The authors aim at studying this impact by requesting participants to keep a digital diary on computer or mobile. Hence, the relation between adherence and frequency and severity of seizures can be automatically deduced. These studies should concern long term intervention periods and also include patients with lower seizure frequencies.

A final recommendation for future research concerns the use of the adherence data by involved specialists and nurse practitioners. To what extent and how do involved medical professionals use this data logged by the RTMM service and how does it influence their (medication) treatment of people with refractory epilepsy?

ACKNOWLEDGMENTS

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Impact of Robotic Telemedicine in a Remote Community in Canada

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Abstract-Mortality and morbidity is higher for patients living in remote Canada. A telerobotic demonstration project was conducted in a remote community of 1500 in northern Labrador. A wireless, mobile robot allows the physician to be virtually present. The physician uses a laptop to move the robot unfettered and zoom and pan the camera, while freely interacting with patients and nurses. The evaluation focused on: access, quality, acceptability and costs as they related to the nurses, attending physicians, patients and the healthcare delivery in Nain. The number of telerobotics encounters was 157. The evaluation findings indicate a positive impact on the health care delivery from the perspective of patients, nurses, physicians and health care system. The findings of this evaluation indicate that remote robotic presence can have a positive impact on health care delivery in northern Canada.

Keywords-robotic, telemedicine

I. INTRODUCTION

Travel for health care in northern Canada is expensive. In Nunavut, a northern territory in Canada, the cost of transportation project for 2011-12 is 22% of the health care budget [1]. For patients living in our remote communities cost of travel for health care in northern Canada is huge, about $1000-$2000 for a return flight and $100-$200 per day for accommodation. A routine visit will require 3 days – to fly in the day before the appointment and if there is no immediate follow-up tests required to return home the following day. About one-half of the patients requires traveling companion to support the patients for during the travel and the clinical encounter. This doubles the cost for travel for health care outside the community.

In Canada, twenty one percent of its population lived in rural communities of less than 10,000 population but only 9.4% of the physicians live and work in these communities. The burden of illness is higher in rural versus urban – rural Canadians less than 45 years of age have about a 30 percent higher mortality rate than urban dwellers of the same age [2]. Morbidity and mortality is higher, the further one lives away from the city. The highest death rates are in most remote communities. The most isolated rural Canadians live three years less than their urban counterparts [3]. Life expectancy in the Canadian male Inuit is 12.6 years less than the general Canadian population, with the greatest disparity in the 20-24 years age group [4].

Telehealth is one of the tools that improve access to health services for patients living in remote communities. There have been varying degrees of success in the utility of telehealth - from regions where telehealth is not well utilized [5] to places where video is used for leading of resuscitation remotely [6].

This project explores the effectiveness of robotic telemedicine in a remote community in northern Canada. A telerobotic demonstration project was conducted in northern Labrador between January 2010 and March 2011 to assess the impact on health care delivery in a northern remote fly-in community of 1500 residents. Off-site physicians provide support for advanced practice nurses in the delivery of urgent and emergent care by using a virtual presence robot.

Section II presents the methods used for the study. In Section III, we present the results. Conclusion and future work is presented in section IV.

II. METHODS

In this project the remote presence robot (RP7), which was named “Rosie”, connects a remote health center with a Regional Health Center. The wireless, mobile robot allows the physician to be virtually present. The physician uses a laptop to move the robot unfettered and zoom and pan the camera, while freely interacting with patients and nurses.

Training of a physician to use the robot takes about one hour. Nurses do not need training. The connection between the laptop and robot is through the internet via a full-duplex operation. The connection is monitored continuously and remote diagnostics are conducted as needed.

The evaluation focused on: access, quality, acceptability and costs as they related to the nurses, attending physicians, patients and the healthcare delivery in Nain. The evaluation was conducted, using forms that were self-administered by 3 physicians and 7 nurses, after use of the robot. The 157 patients also completed patient evaluation forms after the use of the robot. A mixed method study was conducted. Qualitative interviews were conducted with the providers at six months and again at one year (see Appendix 1).

III. RESULTS

The number of telerobotics encounters was 157. The evaluation findings indicate a positive impact on the health care delivery.

1) Patients

Patients reported improved access to physician services and improved physician services at the community level.

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They felt they were more involved in their own care and received treatment earlier without the need to travel. Patients stated they were more willing to access healthcare when they knew they could see a physician via Rosie. Patients reported more ease and comfort with medical care especially as their family members or interpreters could also be present in the session.

Patients felt that being able to access services in their community improved communications with the nurses and physicians. Patients felt that being able to access services at home without the need for travel decreased the disruption to their family and job. "Rosie" decreased their family's financial costs for medical care when they did not have to travel. Patients were highly satisfied with their telerobotic sessions stating they were willing to use Rosie again.

2) Nurses

Among the key findings for nurses are reports of reduced stress due to increased accessibility to the physician. Physicians were readily accessed from home, office or hospital. Nurses reported this eased their stress, especially when faced with an urgent/emergent case that they felt might be outside their scope of practice and/or during inclement weather. Nurses also reported increased job satisfaction with reduced stress of managing urgent or emergent cases. Nurses said that having this technology reduced the stress of practicing nursing in a remote northern community, and that they would consider it a benefit to work in a community where such technology was available.

Nurses felt the partnership between the nurse and the physician deepened with physicians gaining a better understanding of the nurses' knowledge and skills. Nurses reported feeling more of "being part of a team" and that collaboration between the nurse and physician improved with the use of the robot. Nurses felt improved satisfaction with the quality and timeliness of services they were able to provide to the community. They also reported the nurse-physician collaboration increased the community's level of confidence in the health care delivery team. Nurses reported that in 50% of the consultations, using the robot, they learned something new.

Nurses reported that they were able to concentrate their efforts on the patient rather than needing to manage the telehealth equipment. They were accepting of the new technology and felt this was a definitely an upgrade and improvement in telehealth equipment. They expressed an interest in having additional attachments such as ultrasound, otoscope and stethoscope for future applications. Nurses also reported it would be useful to leverage the multi-disciplinary teams such as chronic care / diabetes team by using this technology, to provide the outreach services from Goose Bay to Nain.

3) Physicians

Physicians reported improved access to both the nurses and patients. They felt they were better able to assess, diagnose, treat and manage patients due to the robot. They reported that being able to move independently and manage the movement, focus or zoom of the camera enabled better assessment on how the urgent or emergent interventions were working. Physicians and nurses reported that the functionality of camera and audio capabilities allow them to work together for improved mental health assessments. The physicians felt they were able to lead the triage team in an emergency via using the RP7 robot.

Physicians reported the improved ability to assess, diagnose, treat and manage patients without being present in the community also decreased their job stress as the attending physician practicing in a remote community. They felt by being virtually present with the nurses they also increased their own confidence in the abilities of their nursing colleagues. They reported improved collaboration and communications and improved relationships with nurses. Physicians reported that personal interactions with nurses, patients and family members improved.

Physicians reported they were better able to supervise resident physicians and nurses in performing procedures and that their coaching was much safer using the mobile robot with advanced camera and audio capabilities.

The physicians, with the robot software with their laptops, could connect to Nain from any internet access point at home, office, or hospital. This connectivity using the robot gave them less job stress and more job satisfaction, especially evident during inclement weather when either getting into the community or getting the patient out of the community was not an option. On one occasion, during inclement weather, the attending physician conducted his regularly scheduled clinics via Rosie from Goose Bay.

All the physician and nurse respondents agree that the quality of the interaction with patients is better with telerobotics compared with traditional videoconferencing.

4) Health care system

The evaluation also identified many benefits to the health care system. The improved access to physician services and improved access during inclement weather was viewed by all as a benefit. The use of the RP7 robot supported improvements in the assessment and care of patients and their families. It improved the timeliness and quality of patient care.

Both physicians and nurses (100%) strongly agree that the workflow in the clinic improved with telerobotics. The use of the robot was reported to have improved the workflow of the community health clinic. While the robot did not decrease the workload during the project, it was suggested that the use of the robot could decrease the workload of the physician during his regular scheduled visits. The ability for physicians to see patients as needed and for follow-ups allowed for less over-booked clinics during regular scheduled visits.

The improved access increased job satisfaction and decreased job stress for nurses and physicians practicing in the remote community. The ease of transition to this new technology and acceptability of the robot was also seen as a positive impact on the health care system for nurses, patients including small children, and physicians. The community members readily accepted the robot as a means of accessing

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the primary physician services and they reported an improved confidence in the healthcare delivery team.

Of the forty-seven (47) patients for which complete data is available, twenty-eight (28) patients did not require transportation to Goose Bay. Of the nineteen (19) patients who required travel, nine (9) of the patients were able to travel to Goose Bay on the scheduled hospital flights. More than half of the patients avoided medical transportation. The increased ability to use scheduled flights as opposed to medical evacuation (medevac) also lead to decreased the costs for medical transportation.

The findings indicated the use of "Rosie" the robot facilitated:

- Improved access to physicians;
- Improved management of urgent and emergent care;
- Improved mental health assessments;
- Improved personal interactions between nurse, patient/family and physician;
- Improved collaboration amongst health care team;
- Improved job satisfaction and decrease job stress amongst physicians and nurses; and
- Decreased costs of medical transportation.

IV. CONCLUSION AND FUTURE WORK

The findings of this evaluation indicate that remote robotic presence can have a positive impact on health care delivery in northern Canada. It provides residents living in the northern remote community, improved access to medical services. It enhances the ability of the physicians to collaborate with nurses in the remote community. Telerobotics is associated with a reduction in the cost of medical transportation.

Following the recommendation from the nurses, we have developed a research proposal to evaluate the effectiveness of telerobotic versus usual care for chronic disease management. Because of the positive impact of "Rosie," the local government has decided to fund the continuation of robot telemedicine. "Rosie" is now a permanent member of the staff.

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APPENDIX 1

QUALITATIVE INTERVIEWS FOR PHYSICIANS AND NURSES

1. The robot allows the clinician to participate differently in a virtual consult than with the use of traditional telehealth. On a scale of 1-5 how would you rate the following, with 1 being not important and 5 being important:
   - Ability to move independently in rounds, clinics and emergent sessions
   - Ability to zoom to read charts, monitors, assess patients
   - Ability to utilize ultrasound in diagnosis.
   - Ability to interact virtually with the remote site in a more "natural" way.
2. The ability to access the robot from a laptop wherever they may be, at home, at the office or while traveling may have an impact your workload/workflow. On a scale of 1-5 how would you rate the following, with 1 being not important and 5 being very important:
   - Ability to manage my workload i.e. Less disruptive to my practice, office hours.
   - Ability to allow the physician to see a patient in a timelier manner.
   - Ability to reduce physician patient load during visits to community.
   - Ability for physicians to keep track of patients from home or office.
   - Ability to facilitate better collaboration among team members. Please explain.
3. How would you rate the quality of information received for decision making during the telerobotic encounter from that received using traditional telehealth? Please rate on a scale of 1-5 with 1 not as effective as traditional telehealth and 5 being much more effective than traditional telehealth. Why?
4. How easy was it for you to master the use of the robot? Please rate on a scale of 1-5 with 1 very difficult and 5 very easy
5. Did you see a difference in community acceptance of telerobotics as compared to their acceptance of traditional telehealth? If so, how did it manifest?
6. Did you see a difference in your acceptance of this mode of healthcare delivery compared to traditional telehealth? If so, how did it manifest.

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7. Would having a resource like 'Rosie' be a factor in choosing a new position or remaining in Nain? Please explain.
8. What new applications could you foresee using 'Rosie' for in the future?
9. Has 'Rosie' had any impact on the quality of your work life or how you do business?
   - Reduce stress?
   - Protect professional status in instances where you may be required to work out of scope due to a medical emergency?
10. How would you fix or change the processes or equipment to improve your experience?

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Electronic Messaging to Improve Information Exchange in Primary Care

Reporting from an Implementation and Evaluation Project in North Norway

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***Abstract* – FUNNKe is a large-scale ongoing project aiming to assist in implementing secure broadband communication and support the use of electronic messages between community nursing service, general practitioners and local hospitals in the northernmost region in Norway. The main goal of FUNNKe is to establish electronic communication and information exchange in all sectors of health service delivery in the region. The FUNNKe-project has two distinct parts: The first is the actual implementation phase where the focus is to facilitate and support the municipalities to invest in and start using electronic messages for information exchange. The second part is an evaluation phase focusing on the implementation process, analysing the potential for time savings and perceived changes in quality of care. The evaluation study has a multi-method research approach using quantitative and qualitative methods. This paper describes the planned evaluation, the experiences so far, and reports some preliminary results.**

Keywords - telehealth; electronic messaging; large-scale implementation; community nursing service; evaluation; efficiency.

I. INTRODUCTION

Exchanging health information electronically has been a political goal in Norway since 1997 [1]. In 2010, the Norwegian Health Authorities introduced a strategic program to speed up the implementation process [2]. The main political goal was to improve cooperation between health providers and to improve continuity and integrated patient care. As part this initiative, several projects have been initiated in different parts of the country. In Helse Nord, the northern most health region, a project named FUNNKe was launched in 2010. The main goal of FUNNKe is to establish standardised electronic clinical information exchange in all sectors of the health service in the region. The underlying assumption is that standardised electronic communication will speed up and improve the quality of the information exchanged [3, 4]. And that this will lead to more efficient and high quality service delivery through improved cooperation and better continuity in patient care. Another implicit and common assumption is that the technology alone cannot improve the integration of care, but it can be an important facilitator [5]. FUNNKe aims to assist in implementing secure broadband communication and support the use of electronic messages in all 88 municipalities and four hospital units in the region. The planned e-messaging is between the community nursing services and general practitioners and the community nursing services and local hospitals. Electronic messages between hospitals and general practitioners are already in place and have been operative for several years. The messaging system is based on the ebXML Messaging Service specification (ebMS) and PKI (Public Key Infrastructure). The messages are standardised, fully integrated with electronic medical records (EMR) and sent in a secure national network; the Norwegian Health Network. The technological system has been through extensive risk assessments and has been approved by the authorities.

The FUNNKe-project offers knowledge, technological support, guidance and financial support to the local health services in implementing the messaging platform and start using the messages. Two letters of invitation have been sent to the primary health authorities in all municipalities: one in June 2010; and one in September 2011. Several meetings with local health authorities, community nursing service managers, general practitioners and technical staff have also been arranged to advertise the project and encourage participation. Information leaflets on how to get started, training manuals, and advice on how to organise the implementation process have been distributed and are available online via FUNNKe's web portal [6]. The project will run until December 2014.

The FUNNKe-project has two distinct parts: The first is the actual implementation process where the focus is to facilitate and support the municipalities to invest in and start using electronic messages. The second part is an evaluation phase focusing on assessing the implementation process and analysing the potential for time savings and effects on perceived quality of care of using electronic messages in a nursing care setting. This paper describes the planned evaluation, the experiences so far, and reports some preliminary results.

II. BACKGROUND

There is a considerable interest in implementing digital solutions to improve safety, quality and efficiency of health care provision. It is widely believed that introducing information and communication technology (ICT) systems in health combined with social and organisational changes will improve quality of health care provision, reduce costs and improve efficiency [7]. Little empirical evidence,

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however, exists to substantiate many of the claims made in relation to large scale eHealth technologies [8, 9]. It has also been reported that research in this area is of poor quality [10, 11]. Black et al [8], for example, found in a recent systematic review of reviews that there is a large gap between the postulated and empirically demonstrated benefits of eHealth systems. In addition, they found that there is a lack of robust research on the risks of implementing these technologies and their cost-effectiveness has yet to be demonstrated. Despite this, the technology is frequently being promoted by policymakers and "techno-enthusiasts" as if this was given.

A. *Information exchange in primary care*

The number of patients living at home supported by the local nursing service is increasing. These patients are getting older, they often have multiple diagnoses, and are using a large number of different prescribed drugs [12]. Patients are increasingly being managed by a team of health professionals and this requires an effective communication and information transfer. Time spent on gathering patient level information in primary care nursing services can be substantial. Medication error for example, is one of the more serious challenges in health care in Norway [13, 14]. Limited access to patient information might be one reason for this [4]. Jensen et al (2003) found in a study that there was a discrepancy between what the general practitioners ordered and what the nurses administered in 90 percent of the cases [15].

Inadequate cooperation is claimed to be one of the main challenges the Norwegian health care system is facing [16]. Transfer of patient information and communication in primary care has long been a neglected area [17]. Information transfer both between hospitals and primary care services and within the primary care sector still mostly uses traditional means such as telephone, fax, written notes and verbal communication with the patients themselves. Timey transfer of relevant patient data about diagnostic findings, treatments, and arrangement of post-discharge follow-up may improve continuity of care and patient outcomes. By contrast delayed, inaccurate or lack of information transfer between health care providers may have substantial implication both for patient safety, provider satisfaction and resource use [18, 19]. For example, Kripalani et al found in a recent review that the availability of discharge summaries in primary clinics were low affecting the quality of care in 25% of follow-up visits [3]. About half of adults experience a medical error after hospital discharge, and 19% - 23% suffer an adverse event, most commonly an adverse drug event [20]. Bakken et al. [21] found in a study carried out in Norway, that most general practitioners did not have routines for informing the primary care nurses about changes in patient medication. They also lacked information on how many of their patients the home care nurses had in their care.

It is widely believed that standardised digital solutions will improve both efficiency and quality of care [22]. Several authors have pointed out that lack of common infrastructure is one of the main causes of deficit in information transfer both within and between health care levels [23, 24]. A standardised platform for e-messages is now underway in the Helse Nord region assisted by the FUNNKe-project.

As far as we know, there exists no research on how large-scale ICT implementation processes in primary health care settings should be managed and organised to become successful. Furthermore, research on how electronic messaging between primary care nurses and general practitioners affects quality of care and the efficiency potential in the nursing service is also lacking. Obtaining a scientific-informed perspective on these issues can reduce unrealistic expectations. This might also promote long-term progress and help identifying areas with greatest potential for benefits, suggest priorities for further implementations, and help guide implementation processes in other parts of Norway.

The objectives of the evaluation are to understand the implementation process and to establish if electronic communication between nursing services and general practitioners increase efficiency and improve quality in terms of more continuity and better integrated care pathways. The objectives are: to analyse if frequency and pattern of use is influenced by size, location, living conditions and financial situations in the municipalities affect use; to establish if electronic messaging between nursing services and general practitioners has potential to increase efficiency and improve quality of care; and finally, to provide knowledge of the implementation process that can be used for further development and use.

III. MATERIALS AND METHODS

The evaluation study has a multi-method research approach using both quantitative and qualitative methods. The first part is using quantitative methods to analyse the pattern of use and efficiency potential, and the second part uses qualitative research methods to evaluate the implementation process. The data will be collected using the following strategies: prospective logging of messages; prospective case control study design; a survey using questionnaires and in-depth interviews.

A. *Logging of e-messages*

This part of the project will look into how the health care providers use electronic messaging in the nursing service. Is frequency and pattern of use influenced by size, location, living conditions and financial situations in the municipalities? Will the smaller communities use electronic messaging differently from the bigger ones? And what characterise communities with a high usage rate? These questions will be answered by analysing message logs and municipality characteristics.

Prospective logging of messages including data on sender, recipients and purpose will form the basis for analysing frequency and the pattern of use. All messages in the region will be logged. Frequency of use, sender, where the messages are sent (recipients) and type of messages will be collected over a period of one year. This will also give us insight into how usage develops over time

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and with experience. Seventeen municipalities using e-messaging will be included in this analysis starting after three months of regular use.

B. The time saving potential

In this part of the project, we analyse the effect of electronic messaging on efficiency. The efficiency potential at the local nursing service will be analysed by measuring time savings. The time the nurses spend on the phone collecting patient information from other health care providers and the time spent on reading and writing messages will be will be obtained and registered.

The study design chosen for this part of the evaluation project is a prospective case control study design at the municipality level. This design is suited to estimate the effectiveness of an intervention as it is reflected in routine health care practice. We are interested in analysing the effect of e-messaging in everyday nursing practice.

Specified phone bills from the telephone operators (Telenor and Netcom) will be obtained and used to investigate difference in time costs. The bills will be obtained by the owners of the phone numbers and forwarded de-identified to the researchers. Specified phone bills will provide information about the number of calls, duration and price. We will be able to register who the recipients are (by recognizing general practitioners' and other health care providers' phone numbers) and the duration of the call (waiting and conversation). This will give an estimate on time spent on collecting and confirming patient information. The time spent on reading and writing messages by the nurses will be registered manually using a pre-designed registration form.

A pragmatic approach to sample size calculation is adopted as we want to include as many of the local nursing services as possible. We have invited 20 community nursing services to participate (only one municipality has more than one nursing service unit). We did expect a high no-response rate, hoping to include at least 10 community nursing services. So far 6 nursing services have agreed to participate. The nursing services are divided into smaller units ranging from four to seven units (areas) in each service. The data will be analysed using units (areas) adjusted for number of patients. The outcome measures therefore are number of calls per unit and time spent on the phone per unit. So far we have 31 units to include for analysis. Data have been collected before start-up (at baseline) and will be collected after one year of use. Three of the nursing services have more than one year of experience and will be used for comparison at baseline.

1) Data analysis

The objective above will formally have the form of null hypotheses stating that electronic messaging has no effect on efficiency. Parametric and non-parametric analyses will be used to analyse potential differences. We will use multilevel analysis to adjust for variation within municipalities and nursing services. Regression models will be used to analyse pattern and frequency of use. Additional analyses will be performed for each dimension of the models in order to verify the sensitivity of the results. The effects will be tested at $P < 0.05$ level and the analysis will be performed in SPSS.

C. The quality of nursing services

We also developed a questionnaire addressing the quality aspect of the nursing services after the implementation. We wanted to explore how e-messaging was affecting the quality of the service the nurses provided perceived by the nurses themselves. We had a special focus on the quality of the medication lists (if they felt that medication was more updated and correct), but also asked for general satisfaction and challenges. The questionnaire was piloted on 10 nurses. After one reminder the response rate was only 20% which is inadequate for our purposes. We are now working on an alternative plan on how to assess the quality changes of e-messaging.

D. The implementation process

This part of the project evaluates whether the implementation process has been organised and managed successfully. This part of the study is based on data collected trough questionnaires and semi-structured in-depth interviews.

A convenience sample of project managers at the local health and care services in the municipalities will be approached. We will include municipalities with a varying degree of experiences in using the e-messaging system. These project managers organise, assist and encourage the implementation processes. They are also responsible for supporting and guiding the surrounding municipalities in their designated area.

We have chosen to include a questionnaire as basis for the interviews. This will help form and structure the areas to be covered in the interviews. The questionnaire will be distributed to 17 project managers during October 2012. The main themes explored are: types of collaboration; how they perceive the usefulness of the assistance from the main project; the advice and the competence given; the need for ICT support; problems encountered; and challenges for continuous use of the e-messaging system. The questionnaire also includes spaces for open ended text where the respondents can elaborate on issues they feel are important.

Based on the findings of the questionnaire, semi-structured interviews will be conducted using videoconferencing. The interviews will take place as soon as data from the questionnaires have been analysed. The purpose of the interviews is to gather an in-depth understanding of the findings. The project managers will be asked to explain and deepen their response. The structure of the interview will also open for discussing topics not addressed in the questionnaire.

1) Data analysis

The questionnaire has been developed in the survey and data collection software Questback. Data will be displayed in tables using descriptive statistics. Open ended text will be categorised and analysed according to standard methods. The interviews will be taped and transcribed.

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Notes will also be made after each interview. Two evaluators will read the interviews and identify overall themes. After agreeing on the overall themes, the data will be organised according to main categories and then discussed. This will form the foundation for the data analysis.

IV. PRELIMINARY RESULTS

Halfway into the project seventeen of 88 municipalities in the region (20 %) have implemented the technological platform and are using electronic messages for information exchange. Five of these (Alta, Tromsø Lenvik Dyrøy and Rana) have used electronic messaging for more than a year. The remaining 11 started using the system during the first half of 2012.

A total of 25000 messages have been sent to and from the nursing services in the region during the first 6 months of 2012. Most of the messages have been sent between the nursing services and the general practitioners. These messages are mainly general health related questions about patients and their medication lists in addition to patient updates from the nurses to the general practitioners and information about changes from the general practitioners to the nurses. The nursing services in four of the municipalities (Tromsø and Dyrøy, Harstad and Lenvik) also communicate electronically with the hospital (a total of 1600 messages). Most of these messages contain patient information before hospitalisation and discharge summaries from the hospital to the local nurses. The number of messages sent in the different areas range from 380 in a small local area (Dyrøy with 1270 inhabitants) to 12000 messages in the largest city (Tromsø with 70000 inhabitants), both with more than one year of experience.

As can be seen in Fig 1, the total volume of e-messaging is steadily increasing. The blue curve shows the number of messages sent to and the red curve indicates the messages sent from the community nursing services in North Norway. This figure is borrowed from FUNNKe's web portal with permission [6].

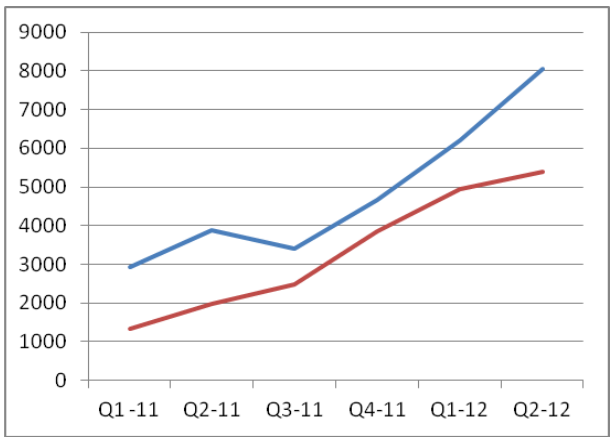

Figure 1. Number of e-messages to and from the local nursing services from the first quarter of 2011 (Q1-11) to the second quarter of 2012 (Q2-12).

The main barriers to actual use reported so far in the project have mainly been around four aspects: lack of political will; shortage of personnel and other resources; lack of ICT skills; and technological difficulties due to old equipment.

Primary care nurses already using e-messaging is reporting that the system seems to be time saving. Previously they spent a considerable amount of time on the phone trying to get in touch with the general practitioners. They are also claiming that having access to ready and updated information is improving the quality of the care they are providing (personal communication).

Preliminary results seem to support the nurses' perceived benefits of e-messaging. We have data from six nursing services. Crude preliminary analyses, unadjusted for patient volume, show that the nursing services who have taken the service into use have 37% less phone volume compared to the control nursing services. Adjusted analyses are planned, but critical data elements are still missing. The time spent on the phone also tends to be less for the e-messaging users. We can, however, not confirm these results yet. The post intervention data collection will start in the first half of 2013. We are also consecutively working to recruit more nursing services to provide data for the quantitative analysis.

V. DISCUSSION

Despite political will and several strategic action plans the health sector has been slow to adopt digital solutions. Over 70 % of the community health services still lack proper ICT equipment and infrastructure to communicate electronically with other health service providers [25]. Information transfer still mostly uses traditional means such as telephone, fax and written notes. The latest health care reform "The Coordination Reform" [26] is encouraging more health services to be provided in local communities where the patients live. More patients are being discharged from the hospital sooner causing a need secure and effective electronic communication between the levels of care [27]. Despite this need for a more timely information exchange the municipalities are slower to implement and use electronic messaging. After two years of active encouragement, technical and financial support and organisational advice still only one in five municipalities have started to use electronic messaging in the region. There might be several reasons for this slow uptake and low use. The main challenge so far has been the integration of the messages into day-to-day work. The administrative routines have had to change to adapt to the new mode of communication. There have been problems with identifying recipients and which addresses to use for which message. Continuous monitoring of the activity and large amount of technological support has overcome these challenges. This highlights the need for a support and troubleshooting plan early in implementation processes.

Another factor that might have contributed to the slow uptake is that most of the municipalities are relatively

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small. Forty-three percent have less than 2000 inhabitants and 77% have less than 5000 inhabitants. This might imply a general shortage of both qualified personnel and financial resources. A general lack of ICT skills tends to limit adoption of the technology [28, 29]. Furthermore, the existing computer equipment is relatively old and of low quality [30] and this can be a major challenge to wider adoption [31]. The cost of upgrading the computer equipment might also be too high. The municipalities are facing a higher cost than expected as part of the latest health care reform.

There might also be a general reluctance towards changing existing routines and implement new working patterns. Organisational barriers such as the absence of clear guidelines defining roles and responsibilities can hamper adoption [29, 31, 32]. There seems to be an overall lack of willingness to innovate in the health sector [29, 31]. The community nurses might also have too busy time schedules caring for patients to innovate.

The main limitation of this evaluation is the low number of community nursing services included for the quantitative analysis. The main problem has been to get the local nurses to respond to our request for data. This might be due to a combination of shortage of time and lack of interest. To get the nurses to register the time they spend on reading, writing and systematise the information is by far the greatest challenge. We will, however, continue our data collection effort.

VI. CONCLUSION AND FUTURE WORK

This paper has described and reported preliminary results from an ongoing large-scale implementation project in North Norway. The project aims to establish standardised electronic clinical information exchange in all sectors of the health service delivery in 88 municipalities the region. Halfway through the project 17 of the 88 municipalities (the community health service providers) have implemented the technological platform and are using e-messaging. The e-messages have mostly been sent between the nursing services and the general practitioners with a much lower volume between the nursing services and the hospitals. Electronic communication between general practitioners and hospitals are already in place. Preliminary results also indicate a potential reduction in number of phone calls to the general practitioners and reduced time spent on the phone for the nursing services using e-messages.

The next step in our study is to begin analysing the implementation process. Questionnaires are now being sent to seventeen of the e-messaging users. Data from the questionnaires will be processed and analysed. This will be followed by in-depth interviews for a deeper understanding of the implementation process.

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Examination of the User Expectations from Hospital Information System

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***Abstract*—Understanding user expectations is an important issue in Hospital Information Systems. The expectations of the users must be well understood and taken into consideration in Hospital Information System design to catch the success and user support. 17 potential end-user expectations from Hospital Information Systems are rank ordered according to the perceived importance of users and the least five expectations appeared to be Privacy, Help Manuals, Security, Research Facilities and Decision Support respectively from the least ranked. These expectations are supposed to be higher ranked. The user assets that may affect this unexpected result are examined. It is seen that perceived importance may change according to the user assets, and these assets have influence on the unexpected result.**

Keywords-Expectation Failure; Expectation Ranking; Hospital Information System; Rank Ordering; User Expectations.

I. INTRODUCTION

Information System (IS) success and failure reasons are largely discussed in the literature. Technical issues, organizational issues, management issues are the main topics for the failure [1-3]. "Expectation Failure" is one of the reasons for the failure, which can be defined as the gap between the users' expectations from the IS and its real performance [4]. IS Success (ISS) reasons are also of great interest to the literature as well as failure reasons.

A. Background

The ratings of the perceived importance usually change from one person to another, because everyone has a different measurement standard and personal approach [5]. Elimination of such individual relativity is possible by means of the rank ordering process [5].

Relative importance and rank ordering of ISS factors directly related to the user expectations are examined in the literature [5-9]. "Realization of user requirements" in Pearson's work [7], "users' confidence in the systems" in Montazemi's work [8] and Eldon's work [5], "user expectations" in Conrath and Mignen's work [9] appear to be in the top five ranked important factors.

In IS context, understanding user expectations is a challenging task [10, 11]. According to the contrast theory, the difference between the expectation and reality is exaggerated, when expectations are not met [12, 13]. The degree of harm increases exponentially. That is, the frustration fuels itself by the word of mouth conversations between users within the organization.

Although the importance of user expectations is known by literature and researchers show great interest to this topic, there is no study about the expectations from Hospital Information System (HIS).

In the previous work, perceived importance of the user expectations from HIS was examined [14]. In this study, it was stated that the expectations of users must be well understood and discreetly worked out to design and implement a successful, acceptable and useful IS [14]. The expectations and priorities of these expectations must be well understood. In healthcare, huge investments are made in IS and failure rate is 60-70% [15]. User acceptance is important to catch the success. It can be provided with high expectation meeting ratios. That may lead higher usage ratios, resulting in successful IS implementations.

B. Motivation

There were surprising results in the previous work [14]. Decision Support, Research Facilities, Security, Help Manuals and Privacy expectations were the least five ranks. Except Help Manuals, the other four are expected to mean more importance to the users according to the literature.

Patient's health data are the most sensitive data about humans [16]. Electronic Patient Records and Information systems give opportunity to easy and unauthorized access to the private and very sensitive data about the patients, when compared to manual archives. For this reason, the security and privacy of the patient data in HIS are questioned.

Decision Support functions are crucial for end-user acceptance [17]. In literature, there are studies proving Hospital Information Systems (HIS) with Decision Support functions be more successful [18-21]. It supports the clinical diagnosis, enlightens the physician in treatment by reminding him the right trials and also provides him with the background information of the patient.

Clinical research is another indispensible virtue of the HIS [22]. Medicine improves by way of the researches. Consider making the research without the facilities of the HIS in medicine. Examining the handwritings in the manual

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archive, within the unstructured data and hard to read handwriting would be long time consuming and difficult process. Additionally, this way of research is prone to mistakes and misleading results.

The literature tells us these expectation variables are/should be indispensible and crucial virtues of the HIS. It would be hard to work in complex healthcare environment for the healthcare professionals without these facilities. The motivation of this work is the low ranks of these important aspects of the HIS, which do not comply with the literature.

The aim of this study is to examine further the unexpected least five ranked expectations. The objective is to get an answer to the question "What personal features of the HIS users (named as 'assets' in this study) may be effective in this unexpected result".

Materials used in the study will be given in the Materials section. In Methods section, the methods used to get the study results will be described. In Results section, the result of the study will be given without any comment, and these results will be discussed in the Discussion section. The findings of the study and the proposed future work will be in the Conclusion and Future Work part.

II. MATERIALS

A. User Expectations

HIS specifications, computer support centers' experiences and interviews with HIS end-users are used to constitute the possible user expectations from a HIS. These possible expectations are grouped to make them more comprehendible. The expectation groups constitute Expectation Dimensions of the study, which are Usage Expectations, System and Data Expectations, Improvement Expectations and Managerial Expectations. Table I lists what an end user may expect from a HIS. These expectations are constituted and presented to the literature to measure the expectation meeting ratios of HIS by a newly proposed evaluation framework for HIS [23].

TABLE I. POSSIBLE USER EXPECTATIONS FROM HIS

Usage Expectations	System and Data Expectations	Improvement Expectations	Managerial Expectations
Ease-of-use	Consistency	Improving Service Quality	Reporting Facilities
Need For Training	Privacy	Decreasing Work Load	Decision Support
Help Manuals	Security	Bringing Positive Change	Function Sufficiency
Speed	Availability	Research Facilities	
User Support	Interoperability		

TABLE II. USER ASSET VARIABLES, TYPES AND VALUES

User Asset Variables	Values	Types
Education	Primary, High School, University graduate	Ordinal
Sex	Male, Female	Nominal
IS Experience	Inadequate, Average, Good and Advanced.	Ordinal
Business Title	Physician, Nurse, Laboratory Technician, Office workers, Others	Nominal
Working Unit	Administrative Unit, Basic Medicine, Internal Medicine, Surgical Medicine	Nominal

B. User Assets

In this study, five user assets, that may affect the least ranked expectations, are examined, *Business title, Education, Sex, IS experience, Working Unit*. User asset variables, their values and types of variables are given in Table II.

C. Data

Expectation Questionnaire is applied in a big hospital for data collection having 1700 (900-1000 online) HIS users.

Volunteered HIS end-users in the hospital have participated in the study.

III. METHODS

A. Expectation Questionnaire

Data are collected using the questionnaire method. The questionnaire, named as "Expectation Questionnaire", is formed and used for collecting medical users' perceived importance. For each expectation variable, a question is asked to capture the importance of that variable. Users are asked to express their importance weights using 5-point Likert scale (very important, important, average important, not so important, not important), ranging from 5 (very important) to 1 (not important).

B. Analysis:

The internal consistencies of the answers to the Expectation Questionnaire are measured by Cronbach´s Alpha coefficient, which is commonly used as a measure of the internal consistency or reliability [24]. Statistical Package for Social Sciences 19.0 (SPSS, SPSS Inc, Chicago, Illinois, USA) is used to compute Cronbach Alpha coefficient. Cronbach´s Alpha greater than 0.70 is considered reliable.

Expectations are rank ordered in variable base for all users in the previous work; the results are given in Table III [14]. In this study, they are rank ordered for user assets under examination and the results are given in Table IV-VIII.

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In expectation based ranking, the final rating RF of the expectation variable *j* is computed by

$$RF_j = \sum_{i=1}^{k} W_i R_i / n \quad (1)$$

where *k* is the number of Likert scales used (5 for this study) , W is the weight (1 to 5) of the Likert scale *i*, R is the number of answers given as that Likert scale and n is the total number of answers.

IV. RESULTS

660 questionnaires are passed out and 504 are returned by the users (response rate is 76.4%); 428 of them are completely filled without any missing importance rating.

Cronbach´s Alpha coefficient, measuring the reliabilities (internal consistencies), is 0.871. It is apparently high and greater than 0.7, meaning the answers to the questions are internally consistent.

The rank orders of the expectation variables are given in Table III. The top five ranked expectations are Availability, Speed, Bringing Positive Change, Ease of Use and User Support. The five least ranked expectations appeared to be Privacy, Help Manuals, Security, Research Facilities and Decision Support respectively from the least ranked.

Tables IV – VIII give the least ranked five expectations according to the user assets under examination in the format final rating/rank, where "/1" represents the least ranked and the others are in ascending order, where n is the number of users. The rank orders in these tables are computed by (1) just as in the table III.

TABLE III. EXPECTATION RANKING

Expectation	r[a]	RF[b]
Availability	**1**	4.792
Speed	**2**	4.790
Decreasing work load	**3**	4.706
Ease of Use	**4**	4.685
User Support	**5**	4.685
Need for Training	**6**	4.657
Improve service quality	**7**	4.633
Function Sufficiency	**8**	4.605
Consistency	**9**	4.537
Bringing Positive Change	**10**	4.477
Interoperability	**11**	4.472
Report Facilities	**12**	4.411
Decision Support	**13**	4.367
Research Facilities	**14**	4.288
Security	**15**	4.255
Help Manuals	**16**	4.245
Privacy	**17**	4.030

a. r = Rank.
b. RF = Final Rating

TABLE IV. LEAST RANKED EXPECTATIONS (TITLES)

Expectation	Physician (n = 147)	Nurse (n = 140))	Laboratory Technician (n = 29)	Office Worker (n = 39)	Other (n = 37)
Privacy	3.680/**1**	4.293/**4**	4.241/**2**	4.000/**3**	4.324/**3**
Security	4.048/**2**		4.241/**3**	4.256/**4**	
Decision Support	4.483/**3**	4.286/**3**	4.310/**5**	4.385/**5**	4.378/**4**
Interoperability	4.517/**4**				
Consistency	4.544/**5**				
Report Facilities		4.221/**2**	4.276/**4**		
Research Facilities		4.108/**1**		3.923/**2**	4.270/**2**
Help Manuals		4.364/**5**	4.172/**1**	3.923/**1**	4.162/**1**

In Table IV, *title* asset values, Privacy and Decision Support is in the five least ranked in all titles, Research Facilities and Security is in the least ranked in three out of the five titles. In Table V, *education* asset values, Privacy, Security, Help Manuals and Research Facilities are in the five least ranked in both graduate groups.

In Table VI, *sex* asset values, Privacy, Decision Support, Help Manuals and Research Facilities are in the five least ranked in both sexes. Security is in the five least only in Men.

In Table VII, *IS experience* asset values, Privacy and Help Manuals are in the five least ranked in all four groups, Security and Research Facilities are in the five least ranked in the three of the four groups. Decision Support is in the five least in two groups.

In Table VIII, *working unit* asset values, Privacy, Security, Research Facilities and Help Manuals are in the five least ranked in all four groups. Decision Support is in the five least in two groups.

TABLE V. LEAST RANKED EXPECTATIONS (EDUCATION)

Expectation	High School Graduates (n = 34)	University Graduates (n = 378)
Research Facilities	4.071/**1**	4.305/**4**
Help Manuals	4.143/**2**	4.257/**2**
Privacy	4.143/**3**	4.029/**1**
Security	4.286/**4**	4.262/**3**
Bringing Positive Change	4.286/**5**	
Decision Support		4.378/**5**

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TABLE VI. LEAST RANKED EXPECTATIONS (SEX)

Expectation	Men (n = 183)	Women (n = 209)
Research Facilities	4.475/**4**	4.139/**1**
Privacy	3.825/**1**	4.215/**2**
Help Manuals	4.257/**3**	4.249/**3**
Reporting Facilities		4.273/**4**
Decision Support	4.492/**5**	4.283/**5**
Security	4.115 /**2**	

TABLE VII. LEAST RANKED EXPECTATIONS (IS EXPERIENCE)

Expectation	Inadequate (n =35)	Average (n = 160)	Good (n = 196)	Advanced (n = 31)
Privacy	3. 800/**1**	4.169/**2**	4.005/**1**	3.350 /**1**
Help Manuals	4.067/**2**	4.238/**3**	4.265/**3**	4.350/**4**
Security	4.133/**3**		4.255/**2**	3.650/**2**
Research Facilities	4.200/**4**	4.113/**1**	4.418/**4**	
Function Sufficiency	4.267/**5**			
Decision Support		4.281/**4**	4.439/**5**	
Report Facilities		4.319/**5**		
Bringing Positive Change				4.300/**3**
Consistency				4.350/**5**

TABLE VIII. LEAST RANKED EXPECTATIONS (WORKING UNIT)

Expectation	Administrative Unit (n =30)	Basic Medicine (n = 51)	Internal Medicine (n = 177)	Surgical Medicine (n = 134)
Privacy	3.967/**1**	4.294/**2**	3.927/**1**	4.090/**1**
Research Facilities	4.067/**2**	4.314/**3**	4.284/**4**	4.358/**5**
Help Manuals	4.100/**3**	4.118/**1**	4.249/**3**	4.343/**4**
Security	4.300/**4**	4.373/**4**	4.175/**2**	4.328/**3**
Interoperability	4.433/**5**			
Report Facilities		4.373/**5**		
Decision Support			4.429/**5**	4.299/**2**

V. DISCUSSION

In the previous work, it was seen that end-users of HIS have the high priority for the Usage Expectations [14]. Four of the top six rated expectations were the Usage Expectations variables. This was commented as "a HIS must be easy to use, easy to learn, fast and well supported to get users' support and appreciation".

The surprising result was the least ranked five expectations, namely, Privacy, Security, Research Facilities and Decision Support. As stated in the introduction part, these are of great importance for HIS. In this study, user assets that may affect this surprising result are examined.

Examination of the user titles' influence shows us Privacy and Decision Support is ranked as the least in all titles. All the users independent of the title think these two properties of the system as the least important. This result is completely opposite of the literature. Nurses, Office Workers and Other titles ranked Research Facilities in the least five. Considering the number of the users in the groups, Office Workers and Others are very small to influence the complete result, so they can be assumed negligible for this variable. As for the Nurses, being the second biggest group with 140 users, it can be said that it was effective for the complete result. Research facilities of a HIS comprise useful tools for nursing informatics. This result can be interpreted as most of the participant nurses are not interested in research.

Education asset does not give us any justification for the unexpected results. The great majority of the participants is university graduate (n = 378); so the least five of this group is identical with the general result.

When we examine the effect of sex, it is seen that Privacy, Decision Support and Research Facilities are in the least five for both. But, Men users have difference in Security. For Security expectation, this group has influence on the general result when considering the large number with n = 183.

In IS experience, Privacy, Security and Research Facilities are in the least five for all. Users defining themselves as having average and good IS experience have rated Decision Support as 4th and 5th least. That makes this expectation be in the least five in the general result.

Privacy, Security and Research Facilities are in the least five according to the working unit for all assets. Only in Internal medicine and Surgical Medicine users' ranking, Decision Support is in the five least ranked expectations. This is another surprising result; Decision Support is a powerful virtue of the HIS for surgeons especially to decide operation.

VI. CONCLUSION AND FUTURE WORK

In summary, in the study it is clear that:

- Nurse users have influence on Research Facilities
- Men users have influence on Security,

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• Users with average and good IS Experience have influence on Decision Support ,

• Users working in Surgical Medicine and Internal medicine have influence on Decision Support to be the least ranked in general result.

Ironically, Privacy is in the least five in all of the examinations.

The users' assets, Title, Sex, IS Experience and Working unit have influence on the unexpected result. The study shows perceived importance may change according to user profiles. Although the literature says these four expectations under study is indispensible virtue of the HIS, the users may think just the opposite.

This study is one step forward for the investigation of these unexpected results opposite of the literature. But still we don't have justifying explanation. Let alone justifying, more surprising findings are faced such as the surgeons thinking Decision Support less important. The study should be deepened to analyze these results and get satisfying findings. These users groups under study may be further detailed and a hierarchical grouping can be made such as Nurses working in different units, users working in different units having different levels of IS experience etc.

Another reason of these least ranked expectations may be related to the quality of the HIS used. If it is unable to give the basic virtues such as working without outage (availability) and fast processing (speed), the top perceived importance may appear as being basic usage expectations. This issue may also be further studied.

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Exchanging Nursing Oncology Care Data With use of a Clinical Data Ware House

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***Abstract*— Isala Clinics Hospital and Icare Homecare under leadership of Windesheim use a multi-method approach to standardize nursing data for oncology care based on Detailed Clinical Models (DCM), and use these DCM as requirements for the Electronic Health Record (EHR) system. Further, the DCM are used for extracting the data from EHRs into a Clinical Data Ware House (CDWH) that will be deployed for different data uses. Data uses include exchanging clinical data from hospital to homecare using Health Level 7 v3 Care Record message, and reuse data for quality reporting. This paper presents the research approach including the design for the infrastructure, and the results from the first phase. The paper illustrates that based on existing materials, widely available for nursing, it is feasible to determine the data needs for exchange and for various data use purposes. In particular the results of standardization and messaging are presented.**

Keywords: oncology nursing, detail clinical models DCM, electronic health record EHR, nursing informatics, clinical data ware house, HL7 v3 Care Record.

I. INTRODUCTION

Many development projects towards the electronic health record (EHR) state that one reason for their existence is the abundance of data for secondary uses [1, 2, 3, 4, 5]. It is assumed that the exchange of clinical data for continuity of care and the extraction of clinical data from the EHR can be taken for granted. However, that is not the case. There are several reasons why the electronic exchange and aggregation from the EHR for continuity of care or for secondary use cannot be taken for granted, but needs substantive work, including tackling privacy issues, EHR performance, data use, EHR format, and data aggregation [1, 2, 3, 4, 5, 6, 7, 8].

These distinct tasks are combined into a project for nursing care for oncology patients, currently treated in the Isala Clinics and supported at home by Icare Homecare. The research questions for this project are the following:

1. How can a CDWH for Isala Clinics be developed for basic patient data, generic nursing data and data about oncology nursing, allowing management of EHR data?

2. Can the nursing data be standardized and mapped to specifications for different data uses as electronic exchange, quality indicators and clinical studies?

3. Can we use existing standards (DCM, HL7) to facilitate electronic exchange of nursing oncology care data?

This paper further describes the background, such as earlier research in medical databases, a short introduction of the participants, and the various concepts involved in this project. The Methods describes the selection of useful DCM for oncology patients. The Results section explains which nursing data and DCM are selected, the requirements for the CDWH, and the legal aspects. A blueprint of the CDWH is presented, and the paper ends with the discussion and conclusions for the project.

II. BACKGROUND

A. Clinical Data Ware House

Huff et al are among the firsts to define a clinical data warehouse as a separate system linked to an EHR [5]. Sahama & Croll define a Data Warehouse as a data structure optimized for distribution, mass storage and complex queries [6]. An ISO Technical specification guides a standard approach to CDWH development [7]. These and other inputs lead to the main tasks for this project:

- Privacy regulations prevent different uses of an individual's clinical data. In order to allow electronic exchange and secondary use of clinical data, regulations, consent, and data protection measures have to be followed [1].
- Performance of the EHR might be jeopardized when large queries are carried out on the records directly [3]. Similarly all clinical data required for continuity of care and specified purposes might not be available in one system and need to be collected and combined from multiple data sources [7].
- Clinical data are useful for continuity of care. Electronic exchange of data requires a high level of standardization of nursing data in order to allow their use by receiving EHR [2, 7, 9].
- The EHR format is not necessarily fit for secondary data use. This format can be both its structure e.g. type and number of record tables, nature of the data (free text, numbers, coded), and use versus non-use of standard or local terminology and coding. To use EHR data for exchange and secondary uses it is required to export data from the EHR, standardize and collect data in the format for secondary data use, and import the data into a clinical data ware house (CDWH) [3, 4, 5].
- Data have to be aggregated for secondary data use [3]. Aggregation involves a process of selection of subsets of data relevant for the purpose, and to collect and store them separately [8]. Next, the intended manipulations to the data have to be defined, such as construction of numerators and denominators, the querying of the data set, and their calculations or statistical analysis [8].

Hence, for our project, a new type of CDWH is defined: use of a polyvalent database with structured data, including

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the data context, linkage to medical knowledge and meta-information, using unique code from standardized terminologies that facilitate data exchange for continuity of care, and queries for different purposes.

B. Participants in the project

The project is carried out by the Windesheim department of ICT innovations in health care. This lector led research group focuses on the quality of information management in health care, meaningful application of health information technologies, and their evaluation. Researchers and students from Windesheim School of Information Sciences (SIS) and School of Health Care (SHC) participate in this project.

Isala Clinics Hospital is the largest Top-clinical hospital in the Netherlands, with 5300 employees and 1000 beds. Per annum Isala Clinics treats more than 502.000 patients in out-patient visits, 47.000 patients via admissions and 48.000 in day care. Besides all basic care and treatment, top clinical functions offered include heart surgery, neonatal intensive care, trauma center, neurosurgery and bone and stem cell transplants. Innovation, education and research is carried out by the Isala Academy, with 180 to 200 annual peer reviewed publications in health research.

Icare Homecare is one of the brands of the Espria concern for home care, child care, maternity care, mental health care, among others. Espria has 16.000 employees at full concern level. Espria offers living, welfare, care and social services. Icare offers the home care, mainly via professional nurses, one specialty concerns the oncology visits in collaboration with Isala Clinics.

C. Detailed Clinical Models (DCM) and Health Level 7 (HL7) v3 Care Record Messages

Detailed clinical Models (DCM) link clinical concepts (data) via linkages to standard terminologies and codes to define the semantics, and identify the clinical context and knowledge. DCM handle the conceptual level and add a logical model in Unified Modeling Language (UML) to represent it [9]. For implementations, these UML models are transformed into the required technology.

The HL7 working group 'Patient Care' developed HL7 v3 messages allowing clinical content to be exchanged between EHR's, or systems for secondary data use [7]. Each message has specific dynamics for the care process. In particular sender, receiver and subject data are included, as well as clinical data. The Care Record message is useful for sending structured nursing data between health care facilities for continuity of care [7]. DCM examples for clinical purposes include their transformation into HL7 v3 Care Record messages. This is using DCM in a Model Driven Architecture (MDA) approach [10].

D. Electronic Health Records (EHR) in Isala and Icare

Both health care institutions work with EHR systems of quite older generations with a major focus on administrative data and elementary clinical data. Both systems do not include all required nursing data for oncology care, and do not include a full nursing care plan. So one of the outcomes of this project is the functional requirements document describing for one specialty what their future EHRs needs to be capable of. The Isala Academy is carrying out clinical research and needs the CDWH for this. At this moment a research data base is used and functions well for the specific purpose. However, it does require multiple manual data entry activities, and the consistency with clinical data and research data can be difficult to keep at some times. In addition, quality reporting is increasingly important. Hence, the polyvalent database in the form of a CDWH is seen as a strategic asset to standardize data, to obtain requirements for the EHR, and to facilitate clinical reporting and research by the oncology nurses.

III. METHODS

The project started in September 2011 and follows different steps including identifying data needs of nurses for oncology care. Next is that these data are standardized using the DCM approach [9]. The oncology nurses reviewed and completed a data set and the relevant DCM.

The literature review of CDWH and analysis of current systems and data uses resulted in a complete set of requirements on which the data warehouse can be built. The final step is the actual functional design and the CDWH implementation.

Along the nursing data content and the technical requirements for the CDWH itself, also specifications for the HL7 Care Record message and its DCM based content where established.

In order to meet privacy regulations data with patient names and id for continuity of care, and data for quality studies, indicators, reporting and research will be anonymous. Using legal inquiry, the way how this can be done is described.

This is all illustrated in Fig 1. Current EHR and auxiliary system data will be mapped to the DCM specifications in the next phase, as are the query definitions.

IV. RESULTS

A. Juridical & ethical aspects

In medical information systems, personal data is stored and processed in patient records. These data are personal and processing data about a person is subject to legislation i.e.: the Dutch Personal Data Protection Act [11], which is in alignment with the European Data Directive [12]. In fact, according to article 16 of the Dutch Personal Data Protection Act, data describing one's health is considered to be special data, of which processing is prohibited except for specific institutions and purposes identified by article 21 [13]. Therefore, special attention is required when processing medical information. This paragraph discusses the impact of juridical and ethical aspects on the design of the CDWH.

According to the Dutch Personal Data Protection Act, several dimensions of data processing are of special interest:

- Transparence. Inform the patient about what data is processed and by whom. Request approval .
- Purpose-specification. The purpose of data processing activities must match the purpose for data collection.

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- Legitimate basis. Data processing activities are in line with business goals, patient approval and (inter)national legislation as supervised by the Dutch Data Protection Authority.
- Retention. Data will be stored for a limited time.
- Data Quality. The processes will include activities to ensure optimal data quality.
- Data Security. Shielding data from unauthorized use will be in line with available technical solutions.

In this case, medical data of patients are used for two purposes: data exchange with care partners and scientific research. A legitimate basis for these types of processing can be created by acquiring explicit approval from the patient. Currently, patients are informed about the use for scientific research only. In this project, Isala is advised to inform patients about the data transfer to business partners as well.

As part of this research a limited survey amongst patients indicates that patients may not feel comfortable with their data being used for unknown purposes. Acquiring approval should therefore include an explanation of the (implications of the) types of data which will be processed. Medical data is classified as the most sensitive group of data available; therefore, additional to creating a legitimate basis, data used for scientific research should be made anonymous by removing all personal identifications.

This has implications for the design of the CDWH. In the CDWH, special data marts for scientific research will be defined, providing researchers access to anonymous data only. Data determined for information exchange between care partners will be made available by separate data marts, giving authorized care partners access to identifying information. In the areas of retention and data quality, additional information needs to be acquired. In the remainder of the project, additional privacy enhancing technologies may be identified and added.

B. Nursing oncology data set and DCM

In order to find out which general patient information is needed in the transfer from the hospital to homecare for oncology patients, 4 lists were created containing general patient information and information on the care organizations and next, were distributed to 13 nurses working in both organizations. These 4 lists came from HL7v3 CMETSs person and patient and from data of the V&VN/NICTIZ project e-Overdracht [14]. The nurses were asked to score whether or not a specific item was important for them to know in the transfer of oncology patients. A total set of 80 data elements/concepts was determined and integrated into one general questionnaire and implemented in the CDWH. Then, the work group in the project started with reviewing existing DCM on their relevance to this questionnaire. This is necessary for the CDWH data and coding requirements. The DCM are partly available from earlier external projects and are drawn up according to the National DCM guideline for DCM projects in the Netherlands [9], and will be submitted to a national DCM repository [15]. A list of DCM was drawn up of which some need smaller alterations in order to be linked to the specific group of patients. Available DCM that are found to be important are e.g. pain, nutrition, length, weight, sensitiveness etc. (Table 1).

TABLE I. **DCM AVAILABLE AND SELECTED**

Table 1: DCM available and selected	
Pain	Sensitiveness
Nutrition	Length
Diabetes treatment	Weight
Usage of appliances	Social information
Decubitus wound classification	Person / patient data (HL7 CMET)
Defecation	

Additional DCM where created to augment the existing examples. After some research, it was concluded that patients with esophagus carcinoma or stomach carcinoma need homecare and that for the nurses who provide homecare, it is important to know which tumor typology the patient has. Therefore, a DCM for the TNM classification of esophagus carcinoma and a DCM for TNM of stomach carcinoma was designed. Also, a start was made on the design of the treatment of esophagus cancer and tube feeding (Table 2). In the next phase of the project, more DCM will be selected or created.

TABLE II. ADDITIONAL DCM'S CREATED

Table 2: Additional DCM's created
Tumor typology esophagus carcinoma
Tumor typology stomach carcinoma
Generic data about cancer treatment esophagus cancer
Tube feeding care

C. CDWH Requirements

Analysis of the existing situation in the Isala clinics and Icare, and the literature study for the CDWH revealed a set of functional requirements for the CDWH. These are presented here:

- Data are standardized and structured according to DCM format in the Dutch National Guideline [9], and draft ISO technical specification DTS 13972. [16]
- Data are coded using a unique code per data element and a unique code per value where a value set is applicable. Codes are used from Snomed CT, LOINC, ICD-10, ICF, ICNP, among others.
- DCM's selected and created are accepted by the nursing profession with Isala and with Icare as fit for purpose and properly defined. To achieve this, a verification and adoption process was used.
- The CDWH shall be able to export data in HL7 v3 clinical statement format in order to have payload for the Care Record message [7].
- Specifications of the current Isala Research Database are to be met. For this reason, besides the basic DCM materials, the tumor typology from existing research was used for additional DCM.

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- The data specifications and import /export for the EHRs and CDWH are based on national or international standards. The same will have to apply to the queries that will be developed in a later phase.
- Standards based automatic import from EHR to CDWH.
- The CDWH shall be able to import raw data from different systems, store them in the agreed DCM based standard format per data element with codes and contextual information.
- The CDWH shall be able to sort data and support different queries, among those that are Structured Query Language (SQL) based.
- The existing data in the hospital will be queried / extracted from EHR and auxiliary systems to be mapped and coded into the required content format for CDWH storage.
- The EHR and auxiliary systems data will be exported in XML format, or transformed to XML for import in the CDWH.
- The CDWH can export the standards based data to XML format.
- Storage of the standardized data in the CDWH shall not be independent, meaning not dependent on specific applications or application formats.
- The CDWH shall allow sorting, combining, grouping, calculating, and aggregating data using different techniques.
- The CDWH should allow defining different queries, reports, and other functions in order to generate data extractions and /or reports, quality indicators, and research data.

The addition, the requirements where used to draw up an initial blueprint for the CDWH. Figure 2 illustrates the main components of the CDWH approach. In particular the distinction that a separate data type is created per use is seen as beneficial for both privacy reasons and for ease of development and deployment.

D. Instructions

Ongoing part of the project is the preparation of teaching materials. These include instructions for nurses with respect to structured and coded data entry in EHR, and for use of results from the CDWH, for instance using quality indicators in practice to improve patient care directly. Further teaching materials will be the CDWH functional design aiming at students and technicians in health care to create such CDWH. A business case package aims at health care managers and decision makers to justify investments.

V. CONCLUSION

There is a challenge for the nursing profession to reuse nursing data. Like with any goldmine: the mining needs a careful construction and security measures to be safe. We have discussed legal implications, consent for data exchange and consent for data use and data protection measures. In a first pilot, some patients were interviewed and think they need to know exactly what goes over the wire about them.

Nurses determined a baseline set of about 80 data elements, grouped in several DCM. Standardizing patient data via DCM methodology proofs a constructive way for professional content and technological specifications. DCM are available in a repository, allowing a jump start in the project because they adhere all to the same technical format. [9,16]

Requirements for the CDWH could be determined via the literature, however, review of current uses of different data bases in the Isala Clinics, did reveal additional requirements. In particular separating the EHR/IT use of data and the queries against the data in the CDWH is seen in practice as an important requirement to keep up system performance. The solution to create a separate data mart for each data use is not uncommon. However, what we have added here is the storage of identified patient data in the CDWH as part of the daily operations in the hospital, as such not requiring additional consent, and allowing measures for data corrections to be dealt with at that level.

Next, each purpose can identify the data required, ensure specific consent issues handled, and specify the query for the data mart. That data mart will store the data, the consent and only identified data will go in the data mart for the continuity of care exchange, and only anonymous data will go into the data marts for quality reporting and research purposes. Hence, for the patient it is always clear were his / her data are used for and consents can be given separated.

On the technical level, the import from data from several source systems into the CDWH is identified, the storage in CDWH, the allowed use in the data mart, and finally the exports to the relevant subsystems. This architecture is solid and allows a step by step completion. CDHW in itself are not new, however for polyvalent data use, and in particular DCM based data storage brings new dimensions.

For Windesheim, the set of methods and examples serves as a large library of instruments useful for ICT in health care projects.

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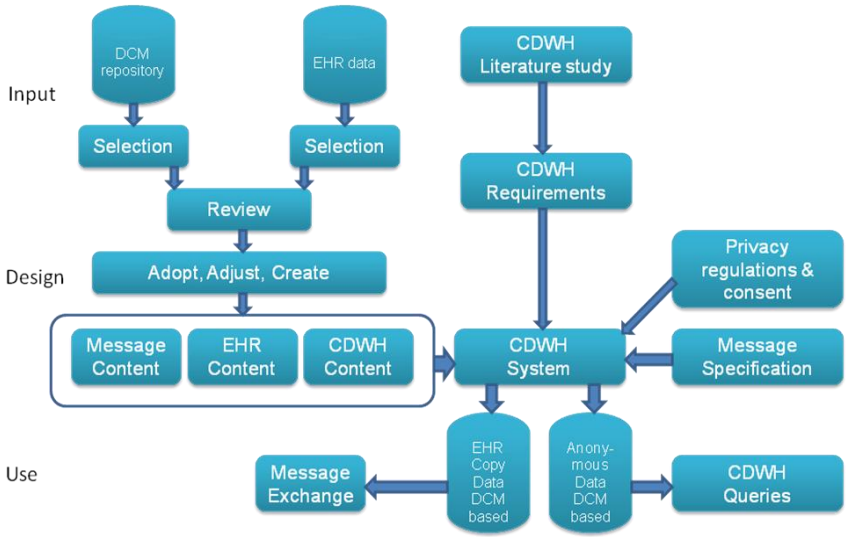

Figure 1. DCM review, adjust, create, CDWH & message specification and uses, and privacy measures for the developmental process.

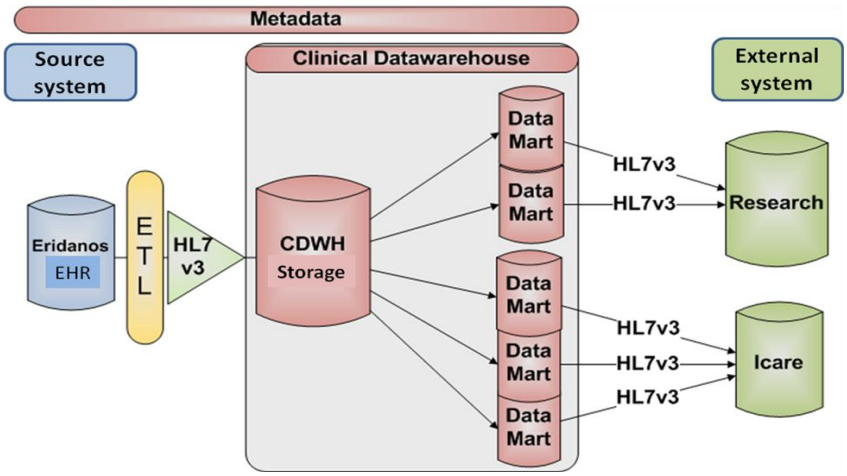

Figure 2. Architecture and main components for the CDWH for oncology nursing.

Get Moving - the Practice Nurse is Watching You!

A case study of the user-centered design process and testing of a web-based coaching system to stimulate the physical activity of chronically ill patients in primary care.

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***Abstract*—This paper describes the development and testing of a web-based coaching system. The system informs the practice nurse about the level of physical activity in daily living of patients who are using the *It's LiFe!* tool. Nurses can monitor patients via a secured website. Patients' physical activity is measured in minutes per day compared to pre-set activity goals. The goals are set by the nurse in dialog with the patient. To increase the probability of effective use, the coaching system was developed and tested in an iterative way, following user-centered design principles. The needs and preferences of practice nurses were determined through qualitative research. Automatically generated feedback messages were defined based on the requirements of practice nurses. The usability of the system was evaluated in a laboratory situation. The results from these tests gave insights into how to improve the structure and the quality of the information of the system.**

Keywords*— *user-centered design; persuasive technology; physical activity; self-management support; primary care.

I. INTRODUCTION

According to guidelines and care standards, stimulating physical activity is an important element in the treatment of people with a chronic disease such as chronic obstructive pulmonary disease (COPD) or type II diabetes (DM) [1][2]. In the Netherlands, the majority of chronically ill patients are treated in primary care. They visit the family practice regularly to monitor their condition and it is the task of the practice nurse to provide lifestyle counseling during these consultations [3][4].

The use of technology for long term monitoring and feedback could support patients in achieving a more active lifestyle and could also help practice nurses to coach patients in establishing this behavioral change more easily. An example of a technological lifestyle intervention is self-monitoring of physical activity using a pedometer or an accelerometer. Although this has been identified as an effective approach towards behavior change, it is not often used in practice [5][6]. In the project ***It's LiFe!*** (an acronym for **I**nteractive **T**ool for **S**elf-management through **Li**festyle **Fe**edback**!**) an innovative monitoring and personalized feedback tool was developed and tested. The tool aims to support patients in achieving an active lifestyle as part of their self-management [7]. The tool consists of three elements:

1. a 3D accelerometer worn on the hip;
2. an application (app) on a Smartphone;
3. a server and a web application called 'It's LiFe! monitor'.

The patient receives three types of feedback on the mobile phone concerning the amount of activity, the amount of activity in relation to an activity goal, and the response of a practice nurse based on the measured activity.

In this paper, the emphasis is on the third element: the development and testing of the server and the web-based coaching system used by practice nurses in primary care.

The involvement of users in the development and testing of technologies is associated with significant benefits such as: the generation of ideas by users; an improvement in system designs and user interfaces; considerable improvement in the functionality, usability, and quality of the system; access to and knowledge about user perspectives [8]. Furthermore, early and on-going user involvement and a close fit with organizational priorities and processes are important because attention paid to socio-technical factors maximizes the likelihood of successful implementation and the adoption of the technology [9].

Therefore the aim of this study was to examine the user requirements for the *It's LiFe!* monitor and to test the extent to which practice nurses were satisfied with the system. The following research questions were posed:

- What are the user requirements for the coaching system from the perspective of a practice nurse?
- How do practice nurses rate the usability (user performance and satisfaction) of the developed system?

In this paper the methods and some preliminary results of the development and testing of the monitoring system will be described and plans for the upcoming years will be explained.

II. METHODS

A user-centered design strategy was chosen for the development and testing of the tool, the coaching system and the Self-management Support Program (SSP), the behavior

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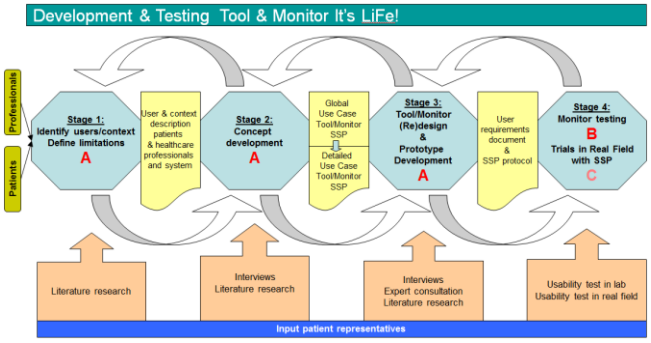

Figure 1. Iterative user-centered design model.

change counseling protocol for practice nurses. This strategy was based on several existing models for the design of medical devices [10-12]. The model is depicted in Figure 1.

From November 2010 to September 2012 three sub-studies were undertaken: a user requirements study (A), a test of the system in a laboratory situation (B), and a pilot study (C). In this paper some preliminary results of studies A and B will be presented. The studies were successive in time, but user-centered design requires iteration, which is why some results of the final study revealed new user requirements additional to the results of the first study. The optimization of the system is therefore an on-going process which started with a general project idea.

This project idea was developed together with several experts and business partners. It was based on a literature review of studies on coaching patients to achieve a more active lifestyle [13–18]. Subsequently a 'use case' was written [19] from the perspective of a practice nurse. A use case is a narrative scenario comprising a description of four main elements (PACT): the people involved (P), their activities (A), the context (C), and the technology used (T) [20]. The use case was a description of the use of the coaching system by a practice nurse coaching a patient in achieving an active lifestyle who started using the tool.

A. *User requirements*

A qualitative study was undertaken using semi-structured, audio-taped interviews in two iterative cycles to determine the user requirements of the coaching system.

Sixteen interviews with care professionals, directly involved in the care of patients with COPD or DM were held. In the interviews, the care professionals gave their opinions of the use case, different aspects of the coaching system and the use of the system in daily practice.

The interviews were transcribed verbatim and the data were analyzed, using the QSR NVivo 2 software package, following a directed content analysis method [21][22]. General themes emerged and these themes were used as input for the user requirements document.

Based on this document, the system was built in collaboration with two companies: Sananet Ltd developed the web-based system as part of a special program (It's LiFe! monitor) in an already existing system (SananetOnline) and IDEE/Maastricht Instruments Ltd provided the upload of the data from the It's LiFe! app on the Smartphone to the Sananet server.

B. *Usability*

The system was tested at Maastricht University by five practice nurses to reveal the utility (whether the system provided the necessary features) and the usability (whether the user interface and content areas of the system were easy and pleasant to use) [23][24]. Practice nurses were asked to perform six tasks while using the system and to give their opinions of the manual. The tasks were:

- registering a new patient;
- viewing an individual client chart;
- setting a daily target;
- viewing the progress report;
- changing the threshold;
- sending a new username and password.

There was no further explanation of the system beforehand, but the participants could use the manual which was organized in chapters corresponding to the tasks. While performing the tasks, they were asked to give comments (think aloud method) and afterwards they provided their feedback for each task and indicated the difficulty of the task on a scale from 1 (very difficult) to 7 (very easy). The sessions lasted approximately 1–1.5 hours, were directly observed by the researcher involved and videotaped. Two laptops were used with the Morae usability assessment software (Techsmith, Inc., Okemos, MI) to record the participants (Figure 2). At the end of all the tasks, the nurses were asked to complete the Post Study System Usability Questionnaire (PSSUQ), a questionnaire with 19 items [25]. Finally, to get an impression of the desirability of the system, participants were asked to mark five words from a list of 118 words (product reaction charts) that in their view best characterized the system [26]. This list was translated into Dutch independently by two researchers. Descriptive statistics and simple content analyses were used to organize the data into categories that reflected the emerging usability themes. Frequently occurring errors were scored by analyzing the video tapes. Based on the results of the usability tests, system improvements were made.

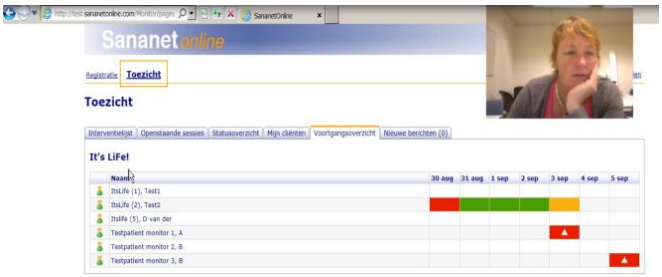

Figure 2. Screenshot of the usability study using Morae.

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III. PRELIMINARY RESULTS

A. User requirements

In Table I an overview of the characteristics of the interviewees is presented.

TABLE I. INTERVIEWEE CHARACTERISTICS

Characteristics of the Interviewees	
Profession	*Number*
Practice Nurse (PN)	7
Diabetes Nurse (DN)	2
Pulmonary Nurse (PN)	2
General Practitioner (GP)	3
Physiotherapist (PT)	2
Age	
Years (Range)	42 (26–58)
Sex	
Male	4
Female	12
Treating patients with	
COPD	6
DM	4
Both	6

The following clusters of user requirements emerged from the interviews.

1) The opinion of the interviewees towards the use case

Most interviewees liked the idea that using the tool would give both patient and practice nurse the ability to monitor physical activity levels. They confirmed the added value compared to self-reported activity because patients often overestimate their level of activity. The use case suggested a mix of the use of technology and extra consultations. Most interviewees indicated that use of the tool should be part of care as usual; the extension of consultation time was not appreciated. Interviewees stressed the importance of goal setting being part of supporting self-management. Furthermore they indicated that the goals should be flexible, tailored to the individual situation of the patient, and that comorbidities of patients should be taken into account when setting a goal.

2) The role of the practice nurse in stimulating physical activity

Although a sedentary lifestyle is often seen with COPD or DM patients, most practice nurses indicated that they normally do not spend much time on the assessment of the level of physical activity during consultations. Therefore, the use of this tool by patients to assess physical activity levels objectively during the first two weeks was considered valuable. Furthermore, interviewees suggested that were a diary for patients part of the system, this would give more insights into the normal activity patterns of the patients.

3) How the information generated by the system should be presented in order to support the practice nurses in their work

Practice nurses wanted to use the coaching system during consultations and therefore the activity data should be clearly represented within the information system they normally used in the practice or it should be linked with this system. A lot of nurses complained about using two or more systems and they wanted to avoid "double registration". Furthermore, the coaching system should present a summary of all information about all their patients' adherence and goal attainment at a single glance, using numbers and graphs.

4) The integration of the system in the workflow and the opinions of practice nurses about giving feedback in between consultations

The majority of the practice nurses were not enthusiastic about giving feedback on the physical activity levels of patients in between consultations. Only a few mentioned that they would probably monitor activity levels to find out if the patient was actually using the tool. They did not by any means want to receive push information, such as notifications from the system.

After these interviews it was clear that providing feedback in between consultations was too much to ask of the practice nurses and therefore it was decided to provide patients with automatically generated feedback messages from the coaching system. Furthermore, automatically provided dialog sessions were developed to support the practice nurse and the patient in preparing for a consultation.

5) The coaching system

Based on the user requirements that were identified, the *It's LiFe!* monitor was developed. The systems consist of a server with two portals, one for care providers (www.sananetonline.com/monitor) and one for patients (www.itslife.nu). The practice nurse subscribes the patient to the system. The login name and password are sent to the patient by mail. At home the patient has to complete an additional questionnaire online (session) concerning physical activity preferences. At 6 a.m. the Smartphone automatically connects to the *It's LiFe!* server to store the physical activity data for the past day on the server. There is a pre-measurement period of 14 days. In the second week, the patient receives short sessions every day to keep a diary. These can be accessed both on the Smartphone and on the website. Furthermore, there are two sessions concerning targets and activity planning. The nurse can see the answers given by the patient in the system on the individual chart of the patient (Figure 3).

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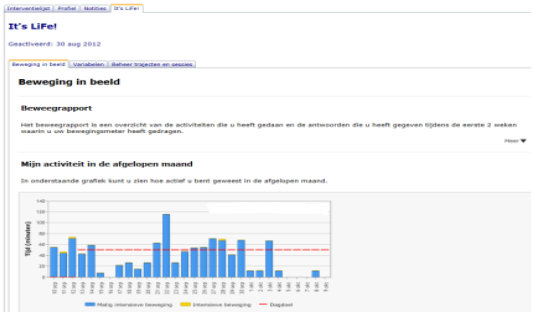

Figure 3. Screenshot of an individual patient chart.

After two weeks a daily target goal is set in the system by the practice nurse in dialog with the patient. Based on the physical activity data, the patient receives feedback messages. There are several types of message (tips, encouragement, positive trend, rewards, barriers, facilitators, and adjusting goals/target values). Participants get such messages when they reach or do not reach their goal after 3, 5 and 14 days. All messages are written in a positive tone, e.g., "Good that you still try to be more active. We can see that it is hard to reach your daily target. If you want to adjust your goal, contact your practice nurse or click here."

