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eTELEMED 2015

Forward

The seventh edition of The International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED 2015), held in Lisbon, Portugal, February 22 - 27, 2015, 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 2015 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 2015 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 2015. 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 2015 organizing committee for their help in handling the logistics and for their work to make this professional meeting a success.

We hope that eTELEMED 2015 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 Lisbon provided a pleasant environment during the conference and everyone saved some time for exploring this beautiful city.

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Table of Contents

Videoconferencing in Mental Health Care

Professional Dilemmas in a Changing Health Care Practice

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***Abstract*—This paper presents the findings of an exploratory study into challenges and dilemmas faced by mental health care professionals when implementing and applying videoconferencing with their clients. Focus was on two different forms of outreaching mental health care: intensive psychiatric family therapy (IPFT) and flexible assertive community treatment (FACT). During four focus group sessions with 19 mental health care professionals, issues, challenges and dilemmas were identified and discussed. Among the issues uncovered are: feelings of missing intangible, nonverbal but nevertheless important cues in the conversation with a client; an increased psychological 'distance' towards the client, making the communication more to-the-point but also superficial; and (for IPFT) difficulties in overseeing and interpreting interactions between family members. The mental health care professionals interviewed realize that, due to ongoing health care budget cuts, they will need to rely more frequently on videoconferencing with clients. This raises the following professional challenges and dilemmas: (1) how to integrate videoconferencing into treatment programs and individual treatment plans while maintaining quality of care; (2) what to take into account when applying videoconferencing in specific situations, such that it is safe and responsible; and (3) how to make their colleagues aware of the potential benefits of using videoconferencing with clients. Based on these findings, an in-depth ethnographic study is currently being prepared.**

Keywords-e-mental health; challenges; ethnography.

I. INTRODUCTION

Like any other domain in the Dutch health care sector, mental health care is under constant pressure by society, government and health insurance companies to save costs and work more efficiently. In response, professionals and organizations in mental health care are increasingly turning towards telecare solutions such as e-mental health and videoconferencing. However, effect studies into the application of videoconferencing in mental health care show a mixed picture: large scale quantitative studies such as randomized controlled trials still leave many questions unanswered, and the effects found are open for interpretation [1][2][3]. Qualitative research has shown that innovation processes, such as the introduction of telecare technologies, typically proceed in rather 'messy' and unpredictable ways, obfuscating quantitative analysis [4]. Qualitative research has also shown that the introduction of telecare technology can influence daily care practice in subtle and unexpected ways [4][5]. Some researchers have therefore argued to use a qualitative, ethnographic approach when studying the effects of introducing telecare and establishing its potential for health care practice [4][6]. These findings have been the starting points for the exploratory study discussed in this paper. The aims of this study were to uncover challenges and dilemmas faced by mental health care professionals when implementing and applying videoconferencing with their clients, and to determine the research questions for a two year long, in-depth ethnographic follow-up study.

The remainder of this paper is structured as follows: Section II describes the method used, and Section III reports the preliminary results. Section IV summarizes the challenges and dilemmas identified and concludes with the aim of the follow-up study.

II. METHOD

To make an inventory of the issues encountered by mental health care professionals when implementing and using videoconferencing with their clients, four focus group sessions were organized in March 2014. Two sessions were held with professionals working in intensive psychiatric family therapy (IPFT) and two with professionals working in flexible assertive community treatment (FACT) teams.

A. IPFT and FACT

IPFT [7] and FACT [8] represent two very different forms of outreaching mental care. IPFT is an intervention aimed at counseling families with children where family members are having multiple and serious psychiatric problems. It consists of clearly outlined phases and takes about six months to complete. During this time, the professional visits the family twice a week at their own home. FACT, on the other hand, is aimed at people with serious and ongoing psychiatric problems. FACT-teams are multidisciplinary and provide coaching and support to their clients which is both flexible (depending on what is momentarily required) and assertive (the professionals taking the initiative, sometimes using coercion). Team members frequently visit clients in their own homes, in day centers or on the streets. In the IPFT and FACT teams that participated in the focus groups, videoconferencing

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had been introduced earlier to partly supplant visits to clients ('blended care').

B. Focus group setup

Focus group sessions were scheduled to last one hour and were structured as follows. After a brief introduction, professionals were first asked to describe their work and how videoconferencing played a role in it. Participants were asked to recollect positive and negative experiences with videoconferencing that they recently had; these recollections were then briefly discussed. Next, a series of more specific questions were asked about videoconferencing, e.g., "What are the benefits and disadvantages of using videoconferencing?", "Does videoconferencing influence what you try to achieve with clients?", "Can it be used with all clients and in all situations?", "How do you decide between face-to-face visits and videoconferencing?", and "What advice would you give to colleagues less experienced with videoconferencing?". Sessions were concluded with a brief wrap-up. During all sessions two researchers were present: one moderating the discussion, and the other taking notes. Interview notes were analyzed by bottom-up clustering (affinity diagramming, [9]).

III. RESULTS

In total, 19 professionals were interviewed: 6 working in IPFT teams, and 13 working in FACT teams. In the IPFT and FACT teams that participated in the focus groups, videoconferencing had been introduced several months to several years earlier, as part of small-scale pilots. In one case (focus group no. 4), the organization was preparing for a wider implementation of videoconferencing. The professionals interviewed therefore had varying degrees of experience with videoconferencing; see Table I for more details.

TABLE I. FOCUS GROUP PARTICIPANTS

Focus Group	Participants		
	IPFT / FACT	***Male / Female***	***Experience with videoconferencing***
1	IPFT	0 / 3	one year
2	IPFT	1 / 2	one year
3	FACT	0 / 4	several months
4	FACT	4 / 5	several months to several years

A. The role of videoconferencing in IPFT

IPFT as practiced by the focus group participants, consists of three phases. In the first phase (a six-week period during which home visits are made twice a week) the professional establishes a working relation with the family, explores their problems and strengths, and drafts a plan with them. During this phase videoconferencing is not yet used, but if both parties consent it will become part of the plan. During the second phase (which can last anywhere from six weeks to four months) the professional counsels the family in working towards the goals set out in the plan. When professional and family have agreed to use videoconferencing, home visits are reduced to once a week and alternated with video calls. The third phase starts when the goals have been reached and counseling comes to an end. The frequency of home visits and video calls is then further reduced, to bi-weekly. This phase usually lasts another two months. After the third phase, families can still contact the professional (they receive vouchers to do so), but only through videoconferencing.

The IPFT professionals in our focus groups emphasized that they had made deliberate choices regarding the use of videoconferencing when they designed the IPFT program. They felt strongly that visiting families, and observing family members in their own homes, was a strength of IPFT that should be preserved. Videoconferencing was considered less suitable for the first phase, when the professional is still in the process of getting to know a family and their problems. In contrast, the participants did see specific benefits of videoconferencing in the later phases, such as more flexibility in planning appointments during evening hours – a time preferred by many families.

B. The role of videoconferencing in FACT

In the FACT teams we interviewed, videoconferencing was also used in scheduled appointments, but more frequently it was the client who took the initiative for a video call. In some cases, videoconferencing at a client's initiative was limited to the professionals' desk hours; in other cases, it was possible throughout the day and team members took turns in answering calls. To further facilitate this, clients could view who was online, and during evening hours their calls were automatically forwarded to a professional at a clinic. Another notable difference is that instant messaging ('chat') was also used. Communication via chat typically happened throughout the day, which allowed for an easily accessible and continuous line of communication between client and professional.

The FACT teams we interviewed did not use predetermined guidelines pertaining to videoconferencing. Instead, during the team meeting at the start of each day, team members would discuss clients' situations and whether or not to use videoconferencing with them. Videoconferencing would only be used with a client if a suitable therapeutic relationship had been established first. Video calls were used to save travel time and to reduce the invasion of a client's privacy. Furthermore, video calls were often used instead of regular phone calls, making these contacts more personal. Last, videoconferencing was considered a first step towards reduced frequency of contact and increased independence of a client.

C. Differences between video and face-to-face contact

When participants were asked to describe the differences between face-to-face visits and videoconferencing, they stressed the importance of face-to-face visits for observing social interactions, getting to know the client and their situation, building up trust, and interpreting what is going on. On the other hand, videoconferencing had its own uses, for instance to quickly check up with a client on their current situation or their progress. The participants agreed that videoconferencing could not fully supplant face-to-face visits, but that it could supplement these visits very well.

 ISBN: 978-1-61208-384-1

1) Videoconferencing is brief and to-the-point

Focus group participants frequently mentioned that, compared to face-to-face contact, videoconferencing is brief, concrete, and to-the-point. There are fewer opportunities to get distracted during a video call, making the conversation more focused. Questions asked are pertinent and short, and the conversation solution-oriented and aimed at reaching agreement (*"Okay, so how will we go about that?"*). There are certain advantages to this conversation style: it sometimes allows for asking 'tough' questions, offering the professional an opportunity to get more quickly to the bottom of a difficult situation. Furthermore, the professional is literally 'at a distance' from the client, forcing the latter in a more active role. Videoconferencing can thus stimulate a client's self-reliance, especially near the end of an intervention. However, all this comes at a price: due to their intensity, video calls require more concentration and effort, and a more thorough preparation by the professional.

2) Videoconferencing improves approachability

Members of FACT teams mentioned that videoconferencing and chat improve the approachability of professionals and clients. Videoconferencing is used to briefly check up on a client without creating the disturbance associated with a regular visit. To some contact-averse or care-averse clients, videoconferencing is less threatening than a visit. Chat, in particular, can be used to maintain a continuous line of communication with a client throughout the day, allowing the professional to gradually coach a client towards a particular goal.

FACT teams explicitly compared videoconferencing to ordinary phone calls. Contact with a client over the phone is common, but videoconferencing adds a personal touch to these contacts. This more quickly creates a bond between professional and client, which in turn helps to reduce the number of 'no shows' at scheduled appointments. An additional advantage of videoconferencing compared to phone calls is that the professional can observe facial expressions and some of the nonverbal behavior of a client.

3) Videoconferencing remains at the surface

During all focus group sessions, participants quickly acknowledged that videoconferencing creates a certain distance to a client, with the conversation itself remaining somewhat at the surface. The focus and intensity of a video call are clearly beneficial for a pertinent conversation, but they make videoconferencing unsuited for situations where the professional needs to get acquainted with a client, or explore what might be going on in a family ('the deeper layer', in the words of one of the participants). Some of the reasons mentioned were that nonverbal signals are easily missed during videoconferencing, and that video calls typically lack the atmosphere and leeway needed to stimulate a more open conversation. As one participant explained, *"In a video call, you continuously have to stay focused. When you visit people at home, there is always a moment when you can lean back and just look around"*.

4) Home visits reveal more about a client

Focus group participants agreed that visiting clients at home reveals more about them and their situations. They mentioned examples such as seeing the interactions between family members (*"Where they sit, how they look, whether the living room looks tidy, and what the teenage daughter is doing in the background."*), clients being more at ease and more 'themselves' (*"People tell different stories when you see them at home."*), 'rituals' that establish trust and maintain a personal relationship (*"Small-talk while hanging your coat or drinking a cup of coffee together."*), brief interruptions that reveal something about daily life (*"The telephone rings, the neighbor steps in."*). As one participant explained, *"Entering someone's house gives you the clues to start a conversation, to build up a relationship. During a video call there is no neighbor who's got something to say, your only clue is to notice that your client is still wearing their pajamas. The atmosphere is very different when someone is making you a cup of tea; you enter a conversation completely different then. Sensing the atmosphere is important; it contains clues about how someone is doing."* Intangible and nonverbal signals, such as these, are absent (or will at least more easily be missed) during a videoconference.

D. Issues in using videoconferencing

The differences between face-to-face contact and videoconferencing lead to certain issues that professionals need to cope with. In the current situation, where videoconferencing still plays a relatively minor role, these issues do not seem to be of great urgency. However, the professionals interviewed expect that they will need to rely more heavily on videoconferencing in the near future: using it more frequently, but also in more complex situations.

1) Situations where videoconferencing is not suited

The participants all work in secondary care. Clients and families with relatively straightforward problems are increasingly taken care of in primary care, hence, only complex cases (e.g., clients with multiple disorders, or families with alcohol or drug abuse) remain. The participants are skeptical about the suitability of videoconferencing for these situations (*"When a family is in chaos, it is going to be very difficult to use videoconferencing for a to-the-point discussion of goals."* and *"When the communication in a family is breaking down, or in fact each time when you need to know what is really going on, videoconferencing just won't do it."*). One of the IPFT team members wondered what to do in situations where there is a suspicion of ill-treatment: *"I might easily miss out on certain signals, yet I have a responsibility. Sometimes you have this feeling that something else is going on, and in such cases home visits are extremely important."* FACT team members also expressed concerns: *"You need to build up a relation first; there must first be a solid foundation before you can rely on videoconferencing, and in cases where coercion is needed, videoconferencing may not be suitable at all"*.

2) Consequences for the profession

All focus group participants had become experienced with videoconferencing in the context of small-scale pilots, making them the pioneers in their respective organizations. And although they had experienced the drawbacks themselves, they had also learned that videoconferencing, if properly used, can bring some advantages. During the focus group

discussions some of them expressed concerns that they were unable to convince their colleagues, who had not partaken in these pilots, of these potential benefits: *"Videoconferencing is primarily regarded as a means to save costs; as something that deteriorates the care we provide. It would help if both the positive effects and the contraindications could be substantiated, to better inform our colleagues and to reduce the resistance they feel towards videoconferencing."* With regard to the professional competences required for properly using videoconferencing, most participants agreed that any mental health care professional should be able to use videoconferencing: *"It may require extra skills to assess whether or not to use videoconferencing with a client the next time. This is a matter of experience, of knowing which signals are important. But this is not new: when you visit a client at home, you also have to make such decisions."* Nevertheless, some participants expressed concerns: *"What will it do to our role as professional caregivers? If I find myself sitting behind a screen most of the time, will I still have the same professional attitude? I will miss visiting clients at home, or going over a conversation when I am cycling back home."*

IV. DISCUSSION

A. The challenges and dilemmas identified

Among the issues uncovered in this exploratory study are, briefly summarized: feelings of missing intangible, nonverbal but nevertheless important cues in the conversation with a client; an increased psychological 'distance' towards the client, which makes the communication more to-the-point in some cases, and somewhat superficial in others; and difficulties in overseeing and interpreting interactions between family members. These issues need to be investigated before recommendations can be given regarding the proper use of videoconferencing. The shared expectation among the participating health care professionals that they will need to rely more frequently on videoconferencing with clients, raises a few important professional challenges and dilemmas. These are: (1) how to integrate videoconferencing into treatment programs and individual treatment plans while maintaining a good quality of care; (2) what factors to take into account when applying videoconferencing in specific situations, or with specific clients, such that it is safe and responsible to do so; and (3) how to make colleagues inexperienced in the use of videoconferencing more aware of the potential benefits of using videoconferencing with clients.

B. Follow-up study

Reviewing the results of this exploratory study, we can conclude that videoconferencing affects the conversation and relation between client and professional, and hence the care that is being provided. Other researchers have drawn similar conclusions [10][11]. Turner [10], for instance, interprets these effects in terms of differences in presence, in particular differences in the available primary, secondary, and tertiary context. Primary context refers to what appears salient to both participants; in face-to-face contact this refers to the immediate surroundings of the participants. Secondary context refers to what is available within the primary context but which is outside the focus of the participants. For instance, the room in which the participants meet, and the objects and other people inside it. Tertiary context refers to ancillary context. This may, for instance, include the walk up to the house and through the hall, or a brief encounter with a neighbor. In videoconferences, these three contexts are very different: the primary context is represented by the viewable image. Within this image, limited secondary context is available: in the background, or as background sounds that give information on what is going on outside of the displayed image. Tertiary context, however, is unavailable in a videoconference, as are the cues that this context may provide. Problems arise when participants fail to realize these effects of mediated communication. Turner illustrates this by a striking example where a telepsychiatrist prescribed physical exercise (bicycle riding) to an imprisoned patient, not realizing that this patient was bound to a wheelchair.

Based on the findings of this study, and informed by the research of Pols [4], Oudshoorn [5], and Turner [9], an in-depth ethnographic study is currently being prepared. The aim of this study is to investigate the sometimes subtle ways in which videoconferencing affects the conversation between a client and a professional. Building upon on the acquired insights, we further aim to develop instruments (e.g., a storybook, an online course, or a serious game) to better equip mental health care professionals, and make them more aware of the benefits and pitfalls of videoconferencing.

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Collaboration in Surgical Training

A qualitative study of mentoring laparoscopic surgeons by using videoconference in northern Norway

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***Abstract*—This paper describes a work in progress, a project studying collaboration among laparoscopic surgeons who are instructed during their education. Access to expert surgeons is a problem at many hospitals. Implementing videoconferencing (VC) as a tool for instruction (telestration) and knowledge-sharing overcomes the distance between mentors and mentees, and has the potential to improve surgical training. Understanding of VC is limited in surgical practice, and the educational and clinical benefits of telementoring should be explored. This project will meet this demand by seeking in-depth understanding of the non-technical aspects or social processes of collaboration in surgical training. Over a three-year period, from 2015 to 2017, this project will examine collaboration in surgical training (CoaST). A hospital in northern Norway at which surgeons collaborate in surgical training to complete their surgical education in general surgery will be investigated. This paper discusses how we will collect the data. When they start to use VC for mentoring in distance surgical training, this will be included. An explorative study will be carried out using video-recorded observations of interactions. The paper is relevant for the conference focusing on the topic of distributed surgery and collaboration between professionals creating new telemedicine practices. This paper outlines the objectives of the study and the qualitative design; the study will explore non-technical aspects or social processes of collaboration in surgical training. The paper concludes by presenting a design for collecting video recordings to explore surgical training.**

Keywords-collaboration; surgical training; telementoring; interaction; qualitative methods.

I. INTRODUCTION

Surgical education in general surgery requires six years of education, training and clinical practice. The clinical practice involves hands-on training during which the surgeons who are being educated (mentees) are instructed by expert surgeons (mentors). Access to mentors for education is a problem at many hospitals. Improving access to mentors in surgical training can be accomplished by implementing videoconferencing (VC) as a tool for knowledge-sharing to overcome geographic distance between mentors and mentees and to allow for organization and full concentration on training locally and through geographic distance.

In surgical practice, procedures are often challenging as unexpected challenges arise and can lead to a point of no return where decisions must be made in the moment [1]. The skills of a surgeon and the collaborating operating team are a prerequisite for a good surgical outcome [2][, 3]. Thus, collaboration and training of team performance are important in surgical practice. Optimal teamwork is essential when mentors and mentees are located in the same room, and if they are located over distance. VC for telementoring is well suited for collaborating and overcoming distance [4]. However, a recent review of surgical telementoring reported limited understanding of VC in surgical practice. The review concluded that little attention has been paid to the educational and clinical benefits of telementoring, and instead, focused on piloting the technology [5]. Studies report that surgical mentoring by VC provides opportunities to alter surgical practice and offers patients the best expertise in surgical treatment despite geographic distance [6]. However, little in-depth understanding of the non-technical aspects or social processes of collaboration in surgical training exist.

During this project, collaboration in surgical training (CoaST), we will examine the organization of surgical training today and the use of VC, as well as how knowledge

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is shared and constructed in order to complete surgical procedures, that is, the organization of training and practice, the team that participates, the knowledge shared, the knowledge needed and the use of resources to solve the problem. Together, this gives insight into team performance and how non-technical aspects or social processes of collaboration influence the way surgeons are mentored.

The rest of this paper is organized as follows. Section II describes the framework for the field, and the need for knowledge about collaboration and teamwork in surgical training. Section III describes the empirical context. Section IV addresses the qualitative design and illustrates how the design with video-recorded observations will be used to explore the field, connecting practice to the design method in Section V. The conclusion is in Section VI.

II. FRAMEWORK

Research regarding the *educational aspects* of VC in surgery stresses the educational benefits [7] and refers to telementoring as effective for the development of surgical skills [8], allowing young surgeons to be educated through distance learning by an expert surgeon [9]. Past research has suggested that VC provides access to the best educational resources and experience without the limitations of distance and time; thus, VC facilitates learning [7]. For example, community surgeons with no formal advanced laparoscopic training benefit from expert advice during procedures [10]. Students reported that the experience was better than conventional procedures because of the enhanced learning, better visibility and verbal accuracy in describing the procedures, since the instructor was not standing in the way [11]. These studies illustrate the outcomes possible with the technology, but no studies have explored the social processes of collaboration and the knowledge necessary to complete the surgery (i.e., the guidance, problem solving and surgical process). Neither did these studies explore how learning might be an outcome of the collaboration.

Understanding of the effects of VC on surgical practice is limited [5]. A special focus is needed for better understanding of the factors that influence surgical outcomes, that is, communication and team performance [12]. The CoaST project expands upon previous work by investigating knowledge-sharing between surgeons and how their use of resources affects the treatment outcome. It aims to investigate the organization of surgical training today, the use of VC, collaboration in practice and the problem-solving process. The project also provides insight into how and why telementoring can be an important tool for improving surgical training.

III. EMPIRICAL CONTEXT

This study which starts in 2015 aims to investigate mentoring among laparoscopic surgeons in northern Norway. First, traditional methods of mentoring locally will be investigated. When VC for improving surgical training and practice is implemented at the hospital (during 2015/2016), this use will be included in the study. The empirical context will include collaboration between the mentor and mentees during surgical training in one hospital in northern Norway (Hospital A). The use of VC will include distance surgical training between Hospital A and a collaboration hospital (Hospital B).

The surgical training will involve laparoscopic surgery and telementoring. Laparoscopic surgery uses several small abdominal incisions. At each abdominal incision (i.e., port), an instrument is inserted. Telementoring happens by connecting the laparoscopic surgery, the surgeon (mentee), the expert (mentor) and the technological artifacts, that is, robots, monitors and a mobile touch screen device. The laparoscopic procedure, which is visual, is transmitted to a monitor in the operating theater. The expert can view the procedure on a touch screen device in the operating theater, when in the operating theater or at a distance. On a mobile touch screen device, they draw freehand mark-ups over the video (telestration) so that the visuals can supplement the verbal instructions.

Telementoring over distance is possible by using VC [13]. VC is when sound and picture are shared in two- or multi-channel communication. By connecting the monitor or the mobile touch device to an external computer and using microphones locally to send the audio to an external computer, the local mentee in the operating theater and the remote mentor are able to collaborate. The surgical operation is viewable on the monitor, transferred to the expert mentor's device. The mentor can be mobile, in the surgical theater and at distance while providing full attention to giving the required training and instructions to the mentee. Together, the visual representation of the picture on the monitor, the instructions given and the mentor's drawing on the device can supplement the collaborative work during surgical training.

IV. QUALITATIVE DESIGN

Exploring collaborative processes requires empirical data and analysis of the social processes and interactions of those who participate. These data and analyses make it possible to explore knowledge-sharing among surgeons, mentors and mentees who collaborate and use VC in surgical training and practice. This research project will use qualitative methods, designed as an explorative study of the practices of interaction. The knowledge shared and constructed will be explored as surgeons with different experience and expertise interact and perform surgeries over periods of time. Observations will constitute the main source of data. The second source of data will be qualitative interviews.

A. Observations

The observations are built on interaction analyses—the empirical investigation of talk and the use of resources [14]. The observations will be undertaken as surgeons collaborate in surgical training and practice, guiding and discussing treatment using tools such as VC. Observations are well suited to exploring team interaction because reconstructing the medical language and using artifacts are not possible. To intercept the social aspects in the collaborative work between the mentors and mentees, the interaction will be video-recorded using three sources: (1) output from a

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laparoscopic camera/monitor, (2) connecting the mobile touch screen device to a recording unit and (3) a camera recording an overview of the operating room.

The use of video recordings during the observation provides access to complex forms of interaction and to collaboration in the visual and spoken data [15-17]. By following the language and the use of resources, that is, talk, gestures, mobile touch screen, and surgical equipment such as knives, scissors and needles, it is possible to see how the mentor and mentees organize the instruction and practice, how problems and routine practices occur and how the surgery (the medical problem) is solved.

B. *Interviews*

To complement the observations, the participating surgeons will be interviewed. The purpose of the interviews is to enrich the context by giving the participants the opportunity to express themselves about the surgical training and the use of VC in training, instructions and collaboration. It is also essential to discuss themes based on the observations. The interviews will be semi-structured [18][, 19]. They will involve dialogue resulting from a mixture of structured questions (from an interview guide) and the themes that emerge in the dialogue. Interviews will provide insight into mentor and mentee experiences. The interviews will be used to validate the interaction analysis. All participating surgeons who have been trained using VC will be interviewed.

C. *Sampling*

The study follows the traditional education program to explore this practice. The observations will continuing until there is a thematic saturation, or until the use of VC for mentoring phase out. The participants will be recruited according to their use of VC for mentoring. When VC is used, it will include the interactions that occur during the training. The sample encompasses all the VCs held and all the cases discussed in two periods until there is methodological saturation. The periods and the length of observation are defined according to the total activity during the education program. Lower frequency of training using VC will require longer periods of data collection. Periods are defined regarding the education program and are referred to as the periods of training. The study will also include empirical material from sequences where VC is not used so that this expansion can offer a complementary focus on the importance of collaborative training in surgery.

D. *Ethical Considerations*

During the surgery, the identification/visibility of the patient in the video-recordings is not possible. The patient is covered by sheets, and only the part of the body undergoing the operation will be visible. The videotapes will be collected and handled according to the guidelines set out by the Regional Committee for Medical and Health Research Ethics (REK). The interviews will be recorded, transcribed and handled according to the REK's code of ethics.

V. CAPTURING SURGICAL PRACTICE

The monitor, which shows the picture inside the abdomen, the same picture the surgeon sees, can record within the unit. The mobile touch device represents the same picture as the monitor can be drawn on. This device has a built-in record unit. These tools record the technical aspects of surgical performance. To capture the social processes of collaboration, an external camera will be located in the room. Figure 1 is an example of how the surgical team, the monitors, the mobile touch device and the camera might be placed during the treatment of the patient. This is an example, since the way the surgical team and their tools are organized might differ between procedures.

The arrows in Figure 1 show the three sources recording the surgical practice. The circles in Figure 1 point out the resources that will be in focus for in-depth understanding of the collaborative work. The green circle illustrates how the social processes of collaboration are an overall understanding of the whole process of surgical practice: the mentor(s), mentee(s), their interaction with each other, the monitor and the mobile touch device as they perform surgery. When connecting VC, the PC is also included in this interaction. The surgical team can see the expert in real time on the computer. The expert sees only what happens on the mobile touch device.

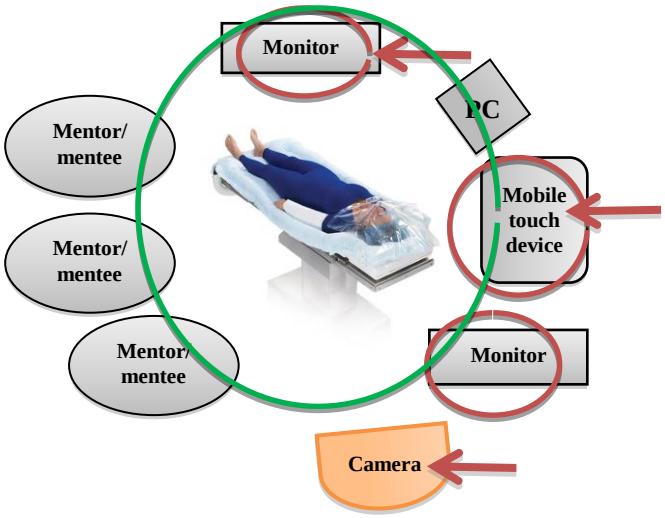

Figure 1. The organization of the surgical team, their resources and the recording units.

By focusing on what happens in the interaction between all elements during surgical training (the green circle), we aim to expand the traditional method of focusing on technical aspects, by capturing the social processes of collaboration among mentors and mentees in surgical training.

VI. CONCLUSION

This paper describes a work in progress, a project studying collaboration among laparoscopic surgeons who are

instructed during education (CoaST). Since there is limited understanding of VC in surgical practice, and in-depth understanding of the non-technical aspects or social processes, this design is outlined to reply to this lack. The project strives to capture the interactions that occur in the team, and their use of resources when training surgeons. The understanding of the social processes can be used to improve surgical education and further the surgical team performance in everyday practice.

Capturing several sources of action is a challenge. The interaction in the team happens in between them around the table, on the monitors that depict the patient's body and the touch device on which to draw. When using VC for overcoming distance, the team can see the expert. It is ideal to include these resources. This challenge will be answered by testing the design and reevaluating it before choosing the ideal design for further investigation.

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Synchronous and Asynchrounous Medical Problem Solving

"The use of videoconference and a discussion forum for collaboration among health care professionals in Norway"

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***Abstract*—The use of synchronous and asynchronous telemedicine technology for medical probl]em solving is often treated as a question of functionality. The objective of this paper is to explore how the use of synchronous videoconference (VC) and asynchronous discussion forums for medical problem solving in Norway contributes to sharing knowledge in order to solve medical problems. A secondary use of qualitative data is analyzed in order to explore interactions over a period of time. The results illustrate, by in-depth analysis of interactions, the importance of the interface between questions and answers, when seeking to expand knowledge and learning. Hence, synchronous and asynchronous collaboration represent different opportunities for expanding knowledge. Even though they both can facilitate regularly use, and continuing problem solving, synchronous collaboration is an engagement for here and now problem solving, which affect the regularity and the types of medical problems discussed. The paper is relevant for the topic of the conference, discussing social relations and processes in telemedicine practice. When considering implementing technology for knowledge sharing, it's a need to keep in mind that the practice affects the learning opportunities, and the knowledge shared.**

Keywords—aysncronous; syncronous; medical problem solving; videoconference; discussion forum.

I. INTRODUCTION

Using different telemedicine tools for collaboration allows for both synchronous and asynchronous access to distributed knowledge. Synchronous tools allow professionals to collaborate instantly from different places, requiring same-time participation. Asynchronous tools enable collaboration whenever wanted, capturing the history of interaction, to be shared and distributed to a greater number of professionals. Diverse synchronous and asynchronous use of telemedicine tools has been investigated extensively. In the 90tees the research outlined i.e., the differences between telemedicine applications in terms of their synchronous or asynchronous nature [1], becoming more related to specific services, i.e. wound treatment [2], audiology [3] and, more specifically, how feasible, cost-effective and reliable asynchronous monitoring and synchronous videoconference (VC) are when compared with one another [4]. The discussion of synchronous and asynchronous use of telemedicine is often treated as a question of comparison to traditional care, and further as a comparison to each other by its functionality. Hence, often with the focus on its capacity, and not on how the social processes is an outcome of the way they are organized.

Knowledge sharing and medical problem solving studies compare face-to-face, synchronous, and asynchronous learning, and have deemed the face-to-face format as a more valuable form of interaction [5]. Asynchronous participants have rated their experience more positively overall [6], as supporting successful distance education, providing access to learning materials from any place at any time [7], and have claimed that asynchronous applications are most likely to provide real change in the practice of medicine [1]. Discussing asynchronous and synchronous medical problem solving is most often attached to education settings, and not as a part of daily practice. These discussions compare which of the two approaches is more suitable for collaboration and knowledge sharing, not focusing on the content in the interaction using the tools, or affecting the outcome of the medical problem.

The manner in which professionals interact while collaborating is of great importance when exploring medical problem solving. Often, when considering different types of technology for learning and knowledge sharing the functionality of the technology are evaluated as important. Here, we explore medical problem solving, and how professionals in daily practice share knowledge in order to solve medical problems using synchronous VC and an asynchronous discussion forum among health care professionals in Norway. Instead of focusing on the functionality, we emphasize the importance of the organization and the social processes of collaboration. The research question is: how does the organization of the collaborative work affect the learning opportunities and what characterize collaboration adjusted for knowledge sharing?

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Section two presents the theoretical approach which constitutes the framework for the paper, as the perspectives create premises for understanding medical problem solving in practice. Section 3 describes the method, illuminating the utilization of the data and how the data was collected for the purposes of the original work. In section 4, the results are discussed in accordance with a focus on interactions when health care professionals use synchronous and asynchronous technology. Section 5 is the discussion and the paper concludes in section 6 with suggestions for future research.

II. FRAMEWORK AND MATERIALS

The empirical field is framed by analyzing the activity in the context in which it occurs [8], namely the VC meetings and the discussion forums, and exploring the ways in which professionals together create meaning through mutual interaction.

A. Videoconference as a tool

VC realizes synchronous "here and now" pictures. Four times a week, the GPs in a local medical centre and the specialists at a hospital discussed and exchanged information and knowledge about patients under treatment. As the VC was a part of the morning meeting in a medical department, all the health professionals who participated in the morning meeting also participated in the VC. The GP on duty participated, sometimes with a nurse as observer in the local medical centre in which the patient was staying.

B. Discussion forum as a tool

In the discussion forum, the health professionals were able to post questions (regarding rehabilitation of the elderly), answer questions, exchange experiences at work and reflect together, independent of time and place. The discussion forum enables writing and asynchronous cooperation. Interdisciplinary health professionals from both primary health care and specialist health care participated.

Both methods of collaboration, synchronous and asynchronous, make it possible to transform culture into a common activity. In IV Results, the collaboration is analyzed according to how problems are handled. Dilemmas in the conversation, expressed as choices [9], may either lead to a break down of the conversation [10] or may close the gap in the conversation [11]. When closing the gap, a common meaning of the activity is created. If the gap is not closed, the conversation breaks down. The written text in the discussion forum will be treated and analyzed as written expressions, and dilemmas will be made visible in the conversations. These analytic tools constitute the framework for the empirical analyses.

III. METHODS

In 2014, we gathered materials from two larger studies conducted in Norway in the period from 2006-2010 [12] and 2007-2009 [13], with the purpose of focusing on the interaction during problem solving using VC and a discussion forum. The study discussing *VC as a tool* are based on an analysis of observations of 42 meetings, held during a five-month period. All meetings were video recorded, transcribed, and analyzed. The findings were discussed in eight semi-structured interviews with the participants in the recorded meetings.

The study of the *discussions forum* is based on periods of weekly observations in the discussion forum stretched out over one year. During this period, 35 written posts and 43 answers were registered. The posts were organized thematically from the text-based material. All the text in the discussion forum was copied and stored. The main focus of the observations of the discussion forum was to gain insight into how participants presented a theme to discuss and how they concluded or ended the discussion.

Traffic data revealed 20 visitors in the discussion forum, 7 of whom also participated in the discussion forum. All 7 persons were interviewed in a semi-structured interview. The purpose of the interviews was to map health professionals' experiences in participating in the discussion forum and how they made use of the forum.

Here, the focus is on the interaction between participants; the materials in this article thus do not include statements from the interviews. The excerpts are chosen because they represent issues in which dilemmas and experiences are exchanged. Contradictions in the conversations constitute a potential to develop knowledge [14].

IV. RESULTS

A. Syncronous medical collaboration

This medical conversation takes place over a period of three days. The three episodes presented here constitute each day of the consultations. The GP works together with a nurse at the local medical center. The synchronous VC is part of the morning meeting at the medical department at a hospital nearby. Several specialists participate, and two of them are involved in the conversation. The result is an analysis of how the problems are handled.

GP- General Practitioner, N- Nurse, SP1- Specialist 1, SP2- Specialist 2.

1st consultation

1. GP. "His name is xxx, he came from you, completed the treatment with clostridium. Infection, diarrhea, infection of the intestinal… eh…I haven`t spoken with him, but… eh… I don`t know when he arrived".
2. GP. "He has been here for several days"?
3. N. "He has been here for several days"?
4. GP. "He arrived on the 3rd, yes, from the medical department in your hospital. And here it is… He has completed the treatment. He is not into antibiotics now, but he has experienced a

recurrence of his diarrhea, has bouts of fever of higher than 39°c in the evening. No fever this morning. He hasn`t had a fever this weekend either…So I don`t know if he will stay or not, or what …".

5. SP1. "I can`t remember him right now…".
6. SP2. "Give him a new treatment with Flagyl for 10 days".
7. GP. "Yes…".
8. SP2. "Give him a new treatment with Flagyl for 10 days".
9. GP. "Okay, how much"?
10. SP2. "One tablet, 400 mg, 3 times a day, over a period of 10 days".
11. GP. "Okay, is this per os"?
12. SP2. "Per os, yes".
13. GP. "Per os, yes".
14. SP2. "Tell me if this doesn`t have any effect in a couple of days".
15. GP. "Okay, in 10 days"?
16. SP2. "Yes".
17. GP. "Yes, ok. We'll do that".

The consultation begins by presenting the patient, a man who had completed the treatment of an intestinal infection, and was transferred from the hospital to the local medical center (1). The GP caters to the nurse (2), who informs him that the patient arrived one week ago (3) and completed treatment from the medical department (4). The GP shares that no antibiotic was given due to the recurrence of diarrhea and fever (4). The GP describes the situation that arose this weekend, and proceeds to seek out advice as to how to face this development (4). SP1 cannot remember the actual patient (5); SP2 follows up by recommending a treatment of antibiotics for the recurrence of the infection (6). The GP confirms this (7), and SP2 specifies that the treatment is to continue to be administered over 10 days (8). The GP requests information about the dose (9), and the specialist suggests the amount (10). The GP then proceeds to ask whether the treatment is to be given orally (11), which the specialist (13) and the GP confirm (13). In light of his expectation of the immediate effect of the treatment, SP2 recommends that the GP contact him again if the patient does not respond to treatment within a couple of days (14). The GP asks for new information and confirmation that the treatment should be administered for a total of 10 days (15) in spite of the fact that the effects should be apparent after only a couple of days. SP2 confirms this (16), and the GP agrees to follow these recommendations (17).

2nd consultation

18. GP. "Xxx, who saw you with a chlostridium infection after treatment with antibiotics, infection after treatment with antibiotics, experienced a recurrence. We started with 400 mg of Flagyl x 3 after advice from xx (SP2), which was very successful. After 2 days, the recurrence subsided, and… he is now functioning normally".
19. SP1. "Seven days, xx (SP2), or 10"?
20. SP2. "Since this is the second time, 10 days".
21. GP. "10 days then? I was about to ask about that. Then we will do so! It turned when we started up again…".
22. SP1. "That`s great! It is always good to receive information about how things turn out".

The GP reports that the patient they discussed two days ago has responded positively to the treatment, and that the patient has now regained normal functions (18). SP1 asks if they decided to proceed with the treatment for seven or ten days (19). SP2 justifies his earlier recommendation of ten days thus: since this is the second time, 10 days is necessary (20). The GP confirms that the treatment will continue for a total of 10 days (21) and that this statement is based on the fact that the patient improved immediately after the treatment began. SP1 confirms the development and the fact that it is good to be informed about this development and the effect of treatment on patients whom they have discussed and treated (22).

3rd consultation

23. GP. "He has improved considerably. I believe that we will send him home over the weekend".
24. SP1. "Has he been using Flagyl for another week or something in addition to the primary treatment or..."?
25. GP. "Yes, he received Flagyl for a total of 10 days, 400 mg x 3. He will finish the treatment during the next week. He is completely free of symptoms at the moment. This turned out very well so we'll send him home next week".
26. SP2. "Yes, yes".

Three days later, the GP reports that the patient whom they had discussed previously and who was being treated was now cured (23). SP1 asks for information: whether this was the patient who got received extra doses of antibiotics (24). The GP confirms this and the fact that the cure was administered over a period of 10 days (25). In addition, he shares the most recent plan for the patient, namely, to send him home next week (25). The SP2 agrees with this course of action (26).

The tree consultations illustrate how the problems are handled, using the analytic tools for our framework. In the first episode, the GP identifies two dilemmas. The first is related to the treatment of the patient (1,4) and the second to medical information tools (1), when he is uncertain about which day the patient arrived. The GP is the individual who conveys the medical problem and identifies the dilemma. The specialists use their knowledge and experience (6) from similar cases to recommend further treatment, and to share how quickly the patient should respond (14).

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In the second episode, the GP responds to the recommendations from the specialist from two days earlier; and shares that the patient responded as desired and expected (18), and the specialist is pleased to receive feedback on his ratings (22). The specialists also discuss the course of action with one another and explain that normally, a 7-day treatment may be prolonged until 10 days if the patient has a back flipping infection (19,20). In the third episode, the GP follows up on the two past consultations by sharing that the patient has responded well to the treatment (23, 25), and that the patient is ready for discharge. Here, the collaboration adjusted for learning and knowledge sharing is characterized by engaging here and now, identifying and solving dilemmas during the conversation.

B. Asyncronous medical collaboration

Excerpt A is a text from the discussion forum, in which three participants have written one post each, regarding persons with dementia and in pain. The participants in the discussion forum have a common base; a post from a health professional regarding pain assessment.

A1 Excerpt A, informant 1
A2 Excerpt A, informant 2, etc.
B1 Excerpt B, informant 1, etc.
(…) Text left out

Excerpt A

16.02 : 12:21. A1. "I know that several of you have met persons with dementia and you have not been sure about how to complete a pain assessment. Was the rule of thumb for xx (name) useful? (facial expressions/sounds/defense mechanisms)".

06.03 : 07:53. A2. "About 12 forms of pain assessment exist for persons with dementia, no single method has been validated. They are under development, and none of them are recommended in international literature. That is why we are working on this case – but it will take time! You can read more about it in xx (reference)".

23:03 : 18:51. A3. "We have a type of pain assessment scale for the elderly called the "observation based scale of pain for the elderly". I believe that this type of pain assessment is a good method by which to assess pain among the elderly. If you have trouble finding this pain assessment scale, you may contact me at xx (name) hospital, and I will have it sent/faxed over to you".

This excerpt begins with a dilemma among the participants, about how to complete a pain assessment for persons with dementia. A1 asks about a general rule of thumb. Facial expressions/sounds/defense mechanisms are useful rules for handling pain assessments. A2 answers that several different forms of pain assessment exist with different qualities. The dilemma is that none of these forms of pain assessment has been validated, and A2 refers to knowledge in the international literature. A third participant, A3, has had some experience in the workplace with using forms of pain assessment, and will share this with the other participants.

This asynchronous excerpt demonstrates how the participants gave their input to an issue in the period of February 16th until March 23rd. The written text allows the participants to discuss issues independent of time, but it results in no immediate follow up, nor does it address the need for knowledge in the moment. The feedback given is anchored in written knowledge to which the participants refer.

Excerpt (B) presents posts on the theme of nutritional status and discussions on using the diet registration form.

Excerpt B

08.02: 13:20. B1. I wonder if there are many (…) who use this method of analyzing nutritional status in the hospital, who performs this analysis and how it is followed up.

08.02: 13:29. B2. In the report (name), the "food card" is a document used to describe the nutrition of the elderly, which gives an indication of the actual problem. Another form of documentation is a nutrition protocol related to the ADL form. I would like to come into contact with someone who has experience using this.

09.02: 13:28. B3. xx (name and title) presented the form of diet record used at xx (hospital). It can be found in archive xx (name).

22.02: 08:40. B4. "In the presentation given by xx (name and position), she gave an overview of the use of PEG-probes/tubes in different countries. In Norway, it has been used very rarely, which I interpret as good news. From personal experience, I know that it is not unusual for patients in nursing homes to be malnourished. Could this be because of the underuse of PEG-probes?"

06.03: 07:52. B5. "The question as to the use of nutrition tubes in different countries is debated and difficult to answer. (…); nevertheless, this question is crucially important to discuss! There may very well be patients in nursing homes who are not adequately nourished, which is not desirable! There are several reasons for this circumstance (…): certain diseases can make meeting nutritional needs difficult (apoplexia, fungia infections in the mouth, cancer, and ulcus, among other things); patients may give up on eating and may refuse to eat because of the limits of age, including weakness, dementia, depression, and psychiatric disease; or health personnel may not follow up enough due to bad food routines, bad food offerings, insufficient vitamins, and the like or a lack of staff and thus not enough time to feed the patients or to sit down with them.

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It is not appropriate to deny the use of a nutrition tube that might be useful for the patient. (...) On the other hand, it is extremely important to seek out the cause of the patient's poor nutrition (...). A PEG probe is not always the right solution. A study of pathology in Oslo (...) shows that a relatively large number of the elderly who were dying were malnourished because as life was ebbing out, eating became less important, which is a natural response (…). Other countries face the challenge that (…) there are not enough staff/health personnel. (...) Nutrition tubes may be a cheap solution compared to paying for educated healthcare personnel. In Norway, twice as many healthcare personnel work in health institutions compared to Germany and Austria, and in the USA, over 80% of employed nursing assistants have an education of over 75 hours. They often must consider other decisions compared to those faced by nurses in Norway".

Excerpt B extends over a period from the 8th of February until the 6th of March. The discussion begins when B1 discusses a certain method by which to assess nutritional status, and asks whether any of the other participants suggest using another method, who uses this method and how. Another participant (B2) follows up on the question by referring to a report that describes the "food card", which may be the answer to B1's dilemma. Another possible form of documentation is also mentioned, namely, the use of a nutrition protocol related to an ADL form. The participant who brings up this method asks for a response from anyone with experience in using this specific form. Participant B3 doesn`t answer the questions directly but refers to a form that registers diet that is used by others and that is stored in an archive.

After several weeks, the topic of diet is returned to in the discussion forum because of a presentation about the use of a specific type of tube (PEG) used as a tool for eating (B4). This tube is rarely used in Norway, which the participant regards as a positive thing. Health personnel have a lot of experience with patients suffering from malnutrition, which gives rise to the following dilemma: In which cases is it correct to deny patients the use of a tube as a means of assistance with eating when the patient is malnourished? After several weeks, B5, who held the presentation, addresses the problem. B5 believes this to be a good question, one that leads to several dilemmas that are difficult to resolve. B5 offers several explanations as to why patients are often not well nourished: due to different diagnoses, the patient may have different incentives to deny eating or there may be a lack of follow-up from health personnel.

B4 relates the question to the fact that feeding tubes are rarely are used in Norway, and B5 relates the answer to national and international experiences. First, B5 refers to research-based knowledge from Norway, and states that patients in the last phase of life eat less. Second, B5 refers to economic aspects in international health care, including the fact that using feeding tubes may be a cheaper solution than hiring employees with education. Third, nursing staff in other countries may less education compared to nurses in Norway, which may be one of the reasons why feeding tubes are used more frequently in other countries compared to Norway. Here, the dilemma is presented, and the knowledge gap is tried to be solved by one way transmission of knowledge. According to our analytic tools, this collaborative work breaks down, as there are no follows up- either by questions or by confirmation on how this knowledge fitted into practice.

V. DISCUSSION

Both synchronous and asynchronous tools represent possibilities for sharing and discussing medical problems. Compared to previous literature, we do not valuable the form of interaction [5] or their positivity [6]. As the results illustrate, the oral (VC) and the written (discussion forum) communication exemplifies that the organization of tools and the tools itself contribute to different patterns of interaction.

In the *VC collaboration*, the GP has questions about patients under treatment as the consultations are running. In the conversation, dilemmas arise about treatment choices. The GP has questions and informs about the patient's condition, while the specialists recommend treatment and explain their treatment suggestions. The GP follows up by asking whether more knowledge is needed. Hence, the medical problem is solved rather than staying unsolved. The consultation takes place over several days, during which the same patient's recovery is discussed through new questions or information as to how the treatment is progressing. The specialists are informed of how their recommendations work in practice.

The *discussion forum* also presents questions related to patient treatment in practice. As illustrated in the excerpts, a question is raised by one participant, and other participants follow up on these questions. The questions are of a more general form, rather than seeking out knowledge to be put into practice in the moment. Follow up questions are generally not posed in the discussion forum. Members in the forum who wish to do so may participate. In principle, the questions are not posed to a specific member. The members refer to their own experience justified by written resources, i.e., international literature and the elaboration of a scheme for registration. The communication does not continue (excerpt A), so we do not know how this knowledge is experienced by the participants at work. Excerpt 5 is an example of one participant (which included a speech about the theme of B4's question) reflecting on a dilemma about the use of a probe.

The written contribution has similarities with the medical conversation, as the health care workers explain and argue on the basis of their experience and knowledge. The discussion forum gives participants the opportunity to catch up on the knowledge exchanged, based on referenced literature, whenever they wish to do so. This procedure differs from the use of VC, in which the journal at the GPs is used as a basis for knowledge exchange.

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B5 exchanges knowledge related to solving the medical dilemma, reflecting different treatment options. No concrete treatment suggestions are made, and if the knowledge exchanged is put into practice, the results are not shared afterwards. There is thus no feedback as to whether or not the dilemma is, in fact, solved in practice.

The episodes and excerpts analysed illustrate oral and written communication over the course of several days. The conversation includes the same participants over several days, while the written forum enables several participants to join the conversation. In the written discussion forum presented here, the participants make one contribution each, over an indefinite amount of time. VC is an interface between questions and answers, in a pre-booked period of time. The participants have a common point of reference in a specific problem in the VC meetings. The discussion forum has a mutual theme of reference, which was previously raised as a result of a joint meeting.

VI. CONCLUSION AND FUTURE RESEARCH

In this paper, we have presented several interactions among professionals sharing knowledge in order to solve medical problems. Early literature in the field claimed that asynchronous applications are most likely to provide real change in the practice of medicine [1]. The results illustrate that in-depth analysis of such interactions gives insight into this type of collaboration in new ways. This article illustrates the importance of the interface between questions and answers, when seeking to expand knowledge and learning. The organization of the collaborative work affects the learning opportunities as asynchronous discussions include several participants and allow for collaboration over time whenever wanted. Meanwhile, in-moment interactions enable information and knowledge sharing that can prompt changes in treatment, illustrating the opposite of Alleley's [1] findings, who account for real change in the practice of medicine using asynchronous applications.

Asynchronous discussion forums are often non-authorized according to data protection, so discussions where biographical data appears cannot be discussed, as discussed in VC meetings. This also excludes the use of journals during the collaboration. Non-commitment to be available in the moment, also exclude discussions of acute medical problems.

When considering implementing technology for knowledge sharing, it's a need to keep in mind that the practice affects the learning opportunities, and the knowledge shared. Synchronous and asynchronous collaboration have a tremendous capacity for information exchange and knowledge sharing. Research is needed to gain a better understanding of how healthcare professionals can work together in everyday practice and how the organization of their collaborative work affects their own engagement.

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Nursing Telecare: Public Stories and Practices

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***Abstract* - There are high expectations on the use of telecare. In this paper, we look into the way these expectations are expressed in what we call public stories and how these stories relate to telecare practices. We have conducted a quick search on the public stories of care organizations and policy documents and ethnographic research on nursing telecare practices in a homecare organization. Public stories tend to describe telecare as a phenomena that is here, that is autonomous and has positive outcomes. The nursing practices show that telecare has effect on care as we know it. With the technology come all kinds of changes in care, brought on by the technology and its users. Telecare needs care professionals and patients to make it fit by tinkering with it, which leads to good care. This is not a part of the public story, a discrepancy that can cause governmental policies to be unfit for day-to-day practices.**

Keywords-nursing telecare; policies; ethnografy

I. INTRODUCTION

The use of technology to be able to care at a distance (telecare) leads to new forms of care, which raise broad attention. Telecare is embraced by governments and some care organizations, looking for new opportunities to reduce cost. The context is a time of rising care demands and declining personnel, leading to rising health care costs [1]. Innovations like telecare seem promising out of the problems healthcare is facing.

Telecare brings new products and players along. Diabetes patients, for example, are active players in these new forms of care, when they use technology to monitor themselves. New services are offered, like house monitoring systems, which aim at making persons feeling more safe. A recurrent example of improved organization is tele-dermatology. Nurses or general practitioners take a picture of a wound or skin disease and the dermatologist evaluates it at a distance. It safes trouble and time for patients and doctors, as the patient does not have to go to the hospital. These new forms of care aim at improving the organization of care.

We sketch a different dynamics between the hopes of (governmental) organizations on how telecare will solve future problems of healthcare and the new care practices that come along with the technology. We see these hopes narrated in different appearances, like governmental policies or care organization's leaflets, which we call public stories. We aim to relate these public stories to the care practice. The governmental and organizational policies have a guiding influence on healthcare, which makes it important to know whether it fits the care practice it is made for. We focus on nursing care with research that is founded in a PhD-project.

The project's main research question is: how do public stories of telecare relate to nursing practices of telecare? We conducted ethnographic research in a project in a home care organization, where a team of oncology nurses initiated and implemented telecare. With this study we want to broaden the research on telecare. The leading form of research for government and insurance companies are effect studies, for example randomized controlled trials (RCT's). Effect studies isolate particular variables to learn about the effects of the new care. Is the newly used device enhancing quality of care, are patients more satisfied or does it prevent rehospitalization [2][3]? Effects are not exclusive or open for interpretation [3] and some of these studies also describe examples of friction [4]. Patients and nurses have different experiences for example about how the telecare experiment influences the care relationship. In these studies such outcomes are shown as side effects; changes in care relationships are not object of study. Other studies do aim at new forms of care, but they use different tactics of research, like ethnography. The design of a RCT's is not flexible, and innovations, like telecare technologies are , do not stay the same over time [5]. It demands for forms of research that can go along with the fluid ways of innovation. Examples are found around the theoretical insights of Science and Technology Studies, from where we draw extensively. Important starting point is that technology is not neutral but it is part of the (care) relations between people. Just a grab from a very rich pot of theory and research: technology is tinkered with to get it right [6], people use it in other ways than it was designed [7] and people get attached to technical devices [8].

In this article we take a first step, in relating nursing telecare practices and public stories.

II. METHOD

In this section we will discuss the PhD project and the methods used for the fieldwork on both the public stories and the nursing practices.

A. The project

The nurses of a homecare organization started a telecare project because they wanted to monitor patients more closely without being more intrusive. At the same time patients would be facilitated to contact nurses more often. Being able to see each other would add an extra advantage over the

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phone. For this goal they used an existing system, made up by a computer and webcam. When the patient starts the computer, a screen appears that shows different buttons. The nurses designed this screen and filled it with information related to cancer, like specialized information on food. One of the features of the system is an digitalized questionnaire on symptoms of patients, on which results the nurses evaluated whether extra contact was necessary. In the second half of the PhD project observations and interviews will be conducted in a nursing telecare practice in mental health care. For the public stories, no fieldwork is exercised yet, apart from the quick search which is described in the next paragraph.

B. *Public stories*

For the public stories on telecare so far a quick search has been done, based on early research design ideas. The search we performed aimed at getting an insight in different ways in which telecare is reported on. We used two sources: at first we retrieved policy documents which were assembled over the last six years. We selected three documents from leading and influential institutions (two research institutions and a council) [10][11][12]. We searched for descriptions and definitions of telecare or eHealth. The samples we used in the results are exemplary for how policy documents define telecare. Secondly we performed a quick scan using a common internet search engine to see how care organizations present themselves. We looked in to websites that hit the descriptions ‘telecare’, ‘care at a distance’ or ‘care and technology’. The search was limited to Dutch websites. A website was included when it told something about the function, promises or applications of telecare (n=10). Whenever possible, terms and results are translated in this article.

C. *Nursing Practices*

A team of homecare nurses specialized in palliative care, mostly for patients with cancer was followed for 18 months. They initiated a project to introduce telecare in their work. A computer with a designated website and a webcam were introduced to patients. Part of this research was aiming at the changes telecare would bring to the nurses care. In order to do so, intensive observation on house calls (‘care as usual’) was performed (n=14). Most of these patients turned out to be candidates for participation in the project. After the start of the telecare, in some cases observations continued during house calls, as the telecare project often was subject of discussion during the house calls (n=8). Patients needed extra instruction or nurses were curious how patients went through the system. The contact between patients and nurses while using the system for care at a distance were also observed (n=19). Field notes were taken during the observations and patients and nurses were interviewed (n=12). For these interviews, we performed auto-ethnographic interviews [9]. Respondents were asked to tell about and reflect upon their (professional) activities. Patients were approached for participation in the research by the nurses, accompanied with a letter of the researcher, which explained the goal of the research and the procedures for acceptance or refusal.

III. RESULTS

A. *Public stories on telecare*

A striking result from our quick search on telecare stories in the public domain is that those stories are mainly positive. Care organizations, to start with, that offer telecare, announce it in different ways, like leaflets or on the internet. Our first example is an arbitrary one, as are many more can be found on YouTube. In this little film we found a still as shown in figure I.

In the still you can see a text box. It says (in Dutch, but translated by the authors): ‘After the conversation I feel better and I can face the day feeling good’.

Figure 1. Still of a Youtube movie.

The short movie shows Yvonne, a middle-aged woman who tells about her illness and how the new technology (a videophone) helps her through the day. It is a telephone with a screen and she uses it to ‘phone’ her caregiver twice a day. Notwithstanding the much broader impact of such care than just this still, it does show a very positive opinion of a client. Positive in a promising way: life will be better when the device is used. Whenever short movies likes these are spread on the internet, along a certain story on telecare is told to the public.

The positive story though can be found in research or governmental reports as well [10][11]. Most of them consider telecare as here to stay. The recent years reports handle subjects of concern or give advice that stem from this reference point. The 'National Institute for Public Health and the Environment' [12] for example pleas for risk management of eHealth, including a system to report failures. Such a plea can also be read as a confirmation of eHealth as an establishment, as it needs risk management and a matching system. That eHealth can be considered an establishment is not so much a surprise, but this example shows how it turns up in reports as well.

Another example of the settlement eHealth as a positive innovation is the way it is defined. The perceptive reader has already noticed that a slight change in discourse just took place. Where we talked about telecare up till now, in this section the word eHealth is introduced. eHealth is the

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language used in most results of our quick search, so we choose to use it in this section too. One example is of the 'Dutch institute for health services research (NIVEL)' [13]. They, as do others [14], use the following definition: 'eHealth is the use of new information and communication technologies and in particular internet technology to support and enhance health and healthcare'. In this definition eHealth is not just here to stay, but also a very positive development, as it will support and enhance care.

It is in definitions like these the public story manifests itself prudently. Obviously, the definition itself doesn't exclude any critical remarks on eHealth. They are not mentioned, but the positive effect is. Our aim is not to disclose opposite camps, as the discussion on telecare and its effects on care is not helped by contradictions. It is helped by nuances. The question is whether this widespread definition is giving enough room for nuances.

Our analysis of public stories is very short, as fits a work in progress. The analysis shows a very positive way of representing telecare (or eHealth). It is here to stay, it enhances health and healthcare and it leaves patients satisfied. Just by caring from a distance, good care is given. But what is happening in nursing practices?

B. Nursing practices and telecare

The data of the nursing practices allows for different lines of thought. On the analysis of the pre-telecare house calls an article is written which is currently under review [15]. This article is on the role of materiality in care. Building on the earlier mentioned insights of Science and Technology Studies, this article shows how materiality plays an important role in care as we know it. In this article, we focus on the materiality in people's homes in the pre-telecare phase. Things in people's homes are part of their lives and turn out to be part of the given care. By introducing materiality as an active and important player in the care relationship between patients and nurses, ideas can be formed on how the relationship will change when telecare is used.

Another line of thought around materiality is on how nurses and patients handle the telecare device that was introduced in the project. Part of the application is the digital questionnaire. With this questionnaire nurses expect to be able to monitor patients more frequently. In the next citation, nurse Annet talks about her expectations of the digital questionnaire:

The USD [questionnaire] is to me the core of the program…even when you ask a lot of questions at the house call… still some things are not mentioned… research shows that people underreport and when you structure these questions… Both them and us will see the relations between things. The beauty of this system is that we get a signal whenever a symptom becomes a burden. So this is an extra aid to guard.

Nurse Katja makes a deal with mister Compaan:

Mister Compaan fills in an average grade for a day. Nurse Katja keeps explaining to mister Compaan that the USD [questionnaire] is designed to register how he feels at that moment, at the actual moment he fills in the answers, but she fails. Eventually she proposes to do it his way. She will evaluate mister Compaans results in that way (field notes house call).

Mr. Compaanis not feeling happy with the instructions and uses the questionnaire differently, which forces nurse Katja to adapt as well. Together they use the technology in an unexpected way. These examples show how materialities play an active role in care and how technology leads to new forms of care, which ask for adaption and tinkering by nurses and patients.

IV. DISCUSSION

Our quick analysis of public stories on telecare shows quite a positive image of telecare. This is not undermined by the insights in nursing practices, but public story and practice do not seem to match. Public stories tend to describe telecare as a phenomena that is here, that is autonomous and has positive outcomes. The nursing practices show that telecare has effect on care as we know it. Telecare needs care professionals and patients to make it fit. It leads to good care when patients and nurses succeed. This tinkering needs time and effort, which is not talked about in the public story.

As this is a work in progress and as the fieldwork has not been exercised completely, these conclusions are open to changes. The conclusions are not just preliminary because of the unfinished fieldwork, but also because we have made correlations that are open for discussion. To start with: what is the relation between public stories and nursing care practices? The line of thought we introduced is that the fieldwork on telecare practices indicates that with telecare comes tinkering, which needs time and space. We also suggested that tinkering and the necessary time is not part of the public story. That suggests that whatever nursing care needs, should be part of the public story. As if battles are fought there. Maybe that is an unjust assumption. Base for this thought is for example a starting point on telling stories: stories are an inextricable part of relations [16] and therefor of society. The way stories are told influence public opinion and hence end up in governmental policies.

Still a lot of questions can be asked. What are the effects of public stories on the health care system? How are public stories read and written down the best way? What insights can be added on any of these questions or what questions should also be raised? As our research continues some questions may be answered, as others inevitably will be raised.

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How to Use Qualitative Interviews in E-health Research

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***Abstract*—Qualitative interviews are much used in e-health research. It is a challenge that qualitative studies in e-health are of varying quality, and not always based in an explicit methodological framework. In this paper, we present easy-to-use guidelines for using qualitative interviews in e-health research that are firmly based in social science methodology. The paper outlines some topics and practical advice that are of special interest for e-health. We draw on the qualitative methods literature and our own experiences from e-health research, where we have used qualitative interviews for more than 10 years and in studies among several different user groups. Qualitative interviews stand out as a well-suited method to grasp the socio-technical complexity and rapid changes that characterise the e-health sector.**

Keywords-Method; qualitative; interview; e-health; telemedicine.

I. INTRODUCTION

E-health research is characterised by studies of the implementation of novel technology in health care. In line with the small scale and explorative nature of many e-health projects, qualitative methods are well suited and frequently used. The benefits of qualitative methods in e-health research have been underlined in the literature [1][2].

In this method paper, we stick to the concept *e-health* and discuss aspects that are especially relevant for this field. We would like to emphasise that we think of e-health in broad terms. The points we make are relevant for all qualitative studies within the field of digital technologies in health care, and thus apply also to studies defined as telemedicine, telecare, telehealth, m-health etc.

The in-depth interview often plays a crucial role in qualitative e-health research, whether as a singular method or along with observations. The interview method is well suited to grasp complexity and individual differences [3]. The human users of e-health technologies are not part of one singular group; rather, there are multiple user groups and differences among them. There are patients in different stages of illness and with different diagnoses; caregivers; health professionals with various institutional affiliations, educations and experience backgrounds; and administrative personnel and IT advisors with different functions and depths of understanding of the technology. In order to understand when, how and why people end up using or not using e-health, we need to understand their detailed experiences and reflections on e-health technology. In other words, user experiences need to be studied in-depth and on their own premises.

The qualitative interview stands out in the field of e-health studies with evident methodological advantages. It is well suited to document not only user experiences from hands-on use of the technology but also reflections on non-use. Through interviews you can gain knowledge on everyday work and patient practices that are not striking or noticeable during observation of user situations. As an example, interview studies have revealed that both patient and professional users of e-health relate to technology as a "security line", and thus incorporate it into their everyday lives even when it is not used [4]. Qualitative interviews can provide insight into how users actually reason, as far as the e-health technology is concerned, i.e., how they construct meaning around their everyday habits and work (for professionals) [5], or health practices (for patients and their families) [6][7]. Open-ended questions and flexibility in the communication between researcher and informant, combined with the researcher's continuous efforts to be active, but never paternalistic, allows for the informants to present in-depth stories [8]. Thus, in qualitative interviews with e-health users, unexpected accounts and new angles can be revealed; these angles and understanding may differ from management, design and policy understanding of what technology is, or is supposed to do [9].

However, it is a challenge, that existing studies relying on qualitative interview-methodology in e-health are of varying quality, and not always based in an explicitly scientific methodological framework. As e-health is a multidisciplinary research field, the e-health researcher is confronted with multiple scientific ideals and various approaches to the process of data production. The qualitative in-depth interview and the techniques used to conduct such interviews should not be confused with other kinds of interviews or scientific methods, e.g., the professional authority and aim to give advice that is present in the clinical patient interview must be avoided; the same goes for the positivist strategies to obtain objectiveness that permeate surveys and strictly structured questionnaire-like interviews

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[10]. In a qualitative in-depth interview, an exact repetition of wording and order of questions is not desirable, as it risks concealing the particular subjective experience of your informant, which is what you want to find and study.

The aim of this paper is to contribute with practical advice and suggestions for method reflections in e-health interview studies. In Section 2, we present an easy-to-use guideline for how to use qualitative interviews, that is based in social science methodology. The three-phase guideline deals with the planning, carrying out and analysis of interviews. Our paper highlights aspects from our own and others' empirical research that are of special interest for e-health. We round off with some reflections on the use of qualitative interviews in this field. We draw on general insights from the social science methods literature and, more specifically, on the interpretative and constructivist traditions [3][8][10].

II. QUALITATIVE INTERVIEWS IN E-HEALTH RESEARCH: A THREE-PHASE GUIDELINE

There are three main phases in an interview study: the planning, the actual carrying out the interview and the analyses of the empirical material.

A. Planning Your E-health Interview

As a first step, you have to reflect on your choice of methods and make sure that the in-depth interview is an appropriate method to answer your research question. As can be seen in the literature, the qualitative interview can be suited for all phases of e-health, from feasibility studies [11][12], through processes of participatory design [13][14], and to evaluation and action research [15][16]. The choice of research methods is always linked to the scope and objective of your study. If your study objective is to understand user experiences, local practices or human constructions of meaning of e-health technology, then the qualitative interview should be considered. When you have decided that you want to interview users of e-health for your study, and you have the methodological arguments for choosing this method over others sorted out, you are ready to start the practical planning.

In the planning phase, there are three main issues to work on: who you want to talk to; where you want the interview to take place; and what topics you want to include in your interview guide.

1) Who to interview: When your method is based on subjective accounts, finding the right informants is crucial. It is important to plan the process carefully and reflect on whom you want to talk to and why. Again, you need to look at the scope of your study.

A common strategy in qualitative research is theoretical sampling, where your aim is to recruit informants that will give you the most and best information on your specific study questions. This is different from representative sampling, where you want to recruit a sample reflecting the population that you are studying. Thus, if you are looking for barriers to e-health implementation and have decided to use qualitative interviewing as your method, non-users will be valuable informants. An example can be found in Sandaunet's study of an online self-help group [17]. She explained how some users experienced a challenge of fitting in and that there were several barriers to use. These findings could be revealed only through the analysis of her sample of *drop-outs* from this particular e-health service [17]. Likewise, for a study on how e-health technology is intervening in existing work practices, the most frequent users will likely provide the most interesting input. This was the rationale behind Savolainen, Hanson, Magnusson and Gustavsson's decision to only include users in their sample who had used a videophone service for frail elderly people at least six times [18]. However, as suggested in the interview literature, when you are assessing potential informants, it is also important that you try to get a range of views on the topic of your study. Those few informants who could potentially express different or contrasting statements or experiences than others can often be central to modifying your assumptions, hypotheses and theories [3].

When you have decided on your preferred sample the next step is to find suitable informants. Depending on the specifics of your study, we advice you get in touch with the responsible management for the e-health service you are interested in. This can be, e.g., a project manager, hospital directors, clinicians, patient organisations or others. Such collaborations are crucial for gaining access to the names and addresses of potential informants, for distributing information about your study, and for discussing practical procedures for the recruitment of informants. There are no strict rules with regard to exactly who you may or may not include in your interview study. However, in e-health, research and the development of new technologies are often closely connected processes. This requires special attention to the interrelationship between researchers, developers, health policy and management, commercial interests and informants. You may want to interview representatives from various groups of actors. As in all research, the researcher has the responsibility to ensure research of high ethical quality.

In qualitative interviewing, there is no standard answer to how many informants you need. A common strategy is snowball sampling [19]. This strategy means you start out with a few key informants and then either asks them to suggest who else you should talk to, or you use the information in the first interviews to decide on new informants who could elaborate on or oppose your first findings. You continue sampling and testing emerging themes with new interviewees up to the point of analytic saturation; this is when you realise that no new themes are emerging, but that all that is said in the last two or three interviews has already been mentioned by previous informants. However, if your interview study is part of an e-health pilot and there are only a limited number of users and involved parties, we suggest you aim to interview all of them.

After having decided whom you want to talk to, you will have to approach the person and check whether he or she is willing to do an interview. Most countries have ethical standards that need to be followed when making contact, and some require an ethics committee's approval of

your recruitment plan. In general, we recommend you make the first contact in writing and include a request for the informants to reply within a week or two. This will ensure that the informant has time to reflect on your request, and does not experience any pressure to participate, but actually does so voluntarily. Before you start the interview, you should gather the informant's written consent. If you are planning to recruit patient users of e-health, it is important you take the necessary steps to avoid deceptive practice. You should be cautious that you do not approach the patients in such a way that they interpret the interview as part of their relation to their doctor or treatment plan. This can be a challenge, as patient lists are protected through privacy laws, implying that you will often need to collaborate with clinicians to get access to potential patient informants. For example, when recruiting patient informants for a study of a videoconference service in psychiatric emergency care, we had to let the treating clinician do the practical recruitment. In this case, we underlined, in both written and oral information, that participation was voluntary and that if they should choose to withdraw this would not have any consequences for their further treatment [20, 21].

2) Where to do the interview: The locations you choose for your interviews will influence the atmosphere and, thus, to what degree the informants open up to you. In addition, there are several practical considerations to make, like economy, travel distance, timing and the option to use videoconference equipment, telephone or e-mail. These all have to be weighed with care.

In e-health research, we recommend that you conduct interviews in the location where the technology use takes place (or is supposed to take place), when possible. This will help you frame the interview and draw the informants' attention to your topic, which is e-health. When the interview takes place close to the technological device, the informant can show you how he or she uses it while you talk, as well as explain experiences with the functionality. If you are able to have such a practical exercise during your interview, this can often give you an entrance to ask more specific questions about the user's relationship with the e-health application. In one of our studies, the aim was to examine patients' use of home-based e-health services; hence, we decided it was an advantage to conduct the interviews in the patients' homes [7]. This proved to be a good decision, as we discovered something we had not thought about in advance: that the patients related to the e-health service even when they did not use it. They thought of it as a safety alarm; thus, it influenced how they handled illness, even when the service was not used. This particular service was similar to e-mail, and opened for the patients to send requests at any time. It guaranteed a reply from a doctor in three days. For the patients, just "knowing that the service was there", was reassuring and eased their self-management of treatment plans and medications. However, in studies where the informants use an e-health service for sensitive or emotional issues, it is crucial to conduct the interview in a location where you can talk undisturbed and without risk of putting the informant in an embarrassing position. For example, in a study of the experiences of adolescents who had a mentally ill parent and used an Internet-based self-help group for assistance with that situation, we chose to conduct the interviews at an office and after ordinary work time, instead of their homes or in a public place in respect of the informants need for privacy [6].

The location of the interview has to be assessed in each interview situation and accommodated to fit the individual interviewees. If it is possible, you should offer the informants a choice and welcome their suggestions as to where the interview should take place.

3) What topics to include in the interview guide: Before meeting with your informant, you have to consider what topics, themes and issues you want to address in the interviews. This is what you outline in your interview guide. The interview guide is a template for how to structure the conversation that is to take place between you and your informant.

Several strategies exist for structuring the interview. For e-health research and evaluations, we suggest the semi-structured interview. In a semi-structured interview, you have a list of pre-defined topics or themes that you want to address in-depth, but the order of themes can vary, and some interviews may comprise more (or less) topics than originally planned [3]. The semi-structured interview is different from the structured interview (where the same list of pre-defined questions is asked to every informant) or the unstructured interview (where you talk without an interview guide). It is not uncommon to have two guides: one with a list of themes/topics, and one with a list of more detailed questions to fall back on in case your informant does not elaborate as much as you hoped. The concepts "semi-structured interviews" and "in-depth interviews" are sometimes used intertwiningly.

In e-health, the researcher is most often interested in studying a change that has happened: for example, the introduction of a new technological device or service in a social setting (such as the work place, an organisation or in a patient's home). Further, if your study is an evaluation, very often you will have observed variation in user patterns during a test or pilot phase. In your research, you want to follow the technology through everyday routine settings and gather various users' subjective experiences.

Some suggested topics for an interview guide addressing users' experiences of e-health technologies are: (1) what the informants' expectations of the e-health service were prior to it being introduced; (2) actual practical experiences with the technology, including benefits and challenges, non-use of the application (and why), and when and in what situations e-health was used; (3) if the e-health service or technology interfered in other work-/health-related processes (and how); (4) if there were any other uses or relations to the technology than the user had expected; and (5) how the informant would assess the actual outcomes of e-health as compared with the expectations held in advance.

It is important to underline that a main advantage with the in-depth interview method is its flexibility, in that your

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interview guide can be changed and adjusted based on emergent themes throughout the process.

When you have designed the initial interview guide, we recommend that you do a test interview with somebody who could be a potential informant, e.g., a health professional, or a colleague in e-health. After the test interview, you can adjust your topics and the wording of questions in order to avoid misunderstandings and ensure that your guide covers the purpose of your study.

There are various guidelines for qualitative research that can be of value when planning your study, e.g., the Critical appraisal skills programme (CASP) qualitative guidelines [22]. Researchers need to assess guidelines according to national, disciplinary and other requirements.

B. Carrying Out the Interview

An in-depth interview is demanding and requires hard work from the researcher. During the entire interview, you constantly work on creating a good trusting atmosphere, as well as developing the structure and deciding how to follow up on your informant and his or her input as you go along. The following aspects are interrelated.

1) Atmosphere: First, you need to introduce yourself in an honest and trustworthy way. You should start by stating the aim of your study, as well as your own relation to the e-health service or application that is to be discussed. You have to emphasise to the informant that, whatever your background and attachment to the application, you are interested in their subjective experiences, and that they can withdraw from or abort the interview at any time. Underline that you will treat the information confidentially and ensure the informant's anonymity when reporting the results. This has to be stated even if you have made these points in your invitation letter. Our experience is that some users of new e-health technology can feel they have to apologise if they have not used the technology as expected, feel embarrassed if they found the technology difficult to use or withhold negative experiences with the e-health technology. Hence, you need to ensure that you tell the informants that you need their individual experiences, including the advantages as well as the challenges, and that there are no correct answers. If you want to record the interview, make sure you ask if this is OK before you turn the recorder on.

2) Structure: A good way to build trust and a comfortable atmosphere is to start with questions related to simple, harmless facts, such as age, job, residence, education and how much experience the informant has with e-health. Afterward, go further into the essential topics according to the scope of the study and your interview guide.

To wrap up the interview, it is important you first let the informant finish his or her reflections on the core topics, and then ask some simple and non-emotional questions. Examples of such can be whether the informant imagines e-health will be much used five years from now, if he or she has any feedback or advice for the developers of this technology and, finally, if there are any other issues the informant wants to bring up. A neutral and non-emotional completion means that the informant leaves the interview with a satisfied feeling. This is always important, and especially so if your topic involves vulnerable groups like psychiatric patients or their close relatives [6][21].

3) Follow up with your informant: In a semi-structured interview, you should be open to include topics that are not on your interview-guide. The interview guide is to be applied as support: as a checklist. The core characteristics of a good in-depth interview researcher is his or her ability to follow the informant's talk, allow use of the interviewee's own words and logic, follow up on the informant's themes and avoid organising the interview strictly according to the predetermined list of questions [3]. Dare to let there be silence and do not interrupt the interviewee. Still, be aware that a passive interviewer can create a powerful constraint on the interviewee to talk [10]. The interviewer has to evaluate the need for active communication during each interview. If your informant talks of e-health in general terms, make sure you ask him or her to give examples for each statement. In our experience, this can often be a challenge, especially when the informant is a manager, bureaucrat, policy maker or other who is used to talk in broad terms and relate to e-health on a general level [23].

Some practical advice is to leave your list of questions out of sight until you come to the end of the interview, and only then bring it out and explain to your informant that you want to check the list to ensure that you have covered all the topics you wanted to address. The goal of a qualitative study in the e-health field is to get in-depth insights into individuals' experiences, and it is interesting to find individual variations and nuances in the use of an e-health service to get the whole picture.

Finally, we recommend you take notes, even if you make a recording. Notes are useful not only for the analysis, but to follow up details and aspects of special interest during the interview.

C. Analysis and Report

In contrast to studies based on questionnaires and structured interviews, you will not have the categories you want to compare ready prior to your data gathering, or rather, the production of empirical material that happens during the interviews.

In e-health, a qualitative analysis is about creating categories that reflect the empirical material in a truthful way and that contribute to generating new understanding of the users' stories, as well as the story of the e-health application and its relation to the human actors you have met. A common strategy to ensure an analysis that reflects the empirical material in a truthful way, is that a team of researchers start out independently, producing separate lists of categories. The comparison of categories and further conceptual development can then be a joint second step.

The qualitative researcher often alters the research questions during the research process, as well as in the final stages of the analysis. This practice places a huge responsibility on the individual researcher. There is no pre-defined scheme, no methodological or statistical program that can ensure the reliability and validity of your data. All

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qualitative researchers and research teams are responsible to ensure an active reflexive treatment of the data in all stages of the research process [24].

Be aware that a qualitative analysis often takes much more time than a statistical analysis, where most of the reflexive research work is already done before data is gathered. If you have more than about 20 interviews in your sample, you might want to consider using software for qualitative analysis.

In-depth interview analysis is a constant juggling of interview transcripts or recordings, research literature, and reflections on your method and research question. The product of your analysis will be a list of categories and the comparison of these, often presented in a table.

In qualitative research the analysis of empirical material and the writing of the research report, or paper, will in practice be parts of the same process. As you go from preliminary analysis to drafting your research report, it is important to ensure the informants' anonymity and confidentiality. Pertinent biographical details must be concealed in the quoted material used in the published report.

III. REFLECTIONS ON THE USE OF QUALITATIVE INTERVIEWS IN E-HEALTH

Interviews are well suited to gather knowledge on users' experiences and constructions of meaning, as well as the embedding of e-health in their social environments. User involvement is crucial in the e-health design and development processes. This is well acknowledged, and participatory design is now a preferred method in e-health development work, as well as in health technology assessment [13][14][25]. Nevertheless, a lot of e-health projects and pilots still fail to be implemented as routine services after the development period [26]. We argue that this challenge needs to be addressed by the e-health community through a stronger, more in-depth focus on users' experiences and the local construction of technology. Methodologically, this implies more in-depth interviews. The technology implementation process needs to be followed closely over a longer period of time: that is, longer than the design and development phases that often constitute the project period in e-health research, and where observation fieldwork is often carried out. What happens after the e-health development and project teams have "left the building"? When e-health services and technologies are released for everyday usage, they meet with complex networks of humans and technologies. In most cases, these existing networks surpass the limited environments of the design process.

IV. CONCLUSIONS AND FUTURE WORK

There is no doubt the qualitative interview will continue to hold a strong position in e-health research, as a stand-alone method or in combination with other methods. For the knowledge production in the field, it is important that the method is thoroughly applied when used. Thus there is a continuous need for developing and reflecting on the interview method to ensure high quality e-health research. In this paper we have presented a three-phase guideline for how to use qualitative interviews in e-health research. The guideline is built on social science methods literature as well as our own experiences from using interviews in e-health research. Some practical advice and suggestions for e-health researchers interested in this method have been outlined. Qualitative interview stands out as a well-suited method to grasp the socio-technical complexity and changes that are taking place in an increasingly digitalised health care sector.

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Online Patients in an Offline Health Care Sector: Are Hospitals Ready for Electronic Communication With Patients?

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***Abstract*—Surgery cancellations are undesirable in hospital settings. In order to reduce elective surgery cancellations at the University Hospital of North Norway, the eTeam-Surgery project studied the pre-operative planning to determine if part of the planning process could be moved from the hospital to the patient at home – through electronic collaboration. This paper discusses the actual readiness for electronic communication between patients and hospitals. In order to approach the readiness for electronic communication, the method section is divided in two parts. The first part consists of a documentary study of the most recent health reform in Norway, focusing on the readiness for using IT within the health care sector. In the second part, an in-depth empirical study of the pre-operative planning process at the hospital, is described. The results are reported in three analytical categories, according to the findings: a) Norwegian health policy; b) Health care workers at the hospital; c) The hospital as an entity. The authors' conclusion is that while Norwegian health policy strongly promotes electronic collaboration, and health care workers are ready to use new tools, the hospital, as an entity, is not yet ready for electronic communication between patients and the hospital.**

Keywords-elective surgery cancellations; pre-operative planning; e-readiness; electronic communication; health policy; hospitals; health care workers; Norway health care.

I. INTRODUCTION

In most hospitals, surgical departments are simultaneously the major area of investment, and the greatest source of revenue [1],[2]. Nonetheless, elective surgeries are regularly cancelled; cancellation rates between 10 and 40 % have been reported [2]-[5]. In western countries, up to 20 % of elective surgeries are cancelled on the day of surgery. However, it is also identified that 50 % of these cancellations might be avoided [2],[6],[7]. The reasons for elective surgery cancellation vary, but evidence points to lack of information as being a main cause. These studies refer to information that existed prior to the day of surgery, but was not available when required [8],[9]. The patient often holds such information.

The Norwegian population is well prepared and able to use Information and Communication Technology (ICT): Patients, including elderly or less-educated [10],[11], are using electronic health care services [12]. There is also an increasing tendency for health care workers to use their personal electronic devices to support their clinical work [13],[14]. Such trends in the health care sector, often designated as e-readiness, open new possibilities to approach the elective surgery cancellation problem. With e-readiness, we refer to the preparedness for using Information and Communications Technology in health care.

In line with the aforementioned literature on elective surgery cancellation, in 2008, the University Hospital of North Norway (UNN) did identify inadequate planning due to lack of information as a main cause for cancellations [15]. The aim of the research project, "eTeam-Surgery", is to reduce the number of elective surgery cancellations at UNN, by providing the lacking information from the patient to the hospital at an earlier stage in the pre-operative planning process. The eTeam-Surgery project has studied the pre-operative planning at UNN to determine if, and how part of the process can be moved from the hospital to the patient at home, through electronic collaboration.

To develop a tool for electronic collaboration between the patient and the hospital is not an easy, nor a straightforward task. A substantial amount of the literature in the field of health ICT, reports on unsuccessful implementation projects, challenges and unforeseen consequences of ICT in health care, particularly in hospitals [16]-[28]. In order to evaluate the possibility of using electronic (i.e., web-based)

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communication between the hospital and the patient prior to surgery, this paper focus on what appears to be a paradox in the Norwegian health care sector. Despite the reported e-readiness of the population (patients and health care workers), several health ICT projects have failed to fulfil their expected outcomes, also in Norway [29]-[31]. While literature demonstrates patient's readiness for using web-based tools, knowledge on the political and organizational readiness for such communication are scarce. It is our argument that these are important actors in the success of health IT. This paper addresses the political and organization readiness for health IT and ask; is the Norwegian health care sector ready for electronic communication during pre-operative planning?

In order to gain knowledge on the Norwegian governmental vision on health ICT, a documentary study of the most recent reform in the Norwegian health care sector was conducted. The reform is called the; "*Coordination Reform*" [32], and was published by the Ministry of Health and Care Services. Thereafter, an empirical study was performed at UNN, in order to explore the readiness for electronic communication between patients and the hospital during pre-operative planning. Both the health care workers involved in pre-operative planning at UNN, and the hospital, as an entity, in pre-operative planning, were addressed.

This paper is divided in five sections. In the Section 1, the problem with surgical cancellations is introduced, and the aim of the study is described. In Section 2, the background of the study is presented. It gives a brief introduction to the existing knowledge on e-readiness, and on challenges with ICT in health care. The data collection methodology is presented and explained in Section 3. The results are disclosed and interpreted in Section 4. In the last section, discussion and conclusions, the authors elaborate on the readiness to use electronic communication in health care.

II. BACKGROUND

It is reported that patients from within the Norwegian population are well prepared and able to use ICT [9],[15],[33],[34]. In addition, health care workers use personal electronic devices to support their clinical work [13],[14],[24]. Despite this, there is substantial evidence in the field of health ICT, on unsuccessful implementation projects [16]-[18]. Challenges with implementation, slow diffusion and unforeseen consequences of ICT in health care, particularly in hospitals, have been reported [16]-[28].

Patients already use electronic health care services, and health care workers are extensively using their own devices in their daily work. However, slow diffusion and failed implementation are reported. If patients and health care workers are ready, why are the ICT implementations in hospitals often failing?

The eTeam-Surgery project is approaching this paradox. In order to go beyond individuals' readiness, and explore the possibility of using electronic communication between the hospital and the patient, the need for a new approach was identified. In this paper, the authors are considering the recent Norwegian health reform and the hospital as entities, while focusing in e-readiness in the context of the pre-operative planning process at UNN.

III. MATERIALS AND METHODS

In order to approach the readiness for electronic communication in the Norwegian health care sector, multiple and diverse methods were needed. Therefore, the method section is divided in two parts. The first part has a more general motivation, and consists of a documentary study of the Coordination Reform, focusing on e-readiness. In the second part, in order to approach the e-readiness at UNN, an in-depth, empirical study of the pre-operative planning process was carried out.

In the study of the Coordination Reform, the focus was on the readiness to use electronic communication within the Norwegian health care sector.

The empirical study consists of three phases. In order to keep this paper self-contained, the empirical methodology will be described briefly hereafter; for further information refer to [35].

- *Stage 1* Gather data on the hospital's representation of the elective surgery cancellation problem;
- *Stage 2* Observations and interviews at the hospital, related to the pre-operative planning processes at department level;
- *Stage 3* Individual, in-depth interviews with all professional groups involved in pre-operative planning at a specific hospital department.

In Stage 1, the aim was to gather knowledge on UNN's understanding of the elective surgical cancellation problem, and the hospital representation of the pre-operative planning process. One document, containing information on the use of resources involved in surgery at the hospital was identified and studied [15]. In 2012, UNN initiated a Lean project in order to optimize the elective surgical process. Researchers from the eTeam-Surgery group followed this project.

In Stage 2, the pre-operative planning process at different departments at UNN was investigated. This comprised three weeks of fieldwork at the Surgery and Intensive care clinic, doing interviews while following an anesthesiologist and an anesthetic nurse. In addition, thirteen interviews with physicians, nurses and administrative personnel were conducted, at six different departments. The interviews were semi-structured, done at the workplace, and lasted between thirty minutes to two hours.

During the first two stages, two departments were described to be more efficient. However, these departments still evidenced a representative number of cancellations. One of the departments was chosen to proceed with an in-depth study in Stage 3. The chosen department is not revealed due to ethical reasons. In Stage 3, representatives from all the professional groups involved in the pre-operative planning process at UNN were addressed. At this specific department, extensive knowledge on the pre-operative planning process was collected. The department-specific interviews were semi-structured, done at the workplace, and lasted between one to two hours.

IV. RESULTS

The results section is reported considering the analytic categories of the findings. These categories were defined in

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order to discuss the e-readiness within the health care sector in Norway. The categories are:

a) *Norwegian health policy*: Readiness within Norwegian health policy, where the findings from the documentary study are reported;
b) *Health care workers at the hospitals*: reports from the interviews carried out during stages two and three of the empirical study;
c) *The hospital as an entity*: reports from all three stages of the empirical inquiry.

A. Norwegian health policy

In the preface of the Coordination Reform, the Minister of Health and Care Services stated that: "*Norway ranks among the highest of all OECD nations – but we have not achieved a corresponding high level of health in return*" [10]. The Minister wanted to change this: "*With smart solutions, patients will receive proper treatment at the right place and at the right time. We will achieve this through the Coordination Reform*" [10]. A clear goal on the use of ICT in the Reform, as stated on page 135, is that "*electronic communication should be the standard way of communicating*" [10]. In line with this vision, an extensive ICT investment is currently taking place in the northern health region of Norway, including at UNN. The Northern Norway Regional Health Authority is investing € 62.5 million in the FIKS project (from the Norwegian "*Felles innføring kliniske systemer*") to develop the electronic health record for the future – a fundamental tool for high-quality patient treatment [33]. This is the largest ICT project in the northern health region ever.

The quotations from the Norwegian health policy, as well as the regional health authorities' heavy investment in new electronic tools, demonstrate readiness for health IT, both on national and regional policy level.

B. Health care workers at UNN

During our observations and interviews at the hospital, we did not experience any resistance from the health care workers towards electronic communication. On the contrary, most health care workers expressed frustration over the cancellation situation at the hospital, and stressed the need for new communication tools.

A surgical nurse related the need for new ways of communication to the current "quick in-quick out" trend in elective surgical procedures. The nurse emphasized that this trend requires new ways of communicating with patients prior to hospital admission, in order to prepare them for surgery while they are still at home. The nurse explained, that before, when patients arrived earlier at the hospital, nurses were responsible for nursing and preparing them for surgery. Such preparation included, e.g., cleaning, shaving, and nail trimming according to the hygienic standard required for surgery. Today, many patients are responsible for doing these tasks themselves. They must follow the hygiene instructions, given by the hospital, at home. The nurse's main concern was related to infections. In this context, an electronic communication tool between the patient and the hospital was suggested to help patients prepare for surgery.

From our analysis of the interviews with health personnel, it is our interpretation that nurses, physicians and administrative personnel are ready for new tools for patient-hospital communication. As an example, different health personnel at the hospital have suggested SMS reminders and e-mail conversations during surgery scheduling.

C. UNN as an entity

During the inquiry of UNN's representation of the elective surgery cancellation problem, one internal report was identified and studied [15]. The report acknowledges challenges with the continuity of patient care at the hospital, and links it to poor interaction between the different professional groups involved in surgical practice [15]. This study also revealed that in order to optimize the elective surgical process at UNN, a Lean project had been initiated at the hospital in 2012. The aim of both initiatives was to promote continuity of patient care, improve the use of resources in surgery, and reduce elective surgery cancellations. Electronic collaboration as a mean to improve the continuity of care during the pre-operative planning process was not suggested in these initiatives.

The main finding from the empirical fieldwork done in stage two, was internal variation between the different departments in who plans the surgery and how, and when the planning was done. The departments have developed their own local practices. At some departments, senior surgeons do the pre-operative planning. In other departments, this planning is done as teamwork, involving senior and junior physicians, nurses, and secretaries.

Based on the empirical findings, a homogeneous structure for the pre-operative planning process at UNN could not be identified. In addition to diversity at the department level, the fieldwork revealed heterogeneity in how professionals described the pre-operative planning within the same department. It was not possible to describe a standard pre-operative planning structure at the selected department. It is the authors' understanding that in order to complete the daily schedule, health care workers use personal and empirical knowledge. The main finding from the empirical inquiry at UNN was heterogeneity in how departments and individual professionals carry out the pre-operative planning process.

V. Discussion and Conclusions

Is the Norwegian health care sector ready for electronic communication during pre-operative planning?

Literature argues the patient's readiness towards electronic communication. The eTeam-Surgery project has not yet approached empirically the patient readiness; therefore, no conclusions will be drawn on this subject. However, the Norwegian Government states a strong wish for electronic communication in the Coordination Reform. This interpretation is in line with Tjora and Melby's [36] analysis of the reform.

The empirical study at UNN reveals that health care workers involved in the pre-operative planning are ready for electronic communication. This was clearly illustrated in the suggestion made for an electronic communication tool to help patients prepare for surgery at home.

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Since the Government, the patient and the health care workers are willing and ready for electronic communication, the next step was to address readiness within the hospital as an entity. The main finding from the empirical study of the pre-operative planning process at UNN was heterogeneity in how departments and individual professionals described and carried out this planning process. It is our understanding that in order to complete the daily schedule, the hospital is dependent on the health care workers' personal and empirical knowledge, and enthusiasm. Since the pre-operative planning process at UNN is heterogeneous and dependent on the workers' proactivity, it is our interpretation that the hospital, as an entity, at this stage, is not ready for electronic communication between patients and the hospital. This conclusion is based on the recognition that in order to develop and implement sustainable electronic communication systems, computer scientists need to identify standard patterns of information and workflow. Such patterns are hard to identify in an organization where the pre-operative planning process can be described as arbitrary and dependent on the individual health care worker preferences.

Our conclusion is that while Norwegian health policy strongly promotes electronic collaboration, and health care workers are ready to use new tools, the hospital, as an entity, at this stage, is not yet ready for electronic communication between patients and the hospital in pre-operative planning. It is our understanding that, in order to successfully implement electronic communication in pre-operative planning, the hospital, as an entity, needs to be analyzed, accounted for and prepared for health IT.

The conclusion is interesting on multiple levels. For the eTeam-Surgey project, it has great impact on future work, as it raises an important issue on the e-readiness of the organization. In an applied context, it has relevance for policy makers, managers in the health care sector, and for stakeholder in the field of health ICT, e.g., vendors and large ICT implementation projects. For the scientific field and the debate on e-readiness, it means that the concept of user involvement and the definition of who the users are need to be revisited. As demonstrated in this paper, the health policy and the hospital, as entities, are important non-human actors, which need to be studied, analyzed and accounted for in relation to the question of readiness for electronic communication in the health care sector.

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FUNNKe – A Norwegian Large Scale Implementation Project

Experiences From the Implementing Process in the Light of the Normalization Process Theory

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***Abstract*—The paper presents a case study describing and analyzing a large scale implementation project taking the sociological model Normalization Process Theory (NPT) into consideration. Two of the authors of the article are also managers of the implementation project, and the article summarizes the experiences made in the project period. NPT can help understand the challenges the implementation project met in the last phase of the project period. The NPT focus on what people actually do and how they work, aligns with the experiences made in the project. Although partners say they will start implementing e-health technology, it does not necessarily mean they will start the work immediately. An implementation project must plan for this and adapt the implementation strategy accordingly.**

Keywords; ***implementation; large scale implementation project; electronic exchange of health information; electronic messaging; e-health; Normalization Process Theory.***

I. INTRODUCTION

FUNNKe is a large-scale implementation project in the health region of Northern Norway. The project period was 2010 - 2014. The main objective of FUNNKe was to establish electronic exchange of health information in all sectors of the health service delivery in the region. By electronic exchange of health information, we mean electronic messaging. Such messages include referrals, discharge summaries, requisitions, test results and dialogue-based messaging between health personnel. The project supports all levels of the health sector - general practitioners (GPs), community care and nursing homes, and hospitals - in taking electronic messaging in use.

We will address certain elements of the processes of implementation and discuss empirical experiences in the light of the Normalization Process Theory (NPT) [3].

The project reached its goal within the planned project period. We did however meet some challenges in the last period of the project. Many of the small municipalities were reluctant to implement electronic messaging, and the project had to spend quite an amount of time persuading and teaching the local ICT- and health personnel.

NPT can help us understand the challenges met in the last phase of the project period. NPT focuses on the work that individuals and groups have to do for a new technology or practice to become embedded and sustained in routine practice. The paper is structured as follows: First the background of the project is presented, then the method, followed by discussions and conclusions.

II. BACKGROUND

FUNNKe was part of a National program owned by the Ministry of Health and managed by the Norwegian Health Network. This program implemented electronic messaging in the other regions of Norway. The Norwegian Centre for Integrated Care and Telemedicine (NST) ran FUNNKe's project management.

The purpose of FUNNKe has been quality and efficiency in the health service delivery in Northern Norway. The main objective of FUNNKe was; "a public health service sector in Northern Norway communicating electronically by the end of 2014".

By the end of the project period, 85 of 87 municipalities, Over 400 GPs and all four hospitals in the region had implemented electronic messaging as their main communication tool. The two missing municipalities will start up in February 2015. The project therefore reached its goal.

The challenges of implementing use of electronic messaging are connected to the fact that only nine of the 87 municipalities in Northern Norway have a population above 10 000, and 65 of the municipalities have a population under 5000. Remotely situated municipalities with a small population size often lack personnel in sectors like ICT and health care personnel. Many of these municipalities also have outdated and insufficient ICT equipment. The situation when it comes to updated ICT equipment is better at the four hospitals in the region.

Hospitals and GPs in the region started using Electronic Patient Record (EPR) earlier than many of the municipalities. A survey from 2012 [2] shows that 26 of the 87 municipalities in the region used EPR to little or some extent, or not at all. The leap from this to taking electronic messaging in use required extensive resources, organizational changes and new ways of working.

The hospitals, municipalities and GPs in the region use several EPR systems. All hospitals use the same system delivered by one vendor, while other vendors serve the municipalities and GPs. All EPR-systems can communicate and the actors use standardized messages. The electronic

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traffic goes on the Norwegian National Health Network (NHN), which is the national infrastructure for the electronic interchange of individual health data.

III. METHOD

Two of the authors are the Project Managers of the implementation project. The article and poster summarize the experiences made in the project period, from the point of view of the project managers. We use minutes from meetings, strategy documents and internal discussions as our data. We will not address to what extent electronic messaging as such is part of regular routine in the health sector. An evaluation is under development, in which municipal personnel is asked to evaluate the implementation process. Research is also going on to analyze the potential for time saving and perceived changes in the quality of care [1]. We will discuss the large-scale project's implementation methods.

IV. DISCUSSIONS

The idea behind FUNNKe's strategy for implementation has been to support the municipalities and hospitals towards expertise. The FUNNKe strategy has six characteristics, developed and initiated by the project management:

1. Information work to attain management and users' commitment.
2. Free access to guidance and support from the project organization.
3. Network building and establishing local networks.
4. Sharing experience and expertise among all parties.
5. Small financial contributions to municipalities as a start-up support.
6. Purchasing of services from local expertise (often nurses working as ICT advisors) and offering their assistance to other municipalities,

According to our experience, the implementation strategy has worked well.

The NPT explanatory model builds upon four constructs: Coherence, Cognitive participation, Collective action and Reflexive monitoring.

We delimit our focus to one of these constructs, Cognitive Participation, which is about the "work that defines and organizes the enrolment of participation in practice" [3:2]. Key questions in this construct are: Does key participants *initiate*, in the work to drive the implementation of electronic messaging forward? Do the health and ICT-personnel *enroll* and buy into the idea of electronic exchange of health information? Do the participants believe it is right for them to be in involved in the new practice (*legitimation*)? Will the users of the electronic messaging system involve and *activate* in the sustaining of the practice? [4].

The NPT's foci on what people actually do and how they work as a crucial starting point for implementation align with our experiences. In the project period of FUNNKe we have learnt that although municipalities tell us they will start implementing electronic messaging, it does not necessarily mean they will start the work immediately.

The FUNNKe project management spent much time on attaining commitment to the project from the municipal management since we needed consent from the decisions makers to a starting up of the process. Our experiences show us, however, that in the last phases of the project lack of commitment from the user level caused delays in the project. The personnel were not enthusiastic about the idea of electronic messaging. In some of the municipalities health- and ICT-personnel were worried about the responsibility following the new system, and wanted to postpone the implementation because of this. The project management realize that more inspirational work targeting the users, could have been of help. We believe that the NPT's construct "Cognitive Participation" could have helped us with a more thorough focus on the commitment from health- and ICT personnel.

However, management support is also crucial for e-health initiatives like this. Lacking support from the city managers would have hampered the implementation process, and we miss a focus on this aspect in the NPT model.

V. CONCLUSIONS

The FUNNKe project's strategy for implementation aligns with the NPT theory. Our analyses indicate that the health- and ICT personnel's lack of enthusiasm can explain some of the problems the implementation project faced in the last period of the project.

Electronic messaging in the health sector is now implemented in the northernmost region of Norway. Challenges for the future will be developing the electronic messaging system and commissioning support to the service and. The municipalities together with the hospitals will address this.

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Telerehabilitation after Total Knee Replacement:

Business model proposals and insights from Tuscany

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***Abstract*—In the last years, Total Knee Replacement (TKR) has become one of the most performed surgical procedures and according to recent forecasts, its incidence is supposed to increase further. Rehabilitation after TKR is an effective treatment to ensure full recovery after surgery and its economic burden in Italy accounts for almost 182 million of Euro per year. By considering the impact in other sectors, the adoption of Information and Communication Technology was welcome as a tool able to reduce costs and preserve the quality of care. However, the actual adoption is not as high as it was expected. Perhaps it could be the results of a partial involvement of the stakeholders included into the telemedicine services. Decision makers, physicians, patients and informal caregivers, should be involved in business model development to elect the best one to satisfy their needs and increase the value of the telemedicine service. This article describes the preliminary results of the business modelling phase belonging to a broader project aiming at involving the whole set of stakeholders interested in telerehabilitation after TKR.**

Keywords-Business model; telemedicine; telerehabilitation; healthcare management.

I. INTRODUCTION

Total Knee replacement (TKR) showed to be cost-effective in the last 30 years and it was largely performed in Italy (21st most performed procedure in Italy in 2013) [1]-[3]. According to "Agenzia Nazionale per i servizi Sanitari" (Age.na.s.), the trend observed in the last years by "Istituto Superiore di Sanità", from 26'694 TKR performed in 2001, to 63'125 in 2011, is going to further increase since the reduction in average age of TKR patients and the extension of life expectancy [4][5]. Likewise, rehabilitation has a pivotal role in patients' recovery after surgery [6][7]. By considering the high incidence of TKR in the last years, the related rehabilitation has a considerable socioeconomic impact both on Italian National Healthcare Service (Ita-NHS) and on patients [8]. According to Piscitelli et al., TKR patients lose on average 9 working days per year; this value increases up to 20 days per patient considering hospital length of stay. During 2005, a loss of 368'586 working days was estimated for TKR patients younger than 65 years, leading to a monetary loss of approximately 24 millions Euro (a working day is assumed to last 8 hours; average wage is assumed to be 7.73€ per hour) [9]. From Ita-NHS perspective, the costs accounted for TKR rehabilitation were about 158 million of euro in 2005 (47 million in hospital rehabilitation and 111 million in home rehabilitation) [8]. By considering the results from the recent report of the "Agenzia Nazionale per i servizi Sanitari" (Age.Na.S.), the rehabilitation expenditure is expected to increase since the number of TKR will grow in the next years [5]. In this framework, digitalization seems to be a pivotal milestone to reduce costs and ensure at least the same quality of care. Many efforts have been made investigating telemedicine sustainability and the factors leading to successful business models without reaching a definitive conclusion [10][11]. Likewise, telerehabilitation after TKR was tested in different technical approaches (e.g. videoconferencing CODECs with cameras; wireless sensors) and contexts; especially in rural areas, were it could be an alternative to home visit and could reduce travelling expenses [12][13]. Although the social impact of rehabilitation is evident, to date there is little knowledge on the drivers leading to successful implementation of knee telerehabilitation programs. According to Osterwald [14], the final aim of a business model has to switch from creating value only for the firm, to creating value also for the society. Therefore, we believe that the approach to involve the most important stakeholders in the design of the business model could be a reasonable way to detect the best business models, and to assess and promote them in order to improve the societal value chain for telerehabilitation.

A. The importance of the stakeholders in healthcare

Freeman defines stakeholders as "any group or individual who can legitimately affect or is affected by the achievement of the firm's objectives" [15]. Every firm or organization has different set of stakeholders who can influence the performance of the organization directly or indirectly. For some type of organizations, different stakeholders should be weighted out differently from other stakeholders. Scholars introduced the importance of different stakeholders in NHS, from low to high [16][17]. Stakeholder's perspective for health care can be different from other type of organizations. The role of stakeholders in health care can be underlined taking into account the differences between patients and customers. In the process of decision making in health care, relevant "stakeholders" should be more involved especially when introducing a new technology [18]. In terms of operationalization of stakeholders' theory, many scholars formed various models to show the relationship between

 ISBN: 978-1-61208-384-1

stakeholders and organizations. Within the context of the NHS, healthcare services have an enormous number of potential stakeholders. In 1994, Brown and colleagues divided the stakeholders of NHS into three groups, professional clinicians, managers and patients [19]. To add healthcare policy makers is certainly useful. Adding to these three groups the role of policy makers for NHS cannot be denied. Scholars introduced the importance of *power level* of different stakeholders in the NHS, from low to high [16][17]. According to the literature, in order to design a sustainable business model for health care it is necessary to map the stakeholders according to their difference in power and pursued objectives. The main reason for the un-sustainability analysed in the study by Lin and Hsieh is the lack of value co-creation between the different stakeholders who participated in the new service development project [20]. Although all the stakeholders intended to provide telehealth services, in fact, each of them had different objectives. Even though some aims overlap, for example both policy makers, managers and patients want to improve care and simultaneously saving money, sometimes they also have specific objectives that may conflict with the other stakeholders' ones..

B. Economic evaluation in Health care

The necessity to deliver high quality healthcare to the largest amount of people associated with the monetary constraints that most countries are experiencing, has introduced the need to optimize the allocation of scarce resources. According to the latest guidelines for Telemedicine released by the Italian Ministry of Healthcare [21], telemedicine programs would be implemented and bolstered by Ita-NHS if they will show to have a better Incremental Cost Effectiveness Ratio (ICER) than the current care solutions (i.e., telemedicine programs should have a lower cost with at least the same effectiveness; likewise, higher costs could be acceptable if the telemedicine program shows also a better response in terms of effectiveness). In this direction, there are some preliminary results showing that telerehabilitation could be a cost-effective solution, especially if further assumptions are made on potential business models [22]. By considering the current scenario, an holistic approach merging business modelling, stakeholders' objectives and health economic evaluations could represent the way for a successful implementation of telerehabilitation.

The paper is organized in 4 sections. The next section, *Methods* (Section II), summarizes the approach used to address the research questions; *Results* (Section III) aims to report the preliminary outcomes of our research; *Discussion* (Section IV) addresses future directions and authors' remarks, *Conclusion* (Section V)closes the paper.

II. METHODS

Taking into account the complex scenario we described in Section I, we set up our research within the design science research methodology (DSRM) [23]. This five steps method is composed of: identification of the problem, definition of the objective of a solution, design and development, demonstration and finally evaluation. The introduction of the current paper has described the problem; the objectives of the telerehabilitation service were defined through informal communications with a decision maker, 3 physiotherapists, 2 patients and 2 informal caregivers. The current paper addresses the "design" phase, which was developed according to visual thinking and scenarios approaches [5]. in addition we will highlight the concerns and future directions. The methodology of the forthcoming steps will be reported into the discussion section.

III. RESULTS

The first two steps of our research were aimed to deepen the knowledge into the rehabilitation area to comprehend the real unsolved issues and to identify the relevant stakeholders. According to Freeman, organizations are dependent on the support of stakeholders to achieve their main goal[15]; therefore identifying the main stakeholders in the arena of telehealth was the endpoint of the "problem identification" phase. Based on prior examination of latest rehabilitation guidelines and rehabilitation pathways we ended up identifying different groups based on their expectations [24][25]. As provided in the framework of Dansky and Gamm [26], stakeholders could be categorized into four main non-exclusive domains: political, commercial, community and clinical. Based on this framework we map telerehabilitation stakeholders as follows: Policy makers (Ita-NHS and Ministry of Economy and Finance – MEF, and healthcare units managers), Commercials (Telerehabilitation providers; sensor providers), Community (patients and informal caregivers) and Clinicals (physiotherapists and healthcare units managers).

Once stakeholders were identified, at least one stakeholder of each category was informally interviewed to preliminary point out their needs. As result of this process, we report the current service description and revenues flows in usual care in the sub-section named "Business model as is". According to the remarks of stakeholders' communications, we integrated them into the new business model design. The results are reported into the "Innovative business models for telerehabilitation" section.

A. Business model as is (Scenario I)

The informal communications with stakeholders lead to define the current business pathway for rehabilitation in Azienda Sanitaria Locale 12 (ASL 12) located in Lido di Camaiore (Viareggio, Tuscany Region, Italy). Rehabilitation procedures are provided throughout four channels: hospitals, outpatient service, home-based service and private care service. For our convenience, we assess the first three together as they compose the public health scenario; while private care will be addressed separately. All the stakeholders areas were covered both for public care and for private care.

1) Public Health

After TKR, patients have a rehabilitation program throughout 2 channels out of 3. Firstly, all patients spend on average 14 days in hospital for rehabilitation after surgery.

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Secondly, physicians decide if he or she can have outpatient rehabilitation or in a home-based program. Almost the whole cost, including the transportation with ambulance, are sustained by Tuscany Region with funds belonging to regional taxations and "intramoenia" activities (i.e., private care procedures performed into a public healthcare unit) [25][27]. The patients are asked to contribute according to their income. If the Tuscany Region is not able to cover the entire costs, a national level coverage is provided. A further option consists into a mixed private-public outpatient treatment. Whereas the patients access to public healthcare facilities, the physiotherapy could be delivered in private care regimen (the so called "intramoenia" procedures). However, part of the physiotherapist revenue will be shared with the hospital. The monetary resources flow is graphically described in Figure 1 (Section 1).

2) Private Health

The private physiotherapy could be undertaken generally into 3 structures: Private care, public outpatients' department ("intramoenia") and into the private care units partially subsidized by Ita-NHS. In all of these cases, the patients can access to private care paying the whole service including the transportation. The second scenario was described in the previous section. The third scenario is meant to have a partial co-payment of the Ita-NHS to the private care which had a reimbursement agreement. The monetary resources flow is graphically described in Figure 1 (Section 1).

B. Interactive business models for telerehabilitation

Because of the ethical and legal constrains, we believe that B2B scenarios are the best approaches in early adoption of telerehabilitation. Both from public health and from private healthcare perspectives, a partnership with healthcare providers is a pivotal point to achieve the maximum possible diffusion for telerehabilitation. In other terms, telerehabilitation has first to be recognized as at least a non-inferior mean of care, then its adoption could be discussed assessing the economic implications (i.e., cost-effectiveness and cost-utility analysis) [21]. However, considering the potential resistances of the other stakeholders involved into the healthcare service (e.g., patients, informal caregivers, physicians), a bottom-up acceptance of the service is also necessary. For this reasons, we plan to design different innovative business model scenarios that will have to be able to involve the whole set of stakeholders and deliver the highest possible value for each of them. To date, we developed the first two main scenarios, in which we imagine all the actors could have a benefit from adopting the telerehabilitation service.

1) Public Health (Scenario II)

A firm who that has a partnership with ASL units in a specific Italian region provides the telerehabilitation procedure. Adopting the firm perspective, the main revenue is coming from the ASL, as they would pay for the service (device rental, maintenance, telerehabilitation software and internet connection), the rental and maintenance of the devices. Likewise, the patients contribute with a fee, which has to be shared between the firm and the ASL. We imagine two parts composing the patient payment: a fixed and a dynamic part. The fixed one relies on income and on whether patients hold a high-speed internet connection. The dynamic part is determined according to adherence to rehabilitation adjusted for socio-demographic and clinical features of the patients. Higher is the patients' effort in recovery, lower would be the dynamic part of the fee and vice versa. The forgone part of the fee would be paid by the Ita-NHS/Ministry of Economics and Finance, which could be interested in reducing the productivity loss and improve the quality of care. For graphical representation, please see Figure 1 (Section 2).

Critical Business issues: The strength of B2B in Healthcare is a top-down approach: to adopt the public healthcare provider channel is expected to have a positive influence in terms of trust. However, it could not be sufficient; by considering the potential barriers in adopting new solutions and an incremental cost, patients should perceive the new service as an enabler of time saving, improve their physical condition, comfort and let them be aware to what extent they could be able to influence the clinical outcome and costs. If the patients' performances influence their payment, it would make them more involved into the healing process, with huge societal implications in terms of productivity gain due to faster recovery. On the other hand, we do not know to what extent physiotherapists could perceive the telerehabilitation to be able to reduce their workload and income, leading to reluctance for the new procedure. In this case, the healthcare management should stress the opportunity forgone while treating one patient in usual care scheme, rather than checking telerehabilitation parameters of more patients simultaneously. It could result into a larger acceptance by physiotherapists, who are going to earn less for each patient, but would follow more patients hopefully increasing their overall income. A further implication in reducing the number of patients with a favourable prognosis having face-to-face treatments could be the reduction of waiting lists for those patients with a worse prognosis; resulting into an optimization of healthcare resources.

2) Private care (Scenario III)

Even in the private care scenario, telerehabilitation should access to the market with an initial top-down approach exploiting a partnership with a big private care institution focused on orthopaedics rehabilitation. The telerehabilitation provider furnishes a service (device rental, maintenance, telerehabilitation software and internet connection) based on fees to the private care institution, which provides the devices to its physiotherapists. In this scenario, we identify the highest market access barrier for physiotherapists, as telerehabilitation is perceived as a threat

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for their income. The physicians providing the telerehabilitation service to their patients, compete with the others physiotherapists inside the private organization. The goal is to achieve the best results in terms of recovery for patients. Therefore, the patient assessment should notice also a minimum clinical outcome to preserve ethics and quality of care. In addition, the patients' score should be adjusted on socio-demographic features to ensure a balanced competition among physiotherapists (i.e., some physiotherapists could have patients with a better prognosis than the others, influencing the result of the competition).
Succeeding at the competition, the private care organization will ensure a reward to the physiotherapist because of encouraging an innovative and cost-saving service for the organization. From patients' perspective, the fee varies according to travelling distance from the rehabilitation centres; however, it will never exceed the usual care tariff. Furthermore, informal caregivers would perceive the telerehabilitation as an improvement in their lives. Since the patient cannot drive during the rehabilitation period, employing a telerehabilitation scheme could half the number of travels with a consequential reduction in travelling expenses and productivity loss for the informal caregiver (please see Figure 1 - Section 3).

Critical Business issues: Although a bottom-up approach enrolling single physiotherapists could be an option, a top-down approach during the launch of the telerehabilitation service would ensure a greater adoption. Once the service would reach a sufficient diffusion in private care clinics, a B2B at the physiotherapist level could be a rewarding strategy. In the private care scenario we detected the most important barrier in the physiotherapists which could oppose resistance in adopting a service able to reduce their income. Telerehabilitation should be perceived from the physiotherapists as a tool to increase their income rather than a monitoring service able to threat their job.

IV. DISCUSSION

In this article, we provided a preliminary insight about how telerehabilitation business model should be conceived. It has passed almost ten years since the first performance-based co-payment system in Italy [28]; the risk sharing strategy is aimed to bolster innovative treatments, which would be fully reimbursed from Ita-NHS if they are clinically effective. On the other hand, the pharmaceutical firm is going to cover part of or the whole costs for those patients who did not recover using the innovative pharmacological treatment. Although it could be right if the patients are thought to be a passive stakeholder (i.e., they would only receive a treatment and they do not directly influence the outcome), the performance based payment would be not suitable for rehabilitation at all. In such scenario the patients are directly involved into the healing process and it has an effect on society; likewise, they should be directly involved into the public health scenario as the main actor. Likewise, the private care is relying on professionals who have a direct relationship with the patients. In this case we believe the private physiotherapist to have a pivotal role in diffusing the innovative processes. Therefore, any of these stakeholders could be excluded in the business model design pathway, and the final objective should be a model adjustable on their needs and perceptions.

A. Toward an interactive business model

After identifying different stakeholders in tele-health organizations, the necessity of a sustainable business model is showing up. Business models have received much attention in literature by focusing on the fact that business model innovation is a key success for business [29]-[31].

Although according to existing literature there is not a single definition for what a business model is, in this paper we refer to Chesbrough and Rosenbloom definition: A business model is a "focusing device that mediates between technology development and economic value creation" by emphasizing on the value chain for creating and distributing the offering [32].

A sustainable business model considers the society as key stakeholder [33], which is in line with healthcare perspective as long as patients play a key role in value-creation phase. Zott et al. emphasized on the role of customers, shareholders and any single stakeholder who capture values lied behind firm's entity [31]. According to Baden-Fuller et al., business models are not only the reflections of the firm's strategy to the logic of the firm but also they are the way to show how each firm creates value for its stakeholders [34]. Lehoux and his colleagues suggested that stakeholders vary in the type or quantity of the value that is attached to the characteristics of a given technology [35]. There are in fact multiple categories of customers in healthcare with various types of benefits (e.g., recovery for patients, revenues for physicians, a healthy work-force for employers). Therefore, when entrepreneurs are designing their business model addressing the value of their innovation, they can exploit a large range of dormant attributes of their model; nevertheless, it requires attending to the various and sometimes conflicting expectations of users, purchasers and regulators. Business model motivate entrepreneurs to redefine their key stakeholders and different attributes because their core business can be considered to be sensitive to certain stakeholders and not others especially in healthcare [36]. The healthcare industry is facing multiple challenges. In order to deal with those new arising problems, restructuring by means of industry architecture redesign, as well as business model innovations, may be an answer [37]. Therefore, in this study we suggested two possible business models for telemedicine considering different stakeholders' expectations. When it comes to the healthcare industry, the definition of business model as an activity system is a useful theoretical lens to analyse the latest changes that are why involving stakeholders can create a different perspective.

B. Future directions

The early stages of the design phase were described in this article; however, the forthcoming steps like demonstration and evaluation phases will be crucial for capturing and comparing the different options. Since the

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heterogeneity of the stakeholder, of their values and of the related goals, a multidisciplinary approach is necessary to properly report the final results of the project. As first step we plan to employ a qualitative semi-structured questionnaire. According to the final aim of the demonstration phase, different questionnaires will be designed for the different stakeholders to fill the Osterwald's business canvas sections: key activities, key partners, key resources, customer relationship, customer segments, value proposition, channels, cost structure and revenue stream [14]. The demonstration will involve a set of stakeholders who will be not involved into the project; secondly, a pilot phase will be validated administering the questionnaire to the whole group of stakeholders of a specific ASL. Once the validation process is completed, the questionnaire will be administered to the whole set of stakeholders joining the study. The qualitative results will be reported into a matrix able to summarize the stakeholders' opinions. In the same matrix will be introduced quantitative results obtained from a previously developed decision analytic Markov model [22]. Here, we provide potential examples of quantitative results we wish to include: Clinical and Health Related Quality of Life outcomes, Costs per patient at least over 10 years (from social and third party payer perspective), Break Even Point and Return of Investment.

V. CONCLUSION

The current article provided an insight of the third phase of a larger project. Our preliminary results stressed what we found in the literature. Telemedicine is an innovative topic promising to reduce costs and to preserve quality of care. It is not still adopted as expected, resulting in an undefined market scenario. Proceeding into the study phases we will assess whether the proposed approach could fill the gap between experimental projects and real services in telemedicine. However, we believe an holistic approach, merging the best of managerial, social science and health economics methodologies could provide a better knowledge of the problem.

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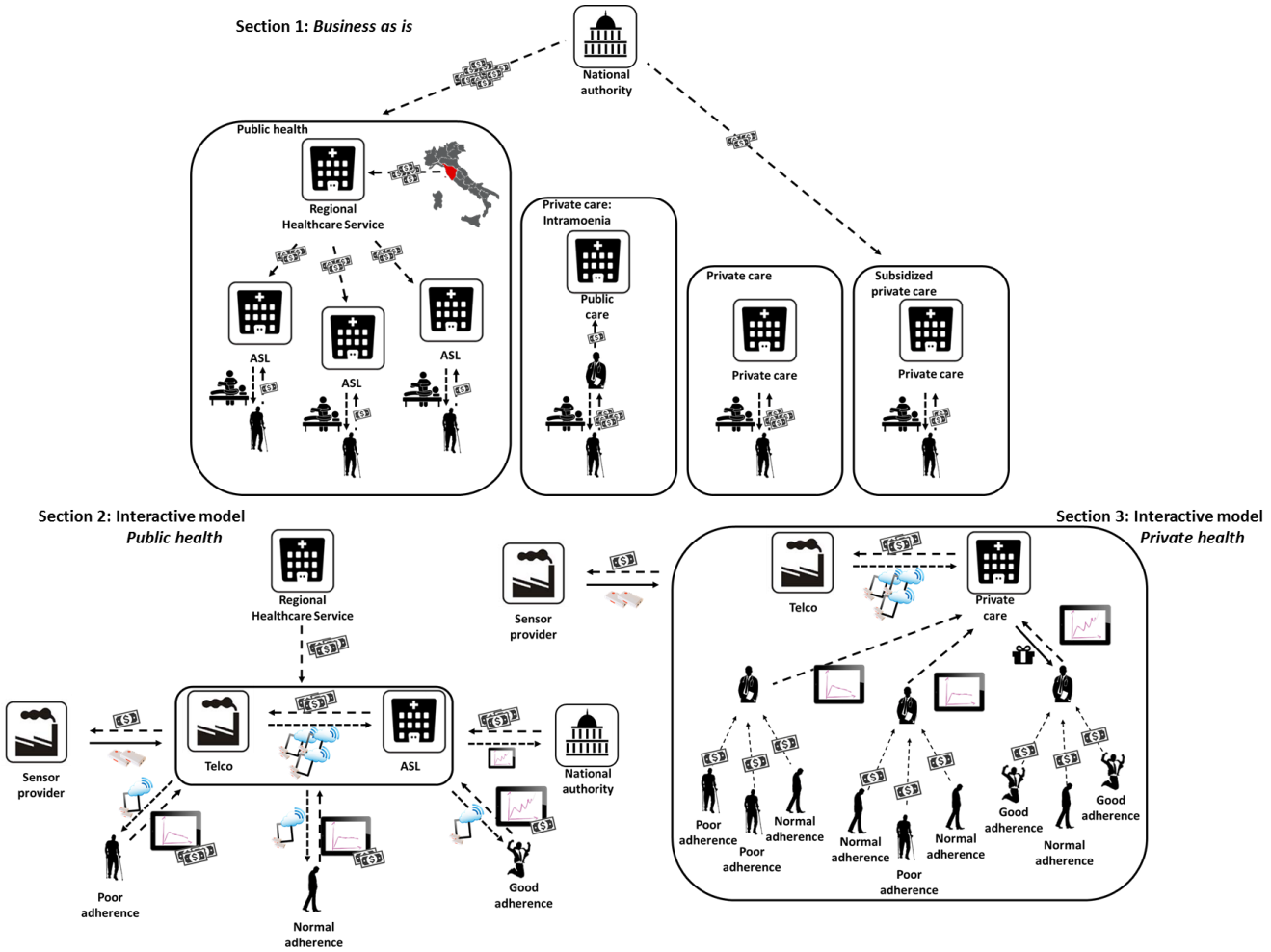

Figure 1. Healthcare business models: from traditional (Section 1) to innovative proposals (Section 2 and 3).

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Unintended Consequences of Telemedicine Implementation

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Abstract— **This poster present preliminary findings and research questions from an ongoing sociological research project on Norwegian telemedicine. The aim is to illuminate unintended consequences of implementing telemedicine technology, and to raise the question if these unintended consequences can explain the slow diffusion of telemedicine in routine clinical care.**

Keywords - Telemedicine; health care innovation; Norway

I. BACKGROUND

Norway´s application of telemedicine has been in the international front [1]. Still, as in other countries, the digitalizing of Norwegian health care takes time. During the more than 20-year history of Norwegian telemedicine the field has met unexpected barriers. Internationally both policy makers and medical expertise now ask for large-scale implementation of standardised systems, whereas most services that exist are local and small-scale [2]. This has caused claims that the diffusion of telemedicine is too slow [3].

The aim of this poster presentation is to illuminate unintended consequences of implementing telemedicine, and raise the question if these can explain the slow diffusion of telemedicine in routine clinical care.

We have conducted a literature review, as well as 10 in-depth interviews with key informants from the Norwegian telemedicine and e-health sector.

II. PRELIMINARY FINDINGS, NEW QUESTIONS AND DISCUSSION

According to preliminary analysis of existing literature and our interview material, there are at least three unintended consequences of telemedicine that actors in the field are aware of, but that receive little attention in implementation processes.

- First, on a micro level: the very access to telemedicine (for expert advice and second opinion) adds to patients and professionals *feelings of trust and reassurance* weather it is used or not [4][5]. This implies telemedicine has consequences also when it is not used, and thus that decisions on weather to continue or close down telemedicine services cannot be based on frequency of use - evaluations.
- Second, on an organisational level: as intended the implementation of telemedicine affects work procedures in health care organisations. An unintended consequence of this is that new work procedures often ends up altering previously established structures of power and responsibility as well, and thus lead to *organisational disturbance* [6]. It is very rare that all actors in an organisation welcome the disturbance of established structures. We ask if the opposition towards the organisational changes that comes along with new technologies might represent a main barrier for the successful implementation of telemedicine systems.
- Third, in health care policy telemedicine is often suggested as a practical means for a more efficient, improved and equal health care service. Our study revealed that actors in administration, management and politics also ascribe symbolic value to telemedicine: and we ask if *telemedicine can become symbolic politics* [7]. If so, this indicates that telemedicine implementation can be slowed down by local, regional and national disputes on health politics and the organising of health care. We therefore argue that on-going local and national political battles in the health care area need to be assessed as part of telemedicine feasibility and process evaluation studies.

III. CONCLUSIONS AND FUTURE WORK

The preliminary findings from our sociological research reveal that there are at least three unintended consequences of telemedicine implementations that in different ways can explain slow diffusion. On a micro level both patients and professionals can be content with the technology ensuring their access to expert advice and second opinion. This implies that actual use is not always the outcome of implementing a telemedicine service. On an organisational level telemedicine brings with it organisational disturbance. Opposition towards the new structures of power and responsibility that comes with telemedicine systems might be a part of the explanation for slow diffusion. On a macro-, or policy level, telemedicine can become symbolic politics; the implementation of new technologies in clinical work is linked to on-going political disputes in health care. This can slow the processes of implementation in local, regional and national contexts. There is need for awareness of intended

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and unintended consequences of telemedicine in implementation processes.

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Assembling Agency for Viability: Videoconference in Orthopaedic Consultations

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***Abstract*— An orthopaedic videoconference (VC) service between a university hospital and a district medical centre was initiated by an orthopaedic surgeon/PhD candidate, who also ran the service. Four hundred patients were included and randomized in two groups for the PhD project, where clinical quality, patient satisfaction and cost effectiveness were investigated. Five years after its initiation, the service was still running even after the data collection was completed. The professionals kept the service running while waiting for the results of the study to be published because of its advantages. However, conditions and regulations established for the PhD project left the service constantly vulnerable to being closed down at short notice. Based upon empirical observations, documents, presentations, articles and interviews, I explore how the service was maintained; that is, the mechanisms accounting for agency/action in keeping the service viable under unclear and shifting conditions. Within a socio-technical perspective I adopt the notion of 'heterogeneous assemblages' to analyse such mechanisms, implying that action is understood as shaped by a number of shifting, heterogeneous conditions or influences which may translate into common strategies through interaction. The paper presents and analyses the assemblages that came into play in certain phases of the service, and reflections about the future of the service. I argue that meaning, issues of improvement of tasks and augmentation of the scope of related activities were main conditions that assembled and translated into agency for stabilizing viability. Human motivation and creativity was therefore crucial for utilising the advantages of technologies and overcoming unsteady conditions. This assemblage surmounted other assemblages that accounted for vulnerability. Studying agency as dynamic assemblages and translations fuelled by motivation, along with the innovative agency portrayed, may be applicable to other VC services.**

Keywords-video-conference in orthopedic consultations; heterogeneous assemblages and agency; vulnerability and viability

I. INTRODUCTION

Videoconferencing (VC) was established between a university hospital (UNH) and a district medical centre (DMC) to strengthen cooperation and to improve services for orthopaedics patients. The background was that 800 patients from the four northern municipalities in Troms County, Norway had travelled to the UNH for clinical consultations and follow up in 2005. Many of them travelled four to five hours for a consultation that lasted for 15 minutes and then travelled back home the same day. Elderly patients and parents of children found this tiring, and long journeys are costly. These experiences were coupled with results of research showing that VC use was clinically useful and entailed patient satisfaction and cost effectiveness; however, such research also indicated more follow-up consultations [1-5]. The results were not directly generalizable to the specific conditions at hand, and an orthopaedic surgeon at the UHN wanted to investigate the use of VC services. In 2006 she initiated a randomized controlled study to investigate clinical effects, economic conditions and patients' experiences with the use of VC. The study later became this surgeon's PhD study: 'Tele-orthopaedics: Decentralization of orthopaedic consultations by means of telemedicine solutions'. The goal for the PhD project was to provide decision-making support for the establishment of a regular service in orthopaedic consultations. Tele radiology, that is, digital transmission of x-rays was a pre-condition.

The service started in March 2007 and is still running in 2014. The initial plan was to include 400 patients randomized in two groups over a period of two years. According to the professional participants, they wanted to continue the VC service after two years because the data collection required more time. However, some of the national conditions, such as legal and economic regulations, necessary for such services as well as regulations that had been established for the PhD project left the service repeatedly vulnerable to being closed at short notice. However, it is still running, as professionals explain, 'on overtime'.

This paper reports on an investigation of the development of the service, as a case study. The contribution of this paper is to highlight mechanisms that account for viability and optimization of the service within shifting phases and unclear conditions. Such mechanisms are considered as dynamic and heterogeneous assemblages where micro and macro influences are shifting and reconfigured [6]. Highlighting not predicted processes that account for the use of certain technologies is a common socio-technical approach. By analysing heterogeneous mechanisms this paper has a sociological emphasis. The intention is to add to the understanding of why planned innovations succeed or

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fail: why was this service still running when its conditions were shifting or unclear?

The paper considers the agency, viability and vulnerability of the service in the following phases: the initial phase of the PhD project before and during 2007; the phase when an additional service for new patient groups not included in the PhD study was established alongside the project around 2009–10; and the period in 2013 and 2014 which was focused on maintaining and securing the future of the services while waiting for the results of the PhD project to be published.

The questions and approach means that this is a study that adopts an actor-network perspective. The questions that will be answered are as follows: What composes the assemblages that account for the vulnerability of the VC services? What composes the assemblages that enact agency in keeping the service stable during the three phases of the project?

The latter is the primary question in this paper, which is structured as follows: In Section II, I present the project within which the investigation was conducted as well as the data sources, theories and the analytical perspectives in this socio-technical study. In Section III, results are presented according to three phases: Phase A. establishing the service for the PhD project; Phase B. when the data collection was completed and additional patients also were offered the service; and Phase C. keeping it running while developing future prospects for making it an official and regular service. Section IV present two discussions: First the shifting influences that translated into vulnerability and then shifting influences translating to surmount the vulnerability and stabilize viability through the different phases. A conclusion section including future prospects closes the paper.

II. METHODS, DATA, THEORETICAL RESOURCES AND ANALYTICAL PERSPECTIVE

As already stated, this paper is based upon an examination of the development of the orthopaedic service, in terms of keeping it running through shifting phases. The examination was made possible through a research grant for a project designed to investigate processes accounting for video-conference collaboration in clinical practice, in general. This project: 'Modelling Videoconference Collaboration', began in 2013 and is still ongoing. Information about the project can be found at the website of The Norwegian centre for integrated care and telemedicine [7]. It investigates processes and outcomes through multi-methodological approaches, including quantitative and qualitative methods and process studies. The overall objectives are to explore new models for clinical VC collaboration and to analyse active mechanisms involved in optimizing the potential of services, that is, the process of attaining goals. Assembling agency as discussed in this paper is considered to depict such mechanisms. The paper thus reports on an investigation addressing dynamic processes. The orthopaedic video conference service was selected as an interesting case for investigating such processes.

The data for this analysis is collected through various sources: literature studies of VC in orthopaedic consultations, presentations of the PhD project, information material and media articles about the specific service from its start in 2007. Minutes from meetings concerning decisions about the project were also studied. This data collection was retrospective in order to understand the processes from the initiation of the PhD project that started in 2007.

In addition, the following observations were conducted from January to October 2014: five observations of VC consultations which included a total of 15 patients (three patients each time). Four of which were conducted at the UHN site and one at the DMC. The aim of these observations was to obtain insight regarding the significance of the service, the actions and collaboration between the professionals and their opinions and reflections on the service. Conversations were held with the professionals at each site after each observation and formal, semi-structured interviews with two nurses and one surgeon were conducted. Sections of the interviews contained factual information about use of VC services, number of patients that had been utilizing the services, economic and practical conditions at present and shifts during the life span of the service/project. Other sections addressed their reflections about the value or worth of the service for the patients and themselves as professionals, challenges encountered on any aspect of running the service and prospects in terms of continuing the service. The responses were written during the interviews and results were confirmed by the participants.

As mentioned, the results of the investigations will be presented and analysed as heterogeneous assemblages. Such assemblages are described within the body of research approaches captured in the notion of complexity studies. In these studies, information and communication technologies (ICTs) are understood as one influence in heterogeneous and dynamic assemblages stretching from micro to macro, gaining power to influence goal attainment in ever-changing constellations. Viability is considered to be an empirical question in such assemblages, resulting from ongoing transparent negotiations between influences, subtle power games and/or material, mental or scientific resource allocation [6, 8-10].

Assemblages may comprise (in various mixes and connections) a plethora of elements, such as professionals, political authorities, technical agencies, bureaucratic organizations, ICT providers, service firms, regulatory bodies, software engineering companies and research centres, together with technical, functional and normative components. In different and unpredictable manners, these

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all influence whether goals are reached and how they are reached. By examining "how they are reached" the perspective indicates an interest in how the various influences affect the interpretation and enactments of the goals. It assumes that in certain ways assemblages of influences may fulfil the innovation within certain world views. All elements (conditions or goals) that are considered to belong within an innovation can in this perspective be subject to being strengthened, disappearing or changing.

An assemblage constitutes a loosely structured, ever-evolving ecology of heterogeneous elements where boundaries and linkages among administrative bodies cannot be unequivocally fixed, tending to shift and drift in time. Assemblages are considered always to be ad hoc, thereby needing constant re-conceptualization. The overall functioning of assemblages and the viability of the ecology itself are based as much on communications and functional relations as authority and norms [8].

These assumptions and concepts are underlying the approach to scientific inquiry submerged under the broad category of complexity studies in which the ways individual roles, groups and organizations emerge, evolve and adapt to their environment are studied [11]. In this paper I also consider human values and actions as influences in assemblages. To consider agency, I use the concept of 'translation' from actor-network theory, meaning that interaction between heterogeneous influences may translate to a common strategy, which in this case can be expressed as follows: assemblages enacting agency for keeping the service viable [9, 10].

For the analysis of conditions, translations and assemblages in different phases of the service, I have summarized data from the different sources and gradually interpreted this summary while considering and selecting concepts from theoretical resources. One of these was a systematic review that identified heterogeneous conditions for innovation in service organizations [11]. This is a combination of a qualitative analysis where I sought to understand how the participants made sense of what they did in the VC service, extended with the analysis of the heterogeneous conditions that made possible and supported enactments and materialization of meaning.

I argue that the three most significant influences that assembled to produce stability and viability through the phases were as follows: the service's compatibility with and support of the professionals' interpretation and actions for obtaining meaning; its affordances which helped accomplish tasks; and the options for augmentation of work practices. These stabilizing influences point to the important role of motivated professionals and their work to obtain meaning. In this case, their focus on the help they could provide surmounted other shifting assemblages which enacted vulnerability [9, 11, 12].

III. RESULTS

The results section describes heterogeneous conditions that formed assemblages during three phases: A. establishing the service for the PhD project; B. the second phase when the data collection was finished, but a regular service was also maintained with new patient groups; and C. keeping the service running while publication of results are pending and developing future prospects for making it an official and regular service.

A. Assembling the PhD project

One of the conditions for the project was the fact that the Department of Orthopaedic Surgery at UHN had decided to increase their proportion of research. At the same time, the Norwegian Centre for Integrated Care and Telemedicine (NST) was pursuing increased clinical relevance for the use of VC in UHN and had initiated a project in collaboration with the DMC in order to decentralize services and increase use of VC. Technical and financial support to set up the VC unit at UHN was provided by this NST project, thereby supporting the PhD.

Different challenges had to be addressed. For instance, there were no reimbursements for telemedicine consultations, which count as a condition for vulnerability. A group of experts were systematically working to establish regulations for reimbursement, which was settled in 2008, so this condition also gradually supported the service. As the orthopaedic service to be established for the PhD was used as an example in the negotiations for reimbursement, this settlement constituted a strong support for its viability. Additionally, only those who are employees of the organization that owns an IT system or service in the health care sector in Norway are allowed to access the system or service. This meant that only the employees of the UHN could legally access the system. The security team at NST negotiated with the authorities and a number of meetings were held. This challenge remains unresolved. To address the immediate challenge, the nurses at DMC were employed at UHN for this specific service. This was a creative move which was a necessary condition for establishing the service. Due to current legislation, UHN employment of nurses was essential as it enabled them to enter the electronic patient record and access booking where they could find out who had been referred for video consultation. This creative move also made routines simpler.

In addition, according to the head of clinic, UHN owns the equipment and is responsible for the radiology operations at DMC. The UHN department also signed a formal agreement to provide equipment for the completion of the PhD project. Before the project started, the nurses at the DMC who were now employed at UHN underwent a period of training through audit. They learned new skills, such as plastering and using the VC equipment. They were enthusiastic. The nurses and the orthopaedic surgeon expressed that being of help to patients was an important motivation for their work to make this happen. At initiation,

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the project was also subject to extensive media interest. The queen of Norway visited the DMC and observed one of the first consultations, and delegations from around the globe also visited.

All these highly heterogeneous conditions, including enthusiasm, interacted to form the assemblage accounting for its success.

B. Assembling a service alongside the project

The service was running and accomplishing specific tasks, for instance, gypsum change, hip, knee and shoulder controls after surgery, and diagnostics of newly referred conditions, such as hallux valgus. Only patients who had been referred to UHN and met the inclusion criteria for the PhD project were selected for the service, which was organized and carried out by the PhD candidate/surgeon as an expert. As such, it was not an official service.

New conditions, such as new x-ray equipment at the DMC in 2006 and improved gypsum expertise, led to fewer referrals to UHN and challenges to reach the sufficient number of patients during the planned period of the PhD project. The challenges influenced the timeframe, which was adjusted. The service was also considered to work very well, and the professionals opened for 150 additional patients who had not been eligible for inclusion. These additional were for instance, patients suffering from senile dementia. They had been excluded because they were not expected to be able to respond to a questionnaire intended for all the included patients. Travel was considered difficult for this group, and the service was important. This expansion thus enacts compassion as a condition.

Motivation to improve knowledge was another condition for the service's expansion and endurance. One of the nurses at DMC stated that, 'It represents a breathing break, a positive element in working life. There is much running at the lab ordinarily, but of course it depends on what is to be done. Like plastering, it is a little more exciting. We learned casts at UHN. We have increased our competence and we also ran inter-municipal plaster courses here'. A nurse at the DMC also described the emotions of the patients: 'The patients feel safe when we are secure; they see the x-ray on the screen and the surgeon informs them about the developments and examinations to be done by the nurses. It is a reassuring situation'.

The surgeon and the nurses both stated that the DMC's access to the patient record was an important facilitator. The DMC can log on to the record and see what has been planned for VC. One nurse from the DMC said: 'We do not need to make appointments with UHN, but can read and plan our resources according to the booking system. It is simple and easy, but the UHN computer (a personal computer assigned for UHN patients and employees) is locked into a separate room and only the two of us have access". The nurses and surgeon described that the service entailed meaningful work processes and that they also learned new skills. The service entailed an augmentation of their daily routines and action. These were conditions for its expansion. However, security issues concerning access to sensitive patient data for unauthorized personnel made it still vulnerable.

C. Assembling the future of the services

In 2014, the results of the PhD project are pending publication. Meanwhile, the surgeon and the nurses keep the service running and they intend to use the results from the PhD project to argue for its continuation provided these results are positive. They informed me that the service now runs under tacit agreement. This tacit agreement is a necessary condition for its viability. The employment of the nurses at the DMC and the ownership of the equipment is still in operation, The x-ray equipment has been improved, but the VC units are old and need replacement. For instance, new versions of programs have been installed, disturbing the compatibility between the x-ray machine and the personal computer.

There are no plans for continuation of the project, nor have any new routines been worked out. At the DMC the need for a new doctor to take care of new patients with fractures has been communicated. Additional doctors who have skills in plastering will increase the resource base. In general, it is also important that additional orthopaedic surgeons at UNH participate in the services. The skills at the DMC have improved, also leading surrounding municipalities to use DMC for examination and plastering of fractures. The good of x-ray labs and professional radiographers have improved the quality of X-ray taken. X-rays are described by a radiologist at UHN. The evaluation of severity, and subsequent decisions about whether or not to send patients to UHN, are taken by the general practitioners. The general practitioner can take contact with the orthopaedic surgeon at call for discussion of the case if needed and the X-ray is easy accessed for the orthopaedic surgeon in the hospitals X-ray records. Some patients can have their treatment by their general practitioners in primary care, who have skills in plastering. The VC unit has not been in regular use for emergencies, but this is an option.
The situation concerning legal regulations is still under development. When it comes to financial issues, reimbursement is partly resolved, but it also depends on the results of the discussion about legal communication between units.

The professionals await decisions on legal regulations.
One of the nurses stated: 'We run it because it works fine and we want it to develop further. It is necessary to have a sense of common meaning and be able to discuss challenges. Now it is dependent on the professionals and their motivation. It is vulnerable but there are great opportunities'.

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IV. DISCUSSION

In this section I consider shifting and heterogeneous influences in the different phases. According to the assemblage perspective outlined, I first discuss the influences that interacted and translated into vulnerability. The second discussion addresses heterogeneous influences interacting and translating to a stabilizing common strategy which made the service viable. The second assemblage is emphasized as it surmounted the influences accounting for vulnerability.

A. Shifting influences translating to vulnerablity

The empirical findings support an impression of some ad-hoc, heterogeneous and shifting influences. These are identified on different levels and in different domains: i.e. political, operational, organizational and economic [13]. The political influences can be illustrated by the ongoing negotiations concerning how to solve legal issues of electronic collaboration between employees at different institutions. As this question is not solved yet, the political domain provides unclear conditions for the future of the service. On an operational level, the character of the routines that have been developed are shifting and ad-hoc as there are no plans for how they should be established if the service continues. The need for new equipment is also an operational challenge. On the organizational level, the need for more resources at the UHN site and at the DMC is communicated. The continued service is rendered vulnerable. With respect to economic considerations, the financial arrangements established for the PhD project, i.e. the UHN ownership of laboratories and employing the nurses, are running without any guarantee of continuation.

The interaction between these heterogeneous influences translates and summarizes into an assemblage of vulnerability, ongoing through all phases of the service, and stretching into prospects for the future.

B. Surmounting vulnerability and stabilizing viability through shifting phases

The initiatives and work to establish a PhD project, to increase the level of research at the clinic and to improve clinical relevance at NST, as well as the nurses' actions to improve their skills, support a view that actors in this field are not passive recipients of change and innovations. Rather, they seek innovations, search meaning in them, develop feelings about them and modify them to fit particular tasks. The discussion of agency therefore acknowledges participants as actors who purposefully and creatively interact with the complexity of levels and conditions for the service described [11]. The influence of human actors, especially those running the service, is distinctive in all the phases.