B. System Usability

All five practice nurses who were invited took part in the test sessions. They were all female and their mean age was 45 years old with a range of 31–54 years. They agreed to the sessions being videotaped. Only one participant was unable to complete all the tasks because of time constraints. At the start of the test session the accelerometer and the Smartphone were demonstrated to inform the nurses about the patients' part of the system.

1) Results of task performances and feedback on the manual

Some of the participants used the manual all the time and others only when they were in doubt. Although it was the first time participants had used the system, they were mainly positive about the ease of use.

TABLE II. TASK PERFORMANCE

Task Performance		
Tasks scores [a]	***N***	***Mean(SD)***
Register a new patient	5	6.6 (0.5)
View an individual client chart	5	5.8 (0.8)
Set a daily target	5	5.6 (1.5)
View the progress report	4	5.5 (1.0)
Change the threshold	4	5.5 (1.9)
Send new username and password	4	6.3 (1.0)

[a] Scores range from 1 (very difficult) to 7 (very easy)

Scores on task performance ranged from 5.5 to 6.6 on a scale from 1 to 7 (Table II). Furthermore, the participants indicated that the manual was understandable and readable.

2) Results of observations and measurements during task performance (errors)

When registering a new patient in the system, three participants used the back button of the web browser instead of the back button in the system. This caused an error with the connection to the server. Furthermore there was one small button (more▼) in the individual charts with more information about the preferences of patients which was overlooked by four of the five participants. Finally, sometimes the system was slow due to internet connectivity problems.

3) Participants' remarks

Most remarks made by the practice nurses related to the structure and the quality of the information.

Structure of information:

- The system is organized in four different layers (subpages). Many practice nurses commented on the difficulty of navigation. *Practice nurse, aged 41:"I get lost in this system."*
- Participants asked if it were possible to remove subpages which were not necessary for the coaching of physical activity (e.g., a medication chart).
- The opening page of the system is a progress report on all participating patients, but two practice nurses preferred to see the individual charts of the patients because in their opinion these charts give the most important information (users had to click three times to open the individual charts).
- There were two types of remarks about the individual charts: the most important information should be presented at top of the page and this page was too long (users had to scroll to see all the information).

Quality of information:

- Participants liked the use of the graph indicating the level of activity over the past months and they were satisfied with the content of the individual charts. They said that it was useful information and that this could support them when talking to the patients during consultations.
- The progress report was not very clear to the participants; although an explanation of the different colors was part of the manual, four practice nurses preferred to see this explanation in the system as well.

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TABLE III. RESULTS PSSUQ

PSSUQ		
Scores[a]	***N***	***Mean(SD)***
Overall PSSUQ	5	5.4 (0.8)
System Usefulness	5	5.6 (0.8)
Information Quality	4	5.3 (1.2)
Interface Quality	5	5.7 (0.8)

[a] Scores range from 1 (strongly disagree) to 7 (strongly agree)

4) Results from the PSSUQ

The results of the PSSUQ (Table III) were also positive and equivalent to the remarks of the respondents concerning the information provided by the system. The overall score of the PSSUQ was 5.4 on a scale from 1 to 7. Scores on the subscales were 5.6 for System Usefulness, 5.3 for Information Quality, and 5.7 for Interface Quality.

5) Results of the product reaction wordlist

From the 118 words of which the respondents could chose, the following five words to characterize the system were chosen twice: "professional", "motivating", "valuable", "customizable" and "innovative". Most words selected were positive. Only two negative words were chosen: "slow" and "time-consuming". An overview of all the words is represented in Table IV.

IV. CONCLUSION AND FUTURE WORK

The *It's LiFe!* monitor was built for practice nurses to support self-management of physical activity by chronically ill patients in primary care. Different components of the system were based on the user requirements of practice nurses, such as the development of automatically generated feedback messages. The iterative approach during the development resulted in a system which was appreciated by the practice nurses. The results of the usability tests gave insights into how to improve the structure and the quality of the information provided. As a next step, the system will be evaluated in two general practices as part of a self-management support program. Finally a randomized controlled trial will be set up to measure the effects of the tool and the coaching system embedded in the self-management support program.

TABLE IV. PRODUCT REACTION WORD LIST RESULTS

Product Reaction Word List[a]					
1	Enthusiastic	Novel	**Professional**	Stimulating	Interesting
2	Confident	Convenient	Familiar	**Motivating**	**Valuable**
3	Approachable	**Customizable**	**Innovative**	Relevant	Slow
4	**Innovative**	**Motivating**	Personal	**Professional**	**Valuable**
5	Clean	Controllable	**Customizable**	Essential	Time-consuming

[a] Words in bold were chosen twice

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A Social Media-based Participatory Epidemiology Approach for Vector-borne Disease Prevention (VBDP) in South Asia

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***Abstract*— Every year millions of people in south Asia and other tropical regions face the threat of vector-borne infectious diseases (VBD) such as Malaria and Dengue. Existing prevention strategies use principles of epidemiology and health communication separately, despite the fact that new technological capabilities may enable us to integrate the two disciplines. This paper describes an ongoing effort in Singapore that plans to integrate hotspot mapping, civic engagement and health communication to extend the boundaries of participatory epidemiology in VBD prevention. We chronicle the research that informed our approach, present the conceptual underpinnings from a participatory epidemiological lens, and describe the challenges and opportunities encountered. It is our hope that, when actualized, this trans-disciplinary model integrating insights from public health, communication and sociology will provide a holistic solution for policymakers and health prevention agencies tackling VBD threats in south Asia.**

Keywords- Malaria/Dengue; mHealth; Participatory epidemiology; social media

I. INTRODUCTION

Despite vastly improved medical and public health services, vector-borne diseases (VBDs) such as malaria and dengue present a serious challenge to public health authorities in many developing countries. In countries like India and Vietnam, malaria threatens the lives of no less than 1,322 million people in the south-east Asian (SEA) region [1]. In Singapore, Dengue remains a threat despite a steady drop in infections since 2005's dramatic outbreak of nearly 14,000 cases [2]. As public health authorities work towards solutions to efficiently manage the VBD scenario, it is remarkable that social media is used to a bare minimum in a region known for its technological prowess. For instance, in India, health authorities initiate preventive action (like fumigation) in a reactive manner after receiving on-the-ground information of incidences by their cadre of health personnel.

On the health education side, Indian health authorities use traditional media such as TV, radio, newspapers and pamphlets while the country continues to boast amongst the fastest rates of mobile phone adoption. In Singapore too, health authorities predominantly use traditional media although there have been recent attempts by the National Environmental Authority (NEA) to use digital media for hotspot mapping and health education through a collaboration with an initiative called X-Dengue [3]. The magnitude of the vector-borne disease burden in these regions demands the enhancement of existing reactive unilateral mechanisms with proactive, dynamic, and nimble solutions that are as useful to the general public as they are to health authorities.

We propose an emerging and virgin approach called participatory epidemiology (PE) that can guide future solutions to Malaria/Dengue prevention in Southeast Asia. We present a brief background and organizing principles of PE. Later, we present ongoing work in Singapore that is anchored in PE approaches to develop a tripartite interactive system called MoBuzz. We conclude by presenting challenges and future plans for implementation and scale-up.

II. ICTS & PARTICIPATORY EPIDEMIOLOGY FOR VBDPS

The use of information and communication technologies (ICTs) in public health has rapidly proliferated over the last two decades given the deep penetration of the internet and mobile phones in both developed and developing countries. The nature of use, however, has differed depending on the region and problem context. In developed countries such as the US, where the burden of chronic diseases such as obesity and cancer is high, ICTs have been used for designing and testing educational and behavioral interventions and delivering remote care through telemedicine [4].

At a systemic level, ICTs have been deployed in the design of health information management systems giving rise to the study of disciplines such as clinical informatics and patient informatics. Developing regions such as Africa and Asia are rife with infectious and communicable diseases, and issues related to maternal and child health. In these resource-limited settings, ICTs (mainly mobile phones) have been used largely for the purposes of data collection, surveillance and mobile-based telemedicine [5]. However, their application in behavioral and/or educational interventions has been largely limited. Interventions that straddle the individual, community and system levels are rare despite the numerous affordances of mobile phones and social media.

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Vector-borne infectious diseases present us an opportunity to creatively address this gap because of the nature of their transmission and the preventive strategies that are required for their management and control. Let us take the case of malaria. Malaria is a preventable, life-threatening disease caused by parasites (called Plasmodium) that are transmitted to people through bites of infected mosquitoes (called Anopheles). It is known that Anopheles mosquitoes usually bite at night, and transmission is closely related to climatic conditions such as rainfall, temperature, and humidity. Anopheles breeding sites can range from pots and vessels, small puddles of water to large construction sites. We also know that malarial symptoms, such as fever, headache, chills and vomiting, usually surface 10-15 days after the infective mosquito bite. The best treatment upon malarial diagnosis is Artimesinin-based Combination Therapy (ACT), although evidence of resistance have been reported. Such a scenario presents core needs for the two main stakeholder groups – public health authorities and the general public. Public health authorities need a system that:

a) empowers them with *a priori* outbreak information to facilitate early preparedness for preventive actions;
b) receives ongoing/dynamic information so as to monitor the disease spread in real-time; and
c) allows them to educate citizens, promote practice of preventive behaviors and, respond to specific informational requests from the general public.

The general public needs a system that:

a) alerts them about potential outbreaks in their area/vicinity;
b) allows them to interact with authorities and share information about any outbreak-related issue;
c) provides authentic information from authorities about what preventive actions to take; and
d) allows them to share information with members in their informal social networks.

At a basic level, PE denotes the use of local, on-ground intelligence to gather information and track the spread, causes, and effects of diseases. The PE concept was popularized by Catley and Mariner's work in East Africa where they employed qualitative community-based approaches to derive animal health status from local farmers [6]. However, the rapid proliferation of the internet and mobile phones has transformed the PE landscape in recent years. As is shown by initiatives such as FrontlineSMS and Ushahidi [7], disease surveillance, health monitoring, and information sharing can now be digitally integrated and used to link disparate stakeholders such as health authorities, health providers and the general public. Chunara *et al*. [8] tested an online initiative where respondents reported their experiences with malaria, and concluded that "micro-monitoring and online reporting are a rapid way to solicit malaria, and potentially other public health information". The Program for Monitoring Emerging Diseases [9] provides an online reporting system and rapid information dissemination related to infectious disease outbreaks. In this sense, participatory epidemiology also denotes employing participatory methods – those nestled in, and involving communities – to collect epidemiological data. The other key principle includes the use of participatory mapping techniques in order to inform prevention activities.

III. MoBuzz – Extending the PE Concept

We propose that the conceptual capabilities of PE can be extended to provide holistic preventive solutions for Malaria/Dengue if mobile phones and social media were to be integrated into the conceptual matrix. We propose MoBuzz, an integrated mobile and desktop-based health risk communication system that is built upon PE principles. MoBuzz extends its reach to provide an interface between citizens and health authorities, and customized health messages to enhance preventive behaviors and health awareness. Our system comprises three main components: predictive surveillance; civic engagement and health communication. Our preventive e-health system provides support for disease prevention among health individuals. We demonstrate how data aggregation and visualization technologies can be used for population health reporting.

A. *Predictive Surveillance*

Let us take Singapore as an example of a city plagued by Dengue. The intention is to develop a color-coded early warning system that displays Dengue hotspots by generating predictive maps (Fig. 2) made available to both health authorities and the public on mobile devices. Raw weather-related information such as rain, temperature and humidity is processed using predictive disease modeling that feeds into an automated system which generates predictive maps of Dengue hotspots.What distinguishes this project from other similar crowd sourcing and crowd informatics platforms is the integration of a disease modeling and simulation component. Here, we build a hierarchy of spatio-temporal epidemic models.

Figure 1. Prototype display of Dengue hotspots in Singapore

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In the simplest of these models, we have a human population density that is averaged over time but not space, and a dynamic mosquito population, i.e. mosquitoes move around in the spatial grid. Susceptible humans ($S(x, y, t)$) can be infected by infected mosquitoes ($i(x, y, t)$), while susceptible mosquitoes ($s(x, y, t)$) can then be infected by infected humans ($I(x, y, t)$). Humans who recover from the infection ($R(x, y, t)$) then become immune to further infection. Infected mosquitoes do not recover, and die at the same rate as uninfected mosquitoes. These are replaced by new mosquitoes that are susceptible. In our simulations, we can control how fast the mosquitoes move, how easy it is for mosquitoes to infect humans, and how easy it is for humans to infect mosquitoes. We then measure the spatial extent of infected mosquitoes. This defines the human population that is *at risk* of infection, which provides more policy-relevant information than the actual incidences of infected humans. As more data become available, either through public health agencies or crowd sourcing, we will refine the epidemic model to incorporate influences from meteorological factors like temperature and rainfall, as well as anthropogenic factors like changes in demographics and land use. For policy makers and crowd sensing participants, the most attractive prospects of having such a component are the short-term forecasts in infection and at-risk patterns that can be generated.

B. Civic Engagement

This component provides the cutting-edge addition to existing PE efforts. The key idea here is to encourage the general public to contribute to surveillance efforts in the event of disease outbreaks. In this instance, citizens can report breeding sites, mosquito bites, and Dengue symptoms using their smart phones in image (Fig. 3), text (Fig. 4) or video formats. These inputs are automatically reflected in the hotspot maps and can be accessed by health authorities for responding to citizen concerns and for initiating preventive actions in specific communities. The process is facilitated rapidly because of two reasons: a) mobile phone-based inputs from citizens are geo-tagged; and b) the MoBuzz system captures geo-spatial coordinates, time and date, and phone number of the contributor.

C. Dynamic Health Communication & Alerts

The repository of outbreak information based on weather and citizen data is used to disseminate health messages to both individuals and communities. At the individual level, citizens receive tailored messages based on their input to the system. For instance, a citizen reporting malarial symptoms to MoBuzz will instantly receive a complete information guide on Dengue symptoms, and cues to various preventive actions. At the community level, the system will automatically send health education messages to communities/zones (Fig. 5) that are highlighted on the maps as possible hotspots. Public health surveillance efforts are

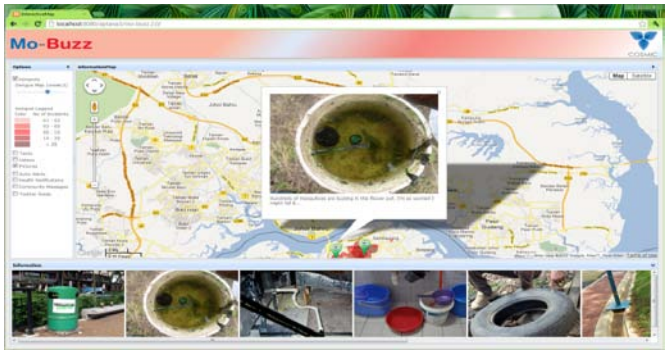

Figure 2.Citizens images of breeding sites reflected on maps

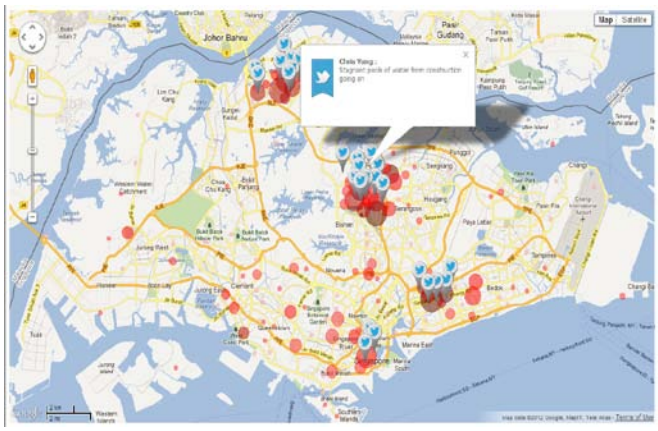

Figure 3.Risk information sent by citizens through Twitter feeds are displayed on the maps

Figure 4.MoBuzz issues automated alerts and health messages using website and mobile apps

thus used to generate and deliver health communication messages. Fundamentally, the system acts as a link between the citizen and the public health system where the contributions of each benefit the other. Overall, the intention is to use MoBuzz for efficient and effective risk prevention and outbreak management. In addition to communication modules, the system is capable of sending alerts to citizens living in areas identified as potential hotspots.

D. Scenario

Fig. 5 shows a possible scenario for the use of MoBuzz. The meteorological department (from left) feeds weather data to the system that is used to generate hotspot maps. Concurrently, a vigilant citizen, John reports a possible breeding site by sending a picture to MoBuzz. In response, the system sends him preventive information that he can send to his family/friends that can further disseminate it to

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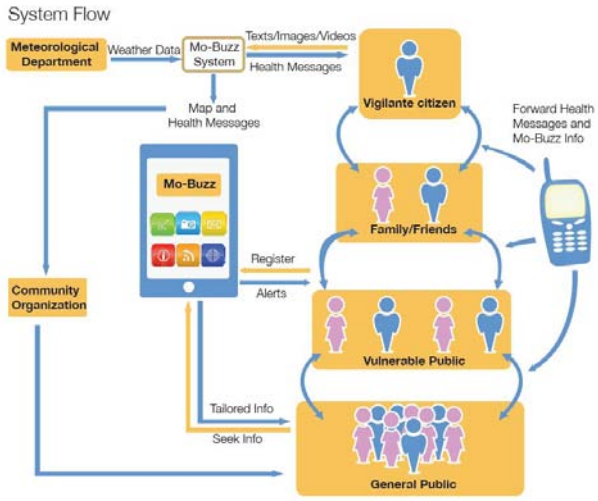

Figure 5.System flow depicting interaction between stakeholders and system

other actors in their social network. The messages contain information about the MoBuzz website/mobile app. This activates the vulnerable actors to register on the MoBuzz website (or download the app), allowing them to receive future alerts automatically. The information continues to go viral as the vulnerable individuals continue to send it to other members in their respective social networks. These individuals follow a similar protocol for registration and can potentially request MoBuzz for specific kinds of information based on their issues of concern. In the meantime, the dynamic maps displayed on the website and available on the mobile app can be used by community organizations and civic agencies to strategize preventive efforts. The innovation in MoBuzz lies in integrating the disparate fields of epidemiology, civic engagement and health communication using social media.

E. Content Validation

One of the major challenges of a technology-driven participatory health system enterprise is validating the quality of informational inputs from citizens. Our validation process is consistent in keeping with the core idea of using participatory media and crowd sourcing technologies. We use people (individuals and health systems personnel) as validation experts. For instance, when MoBuzz receives a breeding site alert from Zone X, the system will send a validation request to all its registered users and health personnel in that zone. These individuals can visit the site and use mobile-based reporting to revert to MoBuzz on the authenticity of this input.

IV. CONCLUSION & FUTURE WORK

One of the key questions we encountered in the process of conceptual ideation and prototype design was: how do we get people to participate? In response, we propose an incentive-based system that offers, say, 5-minutes of free talk time for inputs and an equal number for validation. Such incentives will involve a partnership with multiple stakeholders including telecom companies, civic agencies and health authorities. We recognize that offering an easy-to-use, simple and attractive interface design will add to the adoption and usability MoBuzz and its various affordances. Moving forward, we plan to test the three main components among various audience groups using experimental techniques and assess their responses to the system in terms of media, messaging, design and interface. We are working with collaborators in Sri Lanka and Malaysia to scale-up and test our system. We propose that our system can be replicated to address gaps in the prevention and management of a number of infectious disease outbreaks such as SARS and H1N1. Conceptually, our idea broadens the current understanding of participatory epidemiology and highlights future opportunities for epidemiologists and health communication experts to integrate their expertise.

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CallMeSmart: A VoIP Softphone on Android based mobile devices using SIP

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Abstract **– The Wireless Communication Infrastructure represents a core for information sharing between health care workers in hospitals: Medical staffs work situation is highly mobile, and important information is constantly shared between health care workers to provide high quality service for the patients. Physicians carry mobile communication devices to be able to communicate in their mobile work, and often several wireless devices according to their role and responsibilities. This leads to a number of problems, especially regarding interruptions from these devices. Such interruptions are often due to the caller is unaware or ignoring the situation and context, in which their colleagues are. This can, and often does lead to severe medical consequences. This article deals with the CallMeSmart system (CMS); a communication infrastructure based on collection, analysis and dissemination of context sensitive information through a communication system based on smartphones and DECT devices, to improve the current communication backbones, and to reduce interruptions from mobile devices in hospital settings.**

Keywords - Context awareness; wireless devices; mobile communication; Interruption management;VoIP

I.

II. INTRODUCTION

Activities within hospitals and healthcare settings require reliable communication systems. Sharing information between colleagues, medical attendants, investigatory facilities and other resources, using wired/wireless communication systems is a necessity. This often 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. Wired/wireless phones are less utilized, but also in use. Personal Digital Assistants (PDA) has also been tested for use in some hospitals [2]. More and more hospitals are using wireless phones based on Digital Enhanced Cordless Telecommunication (DECT) or Voice over Internet Protocol VoIP) and Session Initiation Protocol (SIP), like the devices used in [3]. 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' [4]. Because of this, some staff members are carrying multiple devices for different roles and purposes [2, 5].

However, mobile communication in hospitals has shown to suffer from poor practice and inefficiency caused by an insufficient infrastructure, especially when the communication need is urgent [1, 4, 6]. A more extensive use of mobile phones can offer a solution to this problem by improving accessibility and communication in hospitals [1, 6, 7]. 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 to reduce the risk of medical errors [6].

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 interruptions on key human resources, such as, senior physicians, or 'on call' staff [5, 8]. 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 [5, 8]. A context-sensitive system can provide a solution to control availability and interruptions [5]. Context 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 [3, 8].

In this article we present a prototype of a VoIP context aware softphone, based on the Android operating system, integrated in a complete context sensitive communication system for mobile communication in hospitals. The system is built on top of existing infrastructure, as explained in [9].

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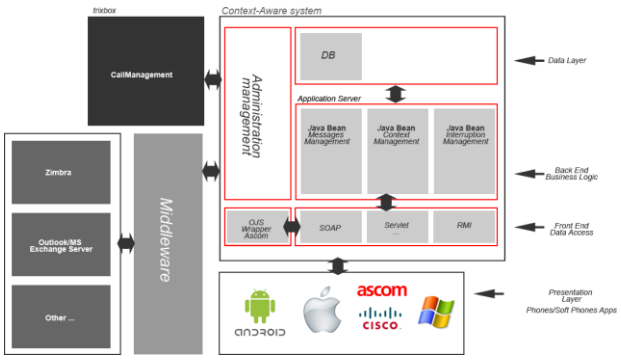

Figure 1: Overall system architecture of the context aware interruption management system, CallMeSmart [9]

III. BACKGROUND

In general, mobile phones are currently not widely in use in hospitals. Only a few staff members carry a wireless phone due to the assumptions of that a phone is more interruptive than a pager [2, 5]. 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 wireless phones), observations and interviews showed that the users were unsatisfied by the current user interface of the phones [3, 10]. It kept them from using all functions of the system, especially the way messages were handled. The feedback from the interviewed and observed physicians was then used to design and develop a prototype for a context based communication system [9] which we have called *CallMeSmart*. Figure 1 presents the overall system architecture of CallMeSmart. The method used here was based on a participatory design process [11] and heuristic evaluation [12, 13], where we used input from the users to design and develop, and then tested the system with real users according to scenarios' from health care settings, adjusted the system according to the feedback, and then tested again, adjusted, and so on. Due to the fact that the cost of replacing a complete communication system will be enormous for a hospital, this system where developed on top of an existing communication system and infrastructure based on DECT, where we re-routed the signals from the DECT system to our context server. Then we used collected context data from the users to control the communication, and thereby avoid interruptions. We believe that utilizing existing systems and infrastructure will be cheaper and experience less user resistance, and thereby it is up to the user and management at the hospital, which devices the user should use and carry. This opens up for including new devices and features together with older communication systems and infrastructure, like including smartphones.

IV. MATERIALS AND METHODS

The phones subjected in this paper are commercial off-the-shelf Android based mobile devices; smartphones and tabs. Android based devices are already widely used both by private and professional users, which means that this is known devices and user interfaces for a lot of users. The devices were configured with the CallMeSmart (CMS) SoftPhone. The softphone is based on VoIP using SIP, offering voice and text services, but also role-based communication, alarms, and pager services, and are controlled by context information, based on definitions in [14], to control the communication and to avoid unnecessary interruptions. In this Section we present the subjected mobile devices, and the method used to develop and test CMS SoftPhone.

A. Mobile devices

1) Samsung Galaxy ace

This mobile phone was set up with Android 2.3.3 and TouchWIZ User Interface (UI).

2) Samsung Galaxy SII

This mobile phone was set up with Android 2.3.5 and TouchWIZ UI installed, but was updated to Samsung original Android 4.0.3.

3) Samsung Galaxy Tab 7"

This Tablet was set up with Android 3.2 and TouchWIZ UI installed.

4) Samsung Galaxy SIII

This mobile phone was set up with Android 4.0.4 and TouchWIZ UI installed.

5) HTC Desire

This mobile phone was set up with Android 2.1 and Sense UI installed, but was updated to HTC original Android 2.2 and 2.3.3. It was also tested with a rooted Android 4.0.4.

6) HTC Sensation XE

This mobile phone was set up with Android 2.3.4 and Sense UI installed.

B. Methods

The software engineering approach used to develop the context-aware system is based on the Unified Process. An iterative and incremental development methodology (also known as spiral development or evolutionary development) based on the ideas of Boehm [15] and Gilb [16]. This approach split the development process into a series of short mini-project, called iterations. The purpose of an iterative approach is to increasingly enlarge and refine a system within each iteration, in order to gradually approach the requirements of the targeted application. An iterative model does normally not start with a full specification of the requirements, but begins with specifying and implementing only the most important features, which are subsequently improved and adjusted to include missing requirements during next iterations. Each iteration includes:

- Requirements: Identified, collected and analyzed.

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- Design: a software solution is designed by using Use Cases diagrams to capture the functional requirements, Interaction diagrams are used to define the interactions between software components and other graphical Unified Modeling Language (UML) notation models are applied to better define the overall architecture of the software.
- Implementation: Program the software described in the previous step, improving the system already developed.
- Testing: New developed features are tested in order to verify if they are consistent and without errors.

If the requirements are not met after these steps, a new iteration takes place.

The tests were carried out by simulating typical scenarios within health care settings, where the functionalities of the application were tested for quality and stability.

V. RESULTS

CallMeSmart SoftPhone is a context-aware SoftPhone, based on the Android operating system, specifically designed for hospital usage. The system have been tested through scenarios', experienced during the first authors fieldwork [3], in our context-sensitive laboratory at Tromsø Telemedicine Laboratory (TTL) hosted by Norwegian Centre for Integrated Care and Telemedicine (NST). Together with the context-aware system, CMS [9], on which it relies on, it is able to change its behavior according the context of the user carrying the device. It supports three different operating modes which automatically is controlled by CMS, but can be manually overridden by the users: "Available", "Busy" and "Pager Mode". The functionality is the same as on the DECT phones in [9]. The Available mode makes the phone fully reachable both for calls and messages with the ringer on. In busy mode the phone receives only calls that have been forced by the caller for emergency reasons. And in pager mode, the phone can only be paged through standard text-based messages sending the callers number/name. The CMS SoftPhone also provides a Bluetooth Tracking module, which allows automatic tracking of the phones through Bluetooth sensors. The information about location is used by the Context-aware system in order to perform location based interruption management. This is used in the same way as the DECT tracing sensors in [9].

Figure 2: a) CallMeSmart SoftPhone keypad, b) The dialog box from which the user can switch the phone's operating mode manually, c) the Message List

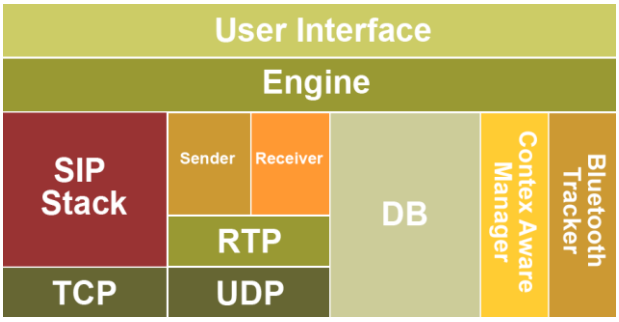

Figure 3: Overall software architecture of the CallMeSmart SoftPhone

During the development, we put particular emphasis on optimizing the battery usage of the software, since having a long battery life is a mandatory requirement for devices targeted for hospital usage. Among other challenges we addressed, the most important one has been finding the right balance between computational power required by the software, audio quality perceived by the users and number of features introduced by the first version of the prototype of CMS SoftPhone.

Figure 2 shows some screen shots taken from the application's UI:

a) the keypad from which the user can access the operating modes of the phone through a suitable button-icon located on the right side of the display.

b) the dialog box which allow the user to manually switch the operating mode of the phone.

c) the CallMeSmart Messaging system, which enable messaging between other CallMeSmart enabled devices and the Ascom DECT phones. CallMeSmart implements in addition a basic Contact list and a CallLog.

Besides the UI, the others components characterizing the application are: the MjSip SIP stack [17], used for setting up and closing calls, Audio Sender/Receiver for managing the streamed audio, Context-Manager which provides services for communicating with the context-aware system, and the Bluetooth Tracker for tracking the device's location.

The Engine of the application bounds and coordinates together with the previous components, and provides the link between the UI and the rest of the application. Figure 3 shows an overview of the CMS SoftPhone software architecture.

A. *Audio Player/Receiver*

CMS SoftPhone manages the phone's audio through OpenSL ES library [18]. OpenSL ES is a cross-platform audio API tuned for embedded systems which provide the developers with a framework for accessing native audio functionality on a wide range of mobile devices, through a

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common API. Among other Native Libraries, this is supported by Android OS since version 2.3 [19]. The use of OpenSL ES allowed us to implement an Audio Recorder optimized for low CPU usage and an acceptable low recording latency, which is a well-known problem between Android developers [20].

We addressed the unpredictability and variability of the network conditions by implementing an adaptive jitter buffer on the phone's receiver, which is a common solution. This solution is adopted for VoIP clients to remove the jitter in the arrival times of the packets. The objective of a jitter buffer is to keep the buffering delay as short as possible, while minimizing the number of packets that arrives too late, by dynamically adjusting the buffer's size containing received audio packets, which are waiting to be decoded and played on the phone's speaker. Our implementation takes in consideration the number of packet loss as well.

One of the problems we had to face was related to Acoustic echo. It occurs when there is a feedback path between a telephone's microphone and the speaker. Moreover acoustic echo can be caused by multiple reflections of the speaker's sound waves back to the microphone from walls, floor, ceiling, windows, furniture, and so on. We faced the echo cancellation on the new Android devices running Android 4.0 (IceCream Sandwich) by using a feature, which allow to tune the microphone of the phones for Voice Communication [21].

B. Audio Codec

The default audio codec supported by CMS SoftPhone is G.711 (µlaw), which is one of the most common supported codecs among VoIP clients. It is a lossless data compression algorithm. Audio compressed with this codec requires a bandwidth of 64Kbps. The CPU requirements in order to compress audio with G.711, is fairly minimal. Due to the perceived good audio quality this codec provides, it is a mandatory choice for mobile devices targeting hospital usage, where in many cases the bandwidth supported by the network infrastructure is high and its conditions are well known a priories. The adoption of this codec is also justified by interoperability reasons; the Ascom DECT based communication system, in which our context-aware system integrates, and the majority of other VoIP based systems, supports G.711.

The tests performed over 2G and 3G network with G.711 were not satisfactory, due the noticeable disturbing audio artifacts caused by the low and unstable bandwidth of these networks. This forced us to test utilize other codecs. The tests performed with the codec; Speex [22] and iLBC [23], gave us better results in terms of audio quality. Over 2G and 3G, they proved to be better due to their strong compression algorithm.

Running Speex and iLBC over mobile devices required a significant amount of CPU in order to compress the audio samples. On Samsung ACE (800 MHz ARM processor), the CPU usage during a call reached the peak of 70%, while with G.711 the highest value we experienced was 13%. On Samsung galaxy SII (Dual Core 1.2 GHz Cortex-A9), the CPU peak reached 35% with Speex, while with G.711 only 4%.

The usage of this codecs over a series of long lasting calls could severely decrease the battery life of the mobile devices, and as a consequence, the operating time of a phone. It should be mentioned that these codecs are mandatory if the system requires communication over networks that do not provide a minimum guaranteed bandwidth. We decided to use the Speex codec only on 2G and 3G networks in case of emergency communication, and to keep the G.711 codec on other wireless networks. In order to solve compatibility problem between Android and DECT phones, which do not support the Speex codec, a solution where we are performing a transcoding on the media gateway, when a communication channel is set up between these two different kinds of phones.

C. Bluetooth tracking

We implemented the tracking of the smartphones by using Bluetooth adapters as sensors, residing on standard PCs placed inside the areas where we are simulating the system. The discovery of these sensors is performed on the phones, by the Bluetooth Tracker component (see Figure 3), which uses the Android Bluetooth API to connect the device's Bluetooth adapters with our Adapters. Once an adapter has been discovered nearby the phone, the Bluetooth Tracker retrieves its MAC address, and transfers the information to the CMS server, in which maps the MAC addresses of the sensor deployed in the testing environment with name and criticality of the area on which they are localized. The location is subsequently used by the CMS server for providing a location based interruption management system.

D. Roaming

Most of the Android phones we tested do not perform roaming within WiFi networks in a seamless way. The time required to switch between two WiFi hotspots is too high; in some cases more than 8 seconds, which making the switching between two WiFi hotspots noticeable during a call. We implemented a solution which keep searching for the best WiFi signal present around the phone, and re-associate the connection of the device to the best hotspot as soon as possible. Even with this approach, the time needed to switch between two WiFi hot spots was not fast enough in order to guarantee a continuous call by some phones, except on the rooted version of HTC Desire. On the HTC Desire it could be used, but this is not the optimal solution due to battery usage. On the Samsung Galaxy SIII, with Android 4.0 they have solved the problem of roaming in WiFi networks.

VI. CONCLUSION AND FUTURE WORK

It is a fact that the usage of mobile phones enables higher availability and accessibility, but also introduces a

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numerous of interruptions [5, 8]. This often leads to user resistance against wireless phones in clinical settings. Having this in mind we developed a context-sensitive system for mobile communication suited for hospital use, which provides the opportunity to control the availability, and thereby the interruptions [9]. The easiest solution is to introduce an already developed system, like the AwareMedia and the AwarePhone systems to Bardram et al. [24, 25]. This system is based on ordinary mobile phones using the GSM/3G network. A new hospital building up their infrastructure for mobile communication could make use of a solution like this, but we believe it is less expensive, and that the user resistance will be lower by utilizing an existing internal infrastructure. Also the idea of using already well known devices in clinical settings, made us look into what was possible to do with an infrastructure based on DECT phones and pagers [9]. From the laboratory experiments done by Gironi [9], with real users, the feedback was clear; the users wants a user interface more equal to conventional 3G/GSM mobile phones, which gave us the idea of including smartphones into CMS, using VoIP and SIP, resulting in CMS Smartphone.

Mandatory requirement for devices targeted for hospital usage is of course long battery life. To achieve this we had to balance the between computational power required by the software, audio quality perceived by the users, which is close related to the bandwidth required, and number of features introduced by the first version of the prototype of CMS SoftPhone. This was achieved by using OpenSL ES and G.711 audio codec to implement the audio recorder, which we optimized for low CPU usage on an acceptable low recording latency. Another reason choosing this was the compatibility of the Ascom system from [9]. By choosing this solution it seems like a Samsung Galaxy SIII with extended battery is able to last at least one normal communication intensive shift.

To count up for the unpredictability and variability of the network conditions, we used the most common solution and implemented an adaptive jitter buffer on the phone side of the system, and thereby keeping the buffering delay as short as possible and minimizing the number of packets that arrives too late. The implementation also takes in consideration the number of packet losses as well, and in combination this really shorten the delay between the caller and the called.

For low bandwidth networks like 3G and 2G, the G.711 codec is not suitable. This codec requires too much bandwidth, and was perceived as not suitable due to; either we had to deal with an increasing delay, or scattered sound losing a lot of audio packages. The solution was to use the Speex codec on the 2G and 3G networks in case of emergency communication, and to keep the G.711 codec on other wireless networks. Since the Speex codec is not supported by the Ascom system, we had to implement a solution where we were performing a transcoding on the media gateway in real time, when a communication channel is set up between the CMS SoftPhone and a DECT phone.

Another problem we had to face was the echo. When calling or receiving a call, we experienced a lot of echo, which was annoying and made the conversation difficult. We tried different approached, but discovered after the Android 4.0 was released that this version included a well working echo cancellation feature, and we concluded that the CMS SoftPhone has to rely on devices running minimum the 4.0 version of the Android operating system.

The tracking of the CMS SopftPhone was done by using Bluetooth adapters as sensors. This was not an optimal solution due to battery drainage, and unreliable tracking, and therefore we need to find a better solution. The solution that seams most reliable and accurate are an ultrasound solution, which requires an ultrasound tag on the phone and a microphone inside of each area we want to track the phones. This is planned tested in the next version of CMS.

Most of the Android phones we tested do not perform roaming within WiFi networks in a seamless way. This is a serious problem, and every device that should be used within CMS, have to be tested and approved able to roam between different WiFi antennas, in real time, without losing the connection or ending the call. This has been a known problem on earlier Android based devices, but after testing new devices, hi-end devices from Samsung and HTC, we found out that this problem is on its way to be solved, and the roaming is working very well on the Samsung Galaxy SIII.

Since both the echo cancellation and roaming within WiFi networks is solved, and that our implementation of the softphone is working just as well as on the DECT system, and since the smartphones has a wider area of usage, for instance to include patient information, medical reference work, etc., we conclude that the first version of CallMeSmart SoftPhone is ready to be tested in real life within health care settings. This also opens up for future work on including more features into CMS.

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Status of IT in Dutch Hospitals in 2011

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***Abstract*—The IT-monitor gives an overview on the use and implementation of information technology (IT) in general and university hospitals in the Netherlands. Using the questionnaire, earlier applied in Germany and Austria, all Dutch hospitals were requested to participate, of which 20% responded. The results show that the introduction of IT is realised in various activities in several departments of the hospitals. Examples are the Electronic Health Record (EHR), electronic medical correspondence and diagnostic tests such as radiology. Desktops are most commonly used, but laptop and notebook are also used. On the other hand, IT use for medical guidelines, clinical pathways and clinical reminders are not generally introduced. Five reasons are named as barriers for the introduction: lack of financial support, shortage of staff, inadequate suppliers, lack of support by doctors and difficulties in showing the return of investment. With a larger budget available, hospitals will increase the development of IT on various areas in the hospital departments in the near future towards a more eHealth orientated Dutch healthcare.**

Keywords: Dutch hospitals; IT implementation; barriers

I. INTRODUCTION

In January 2006, the Dutch government implemented major reforms to their health care system. With an increase in care, changing care demands, and shortage of personnel, a system of regulated competition was introduced. In an attempt to reduce rapidly rising costs, an eHealth oriented attitude was suggested as well. The use of IT in health organizations can help to make healthcare safer, more effective, and more efficient for the patient, at lower costs [4].

IT studies in health organizations focus on a range of topics, all with the aim to bring satisfied, safer, more effective and more efficient care to the patient at lower cost [8][14][16]. However, the use of IT can also degrade the safety and quality of patients' care [5] and can lead to higher costs [1][2][11][12]. Furthermore, a recent study reports that an increase in IT in Dutch healthcare organizations does not necessarily lead to an increase of adequacy of information management [10].

Research indicates that a number of barriers, which are also interrelated with each other, limits the implementation of IT in hospitals. These barriers can have legal, organizational, financial or technical support features [1] [4] [5][15][16], but also depend on psychological or social factors such as acceptance, usefulness, content [2][14][17]. Various methods have been suggested on how to deal with these barriers, in order to improve care and manage costs for specific health organizations, such as more and better research before IT introduction, more financial and IT support and more standardization [1] [10][11].

Research on IT in healthcare has been categorized into three levels: macro, meso and micro [9]. On micro-level, IT is investigated within one hospital. For instance, the effects of adaptation using IT innovations are investigated. Research on meso-level focus on one country or one region in this country. For example, in the Netherlands, in 2001 and 2009, research on IT use was focused on the electronic transfer process for nurses [6][7][18]. A clear picture of the IT use in hospitals on macro-level, that is multi-national and bi-national, was recently investigated by the EC [3]. Here, for 27 European countries and three other countries (Croatia, Iceland, and Norway) it was found that university, and large hospitals, have better IT implemented in healthcare than smaller, non-university hospitals.

In our research, we focus on the results on meso level, and try to discover today's use of information technology in Dutch hospitals. Besides research on the IT usage by nurses (not discussed here), we also investigate various IT aspects in the hospitals such as the amount of IT implementation in the various departments, for a number of activities, the possible barriers for implementation, the available hardware etcetera.

In this paper, after we explain the method used for our questionnaire, we describe the IT department, where IT is used and how far it is implemented in the departments and in various activities. This is followed by the results on the amount of IT implementation of the EHR and the electronic signature. We describe the hardware used, and mention some barriers named by the respondents. We finish with some ideas for improvements and future research.

II. METHOD

We translated and adjusted the German survey 'Informationtechnologie im Krankenhaus 2011' [13], which focus on the chief information officer (CIO) in the health organization. The survey covered a number of categories related to IT in hospitals such as IT usage, IT department, IT priorities, finance, electronic signature and documents management, finance, and of the usage of Clinical Pathways, cooperation, and EHR's.

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The translated questionnaire was implemented in an electronic questionnaire tool and distributed by a web link to 129 members of three Dutch health organizations related to ICT (the Dutch association of hospitals NVZ, the association of informatics and healthcare VIenG, and the association of university hospitals AcZie) working both in university and public acute hospitals. Because of the number of respondents, frequency analyses were executed to report on the situation of IT in hospitals in the Netherlands.

III. RESULTS

A. General information

We received 20 useful questionnaires back (response rate 20.9%) from 16 general and 4 university hospitals. We compared the hospitals who responded to the non-responsive hospitals on three characteristics i.e. academic versus general hospitals, number of beds, and location. 15 % of the general hospitals responded and 50% of the university hospitals. 10 % of the non-respondent hospitals have less than 150 beds, 82% 150 until 999 beds, and 8% more than 1000 beds. The hospitals in this study scored 0%, 90% and 10%. Most hospitals in the Netherlands are located in the western part of the country. Indeed, most hospitals who returned the questionnaires are located there. Based on these results, we concluded that we deal with a representative random sample of the Dutch hospitals.

B. IT Department

All hospitals have an IT department. Most hospitals (57.9%) have more than 20 staff; 20% has between 21 and 25 employees and 15% has 41 until 65 employees. University hospitals have between 135 until 230 workers (20%).

Almost all hospitals (94.4%) have an IT-budget for recent and future IT expenses. Management decides, together with the IT department (38.9%) or with the requesting department (38.9%) on the investments. In most hospitals (55.6%) the IT budget has increased from 2009-2010. For a smaller group (38.9%) the budget remained the same and in one hospital (5.6%) the IT budget decreased.

C. IT usage

The usage of IT in the hospitals is illustrated by the amount of implementation or a plan to implement specific parts of IT usage. In Figure 1 we see that IT is well implemented in clinical documentations, especially in medical correspondence (83.3%) and in the operating room (OR) documentation (77.8%). Also nursing files and medicine usage is available electronically (in almost 70% in more than one department or in the whole hospital). In 5.9% of the hospitals there is no plan to implement electronic nursing records or electronic intensive care (IC) documentation (10.5%) or in medical documentation (5.9%).

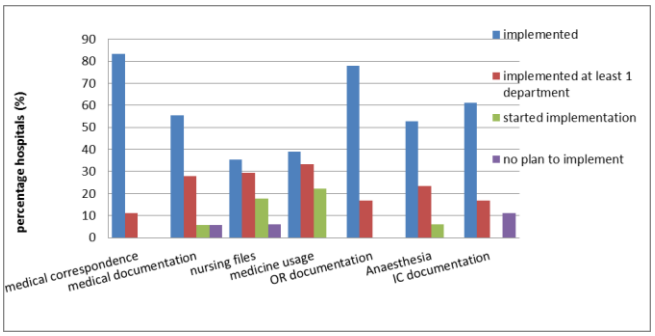

Figure 1. IT Usage in Dutch hospitalS

When we look at the IT usage in administration (Fig. 2) we see that the IT usage is highly implemented in the hospitals administration. Only the electronic administration about the costs of medicine is behind other administrative duties, but there is progress (5.6%).

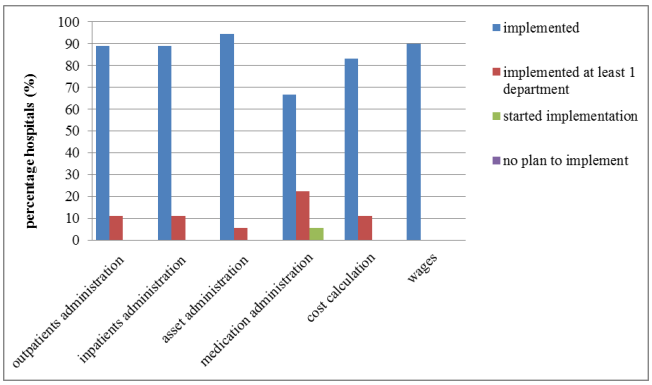

Figure 2. IT in administration

Similar positive results are found in the IT implementation in diagnostic disciplines such as radiology (in 94.4% implemented), laboratory results (in 77.8% implemented), in the management department for example for making duty rosters (in 100% implemented), in patient registration systems for example for patient administration (in 94.4 % implemented),min patient identification (in 64.7% implemented) or in quality management (in 70.6% implemented).

Figure 3 illustrates the introduction of the electronic health record (EHR). In 36.8 % of the hospitals the EHR is completely operational, 35% has started to install EHR. A small amount has already contracts with suppliers (5.3%), or has a plan to implement an EHR system (5.3%). Also, there are still hospitals that have not started to make plans to introduce EHR (5.3%).

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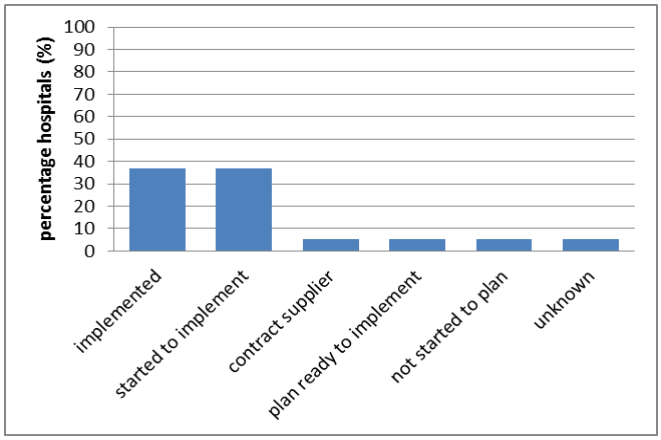

Figure 3. Electronic Health Record

The electronic signature is hardly used in Dutch hospitals. As shown in Fig 4, hospitals do have plans to introduce the electronic signature (33.3%), whereas 22.2% have no plans at all.

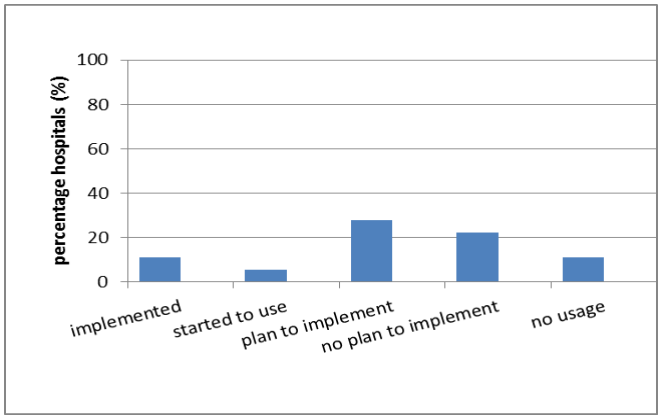

Figure 4. Electronic signature

Also the results on IT usage and guidelines are less positive. Figure 5 shows that the hospitals have only started to implement IT in medical guidelines and clinical pathways, (47.1%), clinical reminders (29.4%) and alerts (35.3%). A small percentage of the hospitals indicate that no plans are made.

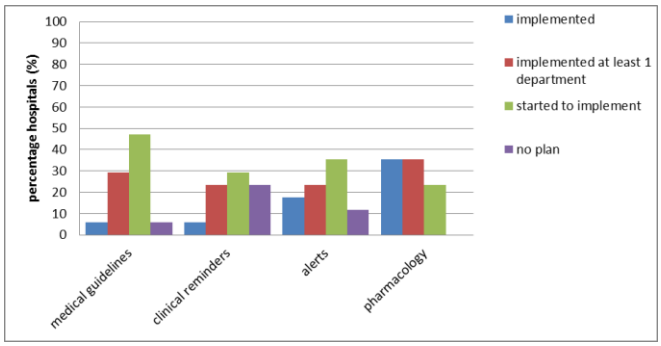

Figure 5. IT and guidelines

Figure 6 shows that hospitals have the opportunity to use modern electronic devices such as laptop (70%), notebook (60%), tablet (25%) or I-Pad (20%), beside pc's (95%) and bedside terminals (4%).

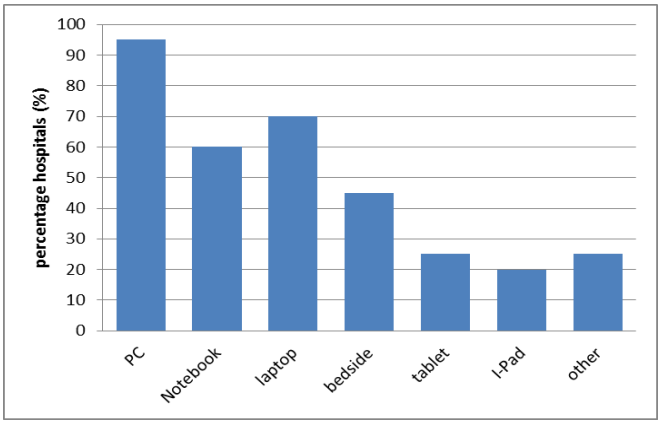

Figure 6. Use of modern electronic devices

Barriers to implement IT successfully in the hospitals are mentioned by 83.3% of the hospitals. Three hospitals (16.7%), i.e. two university hospitals, mention no barriers at all.

Only five of the possible fourteen barriers suggested by the literature are mentioned by the hospitals. The lack of financial support is reported as the most important barrier (38.9%), followed by a shortage of staff in the IT department (16.7%), and inadequate suppliers (16.7%). Also, a lack of support by doctors (5.6%) and difficulties to show the return of investment of IT (5.6%) are named as possible barriers.

IV. DISCUSSION

The study has some limitations. In particular the total number of 20 respondents (roughly 20% of the hospitals in the Netherlands) is rather small. On the other hand, this is quite common for questionnaires, and looking at other parameters like size, location and academic versus general hospital, the study reveals that it is a representative sample.

Another issue could be the questionnaire. If that is implemented the first time, it usually leads to some questions not easy answered. However, the use of the German questionnaire and cross translation and validation ensured that the base quality could be considered adequate. We did not get feedback about the quality of questions or questionnaire. On the other side, this might be a reason for non-response.

Also, this study did not concern any technical aspects of health IT.

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V. CONCLUSION AND FUTURE WORK

The results show that the information given by the hospitals is a representative sample of the country. The results further show that the introduction of IT is realized in Dutch hospitals, but there are some areas where progress is needed.

Whether hospitals will make progress, will depend on the financial situation and the priority that IT gets. Besides money and means, IT systems must be worthwhile in order to get the support it needs. Government, hospitals and various branches show positive signs to support further introduction.

In order the see whether or not the suggested plans have been executed, and progress has been made, another questionnaire will have to be executed in the near future. Furthermore, in order to get a broader view of the IT use in European countries, i.e. research on macro level, more results on separate countries, i.e. on meso level are needed. At the moment, our results are being compared with the results of Germany and these results will be published in the coming months.

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A False Positive Reduction in Mass Detection Approach using Spatial Diversity Analysis

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***Abstract*—Efforts in image processing and pattern recognition have been made in order to help improving the detection accuracy by physicians. In this paper, we present a analysis that study the use of Diversity Indexes in a Spatial approach as a texture measure in order to distinguish suspicious regions previously detected by segmentation scheme. The description of the pattern is based on the fact that the important features could be distributed on the region under certain distance, angle and tonalities. And these tonalities represents species that have a particular associations that may be important distinctions between the pattern of mass and non-mass regions helping do false positive reduction and assisting a physician on a task of verify suspicious regions on a mammogram. The computed measures are classified through a Support Vector Machine and reaches a reduction of 75% of false positives on mass detection methodology.**

***Keywords*-Mass False Positive Reduction; Pattern Recognition; Diversity Index.**

I. INTRODUCTION

According to the estimative of the American Cancer Society (ACS), the chance of a woman having the breast cancer in any period of her live is a just little below of 1 in 8, and the chances of dying from the disease is of 1 in 35 [1]. The screening mammography is the best way for the precocious detection of any kind of lesion in breast, also cancers. An earlier diagnosis improve the chances of cure. It is also know that in early stages, the treatment is more effective. The digitized mammogram is a image that presents overlapping breast tissues obtained by the X-ray exposure. The overlap and physiological characteristics of the patient can generate a mammogram of low contrast which could lead the physician a wrong diagnostic caused by the repetitive task of analyzing the image [2].

Efforts has been made in the use of image processing and pattern recognition techniques to improve the breast cancer diagnosis results. The goal is to increase detection and diagnostic accuracy providing a second opinion also causing a reduction in the rate of false positive biopsies for cases since the sensitivity of mammography exam is around 85% [3]. Mass detection methodologies based on image processing generally has a step of false positive reduction. This is aimed at decreasing the amount of the segmented regions that were marked as suspected mass, when they are actually normal tissues.

We have verified that the false positive reduction of the tissues extracted from the mammogram as mass and non-mass is a crucial stage in the methodologies for detection of breast cancer and that there is a potential to be explored in measurements that describe texture as the diversity indexes applied in a spatial approach. This study began in previous work of the group [4][5][6], which demonstrate the effectiveness of these methods.

Also, the classification of breast masses in mammography images has motivated many research. Some surveys [7][8] analysis different approaches published in literature. Most approaches are based on the extraction of features such as texture (statistics) [9][10][11], geometry (roundness, sphericity, spicularity) [12][13][14][15], morphological or nominal (BI-RADS) [16][17][18]. These features are submitted to a classification using a pattern-recognition machine as Support Vector Machine or Neural Networks.

This work proposes the use of diversity indexes used in Ecology (Total Diversity, Brillouin, Berger-Parker, J, ED, Hill, Buzas-Gibson) in a spatial approach to describe the patterns found in previously segmented images of mammogram. The main goal is to propose an efficient methodology for reducing false positives and assist detection methodologies that are used on Computer Aided Systems to assist the physician on a task of detection breast cancer.

The remainder of this work is organized as follows. Section II brings a brief introduction to Diversity Indexes. Section III presents a detailed description of the proposed methodology and evaluation used in this work. Section IV presents and discusses about the founded results. Finally, Section V presents the final considerations.

II. DIVERSITY ANALYSIS

This work proposes a study of a texture extraction for false positive reduction inspired in biological process using diversity analysis. Following we present the Diversity Indexes used as feature descriptor as well as the mapping of this problem to a traditional image processing task.

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This analysis intends to identify the distribution of a group of species and their interrelations. It is used in Ecology to measure the biodiversity in an ecosystem. The diversity refers to the variety of species in a given community or habitat. Biodiversity is the relationship between the number of species (richness), the pattern of distribution of individuals in their species (evenness) and the dominance of one or more species among others (dominance). All these characteristics can be measured and investigated using indexes usually classified as coverage of local analysis (alpha) or between various habitats (beta) [19].

More generally, the diversity indexes can be used to measure the diversity of a population where each member belongs to one single group or species. This paper intends to study the use of Diversity indexes for false positive reduction in pattern recognition process to distinguish mass and non-mass ROI's extracted from a digitalized mammography image. With this goal we adopt that the pixels are the individuals and their tonalities represents the set of specie.

Considering that each image ROI used has a distribution of gray tones varying from 0 to 255 (8 bits per pixel). Thus, any pixel x of image A have a specie s_i. The set given by $x_0, x_1, ..., x_N$ represents the overall population P where N is the total number of individuals and also of pixels. The set S is the total amount of species of the set $s_0, s_1, ..., s_i$ where i represents a specific specie. The number of individuals of each species is represented by n_i and p_i is the total proportion of the sample belonging to species i, that is $p_i = \frac{n_i}{N}$. This paper investigates the application of the following diversity indexes for texture characterization of mammography images.

The Total Diversity Index [20] estimates the total richness of a population based on species variation. This measure is given by:

$$Td = \sum_{i=1}^{S} w_i(p_i(1 - p_i)) \quad (1)$$

where w_i is the weight or importance given individually to a specie characterized by $\frac{1}{n_i}$.

The Brillouin Index [21] measures the richness of a known population and it is recommended when that population is not random. Also, this index tends to inform similar results comparable to Shannon-Wienner's Index [22] used in a not completely known population. It is defined by:

$$Hb = (\frac{1}{N})(logN! - \sum_{i=1}^{S} logn_i!) \quad (2)$$

The Berger-Parker Index [23] is the numerical importance of the most abundant species, defined by:

$$Bp = \frac{max(n_i)}{N} \quad (3)$$

where $max(n_i)$ is the amount of the most abundant specie.

The J Index [21] compares the observed Shannon-Wiener Index against the distribution of individuals between the observed species which would maximize diversity, and is defined by:

$$J = \frac{H}{H'} \quad (4)$$

where H is the Shannon-Wiener Index calculated by $H = -\sum_{i=1}^{S} p_i \ln p_i$ and his maximum value H' is given by $H' = logS$.

The ED [20] Index compares the dominance of Simpson with the known species that maximize the diversity. It is a relation between Simpson index D and it's maximum:

$$Ed = \frac{Ds}{Ds'} \quad (5)$$

where Ds is the Simpson Index [24] given by $Ds = \frac{\sum_{i=1}^{S} n_i(n_i-1)}{N(N-1)}$ and his maximum dominance Ds' calculated by $Ds' = (\frac{S-1}{S}) * (\frac{N}{N-1})$.

The Hill Index [25] calculates the equally abundance distribution of the species, given by:

$$Hill = \frac{\frac{1}{Ds-1}}{e^h - 1} \quad (6)$$

where Ds and H are respectively the Simpson and Shannon-Wienner's Indexes previously explained. In this index, if the species are equally abundant then the index should take the maximum value. This value will decrease as the relative abundance differ between species.

The Buzas-Gibson Index [26] indicates the degree of evenness trough Shannon index H and is defined by:

$$Bg = \frac{e^H}{S} \quad (7)$$

where H is given by Shannon-Wienner's Index.

III. Proposed Methodology

The methodology proposed in this work intends to study the uses of diversity indexes in a spatial approach to describe breast segmented tissues and allow a discrimination of then into mass and non-mass. The goal is to perform a false positive reduction of a detection methodology previously published in [27]. The methodology has five steps as illustrated in Figure 1: ROI Acquisition, Enhancement, Spatial Diversity Analysis (using the indexes previously described), Recognition and Validation. Each step is explained in the following text.

In order to test the proposed methodology, this work use a database generated by a detection methodology published in [27]. The ROI's were segmented using a circular template-matching technique. It detect the suspicious regions of randomly extracted 603 mammograms obtained in Digital Database Screening Mammography [28] each one containing only one mass. It were generated a total number of 2679 suspicious regions, including all 603 masses and other 2076

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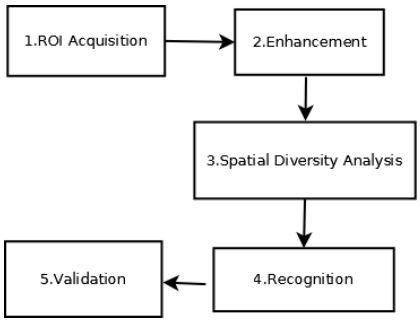

Figure 1. Steps of the proposed methodology

non-masses. Figure 2 shows some examples of these regions. We could note that mass regions are generally rounded, has high and homogeneous pixel values at their core. Non-mass regions has random contour. Their pixel distribution values is less accentuated than a mass region. So they share similar tonalities but mass regions are more concentrated on high values whereas non-mass regions are more equally distributed over many tonalities.

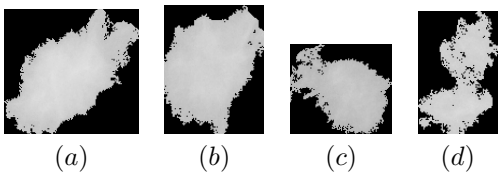

Figure 2. (a-b) Database mass examples and (c-d) non-mass examples

A. Enhancement

To produce an image with higher quality for the next stages, it was applied for each region an histogram equalization [29]. This step aims to make equally important tones of gray to represent spatial and visual image. Also, after the equalization of the image, six versions of each sample were made through the scalar quantization using six numbers of gray levels (2^8, 2^7, 2^6, 2^5, 2^4 and 2^3). This aims to clustering similar tones of gray in order to enhance their participation in the sample.

B. Spatial Diversity Texture Analysis

Each sample generated after the enhancement step was submitted to a spatial texture analysis using the Diversity Indexes presented in Section II. The spatial analysis measures the autocorrelation between the points over a certain localization or distance and even direction. Our goal is to measure also the autocorrelation information besides their diversity and use this information to create a pattern. For this goal, we adopt three approaches to make the spatial association: Rectangular, Circular and Directional.

1) Rectangular (HVDW): In this, the sample is divided into tiles, using horizontal (H), vertical (V), diagonal (D) and windows (W) like exemplified in Figure 3. The image was divided in 4 horizontal, vertical, diagonal tiles and 9 windows. Each resulting region is used separately.

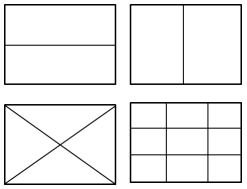

Figure 3. Rectangular scheme for split image region

2) Circular (CIRC-RING): Here the sample is analyzed by circles of different radius $r_1, r_2, ...r_n$ and also rings formed by the subtraction of two circles of different radius, where $r_1 > r_2$, as exemplified in Figure 4. It was used 5 different equidistant radius. They were obtained by dividing the largest radius into five parts. The largest radius was determined as the radius of the larger circle circumscribed in the region. The use of five radius was defined after empirical tests.

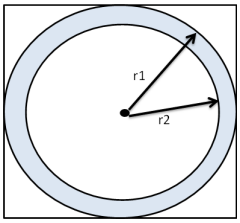

Figure 4. Circular scheme for split image region

3) Directional (DIR): This analysis [30] is done for each pixel of the sample, that will become a Head point in certain moment (See Figure 5a). In addition, to improve the capacity of describing texture patterns, we have conducted a directional analysis. For it, we must define a direction vector, that is an azimuth which corresponds to an angle in x axis, assuming a lag increasing rate. We assume tolerances for lag and azimuth to better capture neighborhood in a matrix arrangement of pixels. These restrictions are exemplified in Figure 5b.

In practice, for a specified direction, the features may be computed for a number of lags and directions take in consideration tolerances of lag and directions. We also split the set of species in 4 sets without intersection, in order of occurrence, to analyze the contribution of separate species to form a pattern and increase the importance of rare species that could have been obscured by the high occurrence of other common specie. For each one, the initial lag separation distance h was 1 pixel. After, this lag was incremented in 1 unity. The maximum number of lags chosen was 10. The tolerance lag adopted was ± 0.45.

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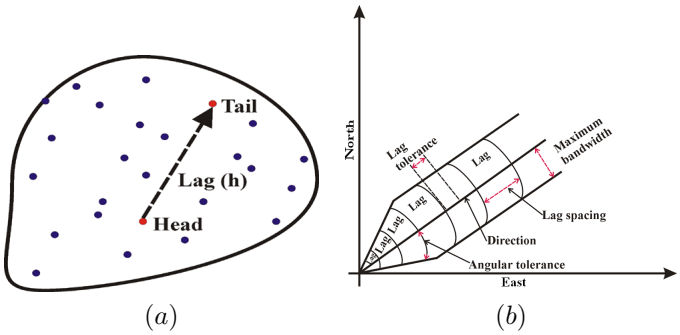

Figure 5. (a) Spatial association between points Head (origin) and Tail (destination) (b) Parameters used for indexes of spatial autocorrelation calculations.

C. Pattern Recognition using Support Vector Machines

In all spatial approaches described in Section III-B, each set of spatial diversity features vectors generated for each samples was classified using Support Vector Machine (SVM) [31] as previous used on [5]. It is a machine learning technique based on the creation of a high dimensional hyperplane of separation optimizing the limits of generalization. It uses radial kernel to mapping characteristics to a high dimensional space where non linear features could be separated. This kernel is defined by:

$$K(x, y) = e^{-\gamma \|x-y\|^2} \quad (8)$$

where $\gamma > 0$ is a parameter that also is defined by the user.

The process of classifying starts with a definition of a set of training samples and test samples. For this study, the training set for all approaches have the same samples to make possible the approaches comparison. The training set was formed by 400 samples of known mass and 400 samples of known non-mass samples. The balancing is important because of the large difference in number of samples non-mass relative to the mass. The rest of samples was used as a test set. Therefore, to prevent the classifier tends to a certain group, was held the balance amount of the samples.

SVM has the penalty parameter C that regulating the classification function for the best overall accuracy. This parameter was calculated for each set of samples during the training stage as the parameter γ for radial function. Also, with the objective to give more importance classification to mass group, was adjusted weight penalty imposed on the group represented to the value 15 in all classifications tests.

D. Validation

In order to evaluate the classifier with respect to its discrimination ability, this work were validated through following metrics [32]:

- True positive rate (Tpr): percentage of masses correctly classified;
- True negative rate (Tnr): percentage of non-masses correctly classified, meaning false positive reduction;
- Mean false positive per image (Fp/i): average number of false positive per image that remain after the reduction process;
- Means false negative rate per image (Fn/i): average number of incorrectly classified masses.

IV. Results

This section intends to present and discuss the results obtained from the proposed methodology. Table I presents results of all executed tests for each approach. The best outcome for this analysis happens when you have a large reduction of false positives while the hit rate remains high for mass group. Reduce false positives, but reduce the mass hit rate implies to produce results that do not detect cancer.

The best result found reaches 75.81% reduction of false positives (Tnr) with a rate of 93.53% of Tpr using DIR approach and Berger-Parker index. This results means that for the image database evaluated were generated 0.833 false positives in average and 13.195 masses were lost during the step of reducing false positives, generating a rate of 0.065 per image. Buzas-Gibson and Total Diversity also shows similar results with the CIRC, RING and HVDW approaches completing the best results found by the proposed methodology. The differential of the approach using directional Berger-Parker may be the division of species into subgroups appropriate for this index that quantifies the importance of the most abundant species in relation to other species.

Analyzing the other results we conclude that there is a low variation in the settling of masses, represented by Tpr averaging of 93.11%. This demonstrates the effectiveness of the diversity indexes jointly spatial approaches to correctly represent the mass group. The same can not be said of the hit rate of non-mass which obtained average variation of 6.7 percentage points. Analyzing how the indexes are obtained, we conclude that the evenness indexes that represent the abundance of the species over the population had difficulty in presenting notable differences between mass and non-mass patterns. One likely reason is the segmentation process, executed in previous methodology. The resulting regions are internally homogeneous, even in their borders. Even though there are different species within each homogeneous region. We observed that only 5 species occur only in regions of mass and all others are shared. Also, the species distribution in quantitative terms are very similar. Therefore, if the population of the samples do not differ enough and its distribution is similar, so evenness indexes will no be able to effectively translate the patterns found. Unless we use the information of the spatial distribution of species to characterize then. In this sense, the spatial approach becomes important to quantify mutual associations between species and include this information in the process of pattern recognition.

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Table I
THE PROPOSED METHODOLOGY RESULTS ORDERED BY OVERALL ACCURACY, TPR AND TNR. BEING THE BEST RESULT SHOWN IN THE UPPER LEFT

Approach	Diversity Index	Tpr	Tnr	Fp/i	Fn/i
DIR	Berger-Parker	93.53	75.81	0.833	0.065
CIRC	Total Diversity	92.03	74.56	0.876	0.080
RING	Total Diversity	92.03	74.55	0.876	0.080
HVDW	Total Diversity	94.52	71.91	0.967	0.055
RING	Buzas-Gibson	93.20	73.21	0.922	0.068
CIRC	Buzas-Gibson	93.20	73.21	0.922	0.068
CIRC	Ed	96.68	69.55	1.048	0.033
DIR	J	89.88	76.30	0.816	0.101
HVDW	Berger-Parker	88.39	77.45	0.776	0.116
RING	Ed	95.68	69.55	1.048	0.043
HVDW	Ed	94.69	70.37	1.020	0.053
DIR	Buzas-Gibson	92.37	70.52	1.015	0.076
HVDW	Buzas-Gibson	91.54	70.32	1.022	0.085
RING	Brillouin	90.05	68.40	1.088	0.100
CIRC	Brillouin	90.05	68.40	1.088	0.100
HVDW	Brillouin	94.19	63.58	1.254	0.058
DIR	Total Diversity	88.88	68.20	1.095	0.111
CIRC	Berger-Parker	92.70	64.02	1.239	0.073
RING	Berger-Parker	92.70	64.01	1.239	0.073
HVDW	Hill	93.36	62.47	1.292	0.066
RING	J	94.36	60.59	1.357	0.056
CIRC	J	94.36	60.59	1.357	0.056
DIR	Brillouin	96.94	53.94	1.586	0.031
HVDW	J	94.02	56.02	1.514	0.060
DIR	Ed	94.02	55.34	1.538	0.060
DIR	Hill	95.02	53.42	1.604	0.050
RING	Hill	94.36	52.98	1.619	0.056
CIRC	Hill	94.36	52.98	1.619	0.056

The Table II show the comparison of the best results found by this work with the previous work from which was obtained the image database. In previously work, the best result was found using jointly geometry and texture features, with the feature selection using a Genetic Algorithm. This result was a false positive reduction of a 83.24%. Although the reduction has been greater, we need to analyze the amount of not detected mass drastically increases in 3 times. So, in comparison with the other work, our methodology ensures that the proposed approach maintains a substantial reduction of false positives while maintaining a high hit rate of mass.

V. CONCLUSION

This paper presented a research on the application of diversity indexes and spatial approaches for the reduction of false positives in mass detection methodologies under digitized mammography's regions. It has been shown that these indexes can quantify with the aid of spatial approaches, texture characteristics able to differentiate masses and non-masses extracted from a image database generated by a previous mass detection methodology.

The best result obtained, decrease at most of 75.81% of false positives without significant loss of mass accuracy rate. Even the result of the lower accuracy attains a reduction of 52.98% of false positives. Compared with previous work, this approach reduces false positive without interfering significantly in detecting masses. We can conclude that the results are promising. But is still necessary to lower the false negative rate, that corresponds a mass regions that are not detected and harmful for a patient. In this methodology we used SVM penalty functions to optimize the rate of mass detection but this was insufficient.

So, although we have obtained good results with this study of diversity indexes applied in a spatial manner, we believe that the reduction of false positives remains to be larger to help permanently specialist. Therefore, as future works, we will extend it using morphological approaches under species to improve the pattern recognition step, also apply feature selection and make more tests in different images databases. Also implementing tools using this methodology to be directly applied by physicians and test it's performance in real situations.

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Table II
COMPARISON OF THE RESULTS OBTAINED BY THE PROPOSED METHODOLOGY WITH PREVIOUS WORK

Work	Approach	Index	Tpr	Tnr	Fp/i	Fn/i
Our	DIR	Berger-Parker	93.53	75.81	0.833	0.065
[27]	CIRC+RING	Simpson Index	78.33	79.9	0.69	0.22
[27]	CIRC+RING	Simpson + Geometry	83.24	84.14	0.55	0.17

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Collection of Patient Reported Outcome Measures Using Short Messaging Service

Experiences from the development process and a pilot study

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***Abstract*—Information and communication technology may improve clinical care and research. The advent of mobile technology offers many new possibilities. We present the development and pilot testing of a system that collects patient reported outcome measures using mobile phones in the field of rheumatological rehabilitation. Ensuring that the system was usable by the maximum number of patients resulted in choosing text messages for reporting from the patients over newer technology like mobile apps. The system was run in a successful pilot study where participants answered both with text messages and pen and paper. The text message reporting was more complete than the pen and paper method. A focus group and a survey showed that participants preferred using text messages to pen and paper. We detail our design decisions and why we feel that for our purposes within the domain of rheumatology, text messages provide the best suited overall solution given their simplicity, ubiquity in Norwegian society, and the fact that no new hardware or software is required for the respondent. The system is currently being used in a yearlong clinical study.**

Keywords: Patient reported outcome measures, electronic capture, short messaging service, rheumatology, clinical research.

I. INTRODUCTION

Traditionally, outcomes measures used in clinical medical research are based on a biomedical model of health focusing on objective and scientifically accepted tests and measures. [1]. Today, it is recognized that the patients' subjective opinion is of importance, thus patient reported outcome measures (PROMs) reflecting the patients' perspective are increasingly emphasized in clinical trials [2, 3, 4]. PROMs address such constructs as health related quality of life, subjective health status and functional status [4]. Concrete examples of such information are pain or fatigue levels reported by patients.

In certain chronic health conditions, such as arthritis and diabetes, it may be appropriate to collect PROMs over time in so called health diaries [5]. Health diaries in this context mean one or more scientifically validated PROM questionnaires completed repeatedly over a period of time, for instance over weeks or months.

It is important that the diary data is of high quality, providing an accurate picture of the patient's subjective experience. The traditional diary collection method has been pen and paper (P&P). There are a number of inherent weaknesses with P&P collection, such as poor protocol compliance, poor data quality and burdensome data management [6]. The problems may lead to the introduction of a variety of biases in the collected data. This may undermine the scientific value of the diary method.

Information and communication technology (ICT) may help combat the aforementioned biases when collecting diary data. With the advent of mobile handheld technology – notably personal digital assistants (PDAs), feature phones, smartphones, and tablet computers – data collection by means of electronic diaries (EDs) has become increasingly popular in clinical research [7, 8, 9]. Electronic capture of PROM data has a number of scientific and practical advantages over the P&P method [6, 8]. According to a systematic review, the ED diary method is superior to P&P collection in terms of feasibility, protocol compliance, data accuracy, and subject acceptability [8]. Additionally, it has been shown that the electronic PROM collection is equivalent to P&P PROM collection [10]. This is important to maintain scientific constructs such as validity and reliability to ensure that the psychometric properties of the questionnaires are carried over into the electronic versions.

With the superiority of the ED method established, one is faced with the questions: given that there are a number ED methods available, e.g., by means of PDAs, feature phones, smartphones, and tablet computers, which one do you choose? Currently, smartphones and applications (apps) are in vogue, but does an app installed on a smartphone always provide the optimal method when one wishes to collect PROMs? In another project, the Short Message Service (SMS) or text messages have been utilized successfully [11]. We need to ask whether this somewhat older and basic technology is obsolete, or is it still an option in ED collection?

This was the dilemma faced by the National Resource Centre for Rehabilitation in Rheumatology (NKRR) when they wanted to select an electronic collection method for a yearlong clinical study measuring the possible clinical effects of physical exercise in heated pools for persons with rheumatic disease. PROMs relating to subjective perceptions of pain, stiffness, fatigue, and how much the rheumatic disease affects the ability to engage in activities were to be collected twice weekly for a year.

Researchers at the Norwegian Computing Centre (NR) designed and implemented an electronic collection solution. As the paper will show, we opted for a solution using text messages. This paper detail the reasons for doing so, and in the process shed light on important issues and aspects that one has to reflect upon when wanting to choose an ED col-

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lection method. We will do so by explaining and describing the technical set up, and the deliberation behind its construction. We will also detail our experiences from a pilot trial of the system that ran over a four-week period with 28 participants with rheumatic disease, as well as share and discuss the findings from a focus group and questionnaire survey conducted as part of the same pilot. Further, a brief conclusion and planned further work is provided.