One of the most influential elements of agency was the professionals' understanding and actions for making the service compatible with meaning. An example of such an effort was the expansion of the service to groups who initially were not included in the PhD project. The compassion for the most vulnerable patients depicts a value-based driving force. This finding is supported by Dearing et al. who also found that the meaning of the innovation for the intended adopter has a powerful influence on the adoption decision [14]. Service innovations which are made compatible with expressed values and norms have been discussed as an additional support for uptake [15]. The orthopaedic VC service is an example of such an effort.

A second influence that stands out from the results is issues around accomplishment of tasks. The decision and work to keep the service running under unclear conditions, along with the way the professionals described the tasks they were able to perform by using the service, support notions of task accomplishment. This point of view has also been discussed by Yetton et al. [16]. They contended that if the innovation is relevant to the performance of the intended user's work and if it improves task performance, it will be adopted more easily.

The third important influence in keeping the service viable which I derived from the results is the service as augmentation of work practices. Aubert and Hamel asserted that if a new technology or service is supplied as an 'augmented product', e.g. with customization, training and a help desk, it will be assimilated more easily [17]. Examples of such augmentation are the surgeon's pursuit of a PhD; the nurses' accounts of the audit at UHN where they learned new skills; the provision of a new x-ray machine; the way the service accounted for a breathing break in a stressful working situation and the inter-municipal plaster courses that came with the service. All of these elements augmented the service and were referred to as being positive.

The influences discussed, i.e. realizing meaning, improving tasks and augmenting work activities, are considered to influence each other in a network of relations. They translate into a common strategy and provide enough firmness and stability to surmount the changing, ad-hoc and vulnerable influences previously discussed for this case. This viability is vulnerable, however, as influences and assemblages are always changing. Human motivation and work are overarching influences.

Assemblages are usually considered as composed of heterogeneous elements, and the main 'engine' driving the agency in assemblages is considered to be an empirical question. In this case, compassion, willpower and meaning fuelled human agency, helping to utilize the advantages of the technologies and overcome the disadvantages that were encountered. The portrait of the assemblages for agency, including the distinctive role of human agency in this specific situation, can be transferable to other clinical areas. Thus, the results may help to understand and develop other services.

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V. CONCLUSION AND FURTHER WORK

The paper contributes empirical knowledge and a discussion of mechanisms for vulnerability and stability in a VC service for orthopaedic consultations.

I argued that the following heterogeneous influences interacted and were translated into a common strategy for keeping the service viable through shifting phases: the professionals' understanding of - and actions for making the service compatible with - meaning, task accomplishment and the service as augmentation of work practices. The interacting influences surmounted shifting assemblages which made it vulnerable. However, the ongoing dynamic of shifting heterogeneous conditions still renders the future service vulnerable.

The next phase of the project will address collaboration models in viable videoconference services which have existed at least from the beginning of, and through the project period. The data collection is limited to services within the North Norwegian Health Region, where the UHN is located.

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An E-health Evaluation Case study : Evaluating The New Laboratory Information System

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***Abstract*—Healthcare is one of the technology-intensive areas. Almost all healthcare organizations use an information system, without it, managing daily works and providing the continuity of healthcare is impossible. Information technologies staff has to support, manage, and improve the information system. To do this, they are supposed to foretell the hardware and software requirements, improve the system they manage in the competitive environment, to survive, and further to pioneer. In this respect, evaluations are carried out to reveal the weak and strong sides of information systems in operation. In this sense, a case study is performed in this study, to evaluate a healthcare information system. Particularly, the recently deployed laboratory information system (LIS) is evaluated by means of questionnaires, applied to both patients and users of the laboratory information system. Laboratory information system is evaluated on the basis of Function sufficiency, Decreasing Work Load, Speed, Learning Ease, Improving Service Quality, Availability, Help Manuals, User Satisfaction, and Patient Satisfaction features. The features needing to be improved in terms of the effectiveness and efficiency of LIS are measured based on the threshold value. The results are presented in a variable table according to the threshold value selected by the evaluator. As the target threshold value increases, the number of features needing to be improved also increases.**

Keywords- evaluation; healthcare information system; laboratory information system; e-health evaluation

I. INTRODUCTION

Healthcare industry is growing and developing rapidly, not only in health services, but also in information technologies (IT) related to it. Particularly electronic health, E-Health, is the main IT related area to meet the immediate needs of this industry. E-Health is in the intersection of medical informatics, public health, and business; it can be defined as the use of information and communication technologies to improve healthcare [1]. From primary care institutions to big healthcare centers, every healthcare organization uses an information system, named as Healthcare Information System (HCIS). HCIS is the system composed of data, workflows, users, and technology; used to collect, store, process, and provide the needed information to support healthcare institutions and professionals [2]. HCISs are composed of several components such as hardware, software, data, database, workflows, business-driven intelligent approaches; to support healthcare institutions and professionals, in terms of collecting, storing, processing, and disseminating the required work-based information. Moreover, these systems are in the interest of many actors such as engineers, technicians, physicians, nurses, laboratory staff, administrative staff, managers, governmental and private social security/profession institutions, and patients. Hence, these systems include many different levels of actors; they should be open systems to help these actors interact with each other. The purpose of a HCIS is; to contribute to a high quality, efficient health care, for patients, consumers, and medical research [3]. HCISs are more complex when compared to other systems, because they incorporate into many sub-systems such as Radiology Information system (RIS), Laboratory Information System (LIS), Picture Archiving and Communication Systems (PACS), Hospital Information System (HIS). Thus, they should be supported by established intelligent mechanisms to manage this level of complexity.

With the growth in the industry, the need for qualified computer support of healthcare organizations grows proportionally. Almost all the hospitals have a HIS; all laboratories have a stand-alone or a HIS built-in LIS. Ironically, although health institutions invest huge amounts in Information Systems (IS), it is estimated that nearly 60-70% of IT implementation projects fail in healthcare [4]. IS projects in other fields share similar aftermath with the healthcare as well. They have bad reputation for exceeding budget and schedule, failure in realizing the expectations and having poor return of investment [5]. Literature tells, of 260.000 projects, 25% were cancelled before finish, 47% exceeded the budget [5]. These findings substantiate that, a huge amount of money is lost together with invaluable efforts and time. Loss of confidence to the systems is the worst of all.

Literature shows “Improving IT Quality” as one of the top five concerns that face IT staff [6]. To improve, first we should know the weak sides of our IS. Taking the current picture will reveal the points to improve, by measuring the level of success and failure. “You can’t manage it, if you

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can't measure it" tells the importance of measuring the quality of your system [7].

To improve IS, in our context it is HCIS, it must/should be evaluated from the time being started to be developed, to the time taken out of operation, i.e. in the system's life cycle, iteratively [8-10]. These iterative evaluations help eliminate the reasons of bad reputations of HCISs given above, by means of early recognition of the problems. They also help eliminate the implementation problems by means of on-time interventions [11].

Briefly, evaluation can be defined, by drawing from the literature, as "measuring the extent of meeting the specified criteria of a system, in a specified context" [12]. Evaluations can be made both by government and public sector organizations; fortunately, the number of evaluations is rapidly increasing [13].

Implementation of a new HCIS is not an easy process. There exist many problems and challenges [14]. Some of these problems and challenges may be technical (low speed system, frequent outages, etc.), and some of them may be organizational or user dependent (poor implementation planning, resistance to change etc.). With a rigorous early deployment evaluation, these problems and challenges can be determined early and improved before the problem deteriorates.

The structure of the manuscript is organized as follows: In section 2, "Materials and Methods", Materials used in the study and the methods used to get the study results will be described, in section 3, "Results", the results of the study will be presented without any comment, and these results will be further discussed in the section 4, "Discussion". The findings of the study and the proposed future work will be in the section 5, "Conclusion and Future Work" part.

A. Motivation

In a Hospital of 1700 HIS users, Biochemistry department outsourced its LIS and quit using the built-in LIS of the HIS. This new system takes the orders of hospital from biochemistry and needed information from the HIS, then disseminates these orders to the related auto analyzers. After the auto analyzers are through with the tests, it gives some facilities to the Biochemistry doctors (Such as delta checks). Finally, if the responsible doctor approves the test result, LIS sends the results to the HIS.

In the old system, the orders were seen in the work lists of the staff in built-in HIS module. An (only one) operator will make the "specimen received" action in the HIS and then the patient will attend a queue for giving specimen. Five nurses get the specimen simultaneously. All the auto analyzers were communicating with the HIS independently. The facilities provided with were limited.

In this study, evaluation of a newly implemented HCIS, namely LIS, is performed. The purpose of the study is to evaluate the LIS on the basis of Function sufficiency, Decreasing work load, Speed, Learning ease, Improving service quality, Availability, Help Manuals, User Satisfaction, Patient Satisfaction features; and get the early deployment evaluation results to determine the weak sides of the system to improve.

II. MATERIALS AND METHODS

A. Questionnaires

Data are collected using the face-to-face questionnaire method. Two different questionnaires are prepared and applied to capture the evaluation results; one for the patients and one for the laboratory staff. Both staff and patients are asked to express their answers using 3-point Likert scale (Disagree, Partially Agree, Agree) ranging from 1 (Disagree) to 3 (Agree). 3 point Likert scale is used instead of 5 point scale, to prevent patients from hesitating between middle answers such as Moderately Agree, Moderately Disagree. In staff questionnaire, also 3 point Likert scale is used to keep the consistency with the patient questionnaire. Patient data are only used for evaluation for Patient Satisfaction whereas staff data are used for all features under evaluation.

B. Data

The questionnaires are applied to the patients visiting the laboratory in randomly selected days. 138 patients and 42 staff (all employees) have participated in the study voluntarily. Staff has biochemistry physicians, nurses, administrative staff, assistants, pharmacists, and biologists.

C. Statistical Analysis:

The internal consistencies of the answers to the questionnaires are measured by reliability coefficient (ρ) given in (1) to (5). Reliability is the degree of measurement being consistent and reproducible [15]. One important goal of a measurement study is to quantify the reliability of a measurement process. A reliability coefficient value of 0.7 or above is usually adequate, although higher reliability is always desirable. Measurements with reliabilities of 0.5 or less are rarely adequate for anything but preliminary research. In this study, ρ greater than 0.70, is considered reliable.

$$SS_{total} = \sum_{ij} X_{ij} - \frac{(\sum_{ij} X_{ij})^2}{n_i n_j} \quad (1)$$

$$SS_{objects} = \frac{\sum_{i=1}^{n_i} (\sum_{j=1}^{n_j} X_{ij})^2}{n_j} - \frac{(\sum_{ij} X_{ij})^2}{n_i n_j} \quad (2)$$

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$$SS_{observations} = \frac{\sum_{j=1}^{n_i}(\sum_{i=1}^{n_j} X_{ij})^2}{n_i} - \frac{(\sum_{ij} X)^2_{ij}}{n_i n_j} \quad (3)$$

$$SS_{error} = SS_{total} - SS_{objects} - SS_{observations} \quad (4)$$

(Reliability)

$$\rho = 1 - \left[\frac{SS_{error}/(n_i - 1)(n_j - 1)}{SS_{objects}/(n_i - 1)} \right] \quad (5)$$

Where

i is the number of users (or patients),
j is the number of questions,
X is the weight of the answer,
SS_{total} = Total sums of squares,
$SS_{objects}$ = Sums of squares for objects,
$SS_{objservations}$ = Sums of squares for answers,
SS_{error} = Sums of squares for error.

Answers to the questions are analyzed by nonparametric Kruskal Wallis test to determine if there is any difference between the branches of staff. $p < 0.05$ level is considered as statistically significant. Nonparametric test is used since data do not come from a normal distribution, regarding the normality test applied to the data.

D. Features Under Evaluation

Function sufficiency, Decreasing Work Load, Speed, Learning Ease, Improving Service Quality, Availability, Help Manuals, User Satisfaction, and Patient Satisfaction features of the LIS were evaluated.

TABLE I. RELIABILITIES

Staff	n	ρ
Physicians	8	0.81
Nurses	8	0.76
Operators	6	0.90
Laboratory assistants	9	0.79
Pharmacists	3	0.68
Biologists	8	0.96
Total	42	0.89

a. n = the number of staff
b. ρ = reliability

The final rating RF of the feature *j* is computed by

$$RF_j = \sum_{i=1}^{k} W_i R_i / n \quad (6)$$

where *k* is the number of Likert scales employed (3 for this study) , W is the weight (1 to 3) of the Likert scale *i*, R is the number of answers given as that Likert scale and n is the total number of answers.

RF can have values ranging from 1 to 3, where 1 is the worst and 3 is the best value. If RF of the feature is below the threshold value, the feature is considered as weak and needs to be improved.

III. RESULTS

A. Staff Data

As stated before, 42 staff have participated in the study. Although the study was on volunteered basis, whole staff participated.

In Table I, the reliability values which are calculated by (1) to (5) are given. Operators have the highest reliability with a value of 0.90, whereas Pharmacists have the lowest reliability with a value of 0.68. All the staff has satisfactory reliability values higher than 0.70, if we accept Pharmacist as 0.70 which is very near. Overall reliability is 0.89.

In Table II, RF values calculated by (6) are given. For RF values, Learning Ease is the first with a value of 2.86, whereas Availability is the last with a value of 2.36. Overall RF appeared to be 2.62.

To see the statistical significant difference among the branches of staff, statistical comparison is employed using Kruskal Wallis test. Only the difference in nurses appeared to be statistically significant in some features, and one in physicians and laboratory assistants. The descriptives about the statistically significant p values of the features under study of nurses are given in Table III. For the features Function Sufficiency, Decreasing Work Load, Availability and Help Manuals, nurses do not agree with the other groups.

In addition to nurses, physicians and laboratory assistants do not agree with other groups in Function Sufficiency as well ($p < 0.011$).

TABLE II. RF VALUES OF THE FEATURES UNDER STUDY

Feature	RF value
Function sufficiency	2.61
Decreasing Work Load	2.46
Speed	2.65
Learning Ease	2.86
Improving Service Quality	2.85
Availability	2.36
Help Manuals	2.46
User Satisfaction	2.82
Patient Satisfaction	2.59
Overall	**2.62**

a. RF = Final Rating

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TABLE III. DESCRIPTIVES OF STAFF COMPARISON

Feature	p
Function sufficiency	0.011
Decreasing Work Load	0.009
Availability	0.019
Help Manuals	0.020

B. *Patient Data*

Reliability of the patients' questionnaire is 0.87. 38.40% of the patients stated that they applied for giving specimen for analysis and the rest were in the laboratory for taking results.

Majority of the patients (84.78%) stated that they had applied to the biochemistry department before, when the old system was in use.

The most important observation is the decrease in the duration of the processes. Patients who had applied before expressed that they have waited shorter than their previous application for transaction (86.96%).

The majority of the patients expressed that they were able to take the service more easily with fewer processes (94.20%).

IV. DISCUSSION

In this study, evaluation of a newly deployed HCIS, LIS, is performed using face-to-face questionnaires. Both the patients and the staff showed great interest in the study by a high rate of participation. The high participation shows that, stakeholders of the system (patients and staff in this study) consider the evaluations as an opportunity to express their feelings and problems faced, to whom in charge of developing and running the systems. The best way to send the message "your ideas are taken into account for improving the system" can be given by means of evaluations. That may certainly help increase user acceptance and attention to the information system. It won't be false if we disclose that the more user-centric the evaluation, the higher the participation is.

If we start from patients' results, having 84.78% patients that took service in both systems gives us a healthy comparison chance. Of them, 94.20% state they get the same services in fewer steps. That means; the new system has shortened the workflow and eliminated some outmoded steps. This is good for a new system; actually one of the most expected virtue of the ISs is to make renovations in the business. The majority of the patients experiencing both systems states that the service time is shorter (86.96%), which fortifies the renovation of the new system. Drawing from the findings of patients data, we can say that the new LIS satisfied the patients.

The results of reliability measures given in Table I substantiate that the study has a high reliability. It shows the internal consistency of the answers, which leads us to the true and unbiased results.

TABLE IV. WEAK FEATURES ACCORDING TO THRESHOLD VALUES

Feature	RF	t = 2.40	t = 2.50	t= 2.75
Function sufficiency	2.61			✓
Decreasing Work Load	2.46		✓	✓
Speed	2.65			✓
Learning Ease	2.86			
Improving Service Quality	2.85			
Availability	2.36	✓	✓	✓
Help Manuals	2.46			✓
User Satisfaction	2.82			
Patient Satisfaction	2.59			✓

RF = Final Rating
t = threshold
✓ = Improvement needed

Almost all the RF values are near or above 2.5. That is also good from the staff point of view. User Satisfaction, Improving Service Quality and Learning Ease have the highest values. Having a high value in Improving Service Quality feature is compatible with the patients' results. With these findings, it can be definitely said that, there is an increase in service quality with this system change. As in patients, the system appeared to have satisfied the staff as well. It seems, it is an easy to learn system.

Speed, Availability and Help manuals are the least ranked features, when compared to the others. In this study, for the new system, we can say that, these features are the main improvement needed areas, although they are not so bad.

The areas of improvement can be determined by a context and management dependent threshold value. We do not propose a threshold in this study. This threshold is relative to the context and situation. For a newly adopted system it can be 2.30 or something, while 2.70 or higher for a high standard-like management. In Table IV, the change in improvement needed areas is given according to the three different thresholds. It is one when the threshold is 2.4, it becomes three when the threshold is increased to 2.5 and becomes six out of nine when the threshold is 2.75.

According to the statistical analysis, there are problems in nurses, physicians and laboratory assistants. Different from other groups, they don't think the functions of the LIS are sufficient. When we think that these groups are the core staff of the laboratory, this finding should be seriously taken into consideration.

Evaluations give some extra messages as well. If the findings are lower than expected, there can be a lack of communication or training in the target users. They may not know some important features or they may not know how to use the system efficiently. Because of these reasons, the results may be lower than expected. The best solution would be eradicating the reasons and then reevaluate the system to see the difference before and after.

Unrealistic expectations are another point of bias in evaluations. In other words, the evaluation results become lower if the expectations of the users are unrealistically high. Some methodologies should be employed to keep the expectations in a realistic level. In this respect, Nevo and Chan find in their study that managers are able to generate

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realistic expectations [16]. As the Ryker et al. put forth, if these groups' expectations from HCIS can be found unrealistic (very relative issue, so the management must be very careful to make this decision), the management can organize some committees and arrange interviews with these users to set realistic expectations [17].

As we have stated above, if there is a problem with the communication (if a variable is expected to give higher values but the result is low) then IS staff should organize on-site trainings and improve the communication channels with users.

V. CONCLUSION AND FUTURE WORK

Many international institutes, both governmental and nongovernmental, regulate many standards about the HCIS; they employ classification and nomenclature systems, security and privacy measures, and many other great effort products and mechanisms. Despite these huge great efforts, they fail. Consecutively some questions arise: How can HCISs be measured, to determine if they are good enough? Do we evaluate them properly? Do they really meet the needs of the owner institutes? Do we really need them? The answers to these questions are mostly overlooked, and eventually HCISs fail.

Evaluations should be done iteratively, both to get user acceptance, and improve the system. Users should be in the center, because, it is the users that makes a system better, it is the users that makes a wonderful system useless. It is the managements' ability that makes the users use the system properly. Evaluating the system in a user centric manner is an option to accomplish.

For a future work, this study can be deepened in staff group basis, to customize the system. A user group (like nurses in our study), can be unhappy with the system, while others are happy. To eradicate the problems of this group, a deeper study is required.

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Use of Cloud Computing with Wireless Sensor Networks in an Internet of Things Environment for a Smart Hospital Network

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***Abstract*—In a hospital healthcare monitoring system, it is necessary to constantly monitor object movements. Wireless Sensor Networks (WSNs) represent a significant technology for collecting important and varied information from users and their environment. In addition, the use of emerging wireless sensor technology has become a significant element in providing next-generation healthcare services in real-time. The emerging technologies ZigBee and Radio Frequency Identification (RFID) are used to collect the data in real-time. Smart objects are universally becoming Internet Protocol (IP)-enabled, e.g., in personal health devices and home automation, industrial automation, smart metering and environmental monitoring systems. The recommendation of IoT6 to exploit the potential of IPv6 connection standards will help overcome the current disadvantages and fragmentation of the Internet of Things. In particular, these features provide interoperability with Cloud Computing, mobility, and supply of information between heterogeneous smart object components, services and applications. The paper indicates that using RFID and ZigBee sensors can provide real-time tracking of objects (patients, staff and equipment) and monitor their movement throughout the hospital.**

Keywords-Smart Patient tracking and monitoring; IoT; IoT6; IPv6 ;ZigBee; RFID; Cloud Computing.

I.INTRODUCTION

In recent years, information technology helped us changing our way of life and work through new methods of communication; this has contributing to Gross National Product (GNP) growth with reduced risk and improved users and customer satisfaction. The increase in competition between companies that provide and produce smart sensor technologies, which cover large areas to meet rapid changes and users' needs, has contributed to competitive advantage in location based services. The number and types of sensors used are contributing to numerous different applications, such as location based services, building environmental control and supply chain management, etc. Studies show that wireless sensor network industry is expected to increase up to 43% every year [1] and a predicted market share £2.3 billion by 2017 [2]. A smart sensor-based Cloud Computing system is composed of several sensors based on top of the physical wireless sensors and data collection layer, which have the ability to receive and transmit data automatically and wirelessly by users based on application demand [2]. The integration of Internet of Things (IoT), sensor technology and Cloud Computing is aimed at overcoming resource constraints as it enables different networks to cover large geographical areas so that they can be connected and used by several users at the same time when required [2]. In addition, the recent emergence of Cloud Computing and sensor awareness of infrastructure-architecture methods, service-oriented architecture, software delivery and development models [3] are also contributing factors to a smart environment. In order to provide real-time healthcare informatics, hospitals need some type of monitoring system to track objects and medical equipment in which security, efficiency and safety are ensured, with reduced occupational risks. The key feature of the smart monitoring system is to provide identification of users and objects, so that an adequate service customisation can be obtained. Accordingly, in this paper, a framework of integrating Cloud Computing technology and wireless sensor technology within the healthcare environment is proposed. The purpose of this framework is to apply the ever-expanding sensor data to our community-centric sensing applications that can be used as a real-time service in the Cloud. Several techniques can provide this framework with the ability to receive and transmit data automatically and wirelessly to multiple users. Since the entire network is dynamic, it can be used for exchanging information, smart identification, locating objects, and monitoring and tracking objects.

The paper is structured as follows: Section II describes the state of the art. Section III describes Cloud Computing. Section IV presents the wireless sensor networks. Section V describes the Internet of Things. Section VI deals with the use of Cloud Computing and IoT on healthcare. Section VII describes the proposed framework. Finally, Section VIII concludes the paper.

II.STATE OF THE ART

Currently, there is no automatic healthcare tracking and monitoring system for patients and asset tracking in Saudi Arabia, and many hospitals still rely on manual operation to collect the 'object' data. The healthcare systems in Saudi Arabia are not operating in

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real-time and this result in the hospital staff having difficulties in obtaining up to date information. For example, a relative cannot receive any help in real-time from the staff regarding patients status after an operation. Using emerging technologies such as RFID and ZigBee sensors which automatically scan and use non-contact and non-intervention for tracking objects. Users will be able to receive real-time information and visualization of objects such patients, staff and equipment location throughout the hospital which will improve the management information systems and provide more effective decision support systems [4] [5][6].

III.CLOUD COMPUTING

Cloud Computing technology was designed by the National Institute of Standards and Technology (NIST) [7] to increase the capacity of shared computing resources in a rapid and secure way in various locations around the world. Cloud Computing is useful because it adds new capabilities to the existing system without the need to invest in new infrastructure, train new personnel, or license new software; it needs only minimal management input or service provider interaction. Cloud Computing [7] is the technology of sharing resources and data collection with users through the Internet, and it can also offer self-service network access [8]. The services which Cloud Computing provides to users are based on resources through virtual servers which the user can access regardless of their location or any detailed specifications [9]. The radical stage of Cloud Computing is the shift from mainframe computers to client/server deployment models, and it covers elements from grid computing, utility computing and autonomic computing [3]. Research shows that the Cloud Computing industry is currently worth £41 billion globally, and this is expected to grow by £10 billion per year, demonstrating a significance to the global economy which cannot be underestimated [10].

A. Cloud Computing Service

Cloud Computing technology services are used to support a variety of technical functions. The services provided by the Cloud are divided into three service models [7], Software as a Service (SaaS), Infrastructure as a Service (IaaS) and Platform as a Service (PaaS).

- *Infrastructure as a Service (IaaS):* This service uses the Cloud for management and continuous infrastructure usage. Users are able to access elements of the computing infrastructure through Internet technologies, and can use the processing power, storage mediums and required network components provided by the service provider, for instance IaaS Amazon, S3 and EC2 [11].
- *Platform as a service (PaaS):* This service allows users to create their own development environment or platform to run applications as a service on the Cloud, for instance PaaS Microsoft's Azure Platform, Google's Apps Engine and the Force.com [11].
- *Software as a service (SaaS):* This service is a model where an application is hosted on the Cloud, and the applications are provided by the service provider as a service through the Internet. Rather than buying the software and installing their own systems, users rent the software through a pay-per-use arrangement. Examples include SaaS, Salesforce and Google Docs [11].

In addition, there are different deployment models for providing Cloud services to enterprises, which include public, private and hybrid [7] [11].

B. Cloud Computing Benefits for Healthcare Applications

The use of Cloud Computing offers various possible benefits to users such as a reduction in waste of both information system resources and power, an increase in data centre efficiency and operation rates, and lower operating costs [12]. Healthcare applications based on Cloud Computing take advantage of the Cloud Computing environment which provides the following benefits to patients and care providers [13][14]:

- *Patient Privacy & Security:* The expertise afforded by the Cloud service provider offers enhanced security (Privet Cloud) to prevent leakage of sensitive healthcare data and processes.
- *Dynamic Sensor Data Rates:* The scalability of Cloud architecture allows for non-deterministic varied data flow collection.
- *Global Access and availability:* Cloud deployment models provide the system with globalised access.
- *Disaster Recovery, Reliability, and Redundancy:* Redundant Cloud architecture allows reliability of data security and processes.
- *Economical System Usage:* The Cloud's service model provides economical resource provisioning and usage.
- *Outsourcing Expertise:* A remotely managed Cloud service allows expertise of the system to be outsourced.
- *Scalability:* Resources for dynamic data flows are guaranteed, any time anywhere on real-time via the Cloud's elasticity.

The most important benefits of Cloud Computing are the large reduction in costs and time compared with conventional methods, for example, where large companies use server farms to keep user information secure become unnecessary as the Cloud offers the economy of scale and would also be the responsibility for the service provider. Cloud Computing systems can provide the accessibility to run a program on

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many connected computers, enabling a user to access an organisation's data from anywhere, at any time, through various devices such as computers or mobile phones. Cloud Computing is responsible for ensuring the continuity of service which is important to the management within organisations. The main disadvantage of Cloud Computing is the possible loss of information due to connection failure or power outages during its use, making it crucial for users to have their own backup servers to secure their data.

IV.WIRELESS SENSOR NETWORKS

Wireless sensor networks are used as novel and smart solutions for information collection via the radio spectrum of different applications, such as transportation, business, healthcare, industrial automation, and environmental monitoring [15]. Collecting patient physiological indicators using multi-channel high-frequency wireless data transmission can enhance a hospital's modern information management system to create a real-time health monitoring system. Wireless sensor networks have a big advantage in term of deployment as sensor devices are small and low-cost and can be used anywhere [16]. In order to build a Knowledge Management System (KMS) for smart hospitals the emerging technologies ZigBee, Radio Frequency Identification (RFID) must be used to collect the data in real-time for use later in Decision Support Systems (DSS) applications. RFID is an automatic identification technology offering a solution to the identification of things by assigning a tag with a unique number, which is used to retrieve object information from the application database [17]. RFID technology can be used in a healthcare environment, which can enable the automating and streamlining of safe and correct information such as patient identification, tracking, and processing important medical equipment [18]. Components of a typical RFID system are one or more readers, antennas and tags, which can be active, semi-active or passive. RFID tags are assigned with a unique identification number (UIN), and, to ensure security, RFID tags can be programmed and protected by password [18]. The frequency bands used for RFID systems are: low frequency (LF) 125–134 KHz, high frequency (HF) 13.56 MHz, ultra-high frequency (UHF) 868–928 MHz, and finally microwave frequency 2.4 GHz [19].

The ZigBee protocol is based on the IEEE 802.15.4 standard and works on the 868/915MHz and 2.4GHz unlicensed bands [20]. ZigBee is a communication standard that can be used as automatic identification to provide short-range, low-cost and low-power consumption wireless solutions in several applications [20]. ZigBee is designed to allow up to 65,500 nodes to be connected in a star, tree or mesh topology network [20] and examples of ZigBee applications include home automation, personal healthcare, sensor networks, monitoring systems, remote control etc [21]. ZigBee technology is an ad-hoc network such that it provides the network with the ability to obtain infinite expendability [22]. Wireless Sensor Networks (WSN) [23] are used to collect the information needed by smart hospital systems. In addition, sensing devices make it possible to retrieve information about objects and their position, taking into account the environment of the sensor, when offering personalized on-line services.

V.INTERNET OF THINGS

Internet of Things (IoT) is a relatively new concept in connecting smart objects together. Smart technology is opening new development opportunities for service providers. Internet of Things was first introduced by Kevin Ashton in 1999 and can be used to identify, locate, track and monitor objects automatically in real-time. IoT is exponentially increasing to an ecosystem connecting billions of smart things [24], offering smart electric meter reading, telemedicine monitoring, greenhouse monitoring, and intelligent transportation using computer technology [25]. IoT enables physical devices to be connected to Smart networks. This concept of IoT along with the use of ubiquitous computing in different environments could improve people’s lifestyle and have specific applications in the field of healthcare.

Currently, Internet Protocol version 4 (IPv4) is reaching a very large number of global IP addresses [24]. Today, Internet users worldwide number approximately 2.4 billion, and this is projected to reach 3 billion by 2015. However, the number of objects connected over the internet has overtaken that of human users considerably, and is predicted to surpass the human population by 20 to 50 billion connected smart objects [24]. The Internet Protocol IPv4 was not designed to connect smart objects using Internet of Things (IoT), partly because of the limitation of 4 billion addresses. IPv6 has been accepted by the Internet Assigned Numbers Authority (IANA) and the Regional Internet Registries (RIRs), in order to go beyond the IPv4 limitations and address the growing demand to provide more address space to enable global reachability and scalability.

IoT6 [26] is a 3-year EU research project that is based on the Internet of Things. Its main recommendation for the future of the Internet of Things was to exploit the features of IPv6, in particular its interoperability with Cloud Computing, mobility, and intelligence supply among heterogeneous smart object components, services and applications [27]. Consequently, in this research project, an end-user perspective with the targeted realization of a green and smart IPv6 building will be integrated based on the Mandat International [26]. Both the Internet of Things and IPv6 may be needed to enable low-power wireless devices [28]. However, the use of IPv6 has the potential to improve the IoT’s progress because of the possible billions of new

 ISBN: 978-1-61208-384-1

sensor devices that will require a unique IP address [29] in order to monitor the largest number of medical devices and the like over the Internet for service users. Smart objects, such as personal health devices and home automation, industrial automation, smart metering and environmental monitoring systems are universally becoming IP enabled [30]. In the network layer protocols for the sensor device, IPv6 will be installed to handle the framework of the IPv6 address that will be required to develop a Smart Hospital Management Information System (SHMIS) [31].

VI.CLOUD COMPUTING AND IOT EFFECTS ON HEALTHCARE

The integration of Cloud Computing with IoT is gaining popularity on ICT prototypes and has come to the attention of researchers over the past few years. Based on the type of resources that were delivered via the cloud, Cloud Computing is used to provide Software as a Service (SaaS) by connecting objects via the internet [32]. Knowing that Cloud Computing manages to store different data apart from its coverage area, the IoT in turn manages to provide systematic orders to be performed for any devices connectable to the internet. Hence, the capacity can be increased and rapidly enhanced by Cloud Computing and IoT without applying further infrastructure investments. Using Cloud Computing and IoT in healthcare impacts on both cost and time when undeveloped countries are provided with Cloud Computing facilities that can provide real-time services.

VII.PROPOSED FRAMEWORK

One of the most important and interesting applications in the smart environment is the Real-Time Locating System (RTLS). The increasing competition between healthcare providers needs to take into account the quality of performance, time management and complexity of the human. This system can be used as a safety mechanism, storing all recordable acts on a smart monitoring system, and thus allowing healthcare providers to track their staff and patients [23]. The proposed framework can be used as a novel and smart solutions for information collection via the spectrum of different applications, such as transportation, business, healthcare, industrial automation, and environmental monitoring [15]. The system is used to identify each object, locate its position automatically and provide users with the required services, without the need for human intervention [4]. A proposed design has been suggested for use in the field of healthcare management systems to track and provide automatic identification and real-time monitoring [25].

In this proposed system, the object is identified and cross-referenced to the RFID and ZigBee tags, thus the process can be recorded and tracked through a management information system. A healthcare service must be available in real-time, which is currently limited; therefore, the future of the Internet can include providing healthcare services through the local network or over the Internet. The proposed monitoring system has the capability to electronically store all patient records including documents, videos, and images enabling users to access patient data and use this information to provide a patient-focused service; for example, patient data could be exchanged between devices via Cloud Computing in real-time.

A. System Architecture

Figure 1 shows the proposed smart hospital network system architecture: a system for the purpose of detecting, locating and monitoring the object. This divided it into the following six layer system structure: a Data Processing layer, a Data Integration layer, a Cloud Computing layer, a Network structure, a Knowledge Reasoning layer and a Visualization layer. The first layer is the Data Processing using sensor-based technology and is responsible for collecting real-time data from different sources. The data will be captured from physical-world devices which have the ability to receive and transmit data wirelessly and would for example include data from location and movement of tagged ‘objects’ and digital imagery etc. The second layer is the Data Integration responsible for the organization, translation, rationalization, copying and storage of raw data from the Data Collection Layer into appropriate database for example data and/or digital imagery. The third layer is Cloud Computing. This layer is used to increase the capacity of shared resources provided by data collection in a rapid and secure way through the Internet for example collection and sharing patient data with hospital staff both at the hospital and high level data such as providing bed occupancy to the Ministry of Health in Saudi Arabia, and it can also be used to ‘mirror’ the database for backup purposes. The fourth layer is the Network Structure: this layer is used to provide the functional and procedural means of transferring multiple length data structures from different sources on one or multiple networks to a destination hub. The Network Structure layer contains several technologies which provide the functionality of a structured data exchange using a computer network. These technologies can work independently or be integrated with each other, and include Cloud Computing, ZigBee, Wireless Local Area Network (WLAN), Cellular Mobile Network and PANs (Personal Area Networks). Cloud Computing can be used to provide remote access, and WLANs or mobile phone networks can also be used to connect data-collection devices to the data hub. The fifth layer is Knowledge Reasoning: this layer is responsible for processing the huge amount of data and information using knowledge to achieve the objectives of the organization for example, the data could be mined to determine how long a nurse or doctor on duty was within 0.6m of a patient in a ward 24/7. The last layer is Visualization, and this layer provides the visual

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representation and organization of data once it has been translated to make it accessible to the user community [4] so relatives of patents undergoing surgery could ascertain if the operation was completed to schedule or bed occupancy levels 24/7.

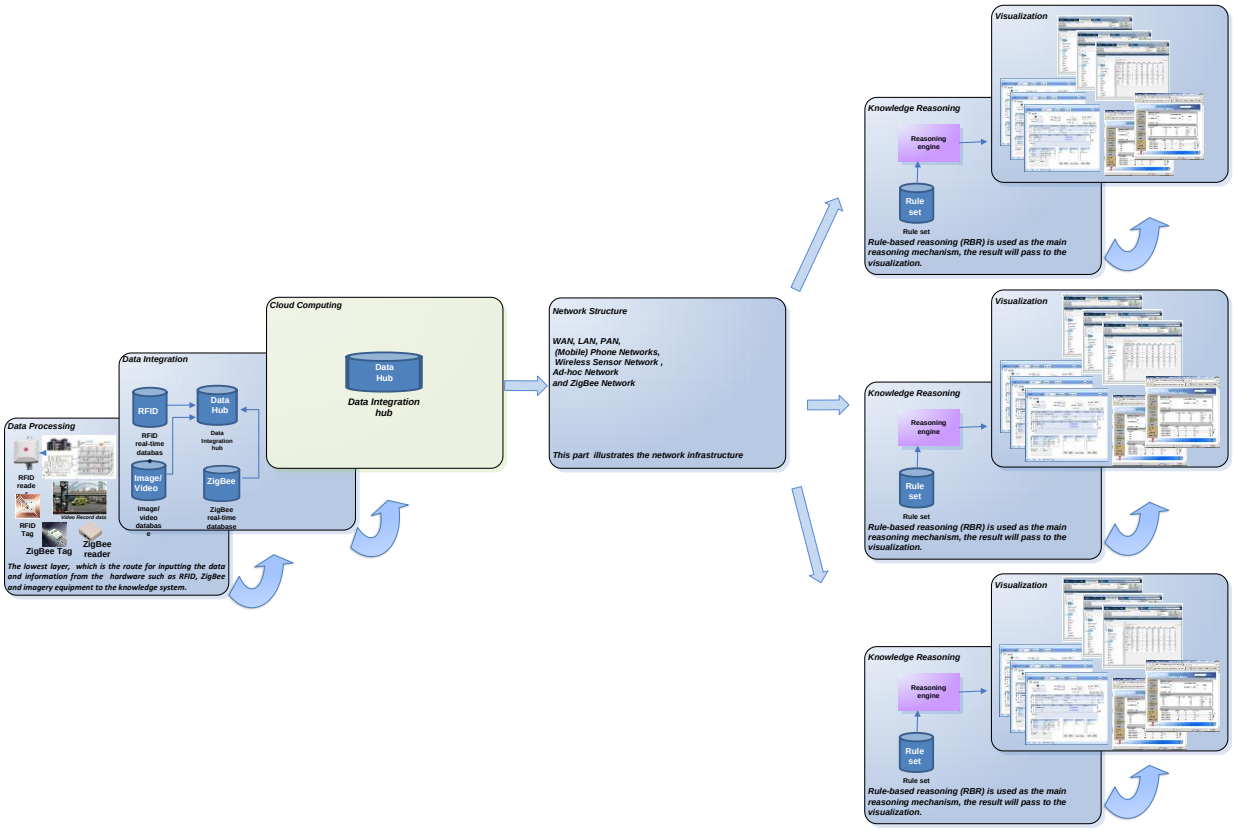

Figure 1: Six-Layers of Emerging Technologies for a Real-time Healthcare Management System

B. *Implementation*

The implementation of RFID system uses Alien Technology Company hardware [34] that includes the RFID equipment consisting of tags, readers, and antenna. RFID was used to provide specific location information through deployed 'gates' or 'check points'. RFID readers are similar to the application of optical bar codes. RFID tags contain information that can be used to identify the objects that carry them but requires no line of sight, automatic, non-intervention, low cost (<1p) no maintenance (tags) and can operate up to 11 meters. The RFID reader reads the tag and checks the database for location and movement with time. ZigBee is used to provide the real-time position of the object, with an average accuracy of less than 2 meters. The implementation of ZigBee system will be using Nebusens hardware [35] that includes the ZigBee equipment consisting of 4 tags, 20 readers, and 2 coordinators. This infrastructure was used to simulate the floor area of a maternity ward and deployed in the research centre of the university with an area of 280 m2. The ZigBee measurement equipment consists of the Coordinator (n-Core Sirius A) which, incorporates several communication ports such as GPIO, ADC, I2C and UART through USB to connect to different devices, the ZigBee Readers (n-Core Sirius D) which, are used as readers and the ZigBee (Core Sirius B) devices, which are used as tags [35]. SkyDrive was used as Cloud storage for framework files and is accessible everywhere. The movement of the object position was recorded through the smart system that generates and checks this object when the targeted object accesses the coverage area of RFID, ZigBee and RFID/ZigBee. The paper discusses the implementation of two important aspects of a Smart Hospital Management Information System: firstly, object identification and location position in real-time, and secondly, the use of low-power output devices using a combination of ZigBee technologies.

C. *Evaluation/Discussion*

The proposed system outlined in Section VII supports real-time functionally using real-time sensors which automatically scan and use non-contact and non-intervention Ultra High Frequency (UHF) RFID and ZigBee technologies. Laboratory experiments using UHF passive tags can provide up to 11 meters read range at the 'check points' ZigBee sensors can operate up to than 100 meters communications range from the antennas and provides real-time position of the objects, with an average accuracy of less than 2 meters. The operating communication range allows

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the system to check every object (patients, staff and equipment's) position in the system and monitor their movement in real time throughout the hospital.

D. The benefits of the proposed system

The demand for healthcare services is increasing in the UK, Europe and the Middle East North Africa (MENA) region with staff providing medical care 24 hours a day, 7 days a week, and the growing difficulties to respond to management information demands and financial constraints placed on healthcare services. For this reason, a smart system can help by linking smart devices to the network and monitoring medical staff 24 hours a day, collating information, storing, combining, and aggregating data. The proposed system can be used for security purposes and as smart solutions for information collection via the Internet including different application such as transportation, business, healthcare, industrial automation, and environmental monitoring. In healthcare cases, it can be used to provide better and smart patient care at a low cost, and can allow patients to access information about their personal treatment and support their ability to interact with medical staff [36]. In addition, the proposed system can be used to assist and support the increasing number of elderly people (>60) in many countries some may have dementia, and the possibility of them getting lost in the hospital environment. The number of elderly people globally is around 600 million, and will reach 2 billion by 2050 [37]. The traditional method of checking patients' conditions in hospitals by doctors using diagnostic non-movable medical equipment has a number of disadvantages, particularly in that it is inconvenient for patients and inflexible for the elderly or those with special needs [38]. The proposed system can be used to support medical staff in different ways, e.g., input-output devices and sensors which, provide improved patient care in different environments and with less human error, such as body sensors, patient activity monitoring and tracking at hospital and also, for elderly care patients, in a home environment [36]. A RFID/ZigBee tag (embedded in a wristband) can be issued to every patient on their arrival at the hospital, to enable the hospital monitoring system to identify and track patients during the period of their stay in hospital. The RFID/ZigBee tags can be used to store important information such as patient name, ID, drug allergies and blood group, etc., and also alert staff before a serious situation arises [18]. In some cases, this system can be helpful with patients who need more and/or regular health checks or who are unable to come to visit doctors or require medical support at home. Healthcare providers should consider smart health technologies because their use means that some medical monitoring, such as movement, weight and blood pressure, can be performed without a patient attending hospital. Using the IoT environment is a flexible way of connecting modern measuring devices and it can create smart networks at home at anytime and anywhere.

VIII.CONCLUSION

The aim of this paper was to evaluate the integration of Cloud Computing, wireless sensor technology and Internet of Things in a healthcare environment. The use of wireless sensor technology is emerging as a significant element of next-generation healthcare services in real-time. In this paper, we proposed a smart monitoring system, using RFID and ZigBee technology which is able to continuously detect, locate and monitor the movement of an object in a hospital. The system consists of a coordinator node to acquire the object information, on the data collection layer. ...

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Impact of Source Parameters and Link Capacity on WBSN Based on Polling Access Scheme

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***Abstract*—The analysis of the impact of the number of sensor nodes, the transmission rate, buffer size, source types and the authorization packet in a Wireless Body Sensor Network (WBSN) based on polling technique is carried out in this paper. A simulation platform is developed in Matlab, contemplating different models of sensor nodes with limited buffer and the polling mechanism to control the transmission to the centralized node. The used performance parameters are the packet loss and the packet waiting time in the queue. The obtained results show that the transmission rate has the greatest influence in the network. Additionally, the ideal configuration obtained uses fourteen sensor nodes with three buffer positions and mixed sources.**

Keywords—WBSN; parameters; polling; waiting time, packet loss.

I. INTRODUCTION

The Wireless Body Sensor Network (WBSN), currently in developing, is a special network for medical application which needs very low energy consumption, very low packet loss and an insignificant packet delay. To achieve such characteristics in a network, the Medium Access Control (MAC) is the most important. There are many MAC proposals based on IEEE 802.15.4 standard with beacon - enabled star configuration for WBSN [1]. However, since this standard is not designed for WBSN applications, some drawbacks were presented in [2] which led to new MAC proposals [2] - [16]. Some of these are variations of the standard [3] - [5]. Others are based on Time Division Multiple Access (TDMA) technique [3] [6] - [11]. All of them exploit some specific medical needs. For example, in [6] [12] MAC protocols that deal with light and heavy loads considering normal and emergency situations are proposed. A MAC based on random access technique is proposed in [13] to ensure the Quality of Service (QoS) of a WBSN. The heart beating is used for clock synchronization in the proposal described in [8]. In [14], to increase the network lifetime, the battery is charged using the beacon that wakes up the sensor nodes. In the 802.15.6, which is the standard for the wireless body area network [17], one of operation mode, the non-beacon mode without superframe boundaries, can be based on polling access technique. A MAC based on hierarchical polling scheme for WBSN is proposed in [18]. The first level of proposed hierarchical MAC consists of sensors nodes divided into groups, and the communication among sensor nodes of a group and a sink node (an external device) is carried out by using the polling technique. In the second level of hierarchy, the sink nodes communicate with a master node that collects data by using also the polling technique. The performance of the proposed scheme is studied by analytical modeling, and studies show its efficiency in WBSN application.

In [19], the MAC scheme based on flexible polling guaranteeing QoS for WBSN is proposed. The proposed MAC has two modes of operation: normal and urgent. In the normal mode each sensor is polled once in each cycle and in the urgent operation a priority of sensors is defined and the higher priorities sensors are served first. The performance analysis was carried out using mathematical models and the results for normal mode showed that the exhaustive service is better than the single buffer in terms of waiting time and the transfer times. For the urgent mode the analysis showed that for light input load the scheme works very well, but for heavier load the system operates in unstable conditions.

A MAC scheme based on polling denoted Fast Polling is proposed in [20]. A simple modification is proposed by adding the authorization packet into ACKnowledgement (ACK) packet. The analysis carried out using OMNeT ++ simulator showed that the throughput improved and the latency was reduced.

The Human Energy Harvesting Medium Access Control Protocol (HEH-BMAC) is proposed in [21] as MAC suitable for WBSN for capturing human energy. The HEH-BMAC is based on two MACs: i) namely polling (polling-ID) and ii) Probabilistic Contention (PC). The idea is to adapt its operation to the different energy and state (active/inactive) variations that the sensor nodes may capture.

The MAC based on polling for WBSN is analyzed in [22] using different scenarios, verifying the packet loss and waiting time in the buffer of a sensor node. The study is carried out through a simulation platform developed in C++ Builder, containing different types of sources. Three scenarios were composed by seven sensors placed in different parts of the body, forming a star topology, with sink node in the network core. The first scenario used a configuration with constant source in all nodes, while in the second scenario three constant sources are mixed with other types of sources. In the last scenario, five sources are mixed in different parts of body. The results showed that three positions buffer is sufficient for WBSN applications using seven sensors.

The impact of source parameters and link capacity on WBSN using polling access technique is investigated in this paper. More specifically, a numerical study using Matlab is carried out to understand the relationship between the polling access scheme and i) the number of sensors on the human

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body, ii) sensors' parameters (such as traffic types and buffer size), and iii) the radio link capacity between the sensors and the sink. This study is conducted measuring the packet waiting time and loss in the sensor node buffer.

The paper is organized in five sections. In Section 2, the concepts underlying the functioning of WBSN and the choices made for the simulation are presented. The models and parameters of the sources for the study are described in Section 3. In Section 4, the analysis of results is presented. Finally, in Section 5, the conclusions are evidenced.

II. WBSN AND POLLING ACCESS SCHEME

WBSN consists of many sensor nodes with limited capacity attached at different locations of a human body, and are continuously monitoring the vital signs of a patient for diagnosis and prescription. WBSN provides real-time updates of patient medical records via Internet, being an economical solution to health systems [23].

A WBSN is illustrated in Figure 1.

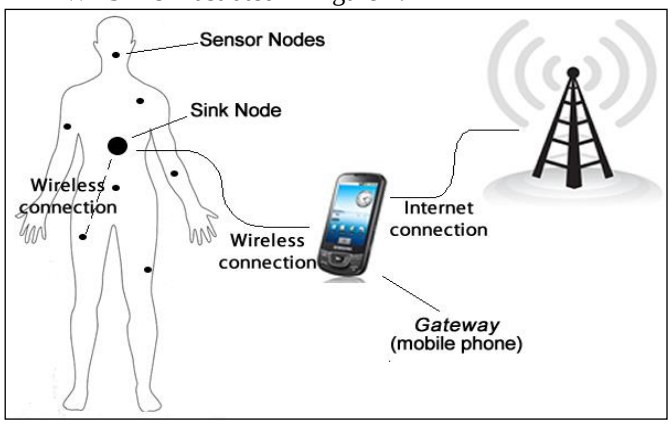

Figure 1. Environment of the WBSN studied.

As shown in Figure 1, several sensor nodes are arranged in the human body to monitor various activities. The sensor nodes collect information and send to the sink node, which has greater storage capacity and processing. In its turn, the sink node works as interface among sensors and external networks.

Since the sensor nodes transmit their information to the sink node, and according to [24] the structure of the network is a star, the sink node is inserted in the middle of the sensor nodes as in [21].

In the polling used in this paper, the sink node establishes the cycle of service to the sensor nodes. Based on this cycle, the sink node interrogates individually the sensor node to see if there are packets to transmit. If there are, the sensor node receives permission to start transmission while others wait their turn. Thus, while a sensor node transmits packets, the others are performing their monitoring activities, waiting their turn to transmit and may store the generated packets in the buffer. After data transmission, the sensor node can activate the sleeping mode, saving energy.

The limited polling is a kind of polling that constrains packet transmission, either in time or in number of packets, so when the limit is reached, the current sensor node stops to transmit and the permission passes to the next sensor node, independent the state of the buffer of the current sensor node. The limited polling is adopted in this paper because can save energy.

III. MODEL AND PARAMETERS OF SOURCE AND LINK CAPACITY

The need for an accurate traffic model to evaluate the performance of the whole system is very important [25]. Since there are no practical traffic traces yet, some assumptions are made. In the practical environment that will be considered the sensors are divided into two types: continuous and event oriented modes. The continuous mode of operation is the case where data are generated continuously as the sensors measuring the heart beating, body temperature or blood pressure constantly. This kind of traffic is called Constant Bit Rate (CBR) source. In the event oriented mode the event occurs occasionally. This kind of traffic could be the measurement of body temperature outside of a range, that is, a sensor sends information only in abnormal situation. In the event oriented mode, the sources can be modeled with intervals On (with packet transmission) and Off (no packet transmission). It is important to mention that the On/Off exponential traffic model for each source is simple to implement and, moreover, the aggregate of these sources represents with good approximation the self-similar traffic. For this reason the model On/Off exponential is adopted in this paper.

The five On/Off exponential sources developed in [22] are used in this paper. A summary of developed sources is shown in Table I.

TABLE I. FEATURES OF THE DEVELOPED SOURCES

Constant On/Off Source	Send all packets generated.
Threshold On/Off Source	Send only packets carrying information above a threshold.
Controlled Threshold On/Off Source	Send only packets containing information above a threshold or next packet when discarded packets reached a predefined number.
Out-range On/Off Source	Send only packets carrying information that are outside a certain range.
Controlled Out-range On/Off Source	Send packets satisfying Out-range On/Off Source criterion or next packet when discarded packets reached a predefined number.

The parameters used for setting sources are shown in Table II.

TABLE II. PARAMETERS FOR TRAFFIC GENERATION

Packet size	904 bits
Peak rate	39322 bits/sec
On Interval	22.989 msec
Off Interval	206.901 msec

The packet size used in Table II is the average of the packet sizes presented in eight papers as mentioned in [22].

The packet peak rate corresponds to the Mica2Dot which is used in most of the literature. The On time corresponds to the packet size divided by the peak rate. The Off time is obtained considering the sensor nodes are 90% of time in the Off state [26][27].

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The transmission rates adopted among the sensor nodes and sink node in the simulation are 19.2 Kbits/sec used in Mica2Dot [28], 38.4 Kbits/sec also used in Mica2Dot and 250 Kbits/sec used in MicaZ [28] [29] which is mentioned in most of the literature.

The numbers of sensor nodes adopted in the simulation for this work are seven (7), fourteen (14), twenty-one (21) and twenty-eight (28).

The buffer sizes in the sensor nodes are restricted in one (1), three (3), five (5) and one thousand (1000) positions, the latter being equivalent to infinite buffer. In the First In, First Out (FIFO) buffer at the sink node is adopted ten positions for packet storing.

To calculate the confidence interval, each simulation was performed three times and an average of the results obtained is presented. 10.000 packets are generated in each sensor, and the transient period is discarded. Thus, the initial 2000 packets are discarded for statistical purposes. Moreover, the sources that use the control parameter, in a group of ten packets not transmitted, a packet indicating that the sensor is active is sent.

To assure that the results are reliable, the results were compared to those obtained in [22]. In [22], three scenarios are analyzed with the same sources and parameters, using seven sensors in the system, and the simulator was developed in C++ Builder.

In [22], the analyzed scenarios are based on five sources listed in Table I, configured with the same parameters showed in Table II of this work. However, it was not considered the walk and propagation times, which is taken into account in the present work. The three scenarios were consisted of: a) only constant sources; b) three constant sources and other four sources using different kind of sources listed in Table 1; c) mixed sources. The analysis was made based on the output link of 250 kbits/sec, and one, three, five and thousand buffer positions. The performance parameters were the packet loss and the average waiting time in the queues of the sensor nodes.

The results of the simulations in the scenarios of paper [22] are consistent with those obtained in this new program because, it was found that the polling performs certain admission control, and with the FIFO scheduler the queue time is zero and there are not packet losses. For the polling, a summary of some of the results obtained in [22] are shown in Table III.

TABLE III. RESULTS OBTAINED IN PAPER [22]

	Scenario I		Scenario II		Scenario III	
Buffer Size	Buffer 1	Buffer 3	Buffer 1	Buffer 3	Buffer 1	Buffer 3
Average Queue Time (msec)	165,18	221,68	96,63	111,6	223,82	281,62
Packet Loss	1699	72	623	6	1761	45

As shown in Table III, the smaller the buffer size is,the higher the number of dropped packets is, but the queue time is less. In this sense, depending on the application being performed is important to consider the ideal buffer size.

The packet losses are small if compared to the amount of packets on the system, corresponding to 70000 packets. It is noteworthy that most sources do not transmit all packets, which is achieved only by the constant source. In this respect, if the loss occurs in one of the sources that transmitted only relevant data, although being an approximate percentage of 7%, this value can be prohibitive.

Analyzing scenarios regarding the packet loss and the queue time, the ideal is the Scenario II.

IV. ANALYSIS OF RESULTS

The first result to observe is that the polling access scheme performs a kind of admission control in relation to the sink node buffer and regardless of transmission rate, buffer size and number of sensors, there is no packet loss and the queue time is zero.

Figure 2 shows the packet discarding in the sensor nodes by using polling access scheme. In the figure, the discarding is plotted as a function of buffer size, link capacity and number of sensors.

From Figure 2 it can be seen that using transmission rate of MicaZ, that is, 250 Kbits/sec, there are no dropped packets, regardless of the buffer size or the number of sensors.

It is also noted that with the rate of 38.4 Kbits/sec, corresponding to the Mica2Dot the discarding with seven sensors is small, or 97 packets lost with one buffer position and none if the buffer is increased. Increasing the number of sensor nodes to fourteen, the discarding is 2503, 48, 2, 0 for the buffer sizes 1, 3, 5 and 1000, respectively. There is no longer impact with twenty-one sensor nodes in the system, because with three and five positions in the buffer the difference in the loss is the nine packets, which is negligible. With twenty-eight sensors in the system the same occur, where the discarding is less with one thousand buffer positions which resulted in 48460 discarded packets.

The packet loss increases considerably if the capacity is reduced by half to 19.2 Kbits/sec. For seven sensors and one position buffer the lost is 1909 packets, whereas the loss for twice of the capacity is only 97. For fourteen sensors in the system the discarding is approximately 19000 for one, three and five positions buffer and the 10000 packets for thousand positions. For twenty-one sensors and twenty eight sensors in the system the discarding has similar behavior but higher than last case analyzed as is shown in Figure 2.

It can be concluded that the transmission rate and number of sensor nodes are the most impacting factors regarding to the packet loss in a WBSN based on polling access scheme. The analysis shows that the capacity of 250 Kbits/sec has better performance, but there are no studies yet showing the influence of this rate in the human body in the literature searched. Thus, it seems that the capacity of 38.4 Kbits/sec is most appropriate for a WBSN in study.

In relation to the number of sensors, the human body could be divided into seven regions and two sensors could be placed in each region, totaling fourteen sensors, giving a system without considerable loss. At last, the buffer with three positions could be chosen because there is no much difference in packet loss between three and five positions when the number of sensors exceeds twenty.

Table IV shows the results of the queue waiting time in function of the buffer size, the number of sensors and the channel capacity.

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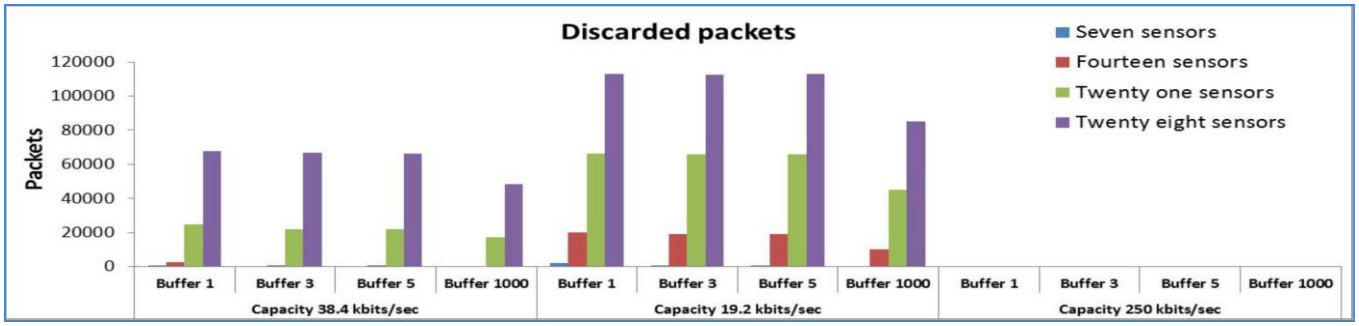

Figure 4. Discarded packets using the polling

The channel capacity is the parameter that most affect the queue waiting time as can be observed in Table IV. The use of transmission rate of 250 Kbit/sec becomes the waiting time almost insensitive to the variations of number of sensor nodes or buffer sizes, keeping very low from 1.55 to 7.93 msec. For the transmission rate of 38.4 Kbit/sec, up to fourteen sensor nodes the waiting time is low from 7.10 to 39.77 msec for any size buffer. However, for number of nodes of 21 and 28, the waiting time increases drastically for 1000 size buffer, meaning that load is too high for the system. For the transmission rate of 19.2 Kbit/sec, the waiting time is reasonable only for 7 sensor nodes; for other cases the waiting times are prohibitive.

TABLE IV. ANALYSIS OF QUEUE WAITING TIME (IN MSEC)

Transmission Rate	Buffer	Seven Sensors	Fourteen Sensors	Twenty one Sensors	Twenty eight Sensors
38.4 Kbits/sec	1	7.10	28.47	116.20	261.84
	3	7.28	39.10	564.59	1232.02
	5	7.25	39.86	1003.44	2311.25
	1000	7.42	39.77	105980.61	357482.20
19.2 Kbits/sec	1	36.51	203.70	535.00	860.10
	3	101.50	1050.40	2309.50	3360.60
	5	61.15	2046.70	4213.20	5932.80
	1000	60.13	262351.10	664652.20	923507.70
250 Kbits/sec	1	1.55	3.29	5.42	7.93
	3	1.56	3.29	5.40	7.91
	5	1.56	3.31	5.41	7.93
	1000	1.56	3.30	5.41	7.93

Keeping the tradeoff between queue waiting time and the transmission rate, it seems that the number of fourteen sensor nodes and the transmission rate of 38.4 Kbits/sec are good choices for WBSN based on polling access scheme.

The third parameter analyzed is the number of authorization packets as shown in Figure 3.

As can be noticed in Figure 3, higher the transmission rate is greater is the amount of authorization packets. This occurs because the data packets are quickly transmitted and not always that the sensor authorized to transmit has the data packets in the queue at that time. In addition, none packet is dropped.

If the network is operating with low load, in stable condition, there is no significant variation in the amount of authorization packet when buffer sizes are considered. For example, considering the transmission rate of 250 Kbits/sec, seven sensors in the system and one position of the buffer, the amount of authorizations is the 5392633. Whereas considering thousand positions in the buffer the amount is 5481470. With fourteen sensors in the system this difference is 2683 packets, which indicates that fourteen sensor nodes are best for the WBSN based on polling access scheme.

Another factor analyzed is the source models. Considering the transmission rate of 250 Kbits/sec and any kind of source there is no packet loss. For other rates, the loss is greater in constant source, because it sends all packets generated. For example, the loss considering transmission rate of 38.4 Kbits/sec is shown in Table V.

TABLE V. ANALYSIS OF DISCARDS PER SOURCES

	Buffer 1			Buffer 3		
Packet Loss	**Seven Sensors**	**Fourteen Sensors**	**Twenty one Sensors**	**Seven Sensors**	**Fourteen Sensors**	**Twenty one Sensors**
Constant	43	1114	14310	0	43	18014
Threshold	8	180	1530	0	1	382
Controlled Threshold	10	355	2508	0	0	596
Out-range	13	288	2463	0	1	1070
Controlled Out-range	24	567	4116	0	3	1854

As can be seen in Table IV, the packet loss in the constant source is higher than any other type of sources, especially when there are more sensors in the system.

Since there are twice more sources with the control parameter, the packet loss in these sources is divided by two, and the influence of these sources is few. This division is necessary to compare equally the amount of packets generated by all sources. The packet loss in the oriented event sources is small until fourteen sensors and similar. However, it can be representative, since only packets indicating changes in measurements are send.

In Table V, it can also be seen that fourteen sensors and the three positions buffer in the system is better if the system is in stable operation. However, with twenty-one sensors the system is already operating in overload condition, so that the discards are greatly increased, and the same occurs when using the rate of 19.2 kbits/sec. This fact can be seen in Figure 2, while in Table IV it is evident that the constant source has higher losses.

Analyzing the influence of source types in queue time, it can be noticed that for transmission rate of 250 Kbits/sec, the

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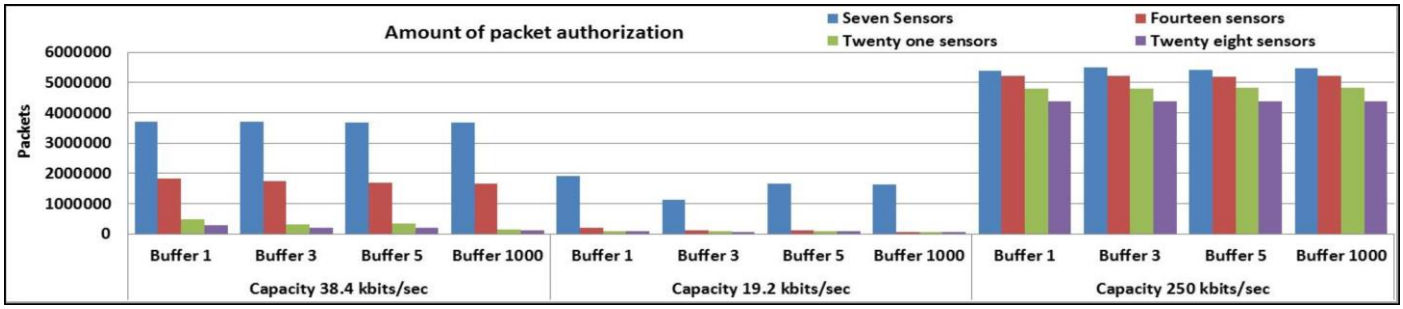

Figure 5. Analysis of the amount of authorization packets.

impact is low independent of the buffer sizes, since all have the same time, which is 1.55 sec with seven sensors, 3.3 sec with fourteen sensors, 5.5 sec with twenty-one sensors and with twenty eight sensors is 8 sec.

For other transmission rates, the behavior of the queue times is similar to the packet discarding. For example, with the rate of 38.4 Kbits/sec, seven sensors, independent of the buffer size and type of the source, the queue time is 7.33 sec. For fourteen sensors in the system the average queue time does not have many differences between sources, which are 36.5 sec. However, from fourteen sensors and the rate of 19.2 Kbits/sec, where the system is already operating in overload condition, the variations are considerable, and the constant source has the longest waiting time. The influence of other source types is low because they don't transmit all data generated and the degradation occurs in the following order: Controlled Out-range, Out-range, Controlled Threshold, Threshold.

V. CONCLUSIONS

The impact of source parameters and radio link capacity on a WBSN based on polling access scheme was analyzed in this paper. The influence of different source types and link capacities on packet waiting time and packet loss at sensor node buffers was examined. A simulation platform was developed in Matlab to carry out the study. The used parameters were the number of sensor nodes, the transmission rate, number of positions in the buffer, amount of authorization packet and the source type.

The first result is that the polling access scheme performs a kind of admission control in relation to the sink node because at output buffer of sink node does not occur packets loss and the queue waiting time is zero regardless of the scenario considered.

When the system is in stable operation, the amount of packets discarded is little or nonexistent, as occurs using the transmission rates of 250 Kbits/sec and 38.4 Kbits/sec with seven and fourteen sensor nodes. However, if the system is operating in overload condition, a significant packet loss is observed. The analysis of results shows that the use of three position buffer and fourteen sensors for a WBSN based on polling access scheme are recommended when the packet waiting time and packet loss are considered. These results can be used to establish practical environment when using polling access scheme, ie, do not used transmission rates under of 38.4 Kbits/sec, more than fourteen sensor nodes and the five position buffer with this scheduler.

It was observed that the constant source generates more packets discarded, and packet waiting time is longer. This is because all packets are transmitted. However, in other types of source that send only controlled information, the packet loss, although smaller, can be more critical because there is no redundancy in the transmitted data. Therefore, the use of mixed sources is more recommended.

In future work, the impact of polling cycle of the sensor nodes on packet waiting time and loss will be analyzed in function of source types, as well as changing the size of the authorization packet. The problems of interference of many people who wear a WBSN based on polling scheme and gathered in a small area such as a coach will be also investigated.

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Enhanced Performance Analysis of a Hierarchical Polling-based MAC Access Scheme for WBAN

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***Abstract*—An enhanced performance analysis of a hierarchically structured access scheme for a Wireless Body Area Network (WBAN) is carried out in this paper. The access scheme uses the polling technique in each hierarchy level. Sensor nodes from first level are provided with infinite size buffers and both first and second levels use exhaustive polling technique. The study is done through computer simulation and mathematical models. Initially, the results of computer simulation are compared to the mathematical modeling. In spite of some approach used in mathematical modeling, the both results are very close. Next, to overcome the sensibility of second level to the input load of first level the performance analysis is carried out using different transmission rates for first and second levels.**

Keywords-hierarchical polling; computer simulation; wireless body sensor network.

I. INTRODUCTION

In Wireless Body Area Network (WBAN), sensors are placed in various parts of the body and measure vital signs, such as temperature, blood pressure, heartbeat, etc., and transmit these data to an external device. The sensors can be placed on the skin or be implanted under the skin, and communication with the external device is always wireless, which ensures greater mobility and comfort to patients with WBAN. When a sensor is equipped with processing and data transmission capabilities will be denoted sensor node and the external device as sink node in this paper.

In the deployment of sensors in the body, certain requirements must be considered, as the short distance transmission, low power consumption and very small dimension of a sensor. These features provide a low level of radiation, longevity in use the sensor without battery replacement and providing comfort for users [1].

When multiple sensor nodes begin to transmit packets simultaneously, collisions occur and packets must be retransmitted, wasting energy. Thus, the MAC must be designed to avoid collision and operate efficiently to reduce energy consumption. One of the MAC access schemes presented in the literature uses the polling technique for data collection of sensors [2]. In the presented work, the sensors are divided into groups and each group has a sink node that collects data from sensors using the polling technique. To collect the data from sink nodes, there is another node called master that collects the data, also using the polling technique. This structure was denoted hierarchical MAC access based on polling technique [2] and the performance of this scheme has been studied theoretically using mathematical models.

In the theoretical models presented in [2], some approaches were used for the analysis of second level of hierarchy and the accuracy of models must be verified. The purpose of this article is twofold. Firstly, the analysis of the proposed structure in [2] is carried out through computer simulation to validate the theoretical model. Secondly, to overcome the sensibility of second level to the input load of first level is proposed different transmission rates for first and second levels and its performance analysis is carried out.

The paper is organized in six sections. In Section II related work is described. The concepts related to MAC access scheme based on hierarchical topology are presented in Section III. The developed computational simulator and the analysis of the results are discussed in Section IV. In Section V the performance analysis using different transmission rates for first and second levels is carried out. Finally, the main conclusions are presented in Section VI.

II. RELATED WORK

To fulfill the MAC protocol requirements for WBAN such as low power consumption, quality of services and security many proposals have been presented in the literature. The main standard for WBAN the IEEE 802.15.6 proposes general guidelines and it is not concerned with a specific type of access. Thus, many MAC scheme proposals can be implemented. Some proposals are compatible with IEEE 802.15.4 as presented in [6] denoted BAN MAC protocol which is a low power, designed for star topology. Upon receiving the data from the sensors, this MAC protocol dynamically adjusts the protocol parameters to improve energy conservation in sensors with low energy level.

Many proposals are based on Time Division Multiple Access (TDMA) access technique [4][5][8][9]. Each of the proposals explores some special features based on medical needs. For instance, in [4] to deal with the light and heavy loads in normal and urgent situations, a context aware MAC is proposed. To guarantee Quality of Service (QoS) of a WBAN, a MAC protocol based on random access technique is proposed in [9]. In the proposal presented in [8], the heart beating is used for the purpose of clock synchronization. In [5], the beacon used for wake-up sensor nodes is used for battery charging, increasing the network life time.

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Some proposals are based on polling access technique [2][7][10][11]. In [7] the MAC scheme based on flexible polling, guaranteeing QoS for WBAN is proposed. In the proposed MAC scheme the urgent traffic has high priority and is served before the normal traffic. The performance of MAC scheme based on polling in [10] is studied under different types of On-Off sources. The hierarchical polling based MAC scheme and its performance study are presented in [2][11]. The study is carried out using mathematical modeling and some approaches are used. Since the performance study of this paper is also to analyze the scheme by computer simulation and without approaches the hierarchical scheme will be detailed in next section.

III. HIERARCHICAL POLLING

The concept of hierarchical topology for WBAN was first presented in [3]. The idea was to minimize the fading of signals due to constant movement of the patient using WBAN. The sensor nodes have short ranges, typically less than 1 meter, and the transmission power is very low so that the fading of signals can be constant. In the work presented in [3], the sensors were divided into groups and each group is attended by an intermediate node using technique based on TDMA. The intermediate nodes are served by other hub node that also uses the TDMA technique.

In the work presented in [2], it was also used the concept of hierarchical topology, however, the technique of data collection is based on polling. In this proposal, sensor nodes of the first level are also divided into groups and the sink nodes collect the data from each group using the polling technique and in the second level, the master node collects all the data from sink nodes using also the polling technique. The hierarchical polling concept applied in a human body is illustrated in Figure 1.