II. DESCRIPTION OF REQUIREMENTS, ENSUING SOLUTION AND PILOT STUDY

This section describes the requirements as expressed by NKRR, as well as detailing the solution that was developed and the pilot testing of the system.

A. System requirements and the solution developed

Below we detail the requirements a potential system had to meet. Further, we provide a description of the ensuing system developed.

1) System Requirements

For their clinical study outlined above, NKRR required an electronic collection system that would allow them to collect selected PROMs twice weekly for a year from persons with rheumatic disease across Norway. The participants were to take part in exercise classes in heated pools suited to the needs of people with joint disease. The PROMs would help indicate whether or not classes had any clinical effect.

The system had to allow flexible access for the researchers from multiple geographical locations. The project required a service that could contact participants, i.e., persons with rheumatism, and have them answer back during a 24 hour period. NKRR also wanted to check on the status of the responses, control the content of the messages, and specify when they were sent out. If a reply had not been received by a certain time, a reminder message was to be sent out.

It was also important that solution was secure and that the privacy of the participants was preserved. This meant that the relevant privacy laws in Norway were followed. Participants would be recruited from several different research and medical institutions, and a contact person at each institution would be in charge of recruiting and adding the participants.

The system would have to stay up during the entire year that the study would be running. The collected data was to be readily available both online and easily downloadable for analysis using statistical software. These requirements helped shape the final solution that was developed by NR in close cooperation with NKRR.

2) The solution developed

The final system is a web application with a front end that is run by a web interface written in Ruby on Rails. We only allow encrypted access (i.e., HTTPS) to the web application and only authenticated users are allowed further access.

The interface (see Figure 1) allows logged in users, e.g., researchers or other relevant staff members, to add participants to a study, schedule what days messages are sent out, write the message text, look at responses from the participants, and export the results for use in spread sheets or

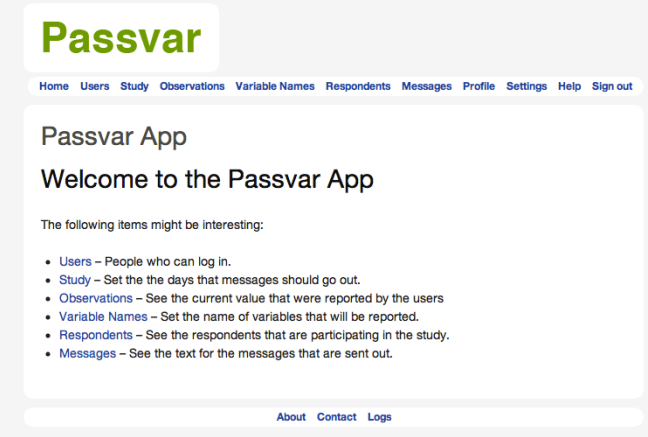

Figure 1. The user interface of the web application.

statistical programs. Special administration users are also able to create additional system users. This allows users to be added for each institution that decides to join in a particular study.

Participants are identified by an ID selected by the researchers. Participants' mobile phone numbers are entered into the database upon creation. For privacy reasons, users with no administration privileges are only able to see the phone numbers of the participants they have added. These users are able to see all incoming results, but they cannot see which result corresponds to which phone number.

As for sending and receiving messages to participants, we decided to use text messages for this. After some investigation, we found a Linux-based software solution called SMS Server Tools 3, and a modem that was well supported by it. We were then able to write some programs that would look at the information in the database, and send out reminder messages to those that had not sent a message yet. The program runs periodically using the cron service on the Linux system. The message that is sent out asks the participants to reply about the level of W, X, Y, Z (e.g. pain, stiffness, fatigue or any relevant PROM) and answer on a scale from zero to ten. The participant should send back the answer with each number separated by a period (e.g., 10.8.7.5). An overview of the whole system is provided in Figure 2.

Another program is run whenever we receive a text message. This program checks the phone number that sent the message and imports the message if it matches any numbers of the participants in the database. It will also parse out the numbers in the message and match them up to the values that are asked for in the study. As a precaution, we also store the raw message in the database as well. This ensures that if a message is incorrectly interpreted, we can look at the original message and see if there was a problem. Administration users also have access to the logs of every message that has been sent out and received, so it is possible to know if the system is working.

The system is designed such that on certain days at a certain time, participants will get a message where they answer with some numerical values. If a response has not been received in 24 hours, a reminder text message is sent out. If participants have not answered the question after that 24-

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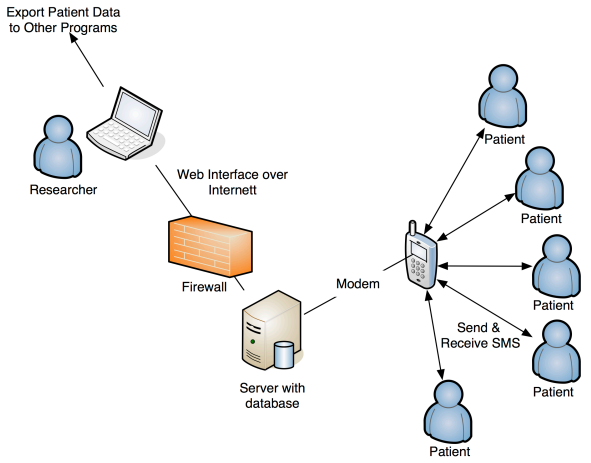

Figure 2. An overview of the system. The patients respond to text messages generated by the system. Their answers are store in a database. The collected data can be viewed in a web interface, or exported for analysis.

hour period, the response for that period is dropped and will be counted as non-compliance in the study protocol. The system interprets the incoming message, and if this is ambiguous or cannot easily be interpreted according to built-in logic, it is discarded. Since the days that the message is sent out is the same for each week, we used a simple interface where we could set up the actions for each day of the week (either send a message, send a reminder, or do nothing) and then specified how many weeks this action should repeat.

The system is running continuously on a virtual machine, and is backed up regularly. There are monitoring scripts checking for and alerting us if there is any malfunction.

B. Pilot study

A pilot study was conducted to test the system in real world conditions, as well as to compare the compliance rate and to examine validity and reliability issues between P&P questionnaires and their text message equivalents. 28 adults with a rheumatic disease were recruited to take part. They were asked to answer the following text message every other day for four weeks: "Degree of pain, fatigue, stiffness and how the disease affects your ability to conduct daily activities? 0=none, 10=worst possible. Remember a full stop separating the numbers. Thank you![1]" The message consisted of abbreviated questions used in rheumatological research, e.g.: "Please, state how much pain you are experiencing! 0 = no pain, 10 = worst pain possible, 0 2 3…9 10". The questions were also provided in full text to the participants on small laminated cards that they could carry with them.

Every other day they were asked to report the same PROMs using P&P. The responses for both modalities were a value between 0 and 10 for each PROM. A text message with the correct syntax could look like this: "1.2.3.4". All the P&P responses were to be mailed to the study coordinator. Detailed written instructions were provided for each participant. Since the pilot study format alternated days with texts and P&P, we did not use the text message reminder functionality if a response was missing.

In total, the participants would respond with 14 text messages and 14 P&P forms to be compliant with the protocol. The data from the incoming texts was imported into SPSS statistical software for analysis. The P&P data was manually typed in to the same software. To obtain the participants' perspective, we conducted a focus group after the pilot was completed to discuss the experiences with five of the participants. In addition we mailed out a questionnaire survey to the participants asking 14 questions related to their participation and ED collection.

III. RESULTS

Below follows a brief summary of the experience from the pilot divided into data collection issues and participants' feedback provided in the focus groups and questionnaires.

A. Data Collection Issues

The system worked satisfactorily for the duration of the pilot with no downtime. Only brief comments about the integrity and quality of the incoming data will be provided here, as such results will be reported more comprehensively in a future publication. Overall, the text message data sets were more complete than the P&P data sets; that is, there was fewer missing data in the text message records when compared to the P&P records.

Further, as we were able to monitor the incoming text message data, respondents could be contacted if there were repeated violations of the protocol, e.g. systematic syntax error in the responses, or numerous missing data. The project coordinator contacted two of the participants once to guide them on how to respond correctly after detecting incomplete incoming data.

Based on the experiences gained in the pilot, we made adjustments to the system and added features. This included new logical rules of how the incoming messages were to be interpreted, and the possibility to access a log of all outgoing and incoming text messages.

B. Focus groups and questionnaire survey

We used a focus group and a questionnaire survey to obtain feedback on how the participants experienced taking part in the pilot.

1) Focus group

The purpose of the focus group was to get input from the respondents on how they experienced taking part in the pilot. This input was used in the development process to further improve the solution. Five participants – two male, three female – took part. The focus group session lasted 90 minutes and was audio recorded. An interview guide was used to structure the session.

In the pilot, all five focus group participants had used smartphones that they carried with them at all times. They stated that they had responded to all messages, except one who had forgotten to answer on a couple of occasions. It was pointed out that it sometimes was socially inappropriate to

[1] Text messages have a 160-character limit per message. This message is 160 characters in Norwegian.

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answer, and this meant that they responded at a later time. One of the participants said that it could be somewhat socially awkward to receive a message in the presence of others, as others may see the message content of the message. This was especially sensitive if the participant did not want others to know that the participant had a rheumatic disease.

In the pilot the text message was sent out to all respondents at 3 P.M. Three informants preferred this time, while two preferred to receive a message between 5 and 7 P.M. If they were to receive a reminder, all agreed that this should be sent out the same day as the original text message.

Few practical problems were raised. One informant reported problems sending a response on a couple of occasions, but was unsure if this was because of problems with the mobile phone or with the network. Another person thought she had used a wrong syntax in a reply once, but assumed that the message went through. Despite this uncertainty, none of the group members wanted to receive a receipt acknowledging that their answer had been received and was a valid response.

One of the informants had been abroad during parts of the pilot, but had not experienced any practical problems receiving and sending texts using foreign mobile networks. Anecdotal evidence of occasional delays in receiving texts sent between international mobile networks are known.

The whole group preferred text messages to P&P, and they thought it was easy to respond using the mobile phone. There was some interest in using a smartphone app as a response medium. It was highlighted that this would enable them to answer more in-depth on suitable questions instead of the 160-character restriction on text messages. As they all had smartphones, this limit of 160 characters per text message poses no practical and usability limitation as the phone will automatically combine and present two or more both outgoing or incoming messages into one message on their screen. Some older phone, however, split messages longer than 160 characters into multiple messages that must be opened separately. This could be a usability issue.

Several of the participants stated that it was very helpful to have the laminated card with the questions written out in full. As for the text used in the text message, it was suggested to include an example of a correct response, e.g. "3.5.6.9".

There were also a number of suggestions and views concerning the principal idea of collecting PROMs. Some of the issues raised were the problem with quantifying subjective experiences such as pain and fatigue. It was also suggested that they would also like to be able to add additional information like stress levels, mood, and other factors that will possibly influence the PROMs.

TABLE I. CHARACTERISTICS OF THE SURVEY RESPONDENTS.

Number of responses (N):	12
Gender:	10 women; 2 men
Age range (years):	27 to 62 (mean 50 and sd 12.2; median 55)
Type of phone:	Touch UI 8 Standard keyboard 3 Touch UI & physical keyboard 1

2) Questionnaire survey

The purpose of the questionnaire survey was to gain insight into how the respondents had experienced taking part in the pilot. It was mailed out to 20 of the pilot participants as we lacked the addresses for the remainder. The characteristics of the respondents are given in TABLE I.

All but two stated that they had a 100% data completion record using the mobile phone. One had simply forgotten to reply on one or more occasions, and another was busy and could not respond on one or more occasions. Two-thirds agreed that 3 P.M. was a suitable time to receive a text message to respond to, while the rest suggested a different time window. Suggested times ranged from 5 P.M. to 8 P.M.

Nine out of 12 would like to have a text message reminding them to answer if they have not done so, whereas two did not, and one did not know. Of those that wanted a reminder, five would like this the same day as the original message while four suggested the next day.

No one reported any technical problems that affected their performance, and one-third of those answering had been abroad during periods of the month long pilot. 10 preferred text message to P&P, one did not have a preference, and one answer was discarded as several mutually exclusive choices had been selected.

Seven would consider using the mobile phone to register health related information such as pain, fatigue and stiffness on a regular basis, two did not, and three were not sure. A comment from one of the respondents was that such information should not be collected more frequently than monthly. In terms of other types of information that they would consider to register on their mobiles was information relating to exercise (50%); dietary information (50%), and intake of medication (25%).

IV. DISCUSSION AND IMPLEMENTATION ISSUES

Below follows a discussion of the collection method chosen, as well as an elaboration on several implementation issues.

A. Discussion

There are a number of electronic capture methods. How wise was the decision to opt for text messages as a collection method in this project? While creating mobile apps or web apps at present is a favourite topic in the business world, we had no guarantee that potential respondents would own phones able to run such apps. To run apps, the participants would need a smartphone that would run Android, Blackberry, iOS, Windows Phone, or similar. Since there are a number of different platforms, it would mean either choosing only one platform or creating versions of the app for all platforms. This would have been very resource demanding for this small project.

Since the prevalence of rheumatism increases with age and it is a chronic disease [12], many of the potential respondents would be older. As smartphone ownership amongst the elderly is still low, we decided that this would preclude many potential participants from entering the study. This would have had the potential to cause bias in the results. One could for instance expect that a majority of participants

would be younger if one opted to go for a mobile app or a web app given this groups higher smartphone ownership.

An option would be to lend participants smartphones for the duration of the project. This measure would be both costly and would require a great deal of training and support. Research has also shown that seniors would like to have basic phones, and that complex phones can be confusing [13]. Making them use a new smartphone seemed to be an option that could end up being both costly and fraught with support problems.

Further, we were sure that there would be a wide variety in the functionality of the mobile phones amongst potential participants. Text messages were the only method we could be sure that everyone had access to. Text messages are also so ubiquitous in Norwegian society that we could be sure that participants could answer a text message without any training. They would be able to use their own phone that they are familiar with.

Another reason for using text messages was that they are cheaper than data costs when participants are abroad. A mobile app or web app would require some sort of data connection, either over Wi-Fi or using mobile data. Many Norwegians with rheumatic disease travel to countries in Southern Europe for the winter as a therapeutic measure, and roaming data is currently much more expensive than a roaming text message. Text messages only require GSM coverage, and this available across the populated world. The use of text messages also allows for two-way communication: allowing us to do things like send out encouragement messages to keep up motivation.

Although, text messages have many advantages in the context of this particular project, there are a number of shortcomings one needs to keep in mind. One limitation is the 160-character limit per message. This limits the number of questions one can pose, as well as the amount of information the responses can contain. In our case, we were able to ask for four PROMs in each message based on abbreviated P&P questions. Using an app we could have been much more flexible in terms of mimicking the original P&P questions used, and thereby presenting the respondent with one question at the time in full. The respondent could then answer a particular question before moving on to the next.

We could have worked around this by sending multiple text messages for the participants to answer one at a time. This has been done in prior projects [11]. We considered this too inconvenient and intrusive for the respondents, so we opted to go for one message per communication.

Another problem using text messages is that the participants need to structure their response in a manner that is easily interpreted by the system, e.g., "value1.value2.value3.value4". This is because there is no inherent structure in the text message itself. When we are parsing, we look for any numbers that are separated by any non-number character, not just a period. We chose to be liberal in what we accept since participants may forget the exact format of the answer. Although we have flexibility in the system, the possibility of the respondent making an error is always there. This may result in missing or corrupted data, and subsequent incomplete data sets.

This problem can easily be addressed when one uses apps as a response medium as each question is linked to a response, and there are measures one can make to ensure respondent answers are well formatted. One can even use text messages as the medium for sending well-formatted responses from an app and avoiding expensive data charges as well. Yet, this may add another level of complexity if there are problems with the text messages. It also does not give a great experience for informing the participants: first, they get a text message informing them they need to answer, and then they need to start up the app to respond.

Another issue with text messages is that there is no guarantee that they will be received and no indication for successful delivery. You can only know that a message was sent. Messages are also either sent with weak encryption or no encryption depending on the service provider that is sending the message. These issues need to be considered to determine the reliability, security, and privacy you wish to have. All of these issues can be addressed in an app.

It seems like text messages are useful when there are few and brief questions requiring short responses, whereas apps allow for many questions as well as opens up for open-ended questions and different types of responses such as multiple choice and Likert scales. We have summarized some of the pros and cons for text messages and apps in TABLE II.

In our project, we believe that the advantages with text messages outweigh their disadvantages. The use of an app would have excluded too many people from taking part. Alternatively, were we to have supplied smartphones to all participants, the added expense and resources for training, support, and follow-up would have been prohibitive.

In addition, an app requires the selection of an implementation platform. This would further have shut out potential participants. A possibility in the future when all phones are smartphones would be to use a web app that would run in a

TABLE II. PROS AND CONS FOR USING SMS OR APP ON SMARTPHONE.

SMS		**App on smartphone**	
Pros	Cons	Pros	Cons
• Universal technology. • Highly adopted in elderly age group. • Works on all phones. • Only requires mobile coverage. • Can use respondents own phone.	• Maximum of 160 characters. • May have to receive/respond with several messages. • Need to interpret incoming message. • No guarantee of delivery. • No guarantee of privacy.	• Very flexible in terms of design and user interface. • Can design layout of questions very similar to P&P originals. • Can control input through design. • Easier to automatically insert data into database.	• Need expensive smartphone. • Many different platforms to design for. • Few elderly have smartphones. • High threshold for use. • Roaming data fees may incur. • May need training. • May have to provide phone for respondent.

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web browser. This would also be able to run on PCs and tablets, providing a solution for the collection of PROMs on multiple platforms.

B. Implementation Issues

We saw two possible solutions for sending and receiving text messages. One solution was to use a commercial text messaging service. These are services that have infrastructure for sending and receiving many text messages and can be controlled through a web service. These are typically used for large surveys. The second solution was to create our own system by getting a subscription for only text messages and either controlling a mobile phone or installing a GSM modem. Regardless of which solution we would choose, we would have to write some custom software to send the text messages and store the responses. Ultimately, we decided to go with our own custom solution instead of using a text message service. The main reason being that adding a text message service meant adding another data processor into the mix; this meant extra cost and paperwork and eventually an extra contract that needed to be signed. Further, we were concerned about the implications of doing this in terms of security and privacy. We also felt that developing our own solution would be good experience in seeing how text messages services worked.

We only allow encrypted access through HTTPS to the web application for the researchers and other admin personnel, and only authenticated users are allowed further access. This solution was chosen as it provides adequate safety, while at the same time allowing access in institutions such as hospitals and research facilities that may have strict security policies when it comes to Internet access that would prevent other types of communication.

An advantage to using a web app is that the website can be accessed by researchers and admin personnel from any location with Internet access instead of having to be on a certain network, e.g. a certain hospital or research institution.

V. Conclusion and Future Work

In this paper we have detailed the development and implementation of a system that collects PROMs by way of text messages, as well as shared our deliberations in the development process. Further, we have detailed our findings and experiences from a pilot run of the system, which included a focus group and a questionnaire survey.

A major issue for us was the decision to use the more traditional medium of text messages for communication as opposed to an app installed on a smartphone. We feel that for our purpose and within the domain of rheumatology, text messages provide the best overall solution. We further expect that text messages will be suitable to use in the foreseeable future.

The context for use is within clinical research, but we also believe that text messages can be an appropriate medium also in clinical practice when PROMs are to be collected over time to be used in patient follow up and care. Its strengths lie in its simplicity, ubiquitousness in Norwegian society and the fact that no new hardware or software is required for the respondent. We are, however, convinced that in future, we will all carry smartphones, and that an app or perhaps a web app will be the preferred medium for carrying out PROM collection. Meanwhile, as our experiences have showed - text messages are more than adequate.

The system is currently being used in the aforementioned heated pool clinical research project that will last for approximately one year. We have a number of concrete features and improvements we would like to include in future implementations of the system. A more flexible and individual text message schedule, and a smartphone version giving patients the option to chose response modes are among the possible improvements.

Acknowledgments

We would like to thank all the persons who took part in the pilot.

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Prediction of Metastatic Events in Patients With Cutaneous Melanoma

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***Abstract*— Cutaneous melanoma, one of the most aggressive malignant tumors, potentially leads to widespread metastasis. The prediction of early metastatic events by using clinical information and data from specific tumor markers could substantially augment the quality of diagnostic and treatment decisions. To predict potential metastatic events during follow-up in patients with cutaneous melanoma, a knowledge-based system will be used during clinical routine by interpreting data from clinical history of the patient in combination with data from tumor markers. Specifically, data will be sent to an expert system including a rule engine which offers the physician a risk assessment and decision support. The interpretation of the tumor markers (n=493) resulted in a prediction sensitivity and specificity of 77.80% and 69.55% while using the multivariate combination of MIA, S100β and LDH. Additionally, the risk of metastasis was calculated based on fitted survival functions and was integrated into our system. Currently this knowledge-based system will calculate the individual likelihood for metastatic events based on the risk of the primary tumor, the duration of observation since the primary event and the recent values of tumor markers. The system aims to produce results that are compatible with medical expert's opinion.**

Keywords- cutaneous melanoma; TNM classification; artificial intelligence; decision support; knowledge-based system

I. BACKGROUND & MOTIVATION

There is substantial evidence that cases of cutaneous melanoma (CM) are still increasing worldwide. The increase of the incidence amounts to about 4-8% [1, 2]. According to Meves, a duplication of the incidence until 2020 is conceivable [3]. Today's incidence in Germany and Austria ranges between 12-15 / 100,000 inhabitants [2].

Clinically, primary CM is usually diagnosed by the naked eye and is supported by the use of diagnostic algorithms (ABCD algorithm) [4-7]. Usually, CM is initially treated by surgical excision. After excision, tumors are classified according to the American Joint Committee on Cancer (AJCC) published TNM classification for CM, based on studies from Balch et al. [8, 9]. The AJCC classification [10] allows to stratify CM into different categories, predicting the risk for widespread metastatic disease. Numerous studies showed that metastasizing CM have a distinctly poorer prognosis than non-metastasizing CM [9, 11]. Consequently, the diagnosis of CM at an early stage and additionally the prediction of metastasis as early as possible stage of development are essential.

Patients suffering from CM require a number of follow-up examinations over a long period of time. These examinations include several imaging modalities like X-Ray, computed tomography (CT), magnetic resonance tomography (MRT) or positron emission tomography (PET) [12]. Additionally, blood tests are commonly used during follow-up, examining the serum concentration of the tumor markers such as S100β protein, melanoma inhibitory activity (MIA) and lactatdehydrogenase (LDH) [13, 14].

A. Relevance of tumor markers

Generally, tumor markers are circulating molecules, which will be obtained from blood or other body fluids. According to Bosserhoff et al. [1], the presence of metastatic disease correlates with the concentration of tumor markers. Hence, it should be probably possible to predict the metastasis and the progression of the disease in CM patients [15-17].

The already routinely established tumor markers for CM are S100β, MIA and LDH. These parameters were chosen

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for our predictive model [13, 15, 18-21]. In a retrospective study, performed by Schlager et al [15], tumor markers of patients with CM were already collected. The data included 176 patients with 493 single examinations. Every patient received state of the art imaging modalities like CT, MRT or PET. In 85 cases metastases were found. Univariate examinations clearly demonstrated the predictive power of these tumor markers clearly. The area under the curve (AUC) calculated by receiver-operator-characteristic-analysis (ROC) was 0.676 for S100β, 0.721 for MIA and 0.725 for LDH, respectively.

B. *Pretest probability for a metastatic event*

In this context, the term *pretest probability* describes the statistical probability of developing metastases before tumor marker levels are taken into account. According to Bayes' rule [22, 23], the posterior (posttest) probability is the arithmetic product of the pretest probability and the likelihood ratio. Assigning a numerical value to the pretest probability amounts to quantifying the clinical expertise of a physician who is able to build an internal, "holistic" impression of a patient that forms the baseline of his or her assessment of that patient. Results of medical tests are then interpreted against this baseline, in the sense that the same test result will be interpreted differently, depending on this baseline. Bayesian statistics offers a means to formalize and numerically represent this procedure.

II. MATERIALS & METHODS

The assessment of the patient's pretest probability is based on predictive characteristics from the literature. These include the tumor thickness according to Breslow [24], mitotic rate and ulceration which can be used to make conclusions about the behavior of the tumor.

The final version of the seventh edition of the AJCC melanoma staging and classification [9] includes the revised TNM classification for CM. This classification is particularly well suited for rule-based programming languages because it consists of IF-THEN rules. Consequently, to a certain extent, it is possible to parameterize the pretest probability and therefore it can be used for the generation of automated decisions. The tumor classification of CMs using the categories of the TNM classification allows prognostic statements of the disease and often determines further therapies.

A. *A knowledge-based system*

The knowledge base developed in this project calculates the present risk for metastasis in CM patients. Calculations are based on the pretest probability for metastasis in combination with the recent results from the tumor markers stated above. Artificial intelligence and rule based systems provide decision support. More precisely, the knowledge base will be a combination of multiple risk assessments:

- Rule-based interpretation of the TNM classification according AJCC
- Interpretation of the tumor markers S100β, melanoma inhibitory activity (MIA) and lactatdehydrogenase (LDH) by a multivariate artificial neural network analysis
- Risk assessment of survival function (present statistical mortality risk) based on the recent published results of the AJCC

The knowledge-based system (KBS) is able to support the physician by calculating the tumor stage. Furthermore, the KBS offers an interpretation whether a given pattern of tumor markers is suspicious for an underlying metastatic event.

Matlab R2009b and SPSS Statistics 17 were used for various calculations, particularly for ANNs, logistic regression [25-27] and ROC-curves [28]. Matlab was used to construct an individual ANN by using scaled conjugate gradient optimization. Standard settings for all ANNs were 70% training, 15% validation and 15% testing, with 20 hidden neurons in each case.

The study included calculations in variant types, whereby every calculation involved the computation of ROC-curves (Fig. 1).

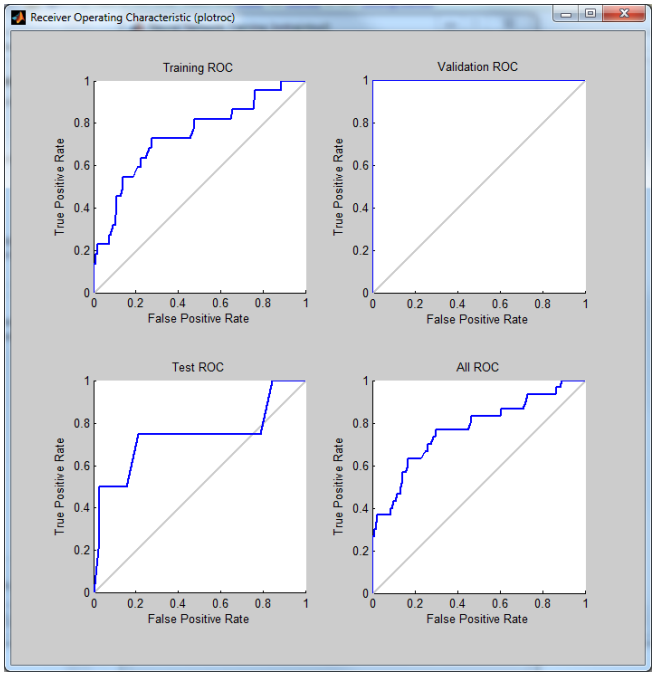

Figure 1. ROC curves for S100β/MIA/LDH.

Pretest probability according to TNM was implemented in Arden Syntax [29, 30]. The rules are grouped in modules, called Medical Logic Module (MLM). An example of an implemented rule is showed in Fig. 2.