The sensors, such as electroencephalography (EEG), electrocardiography (ECG), temperature (TPR), etc., are placed on the upper part of the body and are polled by the sink 2 which is attached to the arm, as shown in Figure 1. The sensors like motion (MTN), electromyography (EMG), glucose (GLC), etc., placed on the lower part of the body are polled by the sink 1 attached in a belt. The master node that polls the sink nodes can be a cellular phone or a device placed near the body. This device has connection to the internet so that the sensor data can be processed in a hospital or showed to a physician for diagnosis.

The communication protocol used to exchange information between the sensors and the sink node in a group works briefly as follows, noting that all communication is done wirelessly. The sink node transmits a broadcast packet containing the number of sensor node (a number that uniquely identifies the sensor node), that is, an authorization for a sensor node to transmit the data. This authorization packet contains in its header enough bits for the synchronization in the sensor node. After recognition of its number, if a sensor node has packets to transmit, begins the transmission. After transmission, the sensor node waits for confirmation packet in case of the need for retransmission. If the sensor node has no packets to transmit, the transceiver remains switched off to save power. The sink node recognizes that a sensor node is off waiting a small time interval after transmission of the authorization packet. If data do not arrive from the investigated sensor node, the sink node concludes that the sensor node has no data to transmit and begins to investigate the next sensor node in the sequence.

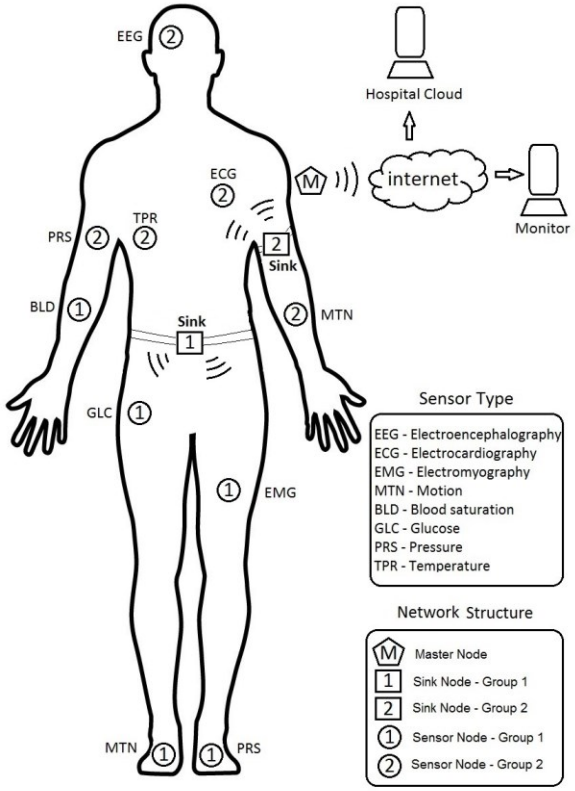

Figure 1. Hierarchical polling concept applied in a human body.

In this communication scheme, virtually all communication functions are in sink node and only the transmission function is assigned to the sensor node, in order to save its energy.

This same communication protocol described above can be used in the second level when the master node investigates sink nodes to obtain the data. Probably for a WBAN, only two levels are sufficient.

IV. PERFORMANCE ANALYSIS

For the performance analysis the hierarchical polling scheme can be modeled as shown in Figure 2.

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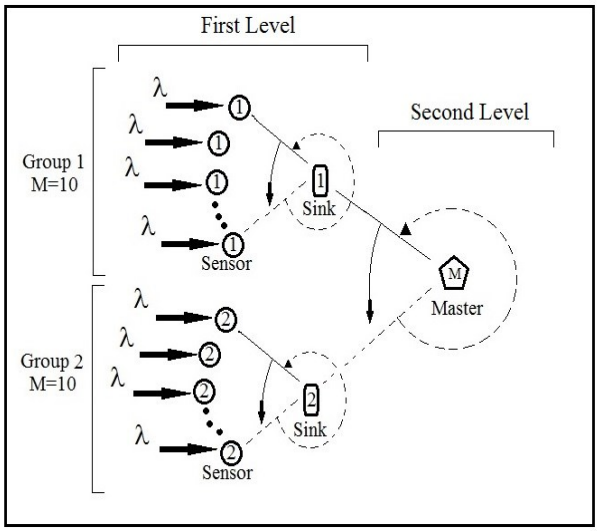

Figure 2. Hierarchical polling model for performance analysis.

As can be seen in Figure 2, the first level of the hierarchy is constituted of a number of sensors divided into groups, and each group is polled by a sink. The arrows represent the packets generated by each sensor with rate λ packets/s. In the second level the sink nodes are polled by the master node.

Based on the network model presented in Figure 2, a simulation program in Java language was developed for performance analysis of hierarchical polling scheme.

The input parameters of the simulation program are mean packet size of E{X} = 900 bits, the link capacity of R_1 = 20 kbps, packet transmission time of 900 / 20k = 45 ms (milliseconds), authorization packet transmission time of 4.5 ms and the packet synchronization time of 2 ms. These parameters are used to perform comparison with the theoretical model presented in [11].

A packet generated at each sensor follows a negative exponential distribution of mean 1/λ. To ensure that the statistics are collected under a statistical equilibrium, the first 10,000 packets are discarded at each sensor node.

The input load, S_1, is defined as

$$S_1 = \frac{M\lambda E\{X\}}{R_1} \quad (1)$$

where M is the number of sensors, λ is the average packet arrival rate, E{x} is the average packet size and R_1 is the channel capacity.

As a performance criterion, it is used the average transfer time of packets defined as the average waiting time of packets in the queue added to average packet transmission time in each sensor node. Another performance parameter is the average cycle time defined as the average time to inspect all sensor nodes in a cycle.

It was considered that the buffer for storing packets has infinite size, that is, lossless and the discipline of service is exhaustive, meaning that the buffer is completely emptied when it is inspected.

The central part of the algorithm used in the simulation is detailed in appendix A, after the references.

In a real case, the proposed body sensor network can monitor different biological signals such as temperature, pressure, among others, as shown in Figure 1. Since the sensors of a WBAN have short-range transmission capabilities due to energy saving, the communication signals among sensors and the sinks for some cases can be very impaired. Thus, two sinks placed in different positions to improve the communication capabilities are proposed in this paper, as shown in Figure 1.

The network structure of developed simulation program is based on the standard IEEE 802.15.6 in capability and function. The network structure of the simulator operates in a star topology and in accordance with the polling protocol. The polling network has a centralized node that controls the packet transmission and avoids collisions of packets as demonstrated in [14].

The developed simulator has the flexibility of adding new parameters to obtain the results, as is shown in appendix A, where a screen of simulator is presented.

Figure 3 shows simulation results and comparison with theoretical results in first level for mean transfer time. It can be observed that the results obtained in the simulation are close to the theoretical up to the load of 0.5. For load greater than 0.5, the simulation and theoretical curves are diverging, but considering that the load is high and the polling scheme is already operating in unstable condition, different results for simulation and theoretical are expected.

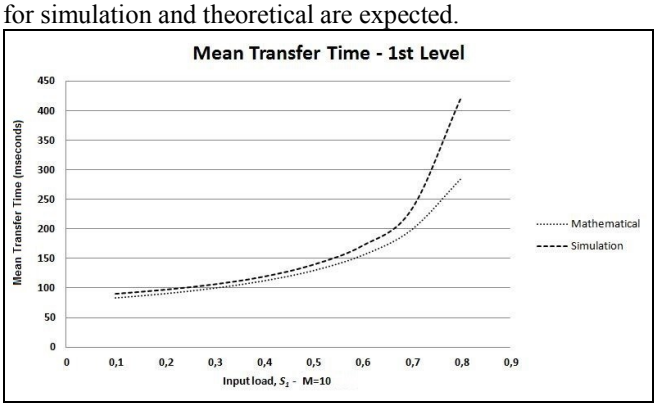

Figure 3. Packet mean transfer time of first level.

Figure 4 shows results for mean cycle time in first level. In this case, for the input load ranging from 0.1 to 0.6 the results obtained in the simulation are very close to the theory. For load greater than 0.6 the same phenomenon observed for mean transfer time occurs, that is, the curves are divergent.

For the analysis of second level it must be observed that in the exhaustive polling technique, the packets are stored in the buffer at each sensor node and wait its turn to be attended, and when a sensor node is polled, all packets are transmitted, so that the packets arrival to the sink node in burst.

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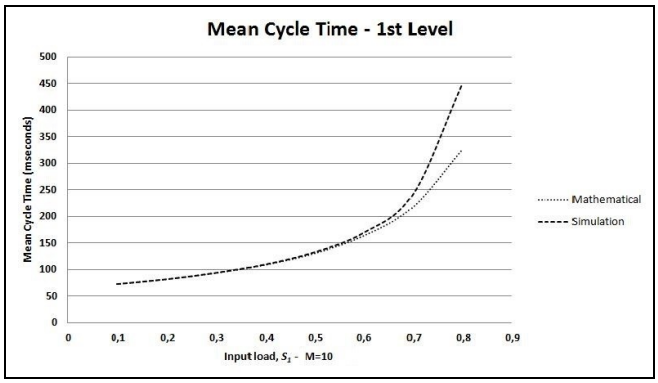

Figure 4. Mean cycle time of first level.

But, in the case of theoretical model, the negative exponential distribution of packet arrival at input of sink nodes is assumed [12]. In the case of simulation, the negative exponential distribution is assumed only at output of a sensor node. Figure 4 shows the comparison of results obtained by simulation and theoretical means for mean transfer time. It can be observed the both curves are very close, meaning that the approach used in theoretical model is very reasonable.

The curves of Figure 5 also show that the polling system, for given parameters, cannot operate with the load greater than 0.3 because the transfer times become prohibitively large, meaning that the waiting time of packets at each sensor node buffer is too large.

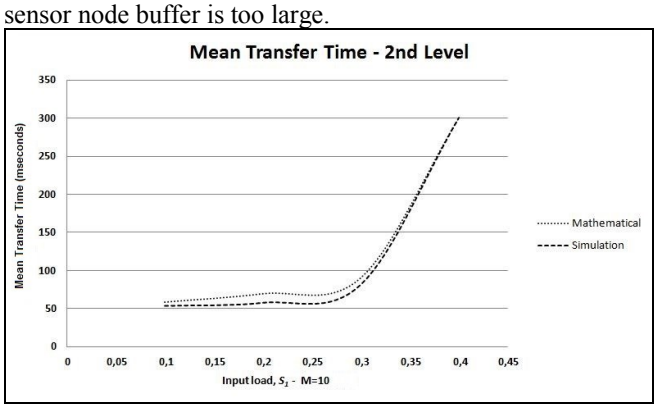

Figure 5. Packet mean transfer time of second level.

Figure 6 shows the behavior of the curves for mean cycle time. The curves show that for load up to 0.3 the mean cycle values are very close but some divergence for load above 0.3 can be observed but it is not significant.

It can also be observed that for load above 0.3, a small increment of input load, a large mean cycle time is obtained, approaching to the infinity quickly, showing the second level high sensitivity to the input load.

The general conclusion is that in order to have stable operation in the first and second levels of the hierarchical polling scheme with the given parameters, the system must operate with a load lower than 0.3.

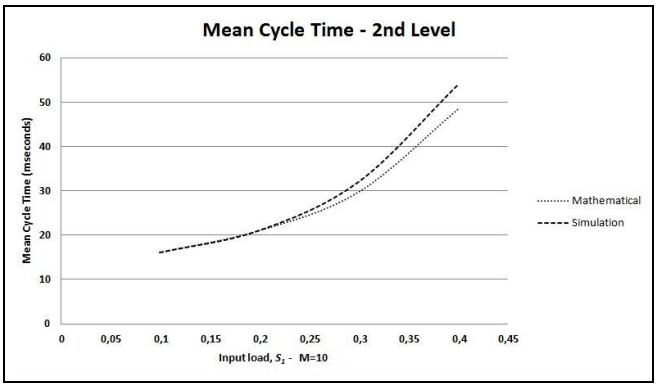

Figure 6. Mean cycle time of second level.

It can also observed that for input load above 0.4, a small increment of the load, both transfer and cycle times have exponential values as can be seen in Figures 5 and 6, meaning a high sensitivity of the second level to the input load.

V. ENHANCED CAPACITY OF SECOND LEVEL

As seen in section four the second level has high sensitivity to the load of first level. To improve the performance of second level a higher link capacity can be used in this level. The use of low link capacity in first level is convenient because the sensors are implanted under skin or placed very close to the skin, so that low frequencies devices can avoid any damage to human body. The hierarchical structure studied in this paper can use different capacities for first and second levels to improve the performance of system.

To show the performance of second level using different capacities a theoretical analysis is carried out.

Since there is no loss in first level, the performance model for second level will be as shown in Figure 7 [11].

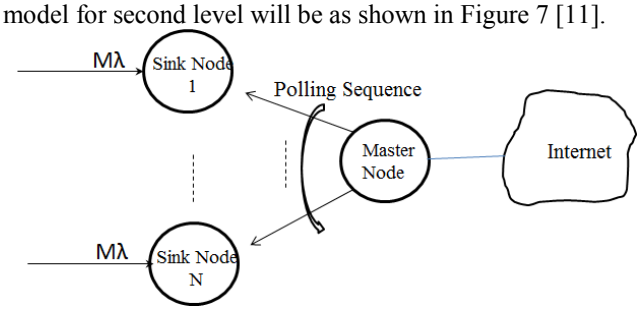

Figure 7. Second level performance model for infinite buffer case.

The mean cycle time for this case is given by

$$T_{c2} = \frac{N w_x}{(1 - S_x)}, \quad (2)$$

where N is the number of sink nodes, w_x is the walk time (packet authorization transmission time plus synchronization time) and S_x is given by

$$S_x = \frac{NM\lambda E\{X\}}{R_x} = NS_1 \frac{R_1}{R_x} \quad (3)$$

where R_1 is the transmission capacity of first level, R_x is the transmission capacity of second level and S_1 is given by (1).

The stability condition is given by

$$S_x < 1 \Rightarrow NM\lambda E\{X\} < R_x. \quad (4)$$

The queuing time in a buffer of second level is given by [11]

$$E\{W_2\} = \frac{Nw_x(1-S_x/N)}{2(1-S_x)} + \frac{S_x E\{X\}}{2R_x(1-S_x)}, \quad (5)$$

for deterministic packet length.

The packet transfer time for the second level is given by

$$E\{T_2\} = \frac{E\{X\}}{R_x} + E\{W_2\}. \quad (6)$$

Assuming the capacity of 20 kb/s for first level and for the second level the following capacities will be assumed: 40 kb/s, 100 kb/s and 250 kb/s. In the literature the most frequent capacities cited are 19.2 Kbits/sec and 38.4 Kbits/sec used in Mica2Dot [12], and 250 Kbits/sec used in MicaZ [12][13]. These capacities are always used in first level in cited references. An advantage of the hierarchical structure is that the capacities of first and second levels can be uncoupled, so that a higher link capacity can be used in second level.

TABLE I. PARAMETERS FOR SECOND LEVEL.

Capacity R_x Kbit/sec	Authorization Packet Time (ms)	Synchronization Time (ms)	Walk Time w_x (ms)
20	4.5	2	6.5
40	2.25	1	3.25
100	0.9	0.4	1.3
250	0.36	0.16	0.52

Table 1 shows the parameters used for second level. The packet authorization time in the first line of Table 1 is calculated considering that packet has 10 % of length of data packet (E{X} = 900 bits) and a transmission rate of 20 Kbit/sec, that is, 90 / 20 K = 4.5 ms. The synchronization time in first line of Table 1 is approached to 2 ms and the walk time is the addition of packet authorization time and synchronization time. The other values of packet authorization and synchronization times are calculated considering inversely proportional to the link capacities.

Using (5) and (6) and the parameters of Table 1, the mean transfer times for various link capacities of second level can be calculated as is shown in Figure 8. The figure shows that the performance limitation of second level using the same capacity of first level can be completely overcame using different capacities.

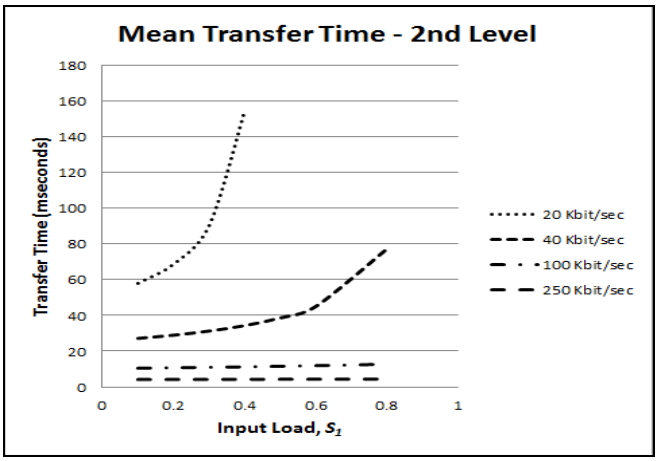

Figure 8. Performance comparison of transfer times for different transmission capacities of second level.

A Figure 8 shows using the double of first level capacity (40 Kbit/sec) the performance in relation to transfer times is much better. For the link capacity of 250 Kbit/sec the transfer time is very low and almost constant for any input load.

As shown in Figure 9 the curves of mean cycle times have the same behavior of mean transfer times. Using the double of link capacity of first level the cycle time of second level becomes stable, and for the capacity of 250 Kbit/sec the cycle time is almost constant for any input load.

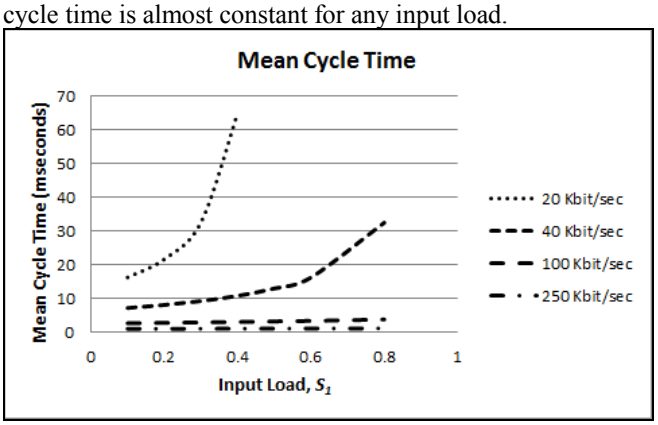

Figure 9. Performance comparison of cycle times for different transmission capacities of second level.

The results obtained in Figures 8 and 9 can be compared to the results presented in [2][11]. The performance study presented in [2][11] considered the same transmission rate of 20 Kbit/s in both first and second levels and as the result, the mean transfer and cycle times of second level were very sensitive to the input load. The second level could operate in stable condition if only less than 0.4 of input load was applied in first level. Figures 8 and 9 show that just doubling the transmission rate of second level, the input load can also be doubled to 0.8 for stable operation of second level. For higher transmission rates, the stable operation of second level is almost independent of load of first level.

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VI. CONCLUSION

A MAC scheme hierarchy structured using polling-based technique was analyzed is this paper. The results obtained for mean transfer times by simulation in first level of hierarchy were compared to the theoretical results, showing good closeness for light loads and some divergence for high loads. For high loads, the polling system is operating in unstable condition so that some divergence is expected. The same conclusion was observed for mean cycle time in the first level. The results for mean transfer times of second level of hierarchy, in spite of some approach assumed in theoretical model for this level, showed a good closeness for both simulation and theory for all range of load. Thus, concluding that theoretical model is a good model. The results for mean cycle times of second level showed that for load up to 0.3 are very close but some divergence for load above 0.3 can be observed but it is not significant. It was also observed that for load above 0.3, a small increment of input load, a large mean cycle time is obtained, showing the high sensitivity of second level to the input load.

To overcome the sensitivity of second level to the input load a study using different and higher transmission capacities in second level was carried out. The study showed that using the double capacity in second level the polling system becomes stable for almost all input load, and for the capacity of 250 Kbit/sec the transfer times, as well cycle times are almost constant for any input load.

In future work, other models of sensor nodes reflecting real situations will be incorporated to the simulation program to study real capability of hierarchical polling-based MAC scheme.

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APPENDIX A

Figure 10 shows the main parts of the developed algorithm for simulator. The first step of the algorithm is the generation of the arrival times of packets using the negative exponential distribution and store in a attribute of class named Packet. Each newly generated packet is placed in a FIFO (First In First Out) queue that represents a Sensor. Two other attributes of this class are the sink and master clock times which are obtained during the simulation. The following step is the verification of sensor queues of Group1 in a polling sequence so that the packets of each queue can be served exhaustively. Each attended packet receives a clock stamp and is moved to the Sink1 queue. When all packets are served, the packets are in a FIFO sequence in the Sink1. Then the process goes to the next Group2 and same procedure of previous step is repeated so that the packets are stored in the queue of Sink2. The next step is the verification of sink queues of second level to serve the packets in the exhaustive polling sequence. Each attended packet receives a clock stamp and is sent to the Master queue. During the polling process the mean transfer and polling cycle times and other parameters are calculated.

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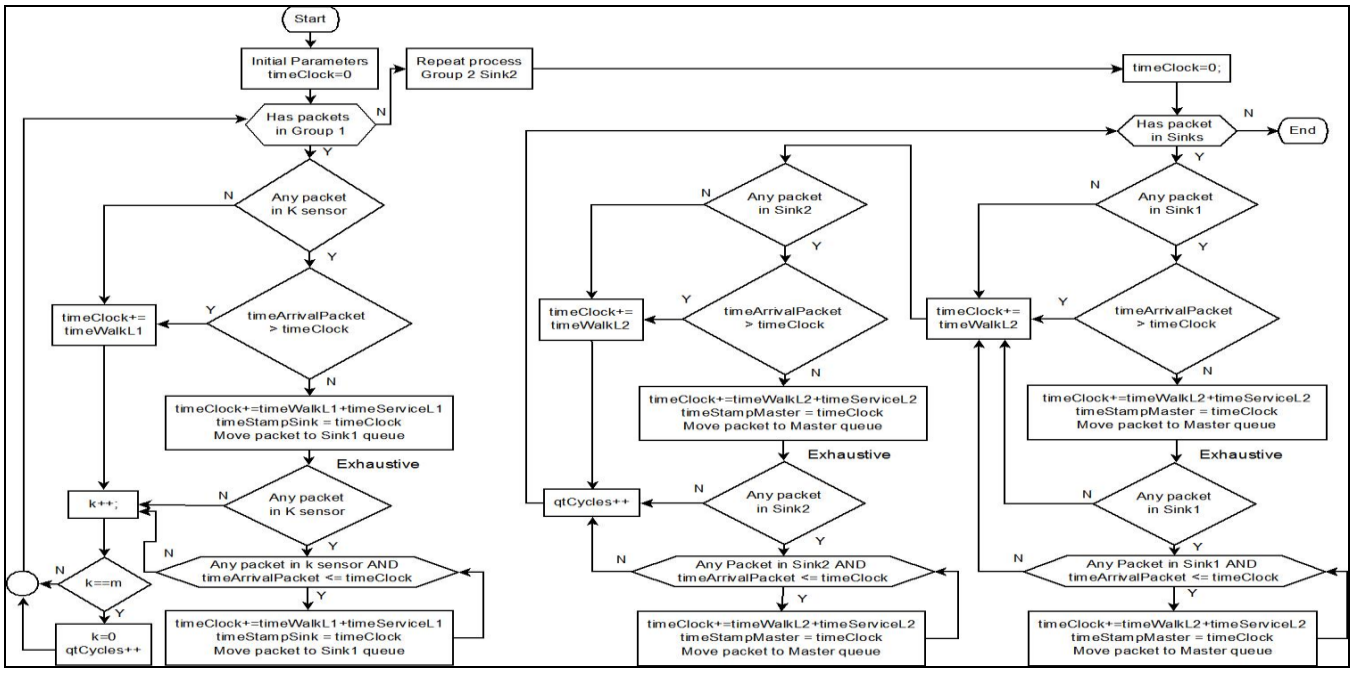

Figure 10. Overview of main algorithm developed for the performance analysis of hierarchical polling-based MAC scheme.

Figure 11 shows a screen of simulator where the changes of source/input values, process and output are possible. In the tab named “Source/Input” the initial values can be typed. They are: numbers of packets and sensors, the mean packet size in bits and the number of packets to be discarded before the statistics. In this tab, it is also possible to select the type of source packet generation distribution ("Negative Exponential" or "On/Off") as well as the transmission rates of first and second levels.

In the tab named "Process" the sensor buffer size can be set, what technique for packet service will be used and the system load range. In the tab named "Output", it is possible to select the result graphs for presenting at the end of the simulation process.

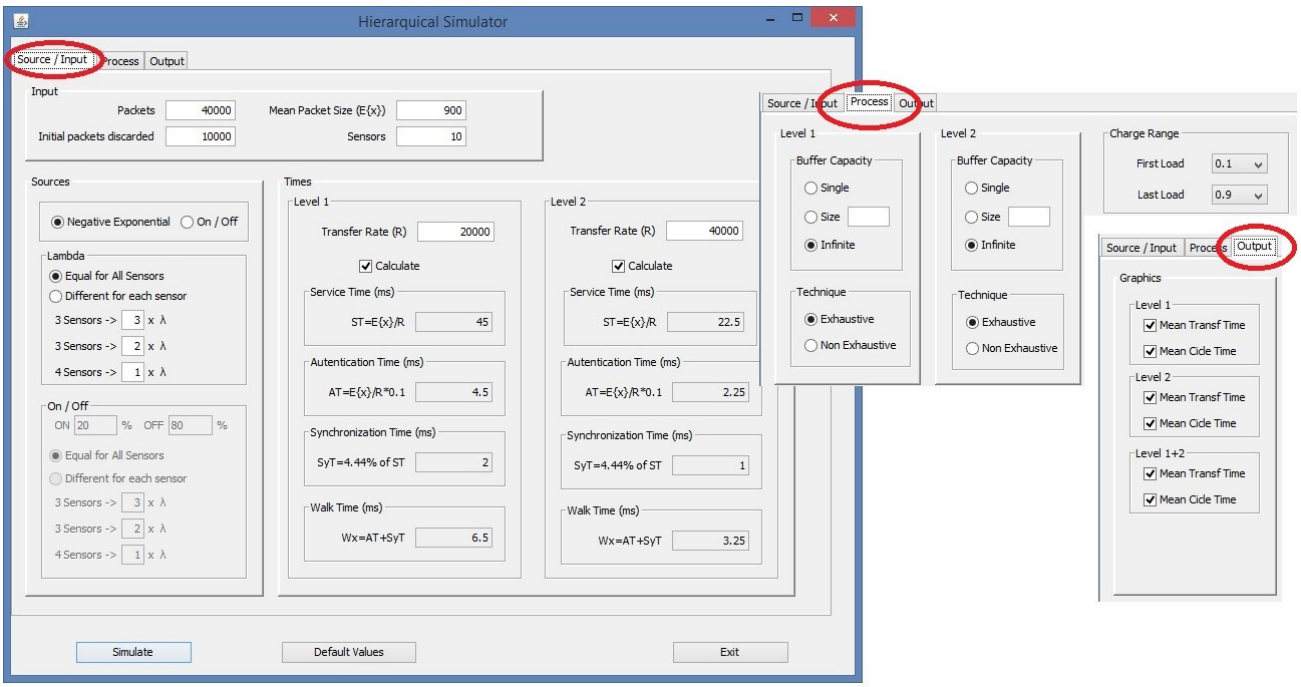

Figure 11. Overview of the simulator screen.

Security Analysis of a Patient Monitoring System for the Internet of Things in eHealth

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***Abstract*—A patient monitoring system for the Internet of Things in eHealth can be established through the integration of wireless body area network, communication infrastructure, and the hospital network. The dynamic and heterogeneous environment of the Internet of Things may facilitate the patient with mobility options. However, security-related problems may obstruct the development of such a comprehensive patient monitoring system. While assessing the security of a patient monitoring system, it is necessary to realise that it may not be enough to only look into the security related aspects of the body area network. Instead, the overall patient monitoring system should be treated as a connected and integrated eHealth system. This paper analyses the important security issues that can put the eHealth system at risk. The specific security goals and requirements, vulnerabilities, threats, and attacks are analysed and some possible security recommendations with direction for future work are discussed.**

Keywords- Internet of Things, Patient Monitoring System, eHealth System, Security.

I. INTRODUCTION

Wireless and mobile communications have played a significant role towards the development of the Internet of Things (IoT). The IoT is a network of interconnected things, such as biomedical sensors, radio frequency identification tags, actuators, and smartphones [1]. The IoT presents a concept of dynamic and heterogeneous network environment, where things communicate and exchange information in an automated or semi-automated way [2], and embed real world information into networks [3]. The communication capabilities and support for dynamic environment in the IoT can provide significant advantages to the existing healthcare system [4]. The IoT can assist the existing healthcare system by developing flexible remote Patient Monitoring System (PMS) that can benefit the patients by getting quick medical responses from the medical practitioners. However, security related issues may obstruct the development of such a comprehensive PMS.

1.1 Contribution and Organisation of This Paper

A significant contribution of this paper is the integrated security analysis of the IoT based PMS, i.e., we highlight the security related aspects in the whole eHealth system including Body Area Network (BAN), communication network, and health care enterprises. In order to analyse the security of a PMS, Section II presents the eHealth system architecture. Section III presents the security analysis of a PMS by focusing on security goals and requirements, threats, vulnerabilities, and attacks. Related work is high-lighted in Section IV. Section V provides discussion and security recommendations. Section VI concludes the paper and addresses future work.

II. EHEALTH SYSTEM ARCHITECTURE

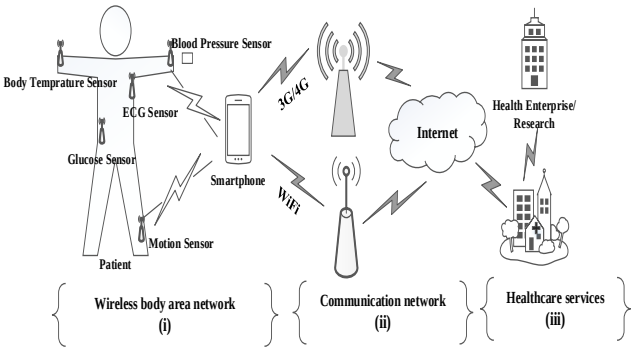

Figure 1. The IoT based patient monitoring system

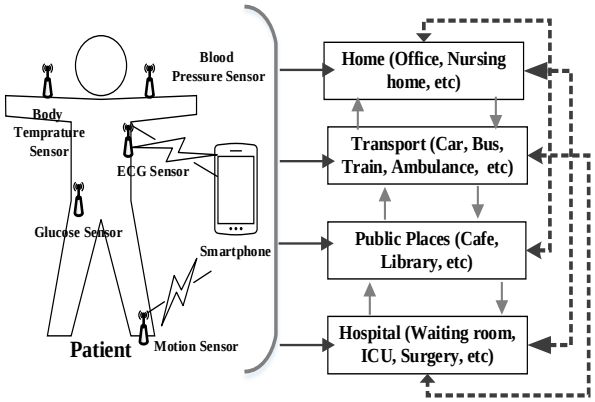

Figure 2. Schematic of the IoT in patient mobility scenarios

A PMS is comprised of three segments, i.e., (i) BAN, (ii) communication network, (iii) hospitals and health care enterprises [5]. As depicted in Figure 1, the BAN includes the actual patient, medical sensors, and the patient's smartphone. The devices in the BAN are configured by clinical staff for data collection. The patient's smartphone collects the monitored information which is then forwarded to the hospital via

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a communication network. The communication networks including broadband network and 3G/4G network connect the BAN with a hospital network. Hospital and the healthcare enterprise evaluate the Patient's medical data and respond accordingly. The healthcare enterprise can also perform further data analysis for research purposes.

The mobility feature of the IoT in eHealth provides various possibilities of patient's locations during the monitoring sessions. As shown in Figure 2, the patient's movement in between different locations is highlighted with dotted lines. The patient monitoring sessions keep the patient connected with healthcare workers, even when the patient is outside the hospital environment.

III. SECURITY ANALYSIS

In the process of assessing the security of a PMS, it is essential to understand that it is not enough to only analyse the security issues at the BAN. Instead, security of the entire system including BAN, backend communication network, and hospital network should be analysed. The different segments of a PMS have several security requirements and possess vulnerabilities that can be exploited by threat agents to launch attacks against eHealth system. Quality of service (QoS), safety, and security are key aspects in the deployment of a PMS. Thus, identification of security related requirements, vulnerabilities, and threats are keys to the development of a trustworthy system. The identification of system assets, possible vulnerabilities and threats, and appropriate countermeasure can help to understand the associated system risks. The terms such as authentication, availability, confidentiality, integrity, information system, threat, vulnerability, and security requirements, are used in this paper in relation to their meanings defined by [6].

From a system point of view, transferring complete and accurate information from the patient to the hospital is always necessary. Failure to do so may cause a threat to the patient's health. People with bad intentions can send wrong data to the hospital by miss-utilising the devices. The quality of data may also vary depending upon the quality of communication links. The data from BAN is sent using public communication infrastructures to the hospital. Hence, data authentication is also very important.

Data security and patient's privacy are certainly the important challenges in the deployment of PMS. In order to highlight specific security requirements in PMS, we analyse the system as a sequence of segments, identify related security requirements, vulnerabilities, threats and attacks of each segment, and possible security solutions for identified issues.

A. Security Goals and Requirements

Successful deployment of a PMS relies upon secure transfer of the patient's vital signs to the hospital. The secure transfer requires that the PMS satisfies major security goals, requirements, and QoS requirements such as device/user authentication, authorisation, confidentiality, privacy, integrity, access control, availability, interoperability, reliability, usability, and resource efficiency. While security requirements are very important, some other factors such as incorrect use of devices, control on data disclosure, and usage also need proper attention. Table 1 provides a summary of the security goals and requirements in a PMS. The specific security requirements and security goals for all three segments are identified in the following sections.

TABLE 1. SECURITY GOALS AND REQUIREMENTS

BAN	Communication Network	Healthcare Enterprise
Data confidentiality, data integrity, data availability, data authentication.	Data confidentiality, data integrity, data reliability, data accuracy, data authentication.	Data confidentiality, data integrity, data availability, patient and data authentication, physical security, access control.

1) Body Area Network (BAN)

The communication links inside the BAN are built using wireless technologies. The security requirements and goals in such network need more attention in comparison to structured networks. Data confidentiality is required to protect data disclosure while in storage at local node or exchanged between nodes. Data confidentiality should sustain even if the nodes in the network are compromised. The leaked data may disclose the patient's disease related information. Data integrity is required to protect against modification of data not only while in transit but also when in storage. The modified data can lead the health personnel towards wrong diagnosis of the patient. Data availability is required to ensure that health personnel get timely access to the patient's data. Delayed or no access to the information may prevent the patient's treatment procedures. Data authentication is required to detect and identify any forged data sent by an adversary. It is also important to establish trust in the received data and in the overall system.

2) Communication Network

Once the patient's health status is monitored and processed inside BAN and stored in the smartphone, then data is transferred by the communication network. Data confidentiality is required to prevent information disclosure in case of interception of communication session. Data integrity is necessary to ensure that the data transferred from BAN to the hospital is unmodified. Data reliability requirement can ensure that the data from BAN to the hospital is available even in case of a link or node failure. Data accuracy is required to ensure that the data is fresh and not reordered by an adversary.

3) Hospital and Healthcare Enterprise

The patient's data are collected at the hospital for medical diagnosis and treatment. Physical security requires restricted physical access to the medical servers in the hospital containing patient's medical records. Weak physical security procedures may allow unauthorised persons to alter the data and system. Data confidentiality is required to limit the data monitoring at the PMS servers for only authorised persons. Data integrity is required to ensure that the data is secure against unauthorised modification. Data availability is required to ensure that data is available to the medical staff even in case of any system failure. Authentication mecha-

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nism is required to not only authenticate the users in the hospital but also to ensure that data is received from the correct patient.

B. Threats, Vulnerabilities, and Attacks

BAN, communication networks, and hospital network are vulnerable to various security threats, mainly due to the inherent vulnerabilities of wireless communication. Table 2 provides a summary of threats, attacks, and vulnerabilities in a PMS. We highlight only specific vulnerabilities, threats, and attacks in different segments of a PMS.

TABLE 2. THREATS, VULNERABILITIES, AND ATTACKS

BAN		Data impairment, dropped data, data counterfeit, data disclosure, frequency jamming threat, data collision threat, compromised data routing threat (e.g. route spoofing, selective forwarding, sinkhole, Sybil, worm holes), data flooding threat, data eavesdropping threat, Denial of Service (DoS) attack [7, 8].
Comm. Network	**Wi-Fi**	Data eavesdropping, data tampering, unauthorised data access and spoofing, rogue access point, man-in-the-middle attack, DoS attack [9].
	3G/ 4G	Mobile-to-mobile attacks, patient's location and activity tracking attack, man-in-the-middle attack, data eavesdropping, scrambling attack, DoS attack [10].
Hospital		Physical security, unauthorised data access, social engineering attack, removable distribution media threat, data interception, faulty hardware, software attacks such as virus, worms, Trojans, and spyware, DoS attack [11, 12].

1) Body Area Network (BAN)

The main participant in the BAN is the patient, so lack of patient's awareness and training or negligence regarding use of sensors and devices may result in lost and stolen data and devices. For data collection and forwarding, the BAN utilises a patient's personal device such, as smartphone that is vulnerable against unauthorised access. The patient may install an application on smartphone that can enable the patient monitoring software to share data with other applications or may even become unresponsive.

Frequency jamming refers to a threat where an adversary intentionally interferes with frequencies of the BAN by using external device. The interference can make the devices and components in the network unresponsive leading into network blockage. Data collision is a threat at link layer communication in the BAN, where an adversary tries to corrupt the data frame by transmitting at same frequency which is used by the actual node. Data collision refers to a situation where the bits sequence in the data frame header is changed due to collision. At the receiving end, the error checking mechanism detects that as an error and rejects received data. Thus, a change in the data frame header is a threat to data availability in the BAN.

Compromised data routing is a threat at network layer communication in the BAN where an adversary can exploit the vulnerabilities of routing protocols to misdirect the data. Some possible routing related threats are spoofing, selective forwarding, sinkhole, Sybil, and worm holes. Route spoofing is a threat to data routing in BAN where an adversary may spoof the routing information. Route spoofing may create routing loops, isolate nodes in the network, and poise the source route. Route forwarding is a threat where an adversary may compromise a node in the network to allow only selective forwarding of medical parameters. Such forwarding can prevent the hospital from receiving complete medical data of the patient.

Sinkhole is an attack where an adversary can forge the routing table so that the nodes forward their data to a selected node. Once the network nodes starts forwarding their data to a compromised node, the adversary may exploit other vulnerabilities in the network to initiate other attacks. Sybil is a threat in which a node illegitimately claims multiple identities in a BAN. Sybil attack can be very damaging where an adversary can forge a network node to act maliciously by claiming false identities or by impersonating other devices with fraudulent intention. Wormhole is a threat that can be setup in active or passive modes. An adversary can selectively analyse network traffic and drop packets to cause disturbance in data flow over the network. In a wormhole attack, an adversary forges a node that can forward packets to a particular node in a tunnel. In reality the forwarding tunnel is a false route that gives control to an adversary to selectively drop or forward received packets.

Data flooding is an attack at the transport layer in the BAN, where an adversary can exhaust the memory resources by sending connection requests repeatedly. The flood of connection requests can consume the memory resource that develops resource constraints for genuine nodes. The lack of data synchronisation is a threat at transport layer in the BAN where an adversary can de-synchronise the pre-established connection by sending request for retransmission of missed frames. Repeated retransmission of frames can exhaust resources and degrade network performance. Data eavesdropping is a threat to patient's privacy and safety, where an adversary can intercept a message for further analysis. The intercepted messages may contain information related to patient's disease and physical location that can help the adversary to extract useful and confidential data.

The DoS is an attack that occurs when the overall traffic exceeds outside the total capacity of the system. The adversary can compromise nodes to initiate the DoS attack. DoS attack is very harmful for patient monitoring because unavailable system may affect the patient's life and safety. Threats such as jamming, exhaustion, flooding, desynchronisation, and compromised routing can cause DoS attack in a PMS.

2) Communication Network

The broadband communication channels are mostly used when patient is at locations such as home, nursing home, doctor's office, hospital, and transported to the hospital in an emergency scenario. The data transmission equipment such as patient's smartphone can perform data switch to the mobile networks that depends upon the patient's activity such as when visiting public places (transport, shop, café, etc.). While the patient's data is transferred using communication network, the adversary can exploit the vulnerabilities in network protocols, system applications, and operating system.

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a) WiFi Communication Network Security Threats

Eavesdropping is a threat where the adversary can intercept the traffic to monitor patient's data. Data tampering is a threat where the adversary can modify the message contents of the intercepted data. Unauthorised access is a threat where the adversary can access patient's data and network resources using patient's identity. The smartphone can connect to a rouge access point that is set up by the adversary to fully control patient's data for malicious use. The adversary can disable the network from serving the patient through DoS attack. Jamming is a common type of this attack, wherein the adversary can use external frequency source to emit random radio signal or let out frequent packets transmission to keep the channel busy, so that the receiver can only receive rather than transmitting. While the smartphone transmits data towards hospital through access point, the adversary can exploit man-in-the-middle attack. The adversary can impersonate the patient to gain access into information and can also inject false data.

b) 3G/4G Communication Network Security Threats

The 4G network offers IP based communication for smartphones through which the devices can directly exchange data. In such a case, smartphone-to-smartphone attack is possible, wherein a compromised smartphone can aim at draining the battery of targeted smartphone through continuous network connection. Data eavesdropping is a threat in 3G/4G networks where the adversary analyse the traffic within a range of particular base station to monitor particular node. An adversary may interrupt management data exchanged between smartphone and base station to extract information regarding encryption scheme. Further, messages intercepted from targeted patient's smartphone can disclose confidential information. The mobility scenario supports patient's movement across different locations. As the patient moves from one location to another, sent messages can be used by an adversary to collect, aggregate, and analyse information regarding patient's movements and activities. Revealing the patient's location, movement, and activity tracking is a threat to patient's privacy. Before patient's smartphone starts transmitting data, it performs preliminary signalling operation with the serving base station. Signalling operations include authentication and key management, registration, and IP-based connection establishment. The adversary can initiate a signalling attack on the serving base station by actuating extra state signals that clog the base station. The excessive burden on the base station results in DoS attacks and the patient's smartphone cannot send data due to base station unavailability. A Man-in-the-middle attack can occur when the adversary exploits the vulnerabilities of the initial handshake between patient's smartphone and the base station. The adversary deceives the smartphone by appearing as a legitimate base station, can eavesdrop on all communication, and insert fake messages. Scrambling is jamming attack on radio frequency for short intervals of time during transmission of control or management information frames. This attack interrupts the communication that can prevent the patient's smartphone from sending data causing availability issue.

3) Hospital/Healthcare Enterprise Threats

An information system at the hospital receives patient's data. Both the patient's data and information system can be attacked from inside and outside of hospital network. An adversary can access the information system to remove and change patient's data or interrupt the system operations. In case of system interruption, the patient's data become unavailable to healthcare personnel that can cause serious harm to the patient's treatment. A malware can infect and propagate to the whole hospital network that can cause unavailability and disruption. Changes and updates in software configuration of patient monitoring servers can unstable the system configuration, resulting in system malfunctioning and communication interruption. The users who are not related to PMS may also browse machines linked to the PMS through the hospital wide network to perform malicious activities. Due to weak physical security procedures at the hospital, the unauthorised users can gain access into the information system. Even for personal gains, the authorised users can also disclose patient's data to concerned parties such as Health Insurance Company. Without proper awareness training, the healthcare personnel are vulnerable to social engineering attacks from adversary for obtaining patient's data. Without having a proper policy for need to know, the administrators responsible only for network management may also access patient's data and use it for wrong purposes. Removable distribution media is also a threat because it can be used to steal information and to propagate viruses in a PMS. The data exchange among computers of PMS through hospital LAN is vulnerable to interception by adversary for data sniffing. The hospital LAN is vulnerable to DoS attack that can jeopardise a PMS. Third party maintenance staff may install contaminated software upgrades that propagates virus into the system. Hardware issues, such as faulty devices can cause interruption in a PMS.

IV. RELATED WORK IN SECURITY OF EHEALTH SYSTEM

The security aspects of eHealth system have been an active research field among researchers. While discussing the security issues in an eHealth system, the existing literature mostly focus on either BAN or healthcare enterprise network. There is a lack of specific security analysis for an eHealth system where the security aspects of BAN, communication network, and healthcare enterprise are combined and treated for the whole PMS. A summary of related research efforts towards security of eHealth system are briefly highlighted in this section.

A case study to assess security risks and threats in a wireless BAN for the real time remote health monitoring system is presented by Lim et al. [13]. The authors assessed the security risk based on the critical needs of acknowledge risks and threats in real time eHealth system. Don et al. [14] described a conceptual architecture of activity based risk analysis for monitoring the health status of the patient. They used event filtration and aggregation based on the concept of situation awareness while utilising smartphone to transfer the data collected through sensors. They conclude that security

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issues such as miss utilisation of the device, authentication, QoS, and reliability need proper solutions. Maglogiannis et al. [15] presented a model approach for performing risk analysis study of healthcare information system. They used Bayesian network to model the interrelationship between assets, threats, and vulnerabilities of healthcare information system in their methodology. They identified high rank risks and suggested several countermeasures to limit the vulnerabilities of the healthcare network operations. Shin [16] designed a framework and provided risk analysis for remote health monitoring systems. The author proposed a health monitoring architecture to provide security services such as authentication, audit, key management, and data fusion using unreliable personal mobile devices. However, they suggested that the concerns about privacy and information quality may obstruct the development of eHealth systems.

Security and privacy requirements in wireless BAN are surveyed and analysed by Li et al. [7]. In particular, the authors looked into security aspects such as secure distributed data storage and fine grained distributed data access control. They suggested that the security, usability, and privacy protection of the data collected from patient is a major concern either it is in storage or transmission. Saleem et al. [8] highlighted the security requirements and DoS attacks in WBAN. According to the authors, it is not appropriate and secure to directly adopt IEEE 802.15.4 security framework for WBAN.

Kargl et al. [17] analysed the security and privacy requirements of eHealth system. They presented an eHealth system model to discuss security threats and attacks, requirements, and recommended guidelines for security mechanisms. The authors analysed some healthcare projects to highlight security and privacy issues in healthcare system [18]. They presented a review of existing schemes to provide security solutions in healthcare scenario. Shahri et al. [12] studied the possible threats on health information system and presented a tree model for identification of threats to perform risk assessment. Leister et al. [19] presented the threat assessment of mobile PMS associated to both short range and long range mobile wireless communication infrastructure. In order to determine the security requirements, they emphasised mainly on biomedical sensor networks. Kotz [20] examined and developed taxonomy of privacy related threats to mobile health technologies. The technologies that could support privacy sensitive mobile health system are also discussed.

Leister et al. [21] presented a framework to evaluate adaptive security for the IoT in eHealth and developed scenarios to access the adaptive security solutions. The authors suggested that security and QoS mechanisms are interrelated and may impact each other. The security objectives of eHealth IoT applications and their adaptive security decision making needs are analysed by Savola et al. [22]. The authors proposed a high level adaptive security mechanism based on the security metrics to cope with that security challenges and issues.

The trend in the evolution of 4G wireless communications and its security is explored by Rahman et al. [23]. The authors introduced the system architecture, security requirements, and security issues of 4G wireless networks. Seddigh [24] studied the security issues in 4G networks. The study focused on the vulnerabilities and attacks at different layers in 4G network. The authors highlighted the security weaknesses in 4G networks and gave few suggestions on security issues and development of appropriate countermeasures. The inclusion of the smartphone into remote PMS can reduce cost and increase flexibility, but smartphone platform does not meet security protection requirements of international standards for health data [25].

V. DISCUSSIONS AND SECURITY RECOMMENDATIONS

The security mechanisms for the IoT in eHealth should be generic enough to avoid interoperability issues among various platforms without affecting a system's usability. The existing security mechanisms that are developed for traditional computer networks may not be very well suited for the IoT in eHealth. One of the reasons for lesser suitability could be the dynamic and heterogeneous environment offered by the IoT, which can allow the patient to enjoy mobility scenarios. As the physical parameters of the patient are changed due to the mobility scenarios, the security requirements, vulnerabilities, and threats may also vary. Another reason could be resource constraints of the sensors, such as lack of storage capacity and processing power that may cause difficulties in terms of implementing traditional security mechanisms. The adaptive security mechanisms may work better than static security mechanisms for such resource constraints and dynamic environments. Adaptive security mechanisms have the potential to adjust security parameters to the level of detected threats, available energy and memory, and application requirements [26]. The adaptive security terminology refers to a situation, where security mechanisms or policies can change in automated or semi-automated way in response to events [27]. According to Abie [28], monitor, analyser, adapter, and adaptive knowledge database are the core components of the adaptive security model. The monitor collects security attributes and environmental data. The analyser determines the current security levels and matches it against the security requirements. The adapter decides by using a planning function about how and what security parameters need to be changed for adaptation.

Adaptive security mechanisms may provide better security against various security attacks in the PMS. For instance, encryption mechanisms are used to counter data confidentiality issues. Mostly, the strength of the encryption mechanisms depends upon the complexity of the algorithm requiring sufficient storage space and processing power. Such algorithms may drain sensor's battery making it unavailable. Thus, lightweight adaptive encryption mechanisms may be a better choice. The encryption mechanism may adapt to various key lengths based on the available energy level in the battery, patient's current location, and current threat level. The authentication mechanisms can provide the data and patient's proof of origin. The traditional authentication mechanisms built on passwords, tokens, and biometric modalities can be made adaptive using context information from the external environment and inside the system's environ-

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ment. The context aware and adaptive authentication mechanisms could provide more flexibility to the whole PMS.

The patient's smartphone is used to collect and process vital signs for further transmission. Smartphone is a mobile device that inherits the risk of lost device. Therefore, the patient should be vigilant towards physical security of smartphone. For the sake of patient's convenience and ease in system's usability, one can ignore the login procedure that is necessary for patient/device authentication. Unencrypted data in the smartphone can be a threat to patient's privacy so clear text storage and transmission should be avoided. Software attacks such as malware, virus, worms, Trojan, spyware, and adware can infect the smartphone resulting in leaked and lost data. The smartphone should be equipped with security mechanism to guard against such threats. The smartphone has constraints in terms of energy and processing power so such security mechanisms that require much processing power may drain smartphone battery. Therefore, light weight security mechanisms should be encouraged to avoid such issue.

VI. CONCLUSION AND FUTURE WORK

The existing healthcare system can gain a lot from the IoT in terms of patient monitoring outside the hospital environment. However, security issues require flexible, context aware, and adaptive security mechanisms. While making a security decision, the security mechanisms should incorporate security requirements, threats, and attacks based on the patient's location and environmental context. We provided a security analysis of PMS for the IoT in eHealth. However, there is a need for a method that could determine the threat and attack level in a given context and adjust security mechanisms to balance system usability and quality of communication. In future, we plan to build a framework to develop context aware adaptive security mechanisms for the IoT in eHealth with a tendency to adapt a security decisions based on the given threat level.

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The Role of Care Pathways in Personal Health Records

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***Abstract*— Care pathways, also known as clinical pathways, are one of the main tools used to manage the quality in healthcare concerning the standardization of care processes. They promote organized and efficient patient care based on evidence based medicine. It has been shown that their use reduces the variability in clinical practice and improves outcomes. However, so far the use of care pathways is restricted on healthcare personnel. We have analyzed the gains of care pathways in the context of new emerging healthcare models such as patient-centered healthcare. Especially we have extended Personal Health Records by the functionalities related to care pathways. We have used Business Process Diagrams for graphical representation of care pathways. Further, these diagrams can be easily translated into executable WS-BPEL code. Their executions coordinate care pathways and automate many of their functionalities, such as the reservation of clinical resources and information therapy.**

Keywords - Care Pathways; Clinical Guidelines; Evidence-Based Medicine; Personal Health Records; Patient-Centered Healthcare; Healthcare Processes

I. INTRODUCTION

A *Personal Health Record* (PHR) is a confidential and easy-to-use tool for managing information about patient's health [1]. It can include a variety of information depending on where that information comes from, e.g., from patient himself, health care providers, pharmacies, insures, and the consumer [2]. It includes information about medications, prescriptions, allergies, vaccinations, illnesses, laboratory and other test reports [3]. It is accessible to the patient and to those authorized by the patient.

Care pathways, (also known as *clinical pathways*, integrated care pathways, or care maps) are one of the main tools used to manage the quality in healthcare concerning the standardization of care processes [4]. They promote organized and efficient patient care based on evidence based medicine, and they aim to facilitate the communication, coordination roles and sequencing the activities of the multidisciplinary care team, patients and their relatives and by providing the necessary resources [5]. It has also been shown that their implementation reduces the variability in clinical practice and improves outcomes.

Generally care pathways refer to *clinical guidelines* [6]. However, a single care pathway may refer to guidelines on several topics in a well specified context [7]. A clinical guideline is a document with the aim of guiding decisions and criteria regarding diagnosis, management, and treatment in specific areas of healthcare [8]. Such documents have been in use for thousands of years during the entire history of medicine [9].

In contrast to historical approaches in clinical guidelines, which were often based on tradition or authority, modern clinical guidelines are based on an examination of current evidence within the paradigm of evidence-based medicine, i.e., the use of current best evidence in making decisions about the care of individual patients. Hence, these modern guidelines usually include summarized consensus statements on best practice in healthcare. Further, a healthcare provider is obliged to know the medical guidelines of his or her profession, and has to decide whether or not to follow the recommendations of a guideline for an individual treatment.

It has been shown that the use of clinical guidelines and care pathways reduces the variability in clinical practice and improves outcomes [4]. However, so far the use of care pathways is restricted on healthcare personnel and their used Electronic Health Records (EHRs) [10]11].

In this paper, we describe our work on extending traditional PHRs by care pathways. So the use of care pathways is not only restricted on healthcare personnel but rather on patient's healthcare team, which may include patient's family members as well. In our solution care pathways are presented by Business Process Diagram (BPD), which are increasingly being used to support healthcare processes. BPD [12] is based on a flowcharting technique tailored for creating graphical models of business process operations [13]. These elements enable easy development of simple diagrams that are easy to understand. Further, BPD processes can be automatically translated into executable WS-BPEL (Web Service Business Process Execution Language) processes [14][15], which activation can be based on the data stored in patient's PHR.

We use WS-BPEL as a computer interpretable clinical guideline language. Such languages explicitly model a care process by specifying the steps and the order in which these steps are to be executed [6]. However, our way of exploiting such a language deviates from its traditional use in that it does not retrieve patient's medical data from EHRs but rather from PHRs. Further, we have restricted on automating the reservations on clinical resources as well as automating information therapy.

The rest of the paper is organized as follows. First, in Section II, we give a short introduction to new emerging healthcare models. Then, in Section III, we shortly consider clinical guideline languages. In Section IV, we present our

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way of using BPDs in presenting care pathways. In Section V, we first present our developed cloud-based PHR-architecture and then we present how we exploit SQL-triggers in automating the activation of WS-BPEL-processes. Section VI concludes the paper by considering our future research.

II. EMERGING HEALTHCARE MODELS

Evidence-based medicine, or *evidence-based health care*, addresses the challenge of finding a way to ensure that clinicians base their day-to-day decision-making on current best evidence [16]. It is explicit and judicious use of current best evidence in making decisions about the care of individual patients. Practicing evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient's unique values and circumstances [10].

Patient-centered care [17] emphasizes the coordination and integration of care, and the use of appropriate information, communication, and education technologies in connecting patients, caregivers, physicians, nurses, and others into a healthcare team where health system supports and encourages cooperation among team members. It is based on the assumption that physicians, patients and their families have the ability to obtain and understand health information and services, and make appropriate health decisions [18]. This in turn requires that health information should be presented according to individuals understanding and abilities [19].

Care pathways model an extended process of patient-centered care by specifying key events, clinical exams and assessment that have been shown to produce the best outcomes for an appropriate episode of care [4]. They are increasingly seen as a means to put clinical guidelines in practice by interdisciplinary teams, as they help reduce patient uncertainty, improve resource utilization and encourage family-centered care. In particular, care pathways can be effective in supporting proactive care management and ensuring that patients receive relevant clinical interventions and assessments in a timely manner.

Information therapy promotes patient-centered healthcare. It is a type of healthcare information service that has emerged in the past decade. The goal behind information therapy is to prescribe the right information to right people at right time [20]. Information therapy is also described as "the prescription of specific evidence based medical information to specific patients at just the right time to help them make specific health decisions or behavior changes" [21].

Information therapy applies to a wide range of situations and context. For example, information therapy may be a physician-written prescription telling a patient what to read, or it may use to help a patient to make treatment decision such as whether to continue medication.

Information therapy can be compared to similar concepts in medicine, such as drug therapy, physiotherapy or bibliotherapy. However, information therapy differs from these in the sense that by exploiting information technology information therapy aims at providing personalization, targeting and documentation.

Many studies have demonstrated that the provision of information therapy can increase compliance with treatment regimens, satisfaction with the health care provider and medical facility, and improve the ultimate health outcome for the individual [21]. It is also turned out that patients who do not understand their treatment instructions, disease management, or prescription requirements are more likely to mishandle their health, be hospitalized more frequently, and have much higher medical costs than their more involved counterparts.

III. COMPUTER INTERPRETABLE CLINICAL GUIDELINE LANGUAGES

The *computer-interpretable clinical guideline languages* explicitly model a care process by specifying the steps and the order in which these steps are to be executed [22]. Examples of these languages include Ashru, EON, GLIF, GUIDE, PRODIGY, and PROforma. A prerequisite for developing these languages is creating computer interpretable representations of the clinical knowledge that is contained in clinical guidelines.

The computer-interpretable clinical guideline languages can be classified into process languages and declarative languages [23]. In the former approach a sequence of tasks is defined for the computer to perform while in the latter approach the logic of computation is defined without describing its control flow, and so leaving a lot of freedom to the user in selecting tasks and defining the order in which they can be executed.

Although process languages allow flexibility by means of modeling alternative paths, they are incapable of handling exceptional or unpredicted situations. Exceptional situations have to be modeled explicitly. However, modeling all possible scenarios results in complex models and is not feasible since exceptional situations and emergencies may arise at any point in time [24]. This makes it difficult or even impossible to oversee what activity should be performed next.

A gain of declarative languages is that they enable late binding, i.e., it is possible to choose an appropriate task at the point of care [25]. On the other hand, late binding resource allocation's point of view means late "reservation", which in the context of scarce resources often means long delays in obtaining the resources.

For example, consider late binding with respect to blood test task and radiographer's consultation. Often the delay for the former task is only a few days while for the latter task it is often some weeks or even months. Hence, late binding may significantly delay the whole healthcare process. This case becomes still more complex, if the tasks have mutual temporal dependencies, e.g., blood test must be taken at least one week before radiographer's consultation.

Due to the problems related late binding we argue that process model are more appropriate for our case, i.e., for modeling clinical pathways and their computer interpretable transformations.

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IV. REPRESENTING CLINICAL PROCESSES BY BPMN AND WS-BPEL

There are three important requirements for health care process modeling notations. First, the notation should be readily understandable by the analyst that create initial drafts of the clinical processes, and by the health care employees who manage and monitor those processes. Second, the notation should have enough expression power to model the temporal constraints of the executions. Third, the used notation should be easily transformed into an executable process modeling language.

Business Process Model and Notation (BPMN) is a standard for business process modeling [12]. It provides a graphical notation called Business Process Diagram (BPD). It is suitable to presenting business as well as healthcare processes.

In BPD, there are three Flow Objects: Event, Activity and Gateway:

- An Event is represented by a circle and it represents something that happens during the business process, and usually has a cause or impact.
- An Activity is represented by a rounded corner rectangle and it is a generic term for a work that is performed in companies. The types of tasks are Task and Sub-Process. So, activities can be presented as hierarchical structures.
- A Gateway is represented by a diamond shape, and it is used for controlling the divergence and convergence of sequence flow.

In Figure 1 we present how a resource allocation process for a diabetes patient can be represented by a BPD.

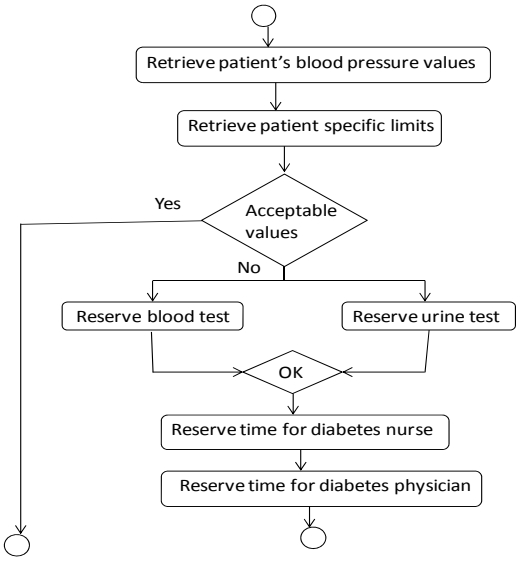

Figure 1. Resource allocation diagram in BPD.

BPD enables the generation of executable WS-BPEL [14]. Thus it creates a standardized bridge for the gap between the business process design and process implementation. In particular, the BPMN specification includes an informal and partial mapping from BPMN to WS-BPEL 1.1 [15]. A mapping of BPMN to WS-BPEL has been implemented in a number of tools, including an open-source tool known as BPMN2BPEL. In such mappings, each activity of the diagram corresponds to an execution of a web service, and the whole process (e.g., Resource allocation process) comprises a Web service. Further, these web services interact with a database management system, and thereby their functionalities can be exploited, e.g. the triggering mechanism as described in the next section.

V. CLOUD-BASED PHR-SYSTEM

A. Using the SaaS model

Cloud computing [26] represents new way of delivering organization information technology: anyone with a suitable Internet connection and a standard browser can access an application in a cloud. In addition, cloud computing allows organizations to use applications without installation. It also allows for more efficient computing by centralizing storage, memory, processing and bandwidth [27].

In designing the architecture of the cloud-based PHR-system we have followed the Software as a Service (SaaS) model. In this model, applications are hosted by service provider and made available to customers over the Internet. It provides access to software and its functions remotely as a Web-based service.

Our SaaS-based architecture is presented in Figure 2. In this architecture a user (a member of patient's healthcare team) can invoke the execution of the web services by patient specific parameters. The execution of each service corresponds to an execution of a care pathway or some other functionality that promotes patient-centered healthcare.

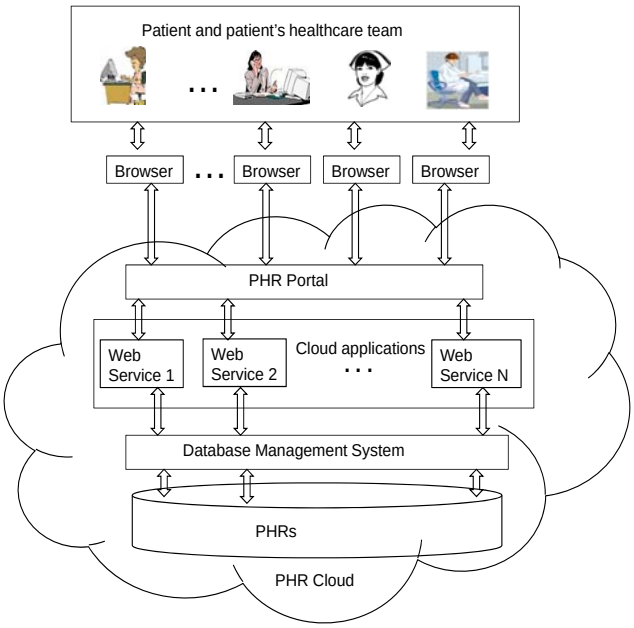

Figure 2. Cloud-based PHR-system.

We have also design a mechanism for automatic activation of executable care pathways based on the values stored on PHRs. In the following subsections, we consider this mechanism.

B. *Representing the PHR Ontology in OWL*

At the conceptual level the PHRs are based on our developed PHR-ontology, which is graphically presented in Figure 3.

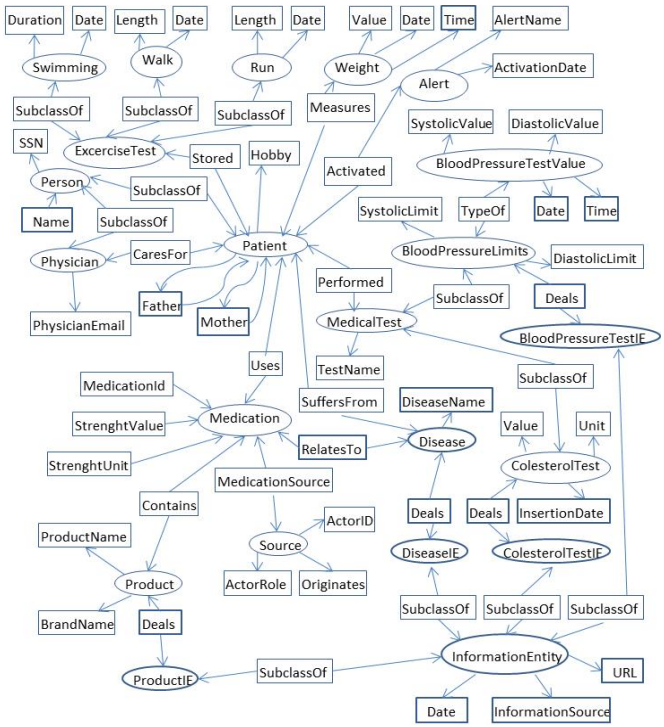

Figure 3. PHR-ontology.

In this graphical representation, ellipses represent classes and subclasses while rectangles represent data type and object properties. Classes, subclasses, data properties and object properties are modeling primitives in OWL (Web Ontology Language) [28]. Object properties (e.g., Uses) relate objects to other objects while data type properties (e.g., MedicationId) relate objects to datatype values. In the graphical ontology in Figure 3 we have presented only a few of objects' datatype properties.

We have used the following rules in transforming the PHR-ontology into relational schema:

- The name of the OWL class is the name of the relation.
- Each property of the OWL class is an attribute of the relation.
- The key of the relation is comprised of the identification of the OWL class and of the identification of those OWL classes that are in a multivalued relationship to the OWL class.

In a *relational database*, all data is stored and accessed via relations [29]. A relation is defined as a set of tuples that have the same attributes. A tuple usually represents an object and information about that object. For example in Figure 4, the first tuple in the first relation indicates that the SSN of Elisa Gray is 1112444-A2, her SystolicLimit is 157 and DiastolicLimit is 71.

The second relation indicates three test values of Elisa Gray's blood pressure tests.

BloodPressureLimits (SSN, Name, SystolicLimit, DiastolicLimit)

SSN	Name	SystolicLimit	DiastolicLimit
111244-A2	Elisa Gray	157	71
121248-B9	John Kent	171	77
120351-A2	Jack Cruz	144	61
120941-C5	Bob Jones	164	68

BloodPressureTestValue (SSN, Date, SystolicValue, DiastolicValue)

SSN	Date	SystolicValue	DiastolicValue
111244-A2	06042011	142	75
111244-A2	07042011	155	79
111244-A2	09042011	160	64

Figure 4. Relations BloodPressureLimits and BloodPressureTestValues.

C. *Specifying Views and Triggers on Relations*

As PHRs are only accessible by the patient and those that are authorized by the patient, we have to control the access of PHRs. In relational database systems such control can be easily carried out by views.

To illustrate this, consider the first tuple of the relation BloodPressureLimits in Figure 4. It should be only accessible for Elisa Gray and her healthcare team. To enforce this we can specify a view 'GrayBloodPressureLimits' in SQL as follows:

```
Create View GrayBloodPressureLimits AS
    SELECT *
    FROM BloodPressureLimits
    WHERE Name = 'Elisa Gray';
```

Now, the virtual relation behind the view 'GrayBloodPressureLimits' corresponds to the relation presented in Figure 5.

GrayBloodPressureLimits (SSN, Name, SystolicLimit, DiastolicLimit)

SSN	Name	SystolicLimit	DiastolicLimit
111244-A2	Lisa Smith	157	71

Figure 5. The virtual relation of the view GrayBloodPressureLimits.

After the view is specified, we can easily set restrictions on its use, e.g., Elisa Gray has rights to read and update it while her physician Ian Taylor has only rights to read it.

Database triggers play a central role in our designed PHR-system. We can easily specify triggers, which activate executable clinical pathways or the functionalities of

information therapy. Technically s database trigger [30] is procedural code that is automatically executed in response to certain events on a particular relation or view in a database.

The SQL trigger statement gives the user a number of different options in the event, condition and action parts. For example, the following SQL trigger activates the execution of the care pathway named ResourceAllocation by a parameter "Elisa Gray", if Elisa's systolic value exceeds her systolic value limit (157mmHg).

CREATE TRIGGER GraySystolicAlert
AFTER INSERTION of SystolicValue
ON BloodPressureTestValue
WHEN SystolicValue > SystolicLimit
EXEC "ResourceAllocation(Elisa Gray)"

By replacing the action part, i.e., the last line of the above trigger, by the action part

"EXEC sendmail´elisa.gray@health-house.com,
"Please familiarize with the advices at http://www.healthinfo.com/high_blood_pressure/"

we can automate information therapy, i.e., advise Elisa to read the guideline stored at the given URL.

In general, providing guidelines does not require the creation of new content as relevant information entities already exist in a digital form [31].

VI. CONCLUSION

The sophistication of information technology and communications is changing our society. In the ongoing healthcare reform, there is an increasing need to control the cost of medical care. In this context the significance of patient-centered healthcare is extensively recognized as it can help by providing information to the patients, their families and physicians, not only for illnesses, but also for prevention and wellness. This, however, requires that patient's health information as well as other relevant medical information is presented in appropriate format according to individuals understanding and abilities.

Advanced PHR systems have the potential to dramatically contribute to patient centered healthcare as they enable patient to become more involved and engaged in their care, and allow other authorized stakeholders to access information about patient that has not been previously been available or difficult to access electronically. The change that can be caused by the deployment of new PHR systems could also have a significant impact on the efficiency of administrative and clinical process in healthcare sector, and thus they will give rise for considerable cost savings.

There are still many obstacles to the widespread use of patient centered healthcare. For example, many patients are not satisfied with the information concerning their future or ongoing care. Our way to alleviate this problem is the automation of information therapy and the deployment of executable care pathways. This is a promising approach as it has been shown that the use of clinical care pathways reduces the variability in clinical practice and improves outcomes.

Still an arising question is how we can promote the production of care pathways suitable for PHRs. Hence, in our future research we will focus on developing graphical tools that assist physicians in constructing care pathways that can be easily stored and executed in PHR-systems. In particular, we will be focused on designing cloud-based solutions, i.e., we will extend the cloud-based PHR-system by new components.

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Innovative Project For Domomedicine Deployment

The PiCADo Pilot Project

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***Abstract*— PiCADo is a pilot project of domomedicine. Domomedicine has been defined by the French Academy of Technologies as "all procedures and care, sometimes complex, given at the patient's home or in his social and professional activities, [...] based on modern technologies. It aims at facilitating home support and promoting medical progress". Domomedicine can be seen as a system coordinating eHealth, telemedicine and social medicine. Through the PiCADo platform -a multi-user and multi-pathology technological platform- the PiCADo project will allow home monitoring of patients with cancer or cognitive impairment with loss of autonomy, based on the latest medical and scientific advances highlighting the importance of biological rhythms in the development of such diseases. As a work in progress, the technological platform has been developed through a collaborative methodology.**

Keywords - Domomedicine; Circadian System; Biological Rhythms; Cancer; Cognitive Disorders with Loss of Autonomy; chronic diseases.