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```
logic:
//Thickness classification
if thickness =0 AND not ulceration then T :=
"Tis";
elseif thickness <1.01 AND (ulceration OR
mitosis >=1) then T := "T1b";
elseif thickness <1.01 AND not ulceration AND
(mitosis <1 OR mitosis = null) then T := "T1a";
//mitosis not available
elseif thickness <2.01 AND not ulceration then T
:= "T2a";
elseif thickness <2.01 AND ulceration then T :=
"T2b";
elseif thickness <4.01 AND not ulceration then T
:= "T3a";
elseif thickness <4.01 AND ulceration then T :=
"T3b";
elseif thickness >4 AND not ulceration then T :=
"T4a";
elseif thickness >4 AND ulceration then T :=
"T4b";
else T := "errT";
endif;
```

Figure 2. Example rule for the classification of tumor thickness

B. *Work in progress*

As an element of work in progress we recently implemented our knowledge base as clinical decision support system (CDSS) in a huge hospital information system (HIS). A screenshot of the implemented form in the HIS is showed in Fig. 3. We aim to validate the system now during clinical routine. This approach has been acknowledged by the local ethical board (EK Nr. 1110/2010).

C. *Workflow of the clinical study*

The CDSS integrates completely into the workflow of the HIS. A feature of the system is the implementation of parameterized documents (PMD) for retrieval of relevant data. Specifically, results from tumor markers are automatically fed into decision support system via the laboratory information system. Additionally, clinical data are extracted from patient's history and from the histopathological report. As a result these steps of data extraction feed the CDSS with all relevant data.

III. RESULTS

Currently, the CDSS calculates the probability whether not a given pattern of tumor markers is suggested for metastatic disease, but will not display this result to the user. The response system is received just in the background and not shown to the physician. Instead, the user is prompted to give his or her expert opinion whether or not the given pattern is suggestive for metastatic disease. Up to now (October 2012) we gathered n=214 clinical cases.

At the end of the clinical study phase, the agreement between the clinical expert decisions versus the CDSS will be analyzed. Technically, we do not experience any problems during the clinical study phase. The system appears to be well accepted by the clinical experts. The median additional overhead of time caused by using the CDSS was 62 seconds.

Initial data show that the comparison of the physicians' decisions with the CDSS resulted in 106 (49.53%) complete matches, which implies that the CDSS and the physician completely agreed. In 48 (22.43%) cases, the system calculated a lower risk for the patient, whereby in 10 (4.67%) cases the calculations resulted in a higher risk, respectively. In 50 (23.36%) cases, no decision was neither possible for the CDSS nor for the physician, due to the lack of parameters. A comparison of the results is shown in Table I.

A. *Problem analysis*

During the routine workflow, it was not always possible to respond to all parameters required for the CDSS, leading to missing data. Additionally, distinct subtypes of CM were not clearly defined by the TNM/AJCC classification system. For example, tumor thickness of uveal melanoma cannot be exactly identified. Yet, the tumor thickness is a mandatory field and a mandatory parameter to classify the tumor according to AJCC.

TABLE I. THE AGREEMENT BETWEEN THE CDSS RATING AND THE EXPERT PHYSICIANS

Comparison of the results	Sum	Frequency
Complete match	106	49.53%
Risk assessment by CDSS is lower	48	22.43%
Risk assessment by CDSS is higher	10	4.67%
No decision possible	50	23.36%
Total	214	100%

IV. CONCLUSION AND FUTURE WORK

The CDSS, developed in the context of this clinical study, facilitates the calculation of the tumor stage for patients with CM and additionally provides a meaningful risk assessment of possible metastatic events. Our preliminary data show, that our system is well accepted by physicians. We think, this is mainly due to the fact that the CDSS is almost seamlessly integrated into the routine HIS. Parameters are automatically extracted from its data sources without any hassle for the physicians in charge. The performance of the system is still under investigation.

Early data indicate a promising agreement between the CDSS and expert physician's judgment. However, the risk analysis has not been finalized yet and a clear decision on benefit and hazard cannot be given at the moment.

Based on the experience made during this project, we are convinced that the integration of CDSS are in different fields of medicine might be useful. The appreciation and compliance with physicians is astonishingly high. Future prospective and controlled studies are mandatory for balancing benefit and risk of CDSS in the clinical domain.

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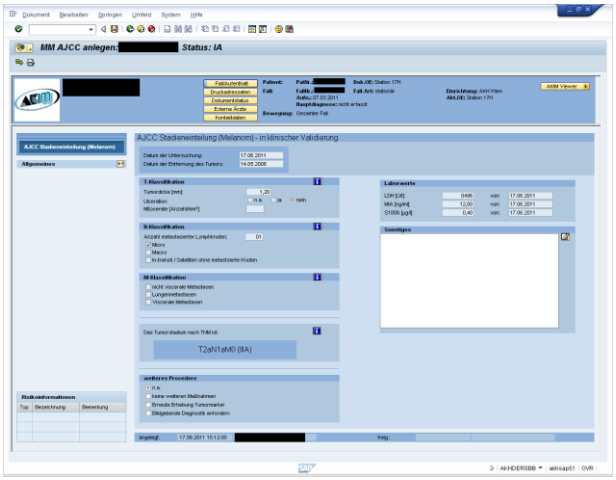

Figure 3. Integration of the clinical decision support system in a hospital information system.

Using Telecare for Diabetic Patients:
A Mixed Systematic Review

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***Abstract*—Numerous telecare interventions and technologies are used in the management of type 2 diabetes mellitus. This systematic review examines the different telecare interventions implemented, the technologies used, as well as their associated outcomes. Such a synthesis aims at optimizing telecare use for diabetic patients and informing decision makers on technology selection and the impacts that can be expected with telecare use. Following a systematic, comprehensive search of databases, 2,139 qualitative and quantitative studies were initially selected; after careful review and screening, 50 studies were coded and analyzed. The results of this review will be used by healthcare professionals, organizations and patient support groups to tailor their policies with regards to the choice, planning, diffusion and monitoring of telecare interventions and the technologies implemented to care for patients with diabetes.**

Keywords- telecare; health information technology; diabetes, systematic review; mixed methods

I. INTRODUCTION

The use of telecare technologies (TT) seems to hold promise for chronic care management since it "produces accurate and reliable data, empowers patients, influences their attitudes and behaviors, and potentially improves their medical conditions [1]." However, there is still a lack of evidence on its clinical effects, cost effectiveness, and impacts on service utilization [1]. The large prevalence of type 2 diabetes mellitus (T2DM) in the patient population and the impetus for quality of care—including monitoring, self-care and close follow-up—are creating a need for the development and use of TT. However, given the large variety of TT currently available and the diversity of interventions, ranging from condition monitoring to instant health diagnoses, it is difficult to fully grasp the actual impacts of telecare. There have been numerous reports of interventions designed to improve the care of patients with diabetes, but their effectiveness is unclear. It is now essential to assess the overall effectiveness and efficacy of telecare in the care of patients with T2DM and to verify whether all TT are beneficial. There is also a need to assess the impact of telecare on adherence to guidelines, enhanced monitoring, fewer treatment errors, and a reduction of overall health care system costs for patients with T2DM. This paper therefore presents an ongoing mixed systematic review of telecare interventions and the technologies used in diabetic care. The specific objectives of this review are: (1) to provide a typology of the different telecare interventions and technologies used and (2) to determine the outcomes, both positive and negative, of telecare used in the context of T2DM.

II. METHODS

A mixed-method systematic review was used to integrate results from both qualitative and quantitative studies [2]. Through a review of evidence from both qualitative and quantitative studies, disparate data were synthesized in order to better understand complex phenomena such as the adoption of innovations [2-5]. This mixed review followed recognized standards for systematic reviews [6,7] and is presented according to PRISMA criteria [14]: (1) eligibility criteria; (2) information source and search strategy; (3) study selection; (4) data collection process and synthesis of results; and (5) critical appraisal.

The studies that met the inclusion criteria were evaluation studies using a quantitative, qualitative or mixed-method study design. We did not *a priori* exclude specific study designs, but quantitative and/or qualitative results had to be available. The review considered all types of telecare interventions, including telemonitoring, telediagnosis, teleconsultation and all types of technologies, including internet and smart phone use. Articles were excluded if they focused solely on describing a telecare intervention or a technology.

The review is based on a systematic, comprehensive search of six databases: Medline, Embase, Cochrane, ISI Web of Science, CINAHL, and Scopus. It considered articles in English or French, published or in press between January 2000 and March 2011. The literature search was performed by a librarian and validated by a researcher. The following sets of keywords and terms were searched in combination: Telecare Technologies: (Telemedicine/, Telehealth/, tele*, mobile health, m?health; remote adj (consult* or monitor* or health), video?conferenc*, e?Health, phone?) and Diabetes: (Diabetes Mellitus, Type 2/, Non insulin dependent diabetes mellitus/, Diabetes Mellitus, Non-Insulin-

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Dependent, diabet* or MODY OR NIDDM OR T2DM OR IDDM). We hand-searched the reference lists of all the selected references. EndNote software was used to manage the references and eliminate duplications.

Studies were independently selected by two researchers. First, references were selected based on title and abstract according to the review study's inclusion and exclusion criteria. When there was any doubt, the study was provisionally included for consideration on the basis of a reading of the full text. The second round of selection was based on the full texts of the papers. Any disagreement was resolved through consensus. In a few cases, disagreements were arbitrated by two other researchers; a study was included only when these two researchers agreed that the study was eligible. Kappa scores were calculated at each stage.

Data extraction from the selected studies was performed independently by two researchers using a standardized form that included: nature of the telecare intervention, technology characteristics, country, year, author, type of study (quantitative, qualitative or mixed), study design, type of participants, region (rural/urban), and all outcomes. The impacts of telecare on each outcome were coded narratively (positive impact, negative impact, no impact, not reported). Once again, any outstanding disagreement on data extraction was resolved through consensus by two other researchers.

We first conducted a narrative synthesis of the studies [8,9] using the validated methodological guide for narrative syntheses in order to ensure that the synthesis would be transparent and reproducible [8,9]. The narrative synthesis was performed by two of the researchers and validated by two others. This allowed us, first, to develop a typology of telecare by creating homogeneous sub-groups of telecare interventions and technologies that go beyond their denomination by the study's author, and second, to narratively analyze the results for each outcome. We grouped them into several categories: health outcomes, other patients' outcomes, quality of care, health service use-cost-productivity and satisfaction.

The methodological quality of the studies was assessed independently by two researchers. As the methods of the included studies were disparate—qualitative, quantitative or mixed—, we used all nine of the criteria from a quality assessment tool developed for systematic reviews of disparate data [10]. Any discrepancies were resolved through consensus.

III. PRELIMINARY RESULTS

The primary search yielded 2,133 references. Another 6 references were found by searching the reference lists of the retrieved articles [11]. Applying the inclusion and exclusion criteria, 1,945 references were excluded on the basis of the title and abstract (Kappa: 0.89) and 144 more were excluded on the basis of the full text (Kappa: 0.93). The final sample consisted of 50 articles.

A. Characteristics of the Selected Studies[1]

Twenty-five studies were conducted in North America: USA (23 studies) and Canada (2). The remaining studies were conducted in Asia (15) and Europe (7). In addition, three studies were conducted in multiple countries. The studies used quantitative designs (41), including randomized controlled trials (27), non-randomized controlled trials (5), before-after designs (6), time series (1); qualitative designs (1), or mixed-method designs (8). The studies involved solely patients (35), solely healthcare professionals (2) or a combination of patients and professionals (13).

B. Typology of telecare interventions and technologies

With regard to the nature of the telecare interventions, the synthesis of the literature revealed 23 articles on simple telecare interventions. Telemonitoring represented the vast majority of this group (17 studies). In addition, 27 articles referred to complex telecare interventions. Complex interventions were mainly a combination of telemonitoring with telediagnosis/consultation (10 studies) or with e-learning (10 studies).

C. Technologies used

With regard to the technology used, half of the studies used a single technology (25 studies). The two most used TT used on its own were distant direct transmission (9 studies) and smart phone/personal digital assistant (PDA) (7 studies). The other technologies used in isolation were: teleconference, website/internet and pager. The other half of the studies were on multiple technologies used in combination, mainly a combination of smart phone/PDA and web site/internet (11 studies).

TABLE 1: TYPOLOGY OF TELECARE INTERVENTIONS AND TECHNOLOGIES USED IN DIABETIC CARE (N=50)

Nature of telecare interventions	Number of articles
Simple interventions	**23**
Telemonitoring	17
Telediagnosis/consultation	4
E-learning	2
Complex interventions	**27**
Telemonitoring + Telediagnosis/consultation	10
Telemonitoring + e-learning	10
Other	7

[1] References available upon request.

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Telecare technologies used	
Single technology	**25**
Direct transmission	9
Smart phone or PDA	7
Teleconference (phone or video)	4
Web site – internet	4
Pager	1
Multiple technologies	**25**
Direct transmission + Web site/internet	4
Direct transmission + Teleconference + Web site/internet	6
Smart phone/PDA + Web site/internet	11
Other	4

PDA: personal digital assistant

D. Outcomes of telecare

A variety of outcomes were studied (Table 2). We grouped them according to five categories: health outcomes, other patients' outcomes, quality of care, health service use-cost-productivity and satisfaction (clinicians' and patients'). Generally speaking, telecare produces positive results for most of the outcomes.

TABLE 2: SUMMARY OF THE OUTCOMES OF TELECARE (N= 50 STUDIES)

Outcome Category	Outcome Type	N*	+	-	Ø
Health outcomes					
Specific indicators	Impact on glucose or HbA1c blood level	38	34	0	4
	Hyper or hypo glycemic events	4	2	0	2
Other health indicators	BMI or weight	13	5	0	8
	Cholesterol or triglyceride blood level	8	1	0	7
	Blood pressure	6	1	0	5
	Quality of life	7	4	0	3
	Self-perceived health	2	2	0	0
	Physical activity	5	5	0	0
	Framingham risk score	1	1	0	0
	Depression/mental health	3	3	0	0
	Nutrition intake	2	2	0	0
	Pain	2	2	0	0
Other patients' outcomes	Patients' knowledge or self-care	8	8	0	0
	Patient transfer or travel time	2	2	0	0
	Social support/functioning	4	4	0	0
	Patient worry	1	0	0	1
Quality of care	Adherence to best practice guidelines	18	15	0	3
	Accessibility to health services	2	2	0	0
	Dose of insulin used	1	1	0	0
Satisfaction	Patient satisfaction	16	14	2	0
	Professional satisfaction	5	5	0	0
Health service use-cost-productivity	Health service use	6	5	0	1
	Healthcare costs	2	2	0	0
	Time spent by clinicians	4	4	0	0

N*: Number of studies for which the outcome type was evaluated. BMI: Body Mass Index

E. Critical appraisal

Our critical appraisal reveals that their abstracts, introductions and aims were generally well written (coded as good or fair in all cases). The research methods used were robust most of the time. However, weaknesses were observed in the descriptions of the methods, particularly in terms of a lack of detailed information on the data collected, on the sampling methods used and the data analysis. Despite these weaknesses, the critical appraisal indicates that the extant research findings and results are credible and generalizable; these results typically have practical implications. A sensitivity analysis [6] was conducted to determine whether the decision to include all the studies, independent of their overall quality, had any effect on the results of the review. Even when we excluded the only article with at least one bad quality indicator, the findings of this review remain robust.

IV. DISCUSSION AND CONCLUSION

Considering the great variety of telecare interventions and technologies and the fact that each outcome is poorly understood, this article clarifies the nature of the different telecare interventions implemented, the technologies used per se, and the associated outcomes. The most common telecare interventions are remote monitoring, which is sometimes combined with other types of interventions such as telediagnosis/consultation or e-learning. These interventions are enabled by a variety of technologies. Half of the interventions reported the use of a single technology (mainly direct transmission), while the others reported use of a mix of technologies.

Based on our preliminary results, our systematic review reveals that, overall, the use of telecare has positive outcomes such as improved health status, increased quality of care, decreased health service use or cost, increased satisfaction and increased patient knowledge. In particular, the use of TT to monitor patients with diabetes allows for more flexibility and more frequent monitoring. In their 12-month study of veterans with diabetes, Chumbler et al [12] found that the

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number of admissions and bed days of care decreased by half in the group receiving less intensive but daily monitoring, whereas it doubled in the more intensive monitoring group. They suggest that "less intensive assessments have a greater effect on reducing service use than less frequent but more intensive evaluations" (p.155). From this perspective, our review shows that telecare improves chronic disease management for patients with diabetes and may play a critical role in delivering appropriate individualized and flexible care for patients with diabetes. Telecare is thus a promising solution in the current search for patient-centered care [13]. It has been shown that interventions targeting healthcare professionals, such as clinical and organizational interventions that facilitate structured and regular reviews of patients, are effective in improving the process of care [14]. Also, interventions targeting the patients themselves, such as educational and behavioral interventions, produce better diabetes self-management and patient outcomes [15].

On the other hand, our typology highlighted the variety of telecare interventions and technologies currently used to improve clinical processes and patient outcomes. Our results suggest that no given intervention or technology is clearly superior. Research results indicate that there is no "one size fits all" solution. Healthcare clinicians and managers need to carefully select the type of TT that will be most appropriate, based on the needs of their organizations and clienteles.

Our results may serve to identify the characteristics and impacts of telecare, optimize telecare use, and inform decision makers on telecare interventions and technology selection and the impacts they can expect from telecare use.

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Applied Fuzzy C-means Clustering to Operation Evaluation for Gastric Cancer Patients

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***Abstract*—Like data analysis, pattern recognition and data mining, fuzzy clustering also has been applied widely, and successful applications have been reported. In this paper we aim to employ the technique of fuzzy c-means (FCM) cluster to prognosticate the operation possibility on gastric cancer patients. Our purpose is to partition some clinical data in two fuzzy clusters. One of them considers patients who have a chance for successful surgery whereas the other cluster contains the patients without a view for surgery. Each patient is given by characteristic biological markers. The initial values of membership degrees taking place in the partition matrix are usually determined randomly. In this work we will use particularly designed membership functions to calculate the degrees of membership.**

Keywords–fuzzy C-means clustering analysis; fuzzy partition; operation decision

I. INTRODUCTION

Nowadays we are living in an era of the rapid development of information technology. A large number of information is sent and received every day. Therefore, finding some data processing methods to discover the partial structure in a data set and to utilize useful information to solve efficiently daily issues becomes of vital importance.

A lot of approaches in this domain have been put forward. Cluster analysis is one of them. This method involves the task of dividing data points into homogeneous classes or clusters so that items in the same class are as similar as possible and items in different classes are as dissimilar as possible [1]. Moreover, some successful applications in clustering analysis have been presented. Among clustering approaches the fuzzy c-means clustering (FCM) is regarded as well-known and efficient [2–4].

In hard clustering, data points are divided into crisp clusters, where each data point belongs to exactly one cluster [5]. In many situations, boundary data points can be difficult to be allocated. Therefore, the realistic picture of the data structure may not be correctly presented by the crisp clustering. However, fuzzy partition can make up the flaw, due to the advantage that data points are allowed to belong to more than one cluster.

The application of fuzzy c-means cluster in medical diagnosis with respect to the operation possibility evaluation is the focal point of this paper. We attempt to utilize the FCM algorithms in order to divide a clinical data set into two clusters, where one presents the positive prognosis for "operation" and the other samples patients-vectors classified for "none operation".

The construction of this paper is organized as follows. In Section 2 the fuzzy c-means clustering algorithm is presented. In Section 3 we generate the methods for calculating the membership degrees to initialize the cluster matrix. Further, we provide a reader with the practical medical study resulting in operation decision in Section 4 to make conclusions concerning the application in Section 5.

II. DESCRIPTION OF FUZZY C-MEANS CLUSTERING ALGORITHM

Let us suppose that $X = \{x_1, \dots, x_n\}$ is a finite data set. Each data point $x_k = \left(x_{k_1}, \dots, x_{k_p}\right), k = 1, \dots, n,$ is a pattern vector in R^p. Fuzzy C-means algorithm tries to partition X in a collection of S_i subsets, $2 \le i \le c$, called fuzzy clusters. By running the algorithm repeatedly, a list of v_i cluster centers and a partition matrix U are returned.

The fuzzy c-means algorithm is based on minimizing the objective function J with respect to the membership values $\mu_{S_i}(x_k)$ and the distance $d(v_i, x_k)$ [2], where

$$J = \sum_{k=1}^{n} \sum_{i=1}^{c} \left(\mu_{S_i}(x_k)\right)^m \cdot d(v_i, x_k). \quad (1)$$

In (1) n is the number of data points and c is the number of clusters. The value of $\mu_{S_i}(x_k)$ or μ_{ik} represents the value of membership degree of x_k in cluster S_i. Moreover, the sum of the membership degrees for each x_k sample in all clusters is equal to 1. The notation of $d(v_i, x_k)$ indicates the Euclidean distance between the cluster center v_i and x_k. The constant $m > 1$ is called weighting exponent, which determines the fuzziness of the resulting clusters.

A linguistic description of the FCM algorithm is presented by the following steps:

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1) Select the number of clusters *c*, initialize the value of fuzzy parameter m $(2 \le m < \infty)$ and the termination tolerance ϵ.
2) Set $l = 0$.
3) Determine the initial values of membership degrees in partition matrix U^l.
4) Calculate cluster centers $\mathrm{v}_i^l, i = 1, \dots, c$, due to [2], as

$$\mathrm{v}_i^l = \frac{\sum_{k=1}^{n}\left(\left(\mu_{ik}^l\right)^m \cdot x_k\right)}{\sum_{k=1}^{n}(\mu_{ik}^l)^m}. \tag{2}$$

5) Calculate the updated partition matrix U^{l+1} by using v_i^l in formula

$$\mu_{ik}^{l+1} = \frac{\left(\frac{1}{d(x_k, \mathrm{v}_i^l)}\right)^{1/m-1}}{\sum_{j=1}^{c}\left(\frac{1}{d(x_k, \mathrm{v}_j^l)}\right)^{1/m-1}}. \tag{3}$$

6) If $\|U^{l+1} - U^l\| \ge \epsilon$, then set $l = l + 1$, and go to step 4. If $\|U^{l+1} - U^l\| \le \epsilon$, then stop the procedure. Matrix U^{l+1} is the most optimal distribution of membership degrees of x_k in clusters S_i.

The prior determination of the membership degrees of x_k in S_i plays a crucial role in this algorithm, as their choice not only can affect the convergence speed, but also may have a direct impact on the results of the classification [6].

The initial cluster centers are just prototypes and unstable. Therefore, they need to be iteratively updated. Every iteration guarantees an improvement of the coordinates of clustering centers. The updating procedure continues until two adjacent membership matrices cease to change. In Section 4 we wish to demonstrate how FCM algorithm has been applied in operation evaluations for gastric cancer patients.

Furthermore, the calculation of clustering centers depends on the values of initial membership degrees in the partition matrix. To avoid inaccuracy in final results we will discuss the own technique of calculation of membership degrees to avoid guessing at their values intuitively.

III. An Approach to Determining the Initial Membership Degrees in the Partition Matrix

The ccurate evaluation of the membership of x_k in S_i can improve the iteration time and the convergence speed. In this article, the *s*-class membership function is adopted for the further calculations due to [7–9]. We recall the formula of the s-function as

$$s(z, \alpha, \beta, \gamma) = \begin{cases} 0 & \text{for} \quad z \le \alpha, \\ 2\left(\frac{z-\alpha}{\gamma-\alpha}\right)^2 & \text{for} \quad \alpha \le z \le \beta, \\ 2\left(\frac{z-\gamma}{\gamma-\alpha}\right)^2 & \text{for} \quad \beta \le z \le \gamma, \\ 1 & \text{for} \quad z \ge \gamma. \end{cases} \tag{4}$$

The curve, implemented as a graph of (4), starts with point $(0, \alpha)$ and ends with $(\gamma, 1)$, whereas β is the arithmetic mean value of α and γ.

By referring to the most decisive medical factors, such as the patient's age, weight and *crp*-values (C-reactive proteins), operation prognoses usually can be expressed by "operation" and "none operation". The possibilities of the decision evaluation can be described by some linguistic terms.

Let us suppose that $L = \{L_1, \dots, L_\omega\}$ is a linguistic list consisting of ω words. Each word is associated with a fuzzy set. In compliance with [8–10], ω is a positive odd integer. Furthermore, let *E* be the length of a common reference set *R*, designed for all restrictions characterizing the fuzzy sets from *L*, provided that $z \in R$. We now wish to divide the linguistic terms into three groups recognized as a left group, a middle group and a right group.

The membership functions assigned to the leftmost terms are parametric functions, which are presented by (5) as

$$\mu_{L_t}(z) = \begin{cases} 1 \text{ for } z \le \frac{E(\omega-1)}{2(\omega+1)}\delta(t), \\ 1 - 2\left(\frac{z - \frac{E(\omega-1)}{2(\omega+1)}\delta(t)}{\frac{E(\omega-1)}{\omega(\omega+1)}\delta(t)}\right)^2 \\ \text{for } \frac{E(\omega-1)}{2(\omega+1)}\delta(t) \le z \le \frac{E(\omega-1)}{2\omega}\delta(t), \\ 2\left(\frac{z - \frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)}\delta(t)}{\frac{E(\omega-1)}{\omega(\omega+1)}\delta(t)}\right)^2 \\ \text{for } \frac{E(\omega-1)}{2\omega}\delta(t) \le z \le \frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)}\delta(t), \\ 0 \text{ for } z \ge \frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)}\delta(t), \end{cases} \tag{5}$$

where $\delta(t) = \frac{2t}{\omega-1}, t = 1, \dots, \frac{\omega-1}{2}$ is a parametric function depending on left function number *t*. When *t* is equal to 1, the formula implies the first leftmost membership function. If *t* takes the value of $\frac{\omega-1}{2}$, then we will obtain the last left membership function.

The membership function in the middle has the form of a clock. It is given by (6) in the form of

$$\mu_{L_{\frac{\omega+1}{2}}}(z) =$$

$$\begin{cases} 0 & \text{for} \quad z \le \frac{E(\omega-2)}{2\omega}, \\ 2\left(\frac{z-\frac{E(\omega-2)}{2\omega}}{\frac{E}{\omega}}\right)^2 & \text{for} \quad \frac{E(\omega-2)}{2\omega} \le z \le \frac{E(\omega-1)}{2\omega}, \\ 1-2\left(\frac{z-\frac{E}{2}}{\frac{E}{\omega}}\right)^2 & \text{for} \quad \frac{E(\omega-1)}{2\omega} \le z \le \frac{E}{2}, \\ 1-2\left(\frac{z-\frac{E}{2}}{\frac{E}{\omega}}\right)^2 & \text{for} \quad \frac{E}{2} \le z \le \frac{E(\omega+1)}{2\omega}, \\ 2\left(\frac{z-\frac{E(\omega+2)}{2\omega}}{\frac{E}{\omega}}\right)^2 & \text{for} \quad \frac{E(\omega+1)}{2\omega} \le z \le \frac{E(\omega+2)}{2\omega}, \\ 0 & \text{for} \quad z \ge \frac{E(\omega+2)}{2\omega}. \end{cases} \tag{6}$$

Finally, the membership functions on the right-hand side can be expressed by (7) as

$$\mu_{L_{\frac{\omega+3}{2}+t-1}}(z) =$$

$$\begin{cases} 0 \text{ for } z \le E - \frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)} \cdot \varepsilon(t), \\ 1-2\left(\frac{z-\left(E-\frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)}\cdot\varepsilon(t)\right)}{\frac{E(\omega-1)}{\omega(\omega+1)}\cdot\varepsilon(t)}\right)^2 \\ \text{for } E - \frac{E(\omega-1)(\omega+2)}{2\omega(\omega+1)} \cdot \varepsilon(t) \le z \le E - \frac{E(\omega-1)}{2\omega} \cdot \varepsilon(t), \\ 2\left(\frac{z-\left(E-\frac{E(\omega-1)}{2(\omega+1)}\cdot\varepsilon(t)\right)}{\frac{E(\omega-1)}{\omega(\omega+1)}\cdot\varepsilon(t)}\right)^2 \\ \text{for } E - \frac{E(\omega-1)}{2\omega} \cdot \varepsilon(t) \le z \le E - \frac{E(\omega-1)}{2(\omega+1)} \cdot \varepsilon(t), \\ 1 \text{ for } z \ge E - \frac{E(\omega-1)}{2(\omega+1)} \cdot \varepsilon(t). \end{cases} \tag{7}$$

A new function $\varepsilon(t) = 1 - \frac{2(t-1)}{\omega-1}, t = 1, \dots, \frac{\omega-1}{2}$ allows generating all rightmost functions one by one when setting *t*-values in (7).

IV. CASE STUDY

To make a decision "operate" contra "do not operate", concerning an individual patient in accordance with his/her biological markers' values, we have to involve the medical experience in the decision process. To facilitate a conversation with a physician we have prepared a linguistic list named "The primary judgment concerning possibility that a physician recommends "operation" opposite to "none operation"" = $L = \{L_1 = \text{"none"}, L_2 = \text{"little"}, L_3 = \text{"medium"}, L_4 = \text{"large"}, L_5 = \text{"total"}\}$.

TABLE I. THE DATA SET OF 25 GASTRIC CANCER PATIENTS

Patient x_k	Attribute-vectors and operation possibilities		
	Attribute-vectors (Age, weight, crp)	*Operation cluster S_1*	*None Operation cluster S_2*
x_1	(71, 85, 1)	Total	Little
x_2	(81, 70, 9)	Medium	Large
x_3	(50, 67, 4)	Large	Medium
x_4	(64, 84, 13)	Large	Little
x_5	(41, 95, 4)	Large	Little
…	…	…	…
x_{25}	(54, 49, 36)	None	Large

The excerpt of the data set, shown in TABLE I, consists of the patients' clinical records and primary judgments of operation possibilities made by the medical expert. The total medical report contains 25 gastric cancer patients randomly selected.

Two surgery states "operation" and "none operation" assist two clusters S_1 and S_2 respectively. By selecting words from the list the experienced surgeon makes the primary graded decision about possibilities of operating or not operating on the patient.

Each verbal expression, being the term of L, is associated with a fuzzy set. L_1 and L_2 represent two left fuzzy sets, L_3 is the fuzzy set in the middle, whereas L_4 and L_5 constitute two rightmost fuzzy sets. Unfortunately, these linguistic items do not provide us with any information about membership degrees expected in matrix U^0 as primary recommendation states of "operation" or "none operation". Therefore we adopted the following technique to assign numerical substitutes to verbal expressions from the list.

By inserting $E = 100$ (the length of the reference set $R = [0,100]$ – typical of density measures in medical investigations), $\omega = 5$ and $t = 1, 2$, in (5), we obtain the membership functions of the first two fuzzy sets, namely, $L_1 = \text{"none"}$ given as

$$\mu_{L_1}(z) = \begin{cases} 1 & \text{for} \quad z \le 16.7, \\ 1-2\left(\frac{z-16.7}{6.6}\right)^2 & \text{for} \quad 16.7 \le z \le 20, \\ 2\left(\frac{z-23.3}{6.6}\right)^2 & \text{for} \quad 20 \le z \le 23.3, \\ 0 & \text{for} \quad z \ge 23.3 \end{cases} \tag{8}$$

and $L_2 = \text{"little"}$ prepared as

$$\mu_{L_2}(z)=\begin{cases}1 & \text{for} \quad z \le 33.3,\\ 1-2\left(\frac{z-33.3}{13.4}\right)^2 & \text{for} \quad 33.3 \le z \le 40,\\ 2\left(\frac{z-46.7}{13.4}\right)^2 & \text{for} \quad 40 \le z \le 46.7,\\ 0 & \text{for} \quad z \ge 46.7\,.\end{cases} \tag{9}$$

By substituting E = 100 and ω = 5 in (6), the membership function of L_3 = "middle" is given as the structure

$$\mu_{L_3}(z)=\begin{cases}0 & \text{for} \quad z \le 30,\\ 2\left(\frac{z-40}{10}\right)^2 & \text{for} \quad 30 \le z \le 40,\\ 1-2\left(\frac{z-50}{10}\right)^2 & \text{for} \quad 40 \le z \le 50,\\ 1-2\left(\frac{z-50}{10}\right)^2 & \text{for} \quad 50 \le z \le 60,\\ 2\left(\frac{z-60}{10}\right)^2 & \text{for} \quad 60 \le z \le 70,\\ 0 & \text{for} \quad z \ge 70.\end{cases} \tag{10}$$

Finally, for E = 100, ω = 5 and t = 1, 2, inserted in (7), we get the membership functions of L_4 = "large" in the form of

$$\mu_{L_4}(z)=\begin{cases}0 & \text{for} \quad z \le 53.3,\\ 1-2\left(\frac{z-53.3}{13.4}\right)^2 & \text{for} \quad 53.4 \le z \le 60,\\ 2\left(\frac{z-66.7}{13.4}\right)^2 & \text{for} \quad 60 \le z \le 66.7,\\ 1 & \text{for} \quad z \ge 66.7\end{cases} \tag{11}$$

and L_5 = "total" as

$$\mu_{L_5}(z)=\begin{cases}0 & \text{for} \quad z \le 76.7,\\ 1-2\left(\frac{z-76.7}{6.6}\right)^2 & \text{for} \quad 76.7 \le z \le 80,\\ 2\left(\frac{z-66.7}{6.6}\right)^2 & \text{for} \quad 80 \le z \le 83.3,\\ 1 & \text{for} \quad z \ge 83.3\,.\end{cases} \tag{12}$$

When substituting $\alpha = 0, \beta = 50$ and $\gamma = 100$ in a new s-function impacted over set R we determine

$$\mu_R(z)=s(z,0,50,100)=\begin{cases}0 & \text{for} \quad z \le 0,\\ 2\left(\frac{z}{100}\right)^2 & \text{for} \quad 0 \le z \le 50,\\ 2\left(\frac{z-100}{100}\right)^2 & \text{for} \quad 50 \le z \le 100\\ 1 & \text{for} \quad z \ge 100.\end{cases} \tag{13}$$

After sampling all membership functions (8)–(13) in Figure 1, we aim at evaluating the membership degrees taking place in the first partition matrix U^0.

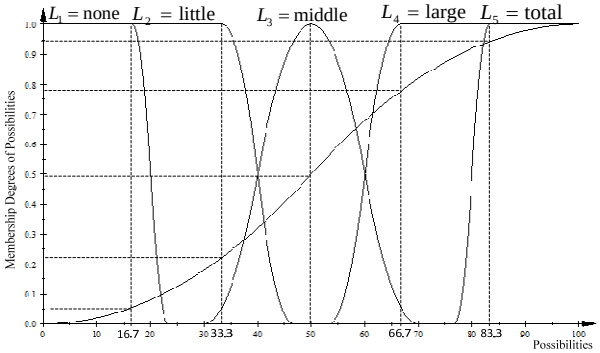

Figure. 1. The collection of all the membership functions.

In the interval [0, 16.7], the membership degree of L_1 = "none" equals 1, which means that the possibility of none operation is the highest in this region. As the membership degrees decrease from 1 to 0 over (16.7, 23.3], then z = 16.7 will become a natural border for sure members in L_1. In (13), $z = 16.7 \in [0, 50]$. From the formula of membership function (13), which is lying over the interval [0, 100], we choose the segment $2\left(\frac{z}{100}\right)^2$ in which we set z = 16.7 to obtain $\mu_R(16.7) = 0.056$. This represents numerically L_1 in TABLE II which is a mathematical adaptation of TABLE I.

We apply the procedure to the second fuzzy set L_2 = "little", where we select z = 33.3 for calculating its membership degree by employing (13) to get $\mu_R(33.3) = 0.22$. For the third fuzzy set L_3 = "middle" the membership value is specified to be $\mu_R(50) = 0.50$. The last fuzzy sets L_4 = "large" and L_5 = "total" are represented by $\mu_R(66.7) = 0.78$ and $\mu_R(88.3) = 0.944$, respectively.

After the data arrangement, the linguistic words in TABLE 1 are replaced by numerical values put in TABLE II.

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TABLE II. DATA SET WITH INITIAL MEMBERSHIP VALUES

Patient x_k	Attribute-vectors and operation possibilities		
	Attribute-vectors (Age, weight, crp)	$\mu_{S_1}(x_k)$	$\mu_{S_2}(x_k)$
x_1	(71, 85, 1)	0.944	0.22
x_2	(81, 70, 9)	0.5	0.78
x_3	(50, 67, 4)	0.78	0.5
x_4	(64, 84, 13)	0.78	0.22
x_5	(41, 95, 4)	0.78	0.22
…	…	…	…
x_{25}	(54, 49, 36)	0.056	0.78

It is assumed that the sum of membership grades in clusters S_1 and S_2 should be equal to 1 for each x_k, k = 1,…,25. It can happen that the distinct sums differ from 1. In such cases some adjustments need to be made; therefore the following techniques are applied.

Case 1: $\mu_{S_1}(x_k) + \mu_{S_2}(x_k) > 1$.
If the sum is greater than 1, we calculate a quotient q_1, designed as

$$q_1 = \frac{\mu_{S_1}(x_k) + \mu_{S_2}(x_k) - 1}{2}.$$

Hence, two adjusted membership degrees are given by the following formulations:

$\mu'_{S_1}(x_k) = \mu_{S_1}(x_k) - q_1$ and $\mu'_{S_2}(x_k) = \mu_{S_2}(x_k) - q_1$.

Proof:

$$\mu'_{S_1}(x_k) + \mu'_{S_2}(x_k) = \mu_{S_1}(x_k) + \mu_{S_2}(x_k) - 2q_1 =$$
$$\mu_{S_1}(x_k) + \mu_{S_2}(x_k) - 2 \cdot \frac{\mu_{S_1}(x_k) + \mu_{S_2}(x_k) - 1}{2} =$$
$$\mu_{S_1}(x_k) + \mu_{S_2}(x_k) - \mu_{S_1}(x_k) - \mu_{S_2}(x_k) + 1 = 1.$$

In contrast with Case 1, Case 2 handles the situation that the sum is less than 1.

Case 2: $\mu_{S_1}(x_k) + \mu_{S_2}(x_k) < 1$.
We now have to derive another fraction q_2, given by

$$q_2 = \frac{1 - \mu_{S_1}(x_k) - \mu_{S_2}(x_k)}{2}.$$

Membership values typical of Case 2 are verified by

$\mu'_{S_1}(x_k) = \mu_{S_1}(x_k) + q_2$ and $\mu'_{S_2}(x_k) = \mu_{S_2}(x_k) + q_2$

Proof:

$$\mu'_{S_1}(x_k) + \mu'_{S_2}(x_k) = \mu_{S_1}(x_k) + \mu_{S_2}(x_k) + 2q_2 =$$
$$\mu_{S_1}(x_k) + \mu_{S_2}(x_k) + 2 \cdot \frac{1 - \mu_{S_1}(x_k) - \mu_{S_2}(x_k)}{2} =$$
$$\mu_{S_1}(x_k) + \mu_{S_2}(x_k) + 1 - \mu_{S_1}(x_k) - \mu_{S_2}(x_k) = 1.$$

After revising the membership degrees due to Case 1 or Case 2 we rearrange the last two columns of TABLE II to renew it as TABLE III.

TABLE III. DATA SET WITH VERIFIED MEMBERSHIP GRADES

Patient x_k	Attribute-vectors and operation possibilities		
	Attribute-vectors (Age, weight, crp)	$\mu'_{S_1}(x_k)$	$\mu'_{S_2}(x_k)$
x_1	(71, 85, 1)	0.862	0.138
x_2	(81, 70, 9)	0.36	0.64
x_3	(50, 67, 4)	0.64	0.36
x_4	(64, 84, 13)	0.78	0.22
x_5	(41, 95, 4)	0.78	0.22
…	…	…	…
x_{25}	(54, 49, 36)	0.138	0.862

The entries of the initial partition matrix U^0 consist of the values coming from the last two columns in Table III. U^0 is a 2x25 matrix given by

$$U^0 = \begin{matrix} \\ S_1 \\ S_2 \end{matrix} \begin{matrix} x_1 & x_2 & x_3 & \cdots & x_{25} \end{matrix} \begin{bmatrix} 0.862 & 0.36 & 0.64 & \cdots & 0.138 \\ 0.138 & 0.64 & 0.36 & \ldots & 0.862 \end{bmatrix}_{2x25}.$$

The numerical values in the first row in matrix U^0 propose membership degrees for patients $x_k, k = 1, \ldots, 25$, in cluster S_1. And the second row suggests the membership values for patients $x_k, k = 1, \cdots, 25$, in cluster S_2. The sum of membership degrees in each column is equal to one.

If we go back to the FCM algorithm and let l = 0, m = 3 and $\epsilon = 10^{-8}$ then, by using Matlab after 31 iterations, the cluster centers become stable and do not change their coordinates due to $\|U^{31} - U^{30}\| = 9.93692 \times 10^{-9} < 10^{-8}$. The last two partition matrices and the optimal cluster centers are listed in the patterns

$$U^{30} = \begin{matrix} \\ S_1 \\ S_2 \end{matrix} \begin{matrix} x_1 & \cdots & x_{25} \end{matrix} \begin{bmatrix} 0.74366062 & \cdots & 0.39447229 \\ 0.25633938 & \ldots & 0.60552771 \end{bmatrix}_{2x25}$$

and

$$U^{31} = \begin{matrix} \\ S_1 \\ S_2 \end{matrix} \begin{matrix} x_1 & \cdots & x_{25} \end{matrix} \begin{bmatrix} 0.74366062 & \cdots & 0.39447229 \\ 0.25633938 & \ldots & 0.60552771 \end{bmatrix}_{2x25},$$

as well as

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$$v_1^{31} = (65.9704, 74.2257, 6.50373)$$

and

$$v_2^{31} = (70.4353, 69.735, 35.8068).$$

The final membership degrees for 25 patients, classified in S_1 and S_2, are depicted in Figure 2. In this manner the primary operation hypotheses, formulated by verbal structures, have been secondarily confirmed or denied by the strength of corresponding membership degrees in both clusters.

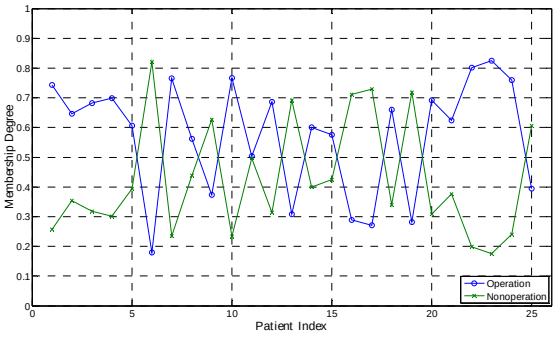

Figure 2. The final cluster membership degrees.

V. CONCLUSION

In this study we have adopted fuzzy 2-means clustering analysis to partition a patient data set, containing clinical records of 25 gastric cancer patients, in two fuzzy clusters. These reveal the numerical decision of states "operation" and "none operation" by the values of membership degrees due to the rule: the higher the degree is the more certain decision should be made with respect to the cluster considered.

We notice that the patients' original clinical marker quantities lead to higher membership degrees in the initial partition matrix when comparing them to the lower values in the final matrix. This phenomenon can be explained by the fact that the decision for an individual patient has been made by the assistance of all data filling the data set. This means that the medical knowledge provided in the form of the collective information, reset numerically, could decide "softer" decisions, which have not deprive the patient of a chance for surgery. We have engaged a new form of experience performed as computerized experience constituting a database.

The obtained results converge to cautious expertise made by physicians who want the patient to survive as well as possible without any unnecessary risks. Therefore, fuzzy c-means cluster analysis can be seen as one of the approaches that would assist medical operation diagnosis. The method can be applied for a large number of patients.

Lastly, we wish to emphasize that the adaptation of membership function families to the purpose of determining the initial membership degrees in the partition matrix has been an efficient tool in the algorithm. The functions, furnished with parameters, allow constructing arbitrary linguistic lists containing many verbal judgments. The mathematical translation of words to numbers has been done systematically without predetermining any casual values. This has improved definitely the convergence speed of the algorithm.

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Advancing in Digitalized X-ray Images Post-processing

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***Abstract*—The aim of this paper is to present some results and comments about the process of increasing the quality of digitalized X-ray images. The presented results are obtained under several projects. The work is aiming at increasing the quality of computer-assisted methods for diagnosis, based on digital X-ray images. Some techniques and solutions for reducing and removing defects in images are discussed. As a conclusion, some new problems and requirements for these systems have been pointed out.**

Keywords-computer-assisted methods; digital X-ray image; adaptive filtering algorithms

I. INTRODUCTION

The development of medical imaging applications based on 2D medical images and their processing can be divided into two stages - before and after 2008. The first stage was focused on the development of medical imaging applications oriented to Computer-Aided Diagnosis systems (CAD systems) [1]. One of the major characteristics of this period is the big growth of CAD systems tools and modules market. The combination between the increasing of the interest of hospitals management in new CAD systems and technologies and the increased use of digital medical imaging devices and tools (X-ray, Magnetic-Resonance Imaging, Computer Tomography, etc.) led to annual growth per year expressed by two-digit number in percentage [2]. At the same time, the quality of medical results has been continuously improved and all this determined the growing demands for this class of application in medical and hospital practices.

Since the middle of 2008 this trend has been changed dramatically. Some of the reasons for this are the following:

- Who is the customer of medical imaging applications – patients or hospitals? Today the right answer is 'The hospitals are medical imaging applications customers. Patients are customers of hospital services.' But after 2008 hospitals have had limited funding for development of new systems and they divert the full financial burden to patients. Patients refuse to pay extra money for services they do not understand and they do not know they need. This resulted in the fact that hospitals decreased investments in new imaging-based diagnosis applications and this is the expected trend for the next several years.
- What types of applications are of interest - stand-alone applications or modules and tools for integration with existing Hospital Information Systems (HIS)? An analysis of the market shows that stand-alone applications have seriously been losing their market position. The market needs modules and tools that can be built-in as subsystems of the existing HIS. This has changed investments in research from more general to specific areas which results in products to be directly put on the market.

The additional effects can be divided into two trends and their impact on the new developments has continued to grow. Any of these trends affects the new research and applications directly and indirectly [3][4][5][6]:

- The first problem can best be defined by the conclusion: "Doctors expect from the new technologies only to increase their sensitivity and ability to understand information. They do not want automated diagnosis services and they do not want to be technicians. They want to be doctors."
- The rapid increase of Telemedical tools and devices and future trends in this area generated many questions of comparability of the CAD-application results based on images from different sources for one and the same patient. One of the telemedical approaches is based on distributed medical data obtaining, analysis and diagnosis. The results should be identical regardless of the source of the digital image (a digital X-ray or a digitalized old X–ray plate), and whether it is made in one or another hospital. For example in 10 years it is expected that there will be a new generation of machines and the image quality they will deliver will differ greatly from current quality.

This article is based on the results of an 8 year study and on a project in collaboration with the biggest Bulgarian hospital complex (the Medical University of Sofia). The main task of this collaborative work was to create a vision and architecture for a new generation HIS, taking into account the performance in Telemedicine, m-Health and p-Health approaches and applications and new devices for hospital and outpatient diagnostics. This has led to several interesting studies related to the investigation of techniques and solutions for increasing the quality of digital X-ray images which is the topic of this paper. The surveys on different techniques for digitalization of radiographic images [3,9] focus our studies on assessing the impact of various

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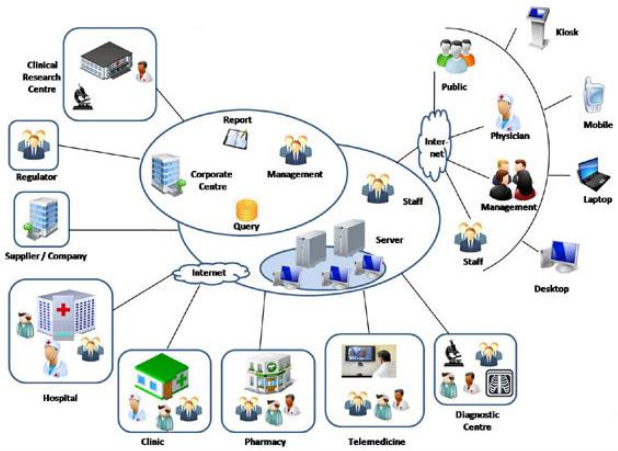
factors on the quality of digitalized X-rays. Three main groups of factor were identified: the process of creating X-ray plates, the condition of digitalized X-ray plates and the technology for digitalization. The results of these studies are presented below.

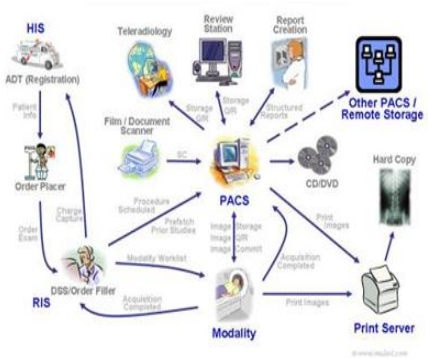
General and innovative structures of Hospital Information Systems are presented on Figure 1. Data sources for HIS and the data flows in these systems are presented on Figure 2.

a) HIS Classic view [10]

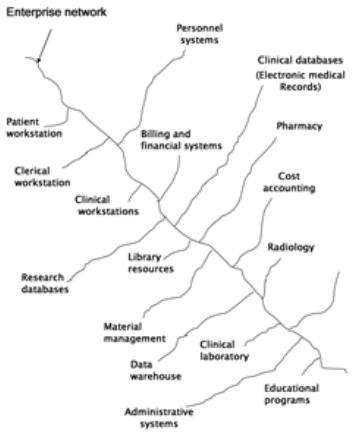


b) Modern HIS [11]

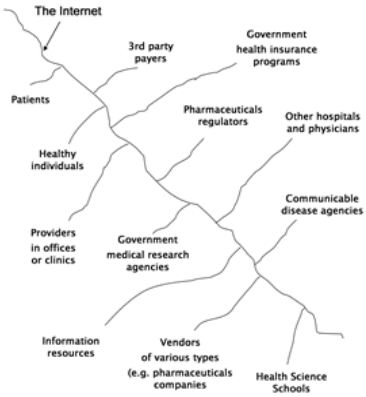
Figure 1. Classic and modern HIS structures and data flows



a) Classic data sources and handling [12]



b) HIS inside data network [13]



c) HIS outside data network [14]

Figure 2. Data sources and data flows in HIS

II. THE PROCESS OF DIGITAL X-RAY IMAGES CREATION AND THEIR QUALITY

The effect is expressed by looking at two sides:

- The need to have methods for normalizing/aligning digital images. The computer-based comparison methods need images of the same quality and characteristics. But different technologies create images with varying contrast, luminance and level of noise.
- Different X-ray machines (by producer and/or settings) produce a different level of illumination in patients with the same health condition. Very often this is accepted as an overexposure (large black areas) and underexposure (large white areas).

In case of underexposed image, shown on Figure 3, the main problem is the lack of information on the image. These types of images have a small dynamic range and unimodal histogram (Figure 3b): a pronounced peak is located at the top of the histogram and there are many small local peaks

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(the histogram isn't smooth). In this case the classical methods for image manipulation based on the histogram correction do not create credible images from a medical point of view: the resulting image is often characteristic of severe pathologies.

This requires methods which will be used to smooth the local peaks in the upper histogram. One useful solution to this problem is the implementation of adaptive filtering algorithms (Figure 3c).

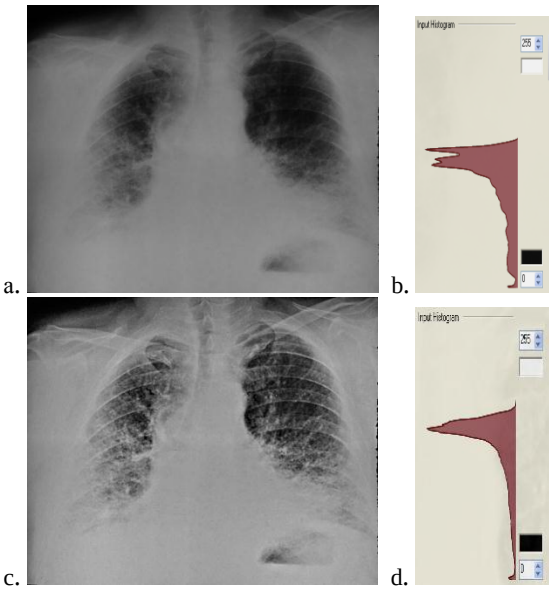

Figure 3. The underexposed X-ray image: a) a digitalized generic image and b) its histogram; c) the image after correction (without medical artifacts) and d) its histogram.

In case of overexposure the problems in X-ray images are different because the dynamic range is much larger and the histogram has a bimodal nature (Figure 4). The results of overexposure are the soft tissue (grayscale levels near black) and areas with low pass X-rays having grayscale tones near white (e.g. thicker bones). In this case the corrections are made at transitions to a unimodal histogram by minimization of the peak in the dark area.

The experiments lead to the conclusion that many of the X-ray plates with the described types of defects can be properly digitalized and can be used for medical purposes. Before the implementation of this processing in many cases the diagnosis made on the basis of defect X-ray plates was impossible or unreliable which led to additional X-ray taking, i.e. increased radiation load of patients.

III. THE CONDITION OF X-RAY PLATES AS A FACTOR OF DIGITALIZED IMAGES QUALITY

The defects in the digitalized X-ray images resulting from changes and defects in the X-ray plates are the next group of problems. The main reasons for these changes are improper storage of plates (usually exposure to direct sunlight) or the effect of aging. As a result, the plates whiten and / or become stained.

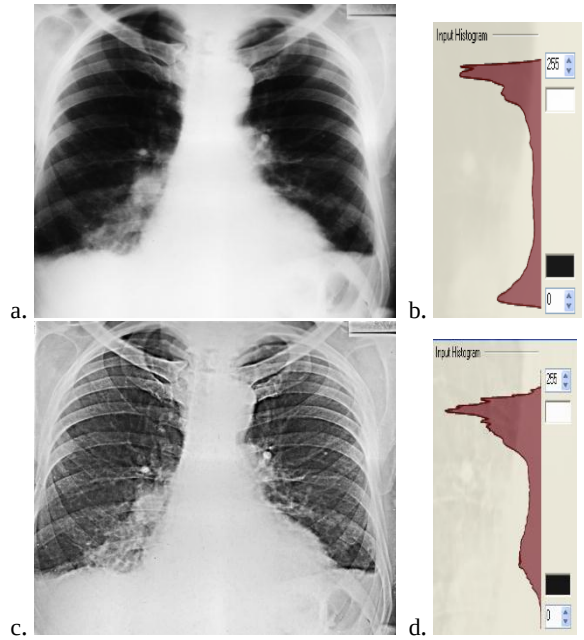

Figure 4. The overexposed X-ray image: a) a digitalized generic image and b) its histogram; c) the image after correction (without medical artifacts) and d) its histogram.

When defects in digitalized images occur the results of physical damages on the surface (scratches, breaking of plates, etc.) a lack of adjustment was demonstrated during the experiments. The reason for this is the lack of information which will allow determining whether the affected place was the fault lesion. Very often the initial form of lesions affect areas of around 2-3 pixels in size and the condition and characteristics of adjacent image areas do not allow to determine the nature of the image in the damaged area.

The changes to the image, which will occur when there is whitening as a result from constant exposure to external light, lead to the following limitations in the digitalized image:

- Reduction of the dynamic range of the image.
- Reduction of the image contrast: uneven whitening of dark and light areas.

It should be noted that these changes can have either global or local nature (according to the exposed area of the plate).

When the change affects the entire image, the actions taken to correct the defects can greatly improve the digitalized image. Examples of these corrections are shown in Figure 3 and Figure 4. In some cases, the order of the application of treatments is essential for the final result.

The quality of the X-ray plate material and the way plates were stored lead to staining, i.e., they are no longer grayscale (Figure 5). For physicians it is not a serious problem to use these modified X-ray plates because of the peculiarity of the human visual system, known as 'approximate color consistence' [3]. Unlike humans, computers do not have this ability. Therefore, after digitalization the added colors often distort the information in terms of computer applications.

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Doctors also began to notice the color: approximate color consistence in this case does not work. This makes it mandatory to switch from color to grayscale when the images will be used for the purposes of clinical diagnosis.

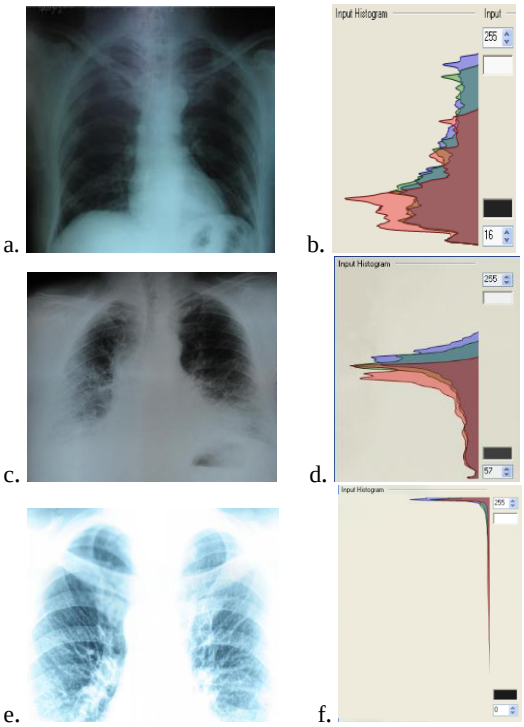


Figure 5. The staining of X-ray plates as a result of improper storage: a), c) and e) generic image; b), d) and f) the histograms of digitalized images (histograms of R, G, and B channels are added).

To minimize the occurrence of artifacts, i.e. to obtain credible medical images, it is necessary to solve the following two major problems: the algorithm used to convert from a color to a grayscale image and the moment of conversion (before or after defect image correction). The studies have shown that the use of grayscale digitalizing devices (scanners or other) is not a solution because today color scanning systems are used. These systems have embedded algorithms for converting the scanned color image to a grayscale one. Unfortunately, assessing the quality of conversion is based on the requirements for printing images and not for medical imaging.

The process of choosing the moment of transformation is essential for the improvements of image characteristics, because the results are not identical. This is due to the fact that these are not commutative operations, i.e. the removal of the color component and processes for quality improvement (correction of the histogram, dynamic range and contrast) give different outcomes in each different order of execution.

In Figure 6, the difference between processing the image before and after conversion from color to grayscale image is shown.

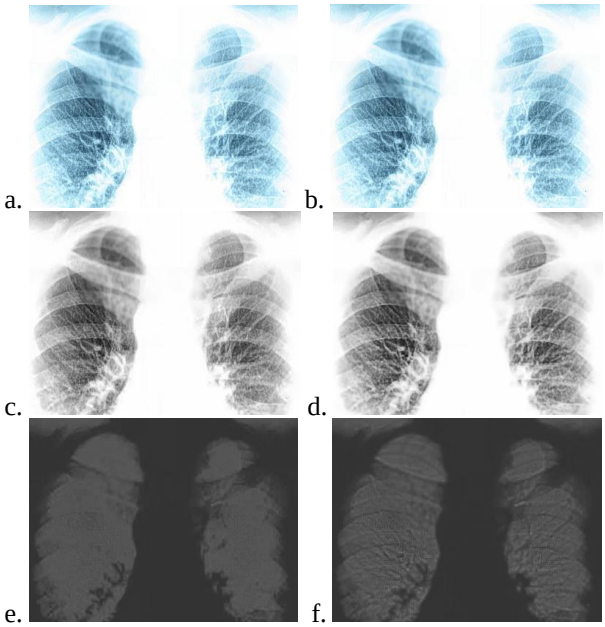
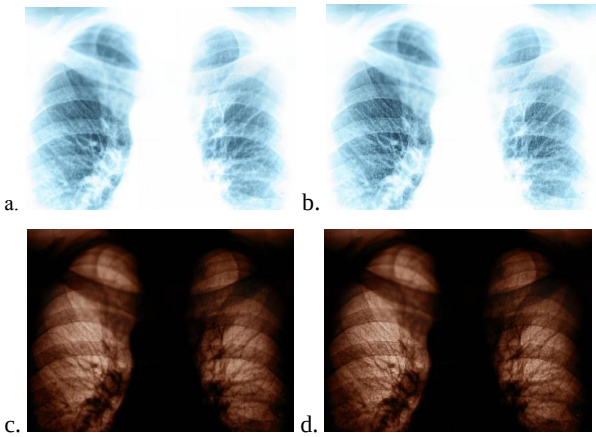


Figure 6. The difference between processing the image before and after conversion from a color to a grayscale image ('a' and 'c'– refocusing; 'b' and 'd' – local contrast correction): a, b) the correction is on the color image; c, d) the correction is on the grayscale image; e) the difference between 'a' and 'c' ('a' is converted to grayscale); f) the difference between 'b' and 'd' ('b' is converted to grayscale).

The purpose of processing the digitalized image is improving its quality without the occurrence of medical artifacts. Processing of underexposed images (very white) proved that the negative treatments give an easier way to implement changes (it is easier to select the degree of change). The reason for this is the problem with the visual weight of objects in the image and the perception of the degree of correction. The experiments and tests have shown that for the grayscale image, the differences between whether correction is on the normal image or on the negative image are very small and most often do not generate medical artifacts. In colored images it is not the same - even less staining leads to very big image differences (Figure 7).



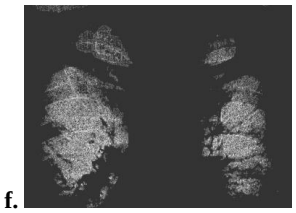


Figure 7. For a color image, the difference between whether the correction is on the normal image or on the negative image is significant: a) generic image; b) corrected image; d) negative of generic image; e) corrected negative image (correction is the same as 'b'); f) the difference between corrections in normal and negative mode.

Over the years some, research of color-to-grayscale converting methods based on a survey by Čadík has been conducted [4]. The metrics proposed by the authors were not acceptable because they are oriented to image processing for the needs of B/W printing. For medical needs, the quality of the conversion must be determined by the occurrence of medical artifacts or loss of important information needed for the diagnosing of diseases. At this point, we use a heuristic criterion based on the degree of difference between the application of the basic treatment method on a normal and negative image.

- The negative image (Figure 8d) is created from a generic (color) image (Figure 8a).
- The generic and the negative images are converted to grayscale images using the chosen algorithm (Figure 8b, 8e).
- Testing correction is applied to grayscale images (Figure 8c, 8f).
- The corrected negative image is inverted back a normal image (Figure 8g).
- The quality is measured by the difference between the corrected images in a normal form and a negative form (Figure 8h).

IV. SOME COMMENTS ON THE TECHNOLOGY FOR DIGITALIZATION AS A FACTOR FOR THE QUALITY OF THE DIGITALIZED IMAGES

The influence of the technology for digitalization generally demonstrates its impact as follows:

- The possibility to digitalize plates greater than the device dimensions and the type of organization of this process
- The existing systems for digitization as color systems
- The characteristics of the lighting systems of the digitalization device.

The lighting system in the scanners is very interesting and has a significant impact on image quality: it can either create defects, or helps to eliminate existing defects. The results received after the experiments leads to the following conclusions:

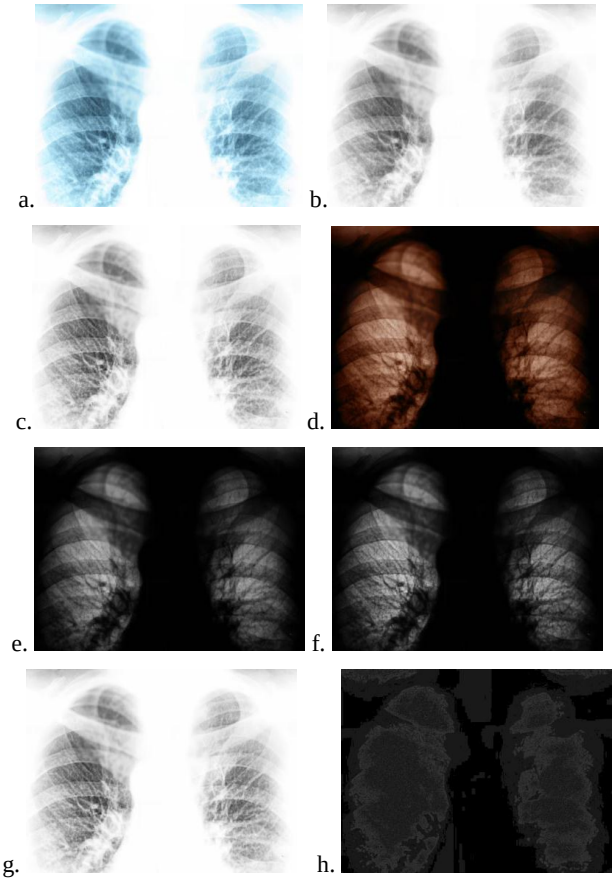


Figure 8. Consecutive activities to evaluate the quality of color-to-grayscale converting methods for medical purposes: a) generic (color) image; b) grayscale image from 'a'; c) corrected image 'b'; d) negative image of 'a'; e) grayscale image from 'd'; f) corrected image 'e'; g) inverted image 'f'; h) difference between 'g' and 'c' (image histogram is stretched).

- The use of a lighting source with variable intensity allows extracting more information compared to the ones with constant intensity. This can be observed better in underexposure images or images with strong staining in the cyan spectrum.
- To take additional advantage of the control of the lighting source intensity it is necessary to develop an algorithm which to determine the optimal intensity. Currently our research does not make possible the development of an automatic procedure for optimal intensity selection: we use manual control and analysis of the resulting images (looking for overexposure areas).
- The use of sources with a different spectrum and the subsequent 'fusion' of the resulting images allows to obtain much more information than the classical lighting spectrum. Here the fusion procedure follows the procedure of images conversion to grayscale.
- The scanners are systems with constant exposure time and parameters. Using a scanner with controllable exposure duration enables the creation of High Dynamic Range Images (HDRI). After

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conversion to Low Dynamic Range Image (LDRI) this allows to obtain a reliable medical image with much more information in comparison to images obtained after a standard digitization procedure (Figure 9). This method produces good results for plates with different quality but its advantages are most pronounced for overexposed images.

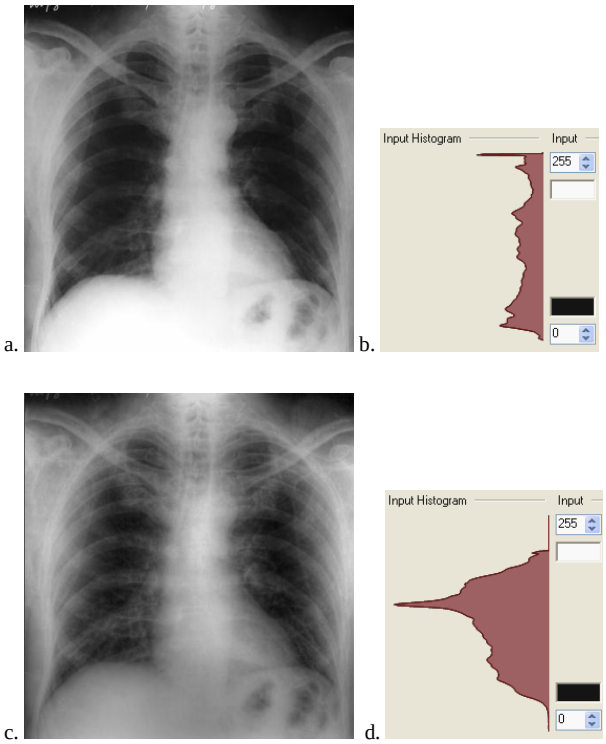

Figure 9. HDRI scanning vs. LDRI scanning: a) generic image (classical scanning procedure); b) its histogram; c) resulting image after HDRI scanning procedure; d) its histogram.

V. CONCLUSION

The need to archive digitalized images obtained during a period of 30-35 years and their use in HIS requires new implementation approaches. According to this, the generation and saving of the native (generic) images, is one of the basic problems to be solved. The need for comparability of the results adds a new level of complexity to this process because it affects the quality concept. When analysis is done by humans (in this case medical doctors) the images quality and comparability is very important but the final result is determined by the doctors' qualification. When the analysis is to be done by computer processing, it requires other approaches. The combination of these contradictory requirements and the fact that doctors refuse to become computer specialists brings new challenges to the well-known area of data handling and representation. One such example is the X-ray images generation, digitalization, handling and processing. This presupposes the development of automated procedures for the preparation of digital radiographic images to be used in the medical system. New types or modifications of the existing adaptive filtering algorithms are also to be developed.

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High Quality Region-of-Interest Coding for Video Conferencing based Remote General Practitioner Training

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***Abstract*—In a video conferencing based remote teaching system, visual quality is of critical importance, specially when it is used for medical training. However, transmission of high quality video data requires substantial amount of bandwidth. Unfortunately, communication systems in remote areas suffer from low transmission rate which demands significant compression of videos at the expense of visual quality. To strike a balance between the requirements of high visual quality and high compression ratio, in this paper, we propose to achieve higher visual quality only in the area of critical importance of a video known as *Region of Interest* (ROI). In the proposed scheme, the increase in the bit rate due to the improved visual quality in ROI is compensated with a degradation in the visual quality of non-ROI so that the effective bit rate meets the available bandwidth constraint. One of the salient features of the proposed method is that it operates outside the rate-distortion optimization (RDO) process of standard video codecs and thus ensures easy integration of the scheme into existing video coding standards and devices. Experimental results demonstrated that the proposed scheme significantly improves the visual quality of ROI without much degradation of the overall visual quality.**

***Keywords*-Region-of-interest; video coding; video conferencing.**

I. INTRODUCTION

With the ubiquitous availability of broadband Internet, video conferencing systems are replacing traditional face-to-face meeting and teaching methods. Video conferencing, which relieves the need for traveling across distance, is not only cost-effective but also energy efficient in terms of carbon footprint. Besides, video conferencing allows participants in rural areas to access quality learning where traveling to a distance is not an option. Indeed, our research motivation comes from the need of effective supervised training of newly appointed *general practitioners* (GPs) in regional Australia. Under the Australian General Practice Training (AGPT) program, every newly recruited GP goes through a mandatory supervised period. During this period, an experienced supervisor assesses the GP's consultation performance, offers on-demand consultation in complex cases, and conduct workshops along with a group of GPs. Ideally, the GP and the supervisor should be co-located at the same facility which is often infeasible as a supervisor has to supervise several GPs practicing at different remote sites. Clearly, in this scenario, remote supervision using video conferencing is an effective alternative.

While in remote teaching, based on video conferencing, the visual clarity is not a ruling factor in general, it is often a critical requirement in medical training. For instance, when a GP wants the supervisor to look at a particular skin rash or the tone of an infection of a patient, a proper investigation is impossible if the video quality is not clear. However, high quality video transmission requires high bandwidth which is often not available in rural areas. In a brute approach, video data need to be compressed significantly, given the low available bandwidth in remote sites, albeit at the expense of visual quality. However, in practice, the participants in a video conference are mostly interested in a small region of the video frames, termed as *region of interest* (ROI), which needs detailed inspection. Therefore, an effective approach is to allocate the scarce bandwidth unevenly between the ROI and non-ROI of a video. Instead of transmitting the whole frame at the same visual quality, the ROI area needs to be transmitted at a high quality which must be compensated by a degradation of the visual quality of non-ROI area.

ROI based video coding has been proposed in a number of contemporary research works [1]–[4]. Since video coding standards such as H.264 and MPEG are characterized by high-complexity encoding, which is often considerable for real time video communications, these works mainly focused on reducing the encoding complexity. Liu *et al.* [1] used skin tone and frame difference to detect ROI and proposed region based computational power and bit allocation by adjusting encoding parameters adaptively. Considering the fact that lower frequency coefficients of an image is less detectable to Human Visual System (HVS) than higher frequency components, Zheng *et al.* [2] proposed adaptively suppressing the low frequency coefficients of non-ROI blocks which, in

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turn, reduces the overall computational complexity. Wang *et al.* [3] proposed using the texture and motion features of a video to determine its ROI and non-ROI. The authors then proposed a dynamic parameter allocation scheme to reduce the computational complexity to attain the low power requirement of portable devices. Considering the importance of rate control in ROI based video coding, Yang *et al.* proposed a rate control mechanism in [4]. The scheme proposed in [4] determines the *quantization parameter* (QP) for the ROI, based on the user defined interest level, and adaptively allocates bits between ROI and non-ROI regions.

All above schemes essentially focused on reducing the computational complexity of encoding. However, with the advancement of VLSI techniques, high computational power is now available even in portable devices like Apple iPAD or Sumsung Galaxy III. Moreover, in recent days, neither the computational power nor the battery life is a serious concern for PC and laptop users. More importantly, these schemes require custom rate-distortion algorithms which are difficult to accommodate in the framework of existing video coding standards. The *rate-distortion optimization* (RDO) algorithms implemented in the standard codecs are well studied and are widely being used in real life applications. Therefore, one of the objectives of our research is to design an effective variable bit allocation scheme that can easily be integrated with the standard video codecs. In this paper, we propose a scheme to transmit the ROI at a high quality where the additional bits used to transmit the ROI is compensated by transmitting non-ROI regions at a lower (than suggested by the standard codec) quality. In effect, we attempt to maintain the same level of bandwidth usage while transmitting the ROI at a higher quality.

The organization of the rest of the paper is as follows. We briefly review the architecture of current video coding standard H.264 and its rate-distortion control mechanism in Section II. In Section III, we then propose our scheme to improve the visual quality of ROI without much degradation of the overall quality of the video while meeting the bandwidth constraint. Extensive experimental results are then presented in Section IV to validate the efficacy of the proposed method. In Section V, finally we conclude our paper.

II. Visual Quality Control in Standard Codecs

Video is a sequence of image frames that are played back at a specific frame rate. The feasibility of video compression stems from exploiting its *interframe redundancy and intraframe redundancy*. The similarity among the successive frames of a video is referred to as interframe redundancy. On the other hand, intraframe redundancy refers to the correlation that exists between a pixel and its neighbors in the same frame. Effective video compression relies on efficient exploitation of all these redundancies.

The techniques of exploiting the intraframe and interframe redundancies are referred to as intra coding and inter coding, respectively. In both of the techniques, a frame is partitioned into non-overlapped, fixed sized, rectangular blocks called *macroblock*. For each of the macroblocks in the current frame, a prediction is made based on the previously encoded data. In intra coding, the prediction is made from previously encoded macroblocks of the same frame, while in inter coding a set of recently coded frames called a Group of Pictures (GOP) are used for prediction. Then the residual, i.e., the difference between the actual block and the predicted block, is transformed. After transformation, such as discrete cosine transform (DCT), most of the energy of the residual is concentrated into a few low frequency coefficients. Since HVS is less sensitive to the distortions at high frequency components, significant compression can be achieved by discarding these high frequency coefficients, by using a coarse quantizer, without much degradation of the visual quality of the reconstruction.

Indeed, in the video coding standards, it is the quantization step that controls the trade off between bit rate and visual quality. In the H.264 video coding standard, the rate-distortion trade off is controlled by the parameter QP which can take a value between 0 and 51 and refers to a matrix of Qsteps, i.e,. the quantization step size. In general, a higher Qstep achieves more compression, however, results in higher distortion and vice versa. The quantization matrices are such that most of the high frequency coefficients become zero after quantization. For more details on H.264 see [5].

In real-time applications, given the available bandwidth, the value of QP is a function of network usage (determined from the emptiness of Coded Pixel Buffer (CPB)) and the estimate of bit allocations for the current frame and its GOP. More specifically, in H.264 video coding standard a RDO algorithm allocates a number of bits to the GOP depending on the emptiness of the CPB. The GOP includes a number frames that can be any of I, P, or B frames. A GOP always begins with an I frame which is followed by a sequence of P and B frames. Depending on the type of current frame and the remaining bit allocation for the current GOP, a frame level bit allocation is decided in the RDO process.

Since QP essentially controls the trade off between the visual quality and the compression ratio, it is an effective tool to achieve varying image quality and enforcement of bit allocation for individual macroblocks. In the following section, we explain how we can adjust QP for individual macroblocks to offer better image quality in ROI.

III. Rate Adjustment for High Quality ROI Encoding

To increase the visual quality of the ROI, we need to decrease the QP values of the macroblocks within the ROI so that the quantization distortion during encoding is less for these macroblocks. This allows the decoder at receiver to reconstruct a better representation of the original frame. However, using a lower QP to offer lower quantization

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distortion at a ROI also increases the data size. If the increase in the bit-rate is not compensated in the non-ROI then it will result in buffer or network overflow. To overcome this problem, the non-ROI needs to be coded using higher QP values to compensate for the increase in data size due to improved encoding of ROI. The compensation mechanism needs to ensure that, while satisfying the bandwidth constraint, the maximum possible information is retained.

Adjusting the visual quality of non-ROI to maximize the overall visual quality, subject to the available bandwidth, is challenging. If a lower value of QP is used for non-ROI, although the visual quality would be better, the resulting bit rate will then be higher than the available bandwidth which will lead to call termination. On the other hand, if the QP for non-ROI is unnecessarily high, some of the available bandwidth will be left unused which could have been used to improve the overall visual quality. The primary obstacle in selecting the appropriate QPs for ROI and non-ROI macroblocks is that although bandwidth and quality control parameters are closely related, their relationships can not be expressed with simple functions. In the following, we explain our proposed method of improving the visual quality of ROI while maximizing the overall visual quality subject to available bandwidth. Although, the proposed scheme assumes the x264 codec as an efficient implementation of H.264, it can easily be adopted to other implementations of H.264 as well.

In x264 codec, a award winning implementation of H.264, after allocating a bit budget to a frame, QP for each of the macroblocks is computed adaptively based on the complexity and compressibility of the macroblock. Therefore, we assume that while adjusting the QP values after the RDO of x264 encoder, the variations in QPs among the macroblocks of ROI and among the macroblocks of non-ROI should be maintained. More specifically, the QP of each of the macroblocks in ROI should be decreased by a constant factor C as specified by the user. Similarly, a fixed factor T must be added to the QP values of each of the macroblocks in non-ROI. Now we need to determine the value of T such that the resulting bit rate after the adjustment of QPs matches the available bandwidth. After extensive experimentation we have observed that to ensure that the effective bit rate is close to the target bit rate, the mean of the QPs of a frame after adjustment should be same as the mean of the QPs computed by the RDO process of x264 encoder. Therefore, QP values of non-ROI should be increased by $T = nC/(N-n)$, where N is the total number of macroblocks in a frame and n is the number of macroblocks in ROI. Clearly, this method operates outside the RDO process and thus can be easily incorporated into the standard codecs.

IV. Experimental Results

In image and video compression, *peak signal to noise ratio* (PSNR) is used as an approximation to human perception of reconstruction quality. A higher PSNR value indicates lower loss during compression and thus is preferable. Therefore, in our experiments we used PSNR as a metric for visual quality.

We implemented the proposed scheme in x264 codec [6]. To implement a real time video communication system with ROI based coding, we extended the linphone [7] software, which is a mature softphone application for Linux, Windows, and Mac, to use in the modified x264 codec. For comparison purpose, we used this modified x264 application on a number of YUV test video sequences. The QCIF and CIF YUV videos were collected from [8] while the higher resolution (4CIF and 720p) video sequences were downloaded from [9] and [10], respectively. Under different target bit rate requirements, we determined the effective bit rate and PSNR of ROI, non-ROI, and overall frame for these video sequences having different resolution and image complexity.

Fig. 1 demonstrates the impact of ROI based encoding on the visual quality of four standard test video sequences: 'Silent,' 'News,' 'Mother & Daughter,' and 'Foreman'. In each of the video sequences, the ROI contained the face which is detected using the Face Detection module of OpenCV [11]. The figure shows that the perceptual visual quality of ROI is improved without much degradation of overall frame quality.

The performance of the proposed technique for a QP-shift of $C = 5$ is illustrated in Fig. 2a-2d in terms of effective bit rate, overall frame PSNR, ROI PSNR, and non-ROI PSNR, respectively. It follows from Fig. 2a that the bit rate resulting from the proposed method is considerably close (within ± 1.5 kbps on average) to the one obtained by original x264 codec. This validates our equi-mean QP hypothesis of readjusting QP values of ROI and non-ROI.

Fig. 2b shows that the overall frame PSNR obtained with the proposed method degraded slightly than that with original x264 codec. The average decrease in overall frame PSNR was found to be 0.3 dB, 0.13 dB, 0.19 dB, and 0.61 dB for 'Silent', 'News', 'Mother & Daughter', and 'Foreman' video sequences, respectively.

It is worth mentioning that the visual quality of ROI improved in every test video sequences. The ROI PSNR was found to be 2.62 dB, 3.09 dB, 2.39 dB, and 2.2 dB higher than that obtained with original x264 codec in 'Silent', 'News', 'Mother & Daughter', and 'Foreman' test video sequences, respectively. This increase in visual quality is due to lowering of the ROI QPs which resulted in additional bit allocation for ROI. This increase in bit rate for ROI was compensated by increasing the QPs of non-ROI which lead to a decrease in visual quality of the non-ROI. The decrease in non-ROI PSNR using the proposed method was found to be 0.45 dB, 0.27 dB, 0.34 dB, and 0.9 dB for 'Silent', 'News', 'Mother & Daughter', and 'Foreman' video sequences, respectively.

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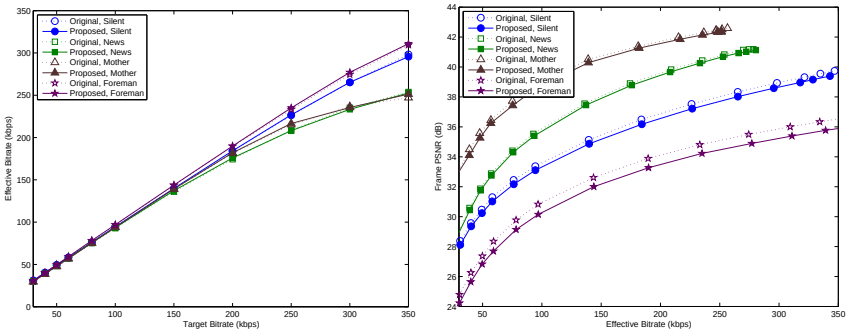
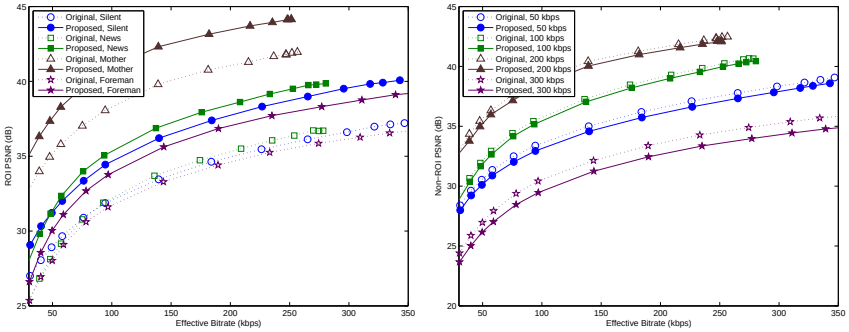
(a) (b)

(c) (d)

Figure 1: Impact of high quality ROI encoding on 'Silent,' 'News,' 'Mother & Daughter,' and 'Foreman' video sequences. The figures demonstrate that the proposed method improves the visual quality of ROIs without much degradation of the visual quality of non-ROIs.



(a) Effective bit rate (b) Frame PSNR



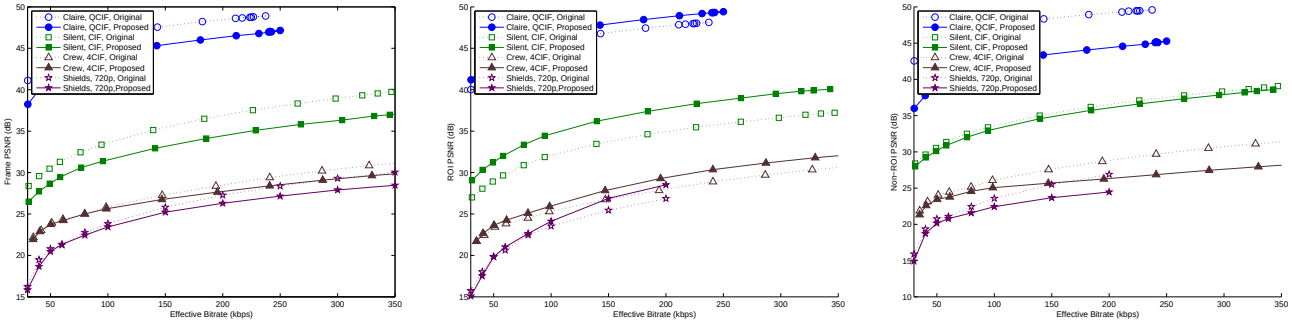
(c) ROI PSNR (d) Non-ROI PSNR

Figure 2: The proposed ROI based encoding with a QP-shift of $C = 5$ improves the visual quality of ROI at the cost of moderate decrease in non-ROI and overall frame PSNR.

The ROI area in the above videos contained only face which is about 5% of the total frame. Intuitively, the performance of the proposed scheme will vary with the ROI area and frame resolution. In the following, we present and analyze our experimental results to understand the impact of these parameters on the proposed ROI based coding scheme.

A. *Impact of Video Resolution*

To determine the impact of image resolution on the performance of the proposed method, a number of tests were



(a) Frame PSNR (b) ROI PSNR (c) Non-ROI PSNR

Figure 4: Impact of varying video resolution on the performance (PSNR) of ROI based video encoding.

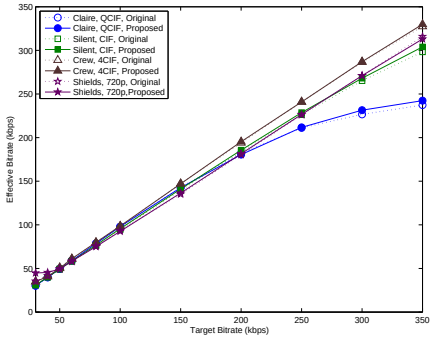


Figure 3: Impact of varying video resolution on effective bit rate.

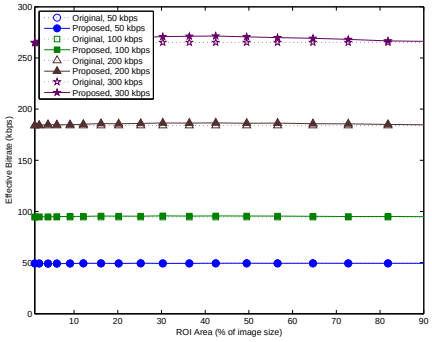


Figure 5: Impact of ROI size on effective bit rate.

conducted on several QCIF, CIF, 4CIF, and 720p videos using a QP shift of $C = 5$. In each of the video sequences, (left) half of the frame was used as ROI and the other (right) half was used as non-ROI. For space constraint, results for only one video per resolution are reported in this paper. However, similar results were observed for other video sequences as well.

It follows from Fig. 3 that the proposed method resulted in good agreement between effective bit rate and target bit rate. The effective bit rate achieved with the proposed method was found to be within 5.2 kbps, 1.03 kbps, 0.48 kbps, and 1.75 kbps of the target bit rate for 'Claire' (QCIF), 'Silent' (CIF), 'Crew' (4CIF), and 'Shields' (720p) video sequences, respectively.

Fig. 4a illustrates that when the proposed method was used the overall frame PSNR degraded slightly for CIF, 4CIF, and 720p video sequences. The CIF, 4CIF, and 720p video sequences showed an increase in ROI PSNR by 2.6 dB, 0.54 dB, and 0.38 dB (see Fig. 4b) at the cost of slight degradation in non-ROI PSNR by 0.45 dB, 1.95 dB, and 1.1 dB (see Fig. 4c). The adverse result for the QCIF video was primarily due to its low resolution for which the QP shift of $C = 5$ was considerably large. The lower QP used for ROI was compensated by using a higher QP in non-ROI which resulted in significantly lower PSNR for non-ROI and for the whole frame.

B. *Impact of ROI Size*

To demonstrate the impact of varying ROI size on the performance of the proposed method, we use the CIF 'Silent' video and change the ROI size from 1% to 90%. The center of ROI was at the center of the video since the important visual objects are usually located at the centre of the video. With varying ROI size, the effective bit rates were found to be considerably close to that obtained by the original x264 codec (See Fig. 5). At target bit rates as high as 200 kbps and 300 kbps, the bandwidth usage in the proposed method differed by 1.49 kbps and 3.47 kbps, respectively. This observation demonstrates the robustness of our equi-mean QP hypothesis with the variation of ROI size, relative to the frame size.

It follows from Fig. 6a that at each bit rate, the frame PSNR decreased in the proposed method when the size of ROI was increased. This pattern can be explained from the resulting ROI PSNR (Fig. 6b) and non-ROI PSNR (Fig. 6c). A much higher ROI PSNR (compared to original x264 codec) was obtained with the proposed technique when the ROI was small. As the ROI area increased, the ROI PSNR degraded and approached the ROI PSNR obtained with the original x264 codec. For instance, at 50 kbps, the increase in ROI PSNR by the proposed method from that obtained by the original x264 codec was 2.25 dB and 0.15 dB when the ROI area was 1% and 90% of the total frame, respectively.

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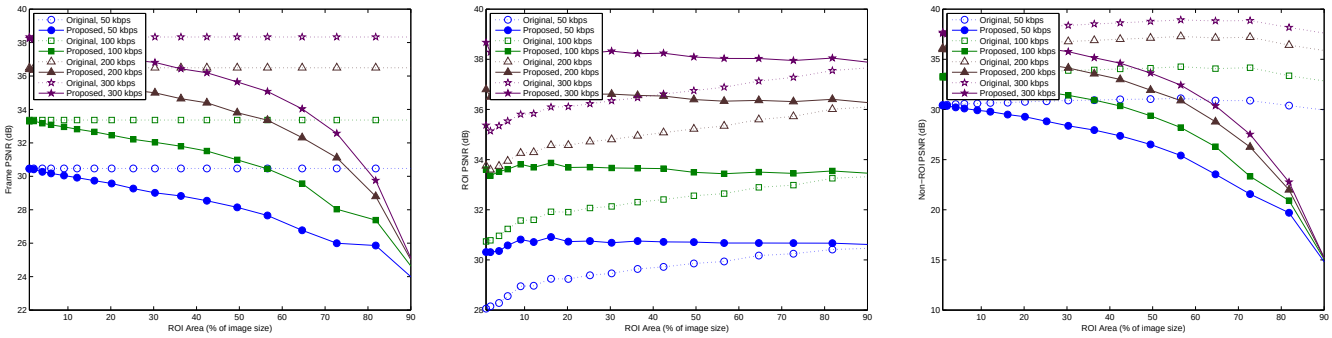

(a) Frame PSNR (b) ROI PSNR (c) Non-ROI PSNR

Figure 6: Impact of varying ROI size on the performance (PSNR) of the proposed scheme on 'Silent' video sequence.

While determining the effective QP shift, we first looked for the minimum original QP within the ROI and then its difference from the QP shift limit was subtracted from the QP of each ROI macroblock. Therefore, as the area of ROI increases, the probability of finding a lower QP within ROI also increases. For instance, when the ROI size was 9.09%, 18.18%, and 27.27% of the whole image, the minimum original QP-adjustment within ROI was found to be around 4, 7, and 8, respectively.

An inverse impact on the image quality of non-ROI was also observed. When the ROI was small, the decrease in ROI QP was compensated with slightly higher QP for non-ROI. Therefore, the non-ROI image quality did not degrade considerably and the non-ROI PSNR using the proposed method was nearly same as that obtained with original x264 codec. However, when the ROI became larger, with the same QP shift for ROI, we needed a much higher QP for the non-ROI to ensure that the mean QP of the whole frame remained same. Therefore, the non-ROI image quality degraded more when the ROI area was larger. For instance, at 50 kbps, the decrease (compared to original x264 codec) in non-ROI PSNR was 0.06 dB and 15.61 dB when the ROI area was 1% and 90% of the total frame, respectively.

In effect, when the ROI size is small, the proposed method gives a considerably higher ROI PSNR and slightly lower non-ROI PSNR compared to the original. However, when the ROI is increased, the increase in ROI PSNR diminishes and the decrease in non-ROI PSNR intensifies. As a result, the overall frame PSNR degrades with increasing ROI size.

V. Conclusion

In this work, we presented a novel approach to transmit ROI at a higher quality than the non-ROI counterpart, subject to the bandwidth constraint. The bandwidth usage is maintained by the use of original H.264 rate control algorithms which are proven to be reliable. The desired result is achieved by decreasing QP for ROI and compensating it in non-ROI without affecting the overall bit allocation per frame. Thus this method can be easily integrated with commercially available standard codecs to selectively transmit the ROI at a higher quality for effective real-time remote medical training.

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***Abstract*—Remote diagnosis has become an important research field to provide high quality health care services to larger communities. Even when the importance of providing these services is undisputed, the computational cost of performing such processes is high. In order to deliver this kind of services, we present a scalable platform in the cloud able to process DICOM files with a modular structure. Our platform extracts and processes relevant information from the DICOM file to be used for support in diagnosis in medical applications. The paper presents a discussion about the cloud infrastructures and our choice of storage and HPC processing capabilities on Amazon AWS infrastructure. We also propose an HTML5 and WebGL web based access interface to allow remote access, visualization and manipulation from the user side, but keeping the computational cost on the cloud. The platform offers Cloud processing for computationally expensive tasks (from DICOM image segmentation to data mining in order to extract relevant information from the DICOM file). We present a basic proof of concept and describe the relevant modules of our platform.**

Keywords—DICOM; X3D; WebGL; HTML5; 3D graphics; mobile medical applications; medical cloud DICOM processing; GPU processing on the cloud; Amazon AWS.

I. INTRODUCTION

There has been extensive research on using the web for medical image processing, remote support diagnosis and visualization [1][2]. Unfortunately, the large amount of data of DICOM files limits the applicability on mobile devices or require high computational cost to extract relevant information that even desktop computers are limited to do. On the other hand, the adoption of the WebGL [3] and HTML5 standards for the new generation of browsers brings back the interest of web based 3D rendering with WebGL and declarative X3D [5], since it will be supported without plug-ins, allowing the same functionality across platforms. Further, WebGL will make possible to render 3D models in real time with the computational capabilities of the new smartphones and tablets. Some attempts to build WebGL-based medical visualization systems have been reported [4], but these only considered the X3D model creation from DICOM on the server side for visualization in a remote platform. In this work, we propose a cloud based platform where DICOMs are stored but also processed, so a remote (desktop or mobile) computer can access and manipulate visual data and extracted information. Our approach is modular, so different kind of studies and data analysis can be applied to the DICOM file, and 2D or 3D data structures can be visualized by the user, in order to help interpretation and support for diagnosis.

The paper is organized as follows: Section II gives an overview of the cloud infrastructure choice. Section III details the processing architecture, and Section IV the implementation and preliminary results. We give some conclusions and directions in Section V.

II. CLOUD STORAGE AND PROCESSING INFRASTRUCTURE

Many PACS like platforms in the cloud only consider data storage. For general PACS functionality, data must be stored and accessed via HIPAA (Health Insurance Portability and Accountability Act of 1996) compliant procedures [8], for security and integrity reasons.

In our case, we are also interested on data processing in the cloud, so the storage infrastructure must be coupled or connected with a fast link in the cloud with a High Performance Computing (HPC) infrastructure. The Amazon AWS infrastructure provides both solutions in the cloud as separate services.

On one side, the Amazon S3 (Simple Storage Service) allows cloud data storage of large files. It also offers easy solutions to develop HIPAA compliant medical applications. Basically, the Amazon infrastructure offers solutions for: Identification & Authentication, Authorized Privileges & Access Control, Confidentiality, Integrity, Accountability, Security and Protection, Disaster Recovery.

On the other hand, the Amazon EC2 infrastructure provides on demand processing nodes, either multicore processor nodes, or HPC nodes with Nvidia Tesla boards. The later are parallel processing platforms based on CUDA-C, a parallel C version suited for multi thread programming on Nvidia GPUs and HPC boards. Typical acceleration with an Nvidia board goes from 10 to 100 times compared to a traditional CPU node.

There are other cloud solutions but for the architecture we are proposing, Amazon AWS provides a scalable environment for storage and processing suitable for medical image processing and analysis.

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III. PROPOSED ARCHITECTURE

The proposed platform is based on a client – server architecture, where the server is in the cloud (Amazon S3 and EC2). Traditional architectures allow physicians/ radiologists to visualize, analyze, and interact with patient information stored in a DICOM repository. This approach has the drawback of requiring large data transfers between the user and the cloud, and limits the amount of processing on the DICOM data in the local computer to basic image enhancement algorithms.

In our case, once the DICOM is stored in the cloud, it can be processed / analyzed on the cloud side, using a large number of nodes (reaching HPC performance), and sending to the final user only relevant information, either data, images or 3D models, as in [7].

A. High Performance Computing on the Cloud architecture

Figure 1 depicts the general architecture. On the client side, there is a visualization tool based on a web interface. On the cloud side, there is an S3 server that contains the DICOM repository where the patient data is stored. A file subsystem and HIPAA compliant access is implemented for file upload, storage, management, and traditional DICOM access for visualization through the net. An administration module (m3DicomAdmin) is in charge of authenticating users and initiate task requests. The general steps are:

1. A user is authenticated
2. The user uploads a DICOM file (or is already stored in the S3 server) and a request for a particular image processing task
3. The m3DicomAdmin communicates the file to the EC2 server,
4. The master node in the m3DicomProcessing configures the HPC nodes for the particular image processing task (plug-in).
5. The image analysis/processing is carried out and the result is sent back to the S3 server
6. The user is notified and he/she can download the results of the type of study into the viewer.

The most elaborate and complex processes of DICOM data analysis are based on advanced segmentation algorithms that locate specific organs or tissue in the data. The architecture allows the EC2 unit to allocate several nodes or HPC resources (ie. Nvidia HPC boards) to solve in short time the tasks.

If the cloud processing generates 3D data or 3D models, they can be embedded into a X3D representation that is sent back into the user visualization interface for visual exploration, alleviating the amount of data compared to visualizing only the DICOM file [7].

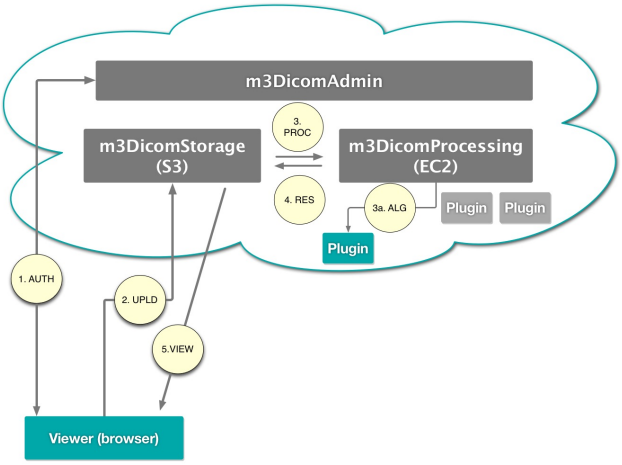

Figure 1. Server-Client architecture of the scalable platform. The S3 service is used for storage and the EC2 infrastructure for cloud processing where several "plug-ins" for each modality can be integrated.

B. Client – web user interface

Figure 2 shows a simplified version of the web interface architecture. On top of figure 2: the cloud processing engine sends X3D files and additional data extracted during the analysis phase and both types of data are integrated into HTML using embedded X3D as a mixed-namespace document (X3DOM implementation [5]). This allows a simple interaction (HTML events) and navigation (zoom, rotate) on resulted 3D objects. The interface is designed to provide cross-browser support (for both desktop and mobiles), using the JQuery Mobile framework [6].

Through the user interface, it is possible to set up algorithm parameters (such as a threshold or other parameters), which are used by the cloud engine to extract and label relevant information from the DICOM file.

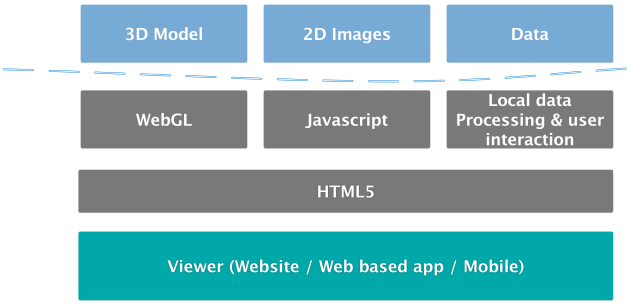

Figure 2. DICOM/X3D data structure from cloud and viewer interpretation for user interaction

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C. The Processing plug-in architecture

Figure 3 presents the HPC platform where the algorithm associated to a particular type of study, is considered at a high level as a plug-in module, but actually it corresponds to a particular software / algorithm configurations for the multi-node HPC part. The platform has a service manager that routes the task requests into a queue, where each task is individually routed to a master node of the HPC. The master node configures the parallel node section of the HPC with a particular algorithm required by the task, i.e. Mammography for a set of DICOMs to be processed in batch.

Amazon EC2 allows to configure a set of nodes with a specific software algorithm, but that can be reconfigured on the fly depending on demand, so the Master node could set up more nodes if there is a large demand of task requests.

The result of the processing is routed back to the Amazon S3 repository and associated with the patient in the database, and signaling the end of processing to the remote user.

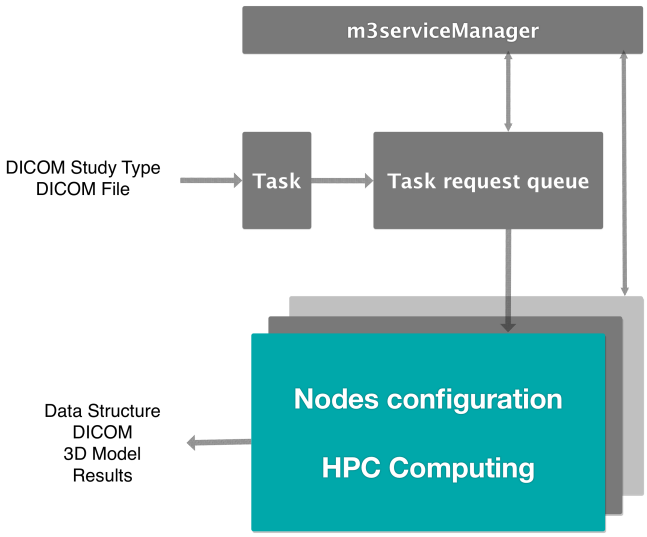

Figure 3. Multi configurable HPC for Image Analysis. Each Node set configuration is treated as a "plug-in" that the m3Dicom Processing node configures on the flight depending on the kind of study to be performed.

IV. PRELIMINARY RESULTS ON CLOUD PROCESSING

An implementation of the platform was carried out. We used the Amazon AWS infrastructure with a basic 4-node server with Nvidia Tesla GPU boards for HPC. For DICOM storage we used Amazon S3. The basic 4-node configuration was chosen to test parallelization and multiple node configuration for the basic test algorithms, but the configuration could be grown to larger setups to reduce processing time. In a multi-user configuration, an additional workload manager is required in order to queue task requests into the server or to dynamically setup more processing nodes.

Some results are discussed below.

A. Mammography analysis in the cloud

Once the user uploads a mammogram DICOM file, it is processed to identify micro-calcifications. This process requires extensive computing in order to segment Regions Of Interest (ROIs), which are possible micro-calcifications, extract features (statistical, texture, and geometric) from the ROIs to be used by a classifier that works on the cloud. The classifier finds the micro-calcifications (eliminating as many false positives as possible) and creates a new mammogram image in which it identifies the micro-calcifications found (adding a mark and id to each possible micro-calcification). This new image is returned to the user to be used as a support tool for medical diagnosis [9, 10, 11].

B. Visualization tool

Figure 4 shows the visualization tool interface. The tool is a web application developed using HTML5 and JavaScript suitable for mobile and desktop browsers. The tool connects to the cloud platform and offers options to select one patient or upload a new DICOM image, to start a processing task and visualize the results, depending on the type of study uploaded. The interface integrates a 3D viewer and a 2D viewer, using X3D objects and HTML5 functionalities to manipulate the 3D objects and images (zoom, brightness/contrast, etc.)

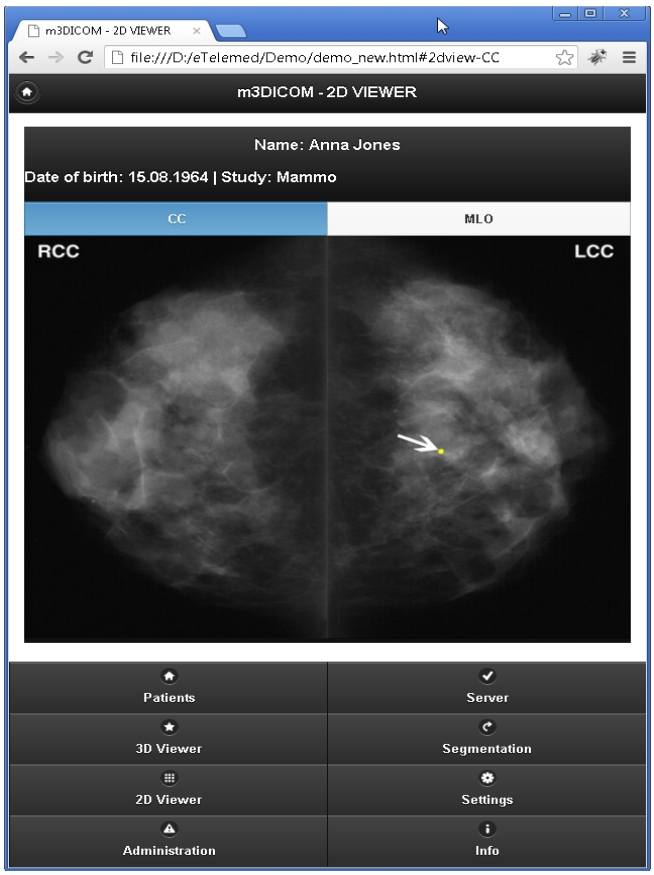

Figure 4. View of the mobile device interface showing a mammography. The detected micro-calcifications are signaled with an arrow.

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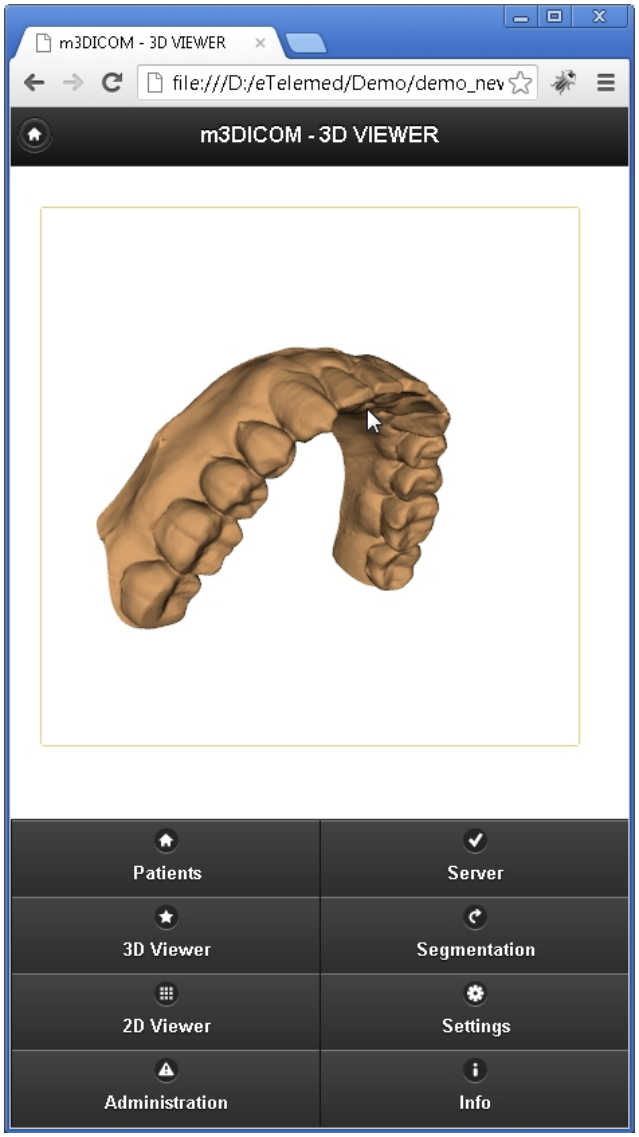

Figure 5. Mobile device interface showing a 3D model extracted in the cloud from a DICOM dental file.

Figure 5 shows the viewer displaying a 3D model from a dental DICOM where the segmentation process was carried in the cloud, following same technique described in [7].

V. Conclusion and Future Work

We have presented a proof of concept of a cloud platform for DICOM processing. The platform stores DICOM files, processes them on a HPC infrastructure and delivers information to a web client using WebGL and HTML5. The platform is the basis for a larger system where different kind of image data processing will be integrated. A basic proof of concept was implemented with mammography analysis based on data mining algorithms and bone/tissue segmentation for dental applications. Some ideas to be explored are pre-computation of volumetric rendering, a scaled up version of the mammography analysis for batch processing large sets of studies and advanced 3D data segmentation.

On the user side, WebGL and HTML allow flexible visualization. Future work will concentrate on an improved front-end tool that can be used in desktop and mobile devices, and define a standard for plug-in processing/integration that could be used by others to grow functionalities of the system.

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Proposal of a System for Intracranial Pressure Telemonitoring

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***Abstract*— The Intracranial Hypertension (ICH) is a neurological condition that affects patients with head injury, stroke and hydrocephalus. Currently, the most suitable treatment for this clinical condition requires continuous monitoring of cerebral function by the analysis of clinical parameters associated with cerebral perfusion. In this context, two parameters are relevant for clinical decision: the analysis of the waveform of intracranial pressure and the temperature. Ideally, a neurosurgeon should have access to this information during the whole period of treatment. However, in most cases this is not possible, because of the limited number of available professionals in this area. Possible consequences for this are delays in clinical interventions and the application of misleading procedures that may result in the death of patients or in worse prognostics. This research proposes the development of a system for temperature and intracranial pressure (ICP) monitoring. It will be developed a computer program that estimates and presents online and continuous relevant information regarding the ICP waveform and intracranial perfusion. This system will contain a remote evaluation module in addition to continuous monitoring at bedside, allowing the provision of periodic information about the evolution of the parameters of ICP, cerebral perfusion pressure (CPP) and intracranial temperature (ICT) via software application available in the mobile phone of the specialist. The software will be validated with synthetic and experimental data. Furthermore, it will be employed in a clinical study with 50 patients in order to compare the performance of two distinct types of equipment commonly used in the monitoring of the ICP. The results of this study will contribute to the improvement of current ICP monitoring systems, which may contribute to the reduction in morbidity and mortality of neurocritical patients.**

Keywords-Intracranial Pressure; Cerebral Perfusion; Telemonitoring.

I. INTRODUCTION

The Intracranial Pressure (ICP) is the measured pressure inside de skull that is influenced by the cerebrospinal fluid (CSF), blood and cerebral tissue volumes, which are maintained at a constant rate under normal conditions. The ICP is the sum of the pressure on the internal wall of the skull. Any volume alteration in the brain and its structures may cause the raise of the ICP, and consequently, changes in the cerebral perfusion [1-3].

In this context, the assessment of intracranial hypertension is of paramount relevance. From literature, it is known that intracranial hypertension occurs when the ICP remains above 15 mmHg measured with the patient in supine position for a prolonged period of time [4].

The ICP monitoring is an important parameter in the area of neurosurgery because in events such as head injury there is a large possibility of ICP increasing. This is proved by studies reporting that 40% of patients suffering from head injury and admitted in an unconscious state have an increased ICP. In addition, 50% of the patients die because of the raise of the ICP [5].

Furthermore, ICP must be monitored because it provides a reliable way of confirming or excluding intracranial hypertension [6]. Unfortunately, the monitoring of the ICP is limited to hospitals that have access to advanced technology and multidisciplinary teams, making the process of ICP monitoring expensive.

The high costs involved in continuous monitoring of ICP have called attention of a number of organizations in the area of telemonitoring, mainly, because it allows for a single professional, i.e., the neurosurgeon, to monitor a number of patients in distinct hospitals simultaneously and remotely.

Thus, the telemonitoring of ICP in neurocritical patients is crucial because it promotes a fast and reliable assessment of the state of patients while reducing the cost of having the presence of a specialist in all locations.

In this context, the main aim of this research is to develop a system for remote monitoring of ICP. This system should to be able to capture, process, monitor and send online information regarding the main parameters estimated from the ICP waveform to a remote device, i.e., a smart phone available to the professional. In addition the whole information will be stored in an online database for further analysis and visualization.

The structure of this paper is as follows: In Section 2 we describe the methodology that will be used to develop the tool, including the block diagram of the project and the steps of development. In section 3 we discuss the system dependability of the system. In section 4 we outline the implications of this approach and the future directions of our research.

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II. METHODOLOGY

The methodology used in the execution of this research will employ modern software engineering concepts and system design. The diagram depicted in Fig. 1 shows the main steps that will be applied in this project. It is important to note that the system development process is iterative and non-sequential. In this way, the knowledge obtained in any of the stages shown in Fig. 1 can be used as feedback in the development of any of the steps.

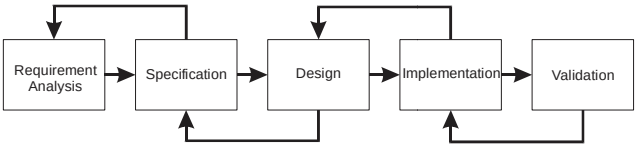

Figure 1. Main steps for developing the system for intracranial pressure telemonitoring.

In the *Requirement Analysis* stage will be identified the specific requirements regarding the monitoring of neurocritical patients in a joint action between the research groups in Neurosurgery and Biomedical Engineering of the Federal University of Uberlândia, Uberlândia, Brazil. The results of this step will guide the development of computational tools.

The *Specification* stage consists in the development of a documentation that describes as accurately as possible the architecture of the proposed system. Use-case diagrams will be used in order to assist the communication between the developers and the end user. These types of diagrams describe the scenario that shows the functionality of the system from the user's point of view. In addition the Unified Modeling Language (UML) [7] will also be employed for the specification and documentation of the system. The main block diagram of the proposed system is shown in Fig. 2.

The *Design* step consists in modeling the (i) interfaces for interaction with the user, as showed in Fig. 3, (ii) database (iii) reports, indicators and queries. The following information will be available in the conclusion of this step: entity and relationship diagrams, data flow diagrams and Graphical User Interface (GUI) design, detailing menus and sub-menus as well as their sequence of operation.

The step *Implementation* is the use of computational tools (e.g. compilers and programming languages) for the implementation of the system design as defined in the step "*Design*".

The *Validation* will be focused on the following aspects: (i) validation of the graphical interface with the end user; (ii) validation of the information generated by the system; and (iii) clinical validation of the system, i.e., the system will be used in a clinical study, with 50 patients, for comparing the performance of two distinct methods for measuring the ICP.

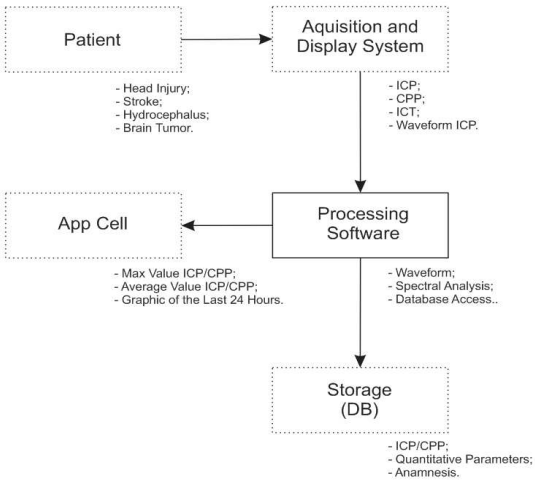

Figure 2. General structure of the system.

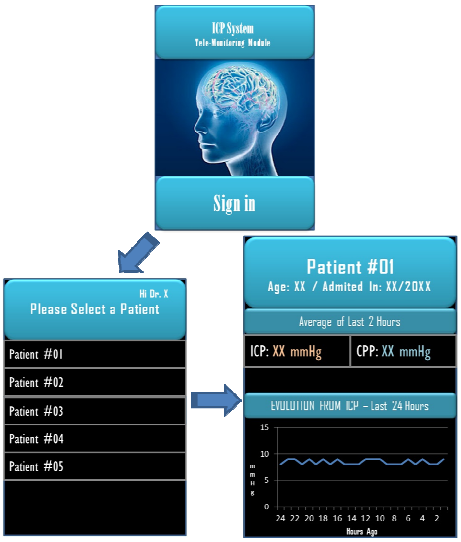

Figure 3. Model of a possible graphical user interface of the system.

Figures 4 and 5 depict typical user case scenarios for the proposed system. When the ICP is normal, the alarm is off (Figure 4) and both the specialist and the staff are following the routine parameters of the patient. In contrast, when the ICP is abnormal (Figure 5), the firing of an event will set off the alarm so that the specialist and staff can act promptly.

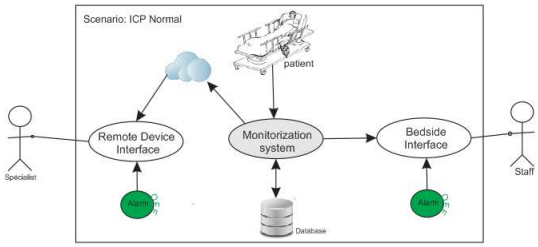

Figure 4. User case scenario when the intracranial pressure is normal.

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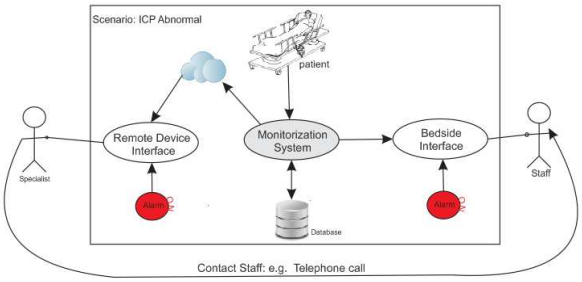

Figure 5. User case scenario when the intracranial pressure is abnormal.

III. SYSTEM DEPENDABILITY

Dependability assesses the quality and reliability in the service provided by a system [8]. This parameter is even more desirable when it comes to biomedical systems for monitoring or life support, due to stringent requirements regarding the availability and reliability of the system, as it is for health maintenance.

It is known that failures are inevitable, but the consequences of the failures, the interruption in the supply of the service and data loss can be prevented by proper use of some techniques that tolerate failures [9]. It is important to note that these tools have a certain cost, thus, users and developers should assess the cost-benefit in each case [10]. The system proposed in this research provides the specialist with further mobility; however mobility can put the patient at risk in the event of a failure in the communication about the state of the patient to a specialist.

For ICP monitoring is necessary a high reliability and availability of the system, in order to minimize the impact in the event of faults, e.g., loss of network connection. A possible mechanism to address these issues would be to include in the system additional alarms, and also distinct communication service providers, so that failures are perceived immediately, and communication can be guaranteed or reestablished as quick as possible.

IV. CONCLUSION

ICP monitoring is a very useful tool, particularly for patients suffering from head injury, mainly because, in this condition, a high measure of ICP reduces brain perfusion. For this reason, we propose to develop a tool for data processing, analysis and remote visualization of ICP parameters and waveform.

The use of the proposed tool in clinical practice allows the continuous monitoring of the ICP and hence of the state of patients. This will be a relevant tool for both the clinical staff at bedside and also for the neurosurgeon that might assess the condition of the patient remotely.

The next steps of the work will be: Finishing the conditioning system and digitalizing the analog signal of the ICP and posteriorly, the development of tools for the digital processing of information from ICP. After, will be implemented the databases. On the last stage, we will develop tools for communication between mobile systems and the bedside systems of information processing and storage.

V. ACKNOWLODGEMENTS

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BioMet®Phon: A System to Monitor Phonation Quality in the Clinics

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***Abstract*— BioMet®Phon is a software application developed for the characterization of voice in voice quality evaluation. Initially it was conceived as plain research code to estimate the glottal source from voice and obtain the biomechanical parameters of the vocal folds from the spectral density of the estimate. This code grew to what is now the Glottex®Engine package (G®E). Further demands from users in laryngology and speech therapy fields instantiated the development of a specific Graphic User Interface (GUI's) to encapsulate user interaction with the G®E. This gave place to BioMet®Phon, an application which extracts the glottal source from voice and offers a complete parameterization of this signal, including distortion, cepstral, spectral, biomechanical, time domain, contact and tremor parameters. The semantic capabilities of biomechanical parameters are discussed. Study cases from its application to the field of laryngology and speech therapy are given and discussed. Validation results in voice pathology detection are also presented. Applications to laryngology, speech therapy, and monitoring neurological deterioration in the elder are proposed.**

Keywords: speech therapy; voice quality analysis; dysphonia.

I. INTRODUCTION

In this paper, we give an overview on an end-user-driven application to study the glottal source and its associated mucosal wave [1] for voice quality assessment, pathology detection and classification. The glottal source may be seen as the pressure build-up in the glottis just above the vocal folds in the laryngeal cavity. It is the result of the phonation cycle, seen as a sequence of openings and closings of the vocal folds under the influence of lung pressure and vocal fold visco-elasticity and air dynamics [2]. The glottal source is expected to follow closely the pattern proposed by G. Liljencrants and G. Fant [3] known as the L-F pattern given in Figure 1. The L-F profile (top blue line) is the result of simulating the flow of air from the lungs to the vocal tract through the glottis as the vocal folds open and close (the equivalent light seen through the glottis is called the *gap* in dash red). Classically the cycle is considered to start at the opening instant (tO), nevertheless, as this instant sometimes is rather inaccurate, the closing instant (t=0) is preferred. The sudden stop of the airflow by vocal folds at contact produces a fast drop of the dynamic pressure from 0 to a minimum (at t=0 and t=tC).

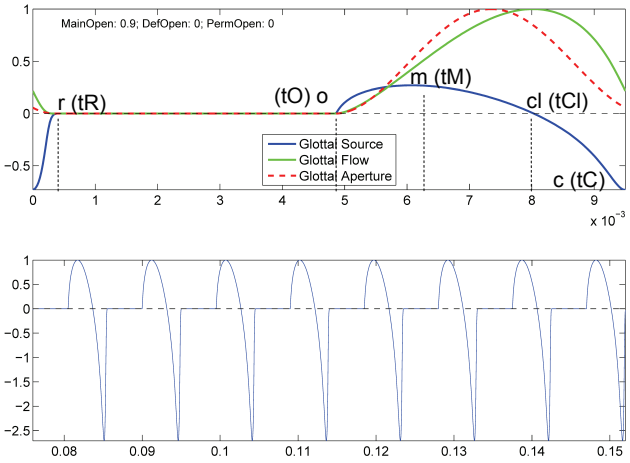

Figure 1 L-F pattern. Top: glottal opening (gap) in dash-red; glottal flow in green; glottal source in blue. Bottom: sequence of L-F patterns for 8 consecutive phonation cycles.

After a time interval (tR: recovery time), the dynamic pressure returns to its quiescent value (0). During the remnant part of the closed phase ending at tO, the vocal folds are supposedly in contact and no airflow is allowed through the glottis. The dynamic pressure remains in its resting value (0). At tO the vocal folds start opening, and a pressure build-up towards a maximum is produced (tM) where the airflow (green line) is in its steepest ascent. As the vocal folds come closer (adduction), the pressure drops crossing the resting value at tCl, and falling to a minimum when both vocal folds produce a complete flow stop (tC). This pattern is repeated each glottal during the phonation process. From what has been said, it may seem clear that the specific profiles of the recovery, closed, open and closing phases will reveal important details of the system biomechanics. A good reconstruction of the glottal source is of most relevance to ensure proper estimates of the system biomechanics. For such, a careful removal of the vocal tract by system inversion is necessary [1]. Biomechanical parameters offer a more relevant semantics of vocal fold physiological structure than classical acoustic parameters derived from voice. Section II presents dysphonic voice biomechanical modeling, in Section III study cases are discussed, Section IV is devoted

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statistical validation of the methodology, and in Section V conclusions and future work are summarized.

II. MODELLING DYSPHONIA WITH BIOMET®PHON

The computer routines providing the inversion of the vocal tract and the reconstruction of the glottal source are encapsulated in a software package referred to as the Glottex®Engine (G®E), which is built as a C++ package generated from MATLAB® [4]. It produces a set of 65 parameters including distortion, cepstral, spectral, biomechanical, temporal, contact and tremor obtained from the glottal source following the methodology in Figure 3. This requires the inversion of the vocal tract and the vocal fold biomechanics, as explained in [1]. A good example of the glottal source reconstruction from a normophonic male subject, non-smoker, pathology-free condition assessed by objective endoscopy, is shown in Figure 2.

The reconstructed glottal source and flow are quite realistic and resemble the simulated pattern in Figure 1. The time references (tR1, tR2, tO1 and tO2) and contact defects (ContGap, AdducGap and PermGap) are also given. In the specialized literature there are other methodologies and products which also estimate parameter sets from voice and use them in the assessment of pathology [5]. The most important feature that the parameters estimated by BioMet®Phon convey when compared with these other approaches is their ability to fill is the *semantic gap* between acoustics and structure. This concept addresses the ability of the biomechanical structural parameters provided by BioMet®Phon to describe the etiologic characteristics of the dysphonia in contrast to other methodologies. For instance, it is well known that many times deviations in the behavior of *jitter* and *shimmer* or *HNR* (harmonics-noise ratio) may point to the presence of pathology in voice [6], but one cannot go any further on investigating which kind of pathology may be behind this behavior. Special care has been devoted in G®E technology to define the biomechanical parameters adding description capabilities of physiological structures.

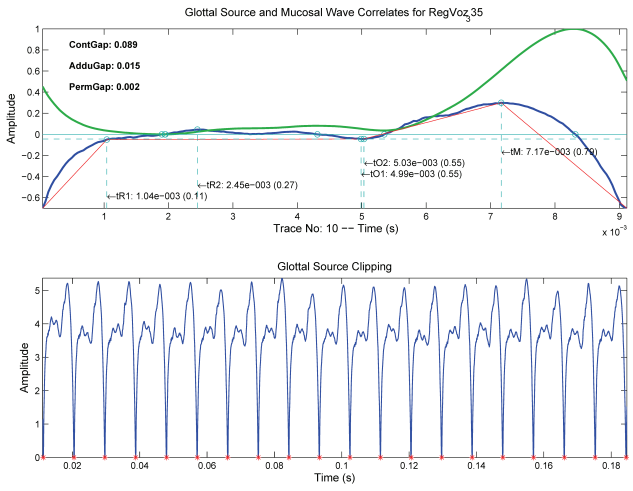

Figure 2 Typical glottal source. Top: a glottal cycle spanning from a closing instant to the next closing instant. Bottom: Sequence of glottal cycles in an interval of 183 ms.

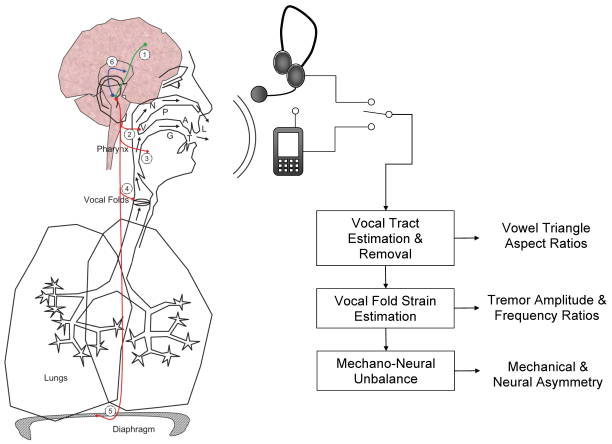

Figure 3 Model inversion to estimate vocal tract, biomechanical and neurological parameters from voice.

This makes the biomechanical parameters by far the most interesting parameter set to assess the dysphonic conditions of a patient in relation with a specific etiology. The biomechanical parameters are defined from a 2-mass model of the vocal folds [7] as the one depicted in Figure 4. The template (a) illustrates the physiological structure of the vocal folds as a body composed by the *musculis vocalis*, and a cover or *lamina propria* and the conjunctive tissues in Reinke's space and the visco-elastic ligament giving support to the folds.

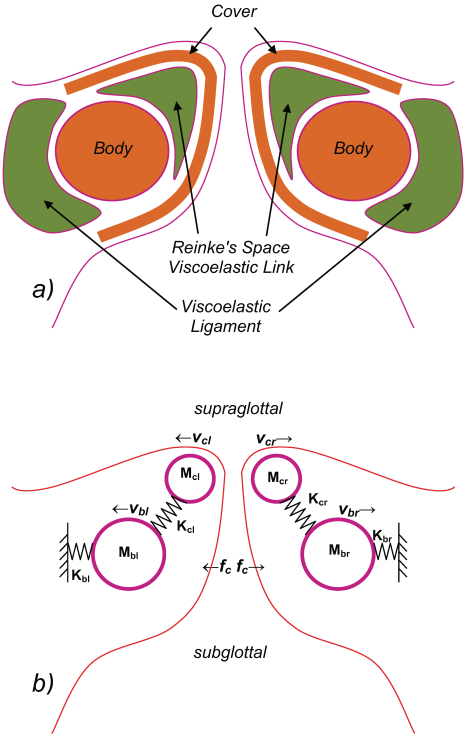

Figure 4 Vocal fold 2-mass biomechanical model assumed in G®E. a) Stuctural description of vocal folds. b) Model equivalent in masses and viscoelasticities.

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The biomechanical model in (b) shows that the massive structures of the cover and Reinke's space have been included in the cover masses M_{cl} and M_{cr} for the left (l) and right (r) vocal folds. Masses M_{bl} and M_{br} account for the body and visco-elastic ligaments. It must be kept in mind that these masses are not tissular distributed masses, but dynamic point-like ones (a dynamic mass is simply a relation between force and acceleration, and is only a fraction of the tissular mass). Visco-elastic parameters K_{cl} and K_{cr} explain the relations between tissue compression and acting forces on the cover and Reinke's space. Parameters K_{bl} and K_{br} bear also the same meaning regarding the body and visco-elastic ligament. Visco-elastic parameters account for the behavior of the conjunctive tissues under compression as well as for the contribution of the *lamina propria* and *musculus vocalis* along its length due to the stretching forced by the crico-arytenoid muscles on the vocal folds during adduction and contact phases. Besides, the visco-elastic parameter encloses also the losses, which account for energy dissipation in heat, radiation and turbulence. Having this description in mind, the subset of biomechanical parameters is composed of the following correlates:

- Parameter 35: Dynamic mass associated to the body, as an average of M_{bl} and M_{br}.
- Parameter 37: Stiffness parameter associated to the body averaged on the left and right folds (K_{bl} and K_{br}).
- Parameter 38: Unbalance of dynamic body mass per each two neighbor cycles.
- Parameter 40: Unbalance of body stiffness per each two neighbor cycles.
- Parameter 41: Dynamic mass associated to the cover averaged on the left and right folds (M_{cl} and M_{cr}).
- Parameter 43: Stiffness parameter associated to the cover averaged on the left and right folds (K_{cl} and K_{cr}).
- Parameter 44: Unbalance of dynamic cover masses per each two neighbor cycles.
- Parameter 46: Unbalance of cover stiffness per each two neighbor cycles.

The estimation of the above parameters is carried out by inverting the 2-mass model in Figure 4 in the spectral domain as described in [1]. Examples of estimates from each parameter on a balanced database of 50 male and 50 female normophonic speakers collected and evaluated by endoscopy at Hospital Universitario Gregorio Marañón are given in Figure 5 and Figure 6. It may be seen that parameter 35 (body mass) is differentially distributed for males and for females, being larger for males, as expected. The distribution for parameter 37 (body stiffness) is distributed differentially but reciprocally (larger for females than for males), as well as parameter 43 (cover stiffness). On the other hand, cover masses (parameter 41) do not show gender differences. Regarding unbalance parameters (38, 40, 44 and 46) all the distributions concentrate towards low values with a few exceptions (outliers). This means that large unbalance may be an indication of dysphonic or pathological behavior. The irregular behavior of these parameters bears a clear semantics on possible dysphonia of pathological etiology.

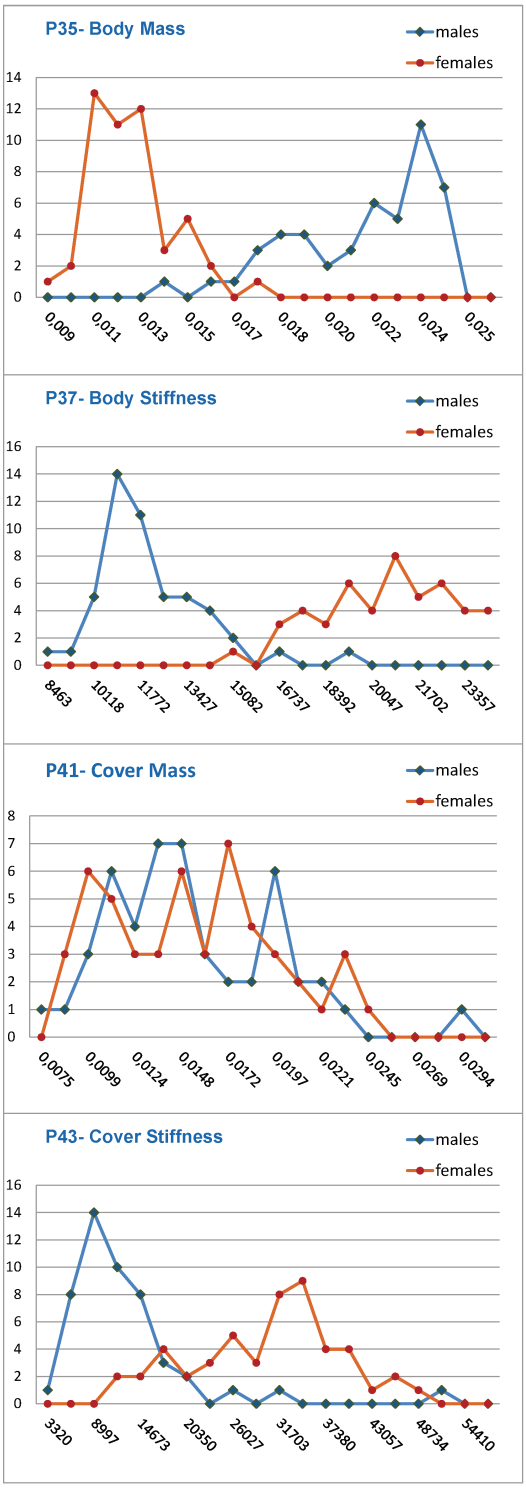

Figure 5 Histograms of the biomechanical parameters (dynamic masses and stifnesses) for normophonic male and female datasets. In abscisae masses are given in g, stifnesses given in $g.s^{-2}$. Ordinates give number of subjects.

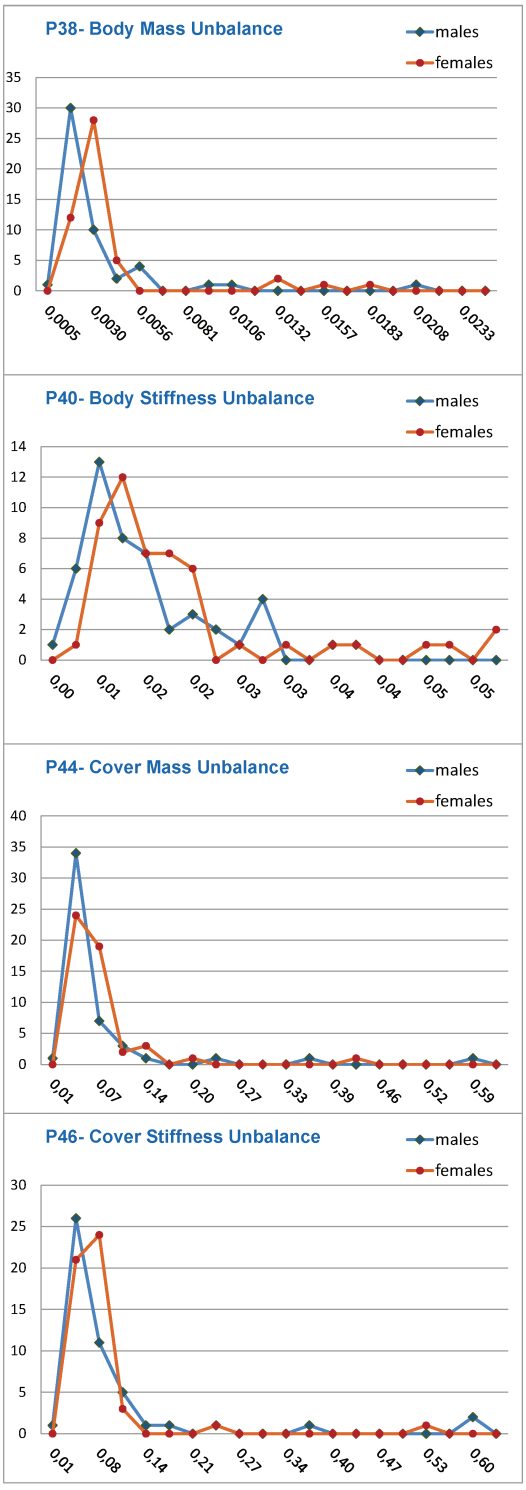

Figure 6 Histograms of the biomechanical parameter unbalance for nomophonic male and female datasets (given in rel. values). Abscisae give unbalance relative to unity (for instance, 0.01 is 1%). Ordinates give number of subjects.

Accordingly to a full study of specific pathologic cases treated at Hospital Universitario Gregorio Marañón the most frequent behaviors may be classified within one of the following groups:

- If body mass and stiffness are significantly increased above normality in a given case, this may be taken as an indication to a possible pathology affecting the vocal fold body. For instance, non-reciprocal body over-stiffness may point out to vocal fold paresis in one or both vocal folds. On the contrary, an increment in the body stiffness accompanied by a reciprocal reduction of mass or vice-versa may point out to a modal variation in pitch as in prosodic intonation or in singing.
- An increment in the cover stiffness not accompanied by a reciprocal reduction of mass most probably will point out to lesions affecting the *lamina propria* or Reinke's space, especially if an increment in mass is also observed. For instance, non-reciprocal over-stiffness in the cover may be a clear indication that a lesion (nodules, polyps, cysts, or unilateral paresis) may be under development or already installed affecting the cover and possibly Reinke's space.
- An unbalance, expressed mainly in the body stiffness may point out also to unilateral or asymmetric vocal fold paresis.
- An unbalance in the fold cover may be associated with unilateral lesions affecting the cover or Reinke´s space (polyps, cysts).

The statistics of the biomechanical parameters for the normophonic sets described have been incorporated into G®E. The package is embedded into a Graphic User Interface (see Figure 7) as the application BioMet®Phon, designed for use in Voice Quality Analysis by Laryngologists or Speech Therapists. The GUI is rather simple: a new voice recording, analysis and its automatic report in Adobe®pdf, and Excel® may be generated in less than 10 s by three button clicks. The GUI allows the handling of a small patient's database. Once a patient is selected either a new recording may be obtained and analyzed or an old one may be processed. A sketch of the glottal source is presented in the upper right window of Figure 7.

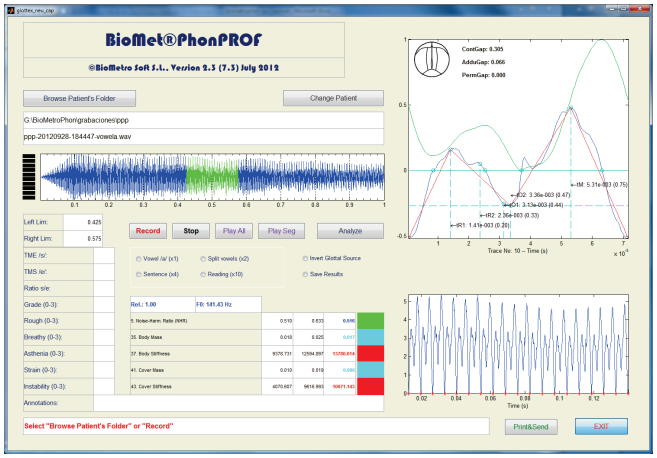

Figure 7 GUI of BioMet®Phon.

A set of five selected parameters are presented in comparative windows (mid bottom) showing normality limits and ticketing the results as green (within normality), blue (under normality) or red (above normality). This code allows a fast semantic interpretation by the laryngologist or speech therapist.

III. PRE-POST-TREATMENT STUDY CASES

In what follows, a typical study case will show how BioMet®Phon may be used in assessing voice quality improvement after treatment. A specific case of pre-treatment compared with three post-treatment inspections are presented and discussed. It corresponds to a female patient 65 years-old who suffered from post-Thyroidectomic Vocal Fold Recurrent Paralysis (pTVFRP). The treatment consisted in infiltration of fat from the patient in the vocal folds. The patient's voice was examined for almost a year (2011) once before the intervention (pre: March) and three times after the intervention (post1: May; post2: September; and post3: November). The behavior of twelve parameters from the set of 65 is plotted in Figure 8. The 8 most relevant parameters for dysphonic voice evaluation are listed in TABLE I. Classically *2-Jitter*, *3-Shimmer* and *5-HNR* are parameters used very often in voice quality evaluation, as they are known to be well correlated with dysphonic voice [6]. Nevertheless these parameters lack structural semantics, as they do not allow producing hypotheses on possible etiological circumstances. On the contrary biomechanical parameters as the subset left (*38-Body Mass Unbalance*, *40-Body Stiffness Unbalance*, *41-Cover Mass*, *43-Cover Stiffness*, *44-Cover Mass Unbalance* and *45-Cover Stiffness Unbalance*) allow casting hypotheses on possible etiological implications based on their specific definitions.

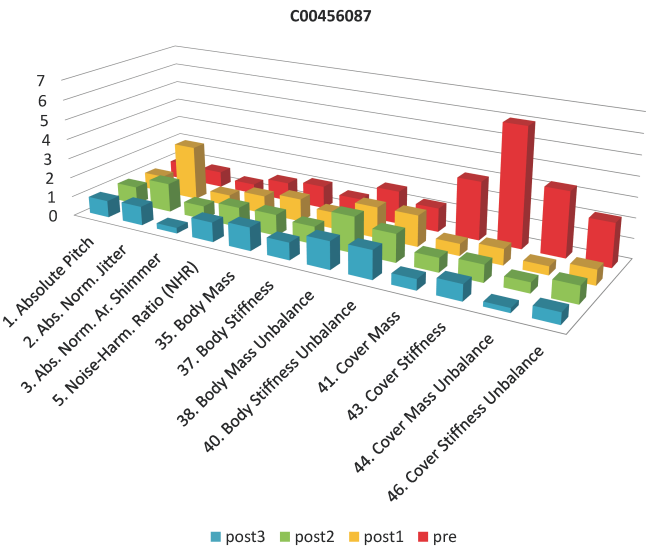

Figure 8 Results of pre- and post-treatment for a specific case of pTVFRP normalized on the reference female set medians.

TABLE I. RESULTS OF PRE- AND POST-TREATMENT FOR A SPECIFIC CASE (PTVFRP) ON A SET OF SELECTED PARAMETERS.

Parameter	Pre	Post1	Post2	Post3
2-Jitter (%)	2.8	5.4	0.6	0.6
3-Shimmer (%)	10.5	3.3	1.5	1.0
38-Body M. Unb. (%)	4	21	<1	<1
40-Body S. Unb. (%)	10	30	1	1
41-Cover M. (mg)	26	8	8	6
43-Cover S. ($g.s^{-2}$)	91,746	24,228	14,175	11,808
44-Cover M. Unb. (%)	47	14	2	1
46-Cover S. Unb. (%)	43	26	3	3

It may be seen that jitter (2) correlates more with fold body unbalance (38, 40), whereas shimmer (3) is more related to cover parameters (41, 43, 44, 46). As jitter and body unbalance suffer an increment after intervention (in *post1* relative to *pre*) contrary to shimmer and cover parameters, it seems that the intervention affected the fold body in a different way than to the cover. It is like if initially after treatment the fold body suffered a regression to pathological behavior, which disappeared later (possible after fat assimilation by surrounding fold tissues). This observation demonstrates the superior introspective power of the biomechanical parameters compared to classical acoustical ones regarding physiological semantics.

IV. VALIDATION RESULTS AND DISCUSSION

The ultimate objective of an application to evaluate voice quality is to produce accurate results in detecting dysphonic voice from normal. Therefore, a validation of the application was carried out using a database of 200 subjects collected at Hospital Universitario Gregorio Marañón divided into two subsets of 100 subjects equally balanced by gender, and these on their turn comprising half normophonic and half dysphonic subjects. Therefore, the set used in the study consisted in 50+50+50+50 subjects balanced by gender and voicing condition. The age span covered from 20 to 60 years, the medians in 35 for male and 34 for females. Sustained phonation emissions of vowel /a/ were recorded in three different sessions. Samples 200 ms long of each emission were used in the extraction of a set of 65 parameters for each phonation cycle. Estimations of medians (Q2), first (Q1) and third quartiles (Q3) were used as distribution descriptors for each emission. Medians from each emission were used in the study, to evaluate the probability of a given patient observation $\mathbf{x_q}$ being associated to the respective gender normophonic set:

$$\Pr(\mathbf{x_q} \mid \mathbf{\Gamma_m}) = \frac{1}{(2\pi)^{P/2}\left|\mathbf{C_m}\right|^{1/2}} \iiint_{(-\infty,\mathbf{x_q})} e^{-1/2(\zeta-\chi_m)^T \mathbf{C_m^{-1}}(\zeta-\chi_m)} \mathbf{d}\zeta$$
$$\Pr(\mathbf{x_q} \mid \mathbf{\Gamma_f}) = \frac{1}{(2\pi)^{P/2}\left|\mathbf{C_f}\right|^{1/2}} \iiint_{(-\infty,\mathbf{x_q})} e^{-1/2(\zeta-\chi_f)^T \mathbf{C_f^{-1}}(\zeta-\chi_f)} \mathbf{d}\zeta \quad (1)$$

where $\mathbf{x_q}$ is the *P*-dimensional feature vector for subject *q*, and $\mathbf{\Gamma_m}=\{\mathbf{C_m}, \chi_m\}$ and $\mathbf{\Gamma_f}=\{\mathbf{C_f}, \chi_f\}$ are the respective Gaussian models for male (m) female (f) datasets. The means χ_m and χ_f and the Covariance Matrices $\mathbf{C_m}$ and $\mathbf{C_f}$ are estimated on each gender set. The likelihood of each subject given a label *v* as normophonic (*n*) or dysphonic (*d*) relative to his/her gender set will be compared to a certain threshold θ:

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$$\lambda_m(\mathbf{x_q}) = \log\frac{\Pr(\mathbf{x_q} \mid \mathbf{\Gamma_m})}{1 - \Pr(\mathbf{x_q} \mid \mathbf{\Gamma_m})}; \quad \nu_m(\mathbf{x_q}) = \begin{cases} n & if \quad \lambda_m \geq \theta \\ d & if \quad \lambda_m < \theta \end{cases}$$
$$\lambda_f(\mathbf{x_q}) = \log\frac{\Pr(\mathbf{x_q} \mid \mathbf{\Gamma_f})}{1 - \Pr(\mathbf{x_q} \mid \mathbf{\Gamma_f})}; \quad \nu_f(\mathbf{x_q}) = \begin{cases} n & if \quad \lambda_f \geq \theta \\ d & if \quad \lambda_f < \theta \end{cases} \qquad (2)$$

The database was processed using a ten-time cross-validation procedure replacing 5 subjects each time out of 50 within a ten-time scale, thus producing 1000 scores per gender set. The results are plotted in Figure 9 and Figure 10 for each respective gender set as Tippet plots, ROC (Receiver Operator Characteristic), Reliability Functions and DET (Detection-Error Trade-off) curves [8].

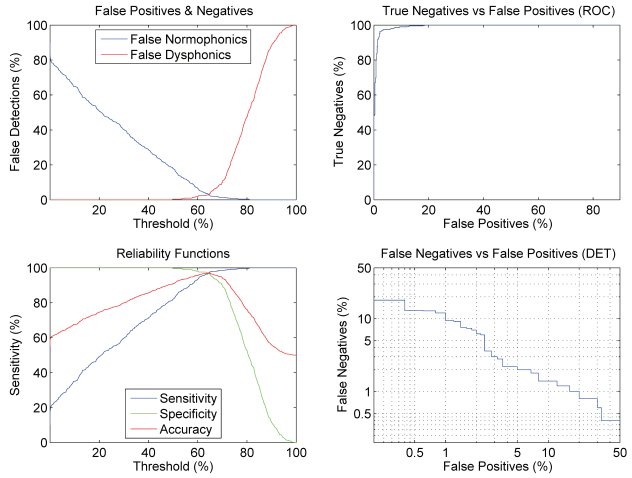

Figure 9 Validation results for male normophonic and dysphonic sets. Top left: Complementary Tippett plots. Top right: ROC curves. Bottom left: Sensitivity, Specificity and Accuracy curves. Bottom right: Equivalent DET plot.

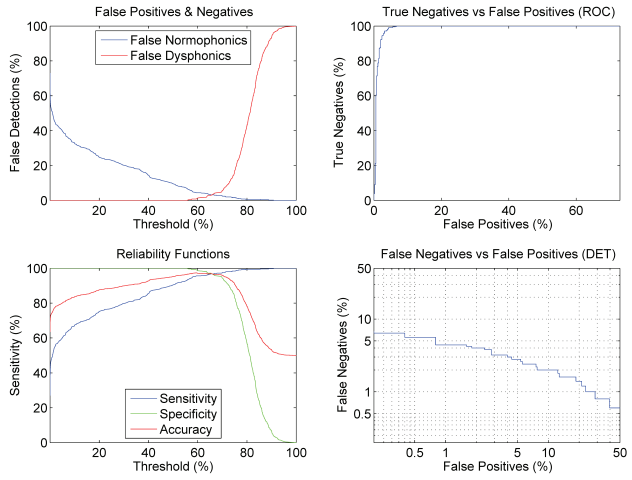

Figure 10 Respective validation results for the female sets (see Figure 9).

The results show that BioMet®Phon provides fairly similar detection capabilities for both genders. Tippett plots (upper left) show the evolution of false positive and negative detections as a function of the threshold θ. DET curves (lower right) scaled in logarithmic axes offer a clear view of the Equal Error Rate point (EER), which is the point of the curve where the rate of False Positives and Negatives equal. This can be taken as a merit factor, which is around 2.7% for the male set and 3.2% for the female set. These curves allow considering different detection scenarios. For instance, to reduce the rate of False Negatives to 1% in the male set a rate of 15% False Positives should be admitted. As the emission of a False Negative in the detection of dysphonic voice is far more critical that the emission of a False Positive, it should be admitted that around 1 out of 6 subjects with normal voice should be labeled in exchange of less than 1 out of 100 dysphonic being labeled as normophonics.

V. CONCLUSIONS AND FUTURE WORK

The present paper introduced a software package for the extraction of semantic information from the glottal source obtained from phonation has been introduced under the name of Glottal®Engine. Based on this technology, a specific GUI to be applied in voice quality analysis in the clinics has been developed under the name of BioMet®Phon. The validation of this application for laryngological and speech therapeutic purposes has been tested on specific study cases, one of which has been discussed to a certain extent. Data from the validation tests have also been presented and discussed, showing the capabilities of the technology in the detection of dysphonia and in hypothesizing its possible causes. Future work foresees the extension of this methodology to neurological disease monitoring and emotional characterization from voiced speech.

ACKNOWLEDGMENTS

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Automatic Heart Sound Analysis Module Based on Stockwell Transform

Applied on Auto-Diagnosis and Telemedicine Applications

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***Abstract*—The aim of this paper is to present an automatic heart sound analysis method which can be used for auto-diagnosis and telemedicine applications. One of the first and most important phases in the analysis of heart sounds, is the segmentation process which partitions the sound into cardiac cycles and further into S1 (first heart sound), systole, S2 (second heart sound) and diastole. The heart sounds (S1 and S2) are localized by applying the Shannon energy of the local spectrum calculated by the S-Transform. Then, to distinguish between the first and the second heart sound, a feature extraction method based on S-Transform is also presented. The methods are evaluated on a dataset of 80 subjects, including 40 patients with cardiac pathologies sounds.**

Keywords-component; Time-Frequency, S-Transform, Heart Sounds, Auto-Diagnosis.

I. INTRODUCTION

The advancement of technology has paved the way for signal processing methods to be implemented and applied in many simple tools useful in everyday life. This is most notable in the medical technology field where contributions involving the intelligent applications have boosted the quality of diagnosis. Proposing an objective signal processing methods able to extract relevant information from biosignals is a great challenge in telemedicine and auto-diagnosis fields. For the cardiac system, many signals can be treated and monitored; ElectroCardioGram (ECG), PhonoCardioGram (PCG), Echo/Doppler and pressure monitor.

The interest of this paper is the PCG signal. PCG and auscultation are noninvasive, low-cost and accurate for diagnosing some heart diseases. The PCG signal confirms, and mostly, refines the auscultation data and provides further information about the acoustic activity concerning the chronology of the pathological signs in the cardiac cycle, by locating them with respect to the normal heart sounds. The cardiac sounds are by definition non-stationary signals, and are located within the low frequency range, approximately between 10 and 750 Hz. The analysis of the cardiac sounds, solely based on the human ear, remains insufficient for a reliable diagnosis of cardiac pathologies, and for a clinician to obtain all the qualitative and quantitative information about cardiac activity especially in the field of time intervals. Information, such as the temporal localization of the heart sounds, the number of their internal components, their frequency content, and the significance of diastolic and systolic murmurs, could all be studied directly on the PCG signal. In order to recognize and classify cardiovascular pathologies, advanced methods and techniques of signal processing and artificial intelligence will be used.

For that, different approaches could be considered for improve the electronic stethoscope:

- Tool with embedded autonomous analysis, simple for home use by the general public for the purpose of auto-diagnosis, monitoring and warning in case of necessity.
- Tool with sophisticated analysis (coupled to a PC, Bluetooth link) for the use of professionals in order to make an in-depth medical diagnosis and to train the medical students.

Whatever the approach, one of the first and most important phases in the analysis of heart sounds, is the segmentation of heart sounds. Heart sound segmentation partitions the PCG signals into cardiac cycles and further into S1 (first heart sound), systole, S2 (second heart sound) and diastole. Identification of the two phases of the cardiac cycle and of the heart sounds with robust differentiation between S1 and S2 even in the presence of additional heart sounds and/or murmurs is a first step in this challenge. Then there is a need to measure accurately S1 and S2 allowing the progression to automatic diagnosis of heart murmurs with the distinction of ejection and regurgitation murmurs.

This phase of autonomous detection, without the help of ECG is based on signal processing tools such as: Shannon energy [1], Hilbert Transform [2], high order statistics [3], hidden Markov model [4], etc.

In this study, we present a new module for heart sounds analysis that aims to segment automatically the heart sound. The goal of this study is to develop a generic tool, suitable for clinical and home monitoring use, robust to noise, and applicable to diverse pathological and normal heart sound signals without the necessity of any previous information about the subject. The proposed module can be divided into two main blocks: localization of heart sounds and classification block to distinguish between S1 and S2.

The proposed methods are evaluated based on a database of 80 subjects (40 pathologic). This study is made under the

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control of an experienced cardiologist, in with the aim of validating the results of each method.

This paper is organized as follows: Section 2 describes the data base used in this study. It is followed by the Section 3 which describes the different methods proposed for the module (localization and classification). The results and discussion are presented in Section 4 and Section 5 gives the future research and the conclusion.

II. DATA BASE

Several factors affect the quality of the acquired signal, above all, the type of the electronic stethoscope, its mode of use, the patient's position during auscultation, and the surrounding noise. According to the cardiologist's experience, it is preferable that the signals remain unrefined; filtration will only be applied subsequently in the purpose of signal analysis. For this reason we used prototype stethoscopes produced by Infral Corporation, and comprising an acoustic chamber in which a sound sensor is inserted. Electronics of signal conditioning and amplification are inserted in a case along with a Bluetooth standard communication module.

Different cardiologists equipped with a prototype electronic stethoscope have contributed to a campaign of measurements in the Hospital of Strasbourg. In parallel, two prototypes have dedicated to the MARS500 project promoted by ESA, in order to collect signals form 6 volunteers (astronauts). The use of prototype electronic stethoscopes by different cardiologists makes the database rich in terms of qualitative diversity of collected sounds, which in turn makes the heart sounds localization more realistic.

The sounds are recorded with 16 bits accuracy and 8000Hz sampling frequency in a wave format, using the software "Stetho" developed under Alcatel-Lucent license.

The dataset contains 80 subjects, including 40 cardiac pathologies sounds which contain different systolic murmurs. The length of each sound is 8 seconds.

III. METHOD

A. Preprocessing

At first, the original signal is decimated by factor 4 from 8000 Hz to 2000 Hz sampling frequency and then the signal is filtered by a high-pass filter with cut-off frequency of 30 Hz, to eliminate the noise collected by the prototype stethoscope. The filtered signal is refiltered in the reverse direction so that there is no time delay in the resulting signal. Then, the Normalization is applied by setting the variance of the signal to a value of 1. The resulting signal is expressed by:

$$x_{norm}(t) = x(t) / \max(x(t)) \quad (1)$$

B. Localization of heart sounds

The localization algorithms operating on PCG data try to emphasize heart sound occurrences with an initial transformation that can be classified into three main categories: frequency based transformation, morphological transformations and complexity based transformations [3]. The transformation try to maximize the distance between the heart sounds and the background noise, and the result is smoothed and tresholded in order to apply a peak detector algorithm. We note here, that the main goal of heart sound localization is to locate the first and the second heart sounds but without distinguishing the two from each other. The boundaries of the heart sounds are determined by the first local minima before and after the located sound.

The results were visually inspected by a cardiologist and erroneously extracted heart sounds were excluded from the study.

1) SRBF localization method

We proposed the RBF method as a transformation to emphasize heart sounds and it was shown to have a good performance on low level noise signals [5]. However, in the presence of high level of noise, the performance of the RBF method decreases. This was not surprising because the method operates directly on the heart sound without any feature extraction step. To deal with this problem, we proposed a method for heart sounds localization named SRBF [6]. This method aims at extracting the envelope of the signal by applying the features extracted from the S-Transform matrix of the heart sound signal to the radial basis function (RBF) neural network. Compared with other existing methods for heart sounds localization, SRBF was shown to have a significant enhancement in term of sensitivity and positive predictive value and the robustness of this method was shown against additive white Gaussian noise.

We will briefly explain the different steps of the SRBF method:

1. The S-Transform of the heart sound is calculated. A frequency range of 0-100 Hz was used to cover the main frequency band of S1 and S2 and to avoid murmurs which have in general a spectral energy above the frequency of 100 Hz [7].
2. A sliding window of 50 ms (so 100 samples) was operated on the S-matrix and an overlap of 75% was chosen. The feature extraction is done by applying some standard statistical techniques and transformations like Root Mean Square (RMS), the maximum and the average of each column of the S-matrix. Each array (100 samples) was divided into 5 segments and the mean of calculated features of each segment was calculated and taken as input to the classifier. So for each step we have a 100 by 100 matrix which gives 15 descriptors.
3. A RBF neural network classifier is used and trained on two heart sounds samples (S1 and S2) and two no heart

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sound samples (systole, diastole) selected randomly from the database. The target is fixed to 1 for S1 or S2 and 0 for the other components. So the envelope of the signal is constructed by the output of the RBF neural network.

2) SSE localization method

A new method for the localization of heart sounds is proposed in this study (SSE). It uses the S-matrix like the SRBF method (0-100 Hz) and it calculates the Shannon Energy (SE) of the local spectrum calculated by the S-transform for each sample of the signal *x(t)*. Then, the extracted envelope is smoothed by applying an average filter (Figure 1).

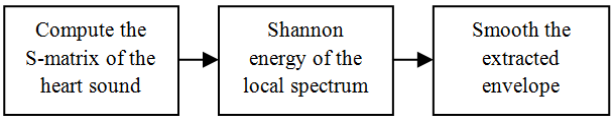

Figure 1. Block Diagram of SSE Method

The S-Transform proposed in [8], of a time series *x(t)* is:

$$S(\tau, f) = \int_{-\infty}^{\infty} x(t) w(\tau - t) e^{-2\pi i f t} dt \qquad (2)$$

Where the window function $w(\tau-t)$ is chosen as:

$$w(t, f) = \frac{1}{\sigma(f)\sqrt{2\pi}} e^{\frac{-t}{2\sigma f^2}} \qquad (1)$$

And $\sigma(f)$ is a function of frequency as:

$$\sigma(f) = \frac{1}{|f|} \qquad (4)$$

The proposed method calculates the Shannon energy of each the local spectrum as follows:

$$SSE(x_i) = -\int_{-\infty}^{+\infty} S(\tau, f)^2 \log(S(\tau, f)^2) df \qquad (5)$$

Each column of the S-matrix represents the local frequency at a specific sample. The advantage of the Shannon energy transformation is its capacity to emphasize the medium intensities and to attenuate low intensities of the signal which represents the local spectrum in the case the SSE method. The main difference between the SSE and the SRBF method is the training phase needed for the RBF module. The RBF neural network in the SRBF method can be considered as a non-linear filter which is replaced with a simple average filter in the SSE method.

C. Distinguishing S1 and S2

Most of the existing methods for the segmentation of heart sounds use the feature of systole and diastole duration to classify the first heart sound (S1) and the second heart sound (S2) [1,9,10]. These time intervals can become problematic and useless in several clinical real life settings which are particularly represented by severe tachycardia or in tachyarrhythmia (Figure 2).

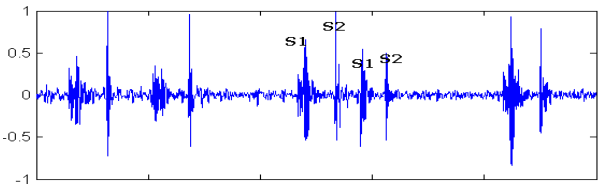

Figure 2. Example of an arrhythmic subject.

Consequently with the objective of development of a robust generic module for heart sound segmentation, we present in this paper a feature extraction methods based on the Singular Value Decomposition (SVD) technique applied on the S-matrix, to classify S1 and S2.

1) Feature extraction based on the S-Transform

The SVD is a powerful tool that provides a compact matrix or compact significant information about single signal. Different ways exist in the literature aims to represent the time-frequency matrix in a compact manner by using the SVD technique. In [11] authors extracted the eigenvalues of the time-frequency matrix. In [12] authors extended the method to also incorporate information from the eigenvectors to classify EEG seizures. In [13] the last technique is applied on the S-matrix in the aim to extract features for systolic heart murmur classification. Following this approach, this study proposes a feature extraction method for S1 and S2 classification.

The time-frequency analysis is performed by the S-Transform. The S-matrix Si of the extracted heart sound Hi is decomposed by the SVD technique as follows:

$$S_i = UDV^T \qquad (6)$$

Where $U(M\times M)$ and $V(N\times N)$ are orthonormal matrices so their squared elements can be considered as density function[12], and $D(M\times N)$ is a diagonal matrix of singular values. The columns of the orthonormal matrices U and V are called the left and right eigenvectors which contains in this case the time and frequency domain information, respectively. The eigenvectors related to the largest singular values contain more information about the structure of the signal.

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Based on our experience, in this study, the first left eigenvector and the first right eigenvector that correspond to the largest singular values are used for the feature extraction process. The histogram (10 bins) for each related distribution function is calculated based on the density function. Five feature vectors obtained by this method are tested in the classification process; the eigentime histogram vector U_1 (T-Features), the eigenfrequency histogram vector V_1 (F-Features), the singular values vector D_1 (SV Features) and the time-frequency vector $U_1\&V_1$ (TF Features). All vectors have a length of 10 features except the time-frequency vector that has a length of 20.

IV. RESULTS AND DISCUSSION

A. *Localization Methods*

The performance of the SBRF and the SSE methods was measured as the methods capacity to locate S1 and S2 correctly. It was measured by sensitivity and positive predictive value:

$$Sensitivity = TP/(TP + FN) \quad (7)$$

And positive predictive value:

$$PPV = TP/(TP + FP) \quad (8)$$

A sound is true positive (TP) if it is correctly located, all others detected sounds are considered as false positive (FP) and all missed sounds are considered as false negative (FN).

TABLE I. SENSITIVITY AND POSITIVE PREDICTIVE VALUES FOR THE SRBF AND SSE METHODS APPLIED ON THE CLINICAL SOUNDS SET WITHOUT AND WITH ADDITIVE GAUSSIAN NOISE.

Method	Sensitivity	PPV	Sensitivity (Noise)	PPV (Noise)
SRBF	92%	98%	91%	93%
SSE	96%	95%	93%	94%

Results in Table 1 show that SRBF method reaches a higher PPV (98%) than the SSE method for the clinical signals without any additive noise. However, SSE reaches a higher sensitivity (96%) than the SRBF method (92%). The supervised approach performed by the RBF block in the SRBF method makes the extracted envelope more discriminative between the different parts of the signal than the unsupervised SSE method. Therefore, it is not surprising that the number of false detected sounds in the SRBF method is lower than the SSE method, which also explains the PPV results. The same reasons can also account for the false negative alarms which are higher in the SRBF method than the SSE method and which gives a higher sensitivity to the SSE method. In the presence of an additive white Gaussian noise, the performance of the SSE method is better with 93% sensitivity and 94% PPV. The robustness of both methods against noise is very significant. This is due to the advantage of performing a time-frequency analysis which makes methods more robust against noise. Figure 3 shows the envelopes extracted by the SSE and the SRBF method that correspond to a pathologic sound with a systolic murmur. Figure 4 shows the robustness of each method against white additive noise.

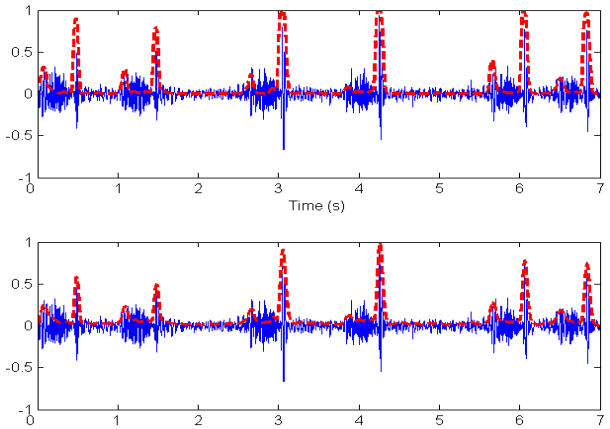

Figure 3. Envelope extraction (dashed lines) for a signal with systolic murmur, (top) SRBF envelope, (bottom) SSE envelope

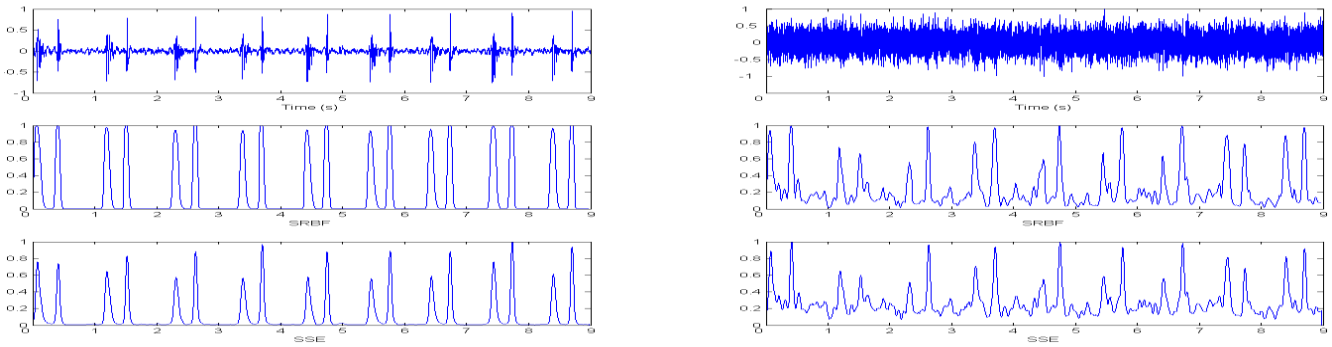

Figure 4. (top) Envelope extraction for two normal PCG signal without and with additive Gaussian noise, (middle) their SRBF envelopes, (bottom) their SSE envelopes.

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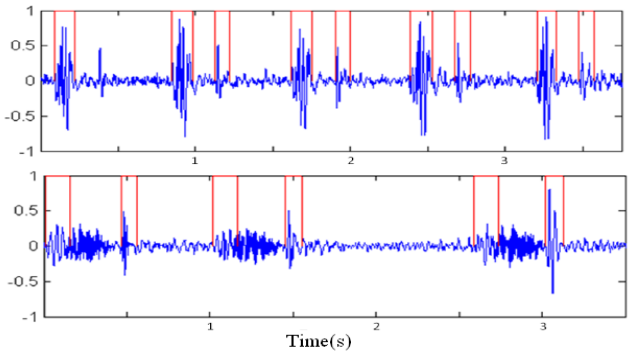

Figure 5. Segmentation module applied on normal heart sound (top) and pathological heart sound (bottom).

B. *Classification of S1and S2*

The heart sounds are segmented (Figure 5) and the results were visually inspected by a cardiologist and erroneously extracted heart sounds were excluded from the study. The feature extraction process extracts a feature vector per extracted sound Si (S1 or S2) and each of these vectors is averaged across available extracted sounds from each subject. So from each subject in the database, we obtain one S1 feature vector and one S2 feature vector to use in the training and classification process.

TABLE II. SENSITIVITY AND SPECIFICITY FOR THE FIVE EXTRACTED FEATURE VECTORS EVALUATED BY A KNN CLASSIFIER.

KNN	T-Features	F-Features	SV Features	TF Features
Specificity	92%	81%	60%	**95%**
Sensitivity	92%	88%	65%	**97%**

A 3-Neirest Neighbor (KNN) classifier is used to evaluate the performance of the four feature vectors obtained by the two methods and the 5-fold approach is used for cross validation. The choice of KNN classifier was based on its simplicity of and its robustness to a noisy training data.

The time domain feature vector reaches 92% classification rate, however, the frequency feature vector reaches 85% classification rate (81% sensitivity and 88% specificity). The Time-Frequency vector (TF Features) reaches the higher classification rate with 95% sensitivity and 97% specificity. The singular values are almost indistinguishable from each other and it is shown by the low classification rate for the SV features (Table 2).

In most cases seen in the medical field, S2 has a higher frequency than S1. This is due to the fact that S2 is the heart sound associated with the closure of the aortic valve in a context of high left ventricular pressure, the mitral closing occurring at low left ventricular pressure (S1). However, this criterion cannot be generalized on all real life cases because some medical conditions are characterized by S2 frequency content lower than S1 frequency content. Hence, the importance of time-frequency features approach, especially in a generic module, which can explain the high performance obtained with the TF and FV features vectors.

V. FUTURE RESEARCH AND CONCLUSION

A. *Classification of heart sounds*

A time-frequency based features is proposed and validated to distinguish with S1 and S2. However, the classification of normal and pathological heart sounds is the final objective of any heart sounds auto-diagnosis framework. The classification rate will depend first on the segmentation results, which was the main objective of this study. Then classic steps of feature extraction, feature selection, designing and testing classification systems, will be needed to complete the classification process

B. *Real time application*

The main objective of this study was to develop an auto diagnosis for various situations encountered in cardiology in real time. However, the S-Transform that can be considered as the heart of the proposed segmentation framework, suffers from a high computational burden. The implementation of a fast S-Transform algorithm on FPGA or GPU card will be necessary.

C. *Sociological and psychological aspect*

Introducing a smart stethoscope as a monitoring tool for home use, involves new problems related to sociological and psychological aspect of the user (patient). A smart stethoscope is a tool to facilitate the diagnosis process and to make it more objective and it will never replace the cardiologist and other advanced techniques of Cardiology. This should be taken into consideration in the deployment process in a telemedicine framework for example. The ergonomic aspect of the measuring instrument, the way to display the data and to transmit it, will be more than necessary elements to any future tool, simple for home use by the general public for the purpose of auto-diagnosis, monitoring and warning in case of necessity.

D. *Conclusion*

The proposed module is divided into two blocks: localization, and classification of heart sounds (S1 and S2). Several methods are proposed during this study:

- A heart sounds localization method based on the S-transform and Shannon energy is proposed and evaluated against white additive Gaussian noise.
- A feature extraction method based on Singular Value Decomposition (SVD) technique to distinguish between S1 and S2 are examined.

The main objective of this study was to present a robust and generic PCG segmentation method useful in real life conditions (clinical use, home care, professional use …). The methods in the proposed framework were evaluated on a real data (80 subjects) with different noise levels and they were validated by the cardiologist. More robustness tests against noisy signals, algorithms complexity, facility of

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implementation and more signals, would contribute to optimize the proposed module.

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SmartNursing - a mobile application to improve communication in home care

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***Abstract*—This paper presents SmartNursing system and discusses how increasing capabilities of smartphone could benefit employees in working environment. A SmartNursing system is developed for home nurses working environment to fulfil their needs. The solution helps to improve communication among nurses, provide customized information and increase work efficiency. Developed system consists of mobile application, web based server and database. This article discusses the solution SmartNursing from design to implementation.**

***Keywords*-home nursing; public health; mobile application; web server.**

I. INTRODUCTION

Domiciliary care is provided by licensed personnel who constantly visit patients at their home and assists with daily tasks, such like giving medicine, bathing and cleaning. Domiciliary care is recommended for elderly generation that needs special care. People that needs care prefer home environment over nursing home [1]. Home adaptation and assistive technology substitute traditional health care in medical institutions reduce the costs [2]. This fact confirms a growing need for caregivers for people living in home environment. Eurostat projections (Europop2010) reveal that, over the next 50 years, the number of elderly people will grow dramatically [3], consequently, it rises new needs for home nurses. Current problem is a lack of interest of working as a home nurse. This job is seen as hard and tiring, every 5th home-nurse is emotionally exhausted and stressed [4]. In order to satisfy increasing needs of licensed personnel and provide better service to elderly people, it is vital to focus on home nurses.

A. Analysis

This chapter discusses the potential users of the system i.e. nurses and their needs. The use case of home nurses in Frederiksberg municipality in Denmark is explored in order to identify requirements for the system [5]. Interviews with the project manager of Frederiksberg Hjemmepleje and conversations with the home nurses illustrate the fact that communication among colleagues, access of information relevant to work, process of planning and organizing daily work need to be improved.

Administration of home nurses work is done by their leader. The leader of nurses is responsible for coordination of care to elderly and the patients that are in need of domiciliary care. It could be transportation, house cleaning, personal hygiene, meals, and other health and wellness related activities. Also, the leader distributes responsibilities for the nurses, thus every nurse provides care to several patients and in that way each patient gets different nurses to visit. The leader also prepares daily reports with information as required. Daily meetings with employees have significant role in planning and organising work. Every morning before the actual work stars, all nurses gather to discuss work experiences, working schedules, substitutes and to get a paper with relevant information for the next visitation. This manner of work requires extra time and is inconvenient for the nurses.

Communication among nurses that is other than during the meetings, is complicated, especially when the nurse wants to contact her colleague, who visits the patient after. Currently, either calling, messaging manually or contacting a group leader is necessary in order to convey a message to another nurse. It requires too much time and concentration, therefore communication tends to be avoided. Same is the case with information handling, if a nurse needs any information then she has to carry papers, when she loses the paper then she loses the information.
Furthermore, the job is physical and requires full concentration, therefore nurses cannot be distracted by side tasks such like making notes during the shift. Intuitive, easy to use and communication tool is necessary in order to improve home nurses working environment work. We live in the world that is so connected, most of the nurses have smart phones, but very rarely have any mobile applications supporting their work. Usually, they need to report and document important accidents that have happened during their shift and they do that when they return to the office. In addition to this, different users document in different, often incompatible, ways that makes hard to keep consistency in overall documentation. Home-nurses need a system that could improve working environment and tackle the problems mentioned above.

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The idea that is evolved in this article is to create an innovative and well-designed application for smartphone considering the home nurses working environment, add different components and features that can improve communication and make daily work easier. After the introduction, this article is organized in this way: the survey of existing applications in the market is discussed in section II, and SmartNursing application is represented in sections III and IV, including modelling, design and implementation of application. Conclusion and suggestions for future work is covered in section V.

II. Related works

There are many existing applications for nursing. Almost every application is focusing on medical approach and in their applications they provides a drug guide (Rx:), diseases and disorders (Sx, Dx, Tx), diagnosing tools etc. But still it is hard to find smartphone applications for the home-nurses working environment. Some well known applications for nursing are described below:

A. Nursing Constellation Plus

This application is developed by Skyscape Inc. and is probably the most expensive application for nursing in apple / android market that costs $179.95. The application includes drug guide, and laboratory & diagnostic tests handbook. In technical words they have managed to bring the medical database into the smart devices. [6]

B. Abbo EMR

Abbo EMR is an electronic medial record program used for both patients and doctors. Doctors can dictate instructions, and a patient can listen it on his phone. In this application the target group is both patients and doctors. This application is developed by ZCO Corporation. [7]

C. Cell Trak

This application is made for home-care companies and includes a scheduler for the nurses, patient care plan, billing and pay role system. This application is made for those countries where home-care system is privatized for example USA. [8]

D. Intelligent home applications

In addition to mobile domain, intelligent home environment is an attractive subject for the research and development. For instance, INHOME project [9] introduces intelligent services at home (alarm-and-notification system, refrigerator), that control living environments so that enable independent living of elderly people at home and improve quality of life. AMIGO applications [10], such like Home Care and Safety, Home Information and Entertainment are based on home networking and connection among several devices, for example lighting system, mobile phones and PC. It has benefits in providing interoperability between services and devices and provides the users with communication that is independent from location and device. Furthermore, new studies focuses on grid technology that is necessary to provide high quality medical services in home environment[11] [12]. The grid is primarily targeted towards applications with high computing demands, that are used in hospital at home. There is still a need of applications and solutions for Home care. All the above mentioned applications are created for a country where the working environment is different from Nordic countries. The drugs guide vary from country to country, thus such applications cannot be used in Nordic countries, in our case Denmark. Existing solutions, that target intelligent home environment, usually requires additional equipment pieces, sensors to be integrated into home environment. This paper focuses on the home nursing and utilizes smart phone capabilities to improve nursing services and daily nurses' work. The application automates common tasks, suggest better work organization and provides unique functionality to communicate by voice messages.

III. Design

In the previous chapter the brief overview of existing applications is given. This chapter is focused on our developed SmartNursing system. The design, structure, different components and their functionalities are discussed. While designing application, consideration is showed for user experience and suitable interface. Figure 1 is a use-case diagram for SmartNursing system. Diagram is visualizing the users that are interacting with the system and the functionalities they perform. All functionalities are represented subsequently.

A. Profiler

Profiler is a functionality that is aware of the application's context. System starts with a profile based on context information. User can always change the profile if it does not suits the context. Purpose of the profiler is to provide customization. The user can select the settings for every profile and when a profile is changed the settings will be fetched from the database and applied. The user (home nurse) could make settings for specific working environment, for example, sound settings as silent or vibrate. Contrary the settings will be different for non working environment, such like home usage. In such way the functionalities are customized. Internal database is used to manage the profiles. Smartphone sensors fetch context information i.e. data from external system and based on context change the profiles.
User status is very important for the home nurses to share information about availability of each nurse. A status of a person provides also an abstract glimpse of the situation of an employee before someone contacts. The idea is to embed the status of each contact in the address-book in order to provide an overview before someone actually contacts someone.

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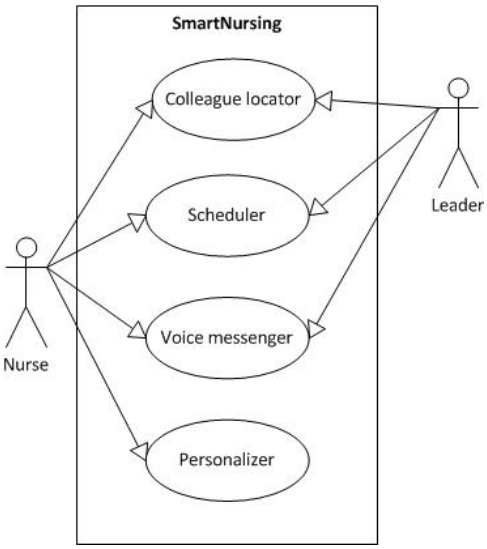

Figure 1. System use-case diagram

B. Voice messenger

Voice messenger is a functionality proposed to make easy communication among nurses and keep track of patient's history. Nurses can record a voice message from her mobile device and repeat the process again until the she is sure that the correct message is recorded. Then the nurse saves the message and it is saved on the home-nursing web-server. When the nurse from another shift arrives she can then listen to the recorded message and process it. Voice messenger is beneficial for work organisation purpose, because all messages are available for the user accessing the system with web interface. Leaders are able to listen to the messages and add important information in the patients history, so that it could reach the nurses as information about the patient. This functionality brings value preposition in saving time, offering better care of a patient, and improving communication among nurses. In order to avoid the nurses spending less time with the patients than they have to and using the work time doing their personal tasks, the application asks the nurse to check-in when she arrives at the patient's home and check-out when she leaves. Figure 2 shows the overview of voice messenger. This diagram represents the functions that a user can perform in this functionality. For example a nurse can record a message and upload it to the server, so that her colleague could listen that message.

C. Colleague locator

Colleague locator is a functionality to display the colleagues of the nurse in a list format or a map view. On selecting a specific colleague it is possible to see the further details of a selected colleague like contact information. The purpose of this functionality is to locate the colleagues either by viewing their details and calling them or by viewing them

Figure 2. Oveview of voice messenger functionality

on maps. On user request the system will fetch the contact list from the web-server and display the list to the nurse. Further she can click on any contact to make a call. In case of viewing the colleagues on a map, the application gets the coordinates of all the colleagues from the web-server and displays them using Google Maps API.

D. Scheduler

Scheduler could be used to contain information about the meetings, and events that a nurse has to attend during the day. Smartphone automatically fetches the schedule from the web-sever, tasks are saved in calendar as events and displayed in the day scheduler. The functionality is beneficial for the nurse, because she could prepared for the work before she actually starts the work. Group leader of the nurses is responsible to create of all the nurses in her group. Leader could access the system using web interface and she creates a schedule. On the smartphone application the nurse can check her schedule and get details of a patient who is in the list. Nurse can see a schedule of the specific date, that is created on the server. By default the system will show the schedule of current date.

E. User interface design

The application was designed applying Tracy Leonard all times rule of design that encourages the developers to remember personal experiences in order to evaluate design of applications and choose the best ones to be used as design guidelines [13]. Well-designed applications such like

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Evernote, Twitter, and Foursquare etc. have interfaces that provides desirable user experience, therefore for inspiration we have employed some features from their design.
In the past software was designed regardless of the usability issues, so the user has to adapt the system somehow. This design approach is not appropriate today because the system must adapt to the user. That is why design criteria for mobile applications are so important. We have followed 5 steps principle to design the application [13]. These five steps include navigation, information visualisation, on screen interaction, notifications and responsiveness as well as emotion and expression. Subsequently, all of them are described in this section.

IV. IMPLEMENTATION

This section represents architecture of implemented system and technologies that were chosen for implementation. The system provides two user interfaces: one is for smartphone application and other one for web based interaction with a server. Smartphone interface is developed in android platform using Gingerbread version 2.3.3. As our target group is home-nurse, so the mobile interface is designed to be used by the nurses. Whereas web-interface has administration functionality and can be used by leader of nurses allowing her to create, replace, update and delete stored data. Web - server is necessary to overcome limited resources of smartphone and execute functionalities for smartphone [14]. The communication between the server application and smartphone client is based on JSON using RESTful web-services. We preferred REST over SOAP because it is light weight, human readable, and easy to build.
On the server side we are using Play! framework which is Java based web-server that connects with the database to to performs insert, delete, update and select operations. We preferred Play! server over other open source servers because of it's structured environment and usability. We are using MySQL as database to store the data on the server.
It is very important to choose the right technologies to make the product reliable and meet the requirements of the system. The technologies are selected based on the open source licensing, past development experience, reliability of software, and promising future of software. The paragraph continues with brief summaries of technologies used in implementation process.

A. Smartphone platform

We have selected Android as the smartphone platform. The market share of Android takes almost half market and has been increasing significantly [15]. Apart from market share there are many other advantages of Android development and few of them are mentioned below.

- Android applications are not restricted to one distribution channel.
- On Android market application is distributed and in the market quickly i.e. without any reviewing process.
- Android applications are written in Java with w set of libraries.
- Android platform give access to many physical and virtual sensors.

Based on above mentioned reasons we choose Gingerbread i.e. Android 2.3.3 version to implement our prototype.

B. System deployment diagram

The deployment diagram, see Figure 3, represents structure of SmartNursing system that illustrates the components of the system and visualize the communication between these components.

C. Relational Database Management System (RDBMS)

MySql RDBMS is open source and is the most popular database with 65,000 downloads per day. MySql also provides MySql Workbench - a tool for designing and modelling database. Reason for choosing this RDBMS is to have a stable database among other open source databases and moreover it is simple to use.

D. Web-server

Play Framework is chosen as a web based server development platform. The reason is that the main scope of application is to develop a mobile application, therefore preference web-server is the one with simplicity, easy to use, and Java support. Play Framework has these advantages:

- The biggest advantage of Play framework over other Java web applications is usability. For example you do not need to restart the server on static changes [16].
- Play framework jobs provide a way of running program logic in the background.
- With the help of CRUD, administrator's UI can build easily.
- It supports different IDE's integration for example Eclipse, ItelliJ IDEA.

E. 3rd party API

ZXing ("zebra crossing") is an open source, bar-code scanning library developed in Java. We have embedded ZXing API version 2.0 into our project for the scanning of bar-codes to identify a patient.
Google Maps is a web mapping service application and technology provided by Google, that powers many map based services. In SmartNursing application Google Maps is used to display the location of nurses on a map.

F. Graphical User Interface

As discussed in the last chapter that we have focused on the usability issue and we provide simple and useful design based on the requirements of the nurses. We have used dashboard concept to bring the idea of home-screen and

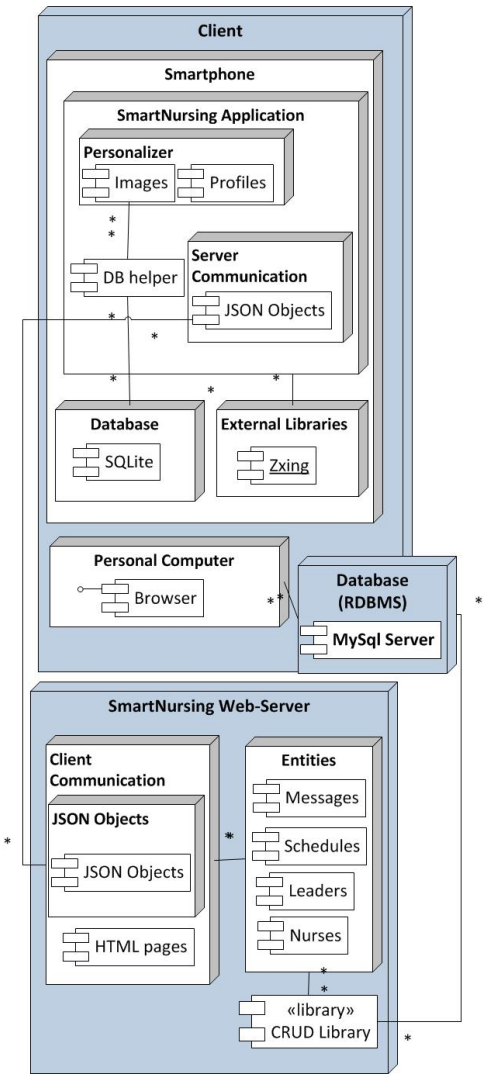

Figure 3. System deployment diagram

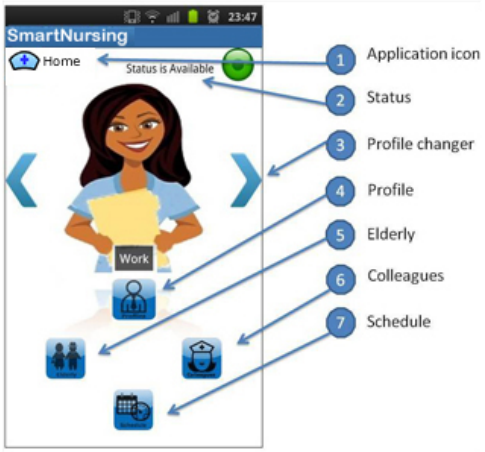

Figure 4. Main-screen components

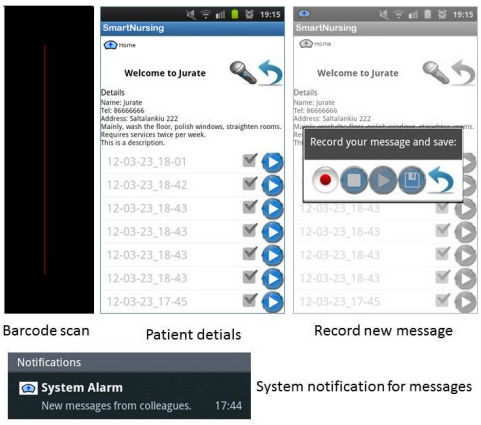

Figure 5. Voice messenger functionality

link to the major functionalities are provided on the main screen. We have also embedded the profiler functionality on the main screen to make our dashboard more usable. We avoid the option menu to bring simplicity in the application. Our target users are nurses and it should require minimum time and efforts to use application. Therefore, we have tried to avoid hidden things and make the functionalities accessible. Figure 4 shows the main screen of application. Main screen is combination of core functionality i.e. profiler and dashboard with link to other key functionalities. It is visualising the context information of the nurses from the selected profile. Voice messenger system with possibility to record a message is illustrated in the Figure 5. Functionality is designed to improve communication among nurses and get easy access to information about patients. First of all, a nurse needs to identify a patient by a unique identification. We have used barcodes to identify the patients. Nurses can scan the barcode from smartphone to get the id of the patient. On identification of the patient, system finds the patient in the database and sends the patient's information and related messages to the smartphone application. All unprocessed messages are displayed to the nurse. To record a new message there is a custom dialog that allows the nurse to record the message. After recording the nurse can listen to the recorded message. If she do not like the recorded message then she can record again, in that case before recorded audio file will be overwritten.

V. Conclusion and Future Work

This paper shows how capabilities of smartphone could improve working environment for home nurses. Implemented functionalities maximise benefits of smartphone at working place. They make daily work easier, reduces the stress and the nurse could do work with full concentration. Solution provides information that is needed at the time and improves process of communication among nurses by suggesting an easy, more convenient and time saving way

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to convey information via recorded messages. Our future research focuses on usability study of implemented application. The idea is to test performance of application by distributing it among targeted users - home nurses. Taking into account user experience and their suggestions, the system could be improved to make it more user friendly and efficient to use. Furthermore, security, utilization of more sensors to fetch context information and implementation of more functionalities. Possible future functionalities might be tracking of detailed patient history, calculation of working hours and scheduler for the patient, access based on context information etc. In addition to this, graphical interface of our application can be improved by providing more assistance to the nurses with interactive communication.

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Recommendations for the Implementation of Exergames in the Context of Workplace Health Promotion: Results From Expert Interviews

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***Abstract*—Exergames are digital games which promote or assist physical activity that is more than sedentary activity. Positive health effects have been reported by several studies. Because exergames have become a popular tool for health promotion it can be assumed that it could be a new promising tool for workplace health promotion. For this purpose, 23 semi-standardized interviews with experts of a financial and insurance company were conducted. The analysis of the collected data identified influence factors for the implementation of exergames in a workplace environment. Out of these, five recommendations for the implementation process were deducted, e.g., the ease of use, the target group, and the acceptance of exergames.**

Keywords- exergames; expert interview; workplace; health promotion.

I. INTRODUCTION

For health promotion in the context of workplace environment currently major changes can be observed due to the advancing introduction of IT-supported programs. Mainly behavioral adjustments of the participants are further fostered through IT-supported developments such as: initial motivation barriers, long-term motivation or home vs. public environment problematic [1]. Products that adapt these topics arise from different businesses areas like sporting goods manufactures, smartphone applications, and gaming consoles [2]. Latter should be further investigated in this article.

Exergames started to develop out of the motion sensor based gaming consoles environment and beginning to touch areas outside the living rooms. Nintendo started in the year 2006 with their Wii console the bandwagon of sport activities combined with classical console gaming [3]. Soon after, Sony and Microsoft adapted these concepts with their respective gaming devices.

For a long time, digital games (the generic term for computer, video, and mobile games) have been associated with predominantly negative health impacts (e.g., obesity) [4, 5, 6, 7]. In contrast of this view, a new type of digital games was developed in recent years.

Serious games are "games or game-like applications that are using technology and design developed from the entertainment software industry and are not primarily or solely for entertainment" [8]. They differ from traditional digital games with its serious purpose [4]. While traditional digital games are primarily created for leisure time and serve exclusively as entertainment, serious games should facilitate knowledge acquisition and behavioral change [9]. These games must be designed with a balance of entertainment and information or education values [8].

Digital games "that promote or assist in user engagement in some form of body exercise" are known in literature typically as exergames [10]. The term exergame (also exergaming) is a combination of the English words "exercise" and "game" or "gaming". Terms such as "Motivating Physical Activity Games" [11], "games for health" [4] or "Active video games" [12, 13] are used interchangeably in the field of exergames. The paper is structured as follows: The next part covers the definitions of the relevant topics as well as a rough overview about the current state of research in this area. In the third part the method of expert interviews is explained and the application details for the research topic are shown. Following, the results of the interviews are presented, separated by qualitative and quantitative findings by the expert interviews. Finally, we discuss the research results and formulate requirements for the successful implementation of exergames into a workplace environment and give a short outlook of future research following from the gained knowledge for exergames. The conclusion pinpoints the most important insights of the conducted expert interviews.

II. BACKGROUND

Exergames differ from classical computer, video, and mobile games in the intensity of physical movements that must be exerted in order to play the games. While traditional video games train the manual dexterity and / or fine motor skills of the players (for example by moving and clicking the computer mouse), exergames require the usage of large muscle groups, resulting in a state of physical exhaustion comparable to sport activities [14, 15, 7]. Many well-known exergames include strength, balance, and flexibility exercises disguised in sports games like tennis, boxing, and aerobics in which players have to realistically simulate the typical athletic movements to move his avatar on screen [14].

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In this way, athletic movements are embedded in a playful context and motivate the players by having fun to a higher incidence of physical activity [16]. Depending on the nature of the game and intensity of the execution of the movements, an increase in heart rate and energy consumption over the basal metabolic rate can be achieved [14]. This effect blurs the boundary between health-promoting sporting activities that have a deliberate, planned, and continued improvement of physical fitness for purpose and exergames.

In recent years, the interest in research on the health-promoting effects of exergames has increased greatly. The effects on physical activity and energy consumption were analyzed most frequently. But a general statement about the physical effects of exergames can not derived as they strongly vary with the various consoles, games, skills of the users and movement techniques. However, all studies meet the joint statement that exergames are able to stimulate the cardiovascular system and the musculoskeletal system and increase the energy consumption above the level of inactivity [17, 18, 19, 20]. Nevertheless, it is repeatedly stressed that exergames cannot be a substitute for real sporting activities but is better than no physical activity at all.

Although exergames have become a popular tool for health promotion, there are no studies on its use in workplace context. It can be assumed that the positive effects of exergames can be transferred to the field of workplace health promotion.

Workplace Health Promotion is a modern corporate strategy to reduce impacts on employees health and increase health-promoting resources by interventions in private and public companies [21, 22]. The workplace poses numerous health risks to employees but at the same time opportunities for self-fulfillment, personal development and well-being [23]. In addition to direct influences, work also indirectly affects one's health including health behavior or lifestyle [24]. The workplace is a major influence factor for one's health with the possible range from adverse health or debilitating factors to health sustaining or promoting conditions [25].

Being such a huge success in the private sector the question aroused if the potential of an accessible, little time consuming and comparably cheap solution can be used for workplace health promotion. However, one has to consider that in such an environment much more regulations and rules are applied than at home. The article serves to answer the following research question:

RQ: "Which factors influence the implementation of exergames into a workplace environment?"

III. METHODE

During September 2011 until April 2012 a series of semi-structured interviews with experts from different departments and business areas was conducted regarding the introduction of exergames into the setting of a company.

A. Recruitment

Several ways were chosen in the recruitment process for the expert interviews. First, a list of important stakeholders was created to obtain the knowledge of well-know experts within the company. This list contained C-Level Management, executives, members of the workers council, company doctors, as well as employees. Experts were recruited in meetings to the topics such as occupational health and safety. During these meetings, recommendations from the participants for further experts were solicited, which could help to broaden the view on the topic of exergames. Secondly, additional interviewees were recruited through the network of contacts from the authors within the company. During the selection process of interview candidates a strong focus was to ensure that a variety of views were contained and being represented. Due to this selection, candidates from different departments and different levels of hierarchy within the company where selected.

A total of 23 experts were recruited, which were either responsible in the selection and decision process regarding occupational health topics, or added knowledgeable insights about criteria for the introduction of exergames within their organization. To obtain unadulterated information and therefore the best possible data anonymity was ensured to all participants for all statements made during the interview process. Table I provides an overview about the different stakeholders and their roles in the company.

TABLE I. ROLES OF INTERVIEWED EXPERTS

Role	Frequency
C-Level	2
Executives	5
Workers Council	4
Doctors	2
Academic Researcher	4
Employees	6
Total	23

Different general backgrounds of the experts were observed. While 35 percent had management experiences, 26 percent offered a medical or health related background and the remaining 39 percent provided user perspective and experience. The roles were defined regarding the job position in the company and the main activity area of the interviewees. For example, members of the workers council can be employees, but in the context of the interviews they answered in their role of workers council members.

In addition to the 23 experts the responsible facility manager was questioned concerning issues of location, accessibility and safety. The selection of 23 participants as the sample-size allowed the fitting balance between time- and resource-intensive interviews and data gathering versus the marginal return of additional insights from further participants. During the interview phase the answers from different experts were quiet homogenous regarding the discussed topic, suggesting that an overall sufficient number of important criteria were received.

B. Interview

All interviews were conducted with a semi-standardized interview protocol [26]. This method allows the creation of comparable responses from the participants, while enabling