I. INTRODUCTION

The development of information and communication technologies and their large distribution in the population allows considering drastic changes in our health care systems. Widespread Internet access and daily use of mobile phones or tablets by users of all ages, from all socio-professional categories, of any culture, and any region, makes it possible to access medical information and health applications, leading people to contribute more actively to decisions regarding their own health. This societal trend of "connected health" allows more patients to avoid hospitalization. Medical care at home ensures safety and quality of care at least equivalent to conventional care.

In the same time, our health care systems must evolve as a result of demographic and socio-economic constraints. Indeed, incidence of chronic diseases is growing steadily, and this is partly related to life expectancy's extension. The average life expectancy has been increasing three months per year since 1950 in France, where expected years of life once at the age of 65 are 23.2 years for females and 18.7 years for men. In France, at least one chronic disease affects more than 60% of people aged over 65 years [1]. Chronic diseases disrupt patients' quality of life and impact the national health expenditures. Most chronic diseases need long-term medical care and, sometimes, complex care. In France, long term diseases affected 8,000,000 patients in 2004, and four groups of diseases alone account for almost 80% of long term diseases: cardiovascular disease, cancer, diabetes and psychiatric disorders [2]. The increasing incidence of chronic diseases, co-morbidities, as well as the length and complexity of their medical, therapeutic and social support, have created a necessity to develop solutions that enable patients and / or elderly people to maintain their autonomy, to preserve a good quality of life, in order to prevent further health deterioration. The reactive nature of the current medical care organization does not appear to be adapted to the complex dynamics of chronic diseases, nor to their frequent associations, and their long lasting courses.

Healthcare stakeholders in France consider that necessary technologies to an evolution towards a home patient-centered health care system are now available. However, their usages remain fragmented, dedicated to a single disease or a single purpose [3]. Hundreds of experiments have been carried out without creating the conditions for the spread of methods and results, because of a lack of perspective of evolution towards an integrated system of health. However, a number of these experiments are considered as real success from the perspective of patients and caregivers. In this context, various French institutions like the Academy of Technologies and the High Authority for Health under the leadership of the General Direction of Care Offer analyzed the reasons of this limited development. The Academy of Technologies has highlighted the need for an integrated solution that considers the overall care of the patient at home, and, if necessary, hospitalization, without pathology segmentation. The Academy has pointed out problems of systems' redundancy, limitations due to a limited range of devices on the market, and difficulties encountered in these experiments to get integrated into the regional health information systems.

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Hence, to deal with the increasing burden of chronic diseases challenging current European healthcare systems on the one hand, and to help facilitating the deployment of advanced technological solutions, the French Academy of Technologies has proposed domomedicine as a new integrated patient-centered model of care, adapted for multi-user, multi-pathologies, hence co-morbidities. The goal is to group acts and care in patient's home or in his social and professional activities. Those acts should be comparable in quantity and quality to those made in the hospital, and supported by information and communication systems and services [4][5]. This should allow maintaining patients at home or in their socio-professional activities with equal or better quality of care, while promoting medical progress. Indeed, the ultimate purpose of domomedicine is to bring medical progress in patients' houses, thanks to scientific and technological advances, as well as to the coordination of health and social professionals and caregivers made possible by the development of information and communication technologies. Telemedicine and telehealth consist in the transmission of medical data between health professionals or between a patient and his doctor. They represent useful tools for domomedicine, but they are usually focused on a single function or disease and/or do not propose social services (e.g., CorBene, Mein Herz, PTP, E-Cardiocare, Patient Briefcase) [6]. Domomedicine implies simultaneously clinical and social aspects. Domomedecine may be seen as the step following the invention and spreading of telecare and telehealth devices. It is the technical and social system coordinating those technologies, to provide a complete health care solution at home. Deployment of domomedicine therefore represents a medical, economic and societal issue at European and international level.

In this context, the French domomedicine Consortium has been constituted in 2010 as a joint initiative of the Academy of Technologies and the Champagne-Ardenne region. Its ambition it co concretize domomedicine deployment. This led to the creation of the first pilot project PiCADo, launched in 2012. This research and development project has been labeled by a French innovation cluster, Systematic, and is co-funded by an inter-ministerial fund. The original PiCADo Consortium is composed of eight academic and industrial groups (including INSERM, Troyes University of Technology, and Altran as coordinator) who have been joined during the project by a number of other interested partners (hospitals, device manufacturers, service providers, health and training networks and associations, mutual insurance company, regional innovation agency) (see Figure 1).

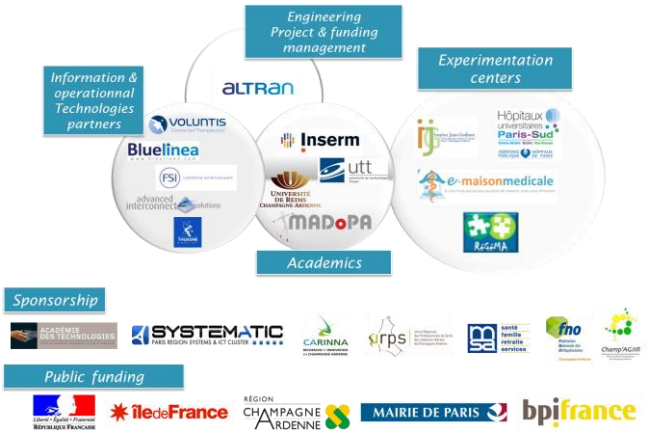

Figure 1. Stakeholders of the PiCADo project

The PiCADo project aims to design, develop, deploy and assess a domomedicine platform. This platform will allow integrated and personalized home monitoring and care, adapted to circadian rhythms, for patients with cancer and cognitive impairment with loss of autonomy. Indeed, recent chrono-biological research has shown that most of physical, physiological, psychological and behavioral parameters, such as exercise, rest [7], and body temperature [8][9], are regulated cyclically on 24 hours by a network of 15 specific genes. This network of molecular clocks is coordinated by a pacemaker, the supra-chiasmatic nuclei of the hypothalamus, which coordinates the various components of the circadian system and adjusts them to environmental cycles. In patients with cancer [9][10] and cognitive disorders [11], strong perturbations of the circadian rhythm have been shown in relationships with quality of life and survival.

Moreover, these two diseases differ both in their temporality (fast evolution for cancer, slow evolution for cognitive impairment with loss of autonomy) and organization of care (focused on hospital for cancer and on home for cognitive impairment with loss of autonomy). Those differences make them good candidate models to prove that PiCADo actually addresses multi-disease and multi-users' issue.

In Section II, we present the methodology used to develop the platform, and Section III describes the developed technological platform as preliminary results. To conclude, Section IV presents experimentation plans as short term perspectives.

II. METHODS

Use-case scenarios have first been specified with relevant stakeholders (including health professionals, patients and engineers) in multidisciplinary workshops, to adapt the platform to pathologies and users' needs. Those scenarios have been completed with a qualitative socio-anthropologic field analysis of current issues related to care support for both pathologies.

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The platform has then been developed using a collaborative knowledge management process to extract important multi-dimensional information (technical, but also social, organizational, economical, legal aspects, etc.).

The PiCADo platform will be deployed in two different French regions (Ile-de-France and Champagne-Ardenne) with two hospitals and one health network, under an interregional multicenter clinical study that will cover initially 70 patients.

The methodology of evaluation will take into account medical, organizational, human, technical, economic, legal and ethical aspects, according to European and French guidelines and criteria (GEMSA, MAST).

III. PRELIMINARY RESULTS: THE PICADO PLATFORM

The PiCADo technological platform (see Figure 2) is a monitoring communicating platform which integrates several lightweight and portable technologies made interoperable (sensor, collector, geolocation watch, digital tablet, digital pen collector, information systems).

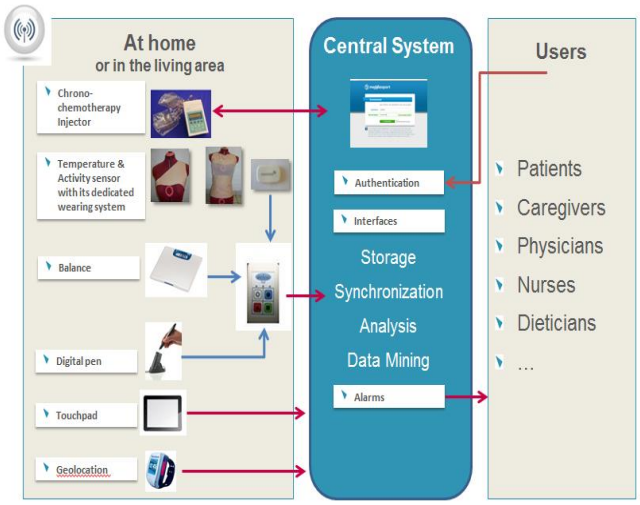

Figure 2. Architecture of the platform installed at home for patients with cancer/ cognitive impairment with loss of autonomy

The platform allows non-invasive and automatic collection of different markers of biological rhythms (activity, position, temperature) and health status of the patient (body weight, evaluation of the quality of life, geolocation, etc.) at home or during his daily activities. Most of the data is sent via Bluetooth to a collector box which transmits them via GPRS to a management server where they are stored securely in a patient's health record. Other devices such as touchpad and geolocation device are able to transmit data directly using the Internet or the mobile network. Authorized users can access record information via a secure web interface, add different type of patient information (health, nutrition, psychology, etc.) and communicate with other care givers via the same interface [12]. Automatic pre-analysis of data is coupled to notifications sending to care professionals, which they can reset. Tele-monitoring allows early detection of potential health deterioration, and consequently better prevention. Data analysis also allows professional caregivers a better understanding of patients' rhythms, to adjust treatments and to propose adapted dietician or psychological services to their patients.

IV. CONCLUSION AND PERSPECTIVES

The objective of the platform is to minimize impacts of chronic disease on patient by acting on several levels: prevention of disease progression, centralization of patient information, and harmonization of coordination between general practice and hospital sectors, formal and informal caregivers, resulting in greater efficiency of care.

The deployment phase, planned for 2015, will allow the multidimensional assessment of the multi-pathology and multi-user values of the PiCADo system for all stakeholders (health professionals of general practice and hospital sectors, home and nutritional monitoring service providers, patient, family and informal care givers, industrials). Adapted business model will be designed through a first evaluation of the service delivered and through proof of concept of domomedicine. This study represents the first step of a nationwide and European deployment of domomedicine.

Furthermore, the clinical study will lead to the establishment of an original database on biological rhythms and symptoms of patients in their living environment. The detection of biological rhythms disturbances are expected to anticipate the deterioration in the condition of the patient and to avoid emergency hospital admissions. Detailed knowledge of the relationship between a patient's rhythms and his pathology evolution should eventually lead to personalized treatments. Moreover, the nutritional status monitoring should improve the prevention of health deterioration through early treatment of malnutrition which is an aggravating factor.

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Managing Self-Management in Healthcare: from a Systemic Perspective

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***Abstract*— Self-management among patients, especially chronically ill patients, has shown to be crucial for their ability to adjust lifestyle, increase empowerment and maintain a satisfactory quality of life. The use of the Internet and ICT tools support self-management on different levels. With the new and improved patient role, the patient becomes more actively involved in decisions and treatments. More personalized care and support become also possible. The question is how enhanced emphasis on self-management affects healthcare. By taking a systemic perspective, this paper elaborates on the complexity of self-management and on healthcare management issues related to self-management. It proposes a holistic view on managing self-management in healthcare.**

Keywords-self-management; ICT tools; complexity; control; management; systemic; viable; holistic.

I. INTRODUCTION

The patient role is becoming more self-managing. Self-management among patients, especially those with chronic diseases, has shown to be crucial for their wellbeing [1]. Self-management includes taking care of the body and disease, adapting in order to carry out daily activities, managing changed life conditions and roles, and also emotional changes and uncertainty about the future. Self-management brings with it a new patient role in which the patient becomes more active. The patients can be said to act as ”prosumers of wellness rather than passive consumers” [2, p. 180]. Greater empowerment is detected among patients who engage in online support groups [3][4], and power is also somehow slightly shifted from the healthcare system to the patient [4].

A sense of control and social belonging are important to all people, but for patients with chronic and severe diseases, this imposes a certain challenge [3]. When becoming a long-term patient, you need to redefine your role and adjust living conditions or lifestyle. This can lead to a feeling of being outside the norm and alienated, why interaction in groups of patient peers becomes important [3]. Through peer interaction, experiences, skills and inspiration can be shared among patients and others with similar health concerns [3]–[5]. This kind of interaction takes place independently of formal healthcare but can be supported by it.

Self-management can help patients develop a sense of control over their situation, and to influence on practical conditions and interventions. Increased patient involvement implies a new approach from the healthcare system and the healthcare professionals [2]. The change concerns attitudes and approaches to care, and to the relations between patient and doctor; it is very much a conceptual change. It also demands for new ways of using ICT for communication and interventions [6]. For effective self-management, conversations between the healthcare and the patients are important [6]. It is also in the conversations that conditions for interventions and self-management tools are decided upon. Allowing the patients to be more in control implicates that these conversations are emphasized. However, it is a challenge for the healthcare to manage the idea of patient-centric care and the support of self-management among the patients. Healthcare management is to be further explored in this respect.

This paper will investigate the concept of self-management from a systemic perspective. The perspective helps us regard the complexity and viability of self-management, and how to manage it. The following section, Section 2, addresses the concept of self-management and complexity in relation to self-management. Thereafter, in Section 3, different types of self-management tools are introduced. In Section 4, a holistic view on how to manage self-management is proposed, and the last section, Section 5, concludes and points out a way forward.

II. SELF- MANAGEMENT

Self-management has been identified as “[...] the tasks that an individual must undertake to live well with one or more chronic conditions. These tasks include gaining confidence to deal with medical management, role management, and emotional management.” [7, p. 3]. Another way to address self-management is to refer to “the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one’s condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life.” [8, p. 178].

Examples of activities included in self-management programs are: how to deal with frustration and pain, what exercises to do, how to take medication, effective ways to communicate with relatives, friends and health professionals, what food/nutrition that is recommended, and how to evaluate new treatments [1]. Encouraging the patient to be more self-managing, and thereby involved in the healthcare more actively, has shown to be helpful for several care goals, for example, increased patient satisfaction, development of healthy behaviors and improved wellbeing of patients [1][8].

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Self-management support includes also educational components, teaching the patients about self-management skills [1] [9]. Examples of key skills for the patients are problem solving skills, including communicating with close ones and healthcare professionals, day-to-day decision making skills, such as knowing when to exercise and when not to. Other examples are skills to access relevant resources, to build relationships with healthcare providers, and the ability to make short term action plans and carry them out [9].

A. *Self-Management and Complexity*

Whenever a person is to handle a situation, and the involved tasks, he or she needs to adjust to the situation and to the complexity it holds. As mentioned previously, for self-management, the tasks include "gaining confidence to deal with medical management, role management, and emotional management" [7, p. 3]. When considering this from a systemic perspective, to manage the situation and its tasks, the person amplifies his or her abilities and skills and attenuates the situation through models and filtering of information [10]-[12]. Both amplification and attenuation are needed to manage the situations we meet (see Fig. 1). How much we are to amplify and attenuate depends on the relation between ourselves and the situation, considering the tasks involved. In everyday situations that we manage without great efforts, we maneuver and adjust often without being conscious about it.

However, we often become overwhelmed by situations due to the imbalance between our own individual complexity and the complexity of the situation [11]. This is especially evident when we face a new or more complex situation. Management of situations unfamiliar or difficult to us requires that we develop relevant models and skills. We need also to look for adequate performance criteria and performance goals [11][12]. Learning can be seen as a struggle with insufficient variety, forcing us to enhance our performance [12]. However, if the desired outcomes are recognized as impossible to achieve, they may have to be changed [12]. Otherwise, they will lead to errors and failures in performance all the time.

The practice of self-management must also consider that given a limited knowledge of the patient, a certain type of self-management may lead to more harm than good. One crucial thing for successful health treatment is that the patient takes his or her medicine as described, for example. The patient may forget to take the medicine, or perhaps takes it too often. One of the most common risks in this area, documented in the medical literature, is the overdose of prescribed medications among diabetic patients [13]. Another example is the corticosteroids and bronchodilators, generally used by chronic obstructive pulmonary disease (COPD) patients during the exacerbation phase. Once again, the risk is the abuse of this treatment, i.e., the patient goes on a light distress and even if it is not needed, he or she uses the bronchodilator. Conversely, if a patient does not use a bronchodilator when needed, he or she will go on a respiratory distress.

There is a need for balance between the desired outcomes, patient's current abilities and the situation at hand. Based on this, appropriate levels, or types, of self-management will be necessary to decide upon. What the patient is able to manage at a certain time, and what needs to be managed by the healthcare professionals, is crucial to have a continuous dialogue about.

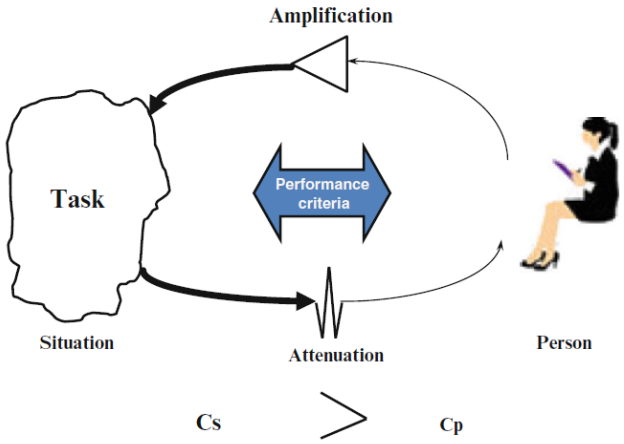

Figure 1. Managing the complexity of a situation [11, p. 55]

B. *Self-Management and Changed Relations*

To enhance self-management of patient groups, especially those with chronic diseases, puts new demands on the healthcare system and the care professionals. The relation between patients and the healthcare provider is to be more characterized by collaboration, with frequent and productive conversations [2]. In comparison with the traditional relation between the patient and the healthcare provider, the collaborative relation is less characterized by the doctor telling the patient what to do and more about combining the different types of expertise that the doctor and the patients possess [1]. The patient is to become part of the conversations and participate in setting goals and developing care plans. While the physician is expert in medicine, the patient is the expert regarding his or her life, situations in daily life, history and past abilities. To include the different expertise, and to let the patient not only be in the centre but also an active participant, physicians and other health professionals are expected to have two-way conversations with the patients about goals, treatments, possible side-effects of medication and evaluations of treatments.

The emphasis on self-management and collaboration makes patient education a necessary activity of the healthcare system: to help the patients with the practical tools so they can manage more easily and be more involved in the interventions and also as independent as possible [1][9].

III. ICT-SUPPORT FOR DIFFERENT TYPES OF SELF-MANAGEMENT

Greater patient participation and control can be achieved through available ICT tools [3][4][6]. There is a wide range of ICT-based self-management tools, spanning from online self-help groups that allow for an autonomous patient role, to home surveillance systems that let the patient take a subordinate role due to the nature of the health conditions [6]. For patients who need home surveillance for their safety, there are video camera surveillance and sensor-based surveillance systems that can

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facilitate this. In these situations, the patient's role is subordinate, and it is crucial that the systems do not violate the patient privacy or become too controlling. In order for these systems to be regarded as self-management tools at all, the patient has to be in charge of how the systems are used [6].

In between the autonomous and the subordinate roles, there are ICT tools supporting a structured patient role. Examples of these are interactive telemedicine consultation and messaging systems, allowing for patient-doctor communication to be more continuous. Other tools for the structured role are blood glucose meters, weight scales, apnea monitors and neurological monitors. There are also tools that let the patient be included in communication, education and decision making processes together with healthcare professionals. These ICT tools address the collaborative dimension of the patient role [6].

A. Online Self-Help Groups

The most autonomous type of self-management tool is the online self-help communities and self-help books [6]. These tools let groups of patients communicate, learn and act independently of the healthcare professionals. Online self-help groups let patients exchange knowledge and experiences, and the groups support the participants in helping each other develop new skills and attitudes. Previous studies have shown how self-help groups for patients with severe illnesses contribute to increased empowerment and improved ability to approach the healthcare with their health concerns [3] [4]. One example of a web-based community platform for different patient groups is PatientsLikeMe in which patients can share experiences, and the system can also aggregate the information as to serve the participants with decision support [2]. If you want to know about the experienced side effects of a certain medicine, for example, you can search for this in the online community and get aggregated data from hundreds of patients who are taking the medicine. Healthcare becomes then more than merely a patient-centric healthcare; it is also about patients co-creating healthcare and wellness [2].

Another example is WeAre.Us, an online health community for supporting conversations between patients, families and related stakeholders. This platform also contributes to a kind of collective intelligence through aggregated tracking and gathering of group information [2]. A further example is the NetDoctor sites in Europe with different areas for information from the healthcare, ask-the-expert systems (Q&As) and conversations in web-based communities for self-help groups.

There are also self-help groups for people who suffer from lifestyle problems, such as unhealthy eating habits, too little physical exercise, smoking and abuse of alcohol, for example. The online communities on lifestyle issues are valuable for prevention purposes, but they are also important for people with chronic diseases, such as diabetic. Another example is stress management through conversations in online communities with the aim to prevent dysfunction due to negative stress exposure [14]. Social support is important when trying to develop new habits and behaviors that last [15] [16]. Also, in comparison with advice from healthcare professionals, the self-help groups have shown to offer complementary and more practical hands-on advice [17].

B. Discussion on ICT-Support for Self-management

For all these tools supporting self-management, it is important that they serve the purpose of allowing the patient as much own control and independence as possible. As mentioned before, even tools that facilitate subordinate patient roles, like the surveillance systems, should not violate the patient privacy or become too controlling. The choice and combination of self-management tools depend on the nature of patient conditions and the decision made by the patient, the doctor and the healthcare institution together. Especially for patients with chronic and multiple diseases, the negotiation about self-management tools, and how they are to be used, is crucial for their wellbeing. Also, if the nature of the health condition changes in character and the patient's health status deteriorate or progress gradually, the communication concerning the tools will have to be continuous. In addition, the learning curve is a factor that needs to be considered.

There are different kinds of knowledge and skills that the patient needs to possess, one is to know how to use the ICT tools for self-management. The more in control of the ICT tools the patient becomes, the more likely it is that he or she will use the technology. The emphasis on self-management makes patient education a necessary component of the healthcare system, to help patients with the practical tools and the practices they need. Patient education includes introduction to self-help groups for peer communication and how to use an apnea monitor, for example.

If we assume that self-management is critical and that we have to figure out the patient, in the context of remote monitoring, we need to move beyond traditional roles. Obviously, until the patient manage to self-medicate, the problem with under- and overdosing is inevitable. But surprisingly in home-care and remote monitoring, this kind of risk is often not managed through the software and telemedicine platforms. What can we then put in place to mitigate the risk of such events from occurring? Most of the clinical picture of the patient involves trying to record in an as accurate as possible manner all the doses taken. However, the situation may be complicated by the fact that the overdose (or a too low dose) in emergency situations may be adequate. The typical example is a diabetic patient where the proportion of glucose in the blood exceeds a certain level for which it is necessary to add an extra dose of insulin, in order to bring it back to normal levels. In this case, the patient knows through the symptoms (e.g., headache) that something is going on. By measuring blood sugar level, this can be verified before adjusting and putting in an additional dose of insulin. In this case, we have an additional medication that is not scheduled, i.e., it deviates from the daily doses of insulin. The majority of current diabetic control software applications allow the patient to simply record additional measurements of glucose and additional insulin medication.

Some improvements could be done by a simple real time alert system for the clinician that is following the patient. The use case will be the following. The patient receives his or her

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medical drug prescription on the home monitoring platform. If, for some reason, there is an additional drug intake registered by the software, an alert should be sent to the clinical care alerting that the patient is overdosing. However, this simple suggestion could be further improved, and a global refactoring of traditional remote monitoring systems should be done in order to archive also the possibility of having a patient that is not only self-medicating but who is also an active part of the cure and able to make decisions with the clinician.

IV. PROPOSAL OF A HOLISTIC VIEW ON MANAGING SELF-MANAGEMENT

This section will explore the systemic perspective of self-management further. A systemic model, the viable systems model, will be introduced, as well as applied and discussed.

With a systemic or holistic approach, systems are regarded as a set of interrelated parts that form a whole with certain systems goals [18][19]. The mutual relations and communication between the parts of the system are as important as the parts themselves, since the whole system is greater than the sum of the constituent parts. A characteristic of living systems is their ability to alter and adapt to new conditions and demands of situations in the environment, in order to maintain viable.

The patient care can be regarded as a living system with the different care components seen together, as interrelated, and with certain goals of patient recovery, health and wellbeing. This includes considering self-management components and the healthcare activities, provided by formal givers, together, in which the different actors and their activities affect each other as well as the outcomes.

In Fig. 2, the viable systems model by Stafford Beer is illustrated [10]. It shows the relations between overall management (the upper square) and the operations (the System 1 circles) being managed. Management is divided into three different subsystems: System 3 is responsible for planning for the System 1 to function well, to distribute resources and to follow up the results. System 2 manages oscillation of System 1 and tries to enhance the togetherness of the different operations of System 1. System 4 deals with changes of the system, and looks for changes in the environment for the system to consider and adjust to. System 5 is the one that makes sure that there is a balance between internal stability and change, i.e., any conflicts between System 3 and System 4 is handled by System 5.

The environment is important for the system, since it provides the context and conditions that the system has to adjust to. In the case of the care of the patient, there are regulations, treatments, development of ICT tools, other patients, work and social environments of the patient, daily situations that the patient has to deal with, and so on. As can be seen in the figure, some parts of the overall environment are better known by the operations of System 1 than management of the top level. This goes for work and social environment, and specific situations that the patient experiences, for example. Variety is to be adjusted to this and should be taken into account when planning for patient care,

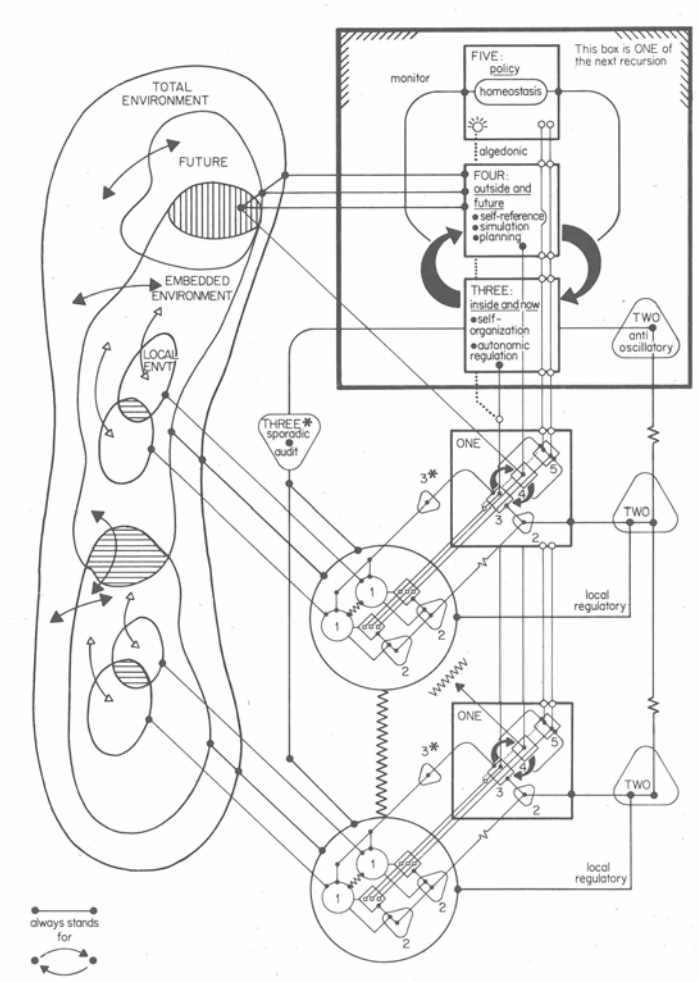

Figure 2. The viable systems model [10, p. 136]

especially the self-management activities. However, as shown earlier, there are also new types of ICT tools that offer possibilities for patients to interact with peers, and help them make use of the collective intelligence of the self-help group. This increases the patients' variety and their ability to have conversations with the healthcare about treatments as well.

A. Self-Management as Part of the Whole

The viable systems model by Stafford Beer can be used to deal with the concerns of integrated self-management in the total patient care. System 1 is the operational part that needs to be managed as a whole. In the patient care system, this System 1 consists of all activities necessary for a patient's health care and wellbeing. Looking into System 1, we find the different operations, such as medication/treatment programs, surgery and aftercare, such as treatments by physiotherapist, for example. In addition, we need to include self-management as one integrated operation. All the operations should be managed as a whole and get resources to work well. This is managed by System 3. It is also dependent on System 2, i.e., the one trying to avoid oscillation from occurring in System 1. In our case, System 2 would be someone who regulates and

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makes sure that there are common health-related concepts and understanding among the operations, and who schedules different care activities so that they are performed in line with one another. System 4 contributes by managing change, and it can suggest addition of care activities or ICT-support to the operations.

In order for the healthcare to manage the situation, in which self-management becomes a natural part of the patient care, the ideas behind self-management need to be well-known to the healthcare. In addition, the use of self-management tools has to be embedded in the everyday healthcare practices. Since self-management includes a demand for education of the patients and their close ones, this will also have to be part of healthcare management.

To have two-way conversations with patients and to let them take part in decision-making situations leads to an increase in complexity in the patient – healthcare relation. More variables will have to be handled. For a well-working overall system for patient care, the health and wellbeing of the patient, i.e., seen from several perspectives, should be present to both the healthcare professionals and the patients.

B. The Viable Self-Management System

In the previous section, we addressed the whole care system in which self-management was one integrated part. If we focus on self-management, i.e., the next recursive level down, we will find different self-management operations. Among the operations of the System 1 of self-management, there are different types of activities and ICT tools appropriate for a certain patient (lifestyle self-help groups and monitoring of blood sugar, for example). As mentioned before, the types of self-management tools relevant for a certain patient should be discussed on a continuous basis due to changes in the patient's health status (both progress and deterioration) and his or her experienced wellbeing. In managing the system for self-management, we therefore find planning and evaluation of self-management operations. While System 3 plans and follows-up the outcome of the different self-management activities, System 4 looks for new ways of supporting self-management for the patient. This calls for ongoing processes of planning, evaluation and for scanning the environment for new tools and situations to be managed by the patient. To keep a balance in the self-management system, System 5 resolves any conflicts between stability (System 3) and change (System 4).

V. CONCLUSIONS AND FUTURE WORK

In this paper, we have discussed self-management for increased health and wellbeing among patients. Since self-management has shown to be of great importance to patients, it has to be an integrated part of today's healthcare. The complexity of patients and their situation is to be addressed. Evaluation of self-management tools will also be needed. If embedded in the healthcare, this will allow for continuous evaluations of the set of ICT tools for a certain patient, including suggestions for improvements in the self-management support. We have therefore proposed a systemic approach to managing self-management based on the viable systems model by Stafford Beer. This view offers different roles and functions necessary to ensure that self-management is viable and also well integrated in the overall care system.

When self-management becomes a natural part of healthcare, the healthcare system has to further develop criteria for measuring effectiveness. Adequate level of control and inclusion in decision-making, experienced wellbeing of the patient, together with health status, are examples of criteria related to self-management. Future research work will focus on how to measure effectiveness, when patients and their close ones come to play a greater role in the care process, and when self-management through ICT tools are being further explored and implemented.

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Diabetes Lifestyle Support with Improved Glycemia Prediction Algorithm

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***Abstract*— This paper proposes a combined model to predict the blood glucose level of people with diabetes. Our method consists of two efficient models found in literature and takes nutrition, applied insulin, and initial glucose level into account during the calculations. An extension has been made to these models using various model training methods. Our aim is to help diabetics calculate the insulin need with this efficient algorithm later implemented in a user-friendly software. The tests, that are based on real data, show a significant improvement in the results if model training methods such as Genetic Algorithm (GA) is used. On the other hand, the numbers reveal the weaknesses of our method, which has to be fixed in the future. During an all-day validation, the prediction error was smaller than 3 mmol/l in 83% of the cases while using GA. Compared to other tests found in literature our model seems to be a good start in predicting glycemia, but needs further improvements.**

Keywords—Glucose-level tracking; eHealth; Genetic algorithm; Glucose-Insulin system; Glucose absorption; Diabetes mellitus; Outpatient care

I. INTRODUCTION

Diabetes mellitus is a crucial problem in modern healthcare, since 8% of the population has diabetes in the target age (20-79), according to a recent survey [1]. Furthermore, the number of diabetics may increase by 50% within 2 decades [1]. These numbers remind us of the importance of treating diabetics. Our aim is to provide a tool for them with the help of modern technology and improved prediction algorithms. In case of success, our method can be easily implemented as an add-on to a mobile lifestyle logging application that can be used by many patients to calculate their insulin need.

The basic motivation of our efforts is to create a tool that diabetics can use in everyday life to calculate their blood glucose levels. To accomplish this, a reliable method has to be developed to predict the glycemia based on the lifestyle and medication log of the outpatients. Our previous work [2][3] showed that the models we chose are capable of a 1-3 hour prediction, but corrections are required to avoid excessive over- and under-estimations. As we reached slightly satisfactory results for the long term (4 or 6 hours) prediction, we started to focus on the model training methods to create better outcomes. There are a lot of methods to be investigated, such as: neural network, fuzzy logic, least square method and genetic algorithm. Some of these have already been applied to the problem of blood glucose prediction [4-12]. In the next subsection we give an overview of the current results.

A. Literature Overview

There are several models available for Blood Glucose Level (BGL) prediction. Most approaches are based on a combination of these models. We review those that include validation on realistic data.

The system demonstrated by Stahl et al. [4] consists of three main parts: Glucose Sub-Model, Insulin Sub-Model and the Glucose/Insulin Interaction Model. These three parts are modeled separately using compartment models and linear black-box models [5][6]. During a 6 months period, input data was collected from a patient diagnosed with Type 1 Diabetes (T1D). Meals, insulin injections and glucose measurements were logged. Researchers had difficulties reaching prediction error smaller than 1 mmol/l in 95% of the cases with 2-hour-ahead prediction.

Robertson et al. [7] used Elman's recurrent Artificial Neural Network (ANN), which predicts BGL based on the history of BGLs, meal intakes and insulin injections. BGL history came from the freeware mathematical diabetes simulator named AIDA (Automated Insulin Dosage Advisor). The data set consisted of 28 days and 2688 values. The ANN was trained using all available BGL data for short-term prediction (up to 1 hour). For long-term prediction the ANN was trained with input vector events. Input vector events included 2 meals, 2 short-acting insulin doses, and 2 long-acting insulin doses a day. The maximum error for blood glucose prediction was 0.27 mmol/l for short-term predictions (15, 30, 45 and 60 minutes), 0.2 mmol/l for the 8-hour, and 0.36 mmol/l for the 10-hour predictions, respectively. These are impressive results, however, we must keep in mind that the validation base was a mathematical diabetes simulator data set. In contrast, we used real life measurements of humans.

Shanthi et al. [8] carried out the prediction of blood glucose with a simple neural network model, which was trained with the assistance of extracted features. They used a novel feature based prediction algorithm for forecasting the blood glucose values ahead of time. The data set was obtained from diabetic patients in a hospital setting with different insulin therapies using Medtronic Continues Glucose Monitoring System (CGMS). The average errors of this approach are 0.55 mmol/l for the 30 minutes prediction, 0.83 mmol/l for 45, and 1.11 mmol/l for 60 minutes prediction, respectively. These results are promising, but the

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validation data was highly controlled, and 50% of data was used for training. In contrast, we used 30% of data for model training with less controlled outpatient data.

The sole aim of the Plis et al. [9] study is hypoglycemia prediction. To perform this, they used the Support Vector Regression (SVR) model with physiological features. Instead of tuning parameters, which differ among patients, they used state variables to create features for the SVR model that was individualized for each patient. An extended Kalman filter was run using the training/test points. Input data were collected from 5 T1D patients. The average errors for SVR are 1.25 mmol/l for 30 minutes and 1.99 mmol/l for 60 minutes. This can be a good comparison base to our results.

There are also other recent approaches not so close to the focus of this paper. Chuah et al. [10], used non-invasive, i.e., less reliable blood glucose concentration measurement including healthy volunteers. Seizaburou et al. [11] also used a realistic data set for validation and reached promising results, but without taking meals into account. Liszka [12] used the hybrid Artificial Intelligence technique, which combines the principal component method and the neural networks. However, the authors estimated blood glucose levels only two times a day, while we estimate every 5 minutes.

The rest of the paper introduces our model, the validation method, and the results. Section II includes a short overview of our model and presents the model training methods. Section III reviews our testing phases followed by the results and the discussion detailed in Section IV. Section V is a short overview of our software that is developed to support the test process. Finally, Section VI concludes the paper and outlines future works.

II. METHOD

A. Model

We created a combined model which reflects the real process happening in our body. Following metabolism, we split the whole procedure in two parts. One of them is insulin absorption, which is simulated with differential equations:

$$\frac{dG}{dt} = -K_{xgi}G(t)I(t) + \frac{T_{GH}}{V_G} \quad (1)$$

$$\frac{dI}{dt} = -K_{xi}I(t) + \frac{T_{iGmax}}{V_I}f\big(G(t-\tau_G)\big) + \frac{1}{V_I t_{max,I}}S_2(t) \quad (2)$$

$$\frac{dS_2}{dt} = \frac{1}{t_{max,I}}S_1(t) - \frac{1}{t_{max,I}}S_2(t) \quad (3)$$

$$\frac{dS_I}{dt} = -\frac{1}{t_{max,I}}S_1(t) - u(t) \quad (4)$$

The first equation calculates the blood glucose level (G), depending on insulin absorption (I), calculated by (2). This model includes two subcutaneous insulin depots (S_2 and S_1) described by (3) and (4). These depots simulate subcutaneous insulin absorption. For further details of this model and the parameters see [13][14] and Table 1.

The second part of our combined model describes the glucose absorption from meals [15]. It is a two-compartment model based on mass balance equations. As Figure 1 shows, it divides the digestion into two parts; stomach and intestine. The model takes protein, lipid, monosaccharide, fiber, and starch intake as input, with each one having its own effect during the absorption. This method can deal with mixed meals with components of different Glycemic Indices [16] and takes into account the effect of fiber. Moreover, digestion overlap between two consecutive meals is handled properly. For more details about the model and the parameters see [17].

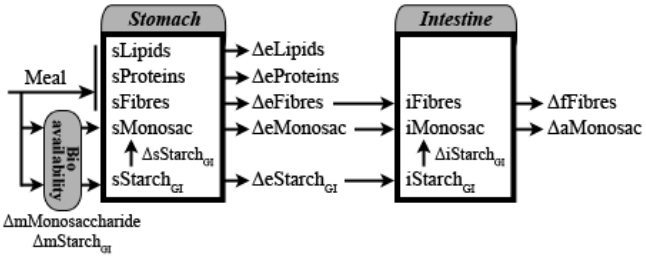

Figure 1. The process of absorption from mixed meals

The combination of these two models can support diabetics, using subcutaneous insulin injections, no matter if they have Type 1 or Type 2 diabetes [18]. The algorithm properly handles insulin and meal absorption overlaps, as for a longer-time prediction (6-8 hours), the absorption of the insulin and the glucose from food could be in progress during the next meal.

B. Parameter Identification Algorithms

We chose models with large parameter sets, which simulate the real life process efficiently. In the current phase of work, the parameters of the glucose absorption model is generalized for all patients, but these parameters should be investigated later as well. On the other hand, the parameters for the glucose control system are different for each diabetic. Some of these parameters can be measured by an intravenous glucose tolerance test [19], but is too complicated to be made for each person in a realistic outpatient setting. This is the main reason why we need model training methods.

TABLE I. MODEL SENSIBILITY TEST (RESULTS IN DESCENDING SENSIBILITY ORDER)

Parameter	Change % in results with the given parameter change %			Order
	5 %	50 %	200 %	
V_i (insulin distribution)	*5.46*	*50.23*	*145.09*	*1.*
K_{xgi} (glucose uptake rate)	*5.27*	*37.45*	*71.46*	*2.*
K_{xi} (insulin disappearance)	*2.25*	*22.38*	*82.57*	*3.*
T_{gh} (glucose uptake balance)	0.27	2.71	10.92	4.
V_g (glucose distribution)	0.26	1.80	3.61	5.
T_{iGmax} (insulin release)	0.07	0.74	2.91	6.
τ_G (insulin release delay)	0.01	0.08	0.33	7.

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The running time of the training algorithms depends on the number of the parameters to be trained. As the glucose control model has many variables, a model sensibility test was made to narrow the parameter set (Table I). This means that the training algorithm can run within the same time with fewer parameters to be trained and a wider search range. The results of this test showed that there are 3 parameters which have a significantly larger effect on the results than the others: K_{xi} (disappearance rate for insulin), K_{xgi} (glucose uptake by insulin-dependent tissues), and V_i (distribution volume for insulin). Thus we concentrated on these 3 parameters in the current phase, and they were trained with the methods as described below. For the other parameters, we used an average value suggested by the literature [14].

Two parameter identification algorithms were used. The first one is the Brute Force Algorithm (BFA) [20], which means a full search of parameters in a specific range. BFA analyzes all possible parameter sets within a specific range with the given stepsize. It is not optimal as the stepsize can be decreased ad infinitum, but the returned parameter values are almost perfect. The advantage of this method is its completeness, the disadvantage is the long running time.

The other method is the Genetic Algorithm (GA) [21]. GA simulates the process of natural evolution, using the tools of genetics like mutation and crossover. We used an open source library called GAlib [22] in a simple genetic algorithm with one point crossover. The fitness function of the GA was the sum of the differences between measured and estimated blood glucose levels.

These training methods themselves have several parameters, henceforth, we performed a test to find the best parameterization. We used 3 data sets including both Type 1 and Type 2 patients. Tables II and III show the results. The best BFA setting was BFA 6, where the stepsize was 0.5, the finding range was 3, and the average running time was 35 seconds. In GA's case, we chose the GA 6 parameterization with the population size of 40, the generation number of 20, the mutation probability of 50%, and the crossover probability of 90%. The high chance of mutation means a more stochastic algorithm. GA 1 was also used during the tests, with the population and the generation of 10, the mutation of 1%, and the crossover of 90%.

TABLE II. BRUTE FORCE ALGORITHM PARAMETER TEST BASED ON TOTAL DIFFERENCE IN MMOL/L

Data set	Base	BFA 1	BFA 2	BFA 3	BFA 4	BFA 5	BFA 6
D1	13.51	9.545	9.33	13.32	10.82	11.68	**9.33**
A1	177.94	171.65	161.80	155.41	155.41	159.09	**146.26**
B1	799.94	417.78	372.76	459.49	375.46	375.29	**375.29**

TABLE III. GENETIC ALGORITHM PARAMETER TEST BASED ON TOTAL DIFFERENCE IN MMOL/L

Data set	Base	GA 1	GA 2	GA 3	GA 4	GA 5	GA 6
D2	13.97	10.19	9.65	9.67	9.32	9.28	**9.18**
A2	552.90	430.37	430.99	419.86	417.71	**415.57**	415.66
B2	600.34	197.84	210.49	208.38	200.37	198.29	**196.41**

III. MODEL VALIDATION

The purpose of the validation is to test the prediction power of our algorithm. Accordingly, we used real life data from both type 1 and type 2 diabetics. We expected a significant improvement due to model individualization compared to our previous test using literature parameters [14]. The following subsections review the input data and the validation method.

A. Data Sets

During the tests, we focused on outpatients treated with subcutaneous insulin injections, which means ca. 26% of diabetics [23]. We had 7 different data sets of 5 persons, each one including at least 3 days of logging and 12 meals. We had a total of 101 meals and 24 days of input data. As Table IV shows, there were 3 Type 1 (T1D) and 4 Type 2 Diabetes (T2D) data sets. Four of the patients used the Medtronic CGMS and one of them (D) used an ordinary blood glucose meter. All 7 logs consist of insulin doses, meals, and blood glucose levels. A professional dietitian calculated the nutrient values for each meal using the hand written logs. Data sets A, B, and C are from the same patient in a controlled experiment, in which the meals were logged rigorously. This patient avoided any sport activities during the monitoring period. In contrast, for the Type 2 patients the meal log may contain inaccurate values as they were cured in hospital to adjust their inordinate glycemia and it was not possible to control if they consumed the same meals as offered in the menu. Moreover, sports were also compiled in their log, making the estimations more prone to error because currently the model can not handle this factor.

TABLE IV. INPUT DATAS

Data set	Type	Age	Insulin	Measure	Meals	Days
A	T1D	21	Apidra	CGMS	15	3
B	T1D	21	Apidra	CGMS	14	3
C	T1D	21	Apidra	CGMS	15	3
D	T2D	62	Humulin R	ordinary	15	6
E	T2D	78	Humalog	CGMS	14	3
F	T2D	61	Humulin R	CGMS	12	3
G	T2D	65	Humulin R	CGMS	16	3

B. Validation Process

The validation process consists of 3 phases. The first phase is the study of the model with parameters found in the literature [14]. We made meal wise tests, where the meals were treated as separate tests. This means zero startup blood insulin level and the model starts without any glucose absorption. In this phase, 2 hour, 4 hour, and 6 hour meal-wise tests were made to measure the correctness of the model in short-term and in long-term as well. We also made daily tests; one without model restarting and one with model restarting. This means that the estimated blood glucose levels have been set back to the measured value before each meal. This approach is a transition between meal-wise and daily tests, because the insulin and glucose absorption calculations

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are continuous, but the blood glucose levels are corrected to avoid stacked errors.

In the second phase, we performed model training, i.e., parameter identification. We made whole day tests with restart using the brute force method and the genetic algorithm according to the model training parameter tests is Tables II and III.

In the third phase, we restricted the training data used for the parameter identification to a single day of the log and we used the rest of the log to validate the model with the estimated parameters. We performed all tests mentioned above. Using only a part of the input data for training and the rest for validation avoids over-training and simulates the planned real application of the model in a lifestyle support software tool.

IV. RESULTS

The results were divided in two categories; all patients and controlled data sets. The first one is a simulation closer to reality, while the second highlights the changes in the model as it contains less false data. Test phase 1 (Table V) clearly shows these differences, because in the case of controlled data sets the results were ca. 20% better on average. This improvement for the good of the controlled measurement is caused by the more precise logging. We can also see that longer the time after the meals, the higher the error between measured and estimated blood glucose level. The all-day tests with restarts show a significant improvement in all of the results and the maximum error is also decreased by at least 3 mmol/l. Also, 62% of the errors were within a 3 mmol/l range, which is a promising result for a whole day measurement. This number is even higher (76%) in the case of controlled measurement.

TABLE V. TEST PHASE 1: DEFAULT PARAMETERS WITHOUT ANY MODEL TRAINING, AVERAGE VALUES IN MMOL/L (MM)

All patients		**Meal wise**			**Whole day**	
		2h	**4h**	**6h**	**No restart**	**Restart**
Average error		5.05	7.92	9.28	4.2	**3.3**
Max error		10.62	14.93	17.25	10.34	7.31
Ratio of error	< 1mM	34 %	24 %	21 %	22 %	32 %
	< 3mM	52 %	43 %	40 %	50 %	**62 %**
Controlled (A,B,C)		**Meal wise**			**Whole day**	
		2h	**4h**	**6h**	**No restart**	**Restart**
Average error		4.26	5.26	5.45	2.5	**1.88**
Max error		8.1	10.04	11.08	6.94	5.45
Ratio of error	< 1mM	34 %	26 %	23 %	29 %	37 %
	< 3mM	56 %	51 %	52 %	65 %	**76 %**

The "Brute Force" caption in Table VI means the BFA 6 parameterization, described in Section III. "Genetic Algorithm 1" means GA 6 and "Genetic Algorithm 2" means GA 1. With model training, the results show a nearly 25% improvement in average error, but the maximum error almost remained almost the same when model restarting was applied. With the brute force method, we could reach a ratio 50% for the errors within 1 mmol/l. This means that during a whole day half of the estimated values were in the error range of the measurement devices, i.e., 1 mmol/l, so they can be stated as perfect predictions.

TABLE VI. TEST PHASE 2: WHOLE DAY TEST WITH RESTART USING MODEL TRAINING, AVERAGE VALUES IN MM

All patients		**Brute Force**	**Genetic Algorithm 1**	**Genetic Algorithm 2**
Average error		1.81	2.18	2.54
Max error		5.83	6.8	7.82
Ratio of error	< 1mM	48 %	42 %	40 %
	< 3mM	79 %	73 %	71 %
Controlled (A,B,C)		**Brute Force**	**Genetic Algorithm 1**	**Genetic Algorithm 2**
Average error		1.51	1.64	1.68
Max error		5.24	5.49	5.64
Ratio of error	< 1mM	49 %	44 %	43 %
	< 3mM	86 %	83 %	83 %

The reason why model training on whole day tests have not been made is that we tried to create a real life simulation during test phase 3, where the calculated parameters were tested with the meal wise method. According to our proposal, the future software will make a parameter identification from a few days data flow and will estimate the blood glucose levels after each meal with the calculated parameters. To see how accurate this method is we used BFA 6 and GA 6 to estimate the parameters. Table VII shows the differences in the results to the default parameters. The improvement is not as significant as in Phase 2, but we can see 5% improvement in average error for GA 6 and an average of 10% for BFA 6.

TABLE VII. TEST PHASE 3: REAL USAGE VALIDATION FOR CONTROLLED TESTS, AVERAGE VALUES IN MM

Meal wise test (1 h / 2 h / 4 h)		**Default parameters**	**Brute Force**	**Genetic Algorithm 1**
Average error		1.9 / 3.9 / 4.7	1.8 / 2.4 / 4.5	1.8 / 3.7 / 4.7
Max error		4.7 / 7.4 / 8.8	4.2 / 5.1 / 8.3	4.4 / 7.3 / 8.6
Ratio of error	< 1mM	53 / 37 / 28 %	54 / 46 / 25 %	55 / 34 / 26 %
	< 3mM	79 / 58 / 51 %	80 / 71 / 53 %	80 / 58 / 52 %

A. Discussion of Results

The results almost fully confirm our expectations as the model training reached more than 20% improvement in the results. The improvement could be even higher with a longer training sample which was only one day in our current tests. We need more data logs for further tests.

Our results are not far from the best results published in the literature. Many other researchers used the Medtronic Guardian CGM system, which indicates that this is a state-of-art device to validate a blood glucose level prediction model. Likewise, in our validation, Stahl et al. [4] had the

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same difficulties with the high peak values and they reached 1 mmol/l error in 95% of the cases with 2-hour-ahead prediction. We reached 1 mmol/l error in 46% of the cases with a 2-hour-ahead prediction during controlled tests. We can still improve this result by handling long-term basal insulins, such as Lantus. We experienced that our model can not simulate these long-term insulins properly. The other remarkable result is by Shanthi et al. [8], where the average error was 1.11 mmol/l for 60 minutes prediction, while Plis et al. [9] reached 1.99 mmol/l for 60 minutes. Our best result is 1.8 mmol/l for this period of time with the parameter identification in the controlled measurement.

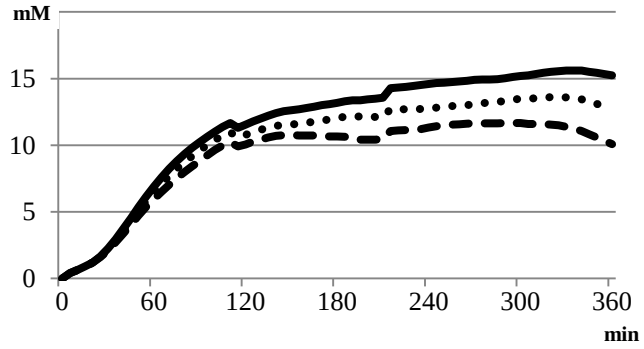

Figure 2. Average errors between measured and estimated values in time (solid line – default parameters, dotted line - GA 6 parameters, dashed line - BFA 6 parameters)

As it can be seen on Figure 2, the error is rapidly increasing during the first 2 hours, but the increase slows down between 2 and 6 hours. This shows that the long term prediction is stable but the difference between the measured and the estimated values is still too large. The graph also shows that the improvements of the model training methods are significant only after the first hour. As we expected, the Brute Force Method gives the best result and the GA is between the BFA and the untrained results.

V. SOFTWARE

A software tool has been designed to support the validation process (Figure 3). The main idea was to provide a useful user interface, which helps us to run the calculations, collect, and process the information. All the data are stored in a relational database. To make the data access faster and consistent for each person participating in the research we chose the PostgreSQL open source database. The patients are organized into groups for the purpose of distinctness by medical experiments.

For the implementation of the graphical user interface (GUI) we chose the Qt cross-platform application framework and the C++ programming language Exporting the results to PDF gives us the opportunity to share via e-mail or display on any other devices.

With the GUI, the user can select the proper episode of the patient, the start time, and the stop time. The tool lists all the meals, insulins, and measured blood glucose levels. The parameters of each algorithm can be modified before the calculation. After the calculation, the results are shown on graphs and tables. The algorithms also provide the optimized values of the parameters. All result are saved in the database for further analysis.

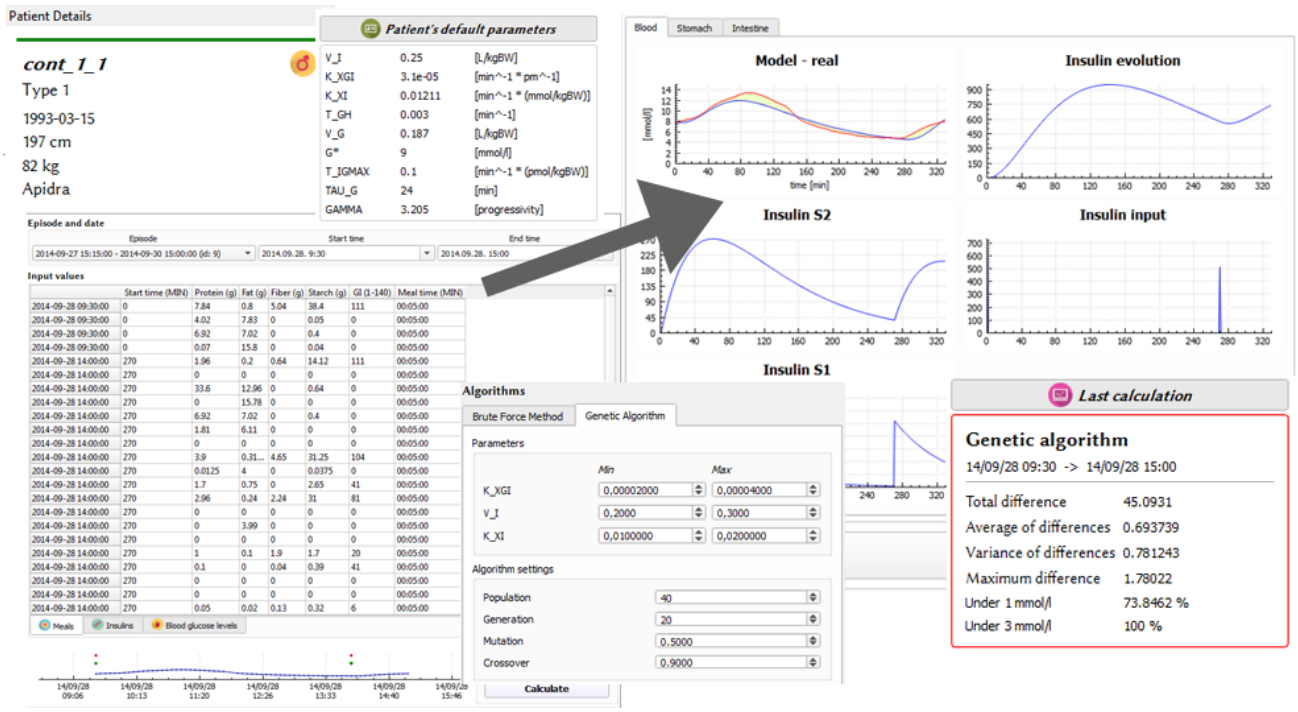

Figure 3. GUI of the software tool: input datas, output graphs and calculated results

VI. CONCLUSION AND FUTURE WORK

As for the difference between the controlled and all the data, we can state that a more precise logging is needed from the patients. To support this, we plan to create detailed manuals about the important events that should be precisely logged. A clinical study involving 20 diabetic patients will be made in the near future. Extending the 1 day model training period to at least 3 days should bring better results as well.

To solve the problems presented in section IV, future research is needed for:

- improving the currently used model training methods
- training the model with other parameter identification algorithms
- extending the model to support physical activity, stress, and weather changes.

The final aim is to decrease the average error under 1 mmol/l during the first hour and under 3 mmol/l during the first 4 hours. If the model proves reliable in clinical trials, it will be integrated into the Lavinia lifestyle mirror mobile application [24] developed at University of Pannonia [25].

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CallMeSmart Becoming Ubiquitous and Self-learning

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Abstract – **A novel system for communication between hospital doctors, CallMeSmart-doctor (CMS-Dr), earlier referred to as CallMeSmart, has been developed and tested at a university hospital. The first version of CMS was dedicated to doctor-doctor communication. In this paper we discuss how we based on CMS-Dr can establish a generic CMS solution: A fundamental new ICT infrastructure for all health care actors (not only doctors), and other actors and sectors with complex, temporarily and time critical communication patterns. The CMS-generic shall become Ubiquitous and Self-Learning (CMS USL). The technological CMS-USL solution will represent the internationally forefront of ICT-research and development through new combination of advanced data-based wireless communication that maintains context awareness, in addition to ubiquitous and self-learning machine mechanisms.**

Keywords – Context-awareness; wireless devices; mobile communication; Interruption management; VoIP; Machine learning

I. INTRODUCTION

Physicians' working conditions rely on mobility. They move frequently between in-patient ward, outpatient ward, emergency ward, operating theatres, etc., and they often do not stay more than a few minutes in the same location. High mobility requires mobile communication systems, which enables physicians to communicate with colleges at any time and place, to avoid any delay between the decision made and action taken. Such delays could result in medical errors [1], and mobile communication systems have been suggested as a solution to improve communication in hospitals [2]. The challenge when deploying mobile communication systems is to handle the balance between the increased availability and possible interruptions [3]-[5]. Most hospitals still rely on a mobile communication infrastructure with dedicated devices for each role, where pagers are the most dominant mobile communication devices.

Pagers provide a cheap and reliable way for contacting staff members. They are ubiquitous and several physicians carry numerous pagers simultaneously to cover the various work roles they have been assigned. Pagers suffer from a number of problems due to their simplicity. The most obvious limitation is that it requires the staff to locate a telephone (landline or wireless) in order to respond to a page. This might cause unnecessary delays and communication overhead, since the person placing the page is not always near the phone when the page is returned [6]. Pagers also create a large amount of unnecessary interruptions [7][8], which is unpleasant and can cause medical errors [1].

The most intuitive solution to improve the communication situation in hospitals is to provide physicians with wireless phones. However, phones can be even more interruptive than pagers [3]-[5]. In [3], a physician states that; "with a pager you just have to glance down at your coat pocket to see who is paging, while with a phone, you have to pick it up from your pocket to see who is calling. Having done that, it is easier just answering and explaining that you are busy" [4].

Preliminary studies points at a diversity of potential benefits from wireless phones in hospital settings, using both mobile text and voice services [6][9]-[11]. These studies also reveal potential technological limitations that can explain some of the challenges of gaining acceptance. Text-chat is a less obtrusive medium than other forms of workplace communication [12]. It is therefore unlikely that mobile text messaging creates the same amount of interruptions as mobile voice services. Improved asynchronous communication systems have in fact been recommended for improving hospital communication practices [2]. In addition to mobile synchronous communication systems, mobile text-messaging systems are therefore an interesting medium to explore in hospitals settings.

However, the current generation of mobile-text messaging systems is no suited for hospital environments. Studies of mobile text-messaging usage in hospitals have, revealed difficulties related to small screen size [10], and problems related to forcing doctors to carry an additional device [9]. It has to be taken into account that these studies are some years old. Today displays and keyboards are significantly improved, which might have changed the situation. A continual problem with mobile text messaging is that senders often need an acknowledgement that an asynchronous message has been read by the receiver [2]. The acknowledgement challenge could be solved by a forced feedback when the message has been opened. Automatic suggestions for replies may ease the difficulties with text-

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messages. It has been reported that predefined messages can meet up to 90% of the mobile text-messaging needs for some hospital workers [13].

Mobile communication systems for hospitals represent an important research area since hospitals are noted to suffer from poor communication practices. The combination of wireless phones and fact that hospital workers seam to exert interruptive communication patterns before non-interruptive methods [2][7][8] and often exhibit a "selfish" and interruptive communication practice, may result in unnecessary interruptions for conversations that otherwise would' not occur [14]. This amplifies the risk of overloading limited resources with special knowledge, experience, and the power of taking medical decisions. The balance between getting immediate access to resources and causing interruptions in moments where it is not appropriate, has similarities with the classical problems regarding collaboration and sharing of resources, such as of disparity in work and benefit, "prisoner's dilemma" and "the tragedy of the commons" [15]. A critical issue for voice services is the potential of make people "fatally available" [6], which cannot be overlooked since health care is a knowledge intensive activity where consulting colleagues or senior staff members is a necessity in many situations [16].

One way of attacking this problem is to provide the caller with context information from the receiver's situation. Context information could be any kind of information which helps to decide if the receiver is available or not, such as; location, activity, surrounding noise, role, etc. In a study by Avrahami et al. [17], they revealed that if the caller is provided with context information about the receiver's situation, it reduces the mismatch between the caller's decision and the receiver's desires.

A number of studies have focused on context-sensitive systems for hospitals. The work done on context-sensitive mobile communication within hospital settings has identified some important elements of context, including location, role, delivery timing and artifact location, and user state [18]. This model has been applied to an instant messaging system based on PDAs enabling contact based on these contextual elements. This approach, however, requires workers to carry additional mobile devices in order to support voice and paging services, since it is not compatible with existing hospital communication infrastructure.

A variety of models for detecting interruptibility have been created for stationary [19][21] and mobile settings [22]-[24]. In general, these models focused on office workers and social settings, and used information such as a user's calendar, interactions with computing devices, switches to determine if doors are open, accelerometers, microphones and motion sensors. Accuracy rates of approximately 80% to 90% have been reported for directly predicting interruptibility and user state, such as "standing" or "walking", and social context, such as "lecture", "conversation", etc. None of these models, by our knowledge, has been explored in health care settings, and there are several factors which suggest that new health care models need to be developed. First, studies on context-aware communication for hospitals suggest information not included in these interruptibility models, such as work role, are critical for detecting proper context in health care settings [18]. Second, another issue is elements, such as location and social relationships, that are inherently different within health care, and need to be accounted for in health care appropriate models. For example, scenarios such as "visiting patients", "in surgery", etc. need to be considered in combination with the work roles of the person initializing the contact and the contacted person.

In addition, appropriate forms for user-interaction on interruptibility models also need to be investigated. It has been reported that users tend to use the information provided about a person's availability for communication, as a presence indicator instead of using it to control interruptions. This suggests that automatic configuration of devices may be the most appropriate approach [25]. The "SenSay" context-aware mobile phone [23] uses a hybrid approach that automatically blocks calls, and also generates text messages notifying the caller that their call have been blocked. Then they are allowed to override the blocking by calling back within a predetermined number of minutes from the same phone number. This problem needs to be reinvestigated in health care settings, since there are some situations where certain calls should not be blocked (such as those for a specific role) whereas other calls may need to be restricted. Thus, the context of both the caller and person being called will need to be considered.

The use of semi-structured messages has shown to be particularly useful for work coordination [26]. Preliminary studies have estimated that up to 90% of mobile text-messages used by hospital workers could be met by the use of such messages [13]. However, we have not been able to find any published work on the style and function of such messages, nor any studies that demonstrate if they would actually be adopted, or if they would have any effect during real work practice. The possibility to create automatic replies, and suggestions for replies, is also an advantage when using predefined messages, but the appropriate replies have not been studied in the context of mobile-text messaging. This could be particularly useful within health care settings, since such replies actually offers acknowledgement when a message has been read [2].

The paper is organized as follows: Status of Knowledge, which will include state of the art and a section about Ubiquitous self-learning computing, methods, which will explain the different method approaches we plan to use, approaches and hypotheses, and then a section to conclude the project.

II. STATUS OF KNOWLEDGE

We know from earlier studies within health care, but also from our own studies [3]-[5], that physicians in hospitals are interrupted unnecessary by mobile devices in situations where such interruptions should be avoided. One of the problems applicable for most of the earlier systems developed was that they required both new devices and infrastructures, and/or were based on public networks, like GSM/3G, which in both cases require considerable investments. A system based on existing infrastructure and

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devices used in hospitals would be much cheaper, and will probably require less training and maybe less resistance from health care workers when introduced. This is important, since early studies show that over half of medical informatics systems fail because of user and staff resistance [27]. We believe that by knowing and understanding the health care workers' work situation, the nature of unnecessary interruptions, and also by involving the participants in the design process, it is possible to build a system suited for their communication patterns and work situations on top of an existing communication infrastructure using devices already in use at hospitals. Our studies [3]-[5] contributed to such knowledge, and were used as input when designing and developing the context sensitive system for doctor's mobile communication, CMS-Dr [28][29].

The CMS-Dr prototype focuses on context sensitive interfaces, middleware, and new interaction forms for mobile devices that support multi-modal communication in hospitals. These devices support media such as voice services, text-messaging and paging services, in an efficient and non-interruptive manner, as well as enable support for individual and role-based contact on a single device. That is, the user only needs to carry one device for both personal and role based communication, which enables other users to, for example, contact someone assigned as "on-call" duties at a specific department, even if they do not know who that person is. At the same time, it aims at balancing between availability and interruptions, while it enables acute calls and alarms be forced through. Currently, by our knowledge, similar devices are not generally available for internal communication systems in hospitals.

The prototype senses the context automatically from different sensors, calendar information, work schedule, etc., to change the physicians' availability and the phones profile, according to the collected context information. At the same time, the caller is given feedback about the physicians' availability, and thereby it is possible for the caller to force through an emergency call, or forward the call to another physician at the same level, that is available. The system is based on ideas from existing research on interruptions, in combination with our ideas presented in [4][30]-[34]. A first version of the prototype is ready and has been tested in lab-settings with physicians as test users. The tests were performed as scenarios observed from real situations. The feedback was positive and has been used as input for improvement and further development of the prototype. CMS-Dr prototype is ready for testing in clinical settings, and a pilot was launched in May 2014, at the Oncology Department at the University Hospital of North Norway (UNN). The solution has so far retrieved overwhelming enthusiasm and positive response from the test users.

A. *Ubiquitous self-learning computing*

Ubiquitous computing, also denoted as pervasive computing, calm technology, or ubicomp, was first described by Mark Weiner et al. [35] as a technology "*which informs but doesn't demand our focus, or attention*". The principles of this technology are [36]: The purpose of a computer is to help you do something else; The best computer is a quiet and invisible servant; The more you can do by intuition, the smarter you are; The computer should extend your unconscious; Technology should create calm. In 2009, Stefan Poslad proposed a Smart DEI model to describe the ubiquitous computing built around three layers [37]: Smart Devices, smart Environments and smart Interactions. Smart devices provide sensitive information in order to enable automated dynamic service delivery like sensors or smartphones [37][38]. A smart environment is "*able to acquire and apply knowledge about an environment and to adapt to its inhabitants in order to improve their experience in that environment"* [39] by using smart devices [37]. Smart interactions enhance the device communication, the human machine interaction by acquiring, and disseminating the information provided by the smart devices and environments [37]. By using these three layers, a ubiquitous computing system could be predictive, self-learning and provide decision-making services, as Weiner has proposed [40].

To realize ubiquitous self-learning computing for pattern recognition and analysis we will make use of machine learning mechanisms. Machine learning has had tremendous success in intelligent systems design and modern technology [41]. One example is the Kinect® full-body tracking system used on the Xbox® games console, providing real-time tracking of the human body using machine learning techniques. The key principle is for the machines to learn from data related to the task to be solved [42]. This enables flexible systems with the ability to adapt and update themselves based on input and corrections from their environments. At University of Tromsø – The Arctic University of Norway (UiT), there is a strong activity on machine learning, focusing in particular on information theoretic learning criteria [43]. This versatile approach has lead to several award-winning publications [44].

III. METHODS

Each step of the project is conducted in three phases, which are constructed in order to ensure that users are involved as much as possible in designing and evaluating the systems targeted by the project. The three phases are observations & interviews, scenarios, and prototyping & effect studies. The approaches will be used in a complementary and iterative fashion.

A. *Observation and interviews*

Creating technology that will work in practice requires a thorough understanding of how technology is used in the workplace. The project will use techniques from Computer Supported Cooperative Work (CSCW) including observations of actual activities, conducting interviews with users [45]-[49] and performing workplace studies. This methodology has recently been advocated for improving medical informatics research [50] and will be used in the project in order to construct preliminary scenarios to present to users during design sessions, and also to investigate qualitative aspects of prototype systems during use in real work environments.

 ISBN: 978-1-61208-384-1

B. Scenarios

A scenario driven approach to research revolves around analyzing specific scenarios and use-cases [51] and subsequently, building technologies in order to serve those use cases. Scenarios in design [52][53] emphasizes both technical and non-technical aspects of systems design. This is especially important when dealing with technologies requiring changes in large and complex organizations. Observations and interviews with workers while using prototypes may reveal information that can be used to define new scenarios worth investigating.

C. Prototyping

Prototype systems will be developed and tested, further developed and evaluated both in laboratory and in real settings. Prototypes will be used in order to demonstrate the feasibility of proposed technical systems, in order to conduct effect studies, and will be deployed during real work practice.

D. Effect studies

Studies analysing the effects of technology on users that are consistent with practices in human computer interaction and information systems will also be conducted. Alternative user-interface designs for example will be evaluated using metrics such as completion time and error-rates for specific tasks.

IV. APPROACHES AND HYPOTHESES

The first research challenge in this project is to generalise CMS-Dr for other professions within hospitals. The second research challenge is to make the system intelligent through pattern recognition, pattern analysis and machine learning (CMS-USL). The intelligence is necessary to identify and analyse the bottlenecks in interaction patterns, unclear interaction patterns, and for the CMS-system to adapt to changing interaction patterns. The interaction pattern in hospitals is under constant change; role changes, tasks changes and responsibility changes. For example, when new IT solutions are introduced, e.g., the new structured EPR system that will be introduced to around 80 % hospital-employees in Norway in 2015 and 2016, roles, tasks and responsibilities will changes as the structured EPR is introduced. Hospitals are complex organisations, but we believe that if we can get CMS to fulfil and adapt to hospitals complex and continually changing communication demands, it will be easier to generalize CMS to the usage in less complex organisations. Therefore, the third research challenge is to generalize the solution to fulfil the usage of CMS outside hospitals. The fourth research challenge is that health care workers need to manually search for needed patient information from EPR systems. The future systems should use context awareness to automatically find the needed information when appropriate, e.g., when the doctor approaches a new patient during his visit, this patient's EPR would automatically pop-up on the doctor's smartphone/tab.

The overall aim is to deliver all the resources required (human, materials, information etc.) for a specific process (e.g. heart surgery) at the right time, to the right person, in a just-in-time configuration. The overall research goals are (1) to establish new knowledge about automatic machine learning and user modelling for complex, temporarily and time critical communication patterns in hospitals and similar organization in which roles and responsibilities, and therefore also the communication patterns, change from time-to-time, and (2) improving intramural communication in a university hospital, which will be the test bed for this project.