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the interviewer to flexibly ask further questions on relevant areas which are revealed during the interview. The average time of an interview was about 60 minutes, while the fastest was 25 minutes and the longest over 100 minutes. The interviews typically were conducted in-person, beginning each with the question about a short background description of the responsibilities of the interviewee, following a short set of open-ended questions. Afterwards the participants were asked to specifically name Strengths, Weaknesses, Opportunities and Treats for the implementation of exergames into a workplace environment. The experts filled the categories with their recommendations and provided additional feedback to them. At the end of each interview the experts were asked about the single most important criterion in their view for the successful implementation and application of exergames in a workplace environment. This allowed the creation of a prioritized ranking of influence factors for the analyses.

C. Analyses

Following the completion of each interview the recorded answers to the discussed questions were documented into a data spreadsheet for further analysis. This approach enabled us to synthesize the most commonly named criteria for each area by selecting the most reoccurring answers in the interview process. Furthermore aspects were included, which were mentioned by just one or two participants, but seemed to be an important addition to the identification process of influence factors.

D. Limitations

Our results are subject to a number of limitations: Firstly, all of the experts were from Germany, therefore a international representative statement cannot be drawn from the results, and a german-centred view is presented. Secondly, all experts were employed for the same large financial and insurance company, so all statements made are situational for a specific company.

The findings show how our predefined set of stakeholders describes their thoughts about the topic at hand. All statements made are personal perceptions of the interviewees and not an assessment of underlying reasons and driving factors which motivated the given answers of the experts. At every possible occasion a cross-check of statements were made between the information provided to us by participants with public available data, such as announcements, surveys, and research publications. Furthermore, the status "expert" of the interviewees holds not for all areas and explains certain biases. E.g., while management experts focused on aspects of motivation the occupational health experts focused heavily on the possible health status improvement of employees after the introduction of exergames.

IV. RESULTS

A. Qualitative analyses

The examination of the interview documentation indicated a qualitative difference between the experts answers. Some experts provided more elaborate insights than others and showed a deeper understanding of the topic exergames. In the interviews all experts mentioned at least one factor for each of the questioned areas, such as Strengths, Weaknesses, Opportunities, and Threats. A commonly made statement for example by one of the experts was:

…The idea of a gaming console for a team room sounds very interesting,…it´s an innovative approach to be active and surely could fit our company…. On the other hand there must be some rules to use it, otherwise people will play all the time or find other ways to abuse it…..and there will be others who don´t like this kind of activity, because they feel it´s inappropriate for them…

This answer was coded for our SWOT overview in the following way: strength-innovative, weakness-clear rules, threat-acceptance. In this example, expert opinion is missing a clear statement for the opportunities of the introduction of exergames into the workplace environment.

Another participant responded to the same questions during the interview with the following:

…I think this is a good way to improve the working breaks, I mean these consoles are cheap compared to what else we spend day-by-day for other stuff… why not use them to get a little more varied gaming opportunities…

In these sentences the expert mentioned the cost-efficiency of exergames, which was therefore coded as an opportunity for the introduction. However, the experts showed the tendency to put arguments forward mostly for one or two of the designated areas: strength/opportunity, weakness/opportunity, strength/threat, and weakness/threat. This was mostly regarded to the fact that once the conversations were taking a direction of pro or contra for exergames, the experts stuck to their opinion and gathered further arguments to support these viewpoints. E.g., strength/opportunity and respectively weakness/treat arguments were mentioned in the interviews.

TABLE II. OVERVIEW ABOUT THE INTERVIEW RESULTS

	Strengths	**Weaknesses**
Opportunities	• Innovative • Ease of use • Cost-efficiency	• (Health)Effects • Place/ time • Clear rules
Threats	• Time efficient • Target group • Employee satisfaction	• Missing long-term development / experience • Acceptance • Target group

B. Quantitative analyses

After the interviews, the statements of the experts were coded comparable to the two examples above and were recorded and counted in a spread sheet. Out of this aggregated interview result an overview of the most important factors was created in Table II.

The overview depicts for each SWOT area the three most commonly mentioned factors for the implementation process. While the innovative approach was clearly seen as the most important strength/opportunity (15), the unclear

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resulting (health) effects were the frequently mentioned weakness/opportunity (10). For the possible strength/threats the time efficiency received the largest reference with 11 mentioning and the missing or unclear long-term development of the topic exergames (8) was especially seen as a weakness/threat.

TABLE III. OVERVIEW MOST IMPORTANT CRITERION BY STAKEHOLDER

Role	Criteria
C-Level	Cost-effectiveness
Executives	Employee satisfaction
Workers Council	Clear rules, anonymity
Doctors	Ease of use
Academic Researcher	Communication / information transparency towards everybody
Employees	Ease of use, innovative

In addition to the general influence factors, the different factors by the stakeholder groups were analyzed. In Table III an overview is presented by the different roles of the experts and their mainly mentioned success factor for the implementation of exergames in a workplace environment. C-Level Management named cost-effectiveness as the most important factor for the application of exergames in the workplace environment. Executives regarded the effect of employee satisfaction as critical. Members of the Workers Council stated that clear rules and anonymity for users must be ensured for the introduction. The ease of use aspect was the general concern of the interviewed doctors, while the academic researchers mentioned the necessity of communication and information transparency towards participants. Finally, concluded by the employees the ease of use and the innovative character of exergames were the most important criteria. However, the numbers of interviewees in the different groups was very low, preventing further meaningful statistical evaluation of the gathered data. At the same time it adds transparency about the general and background interests of the participating experts.

V. DISCUSSION

The role of exergames in a workplace environment and the use for health promotion purposes is influenced by a wide amount of factors. The advantages of exergames are the innovative character of gaming consoles, the ease of use compared to general health promotion activities and the cost-efficiency of the solution. In contrast, the long term development of exergames is at present unclear. Similar results were observed for the acceptance and the fitting target group and the measure pose a potential risk in the success of exergames in a workplace environment. The missing evidence in the application of exergames for health promotion purposes is a barrier that must be overcome to establish it as an alternative way for companies to address the topic of employee health.

Nevertheless, our respondents feel that exergames can help to improve health promotion if the factors are correctly addressed. Particularly the implementation process needs to be defined and analyzed, since exergames have scarcely been able to show their potential because of the difficulty to show the long term development of health effects. Therefore recommendations were deducted from the expert answers to address the main problems that are linked to exergames for health promotion purposes in a company environment.

Recommendations: Our expert interviews revealed information on the incentives and background thoughts about the topic exergames. Below, a set of recommendations is formulated which reflect the critical factors for the implementation of exergames.

A. The gaming console chosen for exergaming must be easy to use

The simplicity of exergames is crucial. In the application scenario, e.g., lunch break, informal meetings, etc. no time consuming ramp ups and further configuration and preparation can be allowed to start with the measure.

B. There must be a clear set of rules for the allowed use of exergames in a workplace environment

Because of the novelty of the topic, clear rules help the employees to adapt to exergames. This might, however, be specifically the case for the German environment in which a set of rules is expected to exist.

C. The introduction of exergames need to be properly announced to every employee in the company

The communication to every employee is from utmost importance to ensure the success and the long term utilization in the company. In contrast a silently introduced new measure will find a small group of users, but will fail to yield a widespread impact on the health status of the employees.

D. There must be a clear cost-benefit evaluation for the introduction of exergames.

To further promote and evaluate the measure a clear statement is required regarding the cost-benefit topic. Especially the benefits within a company environment need to improve to make reliable forecasts.

E. The exergames solution needs to be adapted to a specific target group within the company.

In a counter-intuitive way to the implications of C., the selection and adaption of the exergames measure to a specific target group is an important recommendation. The selection, e.g., of obese and inactive people is a great leverage to create a positive health effect through the introduction of exergames.

VI. CONCLUSION AND FUTURE WORK

This article reported 12 factors in four categories (see summarized in Table II) and five recommendations that were drawn from 23 semi-structured interviews with experts from a large company. Our findings suggest that exergames have the potential to develop into a new form of health promotion in a workplace environment. Due to the innovative character,

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the general easy to use devices and the comparable cost-efficiency of exergames they have the potential to blend in and further evolve the health status of employees.

The experts identified several important factors which influence the implementation of exergames into a workplace environment. They pointed out which are the strengths and weaknesses for the use in a company and named the largest barriers. To resolve these, five points were recommended which have to be considered in an implementation process. However, further study of these points is needed to correct, improve and verify our findings.

In terms of a successful implementation, collaboration between the different stakeholders in the workplace environment is as often, the key. Therefore it is recommended to fostering it in any possible way. Finally, experts agreed that health promotion is an important factor for companies, which is not emphasized enough. However, to make exergames a fully accepted way of health promotion in the context of a company health promotion program, more experience and additional studies regarding the actual use must be conducted. This is why field experiments with different sets of gaming consoles should evaluate the suitability of the measure and document the success in terms of health and employee satisfaction.

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Recommender Systems: an Experience With GenNet Health-Care Social Network

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Abstract— **With the information overload of the Internet in the recent years, recommender systems arise as a solution to indicate content to users and to facilitate their decision processes. In the social network sites context, recommender systems have been used mainly to recommend people profiles to other users. This study analyzes GenNet social network, a collaborative virtual environment that aims health promotion to patients with physical disorders caused by genetic diseases. A recommender system that suggests people profiles to users is implemented and tested, in order to improve the level of collaboration and communication.**

Keywords-Recommender systems; friend-of-friend; social network; SNS, GenNet, healt-care

I. INTRODUCTION

In the last years, the popularity of internet has grown considerably, causing, among other things, an increase of information available on the web, and, consequently, facilitating knowledge dissemination. However, this event brought as a consequence an information overload, which hampers user navigation when they face a large amount of information.

In this context, recommender systems arise as a solution to reduce the information overload by indicating content to users and making easier the decision process. Another key-objective of this type of system in social network sites (SNS) context is recommending to the receiver items which are of its interest [1], [2].

In SNS, recommender systems have been used mainly to recommend people profiles to other users, in order to create new connections, in which the user of recommendations is interested in. Therefore, it is an incentive to make new friends, because from these relationships the virtual social network grows, enabling the knowledge exchange among network members [3].

This study analyzes the GenNet SNS, a project that involves teachers and students of a federal university in the northeast of Brazil. It is a collaborative virtual environment that aims health promotion to patients with physical disorders caused by genetic diseases. To reach this objective, this SNS develops processes that address the promotion of comprehension, adhesion and training of several actors in aspects that can promote health to these patients [4].

This paper aims to present a recommender system that suggests people profiles to users, in order to improve the level of collaboration and communication among GenNet users.

After this introduction, this paper is organized as follows: Section 2 presents some related works and GenNet SNS; Section 3 gives an overview about the methodology applied; Section 4 describes the proposed recommender systems; Section 5 briefly presents the method used to test the proposed recommender system; Section 6 contains the observed results; and finally, Section 7 draws some conclusions and points the way to further studies.

II. BACKGROUND

Pimentel and Fuks [5] define Social Network Sites as an instrument to facilitate interaction between people. Using this type of system, users can find and establish relationships, share textual and multimedia information, exchange knowledge, keep professional contacts and reduce enterprise communication costs and other activities. Thus, SNS are used to support day-to-day problems such as experience exchange between people who live similar situations; knowledge management, through a learning environment that is in constant innovation; record of events that happened in a certain period of time in an organization; reproduction and creation of new connections, even between unknown people and organizations in order to obtain collaboration.

A health social network is an online information service which facilitates information sharing between closely related

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members of a community. Thus, a health social network provides emotional support by allowing patients to find others in similar health situations. This type of social network has shown great potential to empower patient self-care. PatientsLikeMe is an example of patient-driven health care SNS that encourages information exchange and collaboration between patients and between patients and doctors [4].

This domain-specific GenNet SNS is a collaborative social network designed to promote the health and social inclusion of people with physical disorders caused by genetic diseases. The processes performed in the social network involve several actors, such as patients, their families, healthcare professionals and organizations. Each one of those individuals has different types of profile, with some particular features in GenNet [5].

Thus, GenNet is intended to identify people with physical disorders caused by genetic diseases, to supply comprehension about these diseases and the rights ensured by legislation to the patients and their families as well as to promote engagement to treatments. It is also intended to identify associations of patients with similar diseases [5].

Beyond common features found in other social networks, such as receiving and sending messages, creation of groups of friends, among others, the following features may be highlighted in GenNet:

1. Open session for general public (virtual encyclopedia) with several information about diseases and treatments;
2. Topics for orientation about actions and activities;
3. Tools for training (those learning objects are not available yet in the current version);
4. Social profile of users on the network, in which they indicate their role: doctor, association or other kind of user (patient, family, lawyers, etc.);
5. Space for publishing ideas and experiences as a web journal (blog) which may be followed by other users.

Finally, according to Adomavicius and Tuzhilin [7], recommender systems maybe classified in three approaches. The content-based approach assumes that the user must be interested in items, in which they have shown preference in the past. The collaborative approach uses items chosen or rated by people with a profile similar to the receiver of recommendation. The hybrid approach combines the features of content-based and collaborative approaches, merging the positive points of both approaches.

III. METHODOLOGY

The action strategy used to develop the recommendation algorithm to GenNet was subdivided into four steps:

Step 1: involved a literature review to contextualize the research in question, in order to identify the features of recommendation systems as well as the approaches and algorithms used to develop this type of system.

To reach the conception of the recommender system proposed in this paper, four recommender algorithms focused on people recommendation were analyzed, based on Chen´s et al. [8] work:

Content matching: using information posted by users on the network, the algorithm tries to find users associated with similar content.

Content-plus-Link (CplusL): enhances the content matching algorithm adding social link information derived from social network structure to improve recommendations. It creates a network path to an unknown person, and the receiver of the recommendation will be more likely to accept the recommendation

Friend-of-Friend (FoF): this algorithm leverages only social network information of friendship based on the intuition that "if many of my friends consider Mary a friend, perhaps Mary could be my friend too". The algorithm operation can be seen in Fig. 1, in which each node in the graph represents a user, and each edge represents the connections between two users.

The node "Peter" represents the user of the recommendations and the node "Mary" will be recommended to "Peter" because they have four nodes in common (*x*, *y*, *k*, e *b*).

SONAR: this algorithm is based on the SONAR system, which aggregates social relationship information from different public data sources within IBM.

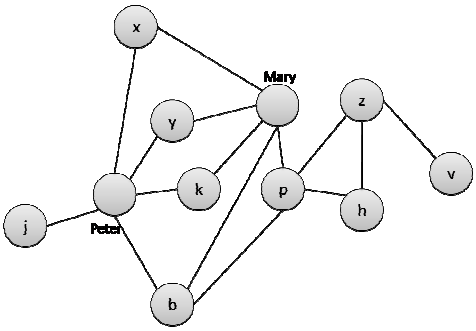

Figure 1. Example of connections among users in a social network using friend-of-friend algorithm.

Step 2: a methodological procedure was defined to build the conception of a recommender algorithm for the GenNet. Therefore, the concepts gained in the previous step were used to define which algorithm was the most appropriate to be used as a model to the algorithm to be developed in this work.

The recommender mechanism was implemented taking as base the friend-of-friend algorithm, which use the friends of friends of a user to recommend profiles, being necessary only the user information of the SNS. To implement the algorithm the following technologies were used: Windows as operational system; MySQL as database server and PHP as programming language.

These technologies were chosen to be aligned to the technologies used to implement GenNet, making the integration easier and keeping uniformity between the system modules.

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Step 3: implementation of the algorithm on the social network, linking the developed algorithm to GenNet.

Step 4: functional tests of the algorithm (presented in detail at section V) were performed in order to validate it. Users were registered in order to observe the behavior of the algorithm. The results of recommendations by the algorithm were compared to manual results of the same test to verify the algorithm accuracy.

IV. RECOMMENDER SYSTEM PROPOSED

Content-based algorithms are more complex than those that are based on the structure of social network [8]. Additionally, the initial behavior of social network users is to find contacts already known [7]. Based on this rationale, algorithms such as friend-of-friend, which are based on social network information to perform recommendations, are indicated to recommend known people and justify the algorithm selection to the purpose of this work.

As shown in Fig. 2, after performing the login in GenNet, a user is identified as the receiver of recommendations (user A). Then, friends of this person are identified in GenNet´s database, because these profiles will be those in common between the receiver of recommendations and the recommended users (step 1).

For each friend of A (step 2), its friends are identified (step 3). The results of this search, i.e., the friends of user A friends, are the inputs to make the recommendation (step 4). Among the results may be some users already connected to user A, therefore, it is not necessary to keep these users, so they are deleted from results (step 5).

The next step is to save these data in a specific database, with recommendation data (step 6), in a table which contains the user of recommendation, its friends and the possible recommendation. It is important to highlight that duplicated lines of data are not saved in this database.

The next step is the selections on the database of users saved as possible recommendations, verifying how many times the same user appears as a possible recommendation to the user, and giving to each one a weight. With these weights a ranking is created with the most frequent users (step 7). Finally, the recommendation of 5 users is shown to user (step 8).

In the example of Table 1, user C was presented twice in the table as a recommendation to user A, while user Y just once. Consequently, user C has weight 2, and Y has 1. The user in the top of the recommendation ranking will be C, followed by Y.

If a user appears in a recommendation and he/she is added as a friend, it is necessary to remove him/her from the recommendation table. So, before the selection of A's friends (step 1) a test is performed that verifies if any of A's friends are already in the recommendation table. If so, this user is removed from this table, in order to not be recommended again.

TABLE I. EXAMPLE OF DATA STORAGE USED TO RECOMMENDATION

Receptor of recommendation	Receptor's friends	Possible recommendation
User A	User B	User C
User A	User X	User C
User A	User K	User Y

V. FUNCTIONAL TESTS

The test performed to verify the algorithm was divided in two steps: the first step was to register members on GenNet and verify the behavior of the algorithm on the SNS, observing the users recommended to each registered user. The second step was to perform the execution of the algorithm, for the same users registered calculating the ranking manually.

The results obtained after the tests were observed under the following scenarios:

- Scenario 1: user is connected to some friends, which have friends not connected to the user;
- Scenario 2: user is not connected to any user;
- Scenario 3: user is already connected to all registered contacts;
- Scenario 4: user has friends, but their friends do not have friends.

Fifteen users were registered, divided in two groups. Group 1 (related to scenarios 1 to 3) with ten members, added among themselves and with no relation with the second group. The Group 2 (related to scenario 4) with five members added among themselves and with no relation with Group 1.

Table 1 illustrates the relationship among users of Group 2, where U11 (located in the first line) is connected to U12, U13, U14 and U15 for example and represented by the number one.

TABLE II. RELATION AMONG USERS IN GROUP 2

SR	U11	U12	U13	U14	U15
U 11	0	1	1	1	1
U 12	0	0	0	0	0
U 13	0	0	0	0	0
U 14	0	0	0	0	0
U 15	0	0	0	0	0

The goal of this test was to observe the results of recommendations generated by the algorithm to each user, as well as the results calculated manually, and compare these results.

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VI. RESULTS

The recommendations showed by the algorithm and the results obtained manually, to the same groups of friends, presented the same profiles.

Scenario 1 showed recommendations from the first to the fifth position of the ranking satisfactorily. This is the scenario with better results, because the algorithm finds inputs to create the ranking and make the recommendations. In some cases, in this scenario, four or less users were presented in the recommendation. This can be justified by the small amount of users registered in Group 1.

In Scenario 2, in which a user has no friends added, the result obtained was expected, because this scenario represents a deficiency of the friend-of-friend algorithm. The algorithm showed no recommendations because it does not find inputs (friends). The friend-of-friend algorithm is based on the friends of a certain user. So, if this user is not connected to any friend, the algorithm cannot recommend any user.

The same result was obtained in Scenario 3, where no people were recommended because the user of recommendations was already connected to all users of the group. Scenario 4 has the same result of Scenarios 2 and 3, showing no recommendations. This happened because this algorithm needs the friends of a certain user, but in this case they have no friends.

VII. CONCLUSION AND FUTURE WORK

Social network sites are very popular nowadays, and these systems allow performing several activities that provide propagation of knowledge and collaboration among its users. Thus, it is necessary to make connections increasingly effectives, in order to obtain more collaboration among users, as well as to avoid huge efforts when performing searches of people in the SNS. The recommender system is responsible to enhance this effect.

Therefore, this paper aimed to reflect over the proposal of a recommender system to recommend people in GenNet social network, which aims to warrant rights to people affected by rare diseases generated by genetic disorders.

The objective of the proposed recommender system is to improve the communication among users, increasing the medical knowledge exchange in the SNS. The higher the number of friends, the better will be the information exchange. Thus, the communication among doctors, patients and other users of GenNet in order to discuss medical information will be improved.

The algorithm developed in this work is based only on social network information. Thus, as a future work there is the intention to improve the proposed algorithm by adding content-based approach to it, making it a hybrid algorithm.

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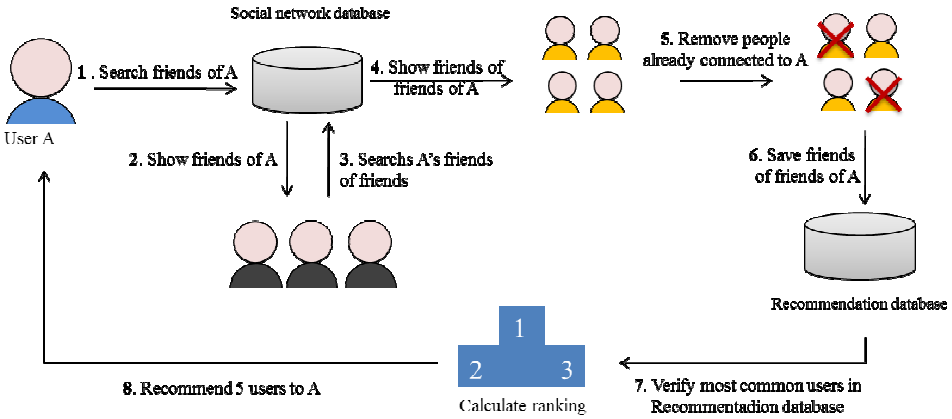

Figure 2. Functional diagram of the algorithm.

Apnea Event Estimation During Sleep Using Polyvinylidene Fluoride Film

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***Abstract*—This paper suggests an unconstrained method for sleep apnea event detection during sleep based on physiological signal from polyvinylidene fluoride (PVDF) sensor. Sleep apnea syndrome (SAS) is a common sleep-related breathing disorder and it is closely related with cardiovascular diseases. Polysomnography (PSG) is the gold standard for SAS diagnosis but it has many drawbacks. Six SAS patients participated in our study and patient's respiratory signals during sleep were collected by a PVDF sensor which was installed on a bed. Sleep apnea events were detected using amplitude of measured respiration signals and the Apnea Hypopnea Index (AHI) results were compared with those from PSG. The Pearson correlation coefficient between paired results was 0.982 (p<0.001) and apnea severity of each patient was accurately assessed.**

Keywords-Sleep Apnea; PVDF film; Polysomonography

I. INTRODUCTION

Sleep apnea is a kind of sleep-related breathing disorders (SRBDs) which is characterized by repetitive abnormal interruption of breathing during sleep. About 4 % of adult men and 2% of adult women suffer from sleep apnea syndrome (SAS) [1]. Since SAS disrupts the sleep architecture of patients, it can lead to systemic hypertension [2], fatigue [3] and heart failure [4]. In addition, previous studies reported that sustained sleep apnea syndrome is associated with cardiovascular diseases [4], such as arrhythmia, ischaemic heart diseases. Continuous monitoring of apnea events during sleep can be a useful tool for the early detection and prevention of sleep apnea-related disorders. It is accompanied by improvement the quality of daily and the reduction of healthcare costs.

In a traditional sleep and sleep-related disorder diagnostic system, polysomnography (PSG) is a representative method. Even though PSG has been regarded as the gold standard to diagnose and monitor SAS, there are some drawbacks. PSG recording during sleep provides a discomforting experience to patient because many electrodes are attached to the patient's face and body. Moreover, it demanded specially trained sleep experts, relatively long set-up time, high costs and a controlled hospital environment.

To overcome these disadvantages, there have been many alternative ways to detect SAS without PSG recoding. In previous studies, the electrocardiogram (ECG)-based method revealed that RR-interval- [5] or R-peak amplitude-based classification method [6] is feasible for apneic epoch determination. Also, respiratory-based or pulse oximetry-based studies reported high correlation coefficient ($r > 0.9$) between AHI from PSG and suggested ones. Despite these attempts, dominant system for the unconstrained monitoring of sleep apnea still does not exist.

Polyvinylidene fluoride (PVDF) film is a piezoelectric polymer which is good for application where mechanical stress is being applied. This thin and flexible film is widely used for film transducer or speaker elements and specially applied where signal to noise requirements influence very low mass loading by the sensors. In previous studies, PVDF film was used as a sensor for recoding of respiration and heart rate [7] [8]. Although these studies have been made to non-intrusively measure subject's physiological signals, the algorithm for apnea event detection from signals measured by PVDF sensor has rarely been studied.

In this study, we established the unconstrained sleep apnea monitoring system using PVDF sensor and assessed the accuracy of our system compared to PSG.

II. METHOD

A. Subjects and PSG data

Six SAS patients participated in our study. According to apnea and hypopnea index (AHI, events per hour), four patients showed severe severity and others were moderate severity. Sleep-related parameters of the patients were summarized in Table 1. Nocturnal PSG was conducted at Center for Sleep and Chronobiology, Seoul National University Hospital (SNUH). Patient's PSG data were scored according to the guideline of R&K by registered polysomnograpghic physicians [9]. This procedure was approved by the institutional review board of SNUH, Seoul, Korea.

TABLE I. SLEEP-RELATED PARAMETERS OF PATIENTS

Parameter	Value (mean ± S.D.)
Gender (Male/Female)	6/0
Age (years)	49.7±26.8
BMI (kg/m^2)	26.8±3.2
Total sleep time (minute)	436.1±59.6
Sleep Efficiency (%)	88.1±6.2

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B. *Respiration signal acqusition system*

Respiratory related signals of patients during sleep were measured using PVDF sensor. The PVDF film thickness was about 100 micrometer (part no.: 3-1004347-0, Measurement Specialties, Inc.) and it was installed between a bed mattress and the bed cover. To prevent damage to the sensor, thin silicon pad was placed on the PVDF sensor and its thickness was 1 millimeter. Consequently, total thickness of combined system was 1.1mm and it could keep the subject's conscious awareness from sensor installation. The PVDF sensors were positioned under the patient's back and they were composed 4x1 arrays. Fig. 1 shows the actual sensor installation on the bed and the size of the combined system. During inspiration and expiration cycle, expanded or diminished volume of the body applies different levels of pressure to the PVDF sensor and output signals of the sensor are changed. Four channel signals from the sensors were collected simultaneously with PSG data using NI-DAQ 6221 (National Instruments, Austin, Texas). The sampling rate was 250Hz.

C. *Apnea event decision algorithm*

Apnea or hypopnea events during sleep were estimated from nocturnal data from the PVDF sensors. First, respiratory-related signals were derived from PVDF data by low-pass filtering (lower than 1 Hz). After filtering, to remove baseline wondering, detrended moving average technique was adopted. Each processed signal does or does not show the respiratory state because best contact channel changes depending on sleep posture or sleep period. So, principal component analysis (PCA) method was applied to each channel signal for best channel selection. Before PCA was applied, each channel of data was normalized to have zero mean and unit variance. The correlation coefficients between PC 1 and each channel signal were calculated and the data of channel that showed the highest correlation with PC 1 was selected. Amplitude of peaks of selected respiration signal was calculated using the self-developed peak detection algorithm. Apnea or hypopnea events were estimated when following criteria are met:

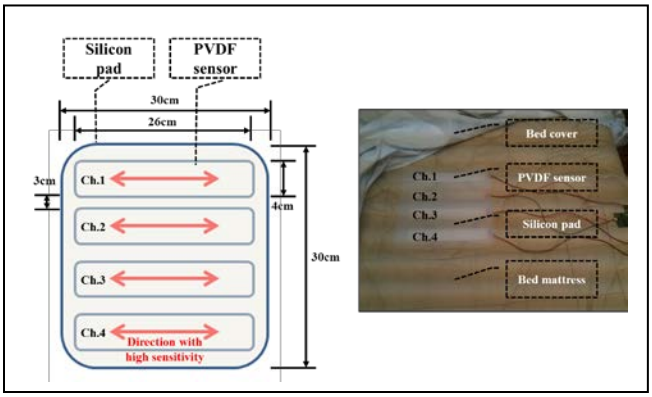

Figure 1. Sensor installation and size of combined system.

TABLE II. RESTULS OF SAS SEVERITY AND AHI ESTIMATION

Subject #	Severity (PSG / Our Method)	AHI (PSG / Our Method)
1	Severe / Severe	46.0/48.9
2	Severe / Severe	34.8/36.1
3	Moderate / Moderate	21.5/21.0
4	Severe / Severe	42.2/46.9
5	Severe / Severe	33.5/38.9
6	Moderate / Moderate	29.2/28.3
Mean ± S.D.		34.5±8.8 / 36.7±10.7

AHI (events per hour) severity;
5-15: mild, 15-30: moderate, >30: Severe
S.D. standard deviation

1) Amplitude of respiration peak drops by >30% of average value of previous 7 peaks

2) The duration of this drop occurs for a period lasting at least 10 seconds.

These rules were determined according to the published manual for the scoring of sleep and associated events [9]. Finally, the apnea event estimation results were compared with the ones from PSG.

III. RESULTS

As shown in Table 2, in all patient cases, apnea severity concordance was revealed by 6 of 6 subjects (100%). Mean AHIs from our methods and PSG were 36.7±10.7 (range: 21.0-48.9) and 34.5±8.8 (range: 21.5-46.0) events per hour, respectively. The root mean square error (RMSE) between paired results was 3.2. In Fig. 2, AHI validation process between PSG and ours was evaluated by using the Pearson correlation coefficient and it was 0.982 ($p < 0.001$, paired sample t-test).

In Fig. 3, agreement between AHI from PSG and ours was evaluated by using Bland-Altman method. In this figure, each black-dot was expressed in terms of the mean difference ± standard deviation between coupled results and all cases existed within 95% limits of agreement as dashed lines (2 x standard deviation).

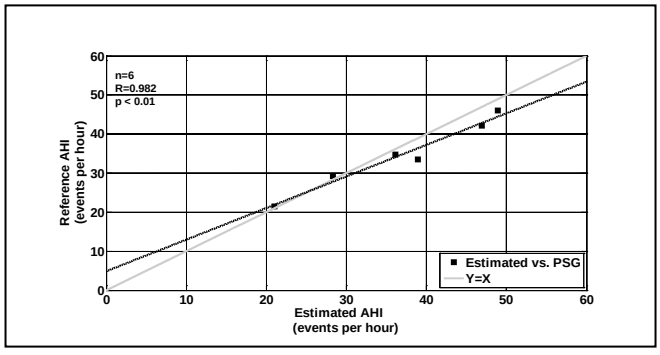

Figure 2. Correlation coefficient between PSG-AHI and estimated AHI

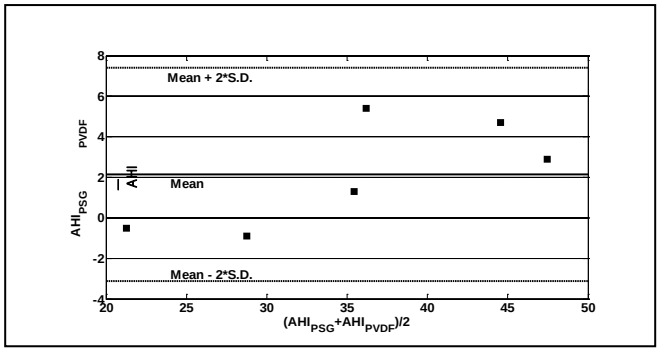

Figure 3. A Blean-Alzman plot for AHI from PSG and proposed method.

IV. DISCUSSION

In this study, we assessed the unconstrained apnea event estimation method during sleep using the respiration signal measurement sensor. Apneic event estimation process was accomplished the following steps;

1) respiratory signal extraction from PVDF data
2) best contact channel selection
3) apnea or hypopnea event decision algorithm.

This sequential technique was applied to the patient's PVDF data during sleep while they can even be unaware of the recording process. AHIs from the proposed method were compared with the ones from PSG and we demonstrated a strong correlation between paired results ($r>0.98$). Furthermore, apnea severity of all participations showed perfect concordance and root mean square error between PSG and ours was only 3.2%. Consequently, our apnea event estimation method for patients with sleep apnea syndrome was proved to be comparable to PSG. Because the suggested method is simple and do not disturb subject's sleep, it can be used for long-term or ambulatory sleep apnea monitoring purpose.

AHI estimation results from the suggested study were compared with commercial systems used in ambulatory purpose. For instance, a wrist-worn device that contains an optico-pneumatic sensor, arterial oxygen saturation sensor and actigraph was used to estimate the AHI during sleep [10]. Even though the wrist-worn device includes SaO2 signal that fully reflects the stop breathing, correlation coefficient between PSG and the suggested method was 0.87. Another example is NightWatch (NW) system that records eye movement, leg movement, SaO2, nasal-oral airflow, chest and abdominal wall motion, etc [11]. The correlation for AHI was 0.94 between NW and PSG and it is lower than those from our methods. However, to establish that the PVDF sensor and our method can be employed to estimate subject's apneic events successfully during sleep, more data of sleep apnea patients or normal subjects will be verified.

In our system, the PVDF sensors were composed of 4 channels under the patient's back position. During recordings, perpendicular vibration to the body which was induced respiration transfers to the sensor in horizontal direction through the bed mattress. Since the PVDF sensor has high sensitivity in a particular direction, sensor array was aligned horizontally long and narrow. By contrast, the sensitivity of PVDF sensor is poor in thickness direction. So, when patients slept with right or left lateral posture, apnea event estimation error was relatively high compared with that from other posture (supine and prone). In PVDF channel selection procedure, channel #1 and 2 were hardly selected as best contact channel. During the PSG, most of the time, patients slept with the pillows and there is a gap between the bed mattress and upper part of the body. Because upper body of patients was not fully contacted with the PVDF sensor, channel 1 and 2 were accompanied by a relative low signal to noise ratio and this is why these channels were not selected as best contact channel.

In our study, as shown in the Fig. 3, the presented PVDF sensor-based apnea event detection method tended to overestimate the AHI for severe severity. For patients with moderate severity, RMSE between PSG-AHI and ours was only 0.7 and it was acceptable result. However, for severe severity, corresponding error was 3.9. The relatively high error from patients with severe severity occurred partly since our system estimated the respiratory signal drop as apnea events that not satisfy standard event scoring criteria. For patients with severe sleep apnea, other sleep-related breathing disorders (SRBD), such as snoring, upper airway obstruction and congestive heart failure, could occur during sleep and these SRBD can also affect the amplitude of respiratory signals [12]. Respiratory event related arousals (RERAs) during sleep may also influence respiration signal drop.

In this paper, a reliable and unconstrained method to estimate the sleep apnea events was suggested. Using the PVDF sensor, apnea event estimation performance was obtained and its result was comparable to that of PSG. We speculate that the proposed method can be used for the continuous sleep apnea ambulatory monitoring system.

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Review of Mobile Health (mHealth) Solutions for Food-related Conditions and Nutritional Risk Factors

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***Abstract*—Representing a subarea of eHealth and Telemedicine, mHealth solutions are becoming more and more widespread. Food-related conditions, like food hypersensitivities, diabetes, obesity and associated risk factors, pose a major threat to the public worldwide. This paper investigates the variety of mHealth solutions in the area of food-related health conditions and assesses their potentials for the affected end-users, related health professionals and possible health economic impacts. A wealth of mHealth approaches targeted at the area of food and health exist; however, several areas for improvement are revealed.**

***Keywords*-Personalized eHealth; mHealth; food-related diseases; diet; nutritional risk factors**

I. INTRODUCTION

With the increased availability of smartphones, tablet PCs and other mobile computing devices, the Mobile Health (mHealth) approach is gaining increasing relevance in the field of Telemedicine. Especially food-related chronic conditions – such as food hypersensitivities, obesity, diabetes, etc. – are of special interest as the number of affected people has been rising in the last decades, and diseases with major nutritional determinants make up 41% of disability-adjusted life years among all diagnosed diseases in Europe [1]. Here, mHealth approaches seem to be promising in the context of primary and secondary prevention through dietary recommendations and food intake monitoring.

This paper provides a state of the art overview of existing mHealth solutions targeted to food-related chronic conditions and assesses their benefits to the end users and health care professionals, if feasible. After a first overview of food-related diseases and their impact, we present solutions available for specific conditions and more general mHealth concepts available for food intake monitoring, food information and diet management. Their current potential and shortcomings are discussed and finally, conclusions are drawn.

II. FOOD-RELATED CONDITIONS AND RISK FACTORS

This section gives an overview of food-related diseases and associated major risk factors. In order to give an indicator for the relevance of each condition, we present prevalence figures where feasible. Most of the presented illnesses show a potential for using mHealth for primary or secondary prevention. In some cases, it also seems appropriate to support the diagnostic process with adequate mHealth tools.

A. Food Hypersensitivity

Adverse reactions to food intake can be roughly separated into two main branches: food allergy and and non-allergic food hypersensitivity. Non-allergic food hypersensitivity, also often named as food intolerance, refers to an abnormal physical response to a food or food additive, whereas (true) food allergy involves the immune system. Food allergy can be linked with a measurable increase of IgE antibodies or can be an immune response that is non-IgE-mediated [1][2]. Some non-allergic food hypersensitivities can be classified through missing enzymes for digestion (e.g., lactose intolerance), whereas others are related to the ingestion of colorants, preservatives or flavor enhancers. Through the involvement of the immune system, the reactions for food allergy can range from mild symptoms to life threatening events, like an anaphylactic shock. Although up to 35% of the German people believe they have adverse reactions to food, food allergy could only be confirmed for 4%, as an example of the western population [3]. The prevalence of lactose intolerance in Europe, for example, ranges from 4% in Denmark and Ireland up to 56% of the adult population in Italy [4].

The management of food allergies and food intolerances consists in educating the patient to avoid ingesting the respective allergen or food component. Some food intolerances allow a mitigation of the symptoms through medication (e.g., lactase), but the root cause can not be eliminated in most cases. As non-allergic food hypersensitivities can not be diagnosed easily using tests for the immune system, food intake diaries are of great value here. Also, for food allergy patients with complicated cases, food diaries help to identify individual allergens in the daily food.

B. Diabetes

According to the WHO Diabetes Fact sheet N312, ”346 million people worldwide have diabetes”. A 2002 study esti-

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mated the average annual costs per patient to EUR 2,834 in eight western European countries [5]. The goals of medical nutrition therapy for diabetes are to a) attain and maintain an optimal metabolic outcome (blood glucose levels in normal range, lipid and lipoprotein profiles as well as blood pressure levels that reduce the risk for complications of diabetes); b) prevent and treat chronic complications of diabetes through lifestyle changes; c) improve the health status through healthy food (and physical activity); d) address individual nutritional needs [6]. For overweight and obese individuals, a weight-loss diet, e.g., through low-carbohydrate or low-fat calorie-restricted diets, may be effective in short term. The scope of application for mHealth in diabetes II management is clearly the primary and secondary prevention as well as the disease management through food intake monitoring and dietary management.

C. Obesity

Obesity and overweight are major risk factors that are associated with several chronic diseases such as diabetes, cardiovascular diseases (CVD), hypertension, arthritis, some forms of cancer, or chronic kidney disease, to name a few. Based on the WHO classification, adults with a BMI from 25 to 30 are defined as overweight, and those with a BMI above 30 are obese. According to an OECD report, more than half of the adult population (50.3%) are overweight or obese, and across the entire OECD region, 17% of the adult population are obese [7]. These figures are even more dramatic when taking into account the predicted further rise, mainly among children, due to physical inactivity and cheaper and thus more easily accessible food in industrialized countries. Newest WHO figures presented in the Obesity Fact sheet N311 indicate that more than 1.4 billion adults in 2008 and more than 40 million children under the age of five were overweight in 2010.

D. Elderly Nutrition

Proper nutrition is essential for health and well-being, but it is often lacking among the elderly. For example, as the elderly reduce their food intake in response to decreasing physical activity, their iron intake also drops [1]. Apart from general nutritional needs of aged people, like increased calcium and vitamin D intake, often (co-)morbidities evolve that can be influenced through dietary behavior.

1) Neurodegenerative Diseases: Neurodegenerative diseases describe a group of conditions affecting the nervous system. Typical is the progressive loss of nerve cells leading to dementia and motion disorders. Popular examples include Alzheimer's Disease (AD) and Parkinson's Disease (PD). Alzheimer's Disease is becoming an increasing burden to the elderly population and very often displays symptoms like forgetfulness, lack of orientation, cognitive decline etc. A recent study found out that concentration of vitamin C and beta-carotene in the serum of AD patients was significantly lower than in control group [8]. In contrast to these findings, a correlation between quality of diet and the occurrence of Parkinson's Disease could not be detected so far [9]. Among subjects aged over 65, crude prevalence rates for dementia varied between 5.9% and 9.4% [10].

2) Malnutrition: Malnutrition is a quite common problem for elderly people. The consequences are a weak immune system, weaker muscle power, poor wound healing, tiredness and mental impairment, as well as less enjoyment of life. A body-mass-index (BMI) of 20 and below indicates malnutrition; if the BMI is below 18.5, the affected person is clearly malnourished. However, not only the BMI is a critical factor but also the supply with vitamin D, vitamin B12 and folic acid is essential, meaning that a person with a BMI above 20 still can be malnourished. In order to correctly assess a dietary condition, it is suggested to consider the weight loss in the past months, the mobility, autonomy of eating, number of main meals, drinking, and finally, the subjective state of health. Among other factors, appetite tends to decrease, leading to reduced food and nutrient intake. Other key risk groups are those with chronic diseases, people who are living in poverty or are socially isolated and those who have recently been discharged from hospital.

Recent research shows that only 17.7% of 80-year-old patients are well nourished, 58.7% are under risk of malnutrition and 23.6% of the patients suffer from malnutrition [11]. A study published in 2012 estimates the annual public health and social care costs associated with adult malnourished patients in Ireland at over EUR 1.4 billion, representing 10% of Ireland's health-care budget [12]. In Europe, an estimated 33 million people are at risk of malnutrition [13].

E. Raised Cholesterol

Raised cholesterol levels (LDL) are a major cause of coronary heart diseases (CHD) and are also strongly linked to diabetes. An LDL-lowering therapy reduces the risk of CHD. It should include therapeutic lifestyle changes accompanied by a drug therapy. The lifestyle changes include reduced intakes of saturated fats (<7% of total calories) and cholesterol (<200 mg per day), therapeutic options for enhancing LDL lowering, such as plant stanols/sterols (2 g/day) and increased viscous (soluble) fiber (10-25 g/day), weight reduction, and increased physical activity [14]. In Europe, the WHO assumes that about 54% of the population have raised cholesterol levels (above 190mg/dl, ages 25+).

III. Mobile Health (mHealth) solutions

The Mobile Health (mHealth) approach experienced a tremendous growth during the last years mainly propelled through the rising availability of mobile hardware, like smartphones and tablet PCs. Initiatives like "Quantified Self" pool self-tracking ideas for general life-style monitoring and tracking health-related data for general purpose. The range of available self-tracking tools encompasses solutions for

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tracking mood, physical activity, sleep, daily habits, food intake and many more. However, the ambitions of those tools are rather to be set in the voluntary self-management. The WHO Global Observatory report defines mHealth as "a component of eHealth" that is "medical and public health practice supported my mobile devices" [15]. The focus of the present paper lies mainly on mHealth tools that are oriented towards the management or prevention of concrete health conditions. Furthermore, the presented technologies rather center around the end users and attending health care professionals, in contrast to the use of mobile technologies within health care service provider organizations, e.g., in hospitals.

The rest of this section is divided into two parts, in which we firstly review condition-specific mHealth tools — concerning food sensitivity and diabetes — and secondly, evaluate more generic food information and diet management solutions currently available. Due to the space limitation, the authors renounce to mention references for the mHealth tools except for scientific papers. The presented approaches are examined with regard to their capabilities of a) providing food information, b) food intake monitoring, and c) diet management. Further, we distinguish between standalone tools and tools integrated in the health care chain with health care professionals.

A. *Condition-specific solutions*

1) Solutions for food hypersensitivity: As indicated in the previous section, the sole "treatment" of food hypersensitivities lies in the avoidance of the respective food allergen or food item. This is also the reason why most mHealth solutions in this specific area are limited to providing information about food items, whenever possible with relation to a patient-specific profile. However, the possibly life-threatening consequences of an unintended ingestion of an allergen due to a false negative rating by a mobile tool are always a huge risk for the user as well as to the solution-provider due to liability issues. Having this in mind, it is no surprise that most solutions are targeted towards non-allergic food hypersensitivity issues where no fatal consequences due to unintended ingestion are known.

Representative for non-allergic food hypersensitivity solutions, we present approaches covering lactose intolerance and gluten intolerance. Apps like **Laktosefrei** provide information about the contents of lactose in food products that have to be selected in a product hierarchy or through simple text search. The 900 products in Laktosefrei are a mix of generic food classes and branded food products. Other apps provide recipes for cooking lactose-free dishes and guidance for finding appropriate retailers and restaurants, e.g., in **Lactofree** (see Figure 1 left). In contrast to that, **Is that Gluten Free?** provides over 23,000 verified gluten-free products that can be easily searched (Figure 1 right), and **Gluten-free Scanner** uses the phone camera to scan the

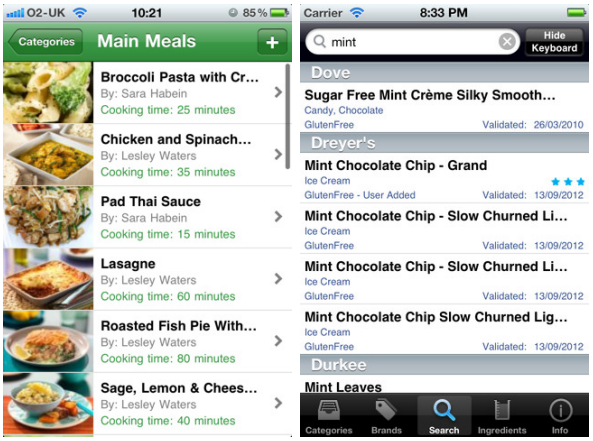

Figure 1. **Lactofree** and **Is that Gluten Free?**

barcodes printed on food packages. A few solutions try to cover multiple areas of food sensitivity. **Food Intolerances** covers histamine intolerance, fructose malabsorption, aspirin intolerance as well as lactose or gluten intolerance, but has only 700 commented foods, which is by far not a sufficient mass of data.

Most of the available food allergy-related solutions cover the requirement of providing information about specific products. There are more general apps that guide to allergy-friendly restaurants (**AllergyEats**) or provide information concerning food dishes available in specific restaurant chains (**Food Allergy Reference - Safe2EatTB4**). **MyFoodFacts** and **ScanAvert**, for example, use the built-in camera to scan the barcode of a food product and present information about the ingredients and possibly opposing allergens. The **FoodAllergy Detective** is an exceptional case as it does not focus on providing food allergy-relevant information to the end user, but it performs food intake and symptom monitoring in order to discover hidden food sensitivities. It should be noted that depending on the stated intended use of this app, it could be seen as providing a diagnostic method. If, however, it can be seen as such, it should have the approval as medical device, which is mandatory by law for such kind of functionality.

The major shortcoming of the presented solutions for food hypersensitivity is that they all are disconnected standalone tools. Thus, the authors want to share their experiences made during the progress of the MENSSANA project (Mobile Expert & Networking System for Systematical Analysis of Nutrition-based Allergies): The smartphone-based **Personal Allergy Assistant (PAA)** allows patients to keep an electronic diary by scanning the barcodes of the consumed food products. For diagnostic purposes, the diary is regularly transmitted to the allergist's electronic patient record. A computer-supported evaluation method for patient diaries has been developed and tested. To further support the individual diet management, the PAA gives a

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warning before consumption of allergenic food. Computer-readable food ingredient lists are required for the PAA diet management. To collect this kind of information, a dedicated web-based ”virtual community” of food consumers and producers (www.wikifood.eu) has been established. Clinical studies have been conducted to evaluate the usefulness of the MENSSANA-PAA approach. A total number of 26,916 diary entries for 28 patients have been transmitted via the telemedicine system. An average of 15.65 [4.49 41.27] entries have been reported per patient and day. It turned out that food diaries can be very helpful for diagnostic purposes if symptoms are in general linked with food intake. A time frame of eight weeks of self-monitoring is acceptable for most of the patients.

2) Diabetes: Mobile health applications and devices can support diabetic persons to better observe their diets through improved self-monitoring with reminders and alerts, and through generating diary information. This collected information can then be shared with the patient’s attending health care professional [16]. Typically, diabetes solutions encompass diary functionalities to record blood glucose levels, physical activity, and food intake. At the beginning of 2011, more than 260 diabetes-related apps have been counted in the iPhone app store, an increase of 400% compared to 2009 [17]. It can be assumed that online markets for other mobile platforms such as Android show a similar availability of diabetes-related apps. Prominent examples include the **BGStar** blood glucose meter and **iBGStar** blood glucose meter and iPhone app by Sanofi Aventis (Figure 2). Both are approved medical devices. The focus of (i)BGStar is the measurement and documentation of blood glucose levels, self-calculated carbohydrate intake, and administered insulin. Physical activities or food intake are only covered via configurable additional notes, such as ”high-fat meal”. Besides the calculated carbohydrate values and additional notes, the BGStar tools don’t allow for any more detailed food intake monitoring.

Another mentionable diabetes support tool is the **WellDoc Diabetes Manager**, which is an integrated mobile and online solution. It includes a message center, goal setting capabilities, information library, collecting glucose level with real time feedback on medicals, recording of where (part of the body) the injections are made, re-test reminder and a rather rudimentary food intake diary. Although WellDoc is a quite comprehensive system and shows a better decline of 1.2% of glycated hemoglobin compared to a conventional care group [18], the usability is lacking as the high drop-out rate of 50% in a study suggests [19]. A similar solution that is integrated with an online platform is **Glucose Buddy**. It also allows doctor printouts to be handed to the treating physician. Users can track glucose levels, carbohydrate consumption, insulin dosages, and activities. Standalone applications include **Actelin** and **iCholesterol**, for example, which mainly allow for diary keeping of glucose levels.

Figure 2. BGStar and iBGStar

B. Generic food information and diet management solutions

A major part of the available food-related mHealth apps are dedicated to diet management, especially aiming at weight loss and calorie counting. Many of these apps are associated with corresponding web communities dedicated to diet management and healthy nutrition. In addition to tracking the user’s food consumption, these apps often also offer the possibility to track further parameters, like physical activity, blood pressure, sleep, mood etc. A part of the apps use camera-based barcode scanning for identifying packed food products through their UPC identifiers. Clearly, these solutions require product information on individually packed food as printed on the corresponding product labels, in contrast to other apps, which use generalized food information related to food archetypes. Similar to the food sensitivity apps, the crucial point concerning the usefulness of diet management apps is the availability of appropriate food information databases.

Mobile apps like **LoseIt!** or **DailyBurn Tracker** allow users to specify their specific diet goals, log their daily food consumption using barcode scanning or through selecting food entries out of a food product hierarchy, and thus to keep an overview of their calorie consumption but also on the consumption of certain nutrients if needed. Similarly, **FitDay** allows the creation and management of personal food journals by choosing food items out of a predefined food hierarchy (without barcode scanning). This app aims at a long term analysis of the food journals and thus at supporting the users in gaining control over their eating habits. With the **iFood Diary** app, users can share their food diaries with their nutritionists via Facebook or e-mail. Apart from the possibility to chose food items from a conventional food hierarchy, the **GoMeals** mobile app additionally sets a focus on restaurant meals. Users can browse the menus of

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nearby restaurants and check the calorie and nutrient values of the offered dishes.

In addition to tracking their own food consumption, with the **alli Food Planner**, users can also plan their upcoming meals in accordance with their self-estimated individual calorie needs. This process is supported by corresponding meal suggestions by the app and a simple traffic light system indicating the appropriateness of certain foods. **CalorieTrack** is similar to the alli Food Planner but with automated calculation of calorie needs based on the user's current weight and height and the target weight.

The recently released **Food Navi** app calculates the optimal food intake in different food categories based on the user's personal profile and a special rating system - UGB's Healthy-Eating-Index (HEI-UGB). In contrast to other scoring systems, this index calculates the optimal intake amounts in different food groups, which are represented in the so-called nutrition circle, instead of being based on individual nutrients. The app is also available in specialized versions optimized for diabetics, coeliacs and cardiovascular prevention.

Beside these mobile apps which focus mainly on weight loss, there are also some apps that merely provide information on the nutrient values of food products without tracking the user's weight or calorie consumption. The app **Nutrition Facts** allows users to browse nutrition information for popular foods, including fast food. A similar functionality is offered by the app **MyFood - Nutrition Facts**, which however concentrates on unprocessed foods, like fruits and vegetables. The app provides complete nutrition data for a number of unprocessed foods, which includes a complete breakdown of vitamins and minerals. The food information app **Fooducate** automatically rates foods and beverages on a scale with 10 distinct grades based on their nutrition facts and ingredient lists. The information is presented in a clear and informative way, using different colors and simple labels. The user is also presented suggestions for alternative food products.

IV. Discussion

The previous section reviewed existing mHealth solutions from the viewpoint of food-related conditions and risk factors. It can be stated that a wealth of solutions for different aspects are available, e.g., apps for different smartphone architectures. However, their utility largely depends on further resources and requirements: a) availability of error-free information about food items and food products in order to be able to predict the tolerance or the usefulness of food for specific persons; b) the integration into a personalized case management process involving health care professionals.

Especially the data correctness is inevitable for conditions that can involve fatal consequences. However, for areas like obesity or other nutrient-based risks, rare data errors could be negligible in favor of an increased volume of available data. Two types of food information data are used: food-related information concerning archetypal food and information concerning specific food products. The archetypal information is most often drawn from food composition databases (FCDB) and includes averaged nutrition information for foods and food product classes. Digital food product-specific data, possibly extracted from food product labels, are not as widely available. For the US market, dedicated commercial databases of consumer packaged goods exist, but for the European dispersed multilingual markets, such databases are not available, apart from solutions available in the UK. Further, this type of data can be found at collaborative food information platforms, in which a community of users, manufacturers and platform operators maintains the data. Both sources of product specific data (commercial and community-based) implicate the question if the collected data is suitable for use in mHealth. This is due to the facts that commercial product information databases are mainly intended for business activities such as monitoring shopping behavior, and the quality assessment in community-based approaches is very often not addressed.

As shown in the previous sections, the presented diabetes solutions are better integrated into case management processes, and their main functionality covers diary keeping of blood glucose levels and food intake for documentation. The food intake is recorded by entering (self-calculated) carbohydrate values, but it is not based on archetypal food information or product-specific data. This is clearly an area where improvements are suggested. Apart from the diabetes apps and some further exceptions, most of the other presented solutions are standalone approaches providing the possibility to send data via email to a clinician at most.

Although not examined in detail in this article, we would like to finish the discussion by stating that a huge factor of uncertainty concerning mHealth solutions in general is the lack of evidence that undermines the quality and safety aspects of medical apps [20]. There is an ongoing discussion in the community of what a medical or health-related app is and how quality and safety characteristics can be guaranteed. In 2011, the U.S. Food and Drug Administration (FDA) initiated a regulation process for mobile medical applications, which has not been finalized yet [21].

V. Conclusion and Future Work

Food-related conditions and associated risk factors pose a dramatic burden to the society, which is expected to increase in the near future. Persons suffering from mentioned conditions can already choose from a wide range of mHealth solutions. However, certain weak spots have been identified: the functionality of the apps is limited to specific features, mainly displaying dietary information or collecting blood glucose levels for documentation. Menu planning or diagnostic support is most often not available. Moreover, the provided dietary information is frequently based on

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data coming from food composition databases and lacks information on specific food items sold in supermarkets. This is mainly true for the European sector. Further, dietary applications are often designed for general weight loss and not adjusted to specific risk factors, like raised cholesterol. Finally, a better integration of the solutions into case management processes is highly desirable. The latter and applied regulation processes for mobile medical applications will enable mHealth suppliers to provide solutions with a higher level of quality and safety, and will eventually allow additional functionalities, like diagnostic support.

Future work will include a more extensive review of actual user experiences of the target groups concerning app usage as well an assessment of number of users, age groups etc. and comments from health care specialists.

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Towards Influencing Factors on Business Models of Ambient Assisted Living Systems

An Analysis of the German Health Care Markets

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***Abstract* — The aim of this paper is to close the research gap by combining state-of-the-art theory of value chain characteristics, business model definitions and financing options in order to realize profitable business with Ambient Assisted Living (AAL) systems. Relating to value chain characteristics, three main categories of elements are detected when comparing several approaches. In terms of AAL business models, a suitable definition is derived which is able to describe the creation of value in a multi-company environment. In order to conduct profitable business, both German health care markets are compared with their specific advantages and disadvantages. Due to the high burdens of Governmental restrictions in the primary health care market, AAL business models should focus on the secondary health care market in the near future. However, further research is required how to integrate service companies, whose daily business is to care for older people, into a business model as distributors of AAL technology.**

Keywords-Ambient Assisted Living; AAL; Business Model; Financing; Value Chain

I. INTRODUCTION

Demographic ageing as an aspect of demographic change is one of the global mega trends in the 21st century [1]. One of the most affected countries is Germany whose population will be one of the oldest in the world by 2035 [2]. By the middle of this century, more than half of Germany's inhabitants will be older than 50 years and the proportion of people aged 60 years and over will increase from 26 per cent in 2011 to 38 per cent in 2050 [2] [3]. Analogically, the group of the over eighty-year-old will triple to more than 10 million people [4]. Although ageing is not automatically equivalent to the need for care, the majority of the elderly increasingly relies on assistance, support and medical care with advancing age. In consideration of demographic change, this will lead to massive costs associated with care giving [5].

To counter this process, new care delivery models supported by information and communication technologies (ICT) are being developed under the name Ambient Assisted Living (AAL) [6]. Despite its tremendous market potential, the AAL branch is yet to make a mainstream breakthrough [5]. Although many devices and systems have been developed in the past years, there is a lack of comprehensive and commercialized AAL-solutions which truly meet customer demands [7].

In connection with this finding, the main problem is seen in the unwillingness of customers to handle the complexity of coordinating different partial solutions. Thus, the customer process must be comprehensively supported by a network of enterprises, offering an all-inclusive, easy-to-handle solution. This also means, from the view of organizational studies, the necessity to develop new forms of collaborative service delivery as well as sustainable and viable business models for enterprise networks [4] [7]. Although present business models of AAL projects are based on governmental or semi-governmental funding, many of these projects have not yet achieved permanent financing [8]. Due to this fact, missing business models are almost unanimously considered to be the greatest market obstacle to a broad implementation of Ambient Assisted Living systems [5]. Therefore, this paper gives an overview of influencing factors on AAL business models and analyzes how they stick together in order to run a profitable business.

II. BACKGROUND

In recent years, Ambient Assisted Living has developed into a decisive factor for scientific and market-oriented research into ageing populations [5]. AAL refers to a situation whereby an electronic environment reacts sensitively and responsively to the presence of people and provides assistive propositions [1]. These solutions can take the form of assistance for daily activities, health and activity surveillance, access to social and medical emergency systems as well as easing social contacts [8]. Accordingly, the AAL market can be divided into the four segments "Health & Homecare", "Safety & Privacy", "Supply & Household", and "Social Environment" referencing the definition of the German Federal Ministry of Education and Research [9].

Since AAL was notably promoted on the political level, most innovative products and services based on technological developments instead of customer demands [10]. In this context, a study by Steinke et al. [11] proved a strong significant correlation between attitude toward a product or service and purchase intention. This means that

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the elderly are willing to pay for AAL products and services when customers' demands are truly met. Thus, from the perspective of innovation literature, AAL solutions rather refer to the term “technology push” than “demand pull” [10]. This trend mainly resulted from the early focus in scientific research on the development of technology without considering the business side [12]. In this process, several authors such as Osl et al. [13], Balasch [14] or Rosales Saurer et al. [15] examined customer requirements from different perspectives in order to give an integrated view on customer requirements for the development of holistic AAL solutions.

Although suitable products and services were created subsequently, many were not introduced into the market since the projects were often discontinued at the end of the funding period due to missing business models [8]. This is why the German AAL Congresses emphasized AAL business models in order to set foundations to ensure sustainable business success without governmental funding. Therefore, three interrelated topics were figured out to be most important: Value chain characteristics, business model definitions for value networks and financing options.

In this context, Balasch [14], Gersch et al. [16] as well as Sassen et al. [17] developed value chain models to provide a framework for the creation of hybrid products in AAL enterprise networks. All of them came up with related groups of actors needed for viable business models. Since there was no commonly agreed definition of business models for value networks in the context of AAL, researchers defined specific elements. In addition, various financing options were analyzed and linked to existing business model definitions. However, the interconnectedness of these three topics has not yet been clearly demonstrated. Hence, the research question reads as follows: How are state-of-the-art theory of value chain characteristics, business model definitions for value networks and financing options interrelated in order to realize profitable business with AAL systems?

Hence, the structure of the paper reads as follows: The introduction and background sections outline the need for AAL and explain why, despite working technology, financial aspects are needed to make a mainstream breakthrough. From the perspective of the value chain, the third paragraph gives reasons why only networks of specialized providers are suited to offer customer-oriented solutions. In the fourth segment, a suitable business model definition for hybrid value creation is derived. The fifth part outlines the financing options of AAL technology and services in both German health care markets. The sixth section concludes that practitioners should concentrated on the second health care market and the last paragraph reveals how still missing distribution partners and sophisticated revenue models may help to implement AAL solutions in the market.

III. VALUE CHAIN CHARACTERISTICS

The implementation of AAL solutions via a fully integrated business model cannot be realized by a single protagonist. The social and the health care systems require new combinations of resources and competencies which cannot be found in any existing corporation [16]. Thus, value networks consisting of legally independent, but interdependent organizations are necessary which have the potential to resolve the conflict between a high level of specialization and a broad range of services [8]. Only several partners will be able to create solutions consisting of a variety of products and services, which meet the conditions of hybrid products. These solutions have to be developed with reference to hybrid value creation. As hybrid value creation applies in the context of a single company, the creation of value in terms of AAL can be considered as an advancement of traditional hybrid value creation [18]. In the course of this, the various services need to be bundled in accordance with the long established principle of “one-face-to-the-customer”, via the use of the customer process of business-to-business (B2B) relationships [19]. This means that a global solution for the customer with a comprehensive support of customer processes is essential [13].

Since there is the necessity of enterprise networks to implement AAL solutions, a new or at least modified value chain compared to value creation in single companies is required. New and innovative solutions are created partly by changing and combining the existing elements used for value creation of different protagonists and partly by adding new components. Hence, Balasch [14], Gersch et al. [16] as well as Sassen et al. [17] provide new value chain models with various elements customized for the added value of AAL. Despite some varieties, their models only differ marginally. With the exception of one missing element, all of them differentiate between three main categories as illustrated in table 1: Infrastructure providers, several types of organizers and different kinds of suppliers or providers. For a clearer understanding of the expressions used, the first two models are explained in detail below (since Balasch [14] did not provide a description).

TABLE I. COMPARISON OF THREE MODELS OF AAL VALUE CHAIN ELEMENTS

Balasch [14]	Gersch et al. [16]	Sassen et al. [17]
Infrastructure Providers	Infrastructure Providers	Infrastructure Providers
-	Orchestrators	Network Manager Platform Operator
Suppliers of Sensors/ Devices Service Providers	Components Suppliers Specialized Suppliers Industrial Service Providers	Providers

According to Gersch et al. [16], *Infrastructure Providers* make the platforms and services, needed for the interaction of all protagonists involved in the solution, available. When considering the associated investments, the provided platform should be used by many users for diverse activities and implementation scenarios. *Orchestrators* coordinate value networks as a user of the provided platform. The main task of an orchestrator is to identify and choose the best specialists within the different value chain steps, to initiate

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their cooperation in a value network, and to coordinate their activities with the objective of creating competitive advantages for the whole service offering. *Components Suppliers* provide functional components or end devices, which work either as a standalone device or are linked to other components and devices. *Specialized Suppliers* focus on service provision for one component integrated in the offering of the network. This service is independently marketable at the same time. Users of the services supplied by orchestrators may be end-users as well as focused suppliers, which also demand services from *Industrial Services Providers* to realize their own service offerings.

In accordance with Sassen et al. [17], the *Network Manager* provides services to the client with its own name or brand. It acts as general contractor and is liable to the customer. The providers, in turn, are liable to the network manager. The cooperation between all the suppliers is set by the network manager. The *Platform Operator* determines the cooperation strategy and executes all operational activities. It defines the processes of the providers offered on the platform. Furthermore, it takes orders from customers who hired a service provider, issues invoices and receives complaints. The *Infrastructure providers* offer the platform as a system. It is crucial for them to use the infrastructure in many application areas. *Providers* offer services to customers. In this process, many different service providers take over the role of the provider.

In addition to the definition of the elements in an AAL value chain, there is the need to investigate how large-scale networks of heterogeneous enterprises are able to do business which is profitable for all participants [7]. Therefore, the following section discusses various business model definitions and explains how an appropriate AAL business model definition has to be built-up.

IV. BUSINESS MODELS

The origin of the business model term as a concept in practice or science has not been conclusively resolved as of today [19]. Since it was mainly discussed by practitioners and investors, it was seldom defined explicitly [21] [22] [23] [24]. Wirtz [25] refers to the long conceptual development of the business model concept which was repeatedly shaped by various trends and connected with different schools of thoughts. This has been supported by other authors such as Samavi et al. [26], Osl et al. [7] and Osterwalder et al. [27] who explain various business model categories and approaches. On the basis of their research, Osterwalder et al. [27] defined the business model term as follows: "*A business model is a conceptual tool that contains a set of elements and their relationships and allows expressing the business logic of a specific firm. It is a description of the value a company offers to one or several segments of customers and of the architecture of the firm and its network of partners for creating, marketing, and delivering this value and relationship capital, to generate profitable and sustainable revenue streams.*"

Unfortunately, most business model definitions – including the one portrayed above – were developed for the application on focal firms only. Since value creation in the context of AAL needs to take place within a multi-company environment, a business model for a network of several companies has to be chosen. Hence, numerous authors have also developed definitions for value networks, focusing on the aspect of cooperation and business networking by defining specific model components, such as "network of actors", "network of partners", or "value network". Yet, these concepts have not gained widespread recognition in literature since other elements also depend on the company's inter-connectedness with its business partners as well. Hence, Osl et al. [7] suggest not adding cooperation as a separate component, but rather emphasizing a collaboration perspective within the other items.

Thus, the Business Model Canvas developed by Osterwalder et al. [28] seems to be appropriate to design a business model for AAL systems. Although it was not developed for a multi-firm context, it has a strong focus on relationships between different actors. Further advantages are its intuitive character as well as the possibility to illustrate the Building Blocks graphically. Thus, the Canvas is able to describe the creation of value for AAL solutions referring to the logic of [7]. The Business Model Canvas consists of nine "Building Blocks". The names of the Building Blocks read as follows: The Customer Segments Building Block, the Value Propositions Building Block, the Channels Building Block, the Customer Relationships Building Block, the Key Partnerships Building Block, the Key Resources Building Block, the Key Activities Building Block, the Revenue Streams Building Block, and the Cost Structure [28].

V. FINANCING OPTIONS

For health care and nursing related products and services – as developed in the context of AAL – there are two markets for financing: the primary and secondary health care market. Gersch et al. [10] call them "arenas" for AAL business models. The primary health care market is the core of the German health care system along with its institutions and medical providers. It is characterized by the medical treatment of all ICD-10 indications and corresponds to the mainly solidarily financed partition in the context of standard care [16]. It includes medical care provided by contributions from the legal and private health insurance, the nursing care insurance as well as from other social security systems and government grants [10].

Besides the primary, a secondary health care market with mainly privately funded health-related products and services has been established [16]. In contrast to the primary, the secondary health care market focuses largely on privately financed, health-related services [10]. Thus, it is characterized by much stronger market potential. Social acceptance and increased value of AAL solutions can be realized if the independent customers, who wants to provide for their old age, or that of their relatives, is addressed.

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Here, the willingness to pay is directly correlated with the significant added value for users and customers [14].

Although the primary health care market with its institutions and providers is still the core of the German health care system (output volume in 2008: 221 billion EUR or 77.5 per cent), the secondary health care market gains in importance (total size 2008: 64 billion EUR or 22.5 per cent). Due to the reduction of funds in the publicly funded sector as of several health care reforms, the secondary health care market has been registering high growth rates (in recent years already 5.5 per cent). At the same time, the growth in the solidarity-funded health care spending was significantly lower (only 2.1 per cent in the same period).

Despite the apparent differences of the primary and secondary health market, a general trend can be observed that the primary and secondary health care markets are growing together and will complement each other in the future. With the aid of AAL solutions, a so called "third health site" will be established alongside existing outpatient care and in-patient service provision [10]. In combination with the primary and secondary health care market as well as the three different health sites – in-patient care, out-patient care and care at home – six segments for health related services can generally be targeted with AAL solutions as depicted as shown in table 2.

TABLE II. SIX SEGMENTS IN COMBINATION OF TWO HEALTH CARE MARKETS AND THREE HEALTH SITES MODIFIED FROM GOLDSCHMIDT ET AL. [29]

Health care markets	Secondary health care market	IV	V	VI
	Primary health care market	I	II	III
		Second health site	First health site	Third health site
		In-patient care	Out-patient care	Care at home
		Health sites		

Besides the basic types of potential revenue models for the primary and secondary health care market, products and services developed and offered at the interface between these two markets can also be observed. These hybrid models try to combine several basic types of potential revenue models and financing systems of both health care markets. The best known of these hybrids are co-payment and deductible models. In addition, there are also a number of different premium, saving and apportionment models. Premium models mostly complement state-funded primary care, as the utilization of additional offerings has to be paid privately. Within the scope of saving models, partially funded health care financing is discussed. Apportionment models are insurance models which work similarly to the current social security system. In accordance with the principle of risk sharing, a direct redistribution of the group of payers to benefit recipients is fulfilled [10].

VI. DISCUSSION

Recapitulating, innovations in the primary health care market need the mobilization on the political level as they are dependent on changes in regulation [30]. The advantage of a solution for the primary health market is that only a few institutional payers have to be convinced instead of many individual customers with low willingness to pay [31]. In contrast, innovations in the secondary health care market are driven more by market demand. These innovations can better evade governmental regulation, but clearly rely on visible value propositions and value-added architectures in order to successfully establish on the market [30]. However, there is also the possibility to reach large customers, such as housing associations. In doing so, each client generates considerably more revenue instead of many small and individual customers and it is more likely to reach the critical mass faster.

Nevertheless, a business model in the primary health care market is not preferable at the moment. Particularly health as well as nursing care insurances only pays for products and services in case an immediate savings potential – which means within one year – can be proved. Since innovations in the context of AAL have scarcely been able to prove this requirement as the amortization period normally lasts distinct longer, the potential to implement a cost-effective business model in the primary health care market has been low. In terms of a business model in the secondary health care market, customers' willingness to pay needs to be analyzed in detail for a specific solution to be successful in the market. The requirements for this are the outcomes from several studies. Whereas some detected a general low willingness to pay, especially in relation to product supporting services [32], others pointed out that the willingness to pay increases significantly if the offers exactly meet clients' requirements. And others again came to the conclusions that the price represents a secondary criterion from the customer perspective. According to this, it only becomes important if the consumer is not able to find any difference in the quality between certain services [13].

By implication, this means that there is considerable demand potential for quality-reduced low-cost offers with respect to services. In order to reach this target, differentiated offerings for price-sensitive customers as well as quality-oriented customers with higher willingness to pay have to be designed [13]. On the one hand, this can be realized by the cross-linked implementation of AAL solutions into integrated care processes [16]. On the other hand, cross-subsidization in the context of hybrid products are necessary elements to offer cheaper products for the mass market similar to many other industries financing forms [16].

VII. CONCLUSION AND FURTHER RESEARCH

Due to demographic change, the development of new solutions to assist the elderly in their daily routine is of high

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economic importance. Despite the Government funding of 18 research projects [33] and the development of suitable products and services, there is still a lack of comprehensive solutions as well as interlinked business models for value networks [5].

With reference to business models and the recommended solution for the secondary health care market, it might be reasonable to consult companies such as Caritas or Diakonie, whose daily business is caring for the elderly, and convert them as distributors in a large value network. Since nursing and even more medical services evade in many parts from the objective assessment of lay people, the setup of medical reputation requires branding. In doing so, a professional appearance and distribution as well as sustainable quality management and quality communication has to be implemented [34]. Therefore, a business model or revenue model, respectively, including brokerage fees for these companies has to be designed. Since these companies are often operated not-for-profit, further research is needed to investigate how these firms can yet be integrated into the creation of value in the context of AAL.

Further research is also required for an optimal pricing of hybrid products developed and distributed in a multicorporate context, such as AAL. Whereas basic approaches for focal firms are described by Burianek et al. [35], their model needs to be transferred to value networks. In view of hybrid products, the clients do not pay for certain components of products, but rather for the functionality of a solution. Thus, pricing should be aligned to the proportion of value added for the customer and pricing systems by applying usage based pricing, performance based pricing or value based pricing. However, there is still a research gap how to apply these pricing systems to a value network, especially with respect to direct cross-subsidization and potential to create a lock-in situation, which bases on products and services of different companies.

In addition, AAL offerings are typically characterized by a variety of economic anomalies which influence the diffusion process in the market directly or indirectly. First, there are uncertainties between special vendors and the demand side. Second, high investments with regard to potentially imbalanced fixed costs and related business risks have to be compensated by the involved companies. Third, the need for cooperation of several actors of the supply and demand side exists. In this context, the development and coordination of complementary division of labor structures each contributing to individual services or business processes in order to implement a comprehensive solution needs to be established. In addition, there is the need to price AAL in accordance with the legal framework of the primary and secondary health care market. Lastly, individual AAL offers may need a critical mass in case the benefit for each adopter depends on the number of additional users connected to the system [10]. Concluding, these issues must be resolved in order to establish viable and sustainable business models in the context of AAL.

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Usability of a Home-Based Monitoring System for Community-Dwelling Elderly People during a Pilot Study

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***Abstract*— The aim of this pilot study was to evaluate the usability of a monitoring system that can monitor indicators of physical functioning (weight, balance, grip strength, and physical activity) in community-dwelling elderly people. Monitoring such indicators can identify elderly people who could benefit from (preventive) interventions. The system can also provide feedback to support elderly people in their self-management. A geriatrician invited patients aged 70 years or older to participate in the pilot study. Participants rated the usability of the monitoring system after using the system at home for three weeks. Usability was measured on a 7-point scale using an adapted version of the Post-Study System Usability Questionnaire and by logging errors that occurred in a diary. Six participants between 79 and 83 years old were included and four of them completed the pilot study. The mean usability score was 5.2 (SD .90) and scores ranged from 3.8 to 6.2. The participants were mostly positive about the usability of the monitoring system but some improvements have to be made before the system can be implemented and evaluated on a larger scale.**

Keywords-telemonitoring; physical functioning; usability; elderly people

I. INTRODUCTION

In community-dwelling elderly people decreases in indicators of physical functioning, for example weight, grip strength, balance, or physical activity, predict adverse health outcomes such as disability, hospitalization and nursing home admission [1-3]. If care professionals would be able to detect decline in physical functioning in their patients at an early stage, interventions could be provided to slow down or prevent (further) decline or adverse outcomes. Elderly people with a decreased level of physical functioning might be the ones who are most likely to benefit from such intervention programs.

Due to the increasing number of elderly people and the decreasing number of care professionals, it is not feasible for care professionals to assess physical functioning in all their patients on a regular basis using physical performance tests. As a result, elderly people and care professionals are often not aware of decreases in physical indicators at an early stage and decline continues until (health) problems arise [4]. Innovative technologies can play an important role in the early identification of decline in physical functioning. Such technologies are on the rise and are often used to support remote monitoring of health conditions, self-management, and the delivery of interventions [5, 6].

A monitoring and feedback system that can be used by elderly people to measure indicators of physical functioning on a daily basis was developed by engineers from the Université de Technology de Troyes (UTT) and researchers from Maastricht University (UM). The monitoring system consists of three devices: a bathroom scale for monitoring weight and balance, a grip ball for monitoring grip strength, and a mobile phone with a built-in accelerometer for monitoring physical activity [7-9]. The three devices are equipped with Bluetooth® so that the results of all the measurements are automatically transferred to the mobile phone. Via an application on the mobile phone, elderly people receive feedback regarding (changes in their) weight, balance, grip strength, and physical activity. Furthermore, the phone transfers the data to a database where health care professionals have access to the measurements that were performed by their patients. This enables care professionals to monitor the physical functioning of their patients from a distance and can help them in providing adequate and pro-active care. Figure 1 illustrates how the system works. Elderly people and care professionals can collaborate to determine realistic and personally relevant goals with regard to physical functioning. Self-monitoring of the indicators of physical functioning and collaboration with care professionals can support elderly people in their self-management [10-12].

The monitoring and feedback system can only reach its full potential when elderly people are able to use it in their daily lives. To optimize the system's usability it has been developed in close collaboration with elderly people and care professionals [13, 14]. During the user-centered development

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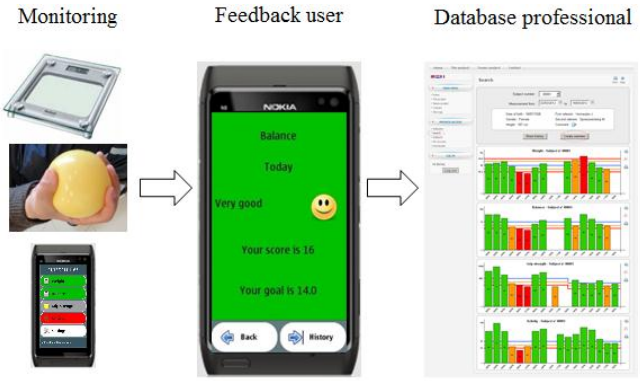

Figure 1. Monitoring and feedback system

process, the system was fine-tuned to the needs and requirements of the end users as much as possible. Taking human and other non-technology issues into consideration during the development process increases the usability and acceptability of the technology [15, 16]. The aim of this pilot study was to test the usability of the bathroom scale and the mobile phone in the daily lives of five elderly people. This small sample size was chosen because according to Nielsen et al. this should be sufficient to identify about 80% of the usability problems of a system [17]. The pilot study only focused on the usability of the system as experienced by elderly people and not on the usability of the database by health care professionals. Unfortunately the usability of the grip ball could not be tested yet due to problems in its production process.

This paper describes the methods that were used to study the usability of the monitoring system and presents preliminary results. The discussion will provide an interpretation of the results and an overview of the strengths and limitations of the study.

II. METHODS

The methods section describes the design of the study, the recruitement of participants, the study procedure, and the measurements and analyses that were used to study the usability of the monitoring system.

A. Participants and design

Participants were recruited via the expertise center for elderly care at the Orbis Medical Center in Sittard (the Netherlands). Inclusion criteria were: 70 years or older, community-dwelling, mobility or functioning problems, Mini Mental State Examination (MMSE) > 23, able to step onto a bathroom scale independently, and willing to learn how to use the interface on the mobile phone. Exclusion criteria were: planned admission to a nursing home/hospital during the period of the pilot study, being confined to bed, serious visual or hearing impairments, and contra-indication for exercise. The center's geriatrician invited eight patients who met the inclusion criteria. They received an information letter and a consent form via mail. Thereafter, the researcher contacted them within two weeks to ask whether they were willing to participate or whether they had questions regarding the pilot study. Patients who decided to participate signed written informed consent. Usability of the monitoring system (bathroom scale and mobile phone) was measured after three weeks follow-up. This study was approved by the Medical Ethical Committee Atrium-Orbis-Zuyd (NL35961.096.11).

B. Study procedure

At the start of the study the researcher (JV) visited each participant in their home. During that visit, instructions regarding the daily use of the bathroom scale and the mobile phone were provided to the participants. They also received two instruction manuals. The first manual was a simple overview of which steps they had to perform on a daily basis to monitor their own weight, balance, and activity. The second manual provided more detailed information about the two devices, using written text and photographs. Once instructions were provided, the participants practiced the use of the bathroom scale and mobile phone with the researcher until they felt confident in their ability to use the system. After that, the bathroom scale and mobile phone (+ charging hub) were installed in the homes of the participants at a place that was convenient for them.

After the home visit, the participants used the bathroom scale and mobile phone on a daily basis for 3 weeks to monitor their own weight, balance, and activity. Participants could use the bathroom scale between 7:00 and 10:30 A.M. They were encouraged to use the bathroom scale around the same time every day wearing similar clothing (and no shoes). After they used the bathroom scale they started their activity monitoring of that day. They did this by pressing the 'Start' button in the activity submenu of the application on the mobile phone and by wearing the mobile phone with them in their pocket. Participants were encouraged to end activity monitoring around the same time every day. Since elderly women do not always wear clothing with pockets, a belt was provided to them to which they could attach the mobile phone. They could wear this belt around their waist.

C. Measurements

After daily monitoring their balance, weight, and activity for three weeks the participants received a modified version of the Post Study System Usability Questionnaire (PSSUQ) [18]. Some items were removed from the PSSUQ because they were not applicable and some questions which focused on the usability of the separate devices were added. As a result, the items from the PSSUQ could be divided in three subscales: usability of the bathroom scale (5 items), usability of the mobile phone (10 items), and usability of the monitoring system as a whole (10 items). The participants rated each item on a scale from 1 to 7 (whether they totally disagreed, disagreed, disagreed a little, were neutral, agreed a little, agreed, or totally agreed). Besides that, free space was available after each question so that the participant could provide an explanation or clarification. Examples of the items were: 'I liked using the bathroom scale daily to measure my weight and balance', 'I needed a lot of help with

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using the mobile phone', 'I liked using the monitoring system', and 'Overall I am satisfied with the monitoring system'.

The participants also received an agenda at the beginning of the pilot study that they could use as a logbook. They were instructed to write down any difficulties they had with the devices on the day that it occurred. If the participants experienced any problems or had questions regarding the devices with the monitoring system, they could call the researcher for help. The researcher recorded the problems that occurred in a logbook as well.

Finally, adherence to the daily monitoring regimen was automatically registered by the mobile phone.

D. Analyses

The scores on the adapted version of the PSSUQ were analyzed quantitatively. Mean scores were calculated for the total PSSUQ and the three subscales of the PSSUQ per participant. Higher scores indicate better usability.

The data that participants provided in the free text space of the PSSUQ, the data that was recorded in the logbooks of the participants, and notes in the logbook of the researcher were analyzed qualitatively. All remarks, comments, and reported errors were structured per device and per function of the monitoring system.

Adherence rate to the daily monitoring regimen was calculated by counting the number of days that data on the three physical indicators (weight, balance, and activity) were saved on the mobile phone. This number was divided by the number of days that a participant was included.

III. RESULTS

The results section provides an overview of the characteristics of the users and how they rated the usability of the monitoring system. Furthermore, data regarding the adherence to the daily monitoring regimen is presented.

A. Characteristics of study participants

Six participants, two men and four women aged between 79 and 83 years, agreed to participate and provided written informed consent. All participants owned a mobile phone but they rarely used it. None of the participants had used a smartphone before. Of these six participants, four completed the pilot study. One female participant (participant 6) dropped out after two days because she was suddenly admitted to the hospital and therefore her data will be disregarded in this paper. Another female participant (participant 4) decided to stop participation after using the monitoring system for 6 days. She indicated that the main reason for her drop-out was that she did not feel supported by her husband in using the monitoring system. Despite her early drop-out, the participant filled out the adjusted version of the PSSUQ after 6 days of participation.

B. Usability scores of PSSUQ

The usability scores that the participants provided on the adapted version of the PSSUQ are presented in Figure 2.

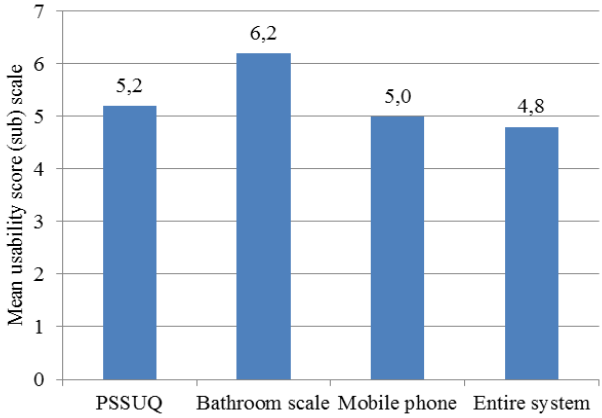

Figure 2. Mean usability scores after 3 weeks

The mean score on the adapted version of the PSSUQ was 5.2 (SD .90) and scores of participants varied between 6.2 and 3.8. The mean scores of the subscales for the bathroom scale, mobile phone and system as a whole were 6.2 (SD .64), 5.0 (SD .84), and 4.8 (SD 1.0) respectively on a scale from 1 to 7. The participant who dropped-out of the study after 6 days (participant 4) gave the lowest usability scores on all subscales.

C. Problems recorded in logbooks and PSSUQ

Analysis of the logbooks and comments on the PSSUQ revealed that some problems occurred with the data transmission of the bathroom scale. Participant 1, 2 and 3 all recorded in their logbook that the bathroom scale did not transfer the data to the mobile phone on one occasion. This made it difficult for the participants to continue with their activity measurement of that day. Besides that, the application on the mobile phone accidentally shut down on three occasions. Due to this error, which was reported twice by participant 1 and once by participant 5, participants had to restart the application before they could continue monitoring their weight, balance, and physical activity. Furthermore, participant 2 had difficulty with starting the daily activity measurement at the start of the pilot study. During an extra home visit it appeared that the participant kept pressing the stop button directly after pressing the start button.

D. Adherence to the daily monitoring regimen

Frequency calculations revealed that participant 1 did not monitor any of the physical indicators on 5 of the 21 days. Combining the logbook with the adherence data revealed that on all 5 occasions, the participant skipped the measurements because the visited family members on those days. Participants 2 and 3 monitored their weight, balance, and activity every day during the pilot study. No adherence rate was calculated for participant 4 because she dropped-out of the study. Participant 5 had the lowest adherence to the monitoring regimen since data of all three indicators were missing on 11 of the 21 days. Thus, the adherence rates of participant 1, 2, 3, and 5 were 76%, 100%, 100%, and 48% respectively. The adherence data from the four participants

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who completed the pilot study resulted in an overall adherence rate of 81% to the daily monitoring regimen.

IV. DISCUSSION

All participants who completed the study gave usability scores of 4 or higher on the different subscales of the adapted version of the PSSUQ and the participant who dropped-out rated the overall usability of the system with 3.8. This positive evaluation of usability is important since this is a prerequisite for the uptake of new technology in daily practice [15,16]. However, another important requirement that should be met is that the monitoring system should operate without interruptions [19]. Analyses of the logbooks that were kept by the participants and the researcher revealed that a few errors occurred during the pilot study and therefore some improvements are still needed in the monitoring system and the application.

The adherence of the participants to the monitoring regimen seemed to be satisfactory since three of the four participants used the bathroom scale and mobile phone at least 75% of the days to monitor weight, balance, and physical activity. Only participant 5 had low adherence, but this was mainly caused by the fact that the participant could not restart the application by herself after it had shut down automatically. So, her low adherence rate was a result of an error in the application that caused a usability problem.

A. Strengths and limitations

A recent review by van den Berg et al. regarding telemedicine and telecare for older patients revealed that the majority of studies in this field are carried out in 'younger older patients' who do not always represent the target group of the innovation [20]. A strength of this study is that the in- and exclusion criteria were formulated in such a way that the group of 'younger older patients' was not included. Another advantage is that the usability of the monitoring system was tested in the daily lives of elderly people instead of in a controlled lab-situation because this provides more accurate and detailed information regarding the usability problems that occur [21].

A limitation of this study is that only few patients participated which makes it difficult to draw a firm conclusion regarding usability based on the data that is available. Furthermore, the relation between the home measurements that were performed by the participants and medical outcomes was not studied. Therefore, no conclusion can be drawn yet regarding the usefulness of tracking health evolution of elderly patients and the possibility of detecting clinically relevant health changes with the monitoring system. During the pilot study some changes in weight, balance and activity were detected, but it is difficult to say whether these were clinically relevant or not. Besides that, small variations in weight might also have been caused by calibration issues that are often present in bathroom scales. But it is unlikely that these variations will lead to serious misinterpretation of weight recordings since participant use the bathroom scale every day which will average these variations.

Another limitation of this pilot study is that an adapted version of the PSSUQ was used to rate the usability of the monitoring system instead of the original version. This makes it difficult to compare the usability scores of this study to usability scores of other studies that used the original version of the PSSUQ. A positive aspect of the adapted version of the PSSUQ is that participants could provide comments to explain or complement their scores on each item. In combination with the logging files, this provided additional insight into what caused usability problems.

B. Conclusion and future work

The participants were mostly positive about the usability of the monitoring system but some improvements have to be made to the monitoring system and feedback application. The monitoring system and interface are currently being improved based on the results of the pilot study. Since the pilot study only had a few participants and a relatively short follow-up period, another study will be conducted during which 50 elderly people will use the improved system (including the grip ball) every day for 6 months. The follow-up study will not only focus on the usability of the improved monitoring and feedback system but also on the acceptability and added value as experienced by elderly people. Besides that, the usability, acceptability and added value of the system and database as experienced by health care professionals will be studied. We expect that the follow-up study will also provide more insight into the possibility of detecting clinically relevant changes with the devices of the monitoring system.

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An Optimized Infrastructure for Deferred Telemonitoring of Home Rehabilitation in Chronic Rheumatic Patients

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***Abstract*—The interest towards telemedicine and its various branches is constantly growing, given the opportunities in terms of costs reduction, efficiency and capillarity in delivering health services. In particular, telerehabilitation aims at improving the quality of life of physically impaired patients, providing the support for home-managed rehabilitation sessions. Moving from an existing outpatient device for the quantitative evaluation of hand rehabilitation exercises, opportunely enhanced to be used in a telemonitoring scenario, in this paper the development of the remaining telerehabilitation infrastructure is presented and evaluated. It includes, beyond the rehabilitation kits, a remote server and a deferred monitoring software application. The kits, entrusted to the patients for rehabilitation in their home, are able to send to the remote server via a GSM/GPRS connection, quantitative measurements of the patients' performance. The physician's monitoring application, retrieving such data and providing an appropriate visualization, allows the evaluation of both the patients' compliance to the rehabilitation protocol and their progresses. The system has been evaluated by a small panel of rheumatologists in order to assess its acceptability in a clinical environment and is currently under test for experimental trials in Italy.**

***Keywords*-telerehabilitation; telemedicine; hand disability.**

I. INTRODUCTION

Telemedicine is a field of medicine which deals with providing health services at distance, exploiting information and communication technologies (ICT) resources to diagnose, treat and prevent diseases and injuries [1]. The interest towards this practice is based on the possibilities disclosed in terms of efficacy, quality and cost-effectiveness of the health services delivered [2] to an increasing number of patients. Telerehabilitation, dealing with delivering rehabilitation services over distance, can be used in a number of different scenarios, from post-stroke to invalidating chronic diseases. In such cases, it is important to step in with personalized kinesitherapies whose effectiveness strongly relies on the patient's rigour in following the medical protocol. Without remote monitoring it is not possible for therapists to assess the compliance to the rehabilitation protocol when it is performed at home and to adjust possible incorrect behaviours which could undermine the rehabilitation effectiveness. At the same time, closely assisting every patient during the rehabilitation (either in person or from remote) would require a huge effort, considerable costs and discomfort for the patients, being hardly practicable.

In fact, several telehomecare systems have been developed including a videoconferencing support in order to interact with the patient, as for the Twoway InterActive TeleVision [3]. This kind of solution requires large bandwidth and it is expensive not only in terms of actual cost but also in terms of time dedicated by the physician to every patient, that is incompatible with the real workload of a clinician. Store-and-forward solutions, where the analysis of the patient's parameters sent to the physician for evaluation is deferred, can be more acceptable provided that a proper data summarization is ensured. In fact deferred monitoring allows keeping track of a large number of patients' therapies with a limited effort. Nevertheless, the introduction of any ICT tool in the clinical practice cannot neglect its overall acceptability from both the patient's and physician's viewpoints. The latter is usually overlooked compared to the former, with the result of drawing unrealistic conclusions about the possibility of exploiting such a tool in a real scenario. Physicians need intuitive and user-friendly software tools able to provide useful, informative data allowing to ease the assessment of the patient's performance, speeding up the evaluation process rather than complicating it. At the same time the system approach must be sustainable in terms of costs for both the patients and the Public Health System.

Moving from the extension of a device for the quantitative evaluation of hand rehabilitation exercises in rheumatology clinics [4], this paper deals with the development of the best suited telemedicine infrastructure able to include such (modified) device into a telerehabilitation scenario. The development of such infrastructure is driven by the need of meeting the requirements of effectiveness, sustainability, acceptability and user friendliness. Such aspects are in depth covered in this paper in order to present the proposed implementation along with its critical appraisal in terms of alternative technologies. The evaluation of the system usability from the physician's perspective has been carried out exploiting a panel of physicians getting in touch with

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it for the first time. The proposed system is currently being used for experimental trials in Italy.

The remainder of the paper is organized as follows. Section II presents the proposed telemedicine infrastructure implementation issues, on a specific use case. The critical motivation of the specific choices in the light of possible technological alternatives is presented in Section III, along with the results of a usability test performed on a small panel of rheumatologists. In Section IV the final remarks are presented along with the future developments of this work.

II. The Proposed Telerehabilitation Infrastructure

As mentioned in Section I, this work moves from the extension of a device for the quantitative evaluation of hand rehabilitation exercises in rheumatology clinics [4]. In such a work, a hardware kit for the outpatient examination of kinesitherapic exercises aimed at restoring the hand functionality in patients affected by chronic rheumatic diseases was presented. That kit enables the therapist to monitor the execution parameters for a set of hand kinesitherapic exercises while they are in progress, by means of a Matlab user interface controlling the device in real-time. The extension of such system to add telemonitoring features requires modification to the hardware kit and the development of the whole telemedicine infrastructure able to include it into a telerehabilitation infrastructure.

The proposed infrastructure is aimed at deferred monitoring, so it is necessarily composed of three main components, as depicted in Fig. 1. A set of rehabilitation kits, in this case modified versions of the portable briefcases presented in [4], are entrusted to the patients. They allow to perform several rehabilitation exercises, extracting parameters characteristic of their execution. The kits are able to send the collected data to a remote server. This is in charge of both gathering and storing such data in a database, keeping track of the progress in the patient's performance over time. The last component is the monitoring software, an application expressly designed for the physicians to access such data and perform some basic analysis. From Fig. 1 it is possible to see how the direct communication over the Internet of the kits with the physician's PC is not allowed. In the following, the different parts of the system are presented.

A. The rehabilitation kit

The kit provided to the patient allows the execution of different rehabilitation exercises, which include both strength and agility exercises, expressly designed by expert rheumatologists [4]. With respect to its first version, the kit has been enhanced in order to support the telemonitoring features. The set of exercises to be executed, the number of series and the number of repetitions within each series, can be adapted to the patients needs. Following the indications provided

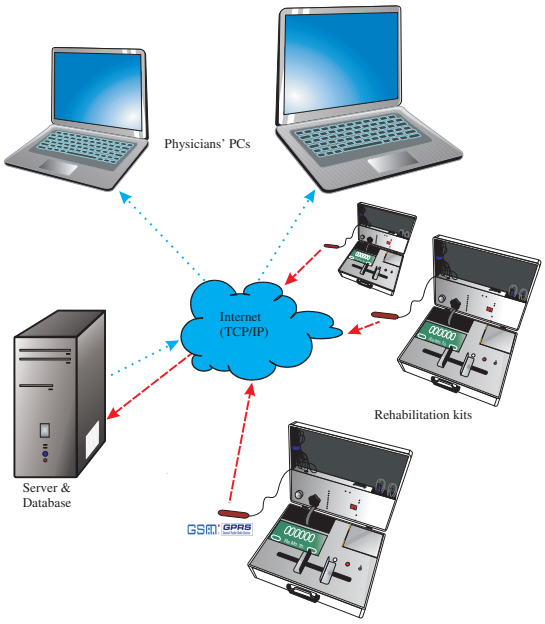

Figure 1. Main components of the telemonitoring system for hand rehabilitation.

by the kit through a simple led-based interface, patients are able to perform a training session autonomously. The kit collects quantitative data representative of the patient's performance in each exercise, summarizing them through a set of statistical values including the mean, standard deviation, maximum and minimum values of the physical quantities of interest for each exercise and the associated temporal information.

The kit has been equipped with a GSM/GPRS module (SIM900 by Simcom) able to provide a wireless connectivity mean to transmit only the summarized data to the remote server over the Internet at the end of each training session without any user intervention. The module is controlled by the central processing unit of the rehabilitation kit via a serial port (USART) interface and is managed exploiting the AT commands. These basically are ascii strings, originally introduced to manage dial-up modems, which encodes operations such as configuring the connection, dialling and hanging up. It first establishes a TCP/IP connection with the remote server and then sends a chunk of data composed of an header and a payload. The header is a unique code extracted from the SIM card installed on the GSM/GPRS module, namely the International Mobile Subscriber Identity (IMSI) code, a 15 digit number. In this way, a patient-SIM couple is intrinsically created, ensuring anonymous data transmissions. The payload is the vector of the training session statistics, in binary format. The amount of data sent is constant, regardless of the actual rehabilitation protocol configuration (the areas corresponding to non-executed exercises are zero-padded), so it is easy to identify the data

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of a given exercise simply relying on their position into the frame. As soon as the server acknowledgement is received, the kit can be turned off, otherwise the data is stored on a persistent storage mean (embedded onto the device) and it is made available for a further try. Hence it is possible to recover the data after an unsuccessful transaction due, for example, to a momentary GSM network malfunctioning.

B. The remote server

The remote server is the software application responsible of collecting the data from the rehabilitation kits and of storing them in a database for an easy retrieval. Furthermore it processes and answers the requests forwarded by the therapist's software tool. The application listens continuously for incoming connections, ready to receive new data at any time (allowing the patients to have no time schedule for their training sessions). The software is a multi-threaded C++ application, developed for a Linux server platform. The server actual functionalities, such as taking care of the data traffic from/to both ends of the system (i.e. from patients' kits and from physicians' PCs) are handled by two parallel threads (S1 and S2), each one listening on a different socket for incoming connections. The first one (S1) is the interface towards the rehabilitation kits. When a new connection is requested, S1 creates a sub-thread which handles the transfer. By default the incoming data frame is accepted, temporarily stored and parsed. If a valid device is recognised the fixed sized data frame is received and analysed to check the data integrity. An error is logged if:

- the client device is not recognised
- an insufficient amount of data has been received
- the received data integrity check fails.

In case of errors the data is written into a separate file (mainly for debugging purposes) but no entry is set into the database. After a successful validation, the acknowledgement is sent to the device, the connection is closed and the data is inserted into the database. The server is capable of managing multiple connections at the same time, since each transaction is handled by a different thread. To avoid issues while accessing the database, all the operations performed on it are protected by mutexes (which implements mutual exclusivity), so only one thread at a time can access it.

The interface towards the monitoring application is handled by the S2 thread. It is capable of answering to nine different queries by which it is possible to request different sets of data. The limited number of allowed queries confers a good flexibility to the therapist in choosing with a fine granularity the data to download, without an excessive increase in the design complexity.

1) Database management: The server application relies on a SQLite relational database for the storage of the patients' historical data. This choice eases the system design, being not necessary the adoption of a database manager. Still it can be accessed by means of standard SQL queries and all its contents reside on a single file, which can be backed-up easily for safety reasons. Its structure is fairly simple and consists of 4 tables (Fig.2):

- a table T1 containing the list of registered kits
- a table T2 containing the list of the rehabilitation session recorded by the system. Each row of T2 is related to a unique row of T1
- one table T3 for each exercise containing the data related to the executions of that particular exercise by each patient. Each row is related to a unique row of T2
- a table T4 containing the protocol (i.e. number of series per exercise, number of repetitions, etc.) associated with each kit. Each row of T4 is related to a unique row of T1.

T2 and T3 can be accessed by both the rehabilitation kits (to insert the data) and the physician's monitoring software (read only, through the 9 access queries). The latter can also modify T4 content. Each query issues a SELECT SQL instruction on the tables they identify. Fig. 3 shows the format of the messages exchanged between the server and the client applications. The messages containing the server answers are formatted as depicted in Fig. 3 regardless of the query being answered to. This eases the monitoring application design and possible modifications/enhancements to the communication protocol. Deleting entries from the database, when necessary, must be done at low level by issuing specific SQL queries by the system administrator, in order to avoid accidental loss of data. To improve safety, a copy of the database is automatically backed-up every day via a Secure File Transfer Protocol (SFTP) connection. This avoids loosing the data stored onto the server memory in case of accidental damages to the machine, saving the costs and the hassle of managing a RAID unit, which is in any case a viable option.

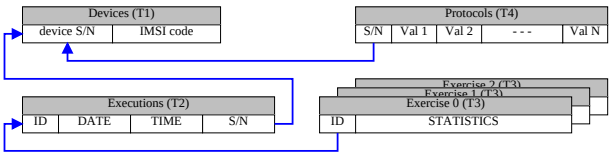

Figure 2. Internal structure of the database.

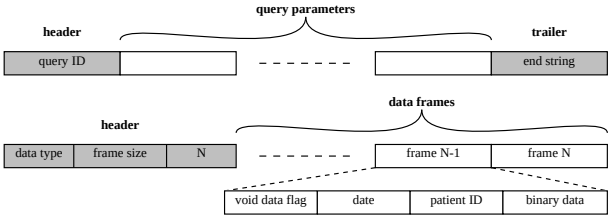

Figure 3. Format of the messages exchanged between client and server applications. From top to bottom, the *request* frame format and the *response* one.

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C. The physician's monitoring application

The therapist can access the data and evaluate the patient performance by means of a custom software. The application is based on the Qt framework, and allows an easy visualization of each patient's data by means of an intuitive graphical user interface (GUI). The GUI is composed of four main views where the user can:

- customize the application settings in the options tab
- send a query to the remote server and download the data
- check the patients rehabilitation sessions
- analyse with more details the historic results achieved by each patient.

The software has been designed trying to achieve flexibility both in terms of data management and analysis. In order to ease the data retrieval, the user can graphically build the query to forward to the remote server by selecting which data he wants to access.

Once the data has been downloaded, the therapist has the possibility to perform different actions. It is possible to verify who is performing the training according to the protocol and who's not. An immediate analysis of the patients' performance can be carried out and the data can be exported in a portable format (a .csv file) and saved locally for a delayed analysis. The first operation can be carried out by means of the Execution tab (Fig. 4), where a table shows which patients do have a correspondent entry in the table T2 of the database (marked with a green "v") and which not (a red cross is shown). This is a fast way to verify if some patients are not following the protocol correctly; the therapist can hence get in touch with them to find out if any problem has arisen.

By means of the Analysis tab (Fig. 5), a more detailed analysis can be performed by selecting specific data subset representative of the historic trend of each patient's performance in the individual exercises. The data are hence plotted on a time chart separately for each hand and series (I and II) executed in the training sessions. In the graphs, each point corresponds to the performance obtained by a patient in a given date. The plotted data are the one mentioned in Section II-A. The performance is quantified approximately by the mean value of the physical quantity relevant for that exercise (e.g.: torque in Nm). The trend of this quantity gives a clue on the patient progresses. Further information such as maximum and minimum values, standard deviation and number of repetitions associated with each series are though necessary to assess the meaning of the mean value. The physician interface makes such data available in an intuitive and easily interpretable way, in order to ease performing such kind of analysis (Fig. 6). For a deeper insight, or statistical data characterization, the data can be exported in order to allow the exploitation of specific external software tools typically used in the medical community.

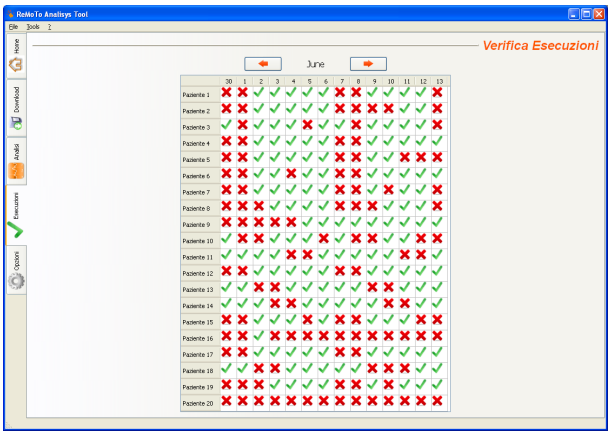

Figure 4. Execution table of the therapist GUI.

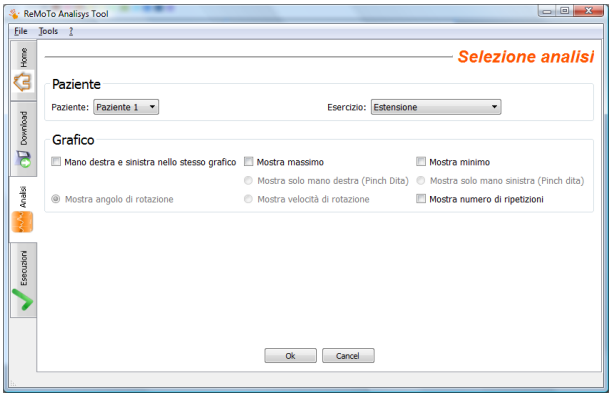

Figure 5. Analysis selection screen of the therapist GUI

III. Clinicians' evaluation

The proposed telemonitoring infrastructure is currently under test in Italy by the Chair of Rheumatology and Rheumatology Unit of the University of Cagliari, within a trial involving 20 chronic rheumatic patients. In order to assess the usability of the system, a panel of 9 rheumatologists not directly involved in the trial has been asked to undergo a simple test in order to evaluate the telerehabilitation system. The choice of asking to experts in the field descends from the need to ensure the user has an idea of the usefulness of the system and all the more so he is able to understand what he is analysing in terms of patient's data.

After attending an half-an-hour presentation on the whole telemedicine infrastructure with details on the physician's monitoring application, the rehumatologists had the possibility of using the system for the time required to carry out 3 simple tasks, without any possibility of interacting with the designers, reporting if they were able to perform a given task and their difficulty in performing it (on a scale from 1 to 5). The tasks were a synthesis of common operations included in a normal use case and consisted of: data download, execution data and statistics visualization, and

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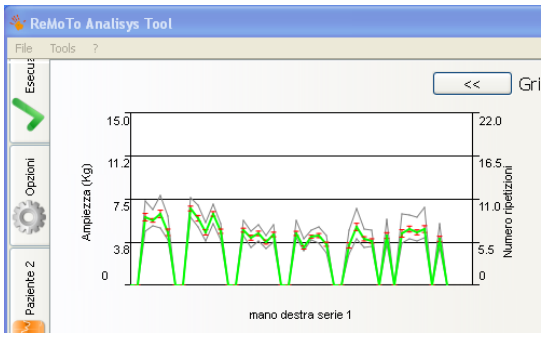

Figure 6. Exemplary historic series for an extension exercise performed by a real rheumatic patient over the first 6 therapy weeks.

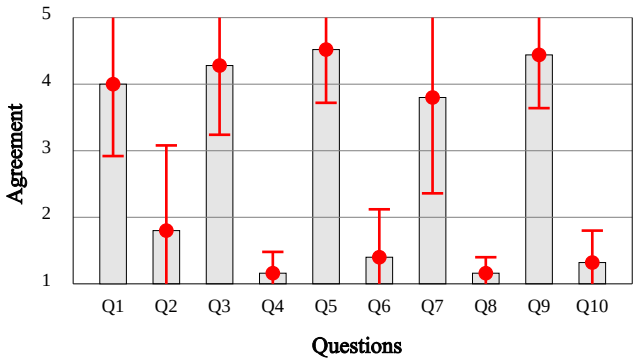

Figure 7. Mean and standard deviation of the answers to the individual SUS questions (the vertical scale represents the level of agreement, with 1 for “strongly disagree” and 5 for “strongly agree”).

raw data comparison through the graphic interface. Then, a questionnaire for the evaluation of the system usability has been administered. To this aim, we chose the System Usability Scale (SUS) questionnaire [5]. Such a scale tries to measure the perceived usability of the system (from the physician’s perspective) within the reference context. In fact, usability can be intended as the perceived appropriateness to a context of a given artefact, and cannot be fairly evaluated outside it (for instance with physicians with a different background and specialization). The 10-item scale yields a single number from 0 to 100 representing a composite measure of the overall usability of the system being studied [5]. The SUS presents 10 statements, the responder being asked to choose the level of agreement within a scale from 1 to 5. The sentences concern the system ease of use and usefulness, e.g. ”Q1. I think that I would like to use this system frequently” or ”Q2. I found the system unnecessarily complex” (the complete questionnaire con be found at www.usabilitynet.org/trump/documents/Suschapt.doc).

A. *Results and discussion*

In the proposed test all the tasks have been performed correctly by the physicians, and the average difficulty level marked was 1.4. In Fig. 7 the results of the SUS assessment are shown. It is possible to see the distribution of the answers to the 10 questions proposed by the questionnaire in terms of mean and standard deviation (the scale is from 1 to 5, where 1 is for “strongly disagree” and 5 for “strongly agree” with the questionnaire statements). The final score is a mean SUS of 85.3 (minimum value 55, maximum value 97.5) with a standard deviation of 13.8. Taking into account that the system has been used for the first time by the panel of physicians in that occasion, it is overall a very good result.

From a physician perspective the system presents several advantages under different viewpoints. At first, the whole infrastructure is completely standalone, i.e. it can be used as it is, without the need of any additional support device at both ends (patient’s and physician’s), limiting possible additional costs for both the patient and the Public Health System. For instance, as said an embedded GSM/GPRS module provides the Internet connectivity. Among all the different solutions, apt to achieve the same result, the proposed one allows to limit the required telecommunication infrastructure at the patient’s home. He is not required to have neither a Wi-Fi or wired (i.e. Ethernet connectivity) wide-band connectivity nor a dial-up telephone line (with all the security and regulatory issues). Getting rid of any burden such as having and managing additional external tools is also particularly important when dealing with elderly patients. For instance, in [6] a telerehabilitation system somehow similar to the one presented here is introduced, but the patient’s kit is not stand-alone, requiring a PC with an internet connection. The same holds for systems requiring advanced mobile phones as telecommunication gates [7] or specific home entertainment devices such as Nintendo Wii [8] and similar tools. Even telemedicine systems exploiting apparently widespread devices such as DVB-T apparatus for digital TV [9] can pose some problems when specific features are required (e.g. dial-up connection from the set-top-box, embedded smart card reader, etc.). This fact could leave out of a telerehabilitation program those patients who are not accustomed to such technologies, not equipped with the basic infrastructure, not able to pay for the connectivity costs. In the proposed system, pre-paid SIMs allow the hospital to easily manage the connectivity costs.

All the low level aspects of the whole telemedicine infrastructure are completely transparent for the physicians. In this way the physician can better focus on the monitoring aspect and the interaction with the patient. The execution table on the monitoring application allows a birdview of the patients population in terms of execution without entering the details. Further analyses on the single patient are also allowed. The patient-physician interactions are enforced: the physician can correct or stimulate the patient whereas the patient, knowing its monitored status, is motivated and more prone to communicate with the physicians if some physical problems arise.

From a more technical perspective, summarizing the data

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in terms of relevant statistics at the source implies efficiency advantages not only in terms of connection costs reduction but also in terms of battery life extension (on the kit) and lightweight database (on the server) which means faster queries response time. Such process also avoids overwhelming the physician with data not immediately interpretable, slowing down the monitoring process. Also the choice of sending only binary data with the header composed only by an IMSI code is particularly useful for privacy issues, avoiding expensive and complex systems to cipher the communications between the kits and the server, mainly, since from the physician's side the decryption process could be more easily implemented.

The cost-effectiveness of the proposed infrastructure is demonstrated by the maintenance values: a 24H server with a dedicated hardware machine by an external provider costs 71 Euros/month; every SIM costs 2.5 Euros/week. Then the maintenance cost of the system is about $(71/N + 10)$ Euros/patient, where N is the number of involved patients having a kit, which seems to be reasonable for the level of the service provided.

IV. Conclusion

The main challenge in designing effective telerehabilitation systems is the correct evaluation of the trade-off between different requirements, such as the medical needs and the economical resources. Within this study a possible solution to these issues has been presented, taking into account both patients' and physicians' needs. The problem of minimizing the system maintenance costs has been carefully taken into account, giving raise to a low cost telemedicine infrastructure which clearly simplifies the system management for patients, exploiting an automatic wireless connection on a stand-alone device. Also, the evaluation of the system therapists' interface by means of the SUS test, performed on a panel of 9 rheumatologists, evidences the efforts that have been done in realizing a system usable in clinical practice.

Although the presented system applies to a particular case of telerehabilitation, the considerations made throughout the paper are common to other telemedicine applications. Telerehabilitation of course does not implies that it is be possible to neglect the patient to doctor human interaction, which still represents an important aspect of health care. In fact, the presented system could evolve just to improve it; for example a web based system where physicians and patients could share opinions, suggestions and possibly also schedule meetings or request assistance could be joined to the existing framework.

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Telestration in Mobile Telementoring

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***Abstract*—The paper analyses the domain of modern video conferencing-based mentoring systems applied in surgery. We aim to introduce mobility to telementoring, accompanied with telestration as an obligatory feature for telementoring systems. A detailed outlook to the domain resulted in encountering the camera movement problem, reported in the paper. As no direct solution was identified, a set of ideas towards the resolution of the problem is presented for further discussion and research.**

Keywords-telementoring, telestration, annotation, camera movement

I. INTRODUCTION

Telemedicine is defined as a set of medical practices, without direct physician-patient interaction, via interactive audio-video communication channel [1]. The advances of Information Communication Technologies (ICT) created a fertile ground for rapid development of software and hardware systems for telemedical purposes. Reported shortage of general practice surgeons with even higher deficit predicted for the future [2] is the main reason for the expansion of the domain of telemedicine. Advances and spread of the technology may be the way for mitigating the consequences of the lack of specialists in this field.

The research explores the field of telementoring. The initial purpose of telementoring is to provide assistance for a less experienced specialist (in our case - a surgeon), when a local expert is unavailable. This traditional approach offers high benefits concerning improved outcome of the procedure, lower time expenditures and reduced cost regarding the relocation of an expert. Moreover, the educational side of telementoring is also of high importance, since the remote expert acts as a personal tutor for the surgeon performing the operation.

The paper is structured as follows: after a brief introduction and motivation for the expanding domain of telemedicine, the reader is provided with an overview of current telementoring systems and challenges they are facing. Moreover, ideas of mobility in the domain are introduced. Together with the new features, new challenges are presented. Section III explores the camera movement problem in detail, while possible solutions and questions for further research are formulated in Section IV.

II. AN OVERVIEW OF CURRENT TELEMENTORING SYSTEMS

Video conferencing based tools are no longer a novel technology in medicine. Reviews by Augestad et al. [3] [4] summarize the benefits of using video conferencing in surgery during the past decade, highlighting the improvements in clinical and educational outcomes. When it comes to telementoring, the solutions are repeatedly demonstrated for laparoscopic surgery [5] [6] due to the simplicity of adopting this technological approach. However, current researches still limits telementoring to PCs/Laptops [7] at predefined "stations" or sites. We identified a general lack of studies exploring surgical telementoring from the mobile perspective. The limitations associated with mobile environments are gradually decreasing and disappearing due to rapid technological advances. Moreover, the fact that remote medical experts who are on call are likely to be moving around and almost always have their mobile phone (or a tablet computer) within reach, provides enough impetus for further exploration of mobile platforms. We believe that introducing mobility to the field of telementoring has potential waiting to be explored.

The use of mobile platform as a medium for telementoring systems introduces new challenges to be considered. As the mentor becomes mobile, dealing with possibly unreliable wireless Internet connectivity, varying bandwidth and limited battery power are the cases that require extra attention [8] [9]. However, limited computational power**,** available on mobile devices, is the most important constraint, as we are dealing with computationally intensive data processing. The mentioned hazards form a different angle for the analysis of current telementoring systems and telestration techniques towards possible adaptation and reusability.

Telestration (a technique, enabling drawing of freehand annotations over a still image or video) is not a very new approach to medical domain [9]. We argue that the telestration feature is an obligatory functionality of telementoring systems due to the increased accuracy of pointing actions. However, no analysis of the impacts of this feature to the workflow of the procedure was identified. This fact draws the guidelines for further research.

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III. CAMERA MOVEMENT PROBLEM

As mentioned before, we are focusing on telementoring for minimally invasive (laparoscopic) procedures. The selection was made due to technological aspects: as only camera-based representation of the operative field is available for onsite surgeon, sharing it with the remote expert is highly feasible.

After an analysis of a set of laparoscopic videos (N = 10 laparoscopic sigmoidectomy procedures) and discussions with domain experts (experienced surgeons from University Hospital of Northern Norway having previous experience in telementoring), we came to a conclusion, that movement of the camera is an integral part of the procedure. However, it may lead to the decreased accuracy of mentoring. Looking from the point of telestration, camera movement results in repositioning of annotations, which are supposed to be fixed on a particular anatomical landmark. As camera movement cannot be omitted, a technological solution towards maintaining constant position of the annotations should be identified. It has to be resistant to homogenous tissue representation, reflections, catheterization smoke and accidental emergence of body liquids. The complexity of this task requires a detailed research towards determining an appropriate solution, especially having the limitations of mobile platforms in mind [10].

IV. DISCUSSION: IDEAS FOR SOLVING THE CAMERA MOVEMENT PROBLEM

In this section some ideas for solving the camera movement problem are presented. The main focus is to analyse the problem by looking from the software perspective in order to use computational techniques towards the solution.

A. Combination of video and still images

Notwithstanding the moving camera, the operative field is also in motion. The deformation of soft tissues responding to the changing pressure inside the cavity and moving surgical tools contributes to the complexity of the representation. A set of stable reference points are needed not only for fixing the annotations, but even for ensuring the required accuracy of mentor's commands. The tissues should not be moving at least while the annotations are made by the mentor and observed by the mentee. This claim transforms the moving operative field into a still image for a discussion.

The described situation offers a direct work-around instead of solving the camera movement problem – combination of laparoscopic video stream and still images at the point when the advices from the remote mentor (including telestration) are necessary. The increased accuracy of annotations should be sufficient impetus for supporting this idea. Moreover, relatively simple implementation and low demand of computational resources are advantages looking from the mobile mentor's perspective. However, the image based representation loses the interactive component, meaning that the actual operative field may change while the surgeons are discussing the still scene. Notwithstanding this disadvantage, the solution offers an improvement to conventional telementoring systems (audio and video conferencing) supporting the mobile mentor approach.

B. 3D models for laparoscopic surgery

3D modelling techniques are one more direction for improvement. Su et al. presented a novel approach of combining Computed Tomography (CT) or magnetic resonance (MR) images and laparoscopic video. It resulted in live 3D model representing not only the surface of a particular organ, but also its inner structure [11].

The described approach becomes handy when solving the camera movement problem. The CT/MR based 3D model is aligned according to the reference points tracked on the surface of a tissue (organ) to ensure accuracy in case of deformations. This step establishes sufficient number of reference points which can be continuously reidentified and used as anchors for fixing the annotations. Moreover, the elements of 3D model also represent stable structures which may be used towards the solution. We see this solution as a long term goal for laparoscopic surgery and telementoring due to extremely high demand of computational power and complexity of the algorithms. Further research is required towards simplifying the computations towards applications in current mobile environments.

C. Other approaches

The core of the problem we are solving is continuous reidentification of fixed reference points in order to maintain constant position of the annotations. Computer vision techniques may also be used for tracking anatomical landmarks, for instance blood vessels [12] [13] [14]. Unfortunately, all studies dealing with blood vessel tracking use still images as an input. However, we hypothesize about extending the functionality of the algorithms for analysing video content. Of course, the techniques have a high demand of computational power, therefore, further research is needed to ascertain the feasibility processing live video stream and the use of a mobile device on the client side.

Researches on soft tissue deformation tracking also offer a solid basis for fixing the annotations [15]. The approaches focus on capturing the reference points on the surface of the tissue in order to create an accurate representation. As the captured reference points are sufficient for solving the camera movement problem, the solution looks promising. Nevertheless, the algorithms are computationally intensive, positive results in processing live video stream were presented [15] [16]. Of course, the sufficient computational resources are not provided by mobile devices yet, but it is only a matter of time until the required improvement of ICT will be ensured.

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V. CONCLUSION AND FUTURE WORKS

The work presented in the paper is in progress towards improving surgical telementoring. Most of the researchers in this field looked at the problems and future tendencies from the stationary point of view (stationary hardware and working position of the mentor). A new mobile approach introduces the challenges that were not considered before. However, we believe, that the potential of mobile platforms and its application in medical domain is still to be revealed. The new perspective leads to encountering the problems that have no direct solution yet. Our case reports the camera movement problem, preventing from maintaining constant position of the annotations and ensuring the required accuracy of mentoring. Ideas for possible solutions were directed towards further discussion and research.

Looking at the presented solutions, we hypothesize that 3D modeling approach (Section IV.B) has the most potential to become the overall direction for laparoscopic surgery and telementoring. The possibilities of advances in 3D modeling are close to unlimited. For instance, it allows having an accurate model of a particular organ, containing its inner structure which would make the surgeon aware of the internal elements of the tissue (blood vessels, nerves, etc.) before the cut is made. If we add live tracking of laparoscopic tools to the model [17], the system may grow to surgical action advice system, alerting the surgeon before the particular move which could harm an element of the inner structure (for example a cut of a blood vessel). In this case, the model of the particular tissue should be extended to the model of the entire operative field, including the surgical tools and the internal structure of the surrounding tissues.

It is not possible to solve the problems we are facing by looking at them from the theoretical point of view only. Therefore, to result in a prototypical implementation a design phase for mobile mentoring software is in progress**.** It will provide a more solid support for the claims made in the paper. However, to generate sound results, impact measurement scale should be established. It also requires a separate study, followed by trials and data collection.

Looking at all the presented solutions, the main obstacle for the mobile telementoring is the limited computational power provided by mobile devices. Fortunately, the technology moves forward, making this limitation to gradually decrease and disappear. It is only a matter of time until advances in mobile technology ensure the required characteristics for data processing. However, together with technological advances, the expectations of potential users evolve, creating new challenges and directions for further research.

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ScrutiniseIT: A Search-Based Approach to EEG Seizure Detection

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***Abstract*—Seizures are both the most common neurological emergency afflicting neonates and the most difficult to detect clinically. Currently, the monitoring of a multi-channel electroencephalogram (EEG) is the gold standard for seizure detection. The accurate analysis of this physiological data requires a neurophysiologist with expertise in neonatal EEG. The provisioning of this expertise on a continuous basis can be challenging for medical facilities. In this paper, we describe a cloud-based platform capable of supporting clinicians through the creation of expert knowledge repositories. While the platform is considered general purpose, in this work it is applied specifically to neonatal EEG.**

***Keywords*—e-health, Seizure detection, Cloud computing, expert knowledge, search, signal processing, EEG**

I. Introduction

There is a correlation between the quality of care given to a patient and the availability of expert knowledge, particularly that which enables specialist care [1]. Therefore, there is a need for a platform capable of alleviating issues affecting the provisioning of this expert knowledge. We propose a platform that would be capable of broadening the scope of expertise, both human and machine, available to medical centres.

The ScrutiniseIT platform is based on a *scan-and-scrutinise* methodology. It incorporates the scalability benefits of cloud computing, enabling large volumes of physiological data to be continuously analysed for the identification of features of interest. It relies on expert annotations to the data and an algorithm designed to search through existing data repositories. The scan phase of the algorithm runs continually on data streams being acquired. A simple evaluation function is used to determine data segments that warrant closer examination. Upon detection of a potential feature of interest, that section of the stream is more closely scrutinised. The scrutinise phase determines if particular features of interest are present in the candidate signal. This is done within a specified confidence interval.

ScrutiniseIT is a live platform that affords clinicians the ability to collaboratively enhance one another's work. Clinicians annotate new data to highlight the occurrence of interesting features, this data becomes part of the overall annotated data repository. Subsequent processing of the data repository will be influenced by these contributions, thus improving the quality of the system over time.

The remainder of this paper is organised as follows: Section II provides an overview of related work on classification techniques for seizures in EEG, Section III describes the technologies that make up the system and provides details of their implementation, Section IV outlines our proposals for the experimental evaluation of the platform. Finally, our conclusions and future work are discussed in Section V.

II. Related Work

Numerous EEG seizure detection algorithms, using a variety of signal processing techniques, have been described in the literature. In [2], the authors present a neural network based system that operates in five stages: filtering, artifact detection, feature extraction (of both candidate and non candidate data), redundancy and relevance analysis. In [3], the author proposes the use of Discrete Wavelet Transformation, in an effort to find an improved time frequency representation of EEG and improve classification results.

In [4] three algorithms (Celka *et al.*, Gotman *et al.* and Liu *et al.*) for the automated analysis of neonatal EEG are evaluated. The algorithms employ a variety of classification

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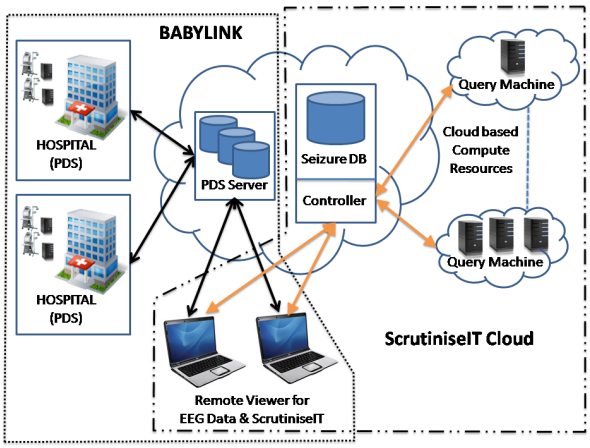

Figure 1. A high level view of the platform showing the BabyLink and ScrutiniseIT components.

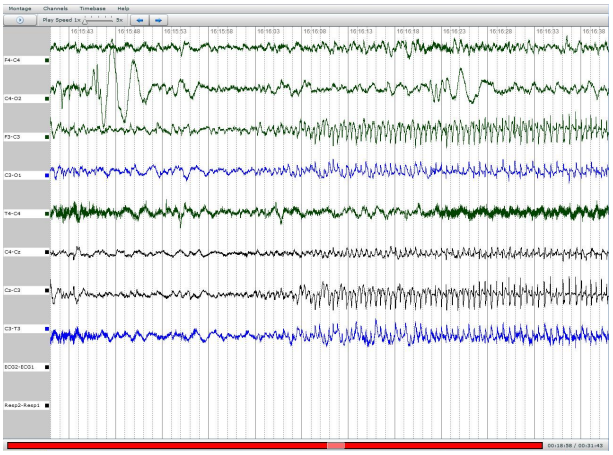

Figure 2. The view of EEG provided to a clinician through the BabyLink viewer. Seizure is visible on channels F3-C3, Cz-C3, C3-01, C3-T3, C4-Cz, so predominantly on the left hemisphere of the brain.

techniques, such as modelling, complexity analysis, rhythmic discharge detection and auto-correlative functions. The algorithms were found to have sensitivities ranging from 42.9% to 66.1% and specificities ranging from 54% to 90.2%.

In [5], it is argued that classifier based approaches are too rigid due to large variance in a neonate's signal frequency, morphology and topography. Instead, the authors attempt to mimic the behaviour of human experts through the creation of an algorithm that recognises the characteristics that enable humans to detect seizures. The algorithm focuses on the background EEG and the recurrence of patterns in the signal as a means of providing automated neonatal seizure detection. While this is an interesting approach, it can be considered a variant of traditional classification techniques.

III. Platform Overview

The algorithms described in Section II tend to use tried-and-tested signal processing techniques. However, this approach results in a static system that tries to identify seizures based on a single formula that does not change. The platform described in this paper uses a novel search-based approach to seizure detection that relies on comparison with a growing body of historical data. As such, it does not compete with traditional signal processing techniques, although these can be incorporated where appropriate during the matching phase. The platform utilises cloud computing in order to provide a scalable seizure detection service. The processing of EEG can be computationally expensive, availing of cloud infrastructure allows us to employ more resources when necessary. The platform is based on two components, BabyLink and ScrutiniseIT, each of which is described in detail below. An overview of the complete platform is depicted in Figure 1.

A. BabyLink

The Physiological Data Server (PDS), presented in [6], a web-based remote monitoring system that allows physiological data streams to be viewed in near-real-time, while acquisition is ongoing, via a web interface. This forms the core of the BabyLink part of the platform. Users are presented with a continuously updating view of the entire data stream, allowing them to view new data as they arrive or review data transferred earlier. The view presented closely resembles that found in the NICU and offers a similar interface to that seen in a traditional EEG monitoring machine. The only tool required for viewing EEG data using BabyLink is a modern web browser with the commonly available Adobe Flash plugin installed.

BabyLink's remote monitoring functionality was further extended, as described in [7], through the introduction of a facility to annotate data whilst reviewing it. Three top-level annotations were made available; *events*, *comments* and *waveform classifications*. Events indicate occurrences at the acquisition location. Comments are general, free-form text markup of the signal data. Waveform classifications represent a categorisation of a recording segment by a human analyst.

BabyLink also incorporates an agent framework, as described in [8]. This enhances the remote monitoring system by allowing a user-configurable set of agents to perform analysis on physiological signals as they are streamed through the system. The output of the agents assist with the analysts' interpretation of the data being streamed through the provision of alternate visualisations and automatically created annotations.

BabyLink is the gateway from the hospital to the platform. Enabling a clinician to analyse a patients data stream, toggle on or off continuous monitoring, or annotate a segment as a feature of interest. The agent framework enables the continuous acquisition of EEG and transmission of the data in real time, ensuring the that the platform is capable of "scrutinising" it as described in the next section.

B. ScrutiniseIT

ScrutiniseIT uses a *scan-and-scrutinise* approach to seizure detection, in which a candidate EEG is compared to a set of known seizures that have been obtained previously. The EEG data stream is treated as a series of epochs. Each epoch

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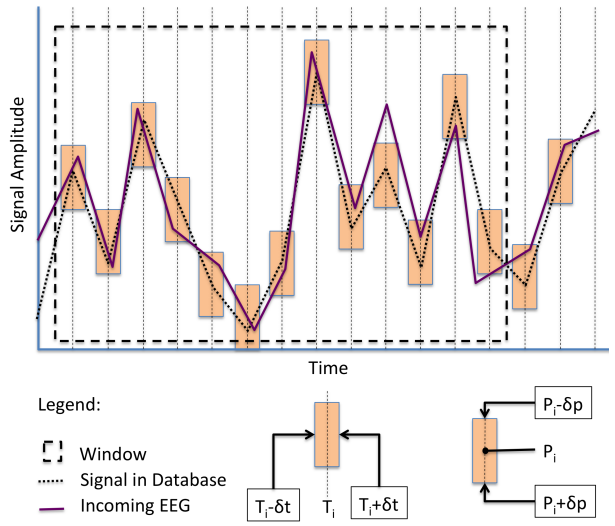

Figure 3. Signal matching in a ScrutiniseIT search.

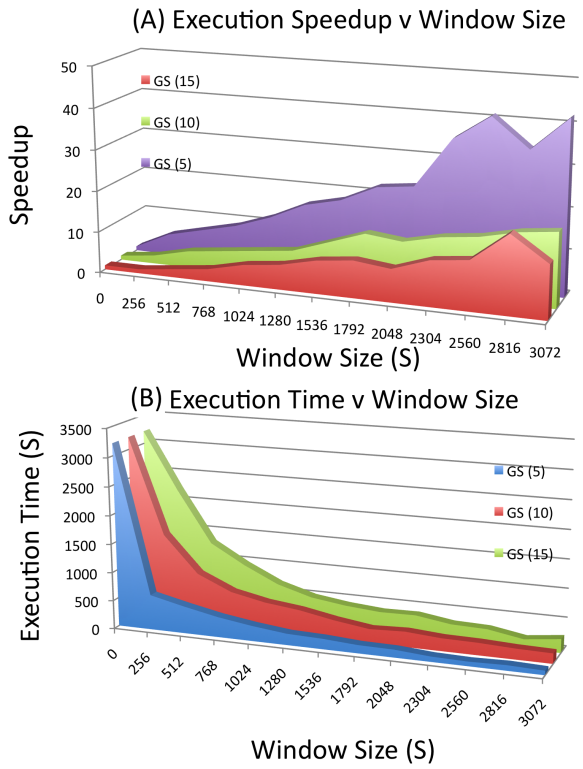

Figure 4. Preliminary results from ScrutiniseIT evaluation.

is examined for potential matches to the database of known seizures. Once a pre-determined threshold has been reached the potential for a match is noted, processing of that epoch ceases, and the process continues by advancing to the next epoch. The size of the epoch is defined by the Window Size (WS) parameter described below. A match occurs when a series of points observed match a similar series in the database.

ScrutiniseIT integrates with BabyLink via the agent framework described in Section III-A. Through the tuning of different parameters, the algorithm can either accelerate its search through the EEG (*scanning*), or perform slower, more detailed, analysis (*scrutinising*). These parameters are:

- **Confidence:** a percentage value indicating a minimum threshold that must be exceeded before a match with a feature of interest is recognised. The higher the confidence specified, the more exacting the match must be before the feature is reported.
- **Window Size (WS):** ScrutiniseIT uses a dynamic sliding window to contextually analyse a candidate signal pattern. Larger windows are used during the scan phase when trying to identify regions of interest in the candidate signal. When such a region is identified, the window size contracts appropriately to scrutinise these regions in more detail in an attempt to report features for a given confidence.
- **Grain Size (GS):** ScrutiniseIT operates by matching turning points in the incoming EEG with similar points in the database of known seizures. The grain size specifies the number of points required for a match to occur and is used to determine when an advance to the next epoch is triggered. The larger the grain size the greater the accuracy of the resulting matches.
- **Threshold Deltas δt, δp** : Matches are compared on each point at time +/- δt, and with accuracy +/- δp.

Figure 3 illustrates the matching process in action. The dotted line shows a sample signal from the database. Each turning point in the signal has a known amplitude which represents a point of interest. The window size being examined is encapsulated by the dashed rectangle. For each point of interest, the boundaries defined by the δt and δp points are shown as a shaded rectangle. The candidate signal is compared against the database of known signals. Although, in this case, the candidate signal exhibits a slightly different form; within the given window there are 11 matches out of 13 possible turning points exhibiting a confidence rating in the order of 84%. If a confidence rating less than 84% had been specified a match would have being reported, if greater than 84% no match would have occurred.

There is a trade-off between the time taken to process the signal and the search parameters such as window size (WS) and grain size (GS). The data shown in Table I illustrates this, the larger the window size the faster the algorithm executes but the less accurate the match with the points stored in the database, similarly the smaller the grain size, the faster the algorithm executes but the less accurate the match.

Therefore, our initial results show that a larger grain size will yield more accurate matches but at a cost of slower execution time. During our preliminary tests we have observed that for signals containing no known seizures, the number of matches is tiny.

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Table I
RESULTS OBTAINED FROM A NUMBER OF SEARCHES ALTERING WS AND GS VALUES. SPEEDUP OBTAINED IS ALSO SHOWN.

WS	GS = 5 Time(s)	Matches	GS=10 Time(s)	Matches	GS=15 Time(s)	Matches	Speedup GS=5	GS=10	GS=15
0	3216	1840	3216	920	3216	613	1	1	1
256	612	176	1536	113	2208	108	5	2	1
512	476	65	898	60	1303	59	7	4	2
768	354	43	634	42	962	40	9	5	3
1024	266	33	511	31	677	32	12	6	5
1280	199	26	441	25	503	25	16	7	6
1536	183	21	329	23	420	21	18	10	8
1792	144	18	244	18	371	18	22	13	9
2048	137	16	268	17	381	16	23	12	8
2304	92	14	224	14	290	14	35	14	11
2560	79	13	216	14	273	13	41	15	12
2816	95	12	189	12	168	12	34	17	19
3072	76	11	178	10	241	11	42	18	13

IV. EVALUATION

Initial tests of ScrutiniseIT have been conducted with a limited database of known seizures. An excerpt of the results from these tests are listed in Table I and depicted in Figure 4. In Figure 4(A) total execution speedup obtained versus selected window size is shown. Three sets of results are shown for different grain sizes. It can be seen that significant speedup can be achieved by selecting a smaller grain size, albeit at the cost of a reduction in the quality of matches. For the tests illustrated in this example, a confidence value of 70% was chosen.

Figure 4(B) illustrates that, as window size is increased, the total execution time is reduced. This is due to the reduced number of epochs that are available for selection. If a significant number of contiguous matches are found, the platform begins the scanning process at the next epoch. So, larger window sizes result in faster, less accurate, searches.

Although the results presented here are preliminary, they are encouraging. To further development, the platform will be evaluated in collaboration with the Neonatal Brain Research Group (NBRG, based in Cork University Maternity Hospital, Cork, Ireland) who have extensive expertise in neonatal EEG and have assembled a data repository consisting of over 800 hours of multi channel EEG containing more than a thousand seizures as well as a validation set comprising 70 neonates (35 seizure/35 non seizure). The main focus of the evaluation will be on the performance of the scan-and-scrutinise algorithm.

V. CONCLUSIONS AND FUTURE WORK

The scan-and-scrutinise approach to seizure detection in neonatal EEG is novel in that:

- Incoming EEG data is compared with a database of known seizures, this is in contrast to more typical approaches that apply generalised formulae.
- The provision of the system as a web service will allow it to evolve over time.

While this is a work in progress, further investigations into the effectiveness of the platform are ongoing, particularly in identifying optimal configurations that balance speed with accuracy.

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A Knowledge Representation for Cardiovascular Problems Applied to Mobile Monitoring of Elderly People

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***Abstract*— Although the decline of physical conditions is a continuous process related to the ageing, elderly people generally desire to maintain their privacy and autonomy for as long as possible. The technology of mobile health monitoring is an important approach to be applied into this scenario, once such technology enables a prompt identification of health problems. One of the trends in this area is to implement levels of intelligence into monitoring systems, so that they can take decisions and act in a more optimized way. For that end, one of the approaches is to provide deduction resources to mobile devices, so that they can manipulate knowledge in form of rules. This work shows how we can implement a light deduction system using a free-context grammar, which is mainly used to codify experts' knowledge. Our focus is on a grammar for cardiovascular problems, once this is the main kind of problem that affects elderly people.**

Keywords- health monitoring; knowledge representation; mobile applications; cardiovascular.

I. INTRODUCTION

As medical science advances, people can live with better health and alone up to a very advanced age. Thus, we have a new kind of social behavior, where elderly people are becoming more independent. In this scenario, where we must allow elderly people to live in their own homes leading their normal life, while, at the same time taking care of them, requires new type of assistant systems [1].

In this context, we have seen an increase in the number of researches towards the implementation of systems that carry out a remote monitoring of patients [2,3]. In fact, such systems bring several advantages, such as reduction of the public health care costs and more convenience to their users. The literature [4] lists interesting scenarios where the use of a health monitoring platform could be useful. One of such scenarios is the support to elderly people who are living in their own households.

Current researches in health monitoring are mainly focused on infrastructure aspects, such as network support [5] and information security/privacy [6]. Independently of the nature of the research, we see the use of mobile devices just as a router of health information. In other words, mobile devices are used as a component that receives vital signals from wearing sensors and sends such signals to central databases. However, we argue that mobile devices can act as an active element, rather than a passive and temporary repository of information. This means that mobile devices should present an autonomous behavior and be able to take decisions in accordance with its current knowledge.

The technique of rule-based systems [7] is one of the classical ways to implement autonomy in a system. Rule-based systems are used as an alternative to store and manipulate knowledge, interpreting information in a useful manner. Typical examples of rule-based systems are domain-specific expert systems that use rules to make deductions or choices. For example, an expert system might help a doctor in choosing the correct diagnosis based on a cluster of symptoms, or selecting tactical moves to play a game.

One of the main advantages of rule-based systems is its difference from standard procedural or object-oriented programs. In order, in such systems there is no clear order in which code executes. Instead, the knowledge of the expert is captured in a set of rules, each of which encoding a small piece of the expert's knowledge.

Frameworks for the development of rule-based systems are complex, mainly because they are domain independent. Thus, we do not have support for implementations of rule-based systems in mobile architectures. Considering this aspect, we restricted our domain to cardiovascular problems and defined a free-context grammar to represent the knowledge associated with this domain. This grammar enables the description of rules and the implementation of a decision making process, as detailed later on in this paper.

The remainder of this paper is structured as follows: Section II describes an overview of the health monitoring area, relating their approaches to aspects such as use of specific or general mobile devices, or presence of intelligent resources. Section III presents the architecture of our monitoring approach, detailing its three modules. Section IV discusses our representation module, which defines a grammar to codification of rules. Section V describes our experiments and results so far. Finally, Section VI concludes this paper with the main remarks and future research directions.

II. RELATED WORKS

A complete elderly monitoring system should consider several typical problems of aging. For example, while this paper is focused on the cardiovascular domain, several other works consider problems such as recognition of unusual behaviors, dementia, detection of falls and diabetes.

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The work presented in [8] uses a structural pattern recognition approach to propose a monitoring model using body sensors networks. This proposal is divided into two stages. First, a processing unit acquires health signals of uses, carrying out a pre-processing and local classification of such signals. In the next stage, a mobile device does a second data classification, storing the important information and triggering critical events, such as alert messages. The final aim of this work is to evaluate patient moving behavior and classify its physical activities. This approach is very useful for elderly monitoring, once activities patterns, such as low levels of activities, are strong indicators of health problems.

The work of Andreao *et al*. [9] considers the monitoring of cardiovascular problems. In this case they use a specific device, called Remote Unit, which receives cardiovascular signals and transmits such signals to a monitoring central where they are analyzed. The work presented in [10] also uses a similar approach. However, it integrates several kinds of sensors, differently of the previous work that only considers the ECG signal. Unfortunately, this work also uses a specific device to transmit data. In both cases, any kind of intelligent analysis is carried out. More recent works [11,12] tried to use traditional mobile devices, such as PDAs or mobile phones, rather than specific hardware. However, the devices are still only acting as a router of information.

Differently, some works started to use intelligent resources during the monitoring process. The system of Copetti [13], for example, uses several sensors, in a home care environment, which send health signals to a personal computer. The patient diagnostic process is carried out using Fuzzy Logic and a set of production rules in the own patient personal computer. In case of problems detection, this computer contacts health professional. Similarly, the work discussed in [14] is also classified as a home care system and it uses pattern recognition techniques to identify the behavior of patients in terms of locomotion and diary activities.

We see that when more advanced processing techniques are used, the monitoring systems tend to be a home care service, rather than a mobile application. The reason is the limited support that the Java Micro Edition provides for the mobile platform. The use of Android and other more powerful operating systems will eliminate the majority of these current limitations. For example, the LaCasa project [15] proposes a novel decision-theoretic model that estimates the risk faced by persons with dementia and decides on the appropriate action to take, such as prompting the person with dementia or calling the caregiver. The model can be tailored to the user needs (e.g. known locations, level of cognitive decline) and takes into account uncertainty, and contextual information gathered from sensors, such as current location, noise, and proximity to the caregiver. A preliminary version of the system has been instantiated in a wandering assistance application for mobile devices running on an Android platform.

From this discussion we see that current embedded systems that run in mobile devices do not support any kind of declarative codification in the form of production rules. Note that such rules are a natural way to codify knowledge. Indeed, ever production systems are not able to run in mobile devices, once we do not have first-order logic engines available to this platform. Rule-based systems are a natural way to codify knowledge if we have the knowledge providers. One of its main advantages is the ability to provide explanations about its decisions, once the reasoning flow can be tracked. Differently, case-based reasoning needs a high number of past cases to be configured, while conexionist (e.g., neural networks) forms of reasoning also need a training set and they generally do not provide ways to identify the reasons for their conclusions.

III. THE RULE -BASED MONITORING ARCHITECTURE

The monitoring architecture that we are specifying is composed of health sensors and an assistant agent running at a mobile device. Health sensors account for capturing important vital signals of patients and transmit such signal to the assistant agent. The sensors can use the Bluetooth technology, which is a standard communication protocol primarily designed for low power consumption, with a short range (power-class-dependent: 100 m, 10 m and 1 m, but ranges vary in practice) based on low-cost transceiver microchips in each device. Because the devices use a radio (broadcast) communication system, they do not have to be in line of sight of each other.

The assistant agent has three main modules (Figure 1): the Bluetooth drivers, the reasoning process and the SMS handler. Bluetooth drivers account for receiving signals from health sensors and transform such signals in facts. In order, getting rid of cables is a trend in the medical field, as it gives patients and healthcare workers more freedom and possibilities. Thus, Bluetooth is used in a variety of medical applications as a secure and reliable connection method.

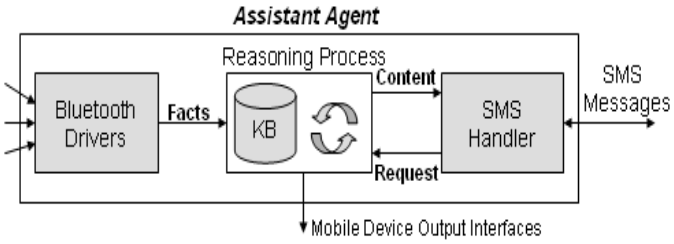

Figure 1. Architecture for a rule-based assistant agent.

Typical implementations have been based on Bluetooth *Serial Port Profile* (SPP) and manufacturers specific proprietary implementations and protocols. Therefore, different implementations have had a poor level of interoperability with each other. For this reason some initial efforts, such as the *Bluetooth SIG Medical Device Working Group*, intend to develop a profile that would introduce interoperability between different medical sensors and collecting devices from different manufacturers. Initial works resulted in the *Multi-channel Adaptation Protocol* (MCAP) and the *Bluetooth Health Device Profile* (HDP) [16].

The facts extracted from the Bluetooth communication are then saved in the *Knowledge Base* (KB) of the reasoning

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process module. These facts must respect a general pattern-value format, which is specified as

((*data time vital-signal-identifier*),*vital-signal-value*)

This could be instantiated to mean, for example, "on 19/10/2009 (*data*) at 17:30 (*time*) the temperature (*vital-signal-identifier)* was 38.5 (*vital-signal-value*)". Apart facts, a knowledge base is also composed of *rules* that represent the expertise of a health specialist. A rule has a left hand side (a sensory precondition or "IF" statement) and a right hand side (action or "THEN statement). The left hand side contains information about certain facts and objects which must be true in order for the rule to potentially fire (that is, execute). Any rules whose left hand sides match in this manner at a given time are placed on an agenda. One of the rules on the agenda is picked (there is no way of predicting which one), its right hand side is executed and then it is removed from the agenda. The agenda is then updated (generally using a special algorithm called the Rete algorithm), and a new rules is picked to execute. This continues until there are no more rules on the agenda.

A production system [17] controls the reasoning process and it also contains a database, sometimes called working memory, which maintains data about current state or knowledge, and a rule interpreter. The rule interpreter must provide a mechanism for prioritizing productions when more than one is triggered.

The reasoning process can generate content to be delivered to its user, via display or sound interfaces; or to the central root via short messages. The *SMS handler* accounts for encoding the content, which was generated by the reasoning module, into SMS messages. The principal reason to use this kind of communication service is its low cost. This aspect is important if we want to monitor the health conditions of different social classes, once we need to reduce the operational cost of this environment. Furthermore, the kind of discrete information that we intend to transmit (*e.g.* blood pressure, pulse and temperature) does not require a high band to be transmitted on.

IV. KNOWLEDGE REPRESENTATION AND USE

The best option to create an instance of a production system is to use a framework, which abstracts several of the production systems concepts. Several options are available to the personal computer platform, such as Jess and JEOPS [18], which are extensions of the Java language.

At a first moment, we tried to use a framework called KEOPS [19], a restricted adaptation of JEOPS to mobile platform. However, this framework requires a previous compilation of the rule base each time that the base is modified. Thus, this requirement prevents the process of updating the knowledge base by the own device. Considering this fact, we decided to create a light and domain-dependent inference mechanism to running in mobiles, as detailed in the next subsections.

A. Grammar Symbols

The grammar language is composed by reserved words, identifiers, punctuation signals and relational operators. The reserved words are only used in specific cases, as in any other formal language. An example is the "conditions" word, which is used to identify the beginning of the preconditions section of a rule. The punctuation signals are used to mark the end of a file (.), the end of a precondition or action (;) and the beginning of a block (:). The relational operators are used to define premises that must be (on not) validated by the system. When we define premises in the same precondition section, we are indirectly applying the "and" logical operator on such premises.

Table I shows all the elements that were considered in this version.

TABLE I. GRAMMAR SYMBOLS

Type	Token	Function
Reserved word	ruleBase	Name of the knowledge base
	Rule	Name of the production rule
	Conditions	Beginning of conditions
	Actions	Beginning of actions
	Normal	Type of detected health situation
	Alert	
	Emergency	
Identifiers	Name	Name identifier
	Age	Age identifier
	Gender	Sex identifier
	Weight	Weight value
	VitalSigns	Health signal identifier
	SBP	Systolic blood pressure value
	DBP	Diastolic blood pressure value
	heartRate	Heart frequency value
	respiratoryRate	Respiratory frequency value
	temperature	Body temperature value
	oximetry	Blood oxygen rate
	SBPVarianceSleeping	Variance of SBP during the sleeping
	SBPVarianceHomeActivity	Variance of SBP during home activities
	SBPVarianceStand	Variance of SBP during rest
	VERY_LOW	Possible constants used to classify the variation of health signals
	LOW	
	NORMAL	
	HIGH	
	VERY_HIGH	
Punctuation symbols	:	Indicates the beginning of a condition in a rule
	;	Indicates the end of a line in a condition or action
	.	Indicates the final of a rule base
Relational operators	< <= > <= = #	Symbols used to carry out relational operations

B. Creating Instances of Rule Bases

To represent production rules using such symbols, we have specified a simple context free grammar to facilitate the

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work of formalizing the expertise used in this work. Figure 2 shows a simple example of rule base specified in accordance with that grammar.