For the latter, we will establish a generic CMS solution, a new ICT-research and communication infrastructure for all health care actors and for other actors and sectors with complex, temporarily and time critical communication patterns. This will require various theoretical and methodological approaches, including requirements engineering methods for ubiquitous systems [54].

V. CONCLUSION

The overall aim of this project is to develop a complete system for a specific process at the right time, to the right person, in a just-in-time configuration. To do this, we need to understand the complexity of the hospitals organization, their communication patterns, analyse the bottlenecks, and thereby adjusting CMS to fulfil and adapt to hospitals complex and continually changing communication demands. The interaction pattern in hospitals are under constant change, and it is therefore important for future systems to make use of context awareness to automatically find and include the needed information when appropriate.

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New Generation Advanced Analytics Tools in Medical Systems

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***Abstract*—Research on the opportunities to create tools for a new generation of advanced analysis is considered to be the most promising direction for investigation, which will enable the successful functioning of healthcare, for better treatment of patients at lower cost. So, today these tools are in the priority group. The paper presents a new project for defining a new generation of advanced analytics tools requirements, constraints, and tasks in medical systems.**

Keywords-e-Health; advanced analyses in medical systems; medical informatics.

I. INTRODUCTION

Since 2005, there has been an explosion of e-Health scientific publications and new surveys and new strategies funded by governments, as well as expansion of the themes within the framework of the European Union at the national and multinational level. At the same time the number of healthcare topics funded by the European Union has grown rapidly.

According to the European Commission e-Health Taskforce report 2007 [6], by the end of 2007, over 10% of jobs in Europe were in the healthcare sector and this sector generated over 9% of the EU gross revenue. According to COCIR, in 2010, the gross income of the companies of the e-Health sector amounted to € 2.5 billion and until the end of 2015, it is expected to rise to € 2.7 billion [8].

In the initial period (2007-2013), the e-Health researches were focused on a wide range of topics: from medical sensors and safety of the technologies to the legal aspects of the protection of medical data and information. The reason for this was the imbalance between the available IT infrastructure and its application - in 2005 Véronique Lessens [9] showed that only 2.3% of the hospitals had decision-making systems and only 18.7% had sustaining banks of clinical results and prescriptions. At the end of 2010, the cost of healthcare services increased and the main reason was the increase of prices for personnel and the increase of use of these services without substantial increase in the quality and accessibility of healthcare. This has set the objective to overcome the obstacles and after 2012 the European Commission [7] set new tasks and activities for research, development and deployment of a next-generation advanced analytics tools in medical systems. These will assist both the processes of administrative management of medical activities and the existing clinical practices.

The necessity and usefulness of the research for a new generation of advanced analytics tools in medical systems has been discussed at length in the last 2-3 years. Very indicative of this are the analyses of the IBM Institute for Business Value [1], Deloitte [2], McKinsey & Company [3][4], and Markets and Markets [5]. Other analyses are presented in the works of Nikolova at al. [10] and Tcharaktchiev at al. [11]. Some of these analyses together with the research of the archetypes applications for medical purposes [12] have led to the present research.

This paper presents the objectives of a new project, oriented to advanced analytics in medical systems. The aim of the project is to conduct an extensive research in the field of e-Health: a comprehensive study of the concepts and methods for a new generation of advanced analytics in medical systems. Research on the opportunities to create tools for a new generation of advanced analytics is considered to be the most promising direction of investigation, which will enable the successful functioning of healthcare, for better treatment of patients at lower cost. So, today they are in the priority objectives group. According to the available data bases, the first medical areas to be targeted are endocrinology (diabetes) and pulmonology (COPD).

The project objectives include: a research of the sources of medical and biological data; a research of the possibility to use information/knowledge about illnesses and their treatment in patients with similar symptoms; structuring the medical data and information following requirements for the methods of advanced analyses.

To achieve the objectives we will conduct research, develop and evaluate architectures of medical systems; new methods for processing, storage and modification over time of medical and biological data / information / knowledge will be developed; changes in the ways of gathering and integration of information in real time will be effected; applicability of mobile agents for semantic search across heterogeneous and distributed sources will be studied and developed; automatic and semi-automatic methods for imaging data structuring will be introduced.

The present paper is structured as follows: Section II presents the scientific objectives of the project; Section III presents the available current results; and Section IV is the conclusion.

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II. THE SCIENTIFIC OBJECTIVESOF THE PROJECT

The analyses of the development of the Healthcare Industry show the expectations of the society for higher service quality, better results and lower cost. This poses a number of serious challenges to this sector, since increasing expectations contrast with the evident critical shortage of resources. Considering the ongoing ageing of the population, each year the use of these resources increases on a daily basis. At the same time there is an increase of the number of chronically sick people, thus additionally limiting the available healthcare resources. Those challenges have led to the development of various approaches and solutions during recent years, the most widely spread being e-Health and Telemedicine. In the early phases of integration of those systems into the existing medical information systems the results have shown improvements in the performance indicators of the health system. These advantages have reduced significantly with the development of medical hardware/apparatus and the appearance of new approaches for patient treatment and tracking. This brings the issue of new paradigms for work with medical information. One of the most promising sphere of research is considered to be the exploration of the possibilities to create a new generation of advanced analytics tools which will allow healthcare to function successfully – the expectations are to improve the balance between the demands and expectations of patients and society, to optimize the use of existing resources, and to increase the ability to respond adequately to changes in medical systems and practices. In order to achieve this, the tools for advanced analytics have to be able to use the increasingly broadening range of information about the patient, thus allowing a much earlier medical and administrative intervention.

The existing academic studies focus only on individual aspects of the problem and most often they only cover a narrowly defined field of application. Corporate developments are oriented towards the possibility of renewal and development of old company systems, through integrating new approaches to collection, unification, search and processing of data, information retrieval and generation of knowledge. The most frequently reported result [2] is the identified impossibility to introduce substantially new tools for advanced analytics due to outdated design of systems of older generations.

The attempt for integration of databases in widely different medical fields, having different requirements for the examination and accompanying the patients, is also an uncommented element of such classes of systems and will represent an innovation.

A. *Heterogeneity, distribution, variability and interoperability of the data issue*

The existence of multiple databases, storing a variety of information, raises the issues of heterogeneity, interoperability, complex data structures, and integration.

The data are derived from various sources: internal (electronic health records, clinical systems for decision making, etc.) and external (laboratories, pharmacies, insurance companies, etc.). The data are in multiple formats (flat files, relational tables, text files, etc.) and they come from various geographical locations. Nowadays data sources include: data from websites and dedicated servers, social networking and blogs; remote sensors and measuring devices; invoices related to health care (both in unstructured or semi-structured formats); biometric data (medical images, blood pressure, etc.), unstructured and semi-structured data such as electronic health records, annotations, medical prescriptions, e-mails and paper documents. These are data with an extremely high degree of heterogeneity in respect to the type of the used data model, as well as the incompatible formats and nomenclatures of the values.

At the same time the data are highly decentralized, with a high degree of terminological variations, records specifics, data presentation formats and applications. This in turn is associated with problems when conducting manual search for specific data or information.

B. *The retrieval of semantic information from textual medical data*

Semantics is a science which studies the meaning or relationship of words, phrases or symbols. This determines the priority research on its use in the modern information systems, designed to work with large amounts of medical or biological data. This includes a research on the possibilities for access, capture, storage, search, sharing, transfer, analysis, and visualization of data, according to their size, velocity, variety and value.

The current systems work with very different medical or biological data. From the semantic point of view the most common operations are search and interpretation of big data. This is the lowest level of use of the semantic systems, leading to retrieval of information from data. The main problem is that the information is not generated to be appropriate for its end-user (the problems identified by the user's cognitive psychology are not taken into consideration). We must explore the possibilities to move to a new level, at which the information is used for retrieval of knowledge. When handling patient data, or studying the characteristics of diseases this will allow systems operations to be influenced by the specifics of the end-user. The expected result is that future medical systems using advanced analytics will be able to derive knowledge about successful approaches for treating a particular patient. They will be based on analysis of the decisions made by other physicians in similar cases.

The purpose of our work is to explore the possibilities of semantic retrieval of information and knowledge from textual sources (medical records, annotations, emails, blogs, social networks, etc.).

C. *Information extraction from unstructured data*

Modern non-invasive medical imaging techniques allow a generation of highly detailed anatomical and

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physiological information about the human body to be easily accessible. This information is usually represented by a sequence of high-quality medical images (slices) stored in specialized and non-standardized formats. In general, this information is two-dimensional (static images, such as chest X-rays), three-dimensional (3D reconstruction of bodies from a set of slices) and four-dimensional (information about changes of 3D structures in time, e.g., the fetus movies). In addition, a pseudo-colour may also be used as an additional procedure in order to extract specific information about the patient. All these data are unstructured.

An additional problem of the use of medical images as an information source is that often the images are subject to linear or non-linear distortions, shifts, rotations, scaling, etc. This determines the ineffectiveness of many of the existing algorithms.

All these problems reduce the possibilities to structure the imaging data. This is the base for improving the efficiency of the information retrieval process.

D. The use and analysis of biological data.

Bioinformatics is one of the fastest growing sciences in the 21st century and belongs to the so called "life sciences", covering the studies of the living organisms such as plants, animals and human beings. Prior to the era of bioinformatics there were only two types of biological experiments: in a living organism (*in vivo*) or in an artificial environment (*in vitro*). It is commonly assumed that bioinformatics is "*in silico*" biology, i.e., the biological experiments are realized through computer models simulated on silicon chips.

The potential of bioinformatics to identify useful genes resulted in studies of the changes of the normal cell activities in various disease conditions. It also let to the creation of new gene products like drugs and vaccines. All this has led to a paradigm shift in biology and in biotechnology. The existing science paradigms have changed and now the genome science research provides an opportunity to carry out scientific experiments using computer modeling and simulations in such areas as drugs and vaccines synthesis, genomics, gene therapy, the study of the evolution, etc.

A major challenge in the analysis of biological data is to offer an integrated and contemporary access to exponentially growing amounts of data in multiple formats, as well as efficient algorithms for their processing.

The purpose of the study is to investigate how to retrieve and how to integrate biological data and biological information in on-line medical systems and services.

E. Possibilities for integration of medical information

Organization, storage and maintenance of a huge diversity of medical and biological data remains a challenge due to the following factors:

- The volume of the data has been increasing almost exponentially in the last decade.
- New data types are emerging and new medical and biological concepts are being developed.
- There is no standardization in the nomenclature of the data.
- The data is most often stored in flat files and relational databases: about 70% of the data is stored in text format or as static images; the remaining 30% of data is stored in different types of databases, organized in indexed files or in specialized relational databases.

The strong decentralization of the medical and biological data, the considerable differences in terminology and the peculiarities of the generic data sources description, as well as the difference in format of data search queries requires automated procedures for databases integration to be developed. The aim is to achieve more than just retrieving and modifying of data because nowadays the professional performance in any field is increasingly dependent on accessing the proper data and information. This requires surveys which are comprehensive, easy to use and linked to the other databases so that they will provide the necessary data resources. The heterogeneity and decentralization require suitable methods to provide access to the actual data associated with a specific disease or a specific medical problem. This involves the integration of large and diverse databases / information / knowledge associated with different levels of performance.

The goal here is to investigate the platforms of advanced analytics, the input data formats and the systems analysis of big datasets and to propose a conceptual architecture for an advanced analytics system of a new generation in medical practice. The proposed architecture must provide an opportunity for design of an integrated and modern access to the exponentially growing amounts of data in multiple formats. The further exploration includes providing an access to a constantly updated representation of the accumulated knowledge in the medical field.

III. CURRENT RESULTS

At present, the project is in its first stage. This decreases the amount of current result. Nevertheless, some of the obtained data and achieved results can be summarized.

One of the main project goals is to propose requirements for the logical design of the new generation of tools for advanced analytics in medical systems, as well as recommendations for the limitations and capacities for generating new approaches for this category of tasks. To achieve this goal, our investigation starts from determining input/output data streams to/from hospital and hospital networking. As a generic source of raw data we use data streams in Sofia Medical University hospitals complex - the biggest Bulgarian hospitals complex.

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The study of the hospital information systems and their networking determines the following data/information/knowledge sources: medical staff computers, clinical workstations, microbiology, radiology, clinical laboratories, pharmacy, clinical databases (electronic medical records), patient computers, financial systems (billing, cost accounting), material management, administrative systems, research databases, library system, and educational resources.

The study of the input/output data streams has determined the following sources and consumers of data/information/knowledge: patients (home workstations), other hospital systems, other physicians, government healthcare systems (e.g., electronic medical records), pharmaceuticals regulators, insurance agencies, medical research groups/institutions, the Internet, other information resources/libraries/databases, vendors and providers of various types, and medical education centers (e.g., medical schools).

The heterogeneity and the distribution of data at this stage show that the main problems of multiple data sources are the following:

- Heterogeneity of names – different databases store the same values, but the names of the attributes given are different.
- Heterogeneity of relational structure – the composition of attributes in a complex structure is varies, but the stored values are identical.
- Heterogeneity of values – the method of presentation of values differs in different data sources.
- Semantic heterogeneity – according to the type of storage, different assumptions can be made about the data relevance, reliability and usefulness.
- Heterogeneity of the models of data storage – this raises the issue of transformation between models.
- Heterogeneity by time – different data are obtained at different times.

The reduction in number of all of these kinds of heterogeneity is important for investigation and evaluation of data variability and interoperability.

IV. CONCLUSIONS

The accumulation of large amounts of data in the process of examination of certain types of patients (especially those with chronic diseases) raises the problem of how to catalogue the obtained (often heterogeneous and dispersed) information, its machine processing in order to facilitate its understanding, as well as the ability to perform comparable and traceable measurements, especially in image (photographic) data. This calls for new research in the field of:

- analyses of medical images;
- text analyses based on given semantic criteria (most often for the purpose of real time processing);
- analysis of diverse types of clinical information to support the clinical decision making;
- comparative studies on the effectiveness of approaches and medical practices;
- predictive analysis, quality analysis of medical data and many others.

It follows from the above that the most important task for the creation of a new generation of tools for extended analyses is to analyse the modality of the various data, which in turn would allow the retrieval of information for specific diseases and the development of spatio-temporal descriptions for comparing the data and their modality. This would allow the development of new approaches which will facilitate the decision making process based on similarity between patients' data. Merging this information based on certain semantic features and generating new ideas for good medical practices will open up new vistas for patient treatment.

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Knowledge Management Framework for E-Healthcare in Saudi Arabia

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Abstract--In the last decade, the government of Saudi Arabia has given high priority to developing and implementing e-healthcare services and technologies. However, it has met a number of barriers in implementing its healthcare initiatives. This paper describes these barriers and proposes an e-health knowledge management framework to overcome these barriers by integrating developments from knowledge management with knowledge discovery techniques. This framework should assist in the delivery of competitive e-healthcare services and improve intellectual capital to provide smart health services in the country. The proposed framework will be applied to the domain of diabetes.

Keywords-knowledge management; knowledge discovery; Saudi Arabia, diabetes mellitus.

I. BACKGROUND

Eysenbach defines e-health as 'an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the internet and related technologies' [1]. According to the World Health Organization (WHO) e-health refers to'...the use, in the health sector, of digital data - transmitted, stored and retrieved electronically- in support of health care, both at the local site and at a distance'.

In the last few decades, the Saudi Arabian government has given a high priority to improve its e-health services. A number of new initiatives have emerged focusing on many aspects of healthcare, ranging from creating electronic files for patients, statistical monitoring of infectious diseases, connecting all hospital systems using technologies of cloud computing and monitoring the arrival of pilgrims and vaccines given to each pilgrim in their home country [2]. However, the implementation of these initiatives has been impaired by many problems outlined as follows (as illustrated in Figure 1):

- ***Non-connectivity of information systems***. Though some regional directorates and central hospitals are using information systems [3], there is no effort to connect these information systems in order to build up a national healthcare system [4].
- ***Lack of technical expertise and computer skills***. Computer skills of healthcare staff and professionals are deficient due to their lack of experience in using computer applications [5]. No guidelines are provided to handle electronic medical records (EMRs), and many complain about poor maintenance of computers and networks and slow computers and terminals.
- ***Failure of adoption Health Information Services (HIS).*** There are critical issues associated with planning and adopting HIS, and its implementation in Saudi Arabia; some of these are caused by the poor technical support and over running of time and budget [5][6].
- ***Human barriers.*** This problem has been considered as the major reason for failing to adopt health information systems in Saudi hospitals [7]. Human barriers include negative beliefs of healthcare professionals towards technologies and lack of trust by medical staff towards computer based medical solutions. Therefore, many medical staff resists the change from traditional to computer based healthcare services.
- ***Cultural barriers.*** Cultural factors contribute to the failure in adopting e-health because of limited human interaction [6]. Aldraehim and Edwards [8] explain that Saudi Arabian people are extremely influenced by their culture and therefore prefer physical interaction to virtual contact.
- ***Medication safety***. According to Aljadhey et al. [9], medication safety raises two major e-health issues. The first issue refers to communication gaps among healthcare institutions, which contribute to medical mishaps and patients' medical historical issues. The second issue is limited use of technology whose consequences occur in illegible handwriting. Computerised Provider Order Entry (CPOE) can solve this problem; however, this is being adopted slowly.
- ***Financial barriers***. Transmitting traditional paper medical records to electronic system can be very costly [10]. Such high expenditure, which needs to be spent on the adoption of IT in health, may lead to the slow uptake of e-health applications.
- ***Security and Privacy***. This focuses on the easiness in accessing EMRs of patients due to the fact that some medical records of patients can be disseminated to others without permission of the patient or the doctor [5].

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Figure 1. E-health Barriers in Saudi Arabia

This paper is structured as follows. Section 1 presents the background regarding e-health barriers in Saudi Arabia. Section 2 explains the role of knowledge management and knowledge discovery in healthcare. Section 3 introduces the proposed framework to overcome e-health barriers in Saudi Arabia. Section 4 presents brief information about diabetes mellitus, which is set to be the domain of our study. Section 5 summaries the directions adopted by this project.

II. KNOWLEDGE MANAGEMENT AND KNOWLEDGE DISCOVERY

Nowadays, patients and health practitioners are connected to hospitals, clinics and pharmacies; they share knowledge in order to reduce administrative costs and improve the quality of care. Although the focus tends to be on managing health records and interoperability of IT healthcare systems, knowledge management plays an important role in providing high quality and effective healthcare system. It also allows the capture, representation and dissemination of knowledge of healthcare professionals such as their strategies, practices and insights. This knowledge is the power that enables organisations and individuals to select the best actions and strategies [11]. Utilisation of best practices provides significant advantage for organisations in term of competition and efficiency. Individuals keep their knowledge in their brain and those individuals have the brainpower or intellectual capital that every organisation desires [12]. Furthermore, their knowledge helps identify current problems as well as achieve desired results [13]. Consequently, many top managers are recognising the importance of capturing and managing knowledge of its healthcare professionals and developing systems to improve their services.

Knowledge Management is a useful mechanism to capture the intellectual capital of organisations, and healthcare establishments, in particular, so that they can deliver the best quality of care. It can help healthcare professionals cope with the fragmented and distributed nature of medical knowledge, the challenges caused by information overload and the importance to access local knowledge in making clinical decisions [14]. Additionally, it can provide healthcare practitioners with educational and training initiatives in terms of professional development and changing environment preparation [20][21][22]. Finally, dissemination of medical knowledge and best practices enable social learning initiatives where evidences can be disseminated to clinicians, nurses, and other healthcare workers [23][24][25] at national and international levels as well as to rural areas.

Knowledge management can provide a dynamic process of capturing, storing, sharing and creating both types of knowledge, explicit and tacit [21]. Explicit knowledge is communicable in systematic language whereas tacit knowledge is obtained through experience and cannot be articulated [22]. Nonaka and Takeuchi [22] suggest that knowledge changes from explicit to tacit and vice versa in two dimensional learning environments through four processes, known as SECI, in the form of a spiral. SECI includes four modes conversion procedures: Socialisation, Internalisation, Externalisation, and Combination (as illustrated in Figure 2). Socialisation enables the conversion of tacit knowledge via interaction among individuals and can be achieved through shared experience. Internalisation enables converting explicit knowledge to tacit knowledge, while externalisation enables tacit knowledge to be converted to explicit knowledge. It makes tacit knowledge understandable and can be recorded or saved by visualising it in an explicit form. Combination is the process of 'systematizing concepts into a knowledge system' [22]; for example, people synthesise different sources of explicit knowledge through meetings, conversations and exchange of documents [16][27]. Nonaka concludes that knowledge is created continuously by restructuring the existing knowledge through the synergy of these four processes. However, a number of issues have been raised regarding Nonaka's premises; consequently, other models have been developed and/or extended Nonaka's basic ideas. For example, Nissen [23] developed the knowledge flows model to capture the organisational knowledge dynamics and added two further dimensions to Nonaka: life cycle and flow time. Harsh [24] proposed a third dimension which accounts for knowledge reusability and where technology and human interaction can play a significant role in management of data, information and knowledge.

Figure 2. SECI Model [22]

Yao et al. [25] argue that SECI assumes that the only source of corporate knowledge originates from the staff within the organisation. In the healthcare sector, patients as well as healthcare workers contribute significantly to knowledge creation and knowledge sharing. Furthermore, tacit and explicit knowledge are not only embedded in people as new knowledge can also be extracted from external sources such as data, databases, and documents. These can be analysed in order to discover new knowledge. Knowledge discovery is another emerging discipline aimed at identifying valid, novel, understandable and useful patterns in data, texts, images, and other media [26]. It uses statistical and artificial intelligence techniques to analyse and process large amount of data [27]; it should be without or at least less human intervention [28]. Data mining is a subfield of knowledge discovery which discover novel and valid trends/associations using machine learning techniques [29]. Typical applications of data mining in healthcare include monitoring high risk of diabetic individuals so that appropriate messages can be communicated to them [30], predicting length of stay of patients with spinal cord injuries [31], and predicting hypertension from patient medical records with eight other diseases [32]. According to Berger and Berger [33] data mining is a useful approach for dealing with the rapid expansion of medical knowledge and healthcare data.

Whilst knowledge discovery can support the discovery of new knowledge from patients' healthcare data, knowledge management provides a forum to share and disseminate this new acquired knowledge and to combine it with the explicit and tacit knowledge acquired from healthcare practitioners. Such integration can address some of the problems discussed above and improve the quality and performance of healthcare services. Furthermore, it can assist healthcare organisations in making strategic effective decisions [34]. Hwang et al. [35] demonstrate how association rules can be applied to extract knowledge from patients' medical records along with medical rules of tumor associated diseases to develop guidelines for clinicians. These guidelines could be then shared among healthcare practitioners through a knowledge management system and deliver a better quality care to patients.

III. E-HEALTH KNOWLEDGE MANAGEMENT FRAMEWORK

It is important here to recognise that despite significant advantages in applying knowledge management in the healthcare sector, there are a number of barriers primarily caused by the absence of clear knowledge management strategy related to deficiency of effective team working, cultural barriers, poor IT infrastructure, degree of sectorial professionalisation, and political conflicts [41][42][43]. Finn and Waring [39] illustrated the importance of effective team working and stated that 'architectural knowledge' is fundamental for efficient team practice to ensure the delivery of safe and effective care to patients. As mentioned earlier, cultural barriers play also a negative role as some cultures do not encourage knowledge sharing; this constitutes an obstacle to knowledge management processes [40]. The healthcare sector tends to be mono-disciplinary and relationships of professionals within this sector are highly standardised, hence there is a resistance among doctors to share their findings and initiatives [37]. Strong governmental regulations and political and management conflicts can also hinder knowledge sharing among healthcare practitioners [41]. Guven-Uslu [38] described the clinician-managerial conflict as one of the important obstacles; the priority of managers is to minimise cost whereas the first priority of clinicians is to provide best care for patients.

To address the above issues, we propose a holistic framework approach to the healthcare knowledge management; this approach is still inspired by the SECI model of Nonaka, we are aware of the critical issues associated with the two dimensional approach to knowledge management. One of those issues is that the SECI model is embedded within the Japanese context. Saudi Arabian cultural is strongly influenced by the Arabic culture which should be taken into consideration when applying the SECI model of Nonaka and Takeuchi [23][42]. This framework is primarily designed to address some of the barriers highlighted above from four perspectives: Business, Human, Financial and Technology. By integrating knowledge discovery into knowledge management we aim at identifying, extracting and organising tacit and explicit knowledge related to problems and solutions from multiple sources and at providing a forum for generating and sharing consistently new knowledge by linking tacit and explicit knowledge to a specific medical domain and its literature. The proposed framework, referred herewith as e-health knowledge management system, is tailored initially to address the healthcare issues in Saudi Arabia and is focused on a specific medical domain (e.g. diabetes mellitus) to evaluate its viability and performance.

This section describes the four components of our framework (as illustrated in Figure 3). The Business component focuses on organisational issues and aims at extracting and managing the barriers associated with the failure of adopting health information services and medical safety such as poor technical support and unrestricted access to medications.

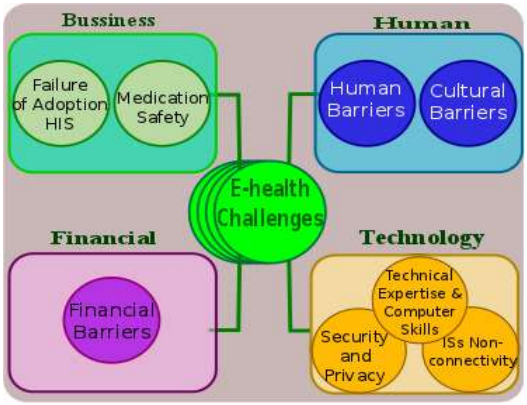

Figure 3. Components of e-Health Knowledge Management System

The Human component deals with the human barriers in relation to the use of technology from the healthcare workers and the cultural barriers from the patient perspectives; this will address the negative beliefs of healthcare professionals and patients towards the use of virtual contact and interaction with technological devices. The role of patients in the process of knowledge production and the computing skills of both, the healthcare professionals and patients, are critical to the success of our framework. To this end, the Technology component manages the non-connectivity issues and focuses on the technical expertise and computer skills, security and privacy issues. This component includes training aspects to address the limited/lack of computer skills among healthcare staff and professionals and their patients. Finally, the Financial component attempts to elicit the constraints and policies associated with the implementation, maintenance and monitoring of healthcare information services, namely the high cost of transmitting from traditional patients' paper records to electronic records. The proposed framework will elicit some of these problems and propose solutions (as illustrated in Figure 4).

Elicitation of problems and solutions will be accomplished through interviews and protocol analysis, and others via simulation and personal construct theory. Also card sorting will be employed to elicit the problems and potential solutions in order to promote best practices. The Saudi e-health data elicited from the four components will be then further analysed using machine learning techniques to elicit best practices and strategies.

Similarly, patients' data will be mined to extract useful trends and associations to improve the healthcare services. The acquired knowledge from these four components will be then represented into a knowledge management system, which will provide relevant knowledge to healthcare professionals who may be seeking or sharing best practices, strategies, guidelines and policies, and to patients who need to contact specific healthcare services or professionals for advice or help.

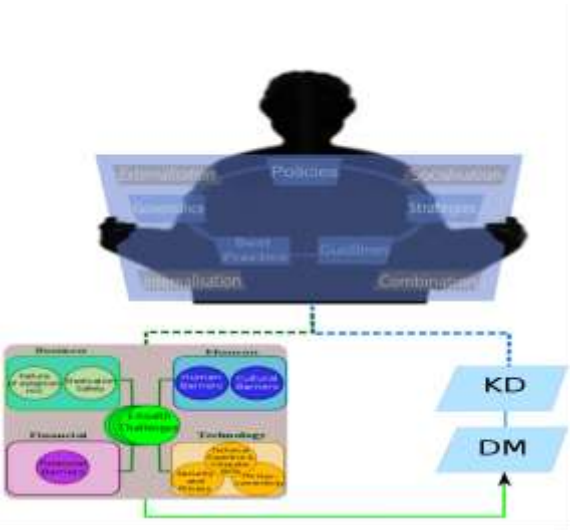

Figure 4. E-health Knowledge Management System

The proposed system will also provide access to academic papers related to specific problems to support healthcare professionals.

IV. DOMAIN OF APPLICATION

Diabetes mellitus, which is one of the highest chronic diseases in Saudi Arabia that affect patients from different genders, ages and weights, is to be used to validate our proposed framework. It can have severe complications such as stroke [47][48], heart attack [44], heart failure [45], kidney failures [44], Alzheimer disease [46] and mortality [47].

It is estimated that 382 million people have diabetes in the world, and by 2035 this will rise to 671 million. There were 3.6 million cases of diabetes in Saudi Arabia in 2013 [48]. According to Shaw, Sicree, and Zimmet [49], the prevalence percentage for diabetes mellitus in Saudi Arabia was 16.8% among adults in the ages of 20-79 years old, and it is expected to reach 18.9% in 2030. Over 96% of all Saudi medical healthcare budgets are attributed to diabetes by Saudi citizens and 4% incurred by non-Saudi nationals. The national healthcare financial burden has reached $0.87 billion, excluding (i) indirect costs such as absenteeism, lost productivity, unemployment from disease-related disability, lost productivity due to early mortality by disease, and (ii) healthcare system administrative costs, cost of medications, clinician training programs, and research and infrastructure development [50]. The proposed framework will include the financial costs and its impact on human and barriers components into the framework. It will also attempt to overcome the barriers by utilising technology components.

A number of data mining applications have focused on diabetes. For example Meng et al.[51] produced a model to detect diabetes using 12 risk factors and Chang, Wang, and Jiang [52] uses risk factors to identify hypertension and hyperlipidemia. Suh et al. [53] developed the WANDA system to remotely help monitor blood glucose, weight, and blood pressure. HealthOrg is an application to monitor high risk diabetic individuals so that appropriate message can be communicated to patients [30]. Roch et al. [54] recognise the need and the challenges that healthcare professionals and researchers face in developing a much needed comprehensive knowledge management support system for diabetes care. To the best of our knowledge, no integration of data mining and knowledge management for diabetes has been attempted.

V. CONCLUSION

Knowledge management and knowledge discovery are well developed research areas. However, the review of the literature has shown that there has been no systematic attempt at integrating them to address critical healthcare issues. The aim of our research project is to bridge this gap in order to improve the healthcare services and provide a forum for healthcare professionals to deliver the best healthcare to their patients. The first stage of this research will focus on the barriers associated with the healthcare of diabetes mellitus in Saudi Arabia. To this end, a survey is

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being undertaken to identify the current barriers and problems regarding e-healthcare faced by diabetic patients, healthcare professionals and IT specialists. This specific domain will be used to validate the proposed e-health knowledge management framework, which is ambitious in its approach. The proposed system is designed to support the recent government initiatives of the Saudi Ministry of Health in improving the national healthcare of its citizens.

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Document-Driven Care Pathways Using HL7 CDA

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***Abstract*—We describe the use of HL7 CDA documents for representing and driving the execution of care pathways in the open source cityEHR health records system. The method is illustrated using example pathways for electronic pre-operative planning, at the University Hospital of North Norway, and for an osteoporosis treatment, at the Nottingham University Hospitals in the UK. Both have a requirement to involve patients in telehealth consultations prior to attendance at the hospital. Template HL7 CDA documents are created using simple tooling (spreadsheets) to model the care pathway. The template document is then instantiated with data from a specific patient encounter to start the pathway. As the pathway progresses, the document is updated to reflect the current status of tasks and actions; once the pathway is completed the CDA document is stored permanently in the patient record, as the history of the pathway and its execution.**

Keywords - HL7 CDA; care pathway; ontology; clinical document; pre-surgical planning.

I. INTRODUCTION

The cityEHR [1] is an open source health records system that uses ontology models to define the structure of the clinical record, following the high-level recommendations of the ISO 13606-1 [2] model and the HL7 Clinical Document Architecture (CDA) [3].

Clinical data are gathered through messaging from external systems, or entered by users as forms or letters. All data are stored as clinical documents in the Extensible Markup Language (XML) [4], using the HL7 CDA standard. This contrasts with EHR systems in which data are stored in a relational database; the rationale for storing as CDA documents is that health records are primarily records systems, incorporating longitudinal data sets and repeated observations of the same data on multiple occasions, rather than normalised data repositories.

Here we describe the modelling of care pathways as clinical documents using CDA, so that they are specified, processed and stored in the patient record in a similar manner to any other clinical document.

Integrated care pathways have been defined as "structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem" [5]. This definition matches clinical practice, and is a useful basis for the implementation of executable pathways in electronic health records systems.

Closely related to integrated care pathways are clinical guidelines, which seek to recommend best practice in clinical care based on the current evidence, and clinical protocols. Clinical protocols are procedures that define how guidelines, and other best practice, should be implemented at a local level. Many approaches have been proposed and adopted for the representation of pathways, guidelines and protocols, but relatively few have been part of an operational health records system, as concluded in systematic reviews by Gooch & Roudsari [6] and by Loya et. al [18].

The study by Wakamiya and Yamauchi [7] identified seventeen standard features of electronic care pathways, and recommended three features to be considered as the most important: adaptable checklists, measuring variance (of the pathway as performed from the original library version), and recording statistics.

We set out the objectives for our approach to modelling care pathways in Section II and describe the representation of pathways in Section III, including references to the literature on alternative approaches. Section IV describes how a pathway, once expressed as a CDA document, can be progressed in an operational EHR system, from inception through to completion. We then present, in Section V, some examples of out approach for modelling pathways in the context of telehealth and draw our conclusions on the effectiveness of the approach in Section VI.

II. OBJECTIVES

Several key drivers led to the consideration of HL7 CDA as the format to represent care pathways. The cityEHR system uses an ontology-driven modelling approach [8] to create a data dictionary which includes data entries, elements (as per the ISO 13606-1 model), and a specification of how entries are combined into sections of compositions. Each composition corresponds to an HL7 CDA clinical document. For the purposes of the cityEHR, these documents can be

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messages (from external systems), forms, or letters. In the future, they may also include orders and prescriptions.

Our research question was to determine the feasibility of using HL7 CDA to specify, execute and document integrated care pathways.

The objectives of our approach were therefore to:

- model care pathways as clinical documents;
- use the same HL7 CDA model as all other clinical documents in the system;
- design user interaction with the pathway that was integrated with other actions on clinical documents;
- store completed pathway documents in the record as a history of the actions completed;
- use that historic record to show the variance of any completed pathway from its original library version.

Implementation of the functionality to meet these objectives has been informed by previous studies, methodologies for representing pathways, and guidelines, most notably the Guideline Interchange Format (GLIF) [9], the guideline modelling language PROforma [10], and the ontology-based approach described by Daniyal et al. [11].

III. CARE PATHWAYS AS CLINICAL DOCUMENTS

A *Clinical Documents in cityEHR*

The cityEHR has a basic architecture for clinical data that includes components from the ISO 13606-1, and HL7 CDA standards. Using this architecture, an information model is created for each specific clinical application. This model defines a data dictionary of entries and elements, together with a specification of how those entries are grouped into sections and compositions. Hence, a form for entering clinical data is represented as a composition that consists of sections (with sub-sections nested to any level), entries within sections, and elements within entries.

The architecture, and the specific information models built from it, are represented as ontologies using the Web Ontology Language (OWL/XML) [12]. The information model is used to generate a runtime configuration for the system, including template CDA documents that are used for forms and letters created by user through a web-based interface. Once completed, the CDA documents are stored in an XML data store as a persistent record for each patient; while in progress, forms and letters can also be stored between user sessions so that they do not need to be completed in a single session, and can be worked on collaboratively by more than one user.

Extensions specific to cityEHR allow for conditional display of sections, entries or elements, calculated element values, default values, and constraints expressed using the standard XPath language [13]. XPath has various built-in functions, and can reference data in entry/element pairs in the historic record, or in the current clinical document.

B *Care Pathways as HL7 CDA Clinical Documents*

Care pathways, in cityEHR, are modelled as clinical documents, adopting the same approach taken for modelling forms or letters. A pathway is a CDA document, containing sections (nested to any level) and entries, as shown in Figure 1. Sections correspond to tasks in the pathway; entries correspond to individual actions. Hence, the pathway is represented as a hierarchical decomposition of tasks and sub-tasks, with actions forming the leaf nodes of the hierarchy.

The XML structure of a CDA document is ideal for representing the hierarchical decomposition of tasks in a pathway, and the processing of the pathway can take advantage of some general properties of XML as a hierarchy of document nodes, in which parent nodes have child nodes which are an ordered set of siblings.

We have used the term 'action' to denote the atomic unit of activity in the pathway, since this meaning is most widely adopted in the modelling of pathways, and guidelines (for example, in GLIF [9], and PROforma [10]). In more general representations of workflow processes, such as the Business Process Execution Language (BPEL) [14] and the Unified Modelling Language (UML) [15], the term 'activity' is used. In our CDA documents, an action is modelled as an entry which is an HL7 Act, so the terminology is quite consistent.

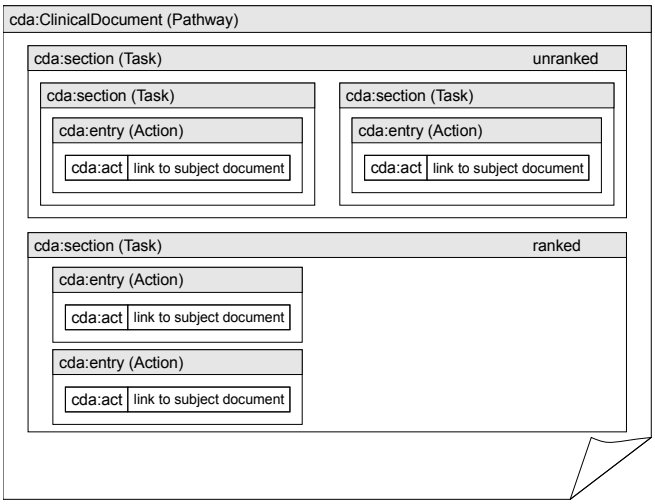

Figure 1. Care pathway as an HL7 CDA document.

Although the importance of hierarchical decomposition of processes is acknowledged in BPEL (as structured activities), and in GLIF, no distinct terminology is used for tasks that can be decomposed into a set of actions. In PROforma, an action is modelled as being a sub-type of task, rather than as having a containment relationship, hence our use of the term 'task' is not consistent with PROforma.

In cityEHR, a task is a section in the document that can contain any combination of sub-sections (tasks), or entries (actions). Sections can be designated as being 'ranked' or 'unranked' (cityEHR extensions to HL7 CDA), which for forms and letters define how the contents of the section should be laid out (vertically or horizontally), but for pathways also define the order in which tasks and actions should be performed (sequentially or concurrently).

An action is performed by a user outside the pathway by completing a form (for clinical data entry and/or review), writing a letter, or completing another pathway. Each of

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these three types of actions has an associated clinical document (form, letter, or pathway) as its subject which is completed by one or more users, and then stored in the patient record; when the subject document is completed and stored, its associated action is completed in the pathway.

C Decisions and Looping

Decisions in the pathway (conditional progression of alternative branches) are modelled in cityEHR by attaching conditions to sections, and entries, in exactly the same way as other clinical documents. When used in forms, or letters, these conditions determine whether the section, or entry, is displayed to the user; for pathways they also determine whether the task or action is performed.

To model loops in the pathway (repeated branches of progression), the repeated branch is created as a separate sub-pathway which is performed as the subject of an action in the main pathway, and includes an action which performs the sub-pathway itself. The loop will continue until a condition on that action in the sub-pathway evaluates to 'false'.

IV. PROGRESSING THE CARE PATHWAY

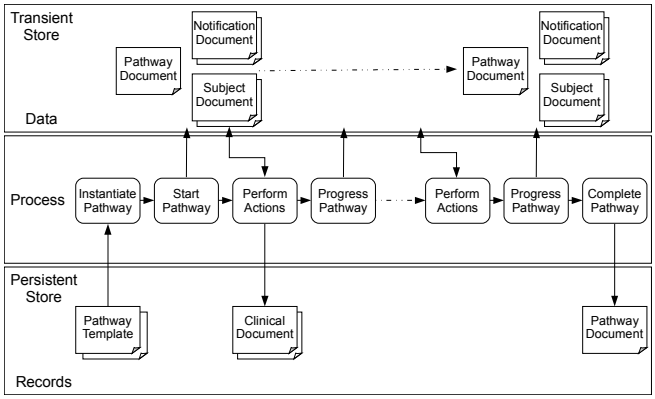

Figure 2. Automatic progression of the care pathway.

A Automatic Progression

Tasks and actions in the pathway have a status that can assume one of four values:

Charted;

Triggered;

In progress;

Completed.

All tasks and actions start in the 'charted' state (equivalent to the dormant state in PROforma) and progress through to the 'completed' state. A pathway is completed when all its top-level tasks are 'completed'; at this point every task, and action, in the pathway also has the status of 'completed'.

A task is 'in progress' when any of its contained tasks or actions are 'in progress', and is 'completed' when all its contained tasks and actions are 'completed'. Each action has an associated subject document, and is 'completed' once that document is completed and stored in the patient record.

The 'triggered' state extends the set of action states in PROforma, and is required because specific processing is needed to move the status of an action from 'triggered' to 'in progress'. The sequence in which tasks and actions are triggered is determined by the document order of the corresponding sections and entries in the pathway. A task or action can only be triggered when its parent task (i.e., the task that contains it) has progressed to 'in progress'.

For an 'unranked' task, all its immediate children in the document hierarchy are triggered as soon as the parent task is 'in progress'. For a 'ranked' task, each child is triggered when it has no preceding siblings (i.e., is the first child), or once its preceding siblings have all been completed.

The progression of the pathway begins when the user selects a new pathway from the templates available in the data dictionary. The template CDA document is loaded, and the CDA header is instantiated with the demographics data for that patient. The user interaction in cityEHR uses the XForms standard [16] which is a useful way to implement web-based forms. In XForms, there is a clear separation of concerns between the model in XML (the CDA document in this instance), the view in XHTML, and the user controls (e.g., controls for data entry, drop-down selection, etc.).

The recursive nature of the triggering of tasks/actions, and the completion of tasks, can be managed by binding of the status attribute on XML elements for cda:section and cda:act. Hence, triggering and completion 'bubble' through the document without the need for recursive function calls.

Once loaded, the user can review the pathway and adapt it to the current clinical context before starting it. On start, each of the triggered actions results in two documents being created in the transient data store for the patient. The first is the HL7 CDA document required as the subject of the action (i.e., a form, letter or pathway to be completed); the second is a notification document (also HL7 CDA) which holds details of the user role designated to perform the action, and the timing of the notification to those users (can be immediate or with a specified time delay). The pathway document itself is also stored in the transient store; the pathway is now 'in progress' and can be accessed by other users. The relationship between the pathway, subject and notification documents is shown in Figure 3.

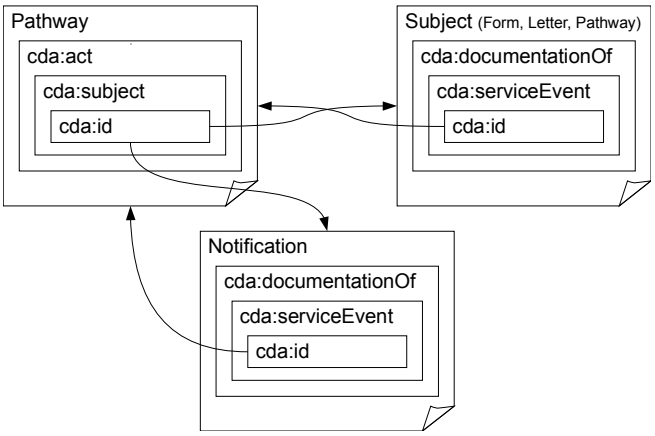

Figure 3. Linking pathway, subject and notification documents

Users perform actions by completing the associated subject document, which can be accessed by several means. Firstly, it can be accessed directly from the pathway by clicking on the action; the subject document will then be loaded in place of the pathway document. Alternatively, the subject document is also shown in the list of 'in progress' documents of that type, whenever any user views the record for that patient; it can then be loaded directly from there.

Finally, subject documents can also be accessed through the user's "In-Tray". This is a user-centred, cross patient view which shows the list of all notifications that are targeted at the role of the current user. The user can click to view the details of any notification, and can then move directly to the record for that patient, to access the subject document.

When any document is completed, and is stored in the patient record, a check is made to see whether it is the subject of a pathway action. If it is, then that pathway is immediately loaded, causing its automatic progression. On load, all 'in progress' actions are checked to see if their subject document has been completed, which will in turn complete the action. These then bubble through to complete applicable parent tasks and trigger any subsequent actions.

B Manual Progression

A user can adapt a pathway before it starts, or while it is in progress, by setting the start time of actions, changing the role of user performing an action, or forcing tasks or actions to complete.

With the pathway document loaded, the user can make any of these changes, and then commit them to the pathway document, by selecting a manual progression. The status of each task and action is held in a 'session status' attribute for the duration of the user session. On load, the session status attributes of each task/action is set to the status as recorded in the pathway document. The session status can then be changed by the user, with any consequent changes to completed tasks, or triggered tasks/actions, bubbling through the document. The following changes can be made:

- Tasks can be 'completed' from 'charted' or 'in progress' states and can revert from 'completed' back to the committed status;
- Actions can be 'completed' from 'charted', 'triggered' or 'in progress' and revert back to 'charted' or 'in progress'.

This means that a 'completed' task, or action, may gain that status through automatic progression when actions are completed by users, or through manual progression as the pathway is adapted by a user. Hence, the result of a completed task or action is recorded in an attribute which takes one of the following values:

- Completed - the task or action was completed after users had completed the subject documents associated with the charted action(s);
- Skipped - manual progression to 'completed' from the 'charted' state;
- Aborted - manual progression to 'completed' from the 'in progress' state.

V. EXAMPLES OF DOCUMENT-DRIVEN PATHWAYS

We illustrate our approach to document-driven care pathways using two examples; one for electronic pre-operative planning at the University Hospital of North Norway (UNN), the other for an osteoporosis treatment at Nottingham University Hospital in the UK. Although based on clinical practice, both have been adapted here for the purpose of illustration. Care pathways are often documented as flowcharts and there have been some efforts to formalise this representation using UML Activity diagrams [17]. We have chosen to show the two examples using this familiar visualisation.

In contrast, the cityEHR models pathways as HL7 CDA documents through a multi-stage process that starts by using a spreadsheet to specify the pathway with its constituent tasks, actions, and conditions, as part of the full information model for the application. This model includes the data dictionary of clinical entries and elements, together with the forms, letters, and pathways used in the EHR. The spreadsheet is saved as XML, transformed (using XSLT, the Extensible Stylesheet Language for Transformations) to an OWL/XML ontology, as the base representation, and then further transformed to a set of HL7 CDA XML documents.

A Pre-Surgical Planning

Our first example is a pathway for electronic pre-operative planning at UNN (Figure 4).

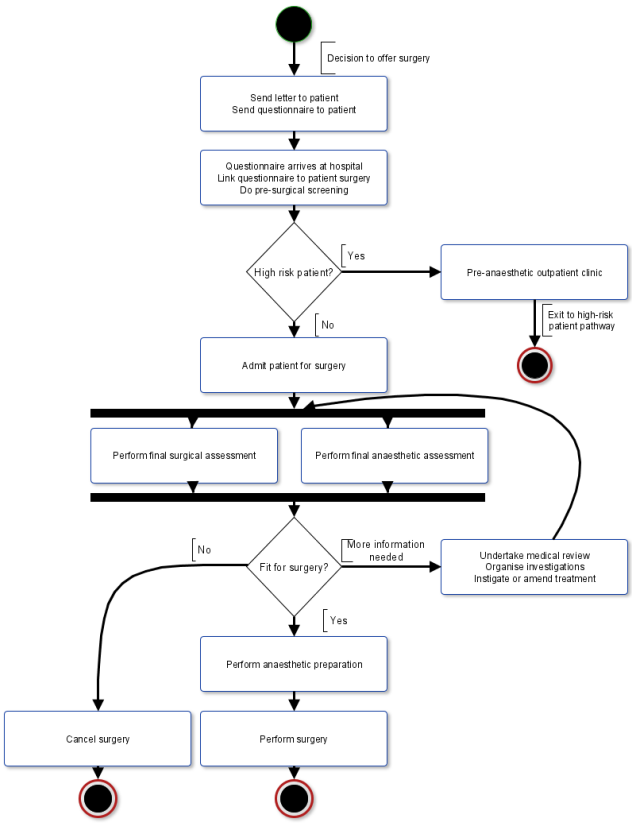

Figure 4. Pre-operative assessment as a UML Activity Diagram

Patients provide information for assessment before attending the hospital, and then undergo separate surgical and anaesthetic assessments. Following these, the surgery may be cancelled, may proceed or the patient may undergo further assessment and/or treatment, before being reassessed for surgery. For modelling, this pathway is interesting, since it includes concurrent progression of two main assessments, and a decision point, with three possible outcomes.

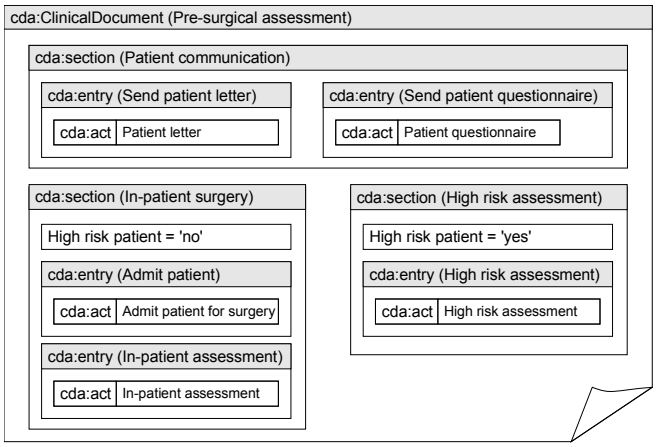

Figure 5. Pre-operative assessment pathway as an HL7 CDA document

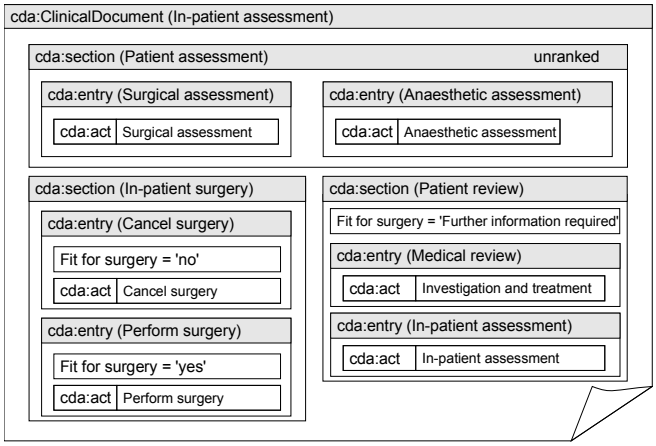

Figure 6. Sub-pathway for In-patient Assessment

When modelled as HL7 CDA, the pathway is split into three documents; one for the overall assessment (Figure 5), one for assessment as an in-patient (Figure 6) and one for further assessment of high risk patients (outside our scope).

B An Osteoporosis Treatment

Our second example is a pathway for an osteoporosis treatment at Nottingham University Hospital in the UK. This forms part of the ORCHID system [8] which is designed to gather data in routine outpatient encounters, both for clinical care and for secondary use in clinical studies, linked to samples in the local biobank. The pathway (Figure 7) covers a bone health assessment with various outcomes, including denosumab treatment, which is the focus of our example.

When modelled as a CDA document (Figure 8), this pathway is split into two, allowing for repetition of the denosumab treatment. Three consecutive decision points, at the start of the pathway, are combined into sets of conditions on the possible branches of progression, and the data required to evaluate those conditions are reviewed on a single form at the start.

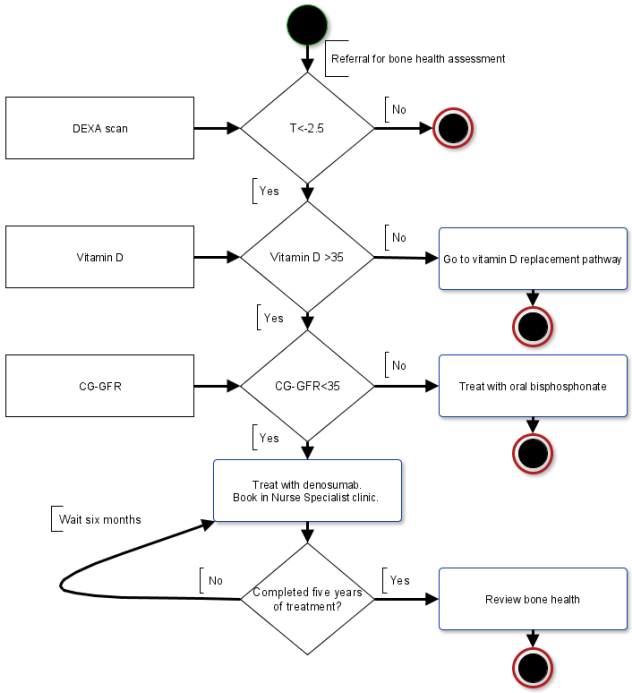

Figure 7. Bone health assessment as a UML Activity Diagram

The data required for the decision (i.e., DEXA scan, Vitamin D, and CG-GFR) are received using HL7 messages from laboratory systems. The pathway can be progressed using the most recently recorded values from the laboratory, but a manual review step is necessary to ensure that the tests were performed within an acceptable timescale; if not, then new tests must be ordered.

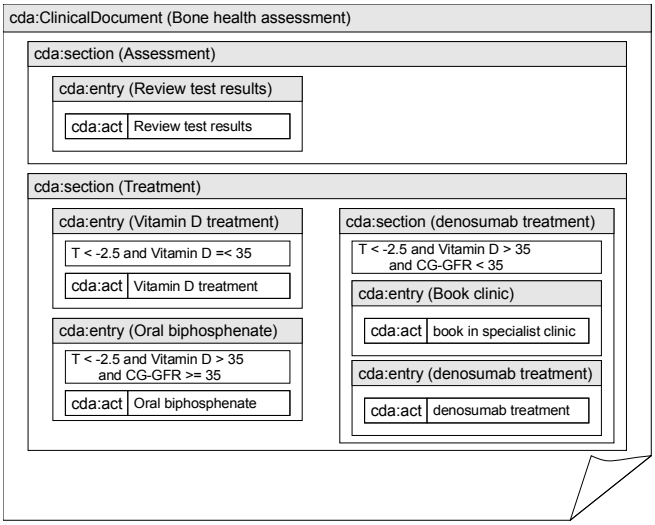

Figure 8. Bone health assessment as a an HL7 CDA Document

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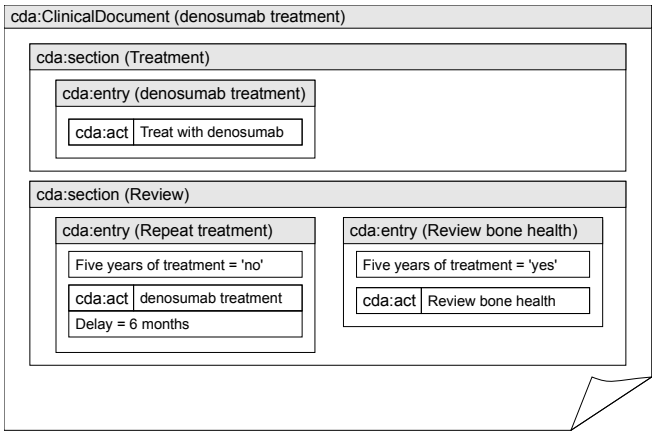

Figure 9. Sub-pathway for denosumab treatment

The sub-pathway for denosumab treatment (Figure 9) is called recursively in an action until five years of treatment have been completed. Note that similar pathways exist for the treatments of vitamin D replacement, and oral bisphosphonate, but are outside the scope of this example.

VI. CONCLUSIONS

We have implemented support for executable, integrated care pathways in the cityEHR health records system, using HL7 CDA documents to model and record the pathway. This approach enables pathways to be handled in much the same way as other clinical documents in the system, and allows them to be stored as a permanent record of the actions taken to fulfil the pathway. Hence, any variance from the original library pathway is captured in the final version of the document stored in the patient record, and statistical analysis of variation can be made by querying the records database.

We have demonstrated that the approach is sufficient to implement typical pathways in different clinical settings, including pathways with conditional branches and repetitive loops. The actions that can be performed in a pathway are currently restricted to clinical data entry/review, clinical letters, or sub-pathways; hence not all the standard features of pathways identified by Wakamiya and Yamauchi [7]. However, the addition of order communications (i.e., computerized physician order entry) to cityEHR would enable support of the full set of standard features.

At present, the transition from a UML Activity diagram as the representation for a pathway, to HL7 CDA document models is not automated. The template pathway CDA is created using the same tooling as for other clinical documents in the system: a spreadsheet is used to define the document, its sections, and entries, saved to XML format, transformed to an ontology representation in OWL/XML, and then transformed again to a CDA document. It would be possible to use UML tooling which enabled the activity diagram to be saved as XML, but whether this could then be transformed into the OWL/XML model remains an open question. However, the reverse transformation is relatively straightforward, whereby a representation as a UML activity diagram is generated from the OWL/XML model.

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Towards Integrated Analysis of Risk Factors and Diabetes Prevention using Big Data and Natural Language Processing

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***Abstract*—This paper demonstrates the potential of natural language processing for extracting patient-related data from very big repositories of semi-structured patient records. We mine 37.9 million outpatient records, extract risk factors and show how to integrate the findings in a system that enables effective diabetes prevention. The findings show the weak points in the organisation of primary care and specialised outpatient care in Bulgaria.**

Keywords–Diabetes prevention; Discovery of risk factors; Automatic text analysis; Entity extraction; Outpatient record; Data integration, analytics.

I. INTRODUCTION

Automatic text analysis is applied to clinical narratives since decades. Many researchers work on this hot topic, developing Natural Language Processing (NLP) algorithms and experimental prototypes in various natural languages. Recently, the NLP tools reached such a level of maturity that one can think about their integration in real software systems, i.e., outside the academic settings, in order to improve knowledge discovery and support decision making. Usually only certain events are extracted from the analysed clinical texts since full "understanding" is hard to achieve; and in general NLP tools deliver a small percentage of erroneous results. But these shortcomings are somehow compensated by the NLP ability to process big repositories of clinical records [1]. The results of automatic information extraction from patient records are relatively good and can be compared with other systems that solve similar tasks, such as CLEF (Clinical E-Science Framework) that retrieves data for cancer patients [2] and AMBIT that retrieves information from biomedical text [3]. Another successful platform is the Mayo Clinic NLP System [4] for structured retrieval of patient records taking into consideration patients' smoking status.

In this way, NLP turns to be an integral component in the initiative for Secondary Use of Electronic Health Records (EHR) data and one of the few technologies that enable tackling of unstructured big data in medicine. In principle, its application is evaluated in terms or precision and recall; these indicators give hints about possible erroneous results.

One of the most important tasks is to extract patient status in structured format (Attribute–Value). The "attributes" can be for instance anatomical organs, major anatomical systems, their characteristics, physician examinations performed during the admission etc. The "values" describe the actual condition of the patient. Thus, structured representation of the patient status can be viewed as a set of "attribute-value" tuples. To solve this task NLP uses Support Vector Machines and related unsupervised and supervised approaches to machine learning. For example [5] presents classifiers based on supervised methods; [6] applies Maximum Entropy classifiers; and [7] uses semi-supervised relation extraction.

Analysing patient records in order to reveal the diabetic patient status or prevent diabetes is a particularly challenging task. NLP tools that extract entities from patient-related documentation can help to optimise the treatment, reduce its costs or deliver early alerts about potential diabetes by identification of high risk factors. For instance, the paper [8] presents prototypes that (*i*) analyse discharge summaries for evidence indicating a presence of diabetes, (*ii*) assess diabetes protocol compliance and (*iii*) identify high risk factors. The tools extract entities like assertion of the disease and associated findings in the text, numerical clinical data and prescribed medications. The classifier analyses reports for the presence and absence of diabetes and recognises the status with accuracy higher than 97%. The evaluation was done for 444 discharge summaries.

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The high risk factor classifier extracts the blood pressure values and cholesterol values; it works with accuracy exceeding 90%. The tools also estimate the record's adherence to quality of care protocols for indicators such as ABCS (i.e., A1c-glycosylated hemoglobin, Blood pressure, Cholesterol, Smoking). This classification is also done with accuracy exceeding 90%.

Here we present results of large-scale NLP applied to a big repository of outpatient records. Big Data pose special requirements to NLP, for instance one cannot inspect manually the corpus that is processed. Our objective in this study is to mine records submitted to the Bulgarian National Health Insurance Fund (NHIF) and, despite their primary accounting orientation, to discover patients with risk factors that are potentially related with development of diabetes. In Bulgaria, there are no established programs for prevention of socially important diseases. An automated system discovering the citizens with increased risk to develop diabetes represents an important contribution for the amelioration of public health system. Having in view all the patients' pathways, including reports of the General Practitioners and all frequently visited specialists, the proposed system can analyse more risk factors than one single doctor, who has no access to all the data obtained in various clinical examinations and reported to NHIF by different specialists.

This paper is organised as follows: Section 2 describes the project objectives and sketches the previously developed modules, which are improved and integrated in the current system. Section 3 discusses data formats and overviews the repository. The results obtained in the present study are reported in Section 4. Sections 5 and 6 contain a brief discussion, the conclusion and further work.

II. Project Context and Available Tools

The ultimate objective of our project is to accelerate the construction of the Register of diabetic patients in Bulgaria by integration of language technologies and business intelligence tools [9]. Today the growing administrative burdens and multiple registrations are considered as a major obstacle for the development of the Register. However, advanced information technologies would enable to: (*i*) keep the established practice of patient registration without overloading the medical experts with additional paper work; (*ii*) reuse the existing standard records in compliance with all legal requirements for safety and data protection; (*iii*) save time and resources by avoiding multiple patient registrations and disturbance of the diagnostic and treatment process. Practically, once entered in the healthcare system, the patient data might be reused in multiple aspects. A web-interface for self-registration to the Bulgarian Diabetic Register is foreseen as well.

The Register contains 28 indicators of diabetic patients' status, including age, sex, ICD-10 codes of diagnoses of diabetes and its complications, diabetes duration, risk factors, data about compensation, laboratory results, hospitalisations and prescribed medication. Manual collection of data proved to be impractical during the last ten years; in addition there are many diabetic patients who are not formally diagnosed and not treated at all. In the case of diabetes, a progressive chronic disease with serious complications, it is highly desirable to develop a system for early alerts that might signal eventual diabetes symptoms.

It turns out that all the information needed for the Register is available in the outpatient records, collected by the Bulgarian NHIF. There are multiple records stored for the same patient along the months and the years. Thanks to the support of the Bulgarian Ministry of Health and the NHIF, the Medical University - Sofia has received for research purposes a large collection of outpatient records. The data repository currently contains more than 37.9 million pseudonymised reimbursement requests (outpatient records) submitted to the NHIF in 2013 for more than 5 million patients, including 436,000 diabetic ones. In Bulgaria the outpatient records are produced by the General Practitioners (GPs) and the Specialists from Ambulatory Care for every contact with the patient.

We have previous experience in automatic analysis of diabetic patients' discharge letters in Bulgarian language. In 2010-2011 a drug extractor has been developed, based on algorithms using regular expressions to describe linguistic patterns [10]. There are more than 80 different patterns for matching text units which deal with the ATC and NHIF drug codes, medication name, dosage and frequency. Currently, the extractor is elaborated and handles 2,239 drugs names included in the NHIF nomenclatures. Recent extraction evaluation has been performed with large-scale analysis of the outpatient records of 33,641 diabetic patients for 2013. The precision is 95.2% and the recall - 93.7%. This result is slightly better than the accuracy reported in 2011 [10] when the extractor was a (research) prototype dealing with less than 500 drugs. The performance of the module is evaluated manually. The labelled data is split to 20 equal subsets and randomly selected records are evaluated by an expert (about 40% of each subset). The average of the subset evaluation is the final score of the module.

The major reasons for incorrect recognition of drug events are: (*i*) misspelling of drug names; (*ii*) drug names occurring in the contexts of other descriptions; (*iii*) undetected descriptions of drug allergies, sensibility, intolerance and side effects; (*iv*) drug treatment described by (exclusive) OR; (*v*) negations and temporally interconnected events of various kinds: undetected descriptions of cancelled medication events; of changes or replacements in therapy; of insufficient treatment effect and change of therapy. About 30% of the medication events in the test corpus were described without any dosage. Lack of explicit descriptions occurs mostly for treatment of accompanying diseases. After applying the recognition algorithm and default daily dosage, the number of records lacking dosage has been reduced to 15.7% in the final result.

Another extractor that has been developed in 2010-2011 identifies values of clinical tests and lab data in the free text [11]. In 2011, the extractor recognised more than 90 types of laboratory tests, some of them with accuracy higher than 98%. The evaluation was done on 6,200 discharge letters of diabetic patients. Today the extractor is extended to cope with the clinical test values in the NHIF repository of outpatient records. In particular, our current study is focused on the indicators: age, body mass index (BMI), waist circumference, triglycerides, cholesterol, HDL-cholesterol, blood glucose on fasting, and blood glucose on the 120-th minute of the glucose tolerance test.

Moreover, we invested efforts in automatic recognition of temporal markers in discharge letters. In 2011, we proposed an algorithm and tool that recognised drugs taken by the patient at

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the moment of hospitalisation (day 0) [12]. This tool analysed the Case History section of hospital discharge letters. In 2012, we did a more systematic study of the temporal information in diabetic patients' discharge letters and proposed an algorithm for splitting the case history into episodes [13]. The temporal markers, which refer to the absolute or relative moments of time, are identified with precision 87% and recall 68%. The direction of time for the episode events: *backwards* or *forward* (with respect to certain moment orienting the episode) is recognised with precision 74.4%.

To tackle the Repository of outpatient records, we use a Business Intelligence tool (BITool) that processes the database of extracted entities. In principle the BITool can deliver various types of findings to decision makers in order to improve the public health policy and the management of Bulgarian healthcare system. The tool is useful anyway because the Health Insurance Fund data contains a lot of information that is structured using codes of medical classifications and nomenclatures. However, we are interested in the analysis of free text sections and capturing some essential entities described there. By means of NLP techniques integrated with the BITool we discover the potential diabetic patients, which were not formally diagnosed with diabetes. The paper [9] presents the study and more especially, how we classify with precision 91.5% the records according to the hypothesis "*having diabetes*" using only text comments in the sections with unstructured content. The experiment was run on 1,206,276 records of 156,000 patients who are not formally diagnosed with diabetes but the word "diabetes" (in Bulgarian "диабет") occurs in their records. In total, there are 190,189 such records for 156,310 patients in our dataset.

III. MATERIAL

The outpatient records are semi-structured files with predefined XML-format. Despite their primary accounting purpose they contain sufficient text explanations to summarise the case and to motivate the requested reimbursement. The most important indicators like Age, Gender, Location, Diagnoses are easily seen since they are stored with explicit tags. The Case history is presented quite briefly in the Anamnesis as free text with description of previous treatments, including drugs taken by the patient beyond the ones that are to be reimbursed by the Insurance Fund. Family history and Risk factors are often included in the Anamnesis. Patient status is another section containing free text. It includes a summary of the patient state, symptoms, syndromes, patients' height and weight, body mass index (BMI), blood pressure and other clinical descriptions. The values of Clinical tests and lab data are enumerated in arbitrary order as free text in another section. A special section is dedicated to the Prescribed treatment. Only drugs prescribed by the GPs and reimbursed by the NHIF are coded, using the specific NHIF nomenclatures. All the other medications and treatment procedures are described as free text. In contrast to clinical discharge letters that might discuss treatments in longer past and future periods, the Prescribed treatment section in the outpatient records is more focused on the context at the moment when the record is composed.

The repository given to the Medical University - Sofia is pseudonymised by NHIF which has the keys for mapping the records to the original patients. Our experiments use a completely anonymised data set. Fortunately, the pseudonymised patient identifier helps to track automatically the multiple visits of the same patient to GPs and Ambulatory Care, which is important for a chronicle disease like diabetes.

An outpatient record includes up to 160 tags. The average length of the files is about 1MB. Here, we work with 20-30 tags and consider the unstructured content of four sections.

Our findings are obtained after the extraction of the patient age and seven risk factors. Our source repository for the present study consists of 1,206,276 records of 156,310 patients who are not formally diagnosed with diabetes but the word 'diabetes' occurs in at least one of their outpatient records.

IV. RESULTS AND FINDINGS

We studied the inter-dependences of the age (40+ years), the seven risk factors, drugs taken by the patients and phrases suggesting diabetes in the free text of the outpatient records.

A. Extraction of Lab Test Values

At first we extracted automatically the values of all tests related to the risk indicators enumerated on Table I. The total number of patients having two and more risk factors (being older than 40 years is one of the risk factors) is 68,681. The records of these patients are mined for extracting the values of BMI, waist circumference, triglycerides, cholesterol and the blood glucose tests. The number of patients having the different risk factors is given on Table I. We consider only the records of patients who have at least one risk factor.

TABLE I. NUMBER OF PATIENTS WITH DIFFERENT RISK FACTORS.

Age $>$ 40 years: 68,681 patients with Risk Factors	
Indicators	Number
Body mass index (BMI) a	49483
Waist circumference	47921
Triglycerides	6834
Cholesterol	9063
HDL-cholesterol	1226
Fasting blood glucose	8020
Combination of 2 factors	27773
Combination of 3 factors	31009
Combination of 4 factors	7173
Combination of 5 factors	2271
Combination of 6 factors	437
Combination of 7 factors	18

When the results of fasting blood glucose are uncertain the diagnostic of diabetes should be confirmed by the oral glucose tolerance test (OGGT). The fasting blood glucose for 8,020 patients, aged 40+, exceeded 6,1 mmol/l and the diabetes was not registered in their records. So, we searched for patients having more than 2 risk factors who have accomplished a OGGT. We discovered that only 1,103 OGTTs were executed, in 687 cases the patient age exceeded 40 years. In 102 cases the diagnostic of diabetes was confirmed. We note that 687 cases represent only 8.56% of the 8,020 patients with risk factors.

B. Analytics on the Outpatient Records' Database

A key finding that is easily seen in the NHIF repository using our Business Intelligence tool is the heterogeneous source of the submitted outpatient records. An outpatient record is created for each visit to the GP or to Specialists from Ambulatory Care, in doctor's office or patient home. Figure 1 summarises the number of visits of the "risky" patients to 24 types of medical experts in the primary and the specialised

outpatient care. Column 2 at Figure 1 means that 10,878 citizens had only one visit to the GPs (row 1), 3,217 citizens had a single visit to Gynecologists (row 2), 313 citizens visited an Allergist only once (row 3) and so on. Column 3 presents the number of citizens who visited the corresponding medical experts 2-5 times; Column 6 - the number of citizens who visited the respective medical specialists 16-42 times.

Figure 1 shows that the citizens aged 40+ visited often their GPs (38.72% of all visits) but also had consultations with other specialists. In Bulgaria one specialist can send a patient to another specialist without obligation to inform the GP about this. The clinical information systems of the GPs and the specialists cannot exchange any information among them and this is not required by the health authorities. The only obligation of the specialists is to provide information in xml-format to NHIF. Therefore the GPs, in general, have no access to all the information concerning the patient. In this way, the collection of all relevant documents in the GP's archives depends only on the good will of the patient, who needs to bring the documentation to his/her GP as paper copy (and therefore, the GP has to store a paper archive). Thus, the GPs have a rather partial view to the patient status.

	Visits_					
Specialist	1	2-5	6-10	11-15	16+	Total
00 GP	10878	26828	17429	8635	2929	66699
01 Gynecologist	3217	2789	92	10		6108
02 Allergist	313	362	10			685
03 Gastroenterologist	1858	1554	24	3		3439
04 Dermatologist	1931	1686	26	3		3646
05 Endocrinologist	2440	3567	70	1		6078
06 Internist	1022	710	57	9		1798
07 Infectionist	92	56	1			149
08 Cardiologist	10526	11353	419	8		22306
10 Neurologist	5016	5802	272	20	6	11116
11 Nephrologist	869	1086	22			1977
12 Oncologist	187	71				258
14 Otolaryngologist	3041	2239	20	3		5303
15 Ophtalmologist	9949	5241	111	4		15305
16 Parasitologist	8	10				18
18 Psychiatrist	846	1108	145	11		2110
19 Pulmonologist	1658	1823	18			3499
20 Rheumatologist	718	596	11			1325
22 Urologist	1886	1631	46	4		3567
23 Physiotherapist	9	3059	121	4	3	3196
24 Hematologist	289	286	15	2		592
25 Surgeon	2771	2219	98	12	4	5104
26 Anaesthetist	60	2				62
29 Neurosurgeon	118	61	1			180
Total	59702	74139	19008	8729	2942	164520

Figure 1. Number of visits (1, 2-5, 6-10, 11-15, 16-42) of citizens to specialists

C. Extraction of Drugs

We have extracted the drugs from the outpatient records that are considered in the present experiment. Please note that the records contain a variety of drug presentation formats: from free narrative in the text to fully structured information in XML, from partial to complete details, in Bulgarian language only or as a mixture of English and Bulgarian language. To illustrate the varieties we present here three examples:

1) Drug names in Cyrillic immediately followed by the dosage daily scheme:
НовоРапид 20/19/ +15+12+18 и Левемир 10+22 E
(in English: NovoRapid 20/19/ +15+12+18 and Levemir 10+22 E)
2) Drug name in English language with information about the NHIF registration code for this drug - AF433, and description in Bulgarian language about the dosage 20E and the scheme:
АФ433 Левемир (300 UI x10) - доза: 20E в 22 часа, подкожно
(in English: AF433 Levemir Penfill (300 UI x10) - dosage: 20E at 22 o'clock, subcutaneously)
3) Drug information about Levemir Penfill structured in XML format with NHIF registration code:

```
<DrugCode>AF433</DrugCode>
<DrugICD10>E10.9</DrugICD10>
<Quantity>4</Quantity>
<Day>30</Day>
```

Some 30,486 patients (out of the 68,681 patients we deal with) admit drugs. Drug names occur in 117,798 outpatient records. The 7-digit ATC codes, identified in the outpatient records, are 306. The identified 3-digit ATC codes are 47. The drug trade names are 356. Having in mind the risks for diabetes developments, we have analysed the number of patients that use glucocorticoides (H02), hydrochlorothiazide (C03AA03) and combinations of thiazides with other diuretics (C03EA01-hydrochlorothiazide and potassium-sparing agents).

Analysing the prescription of thiazides and their combinations at Figure 2, we notice that the percentage of patients taking thiazides (2%) is higher than the number of outpatient records containing thiazides (1%). This means that in general, the prescription of thiazides is not multiple so the medication is taken in short periods only. It can be assumed that the doctors are careful when prescribing thiazides to patients with risk factor for diabetes.

In Figure 3, we present the inter-dependencies of the risk factors and the number of patients aged 40+ who use glucocorticoids and thiazides. We note that the C03AA03 hydrochlorothiazide is most often prescribed to patients with high BMI and high waist circumference. The combination of hydrochlorothiazide and potassium-sparing agents C03EA01 are also often prescribed for these patients. Figure 3 supports the finding in Figure 2 that thiazides are prescribed relatively rare.

D. Mining Free Text for Opinions of Medical Experts

In addition to the extraction of Lab data and Drugs, we process the doctors' utterances to discover phrases that potentially signal risk factors. To confirm/reject the hypotheses of (*i*) **having diabetes** and (*ii*) **family heredity**, we apply a hybrid approach of rough rule-based pre-filtering followed by training of machine learning models. For testing both hypotheses we use text chunks extracted from a concordancer around the string "диабет" (diabetes). The data set consists of 67,904 distinct chunks extracted from the records of 156,310 patients who are not formally diagnosed with diabetes. Each chunk contains the string "диабет" (diabetes) and a 6-token window of its left and right context. The text is only tokenised (i.e., split to words and meaningful strings) and stemmed (word endings are deleted). Figure 4 shows 2 examples from the manually

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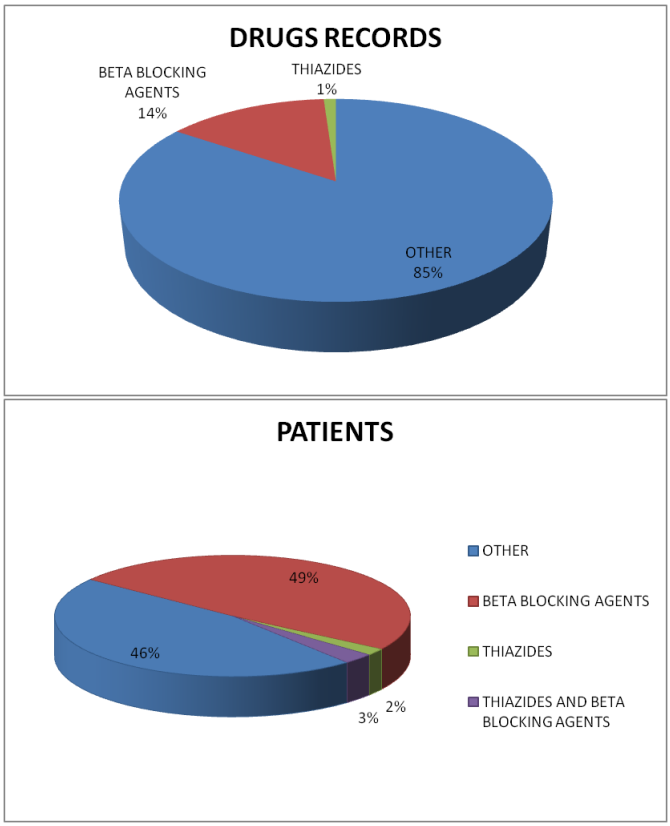

Figure 2. Statistics about using Thiazides, Beta Blocking Agents and other drugs

Risk	Atc C03AA03	C03EA01	H02	Total
Body mass index	980	447	122	1549
Cholesterol	191	73	28	292
Fasting blood glucose	208	101	21	330
HDL cholesterol	20	8	1	29
Triglycerides	160	65	14	239
Waist circuference	946	444	139	1529
Total	2505	1138	325	3968

Conbination Of	Atc C03AA03	C03EA01	H02	Total
2 risk factors	468	226	86	780
3 risk factors	604	290	85	979
4 risk factors	193	74	15	282
5 risk factors	57	20	5	82
6 risk factors	5	6	1	12
Total	1327	616	192	2135

Figure 3. Drug Prescription to Patients Aged 40+ with Risk Factors

(*i*) NEG-diabetes; POS-familyHeredity
Фамилност - обременен/а - диабетици по майчина линия.
Family - heredity - diabetic on maternal line.

(*iii*) NEG-diabetes; NEG-familyHeredity
Липсва фамилна обремененост за захарен диабет.
No family heredity for diabetes mellitus.

Figure 4. NEGative and POSitive chunks examples from free text descriptions

annotated training data prepared in order to train the classifier. The last example is negative to both hypotheses whereas the first one is positive to family heredity and negative to having diabetes. These chunks come from records of patients who are not formally diagnosed with diabetes so, in principle there are more negative examples to our hypotheses.

1) Rule-based rough pre-filtering: In first place we do rough pre-filtering of the data in order to reduce its size. The expressions we used for filtering were manually selected by analysing the data, they are such as "no evidence about diabetes", "no diabetes in the family" etc., and for the second experiment "no family heredity", "no heredity" etc. After applying the rules in the first experiment the data reduced to almost 1/3 of its initial size while in the second case about 7% were reduced.

2) Supervised classification of positive/negative examples: In the second phase we apply a number of machine learning techniques on the reduced datasets. We create datasets of randomly extracted records from the full set and manually annotate them. The dataset used for testing the hypothesis "*having diabetes*" has two subsets – one of 282 documents and one of 1,000 documents. The first one is our development set, it is used for selecting features and for initial tests. It contains 74 positive and 208 negative examples whereas the second one (our test set) contains 187 positive and 813 negative examples respectively. By using various features and classification algorithms we check the applicability of machine learning to the automatic extraction of records referring to "*having diabetes*" (similarly to [4], [12], [14]) and set a reasonable baseline for this task. We tried several algorithms on the same dataset: NaiveBayes, J48, SMO and JRip and MaxEnt, all with boolean features. JRip, J48 and MaxEnt performed best and MaxEnt algorithm outperformed all. We measure the performance of the models in terms of $precision$ (percentage of true positive examples in all extracted examples), $recall$ (percentage of the true positive examples in all available positive examples) and their harmonic mean $f - measure$.

The features we used were - words' stems, bigrams and trigrams. The classification with MaxEnt reached 91.5% $precision$ on the positive examples and 88.55% on average (positive/negative). The $recall$ was comparatively low (52.1% on average) but for us precision is of major importance here because we want to select potential diabetic patients with high certainty. Some 37-42 phrases (depending on the selected model) were extracted as positive examples out of 1000 randomly selected test documents with $precision$ higher than 91%. This suggests that several thousands of positive assertions would be found in the free texts of the original data set. We consider this number significant given that the patients we deal with were not diagnosed with diabetes.

The dataset for classification of records according to the hypothesis "*family heredity*" has the following subsets: development subset - 600 documents (300 positive and 300 negative examples) and test set with 1,727 documents (915 positive and 812 negative examples). As features we use the words stems and bigrams and trigrams available in the development set (including punctuation). We use the same classification algorithms as in the first experiment, with boolean vectors. The best performance was achieved with MaxEnt algorithm using all features without feature selection - 93.8% $f - measure$. This means that out of 600 records, 276 were selected as

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approving the risk factor "*family heredity*" with precision over 95% (we keep in mind that the class distribution in the development and test sets may differ from the distribution in the original data). For comparison in [15] is achieved 100% $f - measure$ on extracting the "*experiencer*" feature of an event (whether the event is experienced by the patient or by other person). The experiment which is closest to ours is done on discharge letters and the authors report that there was insufficient data for thorough testing of the "*experiencer*" feature extraction.

V. Discussion

The results presented here clearly confirm the lack of prevention-orientated thinking of the general practitioners and the specialists. The organisation of primary care and the specialised outpatient care in Bulgaria do not stimulate the doctors to do the prevention. The preventive measures are not systematic and are not adequately reimbursed. In addition the specialists have no access to the complete adequate information concerning all Lab data, clinical examinations and consultations made by the patients.

VI. Conclusion

Information extraction from clinical texts matures only recently but its performance gradually improves and often exceeds 90% [16]. Our experience shows that in a rapid development process, one can achieve good performance in separate extraction tasks within 2-3 years. The review [16] however states that "current applications are rarely applied outside of the laboratories they have been developed in, mostly because of scalability and generalisability issues". We would add here that the negative results are partly due to the inconsistency, incompleteness and fragmentariness of the medical documentation per se; these shortcomings become obvious in the computer age when ambitious goals like the Secondary Use of EHR data are set.

The erroneous results that might include also overgeneration (false positive indications) are an inevitable part of the NLP technologies. They might be dangerous for further use unless the applications are based on very large resources. In these cases the small percentage of false positive entities is statistically insignificant and practically negligible. Human recognition of entities might also include some erroneous choices. We test carefully our extractors and integrate them only in scenarios where their role is to deliver primarily supporting evidence.

From the social medicine perspective the present system is an important achievement. It enables to develop a diabetes prevention procedure after the analysis of the risk factors and delivering the codes of the "risky patients" to the National Health Insurance Fund. In this way the National authorities can send alerts to the GPs and also to the patients, informing them electronically about risk factors and the necessity to implement active prophylactic measures.

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On the Need for Interdisciplinary Teams in Health IT Design

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***Abstract*—Health Information Technology is recognized as a solution to manage health care and improve the quality of care. However, literature reports on unsuccessful implementation projects, challenges and unforeseen consequences of IT in health care. In order to define health IT system requirements, a methodology to comprehensively model health care processes is described. It is concluded that the design of health IT systems should not be done by software engineers or technical personnel in an isolated manner. It is argued for the necessity to engage with the health care sector as an empirical field, and the need for interdisciplinary teams, to tackle the idiosyncrasies of health care processes. The suggested methodology is a useful approach for supporting the definition of the IT requirements, aiming a successful implementation.**

Keywords- Methodology; Interdisciplinary Studies; Health Information Systems; Workflow; Physicians; Nurses; Secretaries.

I. INTRODUCTION

Many studies have identified inefficiencies in the current health care systems. Health Information Technology (IT) is often presented as a solution to such inefficiencies, as it supports health care management and improves the quality of care. However, health IT has only proven its full potential and benefits in specific fields [1]. The aim of the work presented herein is to describe a methodology to comprehensively model health care processes in order to define health IT system requirements. The elective surgery cancellation problem, in a University Hospital in North Norway, is used as a case study to describe the methodology and the gains that come from its application in health IT design.

In order to reduce elective surgery cancellations due to lack of information, at the University Hospital of North Norway (UNN), the eTeam-Surgery project was established. eTeam is approaching the pre-operative planning process to determine if it can be moved from the hospital to the patient at home, through electronic collaboration.

To develop a tool for electronic collaboration between the patient and the hospital is not an easy, nor a straightforward task. Literature surveys report on unsuccessful implementation projects, challenges and unforeseen consequences of IT in health care [2-12]. A contributing factor for the slow diffusion of health IT may be found on its focus on improving individual tasks, rather than supporting value added care processes.

The aim of the work presented is to describe a method on how to comprehensively model care processes to establish a basis to define health IT requirements. It is argued the necessity for health IT designers to understand the complexity of care processes, and their dynamic relation with the environment in which it takes place. Given the idiosyncrasy of care processes, it is recognized that an interdisciplinary team is essential.

This report is divided in four sections. In the first section, the health IT limitations are introduced and the aim of the study is described. In the second section, a brief introduction to the challenges in Health IT implementation are presented. The methodology to model health care processes is described and explained in the third section. The last section elaborates on the need for interdisciplinary teams to understand care processes, in order to achieve successful health IT implementations.

II. BACKGROUND

The patients within the Norwegian population are well prepared and able to use IT [13-15], and health care workers use personal electronic devices to support their clinical work [9, 16, 17]. Hence, there is a substantial evidence in the field of health IT, on unsuccessful implementation projects [2-4]. IT implementation challenges, slow diffusion, and unforeseen consequences in health care, have been described [2-12].

There is vast amount of literature on how to design IT systems that address the problem of unsuccessful IT implementations. A cause may be found in the inadequate design of IT. Several techniques for IT design are used as a tool to approach this issue, e.g., goal-oriented requirements engineering (GORE) [18], user-centered and participatory design [19], and others. However, within this report, the focus is on how to model a care process, in all its aspects (i.e., patient flow, workflow and information flow), so its complexity can be understood, and described in health IT design. It is argued that, when applied to healthcare, this task requires a different methodology that uses an interdisciplinary approach.

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III. METHODS AND RESULTS

The methodology is described below; for further information refer to [20].

Stage 1 Gathering data on the hospital's representation of the problem;

Stage 2 Observations and semi-structured interviews at the hospital, related to the processes at the departments;

Stage 3 Individual, in-depth interviews with all professional groups involved in the process at a specific department.

In Stage 1, the aim was to gather knowledge on how the problem is represented by the field itself. The hospital understanding of the elective surgical cancellation problem and the hospital's representation of the pre-operative planning process was approached.

In Stage 2, the aim was to model the process at different departments at the hospital. This comprised three weeks of fieldwork at UNN, conducting observations and thirteen interviews with physicians, nurses and administrative personnel. The main finding from this stage, was internal variation between the different departments in who plans the surgery and how, and when it was done.

In Stage 3, one department was chosen to proceed with an in-depth study based on the knowledge gained in the two first stages. This department was described to be more efficient but still evidenced a representative number of cancellations. The aim at this stage was to comprehensively model the process at this department. We interviewed representatives from the different health professions (e.g., physicians', nurses and secretaries) involved in the preoperative planning, at this specific department. The interviews were semi-structured, on the pre-operative planning process at the department, lasted between one to two hours, and were done at the workplace. This enabled the identification of decision activities, and the health worker responsible for each of them. In addition, knowledge on the information flow was gathered, and the underlying process issues were identified. The main finding was heterogeneity in how departments and individual professionals carry out the pre-operative planning process

IV. DISCUSSION AND CONCLUSIONS

The described three-stage methodology permitted the modelling of the information flow and the workflow, and to describe the complexity of the process.

For the eTeam-Surgery project, the models will facilitate the development of a standard preoperative planning process, as future work. It is our understanding that in order to move the pre-operative planning from the hospital to the patient at home, through electronic collaboration, the preoperative planning process at UNN needs to be re-engineered, in order to resolve the identified bottlenecks, targeting the process standardisation. This is a sensitive job that has impact on the whole organization. The knowledge gathered while applying the described methodology will enable a sensitive analysis, and the integration of the health care workers empirical and/or personal knowledge into IT.

It is concluded that the design of health IT systems should not be done by software engineers or technical personnel in an isolated manner. It is necessary to engage with the health care sector as an empirical field, and an interdisciplinary team is required to tackle the idiosyncrasies of health care processes. The suggested methodology is a useful approach for supporting the definition of the IT requirements, aiming a successful implementation.

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Multiple Sites, Multiple Technologies, One Objective:

A Work in Progress

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***Abstract*--This paper reports on the early stages of a demonstration project in which selected technologies are introduced into eight facilities which provide care to individuals with Intellectual and Developmental Disabilities or Severe and Persistent Mental Illness. A two-year planning process emphasized that the project was to determine which technologies would be introduced, not if technologies were to be introduced. Thus, emphasis was placed upon evaluating: how the technologies altered staff performance; the quality of care; and the ability to be reimbursed for the care provided.**

Keywords—telecare; multiple technologies; demonstration project; intellectual and developmental disabilities; severe and persistent mental illness

I. INTRODUCTION

The necessity to contain the cost of health care has seen the development of new technologies, as well as the innovative use of existing technologies, in an ever enlarging number of care models. Thus, it should not be surprising that technologies aimed at the provision of care and services to individuals with Intellectual and Developmental Disabilities (IDD) and with Severe and Persistent Mental Illness (SMI) are increasingly being developed and used [1][2]. As in the use of new technologies, in each and every care model there are challenges to using innovative technologies in addressing the needs of these two populations, but the necessity to contain, and if possible, reduce the cost of providing care to these populations, makes the use of technology, in some form, inevitable.

There are two main reasons for the urgency to develop more efficient care models for the IDD and SMI populations: the cost of care; and the aging of the populations. Deinstitutionalization, in both the United States and Europe took place from the mid-1960's through the 1970's, had a dramatic impact on the care models used for both populations [3][4]. Prior to the deinstitutionalization the majority of care was provided for individuals with IDD and SMI in large institutions which were often dehumanizing. The impact of deinstitutionalization on the cost of care varied significantly, but the impact on the care model was significant as most individuals with IDD and SMI moved into the community, many living in some form of group home. The number of individuals living in any particular group home varies based upon the needs of the individuals. The most common number of residents is four with some group homes having as many as eight to ten residents. In the most severe cases, a resident could live alone. Although costs of providing care to the residents in group homes vary based upon the needs and location, the average cost is between $40-50,000 per year per resident and if an individual needs to live alone, the cost can top $150,000 per year [5][6].

Adding even greater cost to the care of IDD and SMI populations is the rapidly increasing number of such individuals brought about by the same demographic factors as for the general population [7]. As individuals with IDD or SMI age they are as susceptible to chronic illnesses as the general population, but the cost of caring for them is much greater. For example, care for an individual with IDD who has congestive heart failure costs approximately eight times more than for a person without IDD [5]. The ratios for other chronic diseases and individuals with IDD versus SMI vary somewhat, but the reasons are consistent. Many individuals with IDD and SMI make poor lifestyle decisions—use tobacco products and abuse alcohol and drugs. In addition, many are unable to self-manage disease, e.g., adhere to complicated medication regimes and follow complex health care instructions. Thus, greater cost of care for individuals with IDD and SMI when combined with the cost of residential care in general, results in a compelling reason for attempting to use technology to contain costs.

In the next section, the overall project is described including the eight locations, the technologies being introduced, the economic model employed and the changes needed in how care is to be delivered. In Section III, the methodology employed to evaluate the effectiveness of the technologies in the delivery of care is discussed, as well as the common methods which are being used across the eight locations. In the concluding section, the reasons for the success of the project, up to this point, is presented.

II. THE PROJECT

I was hired in March 2013 as a consultant by a large ($500 million annual revenue) multi-state care organization to help develop, organize and evaluate a multi-year, multi-site demonstration project of a variety of technologies aimed at aiding in the provision of care to individuals with IDD and SMI. Even though my previous work was with at-risk elderly individuals living in their own residences, there was agreement that my experience could translate well to the IDD and SMI populations [8]. As a consultant, I have not been responsible for the major decisions concerning the scope of the project, nor have I had the ability to play a

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major role in the selection of the sites or technologies to be included in the project. However, I have been more than a passive observer as I have been asked to help develop installation, training and evaluation protocols. In addition, I have had access to material describing the staff and clients to be included in the demonstration project and I have reviewed each of the technologies to be employed. Perhaps my most important contribution has been to emphasize that the project is not a test of whether the various technologies work, but rather an evaluation of whether and how the technologies can be incorporated into the organization's care models. In other words, the project's focus had to be on people and how they did their jobs, not the technology.

A. The Planning Process

Planning for the demonstration project began in mid-2012 with a statement from the CEO of the organization emphasizing the need to introduce innovative technologies. A committee was formed, headed by an upper administrator, and employees were encouraged to propose sites at which new technologies could be used. During the remainder of 2012, proposals were received and evaluated based upon specific criteria: administrative and staff buy-in; existence of suitable technology; evidence that technology would enhance care provision; evidence that, if successful, the technology could be used at a large number of other care facilities within the organization; and a financial model showing that the technology was sustainable—the organization would be reimbursed for its use. Finally, there was an attempt to achieve a rough balance among the different care models employed throughout the organization. This process took over a year, which frustrated individuals who wanted to move more quickly, but afforded a thorough evaluation of the resources available at each of the selected sites. The final decision was confirmed at an all-day meeting of administrators and representatives from each of the chosen sites in the fall of 2013.

B. The Selected Sites

Eight sites were selected for inclusion in the demonstration project. In order to ensure confidentiality, no names, or even locations, are used to identify the sites, but rather, the sites are numbered consecutively. Given the large number or identical sites within the organization, reference to the specific care model and the number of residents at each site should not jeopardize the sites' identity. Six of the sites provide care to individuals with IDD:

Site 1 community group home, four females with physical disabilities;
Site 2 community group home, four males each medically fragile;
Site 3 congregate intermediate care facility, sixteen individuals with physical disabilities;
Site 4 community intermediate care facility, five males with medical issues;
Site 5 community intermediate care facility, four males with physical disabilities;
Site 6 day program, variable number of males and females with physical disabilities.

Two of the sites provide care to individuals with SMI:

Site 7 long term structured residence, eight individuals some with predatory sexual behavior;
Site 8 outpatient clinic with approximately 150 individuals in the project.

Team leaders were appointed at each of the sites and staff at all levels was included in the planning for the introduction of the technology. Start dates were sequenced in order to reduce the stress on both local staff and administrators if and when things went wrong. The first sites began their projects during June 2014 and the final sites began operation at the end of November 2014.

C. The Selected Technologies

Unlike other projects with which I have been associated, there was no one-size-fits-all approach to the selection of the technologies. Thus, staff at each of the eight sites was charged with researching, testing and recommending the technologies which best suited the needs of their clients and the specific care model. Allowing staff at each of the sites to select the technologies to be used took much more time than if administrators had imposed a centrally selected technology. However, the benefits of allowing local administrators and staff to choose the technology to be employed, not only ensured buy-in, but also established ownership over the demonstration as a whole. This is not to diminish the complexity of vetting numerous technologies, negotiating with several, rather than one, vendor, nor the time it took to get each separate technology and vendor approved by individuals at each of the eight locations, the organization's administrative committee, and ultimately by the organization's chief operating and chief financial officers, but the benefits of this approach far outweighed the added time.

There was, however, overlap in the selected technologies. For example, in five of the sites (1, 2, 4, 7 and 8) it was decided that vital signs needed to be collected—blood pressure, weight, temperature and pulse rate—and the decision was made to work with a single vendor. In this way, not only would the cost be reduced, but there would be more comparable data collected across the sites. At the other end of the spectrum, bed and door monitors are being employed in only one of the sites (3), smart televisions in only one site (5) and a specialized computer interface system in one site (6).

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D. Paying for the Technology

An essential consideration in the selection of any technology to be used in the provision of health care is, "who pays." In my previous work, the question of who pays for the technology after the pilot project ended was always the most perplexing question; and the one question that was never adequately addressed during the project [9]. A key factor in answering this question in this project is that a significant majority of the organization's revenue derives from Medicare and Medicaid reimbursement for services. Thus, any new technology employed by the organization has to be a "billable service" to Medicare and Medicaid if the use of the technology was to be sustainable over time.

On one level, it didn't matter whether the selected technology worked as proposed and that it aided in the provision of care. It really didn't even matter if the technology actually reduced the cost of delivering care. What mattered was that the selected technology was considered a billable service under existing Medicare and Medicaid regulations. A brief example illustrates how the reality of reimbursement impacted the selection of the technology to be used in the project. One of the objectives of using vital signs sensors was so that alerts indicating an abnormal reading could be sent off-site to a nurse who could contact the live-in care provider and assess the severity of the situation without traveling to the residence. The problem was that if the nurse traveled to the residence her visit was a billable service, if she solved the problem over the phone, it was not. Quite simply, if Medicare and Medicaid did not change its reimbursement policy, there is no point to install and use the new technology because the organization could not be paid for the services it provided. The good news for the project is that Medicare and Medicaid are in the process of changing their policy and will reimburse virtual nursing visits.

E. Change in Care Models

Equally important as the issue of resolving who pays for the successful introduction of a new technology is the recognition of and the planning for a change in how people will do their jobs after the technology is introduced. In my experience, if there is no plan to deal with the fact that after the introduction of the new technology, people at all levels within the organization will have to change how they do their jobs, the technology will not be adopted [9]. This is the case even if the upper administrators are committed, there are champions for the use of the technology and there is a general belief that the technology works. It may be trite to state that people don't want to change how they do their jobs, but being trite doesn't make it wrong.

The almost two years of planning for the demonstration project has allowed for a thorough discussion of how the introduction of the new technologies would alter jobs. In particular, there is the recognition that, for example, some nurses will be spending more time looking at computer screens and talking to people on the phone rather than driving to residences. The nurses who are looking at screens are clearly providing care; it is just through a different care model. It is a fact of life that some people are more willing to alter how they do their jobs than others and some care providers only want to have a face-to-face relationship with a patient, while others are comfortable making care decisions at a distance. Administrators and supervisors at the organization have been careful to channel individuals who are willing to change into the demonstration project, while allowing others to remain outside. This approach has worked very well for the demonstration project, but other strategies will have to be adopted when the technologies rollout throughout the organization.

III. METHODOLOGY

My major consulting role has been to develop a means of evaluating the demonstration project. This evaluation is complicated by the number of sites, the variation in the care models employed and the fact that different technologies are employed in different sites. It would obviously be a simpler task if the project consisted of a single site or if only a single care model was included or a single technology employed. However, the real world of care provision is not that simple and the selection of sites, care models and technologies were based upon the belief that a number of new technologies must be incorporated throughout the organization and thus, the evaluation must deal with the existing complexity.

A. What is Not Being Evaluated

The technology itself is not being evaluated. All the products being used in the project have been on the market for years and, from a technology perspective, do what they were designed to do. What is being evaluated is how the technologies can be used to bring about better and timelier care while being cost effective. Additionally, the organization is not using the demonstration project to determine whether it wants to introduce new technologies. The strategic decision has already been made that new technologies must be incorporated into the organization. The objective of the demonstration project is to determine which technologies can be the most beneficial to the provision of care.

B. What is Being Evaluated

As a consequence, the evaluation is focused on: 1) the way that staff uses the technology to provide care to their clients; and 2) on how the clients are impacted by the introduction of the technology. To facilitate this evaluation a series of very specific outcomes were developed for each of

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the sites along with the factors that needed to be measured in order to gauge whether the outcomes were achieved.

For example, at **Site 1** the desired outcomes are: improved physical health; better chronic disease management; decreased visits to the emergency room; and decreased hospitalizations. In order to assess whether these outcomes were achieved, five factors need to be assessed: vital signs for each of the residents; information on the communication of vital signs information to medical personnel; data on number of visits to emergency rooms; and number of and reasons for hospitalizations. In addition, it was decided to use both a short life satisfaction and depression scales in order to determine if the introduction of the technology brought about change in the residents' well-being. The actual instruments to be used are a combination of self-created and "packaged" products. At **Site 1** the vital signs are automatically recorded by the system that is being used, while a baseline for each of the residents has been established by recording the information in the resident's medical records for the last six months. An incident form has been created to record events that require medical intervention whether by a nurse, a referral to a physician, an emergency room visit or a hospitalization. Once again, a baseline has been established by extracting this information for each resident for the six months prior to the start of the project. Standardized life satisfaction and depression scales have been administered at the beginning of the project and at three month intervals during the project.

In contrast, at **Site 5** the desired outcomes are: to improve the residents' quality of life; to offer new opportunities in order to increase independence; and to create efficiencies in operation. Thus, the factors to be measured at **Site 5** are: residents' level of participation in meal preparation; residents' independent access to kitchen equipment; and monthly utility costs. As at **Site 1**, both a short life satisfaction and depression scales are used in order to determine if the introduction of the technology brought about change in the residents' well-being. Once again, the actual instruments to be used are a combination of self-created and "packaged" products. Obviously, the utility bills are standardized and can be easily compared from before and after the project's initiation. Similarly to **Site 1**, standardized life satisfaction and depression scales have been administered at the beginning of the project and will be at three month intervals. Residents' independent access to the kitchen and participation in meal preparation have been recorded by staff on a daily basis for approximately three months prior to the start of the project and will continue to be recorded throughout the project.

C. Common Methods

Although in general, the outcomes, the factors to be measured and the instruments employed are site specific, there is a relatively large degree of overlap. The same scale to record vital signs data is being used, the same life satisfaction and depression scales are being administered at the same time intervals and the same incident form is being used. Therefore, there will be an opportunity to compare findings across sites at which the same data have been collected. However, the main emphasis is on evaluating the contribution made by the selected technologies on the provision of care at each individual site.

IV. CONCLUSION

The project is now underway at all eight sites. This is not to say that there have not been some problems. There were initial difficulties with the use of the vital signs technology at two of the five sites in which it is being used. The problem, however, was not with the technology per se, but instead with the staff's use of the system. Additional staff training alleviated this problem. Remodeling at **Site 5** took two months longer than anticipated, thus delaying the start of the project at this location. The start of the project at **Site 8** was delayed by almost three months because of the complexity inherent in the use of innovative technologies at an outpatient clinic; especially the need to train non-professional individuals in the use of the vital signs technology and ensuring that the organization would be reimbursed for the cost associated with the collection and transmission of the resultant data. However, overall the project is proceeding well and data from all of the sites should be available by the end of the year.

There are several, on the surface, simple reasons why the project has gone as well as it has. First and foremost, the decision by the organization's upper administration to make the introduction of new technologies a key element in the organization's strategic vision was essential. Second, the thorough planning taking two years allowed all stakeholders to be involved at each of the project's stages: selection of sites; choosing the technologies; developing outcome measures; and deciding which instruments to use. Third, from the very beginning, the emphasis of the project was on making the technologies financially sustainable. The project was not a pilot to see if the technologies worked, but instead a demonstration of how the technologies could be incorporated into the organization's care models and, at the same time, ensuring that their use was billable. Only when the data collected are analyzed will it be possible to judge the overall success of the project, but, the fact that such analysis is possible elevates this project far above many other similar projects.

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Strategic Framework for Cloud Computing Decision-Making in Healthcare Sector in Saudi Arabia

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***Abstract*—This paper outlines some of the challenging issues faced by traditional healthcare services in Saudi Arabia (SA) covering a relatively large geographical area including remote areas requiring healthcare facilities similar to urban areas. There are also issues of shortages of healthcare professionals together with an increase of chronic diseases, such as diabetes, hypertension, heart diseases etc. Many initiatives have been undertaken to reform healthcare systems including e-Health and the concept of Cloud Computing. This paper discusses some of the issues for e-health projects and how Cloud Computing will help in solving some of these issues. Then, the paper proposes a strategic framework for Cloud Computing decision making processes based on a Holistic Approach Framework for use in Saudi Arabia to assist in improvements for stakeholders involved in healthcare services.**

Keywords: Cloud Computing; e-health; Strategic framework; Saudi Arabia.

I. INTRODUCTION

Improving the healthcare system is one of the main priorities for many governments and organisations and the traditional healthcare system is facing many issues.

The increase of life expectancy is an issue for the traditional healthcare system for instance life expectancy in Canada is 82 years, 75 years in SA, 80 years in the UK and in the USA 79 years [1]. Geography is another obstacle for the development of the healthcare system for many nations for example Canada covers an area of 10 million km^2 with a population of approximately 30 million and in comparison SA has 2.2 million km2 and a population of 27 million both countries having remote sparsely populated areas [2]. Providing healthcare for all citizens with the same quality particularly in rural areas such as in SA results in challenging issues for traditional healthcare organisations [3]. The shortage of healthcare professionals, such as physicians, nurses and pharmacists together with the increase of chronic diseases, such as diabetes, hypertension, and heart diseases, and childhood obesity contribute to the issues for healthcare systems [2] and these factors contribute the higher operational cost of health services provision in SA. Total expenditure on health in SA has been increased from 5.5% in 2008 to 6.8% in 2012 of the national budget [4].

Many initiatives have been implemented to deal with these challenges and to find ways to reform the healthcare systems for examples privatisation of healthcare services and the movement toward preventive healthcare. Another initiative is the use of information and communication technology (ICT) in health organisations to deliver healthcare more efficiently and effectively. This movement towards applying ICT in healthcare systems is subsumed by the term e-health. Eysenbach [5] defined e-health as 'an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology'. This definition is preferable because it takes e-health beyond the technology aspect [6]. It covers other aspects that may affect healthcare such as business and organisational issues. Although this definition was presented in 2001, new technologies such as mobile phones and Cloud Computing can fit well in this definition.

E-health encompasses many applications, systems and services. Each system has different functions and different stakeholders' perspectives. E-health or Health Information technology (HIT) provides many benefits for health organisations and patients. It eases the information sharing for patients, physicians and other clinicians [7]. The adoption of HIT in hospitals improves health care quality and safety [8]. E-health also reduces human errors in medical procedures [7]. Many e-health applications have been used as a medium for education and behaviour change for patients and physicians [8].

Current e-health practices face many challenges from development to implementation. The challenges of e-health projects can be categorized into six general categories (Economic, Technical, Organizational, Behavioural and Environmental and Legal) [9]–[11]. One of the main issues facing e-health is the need to change the traditional business model of healthcare system. Current healthcare systems are

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doctor-centred, reactive and focused on disease. This should be changed to patient-centred, proactive and preventive and focused on quality of life and well-being [6]. The higher cost of implementing HIT projects is considered another critical barrier for e-health. The cost of IT systems in healthcare services is very expensive due to the higher cost in terms of capital expenditure (CAPEX) and operational expenditure (OPEX). Maintenance, supporting and updating ICT projects in health organisations are challenging and require further funding and support. Another obstacle that faces some e-health projects is the need for skill enhancement in the development, management and maintenance of ICT projects in healthcare organisations [12]. Additionally, change will be required in work procedures and routines for the healthcare providers. This change will affect the healthcare services and the related administrative processes [9]. However, this issue has been overlooked by researchers [11]. Support from top management is vital for widespread adoption of e-health. This support can be hindered because of the high cost and other risks that allocated with HIT projects [11].

To overcome e-health issues and problems, many healthcare organisations are moving towards new business models and leveraging technologies. One of the new computing models is Cloud Computing.

The aim of this paper is to develop a strategic framework for Cloud Computing decision making processes based on Holistic Approach Framework. This paper is organised as follows. Section II describes current E-health implementation in Saudi Arabia. Section III presents the concept of Cloud Computing and why it useful in the domain of e-health. Section IV discusses the related works. In section V, the proposed framework will be presented. Section VI concludes the paper.

II. E-HEALTH IN SAUDI ARABIA:

The Saudi government has noticed the importance of using ICT to provide high quality services to Saudi citizens. As a result, the first national E- government strategy was launched in 2005. Consequently, many healthcare services providers have adopted some ICT solutions in their facilities. In 2011, the Ministry of Health (MOH) launched the National E-health Strategy to support the primary MOH business goals [13]. The adoption of HIT in Saudi healthcare organisations is still low for many reasons [14]. Khudair [15] discussed the implementation of ICT in healthcare organisations from physicians' perspective. The researcher expounded the reasons as poor leadership, the weakness of the information system infrastructure and technical support and the absence of implementation strategy. Khalifa [14] found that factors related to human dimensions such as shortage of health informatics specialists, lack of experience of computer applications and lack of experience and knowledge of using EMRs (Electronic Medical Records) are the main barriers that hinder successful implementation of EMRs. The paper also stated that financial barriers such as high initial cost of EMRs implementation and high operation and maintenance costs of EMRs are the second category of barriers that challenge EMR use in Saudi hospitals. Alkraiji, Jackson and Murray [16] studied the barriers to the adoption of health data standards in SA. They found other barriers in addition to the barriers mentioned in [14]. Issues related to technology context such as complexity, compatibility and insufficient IT infrastructure could delay the adoption of health data standards. Hasanain and Cooper [17] found social barriers such as language and resistance to the use of new systems affected EMR implementation in Saudi hospitals. They also mentioned some technical barriers such as: instability of EMR vendors and lack of computers for staff. As a result of these barriers, implementation of e-health services in SA is still facing difficulties. However, there are some success stories such as the King Faisal Specialist Hospital and Research Centre (KFSH) which has almost fully implemented an EMR system [17]. Despite these barriers, Healthcare providers in Saudi Arabia have demonstrated a willingness to implement and improve e-health services. This creates a foundation for the use of new technologies and models that may move them forward such as the adoption of Cloud Computing.

III. MIGRATION OF E-HEALTH TO CLOUD E-HEALTH:

A. *The concept of Cloud Computing:*

The continuous revolution and evolution of ICT has affected the way that organisations conduct their business. The ICT industry has moved through many stages, starting from mainframe computing to Cloud Computing. Cloud Computing is a new computing paradigm that has changed the way of delivering IT services [18].

Although there is no generally accepted definition of Cloud Computing [19] [20], most of the definitions emphasise some aspects. First of all, Cloud Computing is a model of delivering IT services and resources not new technology. Secondly, the provisioning of resources is automatic and with a minimum of human interaction. Thirdly, the access to the large pool resources is over a network. Fourthly, IT services and resources are available on demand with dynamic scalability and elasticity. The provisioning of IT resources should be independent of device and location (i.e., ubiquity). Finally, the use of IT resources must be built on a clear business model and clear measurement methods. Figure 1 provides a Cloud Computing definition schema based on National Institute of Standards and Technology's (NIST) definition [21].

In literature, researchers have recognised many benefits and advantages for Cloud Computing. Costs reduction in either operational [20] [22] or upfront costs [20] is considered as one of the main benefits of Cloud Computing. For example, Maharashtra Government in India saved Rs. 50 Crore by using Cloud Computing solutions [23]. Decreasing the upfront cost will eliminate obstacles to entry in new markets [20] [24]. This could be a clear advantage particularly for Small and Medium sized Enterprises (SMEs) [20]. On-demand promises of Cloud Computing provide scalability and elasticity advantages that allow the organisations to react quickly for their customer demand [22]. Another business benefit from Cloud Computing is the flexibility to react to changing market conditions [20]. Green computing is another advantage of Cloud Computing since it

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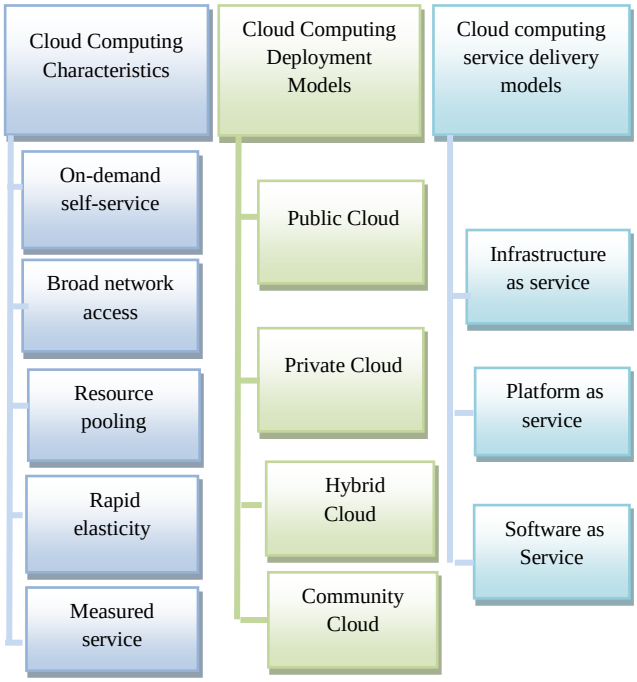

Figure 1. Cloud Computing Definition Schema

has the potential to reduce companies' carbon footprints [18]. Cloud Computing can eliminate IT obstacles to innovation [20] [25]. Cloud Computing also helps organisations to provide new services that were not possible before as result of higher cost for IT solutions [20]. As a result, all the benefits and advantages of Cloud Computing enables organisation to become more focused on their core business [20].

Cloud Computing has its own disadvantages and risks. One potential risk is Data Lock-In where customers may have difficulty of extracting their data from the Cloud [26]. User privacy could provide an issue for Cloud Computing [20] and security issues are the main obstacles for some organisation for not going Cloud [22]. Lack of proper regulations and standards is another barrier to Cloud Computing adoption. However, there is more research being undertaken to deal with the obstacles of Cloud Computing either via technology [22] or policies and legislations [20].

B. E-health Cloud:

The Cloud computing market in healthcare is reported to reach more than $5.4 Billion by 2017 [27]. Many researchers suggested that the health care industry should move toward Cloud computing. Some researchers have discussed the opportunities and challenges of Cloud Computing in e-health [3] [28] [29]. They indicated many advantages for cloud in e-health such as better patient care, reduced cost, enhanced the support for research, and overcome the shortage. However, they pointed out some issues like privacy and security issues, data ownership and lack of legislations and standards. Examples of real and lead projects in the healthcare domain include the MUNICH platform and DACAR project. DACAR is a first e-Health Cloud platform in Europe aiming to develop and implement a secure platform in the Cloud to support Data Capture and Auto-Identification technology [3]. DACAR has been implemented successfully in London's Chelsea and Westminster hospital [30].

Cloud computing may solve some of the challenges of healthcare organisations in Saudi Arabia. Since financial issues are affecting e-health projects in the country, Cloud Computing can offer economic savings by decreasing the initial and operational costs of e-health projects in Saudi hospitals. Cloud Computing can eliminate the obstacle of shortage of health informatics and IT since less technicians than before will be required by the healthcare organisations [30]. Cloud-based medical applications will also make IT departments at healthcare organisations to focus more on supporting the implementation of e-health projects by moving some of their responsibilities to the Cloud providers' side. For healthcare organisations, Cloud Computing will provide better integration and exchange of medical records across multiple organizations. By using Cloud Computing, Saudi healthcare organisations will be able to have sufficient computing resources to deal with large amount of data that are created by e-health services. This feature will also help R&D departments in healthcare organisation on the national level. Cloud Computing with collaboration with other technologies such as Internet of Things, m-health and Big data will help reshape healthcare services in Saudi Arabia.

Some researchers recommended that Cloud Computing in general and in e-health particularly is still in its early stages and need more research and efforts [3] [22] [28].

Although, there are many studies and projects about Cloud Computing in the health sector, most of them are focusing on the operational level. Successful Cloud Computing adoption in the health sector requires strategic planning and risk assessment to avoid the risks and gain the full advantages of this new model [28].

IV. RELATED WORK:

In healthcare, few studies have discussed Cloud Computing decision-making procedures [3]. Kuo [28] recommended four aspects to be assessed when adopting the health Cloud Computing: management, technology, security, and legal. Kuo also proposed a Healthcare Cloud Computing Strategic Planning (HC2SP) model. This model could react as a SWOT analysis for health organisations to determine how to migrate from traditional health services to cloud-based services. This model did not focus on the decision making process. Lian, Yen and Wang [31] studied the decision to adopt Cloud Computing. They integrated Technology-Organisation-Environment (TOE) framework and Human-Organisation-Technology fit (HOT-fit) model to study the adoption of Cloud Computing in Taiwan. Their study indicated that the five most critical factors are: data security, perceived technical competence, costs, top manager's support, and complexity. This study focused on small and medium sized hospitals in Taiwan. Hence, the result of this paper would not be generalised to large hospitals. Rijnboutt and et al. [29] categorised the challenges that are facing the use of Cloud Computing in e-health

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services into six categories (technical, privacy, legal, organisational, economical and medical). However, this paper ignored environmental issues. Additionally, this model did not focus on the decision making process.

Evaluating the existing frameworks for Cloud Computing decision-making, these frameworks are limited (i.e., they do not cover multiple perspectives). Current models and frameworks also focus mainly only on the operational and tactical level (i.e., ad hoc frameworks). Furthermore, while most of the frameworks are emphasising the technical side of Cloud Computing, they ignore the other sides such business and organisational. There is also a lack of quantitative measures in the reviewed frameworks. The use of quantitative measures within the framework is important because they make the decision-making process more accurate and objective [32]. Although, Low, Chen and Wu [33] pointed out that the influences of environmental and organisational factors on Cloud Computing adoption vary across different industry contexts, most of the frameworks are designed to be general and do not focus on specific sectors. Healthcare industry environments may vary across different countries. As a result, each country must be considered to be studied as individual case (i.e., private and public health care). Although, some concepts of Cloud Computing will be generic, some of the concepts will be different due to the variation of the contexts and country requirements. For example, Cloud Computing applications must comply with HIPAA privacy and security rules in USA [34].

Cloud Computing in Saudi Arabia has not received much attention [35] and little research has been conducted in studying the implementation of Cloud Computing in the country. For example, Alharbi [36] studied users' acceptance of Cloud Computing in Saudi Arabia based on Technology Acceptance Model (TAM). From an organisation level, Yamin [35] completed a survey of Cloud Computing awareness in Saudi Arabia. The study showed that Cloud technologies will be a new trend for Saudi's organisations. However, this research provided a general view of Cloud Computing adoption in Saudi Arabia. Yamin claimed that his study is the first of its kind in Saudi Arabia. This indicates that adoption of Cloud Computing in Saudi Arabia in general (and in healthcare sector in particular) needs more investigative efforts.

V. THE PROPOSED STRATEGIC FRAMEWORK FOR CLOUD COMPUTING DECISION-MAKING IN HEALTHCARE SECTOR:

Many researchers have recognised a need to use holistic and multidisciplinary approaches when studying or designing HIT frameworks in healthcare [37] [38]. The framework is supposed to support the decision maker in health organisations in by covering multi perspectives. It will be also designed in a flexible way to be adaptable to changing market conditions.

The decision of adopting Cloud Computing is potentially a complex process and consequently there are many perspectives to be considered. Thus, studying this process requires multi-perspective framework. The proposed framework will integrate more than one theoretical framework to make the suggested framework more robust and cover multi aspects of the organisation. TOE has been chosen as a concept for this research together with Strategic Triangle and HOT-fit.

Since Cloud Computing is a new innovation of dealing with IT services [18] the appropriate framework is the one which is aiming to study innovation decision making at firm level. Technology-Organisation-Environment (TOE) Framework was introduced by Tornatzky, Fleischer and Chakrabarti [39]. This framework focuses on the process by which a firm adopts and implements technological innovations and how the technological context, the organisational context, and the environmental context can affect the implementation of new innovation. Oliveira and Martins [40] suggested that TOE framework is useful in studying the adoption decision-making process of different types of IT innovation. TOE studies the adoption decision-making process at an organisation-level not at user-level which makes it relevant for this paper [20]. Many researchers have studied technology innovation based on TOE framework. Many examples could be mentioned here such as RFID Adoption in the Healthcare Industry [41], in web site development [42], in e-commerce [43], in Cloud Computing adoption by SMEs in England [44] and in Cloud Computing adoption by hospitals in Taiwan [31]. Although, TOE framework has been implemented by many researchers for different technology innovation, some researchers argued that the TOE framework does not contain all the variables in each context. Hence, for new complex technology adoption such as Cloud Computing, more than one theoretical framework is required to express a better understanding of the adoption decision [33].

Business concepts must be taken into consideration by any decision maker [20]. Thus the strategic triangle will be combined with TOE framework to add the strategic value to the proposed framework. The strategic triangle is a concept developed by Frenzel [45] which emphasises the importance for the organisations to have an alignment between three strategies perspectives (Business, Organisation and Information). This research will apply some of the concepts of a strategic framework for outsourcing decision-making that was called Holistic Approach Business, Information, and Organisation (HABIO). HABIO is a well-documented framework used for outsourcing, and has been discussed by many academic researchers [32] [46] [47].

Human factors are also critical in the adoption of any new IT innovation. Those factors should be considered carefully when making the decision of adopting Cloud Computing in health industry. Hence, Human, Organisation and Technology-fit (HOT-fit) framework will be integrated with previous frameworks. HOT-fit was introduced in [48] as an evaluation framework for health information systems.

The proposed framework will be focused on five dimensions which are Organisation, Technology, Environment, Human and Business. The proposed strategic framework is presented in Figure 2.

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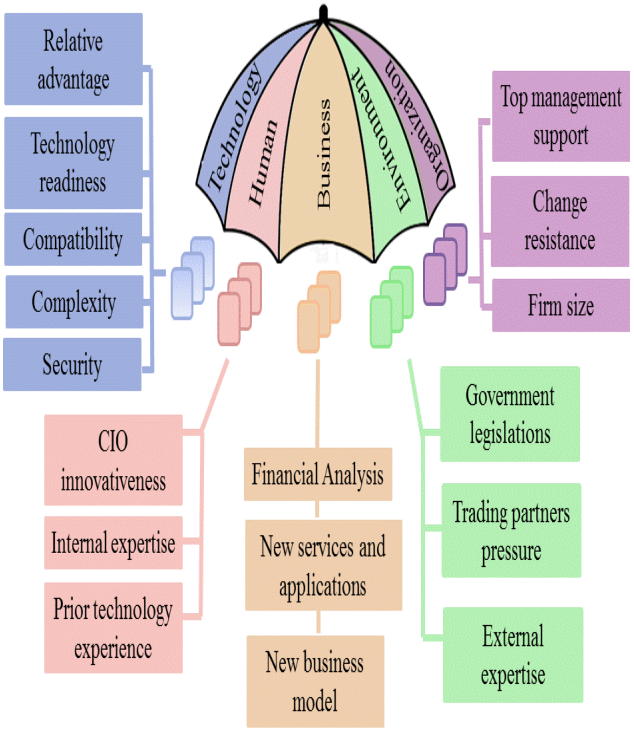

Figure 2. The Proposed Strategic Framework for Cloud Computing Decision-Making in Healthcare Sector

The technology dimension represents the technical issues that will affect the decision of Cloud Computing adoption. Health organisations which are intending to implement Cloud Computing need to assess all technological characteristics that available at the organisations. Relative advantage factor refers to checking if the adoption of Cloud Computing technology will have clear benefits over others technologies for certain health organisation. This factor is expected to be an important and positive significant factor for the decision of Cloud Computing adoption. Alharbi [36] showed that perceived usefulness will positively affect users' attitude towards adopting cloud computing in Saudi organizations. Technology readiness could be an enabler factor of the decision of Cloud Computing adoption [49]. Some researchers found that existing infrastructure has a negative impact on the adoption of health data standards in Saudi Arabia [16]. However, Cloud Computing can solve the problem of the availability of IT resources. E-health usually encompasses many health information systems. Thus, compatibility of Cloud Computing implementation with existing IT systems inside the health organisation should be another factor to be consider when adopting Cloud technology [50]. Some Saudi healthcare organisations found difficulty in making new systems compatible with current clinical systems [51]. Consequently, the complexity can be a significant determinant for Cloud adoption [49]. In the healthcare industry, data security and privacy protection are required not only demanded by the patients themselves, but in most countries they are also required by law. Thus, data security should be essential factor that should be considered during any Cloud Computing implementation [50].

The organisational factors also have their influences on the success or the failure of e-health projects. They are internal factors of an organization that are controlled and by the organization itself. They play an important role in the decision-making process. Top management support can be a significant factor in Cloud adoption [44]. This factor refers to how executives identify the nature and functions of Cloud Computing technology and how this technology will affect the overall organisation [44]. Current research showed that employees in managerial positions in Saudi organizations had positive attitudes toward Cloud Computing adoption [36]. However, the situation in healthcare organisations may be different due to the nature of such organisations. The successful adoption of new technologies requires various changes to be made to the organisational structure, such change may face resistance from physicians, administrative and IT staffs [48]. A recent study showed that resistance to the use of new system is affecting EMR implementation in Saudis hospitals [17]. This factor should be considered when adopting Cloud computing solution in health organisation. Firm size could be also considered as a factor that will affect the adoption of Cloud Computing [33].

Environmental context refers to the different attributes of the external world in which the organisation conducts its business [31]. The use of Cloud Computing in e-health will be affected by the relationship between different parties. Government legislation and policies can affect the decisions of health firms trying to adopt new technology [48]. With the current security and privacy issues in the Cloud, this factor must be considered carefully. Additionally, most health organisations rely on trading partners for their IT solutions so sufficient support from the Cloud vendors will be an influential factor affecting the decision of Cloud Computing adoption [33]. Instability of EMR vendors was found to be one of the barriers of EMR implementation in Saudi Hospitals [17]. Another factor that is associated with sufficient support from the vendor is the availability of external expertise [32]. E-health usually encompasses many health information systems and requires expertise from various domains such as medicine, IT and business processes. Thus the availability of such expertise will affect the decision of Cloud Computing adoption.

Human dimension should be considered before the implementation of any IT project as it is one of the factors that influence the adoption of an innovative technology [48]. Hospitals usually are slow in adopting new information technologies due to the decision makers' characteristics [52]. Thus, the innovativeness of decision makers' considerably influences the decision to adopt Cloud Computing [31]. Another factor which will affect the decision of Cloud Computing adoption is the capability of IT staff inside the hospital to deal with such technologies [31]. Physicians with insufficient technical knowledge can be consider as another barrier for e-health projects in general [11]. Thus, prior technology experience or the Cloud/IT skills of non-IT employees are also expected to impact the diffusion of Cloud Computing inside health organisations [53]. Human factors

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were identified as the main obstacles of successful implementation of EMR in Saudi healthcare organisations [14].

Business perspective refers to the consideration of business issues related to the adoption decision. The first factor is the financial issues regarding to the implementation of Cloud Computing solutions. The cost should be analysed in both capital expenditure (CAPEX) and operational expenditure (OPEX). The decision regarding which deployment models should be implemented also needs to be discussed carefully [29]. The organisation should have clear procurement strategies for Cloud Computing. Another related issue is the impact of the adoption of Cloud Computing on medical and business processes [3]. The absence of implementation strategy has negatively affected e-health projects in Saudi Arabia [15]. The use of Cloud Computing will help the hospitals to move from the traditional health care model (doctor-centred model) to the new health care model (patient-centred model) [6]. Another factor that should be discussed is the strategic value that will be added to the health firm by using Cloud Computing technologies. Adopting Cloud Computing will give the possibility for new classes of applications and delivers services that were not possible before, such as mobile health, telemedicine and big data [3].

The proposed framework will help health organisations in the decision making process by evaluating various factors affecting the Cloud Computing adoption. Migrating towards Cloud needs a multi prospective strategy that supports Cloud Computing capabilities [52]. This framework will try to help the health organisation in bridging the gap between their IT projects and providing better medical care with lower cost and high standards.

VI. CONCLSUION AND FUTURE WORK

E-health is one of the ambitious initiatives that try to solve the traditional healthcare challenges. However, e-health projects usually face many issues. The higher cost and complexity of e-health projects beside the shortage of skilled staff in ICT domain can be consider as obstacles of e-health. Cloud Computing is a leveraging technology that provides many solutions for e-health projects. Healthcare firms may have many concerns about Cloud Computing. Thus, adopting Cloud Computing solutions in healthcare domain requires strategic plan that cover multi prospective.

This paper provides a holistic framework that can support healthcare organisations in their movement toward Cloud Computing. This framework covers five main aspects that are Organisation, Technology, Environment, Human and Business.

In future, a questionnaire and focus groups will be used to collect the necessary data amongst Saudi healthcare informatics participants. Factor analysis will be used to test the validity and reliability of the items constructed to measure the identified factors.

Finally, this framework is still work-in-progress. So, it will have more enhancements in the near future to cover all relevant factors that may affect Cloud Computing adoption in healthcare organisation in Saudi Arabia.

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Implementing a Volunteer Notification System Into a Scalable, Analytical Realtime Data Processing Environment

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***Abstract* - The pace at which next-generation Internet of Things networks, consisting of wirelessly distributed sensors and devices, are being developed is speeding up. More and more devices produce data in automated manners and the demand of smartphones and wearable devices is continuously increasing. With respect to volunteer notification systems (VNS), the resulting vast amounts of data can be utilized for profiling and predicting the whereabouts of people that, combined with machine learning algorithms, complement artificial intelligence (AI)-based decision systems. Hence, VNS benefit from keeping pace with the current developments by using the corresponding data streams in order to improve decision making during the volunteer selection process. In emergency scenarios, the velocity, low latency and reaction times of the system are essential, which results in the need of online stream-processing and real-time computational solutions. This paper will focus on a basic concept for implementing a VNS approach into a scalable, fault-tolerant environment that uses state-of-the-art analytical tools to process information streams in real-time as well as on demand, and applies machine learning algorithms for an AI-based volunteer selection. This work concentrates on leveraging open source Big Data technologies with the aim to deliver a robust, secure and highly available enterprise-class Big Data platform. Within the given context, this work will furthermore give an insight on state-of-the-art proprietary solutions for Big Data processing that are currently available.**

Keywords* - *Volunteer Notification System; Internet of Things; Big Data; Stream Processing; Machine Learning

I. INTRODUCTION

As we are moving towards the Internet of Things (IoT), the number of sensors that are deployed around the world, and devices supporting various different sensory technologies, is growing at a rapid pace [1]. These sensors and devices continuously (and automated) generate high amounts of data. However, in order to add value to the collected raw data, further processing is required that will help understanding the meaning and correlations within.

Bundling the accumulated data into a so called real-time information pipeline does enable scalable real-time query / in-stream processing technologies [2] and regular batch processing, which is currently supported by various state-of-the-art Big Data analytical environments, as will be discussed later. To a given problem (query), the introduced approach will process both persisted as well as real-time data to generate results, which can be further processed instantaneously or stored for subsequent processing. Various machine learning extensions on top of the basic environment do furthermore provide possibilities for extensive profiling and learning approaches that are based on the collected data, whereas the resulting decisions are generated near real-time, enabling a scalable volunteer selection architecture within the application scenario of a Volunteer Notification System (VNS), as primary introduced in [3].

Hence, this paper is going to provide an insight of the various technologies that can be efficiently used in order to create a scalable, reliable and fault tolerant environment as architectural base for a reasonable VNS implementation.

A. Structure

Section I will continue by introducing the various terminologies that are used throughout this work, whilst Section II will discuss the state-of-the-art with respect to the (Big Data) domain specific technologies and analytical frameworks. Section III will give detailed insights on the basic implementation approach and the corresponding concepts and methods, discussing the scalability effects (of the most problematic system components) of the underlying technologies in comparison. The last section, Section IV, will present a brief conclusion on the elaborated approach and shortly discuss those proprietary solutions and standards that are currently well established in the industry.

B. Volunteer Notification System

A VNS is an approach to integrate laypersons and medically trained volunteers into emergency medical services (EMS). By tracking the users' location, and in case of a medical emergency, a VNS aims to alarm those potential voluntary first-aiders who can arrive on scene fast enough to provide the most urgent measures until professional EMS arrive at the victims location.

Whilst the volunteer selection process can be efficiently enhanced by an AI-driven selection system [4], rather than merely using the last known location of a volunteer, this general approach is greatly limited by the input data stream and the available processing power. Thus, in order to provide a technical solution for the basic research questions in regards to an intelligent VNS, the scope of this work will focus on providing a solution in which the supported input data - that is generated by a multitude of devices - ideally is

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limitless and the computational power will be matter of theoretically seamless scalability.

C. The Internet of Things paradigm

The IoT paradigm proposes that everyday objects will be globally accessible over the Internet or other adequate network structures. Opposite to the Internet world, things with a physical shape usually belong to resource-challenged environments where energy, data throughput, and computing resources are scarce.

The focus of typical IoT activities lies on establishing connectivity at a certain protocol level to enable truly distributed machine-to-machine (M2M) applications. In the general protocol specification, the devices must communicate with each other (D2D). A device's data then must be collected and forwarded to the server infrastructure (D2S), whereas the server infrastructure will share the various device data (S2S), possibly providing it back to devices, analytical environments, people and any other subscriber for a specific type of data.

In regards to a VNS, the specific machines are handheld or wearable devices and corresponding servers. Hence, a device-to-server (D2S) infrastructure and a protocol that will secure this communication environment against data loss and eavesdropping, fulfills the basic requirement in the context of a VNS approach. A communication protocol of this type is the commonly used MQ Telemetry Protocol (MQTT) [5]. As device-to-device communication is not necessarily needed within a VNS approach, a pub/sub messaging system similar to a push notification system as lightweight as MQTT offers a suitable approach to fulfil the systems' communication requirements. A more in-depth view about MQTT and similar pub/sub systems will be discussed in Section II.

D. Big Data in the context of a VNS

In a data-driven society, massive amounts of data are being collected from people, sensors, algorithms and of course, the Web itself; storing it in conventional database systems (i.e., online transaction processing) or data warehouses (i.e., online analytical processing) that itself conform to an additional layer on top of single or multiple databases. The term Big Data describes the challenge for handling this continuously increasing data, whereas mainly three reasons posture the arising difficulties: the sheer volume, the velocity (how fast new data is continuously produced) and the variety of different data-types. For some time, an additional challenge has been observed; the so called veracity, which describes the challenge to exclude uncertainty and inconsistency within the collected data.

The VNS must handle these challenges gracefully and overcome the resulting difficulties with scalability and reliability in terms of the technologies that are being implemented. In general, the system approach that is to be illustrated in the upcoming sections of this work will be able to handle large amounts of continuously generated input data and will furthermore be able to detect faulty (i.e., inconsistent) information in an online matter.

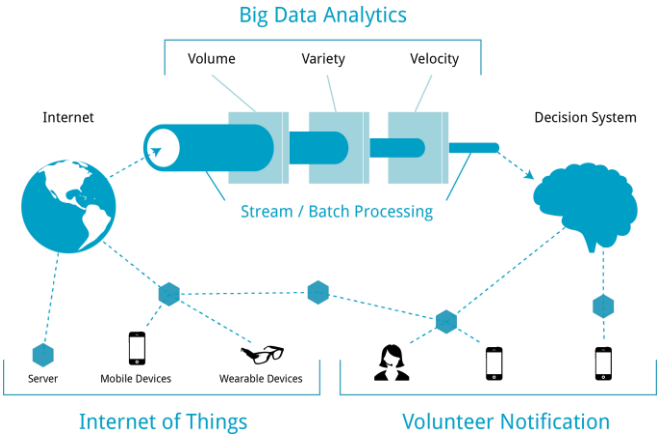

Figure 1. Big Data Analytics within a VNS

E. Stream Processing

As computer systems are creating ever more data at increasing speeds, Hadoop-style batch processing has awakened engineers to the value of big data analysis, whereas the current trend is focusing on the demand for real-time processing. In essence, people do not only want all of their data analyzed, but they want it done as soon as possible, which is driving the current Big Data research trend towards so called high-velocity data [7]. Exemplary use cases within this context are real-time analytics, machine learning, and new generation of decision support and fraud detection systems [8].

The desire to extract real-time insight from high-velocity data led to the creation of so called Stream Processing Engines. These engines include open source projects, such as Twitter's Storm [9], Apache Spark [10] and LinkedIn's Samza [11] as well as proprietary solutions, such as Amazon Kinesis [12] or Google's BigQuery [13]. These engines provide functionalities for routing, transforming and analyzing streams of data at high-velocity for a specified time window or near real-time (depending of the velocity and volume of streamed data chunks). The classical approach in this context would instead store the real-time data in order to apply data warehousing techniques for batch-processing in a subsequent matter. Figure 1 illustrates the conceptual coherence of the IoT paradigm and real-time Big Data Analytics within the context of an intelligent volunteer selection system.

II. State Of The Art

A. Pub / Sub Messaging Systems

Publish-subscribe is a messaging pattern in which occurring messages are not sent directly to a target receiver but rather published to a channel. Subscribers have the option to subscribe themselves on specific topics or channels and hence express their interest on receiving specific messages. The result is a lose coupling between publisher and subscriber, as they are unaware of each other.

 ISBN: 978-1-61208-384-1

In many pub/sub systems, publishers post messages to an intermediary message broker or event bus, and subscribers register subscriptions with that broker, letting the broker perform any type of necessary filtering. Pub/sub Messaging Systems allow implementation of a device-to-device, device-to-server and server-to-server interface, as have been introduced earlier.

The MQTT protocol on the other hand is a lightweight messaging protocol that uses a publish/subscribe architecture to deliver messages over low bandwidth or unreliable networks with a low footprint. Compared to a classical REST/HTTP implementation [14], MQTT imparts various advantages for the use within mobile applications, such as faster response times, higher throughput, higher messaging reliability, lower bandwidth usage and lower battery consumption

In this context, Apache Kafka [15] is a publish/subscribe log for integrating data between applications, stream processing, and Hadoop data ingestion. The project aims to provide a unified, high-throughput, low-latency platform for handling real-time data feeds. The design is heavily influenced by transaction logs to prevent data corruption and/or loss. On the server side, Apache Kafka will be used to create a pipeline between the MQTT broker cluster and the Hadoop/Spark environment to persist and stream process data; it will be managed by Apache Zookeeper for scalability and reliability purposes.

An alternative to MQTT in a proprietary environment are Amazon SNS, Amazon SQS as well as Amazon Kinesis, which are all capable of real-time streaming/distributing data between applications merely within Amazon Web Services (AWS) [16].

B. The Apache Hadoop Ecosystem

Apache Hadoop [17] is an open source software project that enables the distributed batch processing of large data sets across clusters of commodity servers. It is designed to scale up from a single server to thousands of machines, with a very high degree of fault tolerance. Hadoop is supplemented by an ecosystem of Apache projects, such as Pig, Hive and Zookeeper and many more, which extend the value of Hadoop and improves its usability. The core part of Hadoop is the Hadoop file system (HDFS) which comprises two major components: namespaces and block storage service. The namespace service manages operations on files and directories, such as creating and modifying files and directories, whilst the block storage service implements the actual data node cluster management, resulting block operations and replication.

Hadoop was often criticized [18] [19] for its open-source implementation of the MapReduce model [20] based on so called JobTrackers, which due to its problematic structure have be resolved with the implementation of Apache YARN [21] and MapReduce 2 in the scope of Hadoop 2.x. YARN is a resource manager that is based on separating the processing engine and resource management capabilities of MapReduce as it was implemented in Hadoop's original approach. YARN is often called the operating system of Hadoop because it is responsible for managing and monitoring workloads, maintaining a multi-tenant environment, implementing security controls, and managing high availability features of Hadoop. One crucial advantage of YARN in the context of using the Hadoop ecosystem for the VNS implementation is that is allows multiple processing models to be implemented on top of HDFS, thereby allowing Apache Spark to fit into the Hadoop Ecosystem [22]. The resulting flexible architecture allowed companies as Amazon and Google to create cloud computing platforms (e.g., Amazon EMR and Google's Cloud Platform) which implement enterprise-features out of the box and give a transparent in-depth cost overview.

C. Apache Spark

Apache Spark is a cluster computing platform similar to Hadoop designed to be fast and of general-purpose. Spark extends the popular MapReduce model to efficiently support more types of computations, including interactive queries and stream processing. One of the main features that Spark offers, is the ability to run even huge computational queries fully in memory (split over various clusters), reaching performance gains of up to 100 times compared to general Hadoop MapReduce implementations under specific circumstances. However, the system itself is also faster than MapReduce when running merely on disc operations.

At its core, the Spark Engine itself is responsible for scheduling, distributing, and monitoring applications consisting of many computational tasks across many worker machines powered by a high-level structure of components. These components are designed to interoperate closely, supporting a library-like combination of the various data representations (graphs, matrices, SQL like queries). Spark revolves around the concept of a resilient distributed dataset (RDD), which is a fault-tolerant collection of elements that can be operated in parallel. There are currently two types of RDDs: firstly parallelized collections, parallelizing an existing collection in your driver program, and secondly by referencing a dataset in an external storage system supported by Hadoop (e.g., the local file system, HDFS, Cassandra, Amazon S3). This allows Spark to interoperate with various stable established solutions in order to efficiently focus on problems regarding the introduced big data challenges. A recent cloud service that is entirely based on Spark and runs on AWS has been introduced by Databricks (who also drove the adoption of the Apache Spark ecosystem) in 2014. It allows developers to create scalable computing clusters running on Apache Spark for data analysis, machine learning and similar use cases.

This work will incorporate Apache Spark and its core components as the main cluster computing platform to overcome weaknesses of classical Hadoop architectures and to support the incorporation of the various proprietary

 ISBN: 978-1-61208-384-1

solutions, such as Amazon Web Services and the Databricks Cloud Platform.

D. Data Streaming & Processing

LinkedIn's Kafka was designed to support not merely the distribution of data, but also to provide the infrastructure primitives that will enable real-time data processing. Samza on the other hand provides elastic, fault-tolerant processing as being layered on top of real-time feeds. A simple analogy in respect to the batch domain is described by Kafka taking the role of HDFS while Samza relates to MapReduce.

While this architecture scales horizontally due to its MapReduce nature, speed is an important factor which needs to be considered. A combination of Apache Kafka with various Spark components (i.e., Spark SQL, MLlib and Streaming Processor) will result in a more reliable, vertically and horizontally scalable high-velocity architecture. The lack of security options within Kafka and Samza are an important criteria for using Spark's Security implementation and an integrated secure tunnel between Kafka and the corresponding MQTT brokers.

In terms of security, scalability and reliability a commercial solution with Amazon Kinesis and Amazon Elastic MapReduce provides leverage to these problems, including the high-velocity implementation of Spark components, which replicates the scenario in a more enterprise-ready fashion.

As the fault tolerance plays an additional key role for a successful scalable VNS implementation, Apache Cassandra [23] is the state-of-the-art database system in combination with Spark technologies; highly robust and fault tolerant. It protects against data loss or corruption by replicating blocks of data to multiple nodes and supporting replication between geographically distributed nodes. Amazon and Google offer similar enterprise ready data stores, such as Amazon Redshift [24], Amazon DynamoDB [25] and Google Cloud Datastore [26], whilst a general comparison between the Cassandra File System (CFS) and HDFS is given in [27].