```
ruleBase test
    rule first:
        conditions:
            SBPVarianceSleeping = LOW;
        actions:
            alert;
    rule second:
        conditions:
            SBPVarianceSleeping = NORMAL;
        actions:
            normal;
    rule third:
        conditions:
            heartRate = HIGH;
        actions:
            alert;
.
```

Figure 2. Example of simple rule base specified in accordance with the defined language

This example shows that every base is composed for a set of rules and each rule has obligatorily two parts: the conditions and the actions. Given this initial example, next sections discuss both the elements of the grammar and its syntactical aspects.

C. *Intrepretation of Instances of the Grammar*

The description of a knowledge base instance is carried out according to the previous figure (Figure 2). This instance is stored in a text file called "RuleBase.rule", which is loaded to be interpreted by the algorithm described in Figure 3. Such algorithm also uses input signals (health information acquired via sensors) during the evaluation of logic sentences.

The idea of such algorithm is to interpret the conditional part of the rules and, based on the results of such interpretation, to activate the right side of the rules, which are related to actions of emergence, alert or normality. In order, the algorithm can be interrupted to execute an action and, after that, resume such execution.

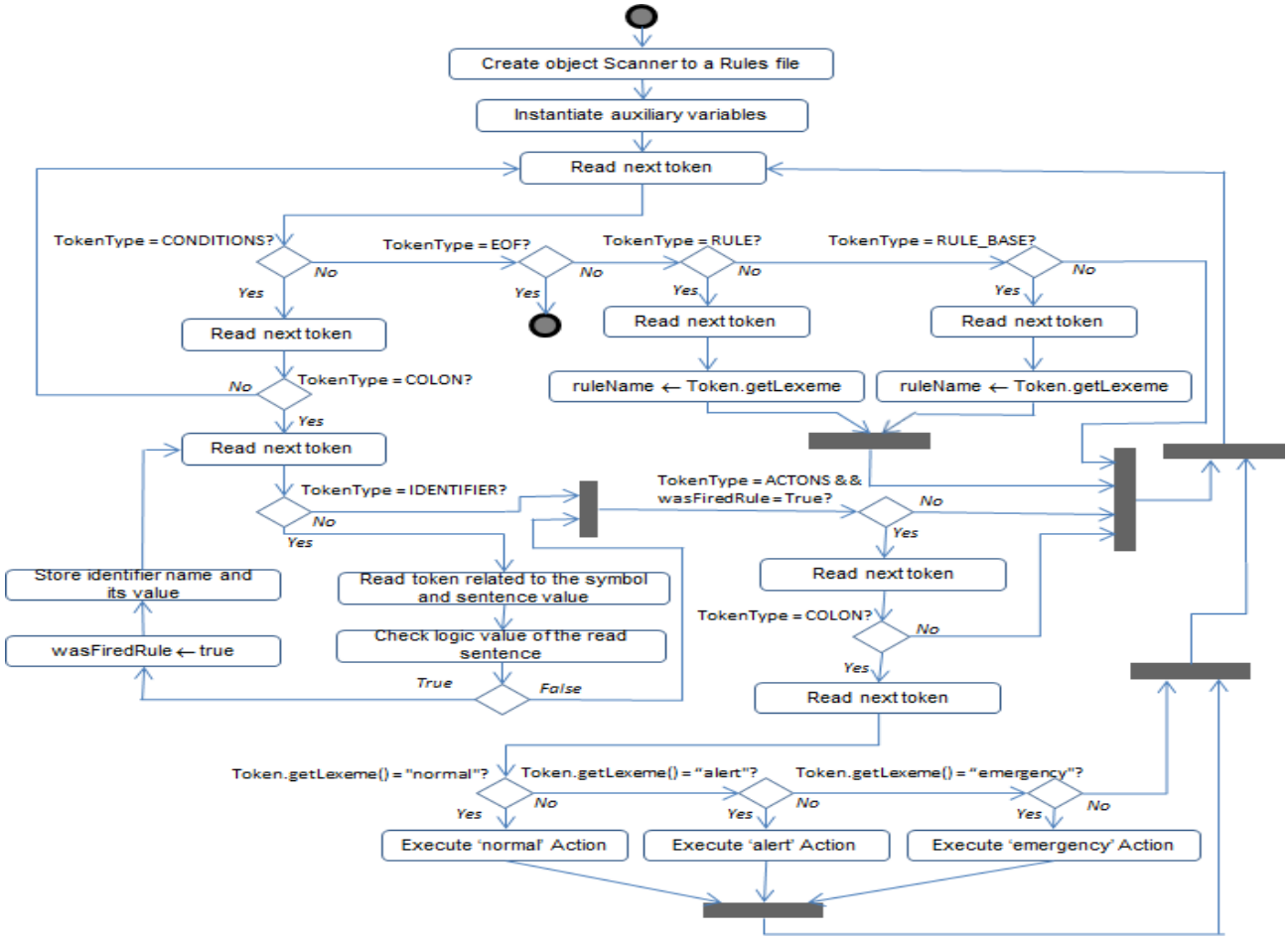

Figure 3. Activity diagram of the rule base analysis algorithm

When an action is chosen, a second algorithm (Figure 4) is triggered to execute such action. This algorithm receives the action identifier and additional data related to the rule that was activated. Then, the algorithm controls the calling of several methods, such as:

- *sendSMS*: this method uses one or more pre-defined telephone numbers to send warning messages. Before transmission, messages are divided into packages of 160 characters;
- *reportHistoric*: this method accounts for reporting all the information of patients that is stored in the devices database, which are stored in the device, to a central database (e.g., web server);
- *activeTimer*: this method accounts for scheduling the automatic execution of the algorithms based on the time that is defined by the production rules.

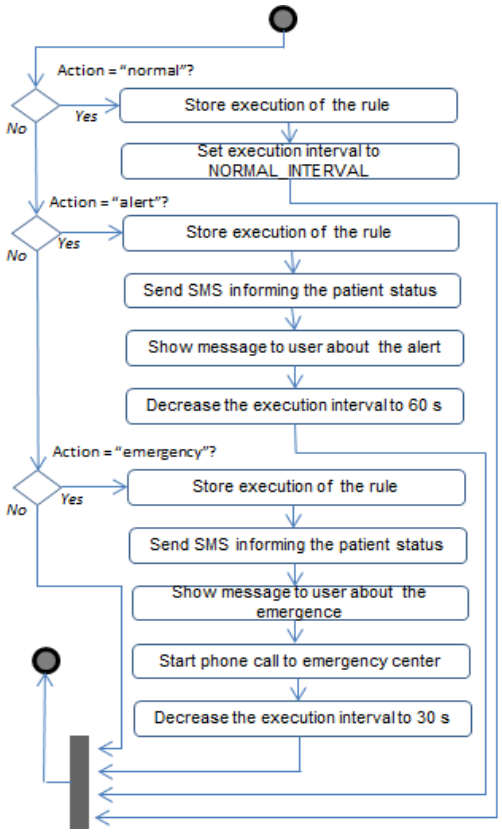

Figure 4. Activity diagram of the action control algorithm

In a situation of "alert", the system sends a message via SMS to pre-defined receivers and displays such message in the device's graphic interface, informing its user about the alert status. This message shows the health signals that are not normal. After that, the algorithm reduces the time regarding the next execution of the rule base. When an emergency situation is detected, the system acts similarly to the alert scenario. The differences are associated with the time for execution, which is adjusted to 30 seconds, and the warning messages. In this case, the system suggests a phone call and prepares a shortcut button for such call.

During the interpretation of rules, the system can stand by its execution to ask its user about her/his current physical activity. Alternatives to answer this question are: Stand, Home Activity, Sleeping, Other. Users can also pre-define the answer for this question. For example, when they go sleep, the "Sleeping" status can be pre-defined.

V. EXPERIMENTS AND RESULTS

To create the knowledge base, we have used the reference patterns for cardiovascular anomalies and different combinations of the set of production rules defined in [13]. The precedence is defined by the order of the rules in the "RuleBase.rule" file. Then, different test cases were defined to evaluate the correctness of the system. For such cases, synthetic facts were used to generate different scenarios. An example of scenario is specified in next table (Table II).

TABLE II. ONE OF THE SCENARIOS FOR EVALUATION, WHERE SIX HEALTH SIGNALS ARE REGISTERED: S1 (CARDIAC FREQUENCY), S2 (RESPIRATORY FRQUENCY), S3 (SBP), S4 (DBP), S5 (BLOOD OXIDATION) AND S6 (BODY TEMPERATURE).

	S1	**S2**	**S**	**S4**	**S5**	**S6**
Measure 1	100	16	120	80	100	37
Measure 2	90	15	141	90	95	38
Measure 3	160	30	120	75	98	37
Measure 4	100	17	120	80	95	38
Measure 5	90	16	110	60	90	36
Measure 6	100	20	160	90	97	38
Measure 7	110	19	120	85	99	37
Measure 8	112	18	120	80	95	36

The print screens presented in Figures 5 show messages that are displayed to users during the execution of one of the test scenarios.

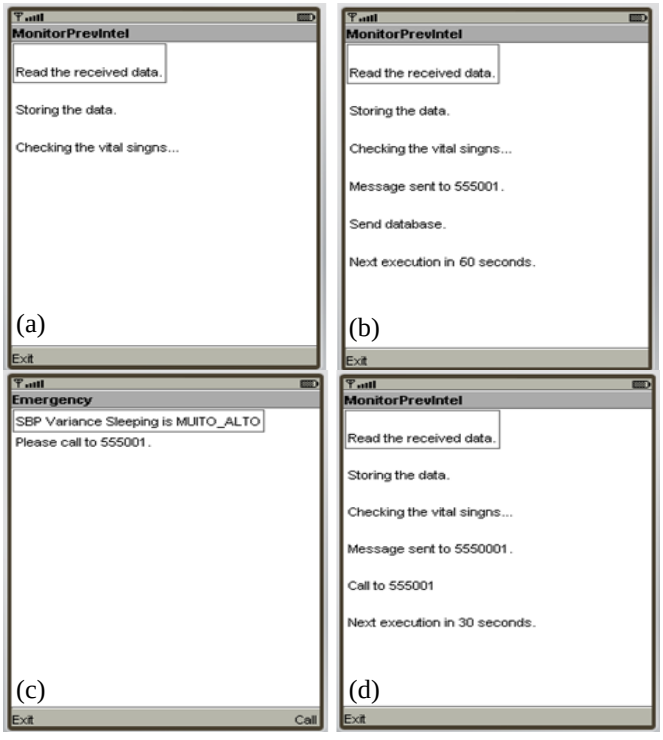

Figure 5. Print screens of the execution scenarios

This emulation was carried out via the Wireless Toolkit 2.5.2. Figure 5a displays messages about the initialization of the system Figure 5b shows an execution where, at the end of the execution, the system performs a backup of the device database to a datacenter represented by the number 555001. In Figure 5c, the system detects an emergency situation and shows a warning message to its user suggesting a phone call to a pre-defined number. Figure 3d presents a moment after the detection of an emergency situation, where we can notice the new period of 30 seconds to check vital signs.

We have used a knowledge base with 21 rules and 20 different scenarios to validate this approach. The scenarios were first analyzed by one health specialist, which described the procedure that should be done for each case. After that, the scenarios were sequentially uploaded by the system, and the results of its behavior were compared to the specialist analysis. This experiment validated the correctness of the rules and also demonstrated the easy way to codify knowledge.

VI. CONCLUSIONS AND RESEARCH DIRECTIONS

One of the advantages of real time and pervasive monitoring systems is their ability of detecting possible problems in an early stage of evolution. Thus, they are very useful as support to preventive medicine. Our main contribution in this context is to present an alternative to codify the knowledge of expertise, so that this representation can be easily manipulated inside a limited computer platform. Unfortunately, this form of manipulate the knowledge is domain dependent, so that it must be changed to deal with other domains.

As monitoring systems provide diagnostic about particular situations, they must be reliable. This means, such systems must provide correct and accurate interpretations of income information. However, a complete reliable system is hard to be implemented once we need to consider possible software and hardware failures. We are aware of this problem, so that we consider that the system outcomes are currently only indications of users` health status rather than final diagnostics. Then, health specialists must evaluate the results before taking some action. To support such evaluation, the system can be configured to generate explanations that justify its interpretations. Future directions of this research can investigate the design of fault-tolerant modules to ensure reliability, using, for example, cross information analysis of diverse sources.

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Real-time Telemedicine in Pediatric Cardiology

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***Abstract*—Point-of-care echocardiography is a very common technique in neonatal intensive care units, but it is often hampered by the lack of on-site specialists. The effectiveness of this procedure is directly related to the quality of the collaboration between the specialists involved, which can be influenced by the convenience of training new specialists in remote districts. In this study we report the results of the REMOTE project, which studied the feasibility of a real-time echocardiographic image transmission system that allows direct interaction between the doctors involved; the project adopts an innovative, low-cost, cross-platform and open-source strategy that enables neonatal ultrasound consultative services in remote districts and secondary care centers. We analyze the results from two perspectives: clinical and technological. From the clinical point of view, we report the preliminary results of our experimentation involving 42 patients and two hospitals in Sardinia, Italy: a tertiary hospital, with senior expertise in pediatric cardiology, and a secondary hospital with a neonatal unit. From the technological perspective, we describe the overall system model and the motivation of its design.**

***Index Terms*—Real-time telemedicine; tele-ultrasound; COTS technologies; pediatric cardiology.**

I. Introduction

Congenital heart diseases (CHDs) are the most common congenital disorders [1][2][3] affecting 6 to 13‰ live-born infants [4][5][6][7]. Critical CHDs, defined as those requiring surgery or catheter-based intervention in the first year of life, occur in approximately 25% of those with CHDs [8]. Although many newborns with critical CHDs are symptomatic and identified soon after birth, others are not diagnosed until after discharge from the birth hospitalization [7][9][10]. In infants with a critical cardiac lesion, the risk of morbidity and mortality increases when there is a delay in diagnosis and in timely referral to a tertiary center with expertise in treating these patients. More than 50% of patients with a missed or delayed CHD diagnosis die at home or in the hospital emergency department with a median age of 13.5 days [11]. Point-of-care echocardiography is the most common diagnostic method for the detection of CHDs (nearly 100% of precision in detection) in fetuses or newborns [12][13], but it is hampered by the lack of on-site specialists [14]. In addition, unlike in Anglo-Saxon countries where the sonographer plays a key role in the management of echo-laboratories, in Italy and many other European countries the echocardiographic studies have to be performed by medical doctors (mostly cardiologists) [15][16]. This model can constitute a barrier to the access of specific exams, particularly in sparsely populated areas and in extremely specialized care, such as pediatric cardiology, because of a lack of physician with a precise expertise in the pathology. Through the REMOTE project [17], based on the results of the first prototype [18], we propose a new model to enable access to specialized care, such as pediatric cardiology exams, in underserved areas through the use of real-time telemedicine. The system devised in this project has been clinically tested in the region of Sardinia where there is a mean incidence of CHDs of 20.25‰ (more than twice the incidence in literature) [19] and where the 17.3% (284,000 people) of population is concentrated in two big cities (>100,000 inhabitants) and the remaining 82.7% (1.4 Million people) is dispersed across a great number of small villages (375) in a relatively large territory (24,090 km^2) [20]. The main objectives of the project are to:

- enable real-time echocardiographic consultations with direct interaction between clinicians involved;
- reuse any echocardiographic devices available in remote districts;
- restrain the costs of additional material/software required;
- lower the learning curve for the secondary care doctors;
- facilitate teaching sessions via video conferences with many participants.

Figure 1. Representation of the two video streams (ultrasound and ambient camera)

II. Materials & Methods

The REMOTE system allows a specialist at a tertiary care center to remotely guide the execution of an echocardiographic exam performed by a medical doctor in a geographically remote secondary care center, seeing both the exam scene and the sonographic video stream while directly interacting with the operator in real-time, Figure 1. The system has been developed with a focus on pediatric cardiology. This remote diagnosis tool, which is already in its testing phase, currently connects four Sardinian hospitals to the specialized pediatric cardiology tertiary center in the island. During

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the course of an examination, a clinician (usually a cardiologist or a pediatrician without specialized expertise in the pathology) visits the patient and operates the echocardiograph. A specialist at the tertiary center uses the combined view of the echocardiograph screen and a robotized remotely controllable camera to determine the patient clinical conditions, his posture on the bed and the appropriate position of the probe. For some pathologies, like CHDs, the accuracy of the examination is highly dependent on the operator: the results may not be revealing when the exam is performed by an ultrasound technologist (sonographer) or by a generic medical doctor, and consequently exams often have to be repeated by a specialized cardiologist. In the study of Meyer-Wittkopf et al. a complete correlation between sonographers and pediatric cardiologists prenatal cardiac findings was achieved in only 62% of cases and the diagnosis accuracy could be improved by allowing a pediatric cardiologist to work collaboratively with sonographers [21]. The technique described in our work reduces the repetition of exams and helps guarantee the correctness of its execution and the subsequent diagnosis.

A. Approach

The main advantages of the system are:

- Real-time transmission. Carrying out the remote consultation through the transmission of audio / video streams in real-time enables the physician to start counseling at the same time of the examination rather than after viewing the whole documentation sent by the remote center (store-and-forward protocol).
- Reduction of both patient and physician transfers. Due to the particular geographic conformation of the region, moving a specialists to the remote center or the patient to the referral center means a significant increase of time before the diagnosis. With this system, local physician can benefit of great specialized services without transferring the patient.
- Scheduling of consultation. Thanks to computerized booking and scheduling procedures, the system can optimize the communication between the local centers scattered in the territory and the referral center.
- Emergency management. An accurate, priority-aware management procedure significantly reduces the time to diagnosis for urgent cases.
- Clinical record and remote reporting. Clinical records and reports are accessible using a web browser, letting all the operative units get immediate access to the patient data.

Each feature has been added to solve medical needs: the following sections highlight the main issues faced during the development of the teleconsultation system and how they were approached.

- **Issue:** operator dependent exam.
  Approach: direct interaction between the operator and the specialist (real-time voice and video chats) enables correct exam execution. Due to the complex nature of the examination and even more to the difficulties in diagnosing a CHD in children, echocardiography in pediatric field is considered a highly operator-dependent practice [22]. This reason invalidates the use of the traditional procedure of second opinion. Thus, our system deals with this issue by providing the specialist with video feed of the examination thanks to a robotized camera with a variable magnification, in addition to the bidirectional real-time voice channel between the operator and the specialist. Driven by the specialist, it makes possible to assess patient conditions and to focus on the precise positioning of the probe, the correctness of the projections performed by the operator and also on the proper use of the ultrasound device itself.
- **Issue:** high incidence of congenital heart diseases combined with lack of specialists in secondary healthcare structures.
  Approach: virtual presence of specialists through telemedicine applications. The system can be activated at a relatively low cost in any remote center [14][23][24][25] equipped with broadband connection: specialists can be concentrated in tertiary hospitals and the logistics and shifts can be optimized at a single point. The physician who requires the teleconsultation and executes the echography does not need to have specific expertise in the field of pediatric cardiology, but he must have proper skills on the use of an echograph. As argued in Widmer et al. [26], it is crucial to improve remote operator skills and reduce the learning curve; in this scenario the system assumes a significant educational value for the echograph operator.
- **Issue:** ultrasound devices heterogeneity and age.
  Approach: any kind of device with a video output can be digitalized and used. Through the use of different types of encoder and encoding technologies, the system is able to capture and stream the output video of any ultrasound device equipped with a nonproprietary video output, from the analog signal of the most dated devices, to the most recent digital ones.
- **Issue:** low investments in remote districts.
  Approach: Commercial Off-the-Shelf (COTS) low cost devices and open source software. Although further research is needed to assess such a telehealth system from an economic point of view [27], some benefits are expected. First of all, access costs of telemedicine and its compatibility with consumer-type hardware decrease to the minimum the initial investment for linking a new remote unit to the pre-existent infrastructure of the system. In addition, the choice of using COTS hardware minimizes the economic and technological risks arising from the use of proprietary hardware and systems. Last but not least is the adoption of open-source licenses for the whole software, which permits a flexible reuse of the developed platform in scenarios not considered in the initial project.

B. Components

The system is based on three main components, as summarized in Figure 2:

- **The control station (one per tertiary care center):** it is a software system that can be accessed using a common laptop; through it a specialist can manage remote requests prioritization, view patient data and start teleconsultation.
- **The base station (one per secondary care center):** based on a mixture of hardware and software, it digitizes echograph video outputs and shots of the exam scene. It also enables voice chats with the remote medical doctor.
- **The data hub (one for the whole system):** this is a central server that stores medical records and patient data, manages voice chats, video streams, resource allocation and bookings.

1) Control Station:

1. **Specialist Desktop Application:** allows the specialist to view the list of patients waiting for teleconsultation, to select the desired consultation, and to perform it through an audio chat with the echocardiographer, using remote visualization of echo and PTZ (Pan/Tilt/Zoom) camera. The specialist may control pan, tilt and zoom of the camera through the keyboard or the on-screen graphical interface.
2. **Web Application:** used to schedule the availability of specialists, view the clinical records and create or edit consultation reports.

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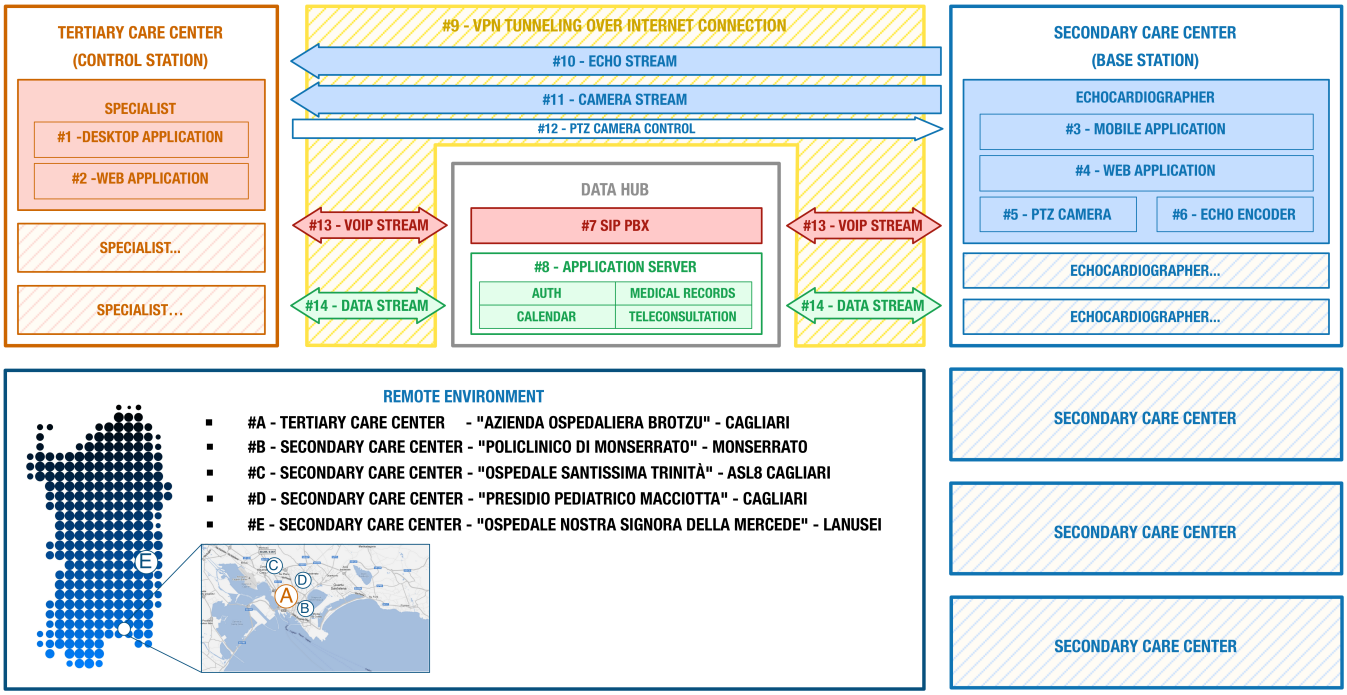

Figure 2. System architecture

2) Base Station:

3. **Echocardiographer Mobile Application:** it allows the echocardiographer to create, manage and run teleconsultations. After answering the call of the specialist, no further interaction with the mobile device is required, in order to leave the operators hands free.
4. **Web Application:** it is used by the echocardiographer or other supporting personal to create and manage personal patient data, to schedule consultation, edit and view clinical records.
5. **Network A/V Encoder:** this device enables remote transmission of video and audio streams generated by the Doppler ultrasound device. Through the use of network and streaming protocols that enable low latency real-time transmissions, it allows the specialist to receive in almost real-time the output of the medical device. Due to the number of sonographic device available, we adopted several different types of encoder: for older medical devices that emit analog video we chose a BNC/RCA to RTP/H264/AAC encoder (using various kind of adapters we can link any standard analog connector), while for modern devices that provide a digital video output we used a network frame grabber (VGA/DVI/HDMI compatible).
6. **PTZ Network Camera:** this device provides the streaming video capture of the entire environment of teleconsultation (room, patient, echocardiographer) and allows the specialist to focus on the details of the examination. In addition, it can be used as a backup for the encoder by targeting the Doppler ultrasound monitor. For experimental purposes we selected a PTZ camera with night/day switch (infrared when 0.005 lux or under) that features an optical zoom (18x) and a reversible horizon (ceiling mount).

3) Data Hub:

7. **Sip PBX:** this component acts as IP PBX and VOIP gateway and is responsible for connecting and managing audio calls between clinicians.
8. **Application Server:** this is the core of the system and it consists of four logical components responsible for user authentication, scheduling and management of teleconsultations and writing clinical records. The authentication module permits application, device and user authentication via a custom version of standard OAUTH protocol. The planning module allows the tertiary center to report the available time slots of specialists and secondary centers as to schedule patient visits during those time slots. The teleconsultation management module is responsible for managing the entire process for the remote visits, starting with the request of the teleconsultation, through its acceptance by the specialist, ending with the correct routing of audio streams video and voice chat. The clinical records module allows the specialist to analyze patient data and past clinical image records during the teleconsultation, thus providing valuable information to help compile the final medical report. It also allows the secondary care center involved in the visit to manage, export and print the report. Finally, it contains an administrative module for the management of care centers (i.e., register devices, sip info, etc.).

4) Interconnections:

9. **VPN Tunneling:** it groups all devices in a single encrypted virtual network, thus ensuring higher security for the transmitted data.
10. **Encoder Stream:** it is an A/V stream carrying both the video and audio channels from the ultrasound device. The stream is transmitted directly from secondary to tertiary care

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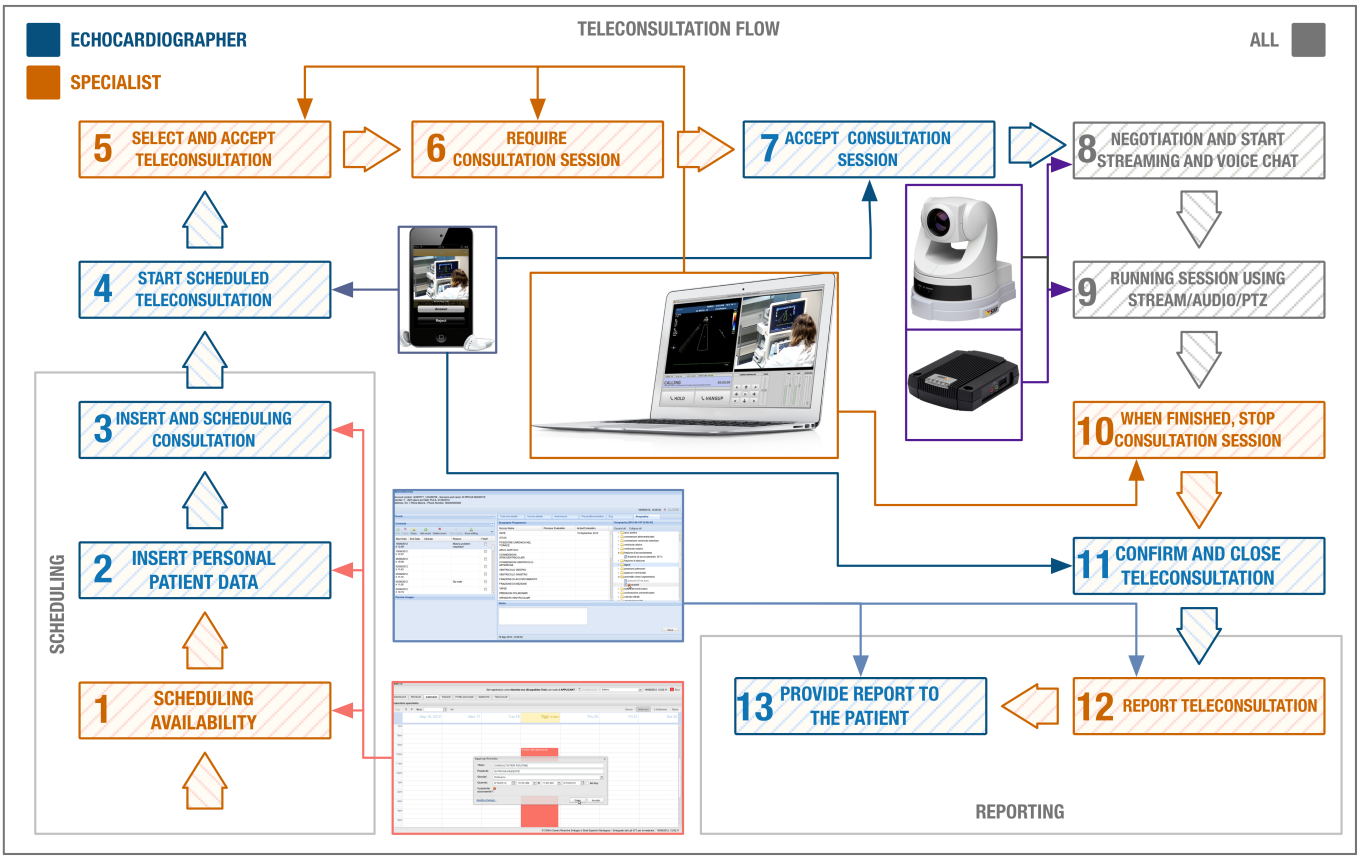

Figure 3. Teleconsultation workflow

center without passing through an intermediate data center.

11. **Camera Stream:** the PTZ Camera video stream, transmitted directly to the tertiary center like the encoder stream.
12. **PTZ Camera Control:** an HTTP channel through which the specialist can control the camera pan/tilt/zoom features.
13. **VOIP Stream:** the audio stream that allows voice communication between sonographer and specialist. It is routed, managed and distributed through the aforementioned Sip PBX.
14. **Data Stream:** an HTTP stream through which all data are exchanged between the data hub components and the other systems.

C. Workflow

The main workflow consists of three phases:

- **scheduling:** the exam is requested and scheduled;
- **teleconsultation:** the examination is performed;
- **reporting:** the medical report is prepared and given to the patient after the consultation.

Figure 3 shows each step in the process. To better understand the diagram, it is helpful to clarify the meaning of Teleconsultation and Teleconsultation Session. The former is the digital representation of the visit provided to the patient. The latter is the single voice chat session between the physicians. Each Teleconsultation may have multiple session within it.

1) Scheduling:

1. **Scheduling Availability:** via a web browser, the tertiary unit registers the hourly availability of the specialists for a given time period.
2. **Insert Personal Patient Data:** the secondary unit enters patient data.
3. **Insert and Scheduling Consultation:** the secondary unit inserts and schedules a new teleconsultation according to the availability of specialists specified at the tertiary unit.

2) Teleconsultation:

4. **Start Scheduled Teleconsultation:** at the scheduled time, the echocardiographer logs in via the mobile app, selects the scheduled teleconsultation and waits for the specialist.
5. **Select and Accept Teleconsultation:** at the scheduled time the specialist logs in and accepts the teleconsultation selected by the sonographer before.
6. **Require Consultation Session:** the specialist invites the echocardiographer to start a teleconsultation session.
7. **Accept Consultation Session:** the echocardiographer accepts the session of the specialist.
8. **Negotiation and start Streaming and Voice Chat:** automatically, the system enables the routing of the audio channel between the physicians involved in the consultation, enables the video streams and provides the specialist with the control of the remote camera.
9. **Running consultation using stream/audio/PTZ:** during the teleconsultation session, the specialist can direct and zoom the camera to improve the quality of the consultation. The specialist is able to take snapshots of streams which are automatically added to the patient medical records and associated with the current visit. Both physicians can arbi-

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trarily decide to pause the session for a certain time (during the pause the audio and video channels are temporarily suspended).

10. **When finished, stop Consultation Session:** the specialist can arbitrarily terminate the session at any time, after which the specialist can resume the teleconsultation by creating a new session, or choose to permanently close it.
11. **Confirm and Close Teleconsultation:** at this stage, the echocardiographer can confirm the end of the teleconsultation to the system. The system enables the possibility to write the visit report for the specialist.

3) Reporting:

12. **Report Teleconsultation:** the specialist can access the patients medical records via web to edit the visit report.
13. **Provide Report to The Patient:** the secondary unit prints the patients copy of the report.

D. Clinical Trial Protocol

Following an agile software development process, the system was tested repeatedly during its development to quickly gather and incorporate suggestions from clinical use. After the first release and a set of preliminary tests, in order to evaluate its diagnostic effectiveness, the system is under a clinical trial involving 42 cases, approved by the ethics committee of Brotzu Hospital (the tertiary care center) on July 2012. The protocol involves two specialists in pediatric cardiology that perform a series of medical examinations using the traditional and teleconsultation approaches according to an established rotation: each physician performs the same number of examinations directly or by the teleconsultation system, in order to minimize the variance, and each subject undergoes both diagnostic methods. Two categories of patients are admitted: children under 6 years and adults over 18 years of age, to test the system with newborns, young children and adults. In all cases, the patients can participate in the trial only after giving their informed consent (personally or through their parents), by which they declare to accept the aims and the conditions of the study. As the procedure states, one of the two specialists performs the assessment of the patient traditionally (direct consultation) by running the echocardiography directly, while the other one guides a third operator a physician trained in the use of the ultrasound machine but without a specialized expertise in a teleconsultation. During the examination the physician executes four projection planes (subcostal, parasternal, suprasternal and apical), as indicated by the protocol, and transfers his findings to a structured report by filling out the dedicated form in the software. The result is a tree-structured document, which is specially designed to make the two reports comparable and suitable for the subsequent statistical analysis.

III. Results

The system has been tested according to the protocol described in Section II, which defines a precise examination sequence and the use of a structured report to better compare the tests performed by two different physicians, with and without the teleconsultation application. The clinical results were very good: considering all the 42 cases, an analysis from the main diagnosis point of view showed a 97.6% agreement rate between the two techniques. Likening the structured report single sections some differences appeared: the detailed results for this point-to-point comparison will be presented in a paper by the clinicians involved in the experimentation. Anyway, these differences are not related to critical aspects of the examination (in fact the global diagnosis is not affected by these punctual disagreements) nor attributable to the use of the teleconsultation system. According to the clinicians, the model created for the report covers all the fields necessary to describe the patients' clinical conditions: the design of this model was fundamental to enable the quantitative comparison of the reports and can be a good starting point to perform statistical and epidemiological studies, since it can lead to a computable formalism easily used for clinical research. Regarding the ability of the participants to collaborate through the system, the feedback was quite positive. The participants considered the system to be a good tool, enhancing cooperation between clinicians with different levels of experience. In preliminary tests the system has been effective for both operators with no experience in pediatric echocardiography and operators who were working for the first time with the model of ultrasound machine used during the examination. Over the course of the study, we also determined that there is a need to establish a very precise procedure for teleconsultation, which must be set and followed accurately step by step to obtain a correct diagnosis. The link created by the teleconsultation application is good, but it can be really effective only if all the components involved (human, technological and about the process) act together. It would be insufficient to use the system only to transmit images and instructions; the specialist connected needs detailed feedback from the operator performing the examination and directly seeing the patient. The more details are coded within this feedback (e.g., checklists), the more effective the collaboration. The training potential of the system has also been evaluated. The system was considered very useful to train specialists through both in-class demonstrations and while training on-the-job. In fact, because of the collaborative design of the system young specialists can be easily supported in their case evaluations. It has also been highlighted that the system alone, as is, cannot be an effective training instrument unless the student has already undergone in-depth clinical training to learn the main projections used in echocardiography and the many important aspects connected to the manual operations necessary to obtain these projections (e.g., where pressure has to be applied, etc.). The technological design of the system was conceived to achieve a real-time transmission system with a latency lower than one second. The adoption of an A/V trasmissions, with priority on constant frames per second, has made possible to keep the streams in sync even in condition of high network traffic. Part of the clinical trials were been performed between the more distant tertiary and secondary centers involved in the project (approximately 120 km) through an xDSL business connection, without any perceivable signal degradation or increased latencies. The maximum bandwidth allocation during a teleconsultation remains within 2.5 Mbit/s (TABLE I).

Furthermore, the system remains operational even in case of a reduction of the available bandwidth by switching to the still-image recording feature. This mode of operation provides static full-resolution images instead of moving video that is usable during the visit and during the reporting. Moreover, the adoption of a mobile device with earphones and directional microphone has subjectively improved the usability of the system for the ultrasound operator. Concerning the quality of the VoIP transmission, the use of the TCP protocol (instead of UDP) with subsequent adoption of a TURN proxy improved the reliability of the audio channel between the sonographer and the specialist and helped simplify network configuration for each operating unit. All the software can be reused and extended with a relatively modest investment on a large number of software platforms, thanks to the detailed analysis performed to select the appropriate software libraries for developing the system and the preliminary tests conducted during the development phase (TABLE II).

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TABLE I
MAX BANDWIDTH USAGE FOR SINGLE CONSULTATION

DIRECTION	**INBOUND**	**OUTBOUND**
TERTIARY CENTER	500 kb/s	2.5 Mb/s
SECONDARY CENTER	2.5 Mb/s	500 kb/s
DATA CENTER	500 kb/s	500 kb/s

TABLE II
SOFTWARE LIBRARIES COMPATIBILITY

	OSX	**Windows**	**Linux**	**Android**	**IOS**
Language	python	python	python	java	objc
Auth	oauth	oauth	oauth	oauth	oauth
API	qt	qt	qt	native	native
Gui	qt	qt	qt	native	native
Voip	pjsip	pjsip	pjsip	pjsip	pjsip
AV	gstreamer	gstreamer	gstreamer	native	native

IV. DISCUSSION

The adoption of telemedicine solutions is spreading out but in most cases the projects, even if good from a technological and clinical point of view, remain local and short-lived [27]. In order to learn from the errors of the past, we made interoperability (technological, semantic and process interoperability, as outlined in [28]) and long-term usability of all components a priority for our project, even when this approach was more difficult than creating a customized solution. The main challenges emerged with the following issues:

- Connecting different clinical institutions also meant connecting different wards inside the institution itself, which often do not really communicate. In this case, it is crucial to follow a general approach that does not focus on any single aspect (clinical, technical, organizational, administrative, etc.) of the integration.
- The importance of clinical training before the use of the system is often underestimated. Interoperability must be also semantic and the creation of a common model greatly facilitates this communication.
- The system has to be designed to easily integrate with previous existent systems, and its results have to be integrated in the hospital system and in the patient electronic health records in order to enable its use in real clinical activity.
- Roles and accountability must be defined in detail so that it is clear who is responsible for every single step of the process, who has to pay and how much. A clear business model is essential for the completion of the pilot project and also for the system to have a chance to continue its existence in the future.

V. CONCLUSION AND FUTURE WORK

The system described in this paper addresses to diagnostic contexts in which the lack of specialists is critical because the ability of the operator performing the examination is essential to obtain a correct diagnosis. To give a solution to the principal aspects related to these situations, we realized a real-time telemedicine system with open technologies and low-cost consumer components. The main components are a real-time teleconsultation application, a precise workflow and a EHR application to support the remote interaction between clinicians, also thanks to a structured diagnostic report. The system was clinically tested via a comparison to direct examination and the results showed a 97.6% agreement rate between the two techniques. The case study was pediatric tele-echocardiography, a test that is strongly operator-dependent where it is crucial that the person performing the examination has a specific expertise in the pathology, but the same approach can be applied in diagnostic areas with similar peculiarity.

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Long Term Monitoring of Breathing Pattern Parameters by a Wearable System at COPD Patient's Home

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Abstract*—Chronic Obstructive Pulmonary Disease (COPD) is a very prevalent disease which causes the deterioration of patient's quality of life and frequent hospitalizations. Telemedicine can be a valid tool to reduce this burden. CHRONIOUS is a FP7 EU project aimed to create a platform for home monitoring of chronic ill patients.. It is composed of a wearable system which is a sensorized T-shirt which collects and transmits data coming from various sensors, among which chestwall and abdomen respiratory volumes by means of two inductive bands sewn into the T-shirt, a technique called respiratory inductive plethysmography (RIP). The aim of this study was to assess the functionality and stability of the RIP included in the CHRONIOUS system for tidal volume (Vt) measurement on home long term setting. COPD patients were equipped with the CHRONIOUS system and were asked to wear the T-shirt for 1 hour per day, 3 days a week, for 2 months. We analyzed the data of one COPD patient (72 years old, BMI = 23 kg/m^2, COPD stage III, FEV1% = 49%, FEV1/FVC = 40%) who used the CHRONIOUS system for a total of 40 days, performing a total of 17 acquisitions of one hour each. We computed the average of Vt for each acquisition session. Normalized Vt showed good stability in terms of mean±sd during the whole period of acquisitions (1±0.3). Moreover it has been possible to discriminate the breathing activity in terms of compartmental contributions (abdominal or thoracic). The preliminary results presented in this study show the potential usefulness of this new telemedicine approach for the long term monitoring of breathing pattern parameters.

Keywords-eHealth; telemedicine; home monitoring; chronic diseases; COPD; respiratory inductive plethysmography.

I. INTRODUCTION

Chronic diseases are the main cause of death in almost every developed country, and deaths from chronic respiratory diseases are second only to those from cardiovascular diseases (1). Chronic pathologies like Chronic Obstructive Pulmonary Disease (COPD), which the World Health Organization has predicted to become the third leading cause of death throughout the world by 2030 (2), determine a serious burden on patients and health care systems because of low quality of life and frequent and expensive hospitalizations.

The need to reduce this burden brought health care providers to promote national and international initiatives based on telemedicine services, which on one hand can perform a better follow-up of the patient at home and on the other aim to provide health domiciliary services and to prevent acute events that can lead to the hospitalization of the patient.

CHRONIOUS is a FP7 European project concluded in May 2012 that aimed to create a home platform for a generic health status monitoring schema, addressing people at risk or with chronic health conditions (3).

CHRONIOUS addresses a smart wearable platform, based on multi-parametric sensor data processing and fusion for monitoring people suffering from chronic diseases in long-stay setting. CHRONIOUS provides a continuous monitoring of the patient's parameters using audio observation methods and selected environmental and social

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context sensors while at the same time tracking their medical condition via vital signs sensors. In addition, the platform offers a touch screen interface for monitoring drug intake, dietary habits, weight and glycaemia values. All the acquired data are sent, through a mobile network connection to the Internet, to a central server, on which a Central Decision Support System (CDSS) addressed data analysis (5) (see Figure 1). Healthcare professionals are provided with full access to the patient's information and data continuously stored in the CHRONIOUS central server coming from the patient's wearable devices, in order to perform the offline remote monitoring of patient's conditions.

The CHRONIOUS wearable system (CWS) (see Figure 2) is composed of a T-shirt, made of washable stretch-material, into which are sewn several sensors that are connected to a microcontroller based concentrator. This device collects and transmits all data coming from the sensors via a Bluetooth wireless connection to a PDA or a personal computer. The CHRONIOUS wearable sensing framework provides a continuous acquisition of electrocardiographic signals, arterial blood oxygen saturation, heart rate, cough, posture, skin and ambient temperature. To evaluate the patient's breathing, the wearable platform acquires respiratory movements and volumes by means of two conductive bands sewn into the T-shirt which measure the movements of the chest and abdominal walls. This technique is called respiratory inductive plethysmography (RIP) and is well-known for its capacity of assessing the patient's pulmonary ventilation in a completely no-invasive way (4). RIP technique can provide information about respiratory volumes, timings, breathing frequency and asynchronies between chest-wall and abdomen.

The aim of this study was to assess the functionality and stability over time of the measurements provided by the RIP included in the CHRONIOUS system installed at patients' home, without any supervision of health care professional and in a long term setting.

In this work-in-progress paper the methods and some preliminary results of the first patient data analysis will be presented and plans for the whole data set analysis will be mentioned.

II. METHODS

A. The CHRONIOUS System at Patient's Home

Patients were equipped at home with a touchscreen computer (TC) which is connected through an USB cable to a device for air quality control. The TC has the possibility to connect to the Internet through a mobile phone network adapter.

Patients at home were also provided with the wearable platform (see Figure 2), which is the result of different test phases performed during the project in which a number of parameters have been considered both for best quality data acquisition and patient's comfort. The platform is equipped with two bands for the RIP, which is a system composed of two inductive bands, one positioned around patient's chest-wall and one around the belly, used to measure volume displacements of the two body compartments during breathing movements. Each band is composed of a conductive wire, the inductance value of which depends on its section area. As the patient breaths chest-wall and abdomen sections change and so its inductance values which are proportional to the volume of inhaled and exhaled air.

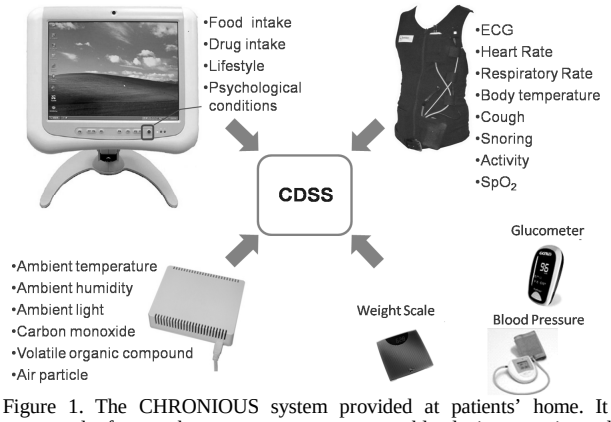

Figure 1. The CHRONIOUS system provided at patients' home. It is composed of a touchscreen computer, a wearable device, an air quality control device and some external devices, a weight scale, a glucometer and a blood pressure meter. All the data were acquired by the touchscreen computer and sent to a central decision support system for data analysis.

A microcontroller based device called Data Handler (DH) was designed and produced specially for the CHRONIOUS project. Once connected to the T-shirt it continuously samples incoming data from all the sensors and RIP signals in particular at a sampling frequency of 12.5 Hz, and communicate them through a Bluetooth wireless connection to a devoted software installed on the TC.

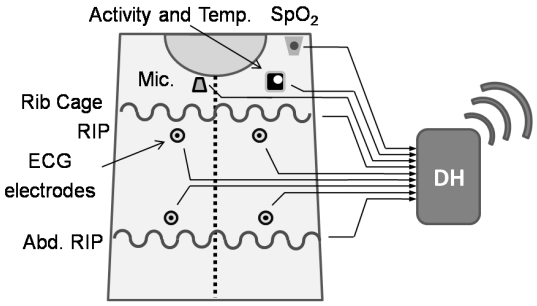

Figure 2. The CHRONIOUS wearable system (CWS) composed of the T-shirt equipped with the SpO_2 sensor, the activity and temperature sensors, the microphone, the four ECG electrodes and the two RIP bands for respiratory movements.

The software installed on the TC acts as a reminder and periodically asks the patient to wear the T-shirt and to switch the DH on. It automatically starts a Bluetooth communication with the DH and stores all the incoming traces of the sensors included in the T-shirt. After one hour the TC ends the data acquisition and automatically transmits the raw traces to the CHRONIOUS central server through an Internet connection enabled on purpose through a mobile

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phone modem. At the end of the acquisition session the patient can switch off the DH and undress the CWS.

B. The Acquisition Protocol

The CHRONIOUS system was provided to COPD patients for a period of four months and they were asked to perform three acquisition sessions per week wearing the CWS, specifically on Monday, Wednesday and Friday of one hour each during which all parameters were sampled continuously and RIP signals in particular.

During each acquisition session patients were asked to sit, relax and breath normally during the whole hour, preferably while watching television or reading a book.

C. RIP Calibration

The data traces acquired through the RIP device represent the volume displacement of rib cage (VRC) and abdomen (VABD) during spontaneous breathing. The acquired data are not calibrated in terms of liters of breathed air as there were no devices at patient's home used as volume reference for calibration.

It is possible to perform a calibration of the volume traces in order to counterbalance the different contribution of the electronic gains on the sampled traces of VRC and VABD. This is done through the Qualitative Diagnostic Calibration (QDC) method (5), which states that variations of VRC and VABD during breathing occur from breath to breath even with breaths of equivalent volume (VT). These variations are reflected in the breath-to-breath standard deviation (SD) which can be used to compute a calibration coefficient.

Calibrated Tidal Volume (VTcal) can be computed as follow:

$$VTcal = M[K(VRC)+VABD]$$

where M is a coefficient that we cannot obtain as we did not provide any reference device for volume measurements to the patient. The coefficient K is a gain coefficient that compensates for sampling circuit asymmetries and can be computed as follow:

$$K = SD(VAB) / SD(VRC)$$

where SD(VAB) and SD(VRC) are respectively the standard deviation of the acquired not calibrated abdominal volume and rib cage volume.

We computed Tidal Volume (VT) using the following equation:

$$VT = K \cdot VRC + VAB$$

D. Data Analysis

For each acquisition the normal breaths were selected in order to exclude artifacts due to the T-shirt movements not related to breaths, and to exclude deep breaths, cough and other extemporary breathing events that might affect analysis.

For each breath we selected end-inspiration and end-expiration points on the VT trace in order to compute the not calibrated tidal volume (ΔVT) breath by breath. We computed mean (ΔVTm') and standard deviation (ΔVTsd') of the VT breaths for each acquisition session. We filtered further the selected breaths excluding the outliers according to the following equation:

$$\Delta VT > \Delta VTm' + 1.5 \cdot \Delta VTsd' \text{ or } \Delta VT < \Delta VTm' - 1.5 \cdot \Delta VTsd'$$

After the filtering we computed the new mean and standard deviation values of the VT: ΔVTm± ΔVTsd. Finally we computed the average value (ΔVTav) of the ΔVTm of all acquisitions and used it to obtain the normalized tidal volume ΔVTn of each acquisition.

As the sampling frequency is known, 12.5Hz, it was possible to compute for each breath some breathing pattern parameters, such as inspiratory time (IT), expiratory time (ET) and respiratory rate (RR), which together with tidal volume can provide minute ventilation (VENT), which is the volume of air breathed during one minute:

$$VENT = RR \cdot \Delta VTn$$

III. RESULTS

For this preliminary study we considered a COPD patient (72 years old, BMI = 23 kg/m^2, COPD stage = III, FEV1% = 49%, FEV1/FVC = 40%) who used the CWS for a total of 40 consecutive days, performing a total of 17 acquisitions, about 1 acquisition every 2 days. We considered a total of 6640 breaths, an average of about 300 breaths per acquisition.

We computed the ΔVTn for each acquisition (i.e. the normalized tidal volume computed as an average of all the breaths in each acquisition session) and plotted the results as shown in Figure 3. The mean value of the plotted values was 1 and the standard deviation was 0.3.

As we were able to discriminate the two volume compartments, we computed the contribution of both to the normalized tidal volume during each acquisition session (see Figure 4).

IV. CONCLUSION AND FUTURE WORK

The CHRONIOUS system is a complex and complete telemedicine system that as a whole should provide very useful information about chronic patient's health conditions and breathing activity at home, and would allow clinicians to monitor the chronic disease progression in normal conditions and during normal patient's activities.

The CHRONIOUS system aims at monitoring chronic ill patients, in particular COPD patients. It gathers different patient's information and physiological parameters in order to combine them and be able to automatically monitor patient's conditions and disease evolution.

This study was aimed at the evaluation of the wearable system and in particular of the breathing activity of COPD patients. Indeed, the CHRONIOUS wearable system allows the sampling of a number of parameters through the use of a

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sensorized T-shirt which, once worn, continuously samples volume displacement data during spontaneous breathing thanks to the integrated RIP system.

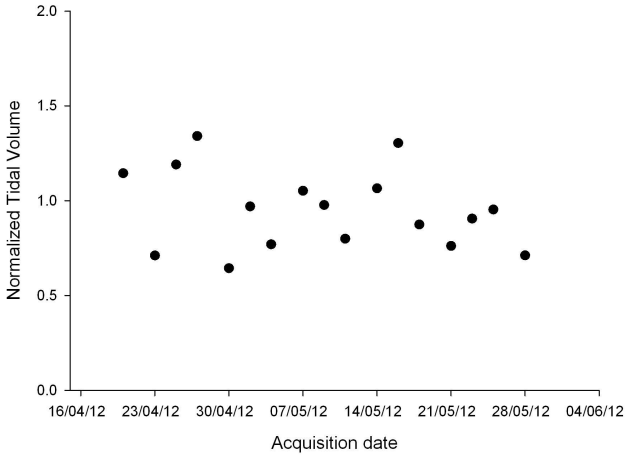

Figure 3. Normalized Tidal Volume (ΔVTn) computed for every acquisition session.

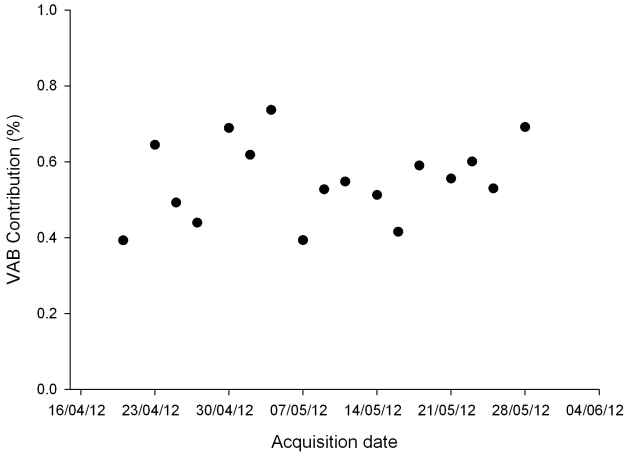

Figure 4. Contribution of the abdominal volume (VAB) to the Normalized Tidal Volume (ΔVTn) computed for every acquisition session. The contribution of the rib cage volume (VRC) can be obtained by subtraction (VRC = 1 – VAB).

The CHRONIOUS wearable system is the result of various tests with patients which highlighted different issues, both technical and of wearability and usability of the system. Each test allowed us to realize the final version of the T-shirt which has been used in the study described in this paper without any complain of the patients, and with their satisfaction in terms of wearability, which was evaluated through special questionnaires at the end of the project. As there were not usability problems, measurements have not been affected by this aspect.

This first analysis allowed us to determine whether the RIP system was able to measure breathing volumes during a long period without any supervision. The CHRONIOUS wearable system was left at patient's home for a period of 40 days, during which he could perform himself the measurement while no technical interventions were done.

Tidal volume measurements showed good stability in long period of time, as shown in Figure 3, taking into account that the system has been used only instructing the patient at the beginning of the study, without any further supervision at home. Patients were asked to wear the T-shirt day by day by themselves, and they were only instructed to perform some peaceful activity, like watching television or reading a book.

Moreover the RIP system allows the analysis of breathing of the two different compartments, rib cage and abdomen (Figure 4), and this is very important in COPD patients. Future work and further analysis will allow us to investigate about the implications of the contribution of one compartment over the other, also related to the position of the breathing patient. Asynchronies will be deepened, as these events are very frequent in COPD patients and indicative on patient's conditions.

Furthermore a wider and more comprehensive analysis need to be made including more patients enrolled in the study and cross-checking patients' conditions based on others sensors data.

AKNOLEDGMENT

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Structured Documentation of Physiological Models and Behavioural Patterns containing Uncertainty

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***Abstract*—In this article, two main requirements on medical documentation in the field of assisted technologies at home (so called AAL) and a process model are introduced. For an integrated health care, the medical documents make interoperability possible. These document formats should be able to be at least structured for further information processing. In the field of AAL it is important to store functional aspects of human activities and data containing uncertainty because patient's health state is measured in a different way than in hospitals. Unknown states of circumstances and context, bad quality sensors and 24/7 measurements can be made. This leads to data containing uncertainty and trends (e.g fitness trend). This data can be stored in structured medical documents though data types and code systems. CDA documents are a medical standard format with a machine-processable and human-readable part. CDA has to be extended in order to be able to represent functional data through equation and data with uncertainty. A process model supports the creation of structured medical documents with AAL-specific data. It supports the mapping of AAL data into a structured document by an application flow. This process is supported by a model-driven technique which makes data description and transformation possible.**

***Keywords*-AAL; CDA; eHealth; Tele-Rehabilitation; Human Models; Uncertainty, Interoperability; PHMR**

I. INTRODUCTION

The many funding programs and research projects have over the last couple of years developed a lot of new approaches in the field of Ambient Assisted Living (AAL), which has close links to Ambient Intelligence and and Ubiquitous Computing. These approaches mostly aim at health related use cases such as tele-rehabilitation, gait analysis [1] or activity detection. Many applications incorporate medical and non-medical sensors from different vendors and different domains. Important questions are: What is a health relevant information, that need to be stored and be communicated to the an external service provider such as a doctor or hospital? How to deal with unclear sensor data? Are standardized medical documents suitable to represent data gathered in home applications?

The need for a standardized representation of medical information in a semantically annotated and further machine processable format is crucial for the interoperability of health supporting systems at home. Therefore, the Personal Healthcare Monitoring Report (PHMR) [2] specifies a model to represent both measurements captured by devices, and narrative information. Defining templates for the HL7 Clinical Document Architecture (CDA) [3] and profiles [4] for monitoring applications is a good step forward, but not sufficient to integrate the quintessence of human behaviour in such documents. The technical world of health supporting applications at home refers to a distributed architecture with loosely coupled components, sensors and actuators. The aim is to enable people to live an independent life in their home environment. Therefore, the collected data are of prime importance for medical care. The state of health is reflected by the application through continuous measuring, plus knowledge that is rather vague and context dependent. This health related information gathered in home environments differs fundamentally from medical information collected in laboratories or hospitals. The main difference is the lack of knowledge to accurately interpret the data under consideration of the situational meaning [5], that leads to a degree of uncertainty and behavioural aspects of physical functions. Vital parameters like blood pressure and pulse react to external factors like weather, sport or stress. A medical decision can only be made when the vital parameters are plausible and when the context is known. For example, a high blood pressure is normal during a training session but requires a treatment when it is long-lasting. New approaches of medical applications with devices from home automation can derive the activity of daily living (ADL) and gait analysis at home to predict falls or upcoming dementia by building behavioural profiles of person. This applications have to deal with many sensor data which are not primary medical. The interpretation of the data from raw data to a clinical decision can contain degree of uncertainty. This uncertainty has to be stored in a structured medical document for further processing. Document standards must represent on one hand the raw sensor data, and on the other hand the semantic information of the context, which must be mapped into a machine processable format. In addition, the process of handling

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AAL data and their mapping into a standardized medical documents is not fully described yet. The aim of this article is to show that medical document standards need an adaption to store functional aspects and uncertainty's in activities to represent medical data in AAL applications "realistic" and to show that a standardize process of mapping the data into a document needs to be invented. In the next chapter the basics of clinical documents (e.g. templates and data types) are described. To understand the differences of data, collected in AAL applications, a new data model is introduced in section III. The requirements of AAL applications leads to an extension of standardized medical document, which are presented in section IV.

II. Clinical Documents

Structured clinical documents must fulfil the demands of the healthcare system. That is, to exchange documents with clinical content easily and to provide a structured mark-up for representing various kinds of information from patient demographics to sensor data to make further processing possible. Also, the human readability is a core requirement. The legal aspect of storing the health relevant information over 10 or more years requires maximum backward compatibility.

A. Clinical Document Architecture

The Clinical Document Architecture (CDA) is a document standard that defines a syntax and semantics for clinical documents like a discharge summary or laboratory results. The structure of CDA is not bound to any exact use case, which makes it applicable for many use cases. Every CDA is a complete information object containing narrative text, images and other content. CDA has a header and a body encoded in Extensible Mark-up Language (XML). The header specifies meta-information about the intended use case, the patient, the author of the document and the custodian. The body is composed of structured mark-up with one or more sections. These sections contains attributes like id, title, text and a coded value. The body can represent information in three levels of granularity, ranging from simple narrative text (not machine processable) to a completely structured coding in level 3, where even the narrative text is completely machine processable.

B. Templates

Templates are sets of constrains on a CDA document structure and content, intended to specialize CDA to specific use cases [6]. The Continuity of Care Document [7] (CCD) is a CDA template that reflects the most relevant administrative, demographic, and clinical information about a patient's healthcare. It provides, for doctors and medical applications, an aggregation of all data about a patient that needs to be stored pertinent to an episode of care or a disease. The primary use case is to provide a snapshot in time to communicate a clinical summary of a patient. The header defines the document meta-data. The body defines sections with semantic coding from "Systematized Nomenclature of Medicine - Clinical Terms" (SNOMED CT) such as past medications, problems, and procedures.

1) Personal Healthcare Monitoring Report (PHMR): The PHMR is a CDA template that carries personal healthcare monitoring information. That encompasses the representation of measurements captured by devices, graphs that show trends of the users' health status, notes, summaries, and other kinds of narrative information that can be added by caregivers. The header is based on the specification of History and Physical Note [8] and the body contains constrained CCD templates. CCD is constrained by adding some section requirements, and a specification of which sections are recommended for use with Personal Healthcare Monitoring Reports, such as "Results" and "Vital Signs".

PHMR is a good step forward for a standardized representation of data gathered from monitoring devices at home. The characteristics of observed device data can be separated into continuous (SpO2) and discrete (Blood pressure, Temperature) vital signs and data.

For continuous measurements, a sub-template named "Waveform Observation" handles the series of measurements connected with a sample period (see code example). The sample period is represented through a generic collection that allows for multiple repetitions of other data types. *LIST* contains discrete values in a defined sequence. A *GLIST* is a periodic sequence of values generated from parameters and used to specify regular sampling points for biosignals. A *GLIST_TS* is a generated sequence of "Point in Time" (*TS*) and has a beginning (*head*) and an increment tag for indicating the step size, that is, the sample period in milliseconds. The *SLIST_PQ* represents the waveform measurements of physical quantities (*PQ*). It is a sequence of sampled values scaled and translated from a list of integer values.

Representation of Waveforms in PHMR

```
<observation classCode="OBS" moodCode="EVN">
<code code="250864000"
codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"
displayName="Pulse oximetry waveform"/>
<statusCode code="completed"/>
<value xsi:type="SLIST_PQ">
<origin value="0" unit="1"/>
<scale value="1" unit="1"/>
<digits>94 92 92 91 90 90 ... </digits>
</value>
</observation>
```

C. Data Types

The data carried in a CDA document are the HL7 Version 3 data types which are described in an abstract notation

for a comprehensive discussion and are also represented in an XML-specific way. The data types can be divided in three categories: (1) boolean, binary, text and multimedia, (2) codes and identifiers, and (3) quantitative data types. The generic data types are collections (sets, lists, interval, etc.) and can be extended to deal with uncertainty, time-dependency and other qualifications of data values. Uncertainty is represented in through two data types which belongs to the category of the generic types extension which are generic types with one parameter. (1) Uncertain Value - Probabilistic (UVP) and (2) Parametric Probability Distribution (PPD). UVP is a generic data type extension used to specify a probability expressing the information producer's belief that the given value holds. PPD is generic data type extension specifying uncertainty of quantitative data using a distribution function. Aside from the specific parameters of the distribution, a mean (expected value) and standard deviation is always given to help maintain a minimum layer of interoperability if receiving applications cannot deal with a certain probability distribution. These two data types are not permit to use in CDA. Beside the semantics all observations are structured by the situation in which they are acquired. Context information about the setting and situational meaning are also data, called context or meta data [9], which are currently not represented in CDA data types. Context information are never 100 percent true or false. And in AAL many sensor data or behavioural patterns contains an amount of uncertainty which has to be expressible in an medical document.

D. Codes

The semantics for carrying the concepts of a a circumstance like a diagnosis or a vital sign is bond by the data type Concept Descriptor (CD) or Coded Value (CV). The Codes systems ICD-10, LOINC or SNOMED CT can be stored in this this data types that contains the field code, codeSystem, codeSystemName, displayName. This data type stores the semantics of the section via a code system (like LOINC or SNOMED CT). This terminologies refers to aspects of the medical domain. The purpose of medical terminology is to support the interoperability between different IT systems. In the field of AAL medical terminology like SNOMED CT or LOINC doesn't fit. The AAL domain consists of new applications measuring human behaviour in a different way than in hospital through assessment tests. The terminologies imply a defined contextual setting that addresses so far not the area of AAL.

E. Procedure Model and tools for CDA Documents

The creation of CDA documents is not a common shared process like in the area of software engineering. The implementation approaches were based on XML processing techniques or a RIM-based approach by HL7. The disadvantage is a generic API requiring CDA specific knowledge. On a more supported level first tools came out with a domain specific CDA API for supporting developers in creating CDA documents. The main advantage was to hide the complexity of the CDA standard by providing a domain specific API. The MDHT (Model-Driven Health Tools) interoperability framework goes much further. They provide a model-driven framework for generating implementations of CDA templates that support domain-specific Java API, a construction and consumption of Java objects for XML serialisation and de-serialisation and a validation mechanism based on OCL (Object Constraint Language). MDHT also provides a work flow targeting the role of a "model developer" who uses the tool kit IDE based on the eclipse modelling framework and an "implementer" who uses the generated domain-specific Java API for producing, consuming and validating the CDA instances (XML).

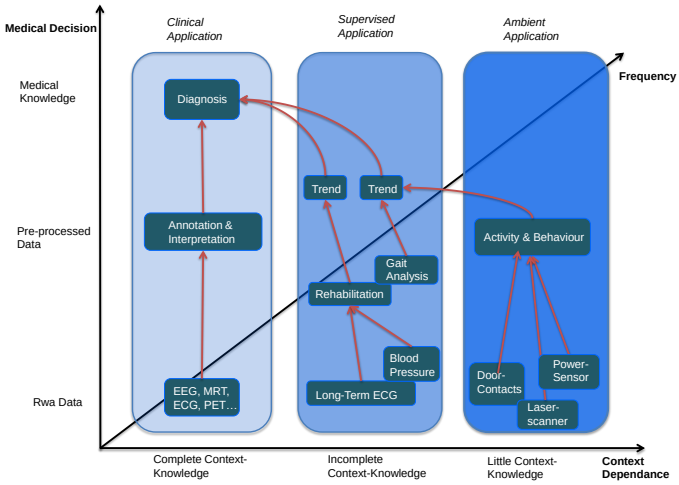

Figure 1. Three Dimensional Layer Context Model (3DLC) [5]

III. Structure of Medical and Non-medical Data in AAL Applications

A. Three Dimensional Layer Model (3DLC)

The 3DLC Models [5] (see figure 1) classifies the medical data from a perspective of context-dependence that is important to differentiate the data gathered in clinical environment or at home. Medical data can produced under laboratory circumstances (hospital), with less context-knowledge in a tele-rehabilitation or with no context-knowledge in Ambient Assisted Living (AAL) application like the gait analysis. Tele-rehabilitation applications such as the OSAmI [10] or SAPHIRE [11] systems developed for patients with cardiovascular disease take place in the home environment. The data are collected in a semi-controlled environment. The data are interpreted in the context of a training session proceeded on an ergometer with medical sensors like pulse. No context information are available in applications for unsupervised applications.

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Beside the context information, sensor quality is lower in home environments than in medical environments. The vital parameters like ECG are of high quality when measured in hospital under laboratory circumstances. Medical applications incorporate vital parameters for usage at home constraint the users themselves to carry out the medical procedure with low-costs sensors. The repeated measurements at home compensate in some degree the lack of quality since trends can be derived.

This leads to a different interpretation of home-based information. Not a single measurement should be interpreted medically, rather than that a trend analysis is needed. Medical information is provided by this kind of applications more or less through the establishment of behavioural profiles combined with trend information. The fact of measuring data over a longer period of time gives a different view on the representation of medical data in a standardized format. A single point documents is not sufficient and should leads to a representation of trends. Nowadays clinical documents do not take this progression of activities in AAL application into account.

IV. Extension of Clinical Documents

A. Functional Model

The description of a functional model reflects an arbitrary human activity that has to be structured represented in a medical document. The mapping of a behavioural pattern, that is reflected through a trend is from a medical point of view a crucial information. This information should be machine processable to derive further information. Mathematical models can represent dynamic processes of a human. A trend is a example for a mathematical view on a human behaviour (see figure 1). Figure 2 depicts the requirements of representing equations in a structured documents by means of a tele-rehabilitation example. Many physiological systems can be seen as a functional model consists of input and output parameters. Also external conditions like weather or other context data can have influence on a patients health. Different scenario and medical problems can lead to diverse mathematical models that needs to be stored in medical documents. At this point a linear model, that is a statistic regression model will explain the process of expanding the document.

In order for a functional model to be represented in a structured document, data types must be defined in an abstract way. With ISO 21090 data types are defined for the purpose of exchange in the health system. These definitions are based on HL7 and ISO/IEC 11404 Information Technology - General Purpose Datatypes (GPD). Linear equations contains place holder with variable-length, for that the equation is expressed as a collection of data types. With this standard ISO 21090 the new data type denoting the equation is derived.

Table I
Semi-formal description of the data type LinearModel

Name	**Type**	**Description**
Variable	$LIST < INT >$	Denotes the variable in an equation
Coefficient	$LIST < INT >$	Gives the quantifier of the variable
Index	INT	Number of variables
Result	INT	result of the equation
Code	CD	Gives the code and semantics

```
type LinearModel class=(
variable : Sequence(Int),
coefficient : Sequence(Int),
index : int,
result : int,
code : CD,
)
```

1) Attribute:

var.: Sequence(Int). the variable represents the parameters which has influence on the physical model. Dependent on the model the variable denotes the demographic data, the weather or earlier performed training sessions.

coeff.: Sequence(Int). In the model, the coefficient gives the importance (weight) of the variables.

index: int. The index i denotes the number coefficient-variable pairs $(b_i * x_i)$

result: int. The result of the equation gives the represented physiological aspects like heart rate.

code: CD. The data type CD gives the meaning (semantic) of the data type. This data type is generic, many use cases of physiological aspects can be described through that equation. Therefore a data type CD is needed.

2) Example:

```
<example xsi:type="LinearModel">
<variable value "34, 57, 1" />
<coefficient value "1, 3, 0" />
<index value "3" />
<code="1234..." codeSystem="2.16..."
codeSystemName="name"
displayName="HF Prediction" />
</example>
```

In this example, a linear model shows a prediction of the heart frequency with three variables and no suitable code system. In this scenario, a functional model is established to predict the heart rate from patient with cardiopulmonary diseases in a tele-rehabilitation [12]. It shows that AAL give the opportunity for new kinds of health related applications. To meet the need of these applications new code systems and tags for CDA has to be invented. The representation of an

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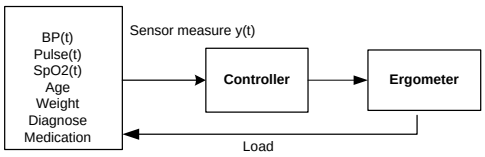

Figure 2. Simplified Block Diagram of an Ergometer Training Session

equation through XML-tags is close to the CDA standard syntax. The abstract notation of the equation gives the possibility to convert it in other medical document standards like DICOM SR [13].

B. Human Model with uncertainty

Sensor data from home applications reflecting the health state of a person. E.g it can reflects problems in mobility or activity (ADL). These data are medical meaningful in a higher abstraction level (see figure 1). Not the raw sensor data shall be stored in a clinical document if there are not from medical or technical importance. In some cases, it is not clear which data have to be stored in a document for further processing. That is where the aspect of uncertainty comes into play.

Damaged sensors, new activity patterns, more than one person in the flat, unclear activities or different kind of problems can occur and leads to misinterpreted data. In worse case, the data are detected as flaws and are deleted. It would be better to categorise the data with a degree of belief and storing them to make a further processing possible. In unsupervised AAL applications the situational-context of a persons behaviour is not fully known, from this it follows that data can be ambiguous. A degree of belief [14] might reflect this lack of knowledge better than deleting it because of uncertainty. The uncertainty could contain information that has to be represented in a medical document. The benefits for representing uncertainty for technicians and doctors are:

- Detection of damaged sensors
- Detection of new activity patterns
- Detection of more than one person at home

Up to now, AAL applications has to deal with uncertain data from an unclear cause. Therefore it is better to document this kind of data as ”unknown data” or with a degree of belief than to delete it. Due to the aspect of interoperability a structured way of storing uncertain data is important.

The reasons for uncertainty in data of home applications are:

- **Erroneous or not interpretable data**: The raw data can not be mapped on events or activities because of measuring errors
- **Vagueness**: Activities are not sharp bounded, they can overlap to each other or be parallel
- **Imperfect data**: In case of a damaged sensor, events or activities can not be detected

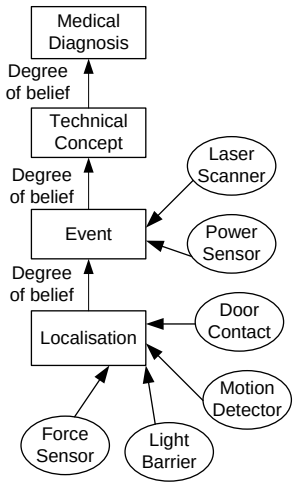

Figure 3. Origins of uncertainty

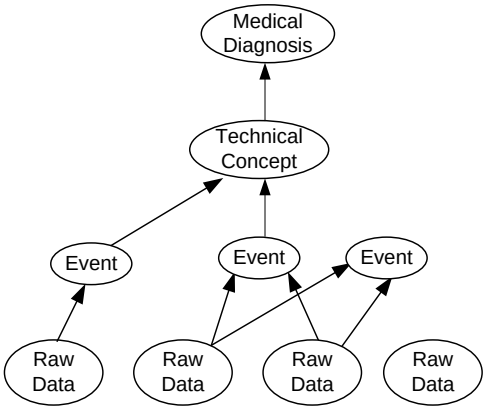

Figure 4. Composite of data

- **Context uncertainty**: Depending on the circumstances (date, place) data can be interpreted as normal or abnormal.

Static sensors like light barriers or door contacts gives pre-existing knowledge about an position unless a spatial model of the flat exists (see figure 3). The trigger of a light barrier is associated with the presence of a person at home. The knowledge of context is limited to one trigger event containing maybe a time stamp and a spatial aspect.

Through the aggregation of more trigger events a higher information like ”primitive events” can be identified. For the chain of raw sensor data to a medical diagnosis a description language is needed. This language describes the origin of the data (the device), the data (data type, unit, etc.), the context (time, space, etc.) and last but not least the uncertainty or degree of belief to transform this information into a structured medical document. Sensors measuring directly an event (like laser scanners or power sensor) should be stored in an medical document if they can not be mapped to a technical concept (automate, pattern matching, profile)(see

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Table II
COMPARED STRUCTURE OF CDA, XML FOR THE CONCEPTS OF INFORMATION, RELATION AND NESTING

	CDA-XML Semantics	**XML**
Information chunks	section, clinical statement, codes, data types	elements and attributes
Relations	components, entry, entryRelationship	elements and attributes
Nesting	count of elements	count of elements

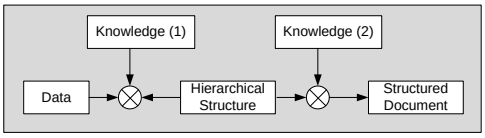

Figure 5. Process Model

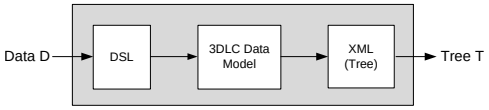

Figure 6. Transformation from AAL data to a tree structure in XML

figure 4 and 3) because not full interpretable data can contain important information, that the AAL application does not observed.

For the structured documentation of uncertain data, the data characteristics, relation, aggregations and the degree of belief shall be described in a formal language. This language can not describe the complete domain of AAL but is applicable in cases where the data are ambiguous or unclear.

C. Process Model

I will develop a process to map AAL specific data with functional aspects and uncertainty into structured medical documents like CDA. To map the data into a structured document a transformation has to be made. By virtue of the standardized approach, mappings into different kind of documents are possible (see figure 5).

The input are the data from the AAL scenario. This can be raw data from a sensor, events or technical concepts which needs to be stored structurally. The knowledge (1) in figure 5 contains three aspects:

1) The input data (data description is taken from the project RAALI [15]) are the data from the AAL scenario. These data are described through a domain-specific language containing the possibility to mark a them with a degree of belief
2) The hierarchical structure (annotated tree graph theory) is the output
3) Function $h = D_{Data} \rightarrow T_{Tree}$. The description how the data are mapped to the tree

The transformation steps from the Data D_{Data} to the T_{Tree} can be seen in figure 6. At first a domain-specific language (DSL) [16] is created with the Xtext (http://www.eclipse.org/Xtext/) framework. It based on the Eclipse Modelling Framework which is extended by Xtext to to build DSL with the extended Backus Naur form (EBNF). The DSL describes the AAL application data with the help of the 3DLC model. An ”integrator” can use this DSL to describe his AAL data (containing uncertainty) with this tool. In the next step a domain-specific Java API is generated. This API gives the opportunity for consuming and processing the AAL data. After this, these data are mapped into a tree (graph without cycles) (function $h = D_{Data} \rightarrow T_{Tree}$). This tree is an abstract structure representing a structured document without a commitment to a definite medical document standard (every structured document can be seen as a tree [17]). This step is semi-automated because the ”integrator” has the ability to enhance the data through additional knowledge. This knowledge can be

- Codes from a code system
- Re-organisation of data
- Sources of uncertainty (if the ”integrator” has knowledge or an idea where the uncertainty could come from)
- Other external sources of information (e.g hospital stay)

This data are represented as a table containing e.g. data and relations to give the ”integrator” the possibility to make changes. After the annotated tree is created the notes and arcs are mapped to a specific standard. This procedure is seen in figure 5 in knowledge (2). In this step, a function $f = T_{Tree} \rightarrow D_{Document}$ maps nodes and arcs to the structure of e.g CDA (see table II).

V. CONCLUSION AND FUTURE WORK

In AAL application the patient’s health state is measured in a different way than in hospitals. Unknown states of circumstances and context, bad quality sensors on the one hand and 24/7 measurements and trend analysis on the other can be made. The health related states are received through vital sensor data and sensors from power sensors or from home automation. An higher aggregation of these data need to be made to derive medical information for care givers or doctors. For an integrated health care, the use of medical document formats makes interoperability possible. CDA documents are a medical standard format with a machine-processable and human-readable part. For the purpose of AAL the CDA documents need to store more than just the snap shot view of a laboratory result or one monitoring session. To deal with an amount of uncertainty rather than to discard the not perfect data makes further process of the data possible. Damaged sensors, new patterns of activity or different research questions for medical, technicians and scientific staff should be persistent stored. We need to store human models that reflects the physiological aspects through equation enhanced with semantics by a coding

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scheme and and activity pattern consisting a certain degree of uncertainty. The HL7 Version 3 data types representing uncertainty are not supported in CDA, that makes it impossible to store ambiguous data. Equations and their code systems reflecting functional models does not exist. Therefore CDA needs to be extended. Also a process of creating a structured medical document is described to support the upcoming AAL domain properly. The next step is to provide different users (domain experts, like doctors, developers and other technical staff) with an integrated software tool, that supports the creation of extended medical documents. At least three domain knowledges has to be incorporated in this software tool. First, the domain knowledge of AAL (devices, abstractions, measurements), second, the clinical document knowledge (structure, data types, templates and codes) and third, medical knowledge (e .g diagnosis). This tool is still under construction. It will represents the different knowledges by domain specific languages and a lot of data transformation to help the domain expert in creating AAL specific medical documents.

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