E. Webinterfaces & API

Responsive web design architecture and supporting the HTML5 specification, esp. Websocket support [28], is efficiently incorporated by implementing Nginx [29] as a high-performance HTTP server for both, static web data as well as proxy requests to an underlying Node.js [30] runtime environment running server-side applications. Node.js applications are entirely written in JavaScript, whereas Express.js constitutes an adaptable MVC framework [31]. Node.js is characterized to be fast (due to event based architecture), offer high throughput, support high amounts of concurrent connections, support clustering and generally has a very low resource footprint. Offering advanced scalability, load balancing, health checks and some additional features, the Nginx Inc. released an enterprise version under the label: Nginx+ [32]. Node.js in this context enables the implementation of simple server applications as well as the requirements in respect to APIs.

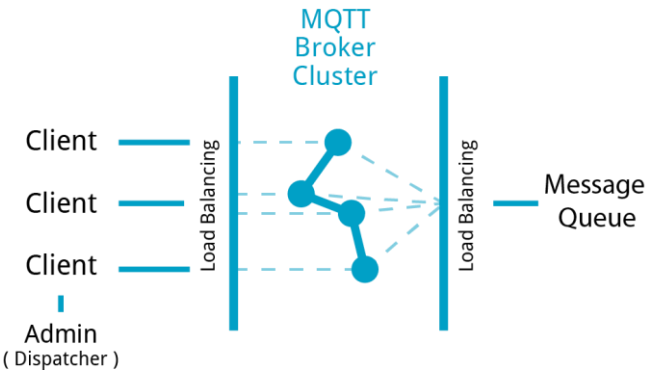

Figure 2. Realtime Data Pipeline

III. System Architecture

This section will illustrate the main strategy that incorporates the introduced technologies into a general system architecture that conforms to the requirements of an enterprise application.

A. Realtime Data Pipeline

Within a VNS, the data that is to be analyzed is generated by individual mobile or wearable devices. As illustrated in Figure 2, clients publish their data to a server which is connected to a message broker, which is responsible for broadcasting the received messages to the corresponding subscribers. Whilst a standard MQTT broker solution is lightweight and performant for a limited amount of connected clients (due to limits in the port range), a horizontally scalable approach will have to balance the various connections between multiple instances (load balancing) residing on different machines. As clients generally subscribe to specific topics in order to achieve push-like notifications, horizontal scaling will result in brokers having different information and topic structures.

To solve this problem, the various brokers (i.e., nodes) need to be connected with each other and share their message structure and permissions, forming a cluster of machines that can be scaled at will. Modern systems, such as RabbitMQ [33] and Apache's ActiveMQ [34], support the application of efficient clustering. Mirroring the message queues between all machines will allow the subscribers to connect to any existing node while still having access to the whole cluster. Established commercial projects that support scalable messaging systems and efficient load balancing for MQTT connections are: HiveMQ [35], CloudAMQP [36] and CloudMQTT [37].

B. Load Balancing

Since most standard load balancing approaches, such as Amazon's Elastic Load Balancer, only support Round Robin (RR) and Session Sticky Algorithms, they are not sufficient

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for balancing MQTT clients or applications between brokers. The already introduced commercial Nginx+ solution supports various advanced load balancing strategies [38], but even the open-source standard Nginx version can be extended with additional functionalities by incorporating the programming language LUA and a TCP-proxy module to support the programmatic injection of algorithms that can filter requests of clients and balance connections between brokers with high performance. This added functionality enables a distinguished consideration of the various active brokers in order to terminate obsolete sessions, run additional scripts for scaling the cluster, and perform regular health checks on running instances.

C. Ad-Hoc / Online Computation

As described in [39], ad-hoc computation on message brokers is efficiently achieved by combining Apache Kafka with Apache Sparks infrastructure; since Kafka efficiently persists the message queue on a data store (e.g., Cassandra or HDFS) while Apache Spark handles workloads both in real-time as well as by batch processing. Kafka is guaranteed to deliver reliable message durability and a fault-tolerant near real-time computation with Spark Streaming [40]. At this point, one might argue about missing security measures within Apache Kafka [41].

Whereas various other messaging platforms (e.g., RabbitMQ) support the persistence of incoming data on data stores, they are usually not performant enough or simply not optimized for processing environments such as Kafka, which itself is very robust in throughput of messages and during read/write operations [42]. Whilst the Apache Spark libraries provide methods for connecting to MQTT brokers and streaming data, the underlying communication has to be implemented manually. In contrast, Kafka can be implemented as a complementing stream processing layer between the MQTT cluster and Apache Spark [43].

Within a VNS, the streamed data will mainly consist of location data of individual volunteers and case update data. Thus, stream processing will be applied to regulate updates concerning a specific case in real-time; deriving decisional, predictive or anomaly detection results. However, an efficient volunteer selection, based on accumulated profile data, will mostly be computed in batches, as discussed in the upcoming section.

As data store, Apache Cassandra constitutes a high performance scalable database with linear scaling that secures an enterprise-ready solution for this work. Similar, proprietary options are Amazon DynamoDB and Amazon RedShift, whereas HDFS would partly limit the performance of Spark and other NoSQL data stores [44].

D. Batch/ Offline Computation

Batch processing on big amounts of accumulated data is commonly implemented based on Hadoop clusters. Within a VNS, finding the most reasonable candidates for an ongoing medical emergency – within a minimum time interval – hereby constitutes a batch processing problem with an increasing (raw) data size over time. Location based data will be analyzed in order to compute behavioral patterns of volunteers; this can be done on a regular basis (iterative) based on batch processing of the acquired location data and in combination with various machine learning algorithms. The results will be available for additional real-time computations, whereas details for an AI-driven volunteer selection discussed in [45].

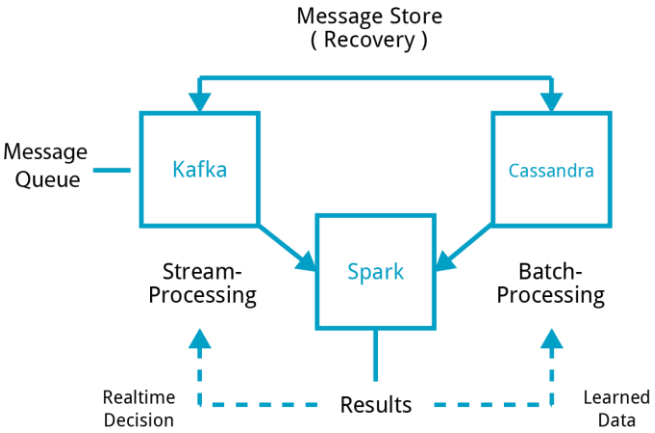

Figure 3. Real time Data Processing

Apache Spark can accomplish both tasks of on- and offline computation quite reliable and fast allowing the results to be stored in data stores or be directly accessible via API or MQTT subscribed topics. While real-time per-case computation and live updates would amass resource consumption it would be possible but unfeasible and unnecessary. With a proper modelling of data stores direct API access allows fast updates of a case without the need of costly computations. Behavioral patterns can be learned after an emergency scenario, as well due to the systems structure.

Figure 3 illustrates the general architecture for a real-time data processing environment, as has been discussed within this section. Nowadays, Amazon EMR, Google Cloud Platform and Databricks deliver the technologies needed for a successful computation environment for similar use cases and allow different services like data stores or real-time computation ecosystems to be fully implemented on commodity hardware.

IV. Conclusion

This work illustrated details on how to implement a VNS into a distributed analytical environment with high velocity data support. Scalability and reliability is hereby achieved by utilizing merely open-source software solutions without relying on any commercially driven software or proprietary cloud solutions. While security and special solutions for load balancing and regulating the corresponding environments cannot be guaranteed by open-

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source Apache software alone, new Big Data challenges arise continuously and more open-source projects are being incubated or upgraded; hopefully solving both, newer as well as older challenges that were formally limited to enterprise solutions.

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Benefit of Telemedicine for Patients With Diabetes Mellitus

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Abstract-The mean HbA1c difference between Sensor Augmented Pump (SAP) therapy and Multiple Daily Injections (MDI) is 0.3 to 0.6% in favour of SAP, but adolescents, although treated with SAP therapy, show a progressive temporary deterioration of glucose control. Telemedicine in Type 1 Diabetes is thought to facilitate diabetes management and to improve compliance to CSII/SAP treatment especially during adolescence. The aim of the present study was to observe the long term impact on glycometabolic controlled by Telemedicine systems (*Telemedicine Group*) compared with traditional follow-up (*Control Group*) in Type 1 diabetes SAP treated adolescents. The observed HbA1c decrease in the group followed with telemedicine was associated with a better compliance to therapy in terms of frequency of sensor use, number of SMBG tests and number of insulin boluses.

Keywords-Type 1 diabetes; adolescence; telemedicine; telemonitoring; CSII; SAP

I. INTRODUCTION

Diabetes is a hormonal disorder that affects an estimated three hundred million people worldwide [1]. Several treatments have been proposed to guarantee patients a good control of symptoms but, when diabetes is underestimated, it can lead to a poor quality of life. Diabetes is a disease characterized by a group of metabolic disorders, caused by defects of insulin's secretion and/or activity. The first condition is represented by a pancreas inability to produce insulin and the latter is characterized by incorrect use of normal secreted insulin (insulin resistance). Insulin, produced by the Beta cells from the Langerhans islets, has a dual function: transport glucose from the bloodstream to the body's cells, where it is converted into energy and is involved in the anabolic metabolism of glycogen. The previously strong association of low HbA1c with severe hypoglycemia and coma in young individuals with type 1 diabetes has substantially decreased in the last decade, allowing achievement of near-normal glycemic control in these patients [3]. At the same time, high HbA1c value can induce, in the long term, the incurrence of co-morbidity diseases, which is well known from literature.

Several meta-analyses of randomized controlled trials have demonstrated that mean glycated hemoglobin (HbA1c) levels and hypoglycaemic episodes are significantly lower with Continuous Subcutaneous Insulin Infusion (CSII) as compared with multiple daily insulin injections (MDI) in type 1 diabetic patients, children, adolescent and young adults [4]. The mean HbA1c difference between treatments is 0.3 to 0.6%, with a greater reduction (> 0.6%) in patients treated with Sensor Augmented Pump (SAP) therapy [5], especially for very young children [6].

During this age period people with diabetes shows a progressive and temporary deterioration of glucose control and one explanation for deteriorated glycaemic control among adolescents treated with CSII and SAP is omitted bolus doses before meals [7].

Telemedicine in diabetes, defined as the use of telecommunications to deliver healthcare services by interaction between the medical staff and the patients/their families, includes the telemonitoring of the transmission of health data (self monitoring blood glucose data, insulin therapy, pump setting, etc.) from the patient's home to the Diabetic Unit, with a consequent real-time health feedback. An online website on web-based intervention for adolescents with Type 1 Diabetes demonstrated that the tele medical approach seems to be a promising tool for a better disease management [8], but, up to now, poor literature related to Telemedicine in adolescents with Type 1 Diabetes is available. The main aim of this study was to observe the long term (five year) effect of glycometabolic control in patient followed with ambulatory visits and Telemedicine assistance (*Telemedicine Group*), compared with a similar group (*Control Group*) followed with traditional trials (only with periodic ambulatory visit) in Type 1 diabetes adolescents treated with SAP therapy. The paper is structured as follows: Section II discusses the methods used for our approach; Section III presents the results; in Section IV we presents conclusion and ideas for future work.

II. METHODS

This is a case feasibility study on using telemonitoring for diabetes follow-up. This was an analytical observational study, carried out at Bambino Gesù Children's Hospital, in the Unit of Endocrinology and Diabetes in association with Research Unit of Health Technology Assessment, over a period of 60 months. A

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total of 29 consecutive Type 1 diabetes, SAP treated, adolescents (mean age 13), regularly followed at Bambino Gesù Children's Hospital, Unit of Endocrinology and Diabetes, were randomly (randomization 1:1) assigned to a Telemedicine assistance (*Telemedicine Group*), with a frequent (monthly) tele-assistance and tele-interaction between the medical team and patients/families, or to a traditional follow up (*Control Group*): only with ambulatory visit (in-hospital periodic visits at 3 months intervals). Patients with diabetes duration < 1 year were excluded from this study.

For both groups HbA1c values, was compared the mean, at 6 months intervals, of: frequency of sensor use, insulin boluses per day, SMBG tests per day and severe hypoglycemic episodes, by engineers of Research Unit of Health Technology Assessment

The study design conformed to the ethical guidelines of the Declaration of Helsinki (1975), and the Ethics Committee of Bambino Gesù Children's Hospital and Research Institute approved it.

At the beginning and during the study all the enrolled patients received a regular and standardized protocol of education about proper control of diabetes, in which a multidisciplinary team (diabetologist, nurse, dietitian and psychologist) was involved.

To the *Telemedicine Group*, plus the standardization protocol, was asked to store the parameters before mentioned, on each personal profile of online website, day by day, to have telemonitoring of the transmission of health data (Telemedicine protocol) by the team of Unit of Endocrinology and Diabetes, with a consequent real-time health feedback.

To the *Control Group*, plus the standardization protocol, was asked to store, the parameters before mentioned, in a diary (*Traditional protocol*). For the *Telemedicine Group* the data was stored by the patients on each personal profile of online website, day by day.

For each patient, was valued the number of doses of insulin/day (bolus/day) and number of self-monitoring of blood glucose/day (SMBG / day).

So for each patient was reported: the value of glycosylated hemoglobin test (HbA1c) at month: 0,6,12,18,24,30,36,42,48,60 in the years since 2009 to 2014; number of boli/die and SMBG/die.

A. Statistical Analysis:

At the end of the study, the recorded outcomes were analyzed using GrafPad software. Difference between the mean values of HbA1c, bolus/day and SMBG/day in two groups was statistically compared and analyzed by student-t test, standard deviation and When p-value was < 0.05, it was considered as statistically significant. When p-value was<0.01, it was considered as very statistically significant.

III. RESULTS

Results showed that both groups were homogeneous on the socio- demographic characteristics. Mean follow-up duration was more than 60 months.

As reported in Table 1, the observed HbA1c decrease in the *Telemedicine Group* was associated with a better compliance to therapy in terms of frequency of sensor use, number of SMBG tests and number of insulin boluses. Our data showed that there is, for the two groups, in the last year of observation, statistically significant difference ($p< 0.004$) of mean values of HbA1c associated to: significant differences of number boli/die ($p=0.036$) and very significant difference ($p=0.001$) between number of SMBG/die in the five years of observation.

Patients in *Control Group* tendency have values of $8 < HbA1c < 12$, individual patients tend to have higher average of HbA1c equal to 8 even surpassing this threshold.

Patients of *Telemedicine Group* tendency have values of $6 < HbA1c < 10$, individual patients tend to have lower average levels of HbA1c to 8. In Figure 1 is reported the HnA1c trand of two group.

The analysis of the graphs shows a increase of boli/day for patients in *Telemedicine Group* higher than patient in *Control Group*. Patient in *Telemedicine Group*, noncompliance with recommended *Telemedicine protocol* had value of HbA1c comparable of patient in *Control Group*. Again, patient of *Control Group*, more compliance at *Traditional protocol* had vale of HbA1c similar of patient in *Telemedicine Group*.

IV. CONCLUSIONS AND FUTURE WORK

Telemedicine can increase the self-management of disease in pediatric patient with diabetes by increase the number of boli/die and SMBG/die with consequent reduction of HbA1c test value. In our study we compared two groups of SAP treated Type 1 Diabetes adolescents followed for a long period (five years).

The *Telemedicine Group* was followed by standardization protocol of education and storage data on each personal profile means online website, day by day, to have telemonitoring of the transmission of health data (*Telemedicine protocol*) by the team of Unit of Endocrinology and Diabetes, with a consequent real-time health feedback (plus periodic ambulatory visit).

While the *Control Group* was followed by *Traditional protocol* manner with standardization protocol of education and only periodic in-hospital visits consultations and storage data in a diary.

We demonstrated a favorable impact of frequent (monthly) Tele-assistance on compliance to therapy: in fact, patients receiving a frequent feedback by the medical/multidisciplinary team, due to the

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telemonitoring, resulted more compliant to self-management of diabetes then patient in *Control Group* followed with traditional trials, without telemonitoring by the multidisciplinary team. In *Telemedicine Group* frequency of sensor use, as well of SMBG tests, and consequently frequency of insulin boluses, were significantly higher as compared to the *Control Group*. This improved compliance to the therapy and to the global management of the disease, seems to have a direct effect on the glycometabolic control. The results of our study, in fact, demonstrated a better level of HbA1c even after a long period of follow-up in Telemedicine.

In conclusion, our study demonstrated that when remote assistance (Telemedicine) is added to technology (SAP Therapy) we may assist people living with type 1 diabetes to become more compliant to self-management of the disease. More and wider studies are needed in order to confirm this data and better define populations appropriate for the Telemedicine approach.

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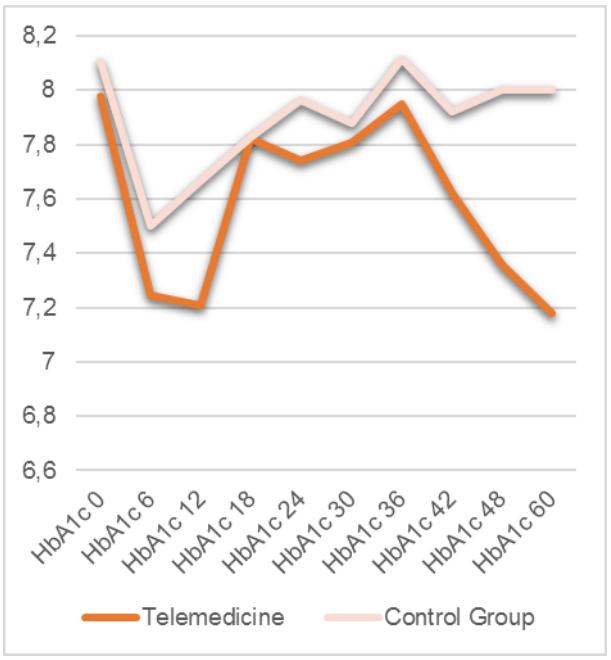

Fig. 1 Trand of HbA1c levels during the follow-up period in *Telemedicine Group* and *Control Group*.

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Deployment of Electronic Prescriptions in Belgium

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***Abstract*—After a two-year pilot, including the ICT (Information and Communication Technology) developments and small scale tests, the Recip-e project for ambulatory electronic prescriptions is currently in national roll-out phase. Along with the operational secure data-flow, an important number of parameters are captured and taken along; these parameters are processed and archived, enabling us to make a first evaluation regarding the approach taken in Belgium, both from a technical point of view and from a methodologic point of view, regarding the technical developments and the involvement of all stakeholders.**

Keywords: electronic prescription; e-health; deployment

I. INTRODUCTION

Prescriptions are a cornerstone in most health systems: in the paper world, the prescribing health worker (general practitioner, specialist, dentist) writes down a medical prescription on a pre-formatted piece of paper, signs it and usually hands it over to the patient. The patient then collects the medication, written on the paper prescription, in a pharmacy. Here, health systems may differ greatly: in some countries the choice of the pharmacy is not free (e.g., Denmark where this is determined at the time of prescribing, and often limited by physical constraints: islands with a single pharmacy [4]). In other countries, the choice of the pharmacy is free: the patient determines where he will collect the prescribed medication. This last case corresponds to the Belgian situation [13].

In this paper, we will highlight the main design features of the ambulatory electronic prescription system "Recip-e" [14] in the sections II and III, then in section IV (Results) the roll-out process is quantified and discussed in the Vth section.

II. MATERIALS AND METHODS

The objective set forward for the Recip-e project phase 0 was to realize an in depth study to identify the elements required to realize the theoretical model. This theoretical model resulted from a study performed in the context of the Belgian Ministry of Health and Social Affairs in 2002 [13].

The pilot study covered following topics:

- Evaluate the functional, technical and operational requirements for a realistic implementation
- Make a stakeholder analysis
- Benchmark equivalent projects abroad
- Study the financial implications
- Communication / Interaction with the stakeholders
- Propose a roll-out plan.

Figure 1 shows the current flows of the paper and electronic prescriptions in Belgium: from the prescribing physician via the patient to the pharmacy which he can choose freely.

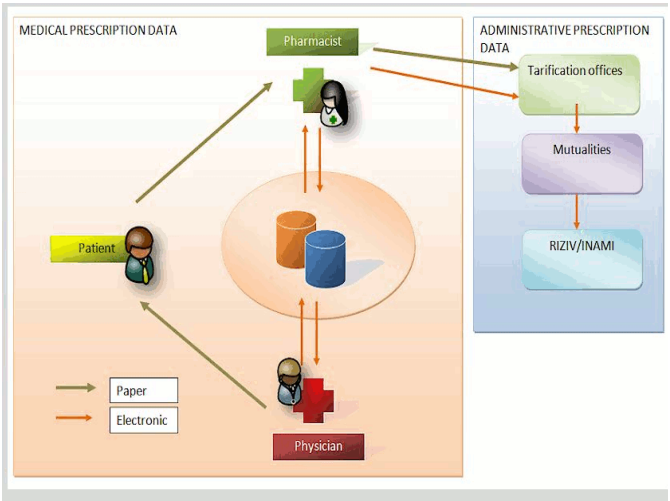

Figure 1. Recip-e dataflows

Benchmarking with Sweden and Denmark [1][7], teaches us that the introduction of EPP (Electronic Pharmaceutical Prescriptions) can take several years. Innovations in the medical sector are confronted with the relatively high inertia

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of the sector. This understanding leads to following eight border conditions for the technical solution of the "Electronic Medical Prescription" (EMP) in Belgium, where we need a system:

- Allowing perfect co-existence between paper and electronic prescriptions during the roll-out phase, which might take some time;
- At least allowing continuity in characteristics and identical functional possibilities versus the paper prescriptions;
- Requiring minimal legal modifications;
- Making use of open technology: standard protocols and platform independence;
- Keeping the medical information managed by physicians and pharmacists;
- Offering immediate benefits to all involved parties, right from the start;
- Identifying long-term benefits, resulting from full deployment;
- Putting emphasis on communication and dialog with the different entities and representative organisations of the health and social security sectors.

These eight points were identified at the start of the project. They obtained a consensus within the project team and were acknowledged by the sector representatives we consulted. Taking into account these border conditions, we designed the conceptual flow model, fitting into the Belgian health system, resulting in the flow diagram of Figure 1.

The flow of the electronic medical prescription starts at the prescribing physician (generated by the prescription module of his medical package) and goes to the EPP system. While in the first phase (during roll-out), the patient still obtains his printed-out paper prescription, complemented with an additional bar-coded number, the unique prescription ID, identifying the electronic prescription in the EPP database. This paper prescription now fulfills the role of a token, enabling the pharmacist or physiotherapist to retrieve the electronic prescription from the EPP system.

After the roll-out phase, paper tokens will become obsolete and identification at the pharmacy will be performed by the appropriate identification system selected by the sector in dialog with the authorities. From 2014 on, the pharmacists will be able to obtain the list of non-delivered prescriptions, recorded in the EPP database for a patient, by querying via the patients eID number. Unlike in the Netherlands [6], the Belgian eID number corresponds to the social security number.

III. TECHNOLOGY DESCRIPTION

A. Data Format

The building blocks required to realize an electronic prescription system are based on an existing technology :

1. Internet communication protocols/web-services
2. The Kind Messages for Electronic Health Records (KMEHR-bis) XML format for medical messages [8], including the medical prescription
3. Patient and medical worker identification by the appropriate electronic cards (eID or equivalent)
4. Advanced digital signature, via the eID resident signing certificate and recognised as equivalent to handwritten signature
5. Accessible and sound encryption technology
6. Adequate authentication portals, identifying the role of prescriber and pharmacist
7. Operational medication databases
8. Cheap and secure database storage

Emphasis here is on the role of the KMEHR-bis messages which play a central role in Belgium: since 2002, about 30 XML formatted messages were defined, they correspond to the most used messages in the Belgian health system. Through labeling sessions, enforcing the implementation of relevant KMEHR-bis messages, the Ministry of Health´s efforts and incentives resulted in the situation where all accredited software packages for general practitioners are now able to generate and read in the

KMEHR-bis messages such as the pharmaceutical prescription. The pharmaceutical packages don't reach this level of integration yet, but the experience with the "General Practitioners" (GP) packages shows that to obtain full compliance, no major effort will be required, moreover, just a single message plays a central role in the EPP system: the pharmaceutical prescription (KMEHR message 12d).

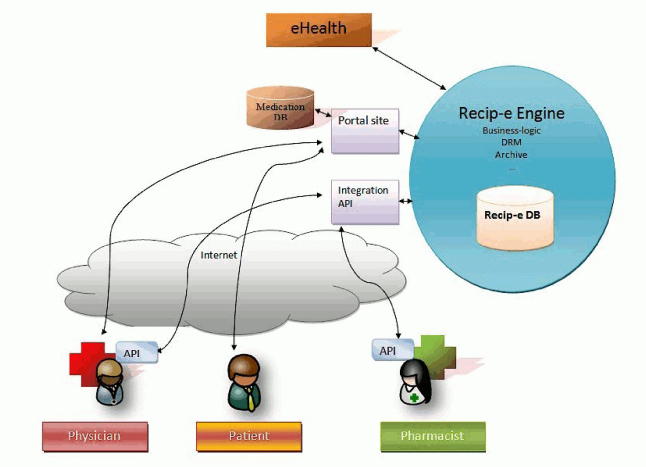

Figure 2. Recip-e components

The KMEHR-bis message "pharmaceutical prescription" comprises an administrative header, followed by a folder (containing the data which are found on a paper prescription) such as the prescriber´s identity, the patient and as many items elements as there are medications on the prescriptions.

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This number would be limited to 9, for practical reasons. The items comprise the market name of the medication, the unique Belgian identifier code for a given drug (CNK), the packaging and quantity, posology, way of administration, and the frequency (daily, morning/afternoon, ...) and free text instructions for patients.

Close examination of this XML message by experts in the field rose a single comment: the pharmacists would like to see the addition of the indication by the prescriber (the reason why this particular drug was prescribed), so that they can be involved in taking up responsibility for more appropriate use of the drug. This remark will be taken into account for the next version of the KMEHR messages and the prescribing physicians will be informed.

Tarification offices, of the pharmacists´ professional associations, health insurance and the social security administration are not part of the *inner loop* of the EPP project. They obtain the administrative and financial data regarding the delivered medication via the pharmacists, as is the case now (see Figure 1). Moreover, it would be desirable to include information regarding the insurance status of the patient and the permissions required for expensive medication (Chapter IV of the Belgian Nomenclature) as early as possible, preferably at the moment the prescription is made. To realize this, a connection with the MyCarenet service of the mutual insurance instances will be required. The MyCarenet services provide safe access to the insurance status of all individuals, registered in Belgium.

B. *Building Blocks*

Modules realized are (Figure 2):

1. The Recip-e portal allowing to define personal profiles by all users and adequate reporting and a prescription module, based, among others, on the "Belgisch Centrum voor Farmacotherapeutische Informatie" (BCFI-CBIP) [16] or other accredited medication database
2. The Recip-e Application Programming Interface (API): Recip-e is mainly be accessed through the API of the physicians or the pharmacists software package
3. The Recip-e engine contains modular building blocks, surrounding the secured prescription database
4. Links to authentic sources for authentication and identification of roles will be made through the eHealth-platform (national infrastructure supporting the generic building blocks).

Some building blocks needed by the Recip-e engine are provided by the eHealth-platform (time-stamping, logging, authentication, encryption, …) as for the whole e-health sector.

C. *Data flows and interactions*

Step 1: creation of a prescription by the prescriber. The prescriber creates an electronic prescription, normally via his medical package or via a web prescription program. The prescription is signed digitally (either each prescription is digitally signed or the prescriber´s session is authenticated via the e-ID + pin code of the prescriber, if a similar procedure can be accepted as in the intra-muros prescription). Then the prescription is transmitted in encrypted format to the Recip-e server. See Figure 2.

Here, some formal verifications are performed: identity of prescriber and patient´s identity. If all tests passed, a RID (Recip-e ID == unique identifier for each accepted prescription within the system) is attributed. The RID is sent in response to the prescribing system within seconds (max. 5s). The prescription is then printed, using the legal format, comprising the RID as a bar-code (Figure 3). Otherwise, a meaningful error message is generated and transmitted to the prescribing system.

For security reasons, the prescription is divided into several data-blocks:

- administrative (patient, RID)
- administrative prescriber (ID,..)
- medical: (medication, posology, ...)

blocks 2 and 3 are encrypted with a key, kept by the eHealth-platform, while encrypted data are stored in the Recip-e database.

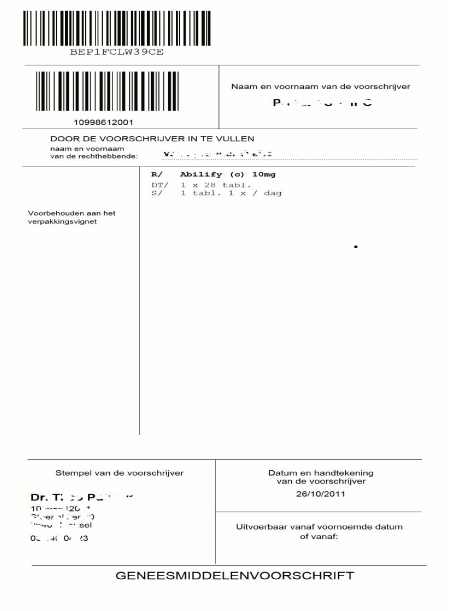

Figure 3. Paper "token" prescription with RID bar-code

The prescriber will automatically add the prescription to the medical patient record (outside the scope of Recip-e) and the patient obtains the printed-out prescription.

D. Technical implementation

During the pilot phase (2011-2013), three infrastructures were set-up:

1. The test-environment at the software developer Accenture (main software developer of the project)
2. The acceptance environment, integrated into the eHealth-platform's acceptance bus, servers and database hosted by Belgacom (the national telecom company and commercial datacenter provider)
3. The production environment, integrated into the eHealth-platform's production bus, servers and database hosted by Belgacom, managed by Recip-e.

These three were maintained throughout the pilot phase of the project and the current roll-out phase. Developments are first made and tested on the test server of the software developer, then transferred to acceptance and made available for testing purposes by software vendors of EMR's and pharmaceutical softwares and the Recip-e team. After approval, updates are then transferred from the "acceptance" to the "production" servers, accessible to the end-users.

In the roll-out phase, a fourth environment was set-up on independent servers, on another location (Uniweb), for the logging and monitoring functions, exclusively accessible to the Recip-e technical team.

Authentication of end-users, both in acceptance and in production environments is performed by a combination of the following elements:

- The national identity card and associated pin-code to authenticate the individual
- A certificate associated with the health worker and attributed via the eHealth-platform.

which result in "sessions". During such session, the health worker can access the system and perform the actions, associated with his role in the health system: a GP can create prescriptions, a pharmacist can deliver and a patient can consult the pending prescriptions, for himself as shown in Table 1.

TABLE 1. RECIP-E FUNCTIONS AND PERMISSIONS

Function	GP	Pharmacy	Patient
Create prescription	*		
Revoke (delete) prescription	*	*	*
List open prescriptions	*		*
Print prescription content	*	*	*
Mark as delivered		*	
Mark as undelivered		*	
Archive prescription		*	
Announce prescription	*		
Create feedback messages		*	
List feedback messages	*		

E. Management by the patient

The patient can manage (list, delete, forward) the prescriptions, related to himself, residing on the Recip-e server via a portal, that will be made available via the network of mutual insurance instances of the country and other health portals. He also can deny certain access rights for health care professionals to his pending prescriptions. Mandates should be managed outside Recip-e, but be part of a more general system, in which the e-Health platform plays a central role. Recip-e will make use of these generic services that will implement the operational access matrix of the complete health system. As long as this service is not yet operational, we will have to work with default values, corresponding to the procedures that exist in the current (paper based) health system, in complete accordance with legal and regulatory frameworks and in agreement with stipulations by the Privacy Commission [x] and the internal Recip-e ethical committee.

Step 2: The patient selects the care provider (pharmacist in case of pharmaceutical prescription) of his choice. He identifies himself by his electronic ID and (in the transition period, while paper prescriptions remain the only legally valid ones, he/she will then recover the pending prescription(s) via his professional package and will deliver what is written on the prescription). The electronic prescription is removed from the prescription server upon receipt by the care provider. The prescription system will not keep an archive of delivered prescriptions: this task remains with the care providers who have this responsibility right now in the paper world. We wanted to avoid a huge accumulation of sensitive medical data in a single place and by doing so, realize a link with another ongoing project by the pharmacies: establishing the medication records of individual patients, which already will include the original prescriptions (soon in electronic, time-stamped format).

IV. RESULTS

A. Deployment with the GP's

After the "pilot phase", national roll-out was prepared and effectively started in May 2013 by involving all recognized vendors of electronic medical records for general practitioners (17) and software for pharmacies (9), active in the country. Via the "registration procedure" managed by the Federal state's institution "eHealth-platform", vendors of GP software were required to implement access to the secure webservices of the health system and a number of applications, amongst which the electronic ambulatory prescriptions via Recip-e. Several mini-lab sessions and from the very start of the pilot until testing sessions were held to assist the software vendors and to assess the operation (end-to-end) via real-life scenarios. In September 2014, 14 of the 17 software packages for GP's complied and by November, all passed the tests.

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Progressive end-user deployment resulted in a consistent increase in the generation of electronic prescriptions as shown in Figure 4, taken on November 24th 2014; by mid-November 2014, we reached 19,000 prescriptions per day, by 1300 GP's.

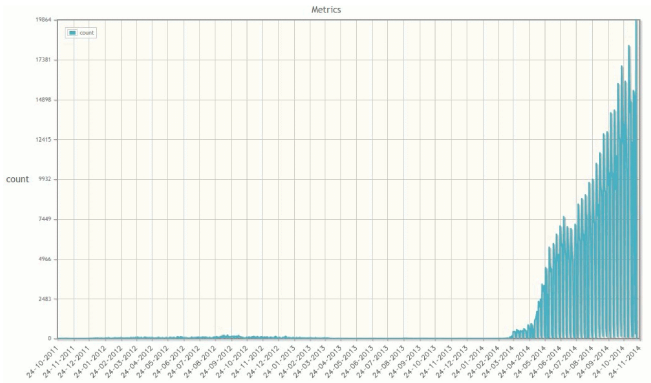

Figure 4. Daily produced e-prescriptions vs. time

We could also measure the rate of incoming prescriptions, vs. the time of the day, as shown in Figure 5. The most active part of the day is between 8:30 am. and 11:30 am., it is followed by a serious slow down between 12:00 and 16:00, then an active afternoon runs from 16:00 to about 20:00, be it at a slower pace than the morning period. These data should be taken into consideration to establish the required performance at full deployment.

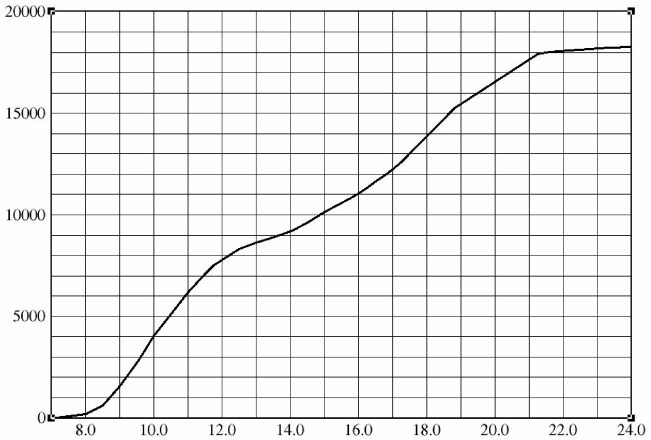

Figure 5. Incoming prescriptions vs. time of the day

It also shows that server maintenance activities and heavy scripts which require CPU power are best run between 2am and 5am when incoming prescriptions are very few in number.

B. Deployment at the pharmacies

The situation of the pharmaceutical software vendors differs, as for them, there is no accreditation procedure. Although this sector was encouraged and given explicit technical support, by September 2014, only 2 vendors (comprising 38% of the 5000 pharmacies) had implemented the Recip-e functions in their packages, but all 9 will be deployed in the first quarter of 2015. Whereas by mid-November 19,000 electronic prescriptions are generated, daily, only just over 1600 are delivered by pharmacies, leaving most indefinitely in our database! This is explained by the current geographical mis-match between GP's and pharmacies who are involved and by the on-going developments by the pharmaceutical software.

C. Informing stakeholders

A major effort was deployed to inform all stakeholders, including the end-users of the introduction of electronic prescriptions.

Software vendors were invited to participate in info sessions and mini-labs. Software demos were prepared, showing all the Recip-e functions in full-source, readily down-loadable and operational within hours in the "acceptance environment". A technical help-desk, ticketing system and interactive follow-up were established.

For the end-users seminars, conferences and demos were performed together with the respective professional associations (mostly GP's and pharmacists) and on-line materials are made available.

D. Deployment in other sectors of the health care system

Next to deployment of ambulatory pharmaceutical prescriptions by GP's, following targets are in the pipe-line:

- Prescriptions by specialists
- Prescriptions by dentists
- Ambulatory prescriptions from hospitals and clinics
- Physiotherapy prescriptions
- Nursing prescriptions
- Prescriptions by midwives

For each of these, the methodology, as followed for the pharmaceutical prescriptions by GP's is followed, be it at faster pace, because the same infrastructure and previous experience can readily be applied.

E. Remaining work

The paper-based prescription with additional RID-bar-code was intended as a transition tool between the paper prescription and the electronic one. In view of fully paperless operation, the approach of how and when de-materialisation will take place needs to be addressed in dialog with the stakeholders involved.

V. DISCUSSION

The deployment of the electronic prescriptions evolves consistently and although we have little leverage to force the end-users to start sending in electronic prescriptions, they

start moving in. Once prescribers have observed how little effort it takes, they continue to use the system.

For the benefits to become evident to the whole sector, we need to obtain a much higher deployment degree and familiarity of the end-users with the more sophisticated functions such as the feed-back messages and the verification of "list open prescriptions" enabling GP's to verify weather the patient has at least collected previously prescribed medication.

Pharmacists have the possibility to link the electronic prescription to their "robots", but the ergonomy of their softwares is a key factor.

Although in very few cases, inconsistencies between the paper-based and the electronic prescription were observed, due to software bugs and due to manipulation errors, in general, the roll-out strategy works.

VI. Conclusion and Future Work

The purpose of the Recip-e pilot study (phase 0) was to perform an in-depth analysis of all aspects of an electronic prescription system for Belgium corresponding to the theoretical model realized previously, fitting into the Belgian health system and aiming to obtain a consensus from all involved parties: physicians, pharmacists, authorities and the patients. The in-depth analysis resulted in pilot (phase 1) that enabled to implement and test on a small scale but with real data. This resulted in phase 2: the current national roll-out, which shows that in the transition, co-existence of paper-based and electronic prescriptions works, but that strong incentives are required to move the whole sector to make use of the electronic functions.

A very important element is the cooperation of all electronic service providers, to make the access by the end-users consistent, so that in a single step, they obtain a complete set of complementary services, combining administrative simplification, support to their medical information and communication in a secure way with guarantees of privacy and professional quality.

After completing the roll-out of the pharmaceutical prescriptions (or in parallel with the final steps), we will move to the remaining types of prescriptions and decide how and when full "de-materialisation" will take place, liberating us from the paper-based prescriptions.

Acknowledgment

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Process Evaluation of a Cluster Randomised Controlled Trial of a Monitoring and Feedback Tool Embedded in a Counselling Protocol to Stimulate Physical Activity

Study protocol procesevaluation RCT *It's LiFe!*

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***Abstract*— This paper describes the study protocol of the process evaluation of a cluster randomized controlled trial of a monitoring and feedback tool embedded in a counselling protocol to increase physical activity of people with COPD or type 2 diabetes in primary care. Both qualitative and quantitative data were collected from participating patients and nurses of the two intervention groups. Functioning and use of the tool were evaluated by system, - and helpdesk logging. The researchers developed questionnaires and interview topics by translating key elements of process evaluations (recruitment, reach, context, fidelity, dose delivered, dose received, - exposure and satisfaction) into structured questions regarding the different components of the intervention; the Self-management Support Program and the use of the tool.**

Keywords- physical activity, behavior change, self-management support, primary care nursing, remote sensing technology, proces evaluation.

I. INTRODUCTION

Physical inactivity is one of the key risk factors for noncommunicable diseases such as type 2 diabetes (DM2) and Chronic Obstructive Pulmonary Disease (COPD). In the global action plan for the prevention and control of noncommunicable diseases, the World Health Organization proposes a 10% relative reduction in prevalence of insufficient physical. All sort of actions are needed to reduce physical inactivity, for example through people-centered primary health care. Primary health care interventions are necessary to empower people with noncommunicable diseases to seek early detection and manage their own condition better, by providing them with tools for self-care and self-management through information and communication technologies such as eHealth or mHealth [1].

In the project Interactive Tool for Self-management through Lifestyle Feedback! (*It's LiFe!*), a monitoring and personalized feedback tool was developed [2] and tested [3][4] according to User Centered Design principles. The tool aims to support patients with DM2 or COPD in achieving a more active lifestyle. The tool consists of three elements:

- a 3D accelerometer worn on the hip;
- an application (app) on a Smartphone;
- a web application[1].

Patients receive different types of feedback concerning the amount of activity in relation to an activity goal (constantly), automatic feedback messages from the system (intermittent), and feedback from their practice nurse (during and in between consultations). Use of the tool is part of a behavior change counselling protocol for practice nurses named the Self-management Support Program (SSP).

The effects of this intervention were evaluated during a cluster randomized controlled trial (RCT *It's LiFe!*) among 24 practices, which were randomized in three groups. The nurses in the two intervention groups provided the SSP, one intervention group with and the other group without the use of the *It's LiFe!* tool. The third group received care as usual. The program was carried out by the nurses during four consultations spread over a period of six months. A detailed study protocol of this effect study has been published in advance [5].

Incorporating a process evaluation is necessary to examine the receipt of the intervention in depth [6-9]. From

[1] Both authors contributed equally to this study.

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the results of a related feasibility study [10], it was known that for most participating nurses and patients the use of mobile technology would be a new experience. Also a wide range of differences in the performance of the intervention by the nurses and in the adherence of participants in using the tool was expected. Therefore, the aim of the process evaluation of the RCT *It's LiFe!* was to examine:

- who participated in the intervention, who dropped out and for what reasons (recruitment, reach and context);
- to what extent was the intervention executed and received as intended (fidelity, dose delivered, dose received-exposure);
- how participants experienced different aspects of the intervention (both the monitoring and feedback tool and the SSP) (dose received-satisfaction); and what suggestions participants had for improvements.

Section (II) of this paper presents the methods of the process evaluation, which was conducted in parallel with the effect study.

II. METHODS

A. Study design

From December 2012 until July 2014, the process evaluation was conducted amongst the participating general practices in the intervention groups of the RCT *It's LiFe!* The research questions were derived from the following elements of the framework of Saunders: recruitment, reach, context, fidelity, dose delivered, dose received - exposure, and dose received – satisfaction [6][11]. The researchers developed the questionnaires and interview topics by translating these theoretical key elements of process evaluations into structured questions regarding the different components of the intervention (Table 1).

B. Data collection

Table 2 provides an overview of the data collection methods and the timing of the process evaluation.

After informed consent was given by the participant, participant characteristics (i.e., demographics) were gathered by means of self-administered questionnaires. The researchers collected reasons for refusal and dropout through-out the intervention period. To establish exposure, the nurses in both intervention groups were asked to keep record of all consultations. Compliance with the use of the tool was also measured objectively by extracting information from the *It's LiFe!* server. Technical problems were logged by members of the help-desk.

TABLE I. COMPONENTS OF THE INTERVENTIONS

Intervention components	
SSP	**TOOL**
Materials and Instruction	
Instruction booklet about the SSP	Manual and instruction by the PN
Leaflet disease specific information	Instruction movies on the website
Leaflet with local sports,-activities	Helpdesk
Consultations 1-4: different aspects	*The accelerometer*, the app and/or the website
Assessment physical activity level (SQUASH and diary)	Views of physical activity results
Risk communication	Use of the "remarks by measurement of today" option
Goal setting and SMART activity planning	Send and respond to sessions: "registration" "diary" "preparation for goal setting" "set up an action plan" "feedback"
Discussing barriers and facilitators	
Feedback	

Approximately two weeks after the second consultation, all nurses of both intervention groups were interviewed per telephone to ask them about their experiences. In the interviews, which lasted approximately half an hour, special attention was given to the factors that influenced compliance with the intervention at two levels: complying with the advised strategies during the first two consultations and using the monitoring and feedback tool. Directly after the intervention period, a questionnaire about their experiences and the feasibility of the intervention was sent to all nurses and participants.

TABLE II. DATA COLLECTION

Data Collection
Patients
Dropout call researchers (when it occurred)
Questionnaire (after the intervention)
Practice Nurses
Inclusion list (at baseline)
Consultation evaluation forms (per consultation)
Interview (by phone after 2th consultation)
Questionnaire (after the intervention)
Tool
System log file server (continuously)
Helpdesk log file (continuously)

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In choosing the outcomes and measurements of the process evaluation, the potential for increased Hawthorne effects was taken into account by minimizing the contacts between researchers and patients, for example by arranging a website for participating patients and an helpdesk which they could contact in case there were questions or problems. For the same reason, patients were not interviewed during the intervention [12].

C. Data analysis

Quantitative data were analyzed by means of descriptive statistics, and Fishers exact and Pearson Chi-square tests, using the IBM Statistical Product and Service Solutions statistics version 22. Qualitative data (results of open questions and interviews) were analyzed by two researchers (RV, SvdW) independently using NViVo version 9 in order to identify relevant themes. A concurrent triangulation strategy was applied to confirm, cross validate and corroborate the findings. The analysis of the process data took place before the outcome data were analyzed, to avoid bias in interpretation [13].

Hypotheses and possible outcomes of the process evaluation were based on the outcomes of a previous conducted feasibility study in two family practices with 20 participants [10]. We expected:

- Difficulties in finding enough practices who were willing to cooperate in the study;
- A drop-out rate of 10% of the patients and 0% of the practice nurses;
- A complete and acceptable execution of the intervention in more than 50%;
- Less technical problems compared to the feasibility study;
- That more than 75% of the participants in group 1 would use the tool until the end of the intervention;
- An overall satisfaction with the intervention in more than 75% of the participants (both patients and practice nurse).

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Cluster Randomised Controlled Trial of a Mobile Monitoring and Feedback Tool Embedded in a Counselling Protocol to Stimulate Physical Activity in Chronically Ill Patients

Study protocol of the *It's LiFe!* RCT

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***Abstract*—Physical inactivity is an increasing public health concern. The *It's LiFe!* monitoring and feedback tool embedded in the Self-management Support Program (SSP) is an attempt to stimulate physical activity in people with Chronic Obstructive Pulmonary Disease or type 2 diabetes treated in primary care. This paper describes the study protocol of the *It's LiFe!* three armed cluster randomized controlled trial in which the effects of the SSP and the added value of the tool were evaluated. The main hypothesis was that the complete intervention increases participants moderate to vigorous physical activity with at least 10 minutes per day, after a 4-6 months intervention period.**

Keywords- physical activity, self-management support, remote sensing technology, primary care, chronic obstructive pulmonary disease, type 2 diabetes.

I. INTRODUCTION

According to the World Health Organization (WHO) physical inactivity is the fourth leading risk factor for global mortality and the cause of 6% of all deaths [1]. Physical activity (PA) reduces the risk of developing several diseases, and in people with an existing chronic condition it improves quality of life and delays complications [2] [3]. Despite the benefits of PA, 31% of the people worldwide were insufficiently active in 2008 [1]. Therefore, the WHO Member States try to reduce physical inactivity by 10% in 2025 by, e.g., making active transportation accessible and safe, developing labor and workplace policies to encourage physical activity, encouraging and supporting schools to have safe accessible spaces for free time activities of the students, and by improving physical education for children [1]. Another strategy is by incorporating the improvement of PA levels of patients into the healthcare process. Especially for practice nurses (PN's) in primary care, coaching people with a chronic disease to become more active has become part of regular care according to guidelines [4] [5]. However, using the right strategies to stimulate people and keep them encouraged to be active, remains challenging. A clear coaching strategy and the implementation of rapid developing technical tools could reinforce and help the PN in this coaching role [6]. In the *It's LiFe!* project a coaching strategy for the PN, which is called the Self-management Support Program (SSP), and a monitoring and feedback tool which should be embedded in this SSP, were developed [7] [8]. A three-month pilot study in two general practices with 20 patients with Chronic Obstructive Pulmonary Disease (COPD) or type 2 diabetes (DM2) showed promising results [9]. However, in this feasibility study no control group was present.

Therefore, the objective of this three armed cluster randomized controlled trial (RCT) was to evaluate the effects of the SSP and the added value of the *It's LiFe!* tool on 40-70 years old patients with COPD and DM2 in primary care. The primary outcome measure was physical activity in daily life. Secondary outcome measures were quality of life, self-efficacy and health status. Section 2 of this paper describes the study protocol of the *It's LiFe!* RCT of which an extended version has been published in advance[10].

[1] Both authors contributed equally to this study.

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II. METHODS

A. Study design

A cluster randomized controlled trial was performed in 24 general practices in the South of the Netherlands. Practices were randomized in three groups. Practice nurses, in practices in group one executed the SSP and provided the tool, practices in group 2 executed the SSP alone and practices in group 3 performed care as usual. Every practice was asked to include 5 patients with COPD and 5 patients with DM2, which made a total of 240 patients.

B. Eligibility

Participants were eligible when they complied with the following criteria:

- Diagnosed with COPD or DM2
- Between 40 and 70 years old
- Treated in primary care
- Did not comply with the Dutch Norm for Healthy Exercise, according to the practice nurse
- Additional inclusion criteria for the DM2 patients were a Body Maxx Index>25 and for the COPD patients: a clinical diagnosis of COPD according to the GOLD-criteria stage 1-3, being at least six weeks respiratory stable and on a stable drug regimen
- Access to a computer with an internet connection
- Not participating in another PA intervention
- Sufficient mastery of the Dutch language
- No coexisting medical conditions with a low survival rate, severe psychiatric illness or chronic disorders or diseases that seriously influence the ability to be physically active

C. Recruitment

1) Recruitment of practices

General practices in the South of the Netherlands were invited by an invitation letter, by telephone and personal contact with general practitioners, practice managers, and PNs.

2) Recruitment of participants

The PN's sent 20-32 patients, which met the inclusion criteria, a general invitation letter. After randomization, the PN called the patients to give specific information about the group in which the practice was allocated and to ask if they wanted to participate. Patients, who decided to participate, received an information letter and an informed consent form.

D. Intervention

Both components of the intervention, the tool and the SSP, were developed in a previous user-centred design process and tested in an usability and feasibility study [7-9] [11]. See Figure 1 for a picture of the *It's LiFe!* tool and Figure 2 for the course of the interventions.

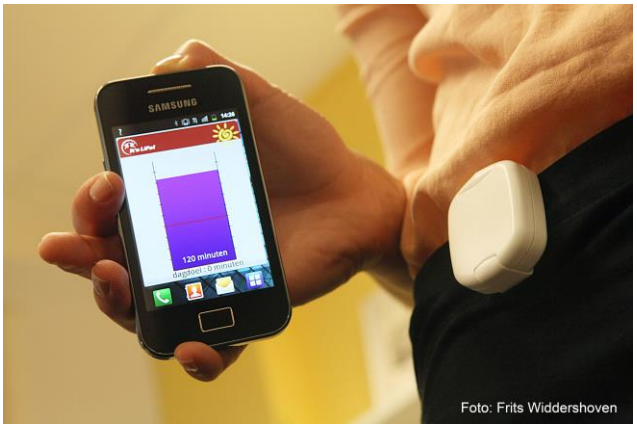

Figure 1. The It's LiFe! activity monitor and Smartphone app

1) Self-management Support Program (group 1 and 2)

The SSP consisted of four consultations with the PN and is based on the Five A's model (Assess, Advise, Agree, Assist, Arrange), a counselling protocol to support self-management in a primary care setting [12]. Before the consultations, the participants received an information booklet with information about the course of the intervention, local PA activities and a questionnaire to assess their activity level (SQUASH) [13]. In the first consultation the PN talked with the participants about the current activity level based on the completed SQUASH questionnaire, and the PN tried to increase the awareness of the health risks of a sedentary lifestyle. The participant received a leaflet with information about PA in relation to COPD/DM2 [14] [15]. During the two weeks in between the first and the second consultation, the PA level of the participant was assessed (the pre-measurement); in group 1, objectively by the tool and in group 2, by filling out a PA diary. Additionally, questions about barriers and facilitators for physical activity were answered during this period. In the second consultation, the PN and participant set a PA goal in minutes per day, based on the pre-measurement and the PN encouraged the participant to set up an activity plan to reach their goals. The third consultation, 8-12 weeks after the start, by mail, phone or in real-life, functioned as an evaluation, PA results, goals, barriers and facilitators were discussed and if necessary adapted. In the last consultation, 16-24 weeks after the start, PA performance was discussed in relation to behaviour changes, habit formation and challenges and goals for the future.

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2) The tool (group 1)

The *It's LiFe!* tool consists of a 3 dimensional accelerometer, a Smartphone app and a web application for the participant and the PN. The participants could wear the accelerometer at the hip or in their pocket and see on the Smartphone app their activity in minutes per day. In addition, dialogue sessions were sent which could be answered on the Smartphone app or the web application. After a goal was set in the second consultation, the real time activity results were presented in comparison to the personal goal and automated feedback messages were send based on the achieved results.

E. Data collection

For the data collection the participants received questionnaires and a physical activity monitor three times per post; at baseline, direct after the intervention (4-6 months after the start) and 3 months after completion of the intervention (7-9 months after the start).

F. Outcome measures

The primary outcome measure, minutes of physical activity per day in the moderate to vigorous category was measured with the Pam AM300 (PAM) [16]. Participants were asked to wear the PAM on 8 consecutive days. A measurement was considered valid if the Pam was worn on ≥ 5 days for ≥ 8 hours.

Secondary outcome measures were measured with questionnaires. Quality of life was assessed with the RAND-36 [17] [18], exercise self-efficacy with the Exercise Self-efficacy Scale [19-21] and general self-efficacy with the General Self-efficacy Scale [22]. Health status was measured with the Chronic Respiratory Questionnaire [23] [24] in participants with COPD and with the Diabetes Symptom Checklist Revised [25-27] in participants with DM2.

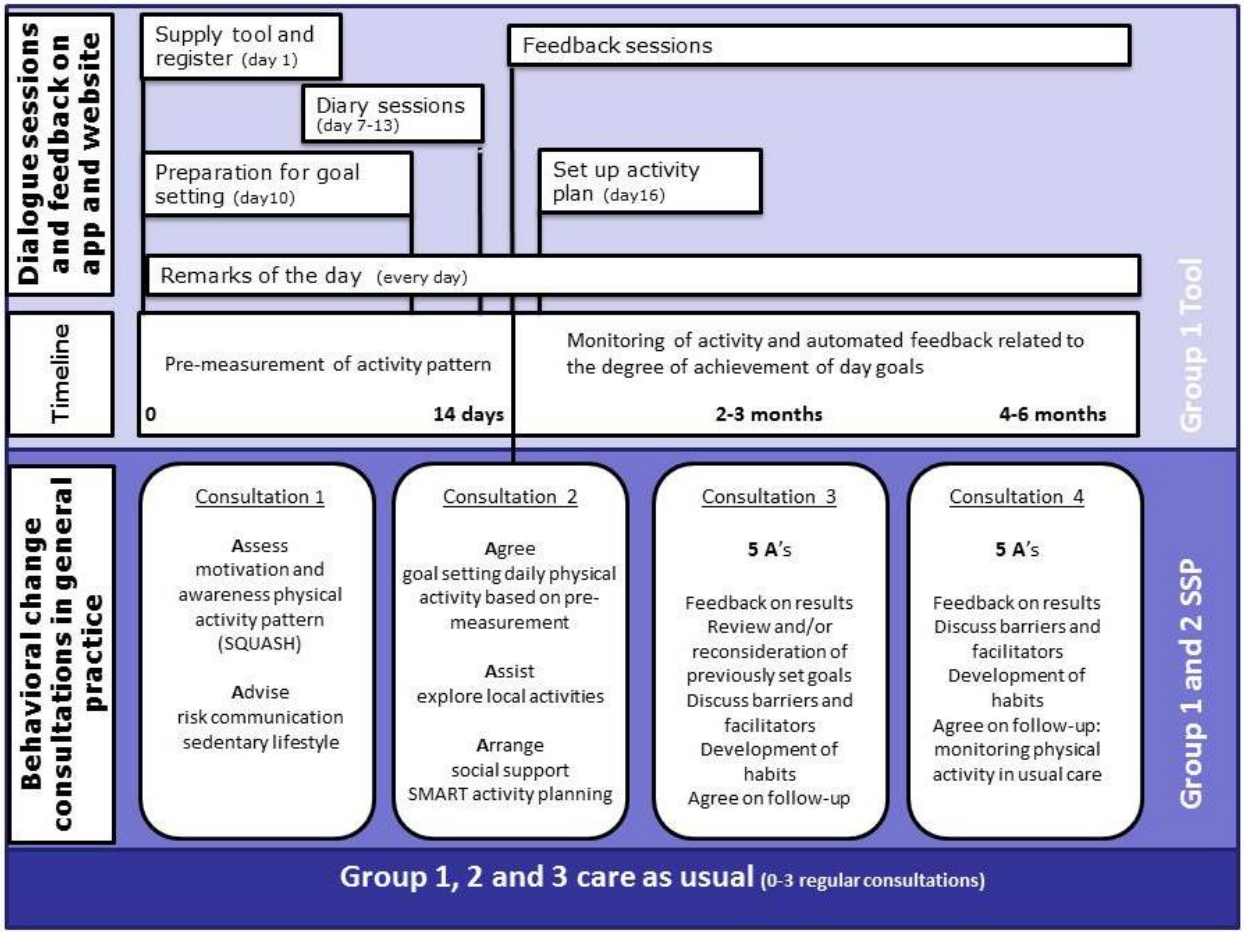

Figure 2. The different components of the (intervention) groups

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G. Statistical analysis

Differences at baseline between the three groups were identified with chi-square, ANOVA and Kruskal Wallis tests, p-value ≤0.10 and those variables were considered as potential confounder in further analysis. To account for dependency among participants in the same general practice multilevel analyses were performed.

The main hypothesis was that the complete intervention, where the tool was embedded in the SSP increases participants' moderate to vigorous physical activity by at least 10 minutes per day, after a 4-6 month intervention period, compared to care as usual and that participants maintained this increase over three months.

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- IDEE Maastricht UMC+ Universiteitssingel 50, 6229 ER Maastricht, the Netherlands, www.idee-mumc.nl
- Maastricht Instruments Ltd. Oxfordlaan 70, 6229 EV Maastricht, the Netherlands, www.maastrichtinstruments.nl
- Sananet Care Ltd. Rijksweg Zuid 22A, 6131 AP Sittard, the Netherlands, www.sananet.nl

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Telecardiology Assistance in Senior Living Houses

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Abstract-**The Chronic Heart Failure represents one of major cause of mortality and morbidity in developed countries. It is expected that incidence of heart failure associated with aging, will rise exponentially, due its higher prevalence among population over 75 years. The Senior Living House are missing an adequate secondary healthcare assistance in order to provide a qualitative secondary prevention to the resident. We have conducted a pilot project of telecardiology in one Senior Living House in 2013, with duration of 6 months; we decided to expend the project as an observational trial with primary objective to evaluate impact of telemedicine on secondary prevention of clinical cardiovascular outcomes /hospitalization in senior living house setting and secondary objectives to evaluate quality of life using Minnesota living with Heart Failure questionnaire and to evaluate cost savings and additional benefits earned by Telemedicine. For the study, 85% powered at the 5 % level of significance; to detect differences, we need 310 patients, including 10 % drop out. As results, during the pilot project, 23 patients with median age of 86 years were monitored; we are currently enrolling new senior living house and patients with CHF that resides in senior living house.**

Keywords-Chronic Heart Failure; Telemedicine; Telecardiology; Secondary prevention; Senior Living House; ECG; Oxygen Saturation; Cardiovascular.

I. INTRODUCTON

The CHF (Chronic Heart Failure) is one of principle causes of re-hospitalization, in population over 75 years of age. With future aging process, the prevalence of cardiovascular disease will rise exponentially [1]. The ratio of healthcare spending for elderly population is already 4 fold higher versus healthcare spending for population under 65 years old [3]. In near future, the elderly will represent one fourth (1/4) of total population; it is estimated that aging process by 2050 will achieve an important share of 25% of total population, represented by elderly population over 65, while in Italy this percentage will reach 33% [1]. Considering the aging process and associated increase of chronic disease prevalence in next future, healthcare systems will face financial and professional constraints in provision of qualitative and equally accessible healthcare services.

The chronic heart failure represents one of major cause of mortality and morbidity in industrialized countries. The incidence of heart failure is estimated from 1 to 5 cases per 1000 population with exponential increase in the population over 65 old, because of what heart failure is considered a disease of aging [4]. High incidence of re-hospitalization due to frequent CHF exacerbation makes this group of patients among the highest consumer of healthcare and social services.

Secondary prevention is an important gatekeeper of hospitalization and over consumption of tertiary care service. Secondary prevention can detect early signs of organ worsening and prevent further deterioration, by intervening with adequate treatment. In order to detect early symptoms, it is necessary to monitor frequently patient's vital signs.

Telemedicine showed positive results in regards of secondary prevention. We posed the question whether the telecardiology assistance in long term trial of 24 months, on large sample can show decrease in re-hospitaliaztion and improvement of quality of life. The article aims at presenting an work in progress project, the methodology used in develompent of the project, the problems that have been encountered and further perspectives. The quality of data transmitted still represent a limitation for telemedicine wider use. We present the Chronic Heart Failure as a future public healthcare problem by introducing telecardiology assistance in SLH and our project pilot. Finally, we present a protocol developed on the basis of project pilot results. Major results are not available yet.

II. CHRONIC HEART FAILURE - FUTURE PUBLIC HEALTHCARE IMPACT

The heart failure represents a terminal syndrome of heart function deterioration, often affected by number of pathology associated with process of aging. The heart insufficiency has an important effect on long life perspective and quality of life characteristics as capacity to perform everyday activity.

Quality of life and social activity are in relation with patient's mobility. With aging, the level of disability is increasing; according to Global Burden of Disease Study, cardiovascular diseases will generate 18(10^3) DALY (Disability Adjusted Life Years) by 2020 [1]. The prevalence of CHF increases with age: 2% for persons from 40 to 59 years, more than 5% for patients between 60 and 69 years, and 10% for persons more than 70 years old [2]. A heart failure is considered a cause of 20% of all re-hospitalization generated by patient's over 65 year old.

The cost of heart failure care is estimated as percent of total healthcare spending equal to 1,3%, with the highest cost spent for hospital care, that represents 77% of total healthcare spending for heart failure [3]. The major causes of re-hospitalization are non adherence to treatment and non adherence to physician advices [4].

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These issues are minor causes of re-hospitalization when patients reside in senior living house, where they are assisted by a nurse. Still senior living house requires cardiology secondary care consultation and additional monitoring of cardiovascular patients. These additional support provided by telemedicine at distance would prevent worsening of patient health status and frequent re-hospitalization, by early symptoms detection and optimization of therapy.

III. SENIOR LIVING HOUSE- ITALY

A Senior Living House (SLH) are residential structure for elderly who is partially or completely non auto-sufficient. The primary function of a SLH is to guarantee physical health and psychological well being. A SLH provides a medical geriatric, nurse and rehabilitation assistance; however, there is a lack of secondary care prevention assistance. Therefore, we want to address an added value of telemedicine in SLH setting, characterized with elderly population mostly affected by cardiovascular diseases, who are in a need for monitoring and secondary cardiology prevention assistance. The percentage of elderly population who resides in SLHs varies by country. The secondary care and tertiary care services provided to the residents of a SLH are reimbursed by national healthcare insurance.

The presence of healthcare professionals, as nurses, in SLHs was important for our project as it facilitated communication between Cardiology Department and SLH. A SLH, usually, has a medical doctor, a nurse, and caregivers; the specialized assistance as cardiologic consultation may be an additional benefit in order to improve the quality of care provided.

IV. SOCIAL INCLUSION – ROLE OF TELEMEDICINE AND PREVIOUS CLINICAL TRIALS OF TELEMEDICINE IN CHF PATIENT

A distance clinical monitoring system combining telecommunication technology and medical device for transmission of vital signs measurement can decrease readmission rate and improve social well being [5] [6].

Telemedicine can offer monitoring of ECG and blood pressure at distance, early detection of symptoms and signs, and secondary prevention through optimization of therapy. Optimization of therapy is represented by real-time titration and adequate dosing of medication through tight follow-up of the patient symptoms. In previous years, research has shown that tight home care monitoring improves functional status of the elderly [7]; the trial conducted by Kornowski [8], who evaluated a weekly home visit by internist specialist, has shown a significant decrease of readmission to the hospital, improved functional status of the patient, with consequent decrease of healthcare expenditure.

V. CLINICAL TRAIL PROPOSAL

The project pilot has been conducted in 2013, with duration of 6 months. During 6 months period, 23 patients affected by cardiovascular disease has been enrolled, after the verbal inform consent has benn given by their family member. The project pilot has shown limitations in regard of telemonitoring frequency and readability of ECG.

ECG readability is very important for accurate recognition of ECG changes from its baseline. We have faced a problem of interferences around the patient (cell phone, TV, vibration from bedsore mattress) which intervened with morphology of ECG line. The readability of ECG has been improved after pilot project; we added additional filters that improved readability and accuracy of ECG .

During the pilot project, the average age of patient enrolled was 86; considering Italian longevity, this population is considered very old. During the pilot project, we had seven hospitalization for non cardiac diagnosis, with length of stay of 76 days cumulative. The number of re-hospitalization for CHF was 2, with the stay length of 2 days and with mortality rate during re-hospitalization of 100%.

The pilot project had the objective to evaluate feasibility of telecardiology, to understand the problems of technology and to evaluate professionals' and patients' responsiveness to the telecardiology. The patients enrolled in pilot project were affected by any type of cardiopathy; those affected by CHF represented 50% of patients included in pilot project.

TABLE I. SUMMARY ON THE PARITICIPANTS.

Pilot project in short figures				
No. of patients	Patients with CHF	Average age	Intervention	Number of teleconsultation
23	10	86,7	ECG PA Saturation	510

The adherence to the guidelines for CHF treatment is one of prerogative of adequate treatment. We evaluated if every patient affected by CHF (10 patients) was using beta blockers and diuretics. In further extended trial, we will observe change in therapy and the need for optimization of therapy, taking in consideration co-morbidities associated with CHF.

TABLE II. DETAILS ON CHF THERAPY.

Usage of CHF therapy, represented in pilot project				
Beta blocker	Diuretics	Antitrombotics, Anticoagulant Clexane,Cardioaspirina, Plavix, Arixtra, warfarin	Statins	Inotropic drugs
100 %	100%	100%	8%	8%

A. Extended clinical Trail

As prevalence of CHF increases with age, the population over 75 years of age was considered as target group population, where secondary prevention via telecardiology would demonstrate a positive effect.

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Primary Objectives: To evaluate impact of telemedicine on secondary prevention and reduction of clinical cardiovascular outcomes /hospitalization in senior living house setting

Secondary Objectives: To evaluate quality of life using MlwHF(Minnesota living with Heart Failure) and cost – effectiveness

B. Definition of patients

The patients were over 75 years old who live in a SLH and with New York Heart Association (NYHA) II and III, but not on dialysis.

We choose over 75 years of age, as the prevalence of CHF and re-hospitalization rate is higher in this population, hence this group will benefit more from secondary prevention than younger group of population.

The patients living in a SLH affected with CHF have nurse assistance; additionally, with trial, we will provide a frequent and continuous monitoring and pharmaceutical- drug titration adjustment provided by cardiologist via telemedicine.

Inclusion Criteria: Patients with heart failure diagnosis based on guidelines ESC (European Society of Cardiology); Patient over 75; Patient NYHA II – III; Patient with ischemic and valvular heart pathology; hypertensive and dilatative cardiomyopathy; EF= 35%

Exclusion Criteria: Patients below 75 years; Patient affected by psychiatric disease and dementia; Patient on dialysis; Cahexia; Non cooperative patient.

C. Study Design

An observational trial, have a duration of 24 months. The telemedicine monitoring will have frequency of weekly vital parameters measurement (blood pressure, oxygen saturation, weight and ECG). In a previous pilot project, we didn't observe weight measurement changes, as most of patients were very old (86 years, average) and were bedridden.Variation in body weight is an important diagnostic parameter of CHF symptomatology,

The design of trial does not include the control group. The rate of re-hospitalization in population over 75 years old, affected by CHF is established from previous large clinical trails. Results from this trial will be compared with results established by large registries for CHF (OPTIMIZE, ADHERE) [9][10][11].

D. Sample size calculation

The previous studies conducted using randomized clinical trial design showed a decrease in readmission of 20-40% with telemedicine [12][13][14][16].

The difference expected is at least 15% decrease of hospital readmission. For the study, 85% powered at the 5 % level of significance, to detect difference we need 310 patients including 10 % drop out. Cumulative probability and survival curves will be constructed using Kaplan-Meier estimates [18] and compared using the Log-Rank test [19]. The rate of hospital readmission, i.e., Hazard Ratio (HR)[19] and 95% Confidence Interval (CI) will be calculated using a Cox regression model [20]. Probability values < 0.05 will be considered significant.

E. Subgroups

Elderly population is affected by multi-pathology; the CHF causes reduced perfusion of other organs. Inadequate perfusion has a negative impact on an organ's function, altering its function. We want to evaluate the effect of secondary prevention for CHF, and its secondary effect on organ functional preservation. Therefore, the next subgroup evaluation will be conducted: 1. Diabetes vs. no Diabetes; 2. Hypertension vs. no Hypertension; 3. Ischemic CM vs. no Ischemic CM; 4. B blockers vs. no B blockers; 5. Dose of loop diuretic (40 mg vs. >40 mg/day).

The co-morbidities represented in subgroups are most frequent co-morbidities, related to structural and functional organ's modification, associated with aging process. We didn't establish a number of patients that would be necessary for each group, to demonstrate significant results among the groups. If during the trial a difference between groups in regard of primary objective (re hospitalization) will be observed, further adjustment of design will be done in order to demonstrate significant results in subgroups.

The long term therapy with diuretics usually causes drug resistance, which requires an increase of drug dosage in order to obtain the same effect. We want to evaluate the effect of combined tight monitoring and secondary prevention via telemedicine on lower dosage of diuretics vs. higher dosage of diuretics consumption.

F. Telemedicine Equipment

A consolidated platform for telemedicine that supports multi-specialty tele-consultations is used. The technical system needs only to be configured at the moment of deployment to the user and is really easy to use. The software allows real-time and storage and forward data sending to manage different need of use and possible lacks of connectivity without data loss. It integrates different types of medical devices tailored for the nurse use. The cardiologist communication and consultation are supported with storing, reporting, real-time communication and high resolution visualization of the documents. Every kit contains medical device (blood pressure device, oxygen saturation device, weight control device, ECG – 12 leads, electronic stethoscope), and a tablet with easy to use software.

G. Intervention

A nurse once a week, usually in the morning, would perform measurements of vital signs, and send them to cardiology department; after clicking on the button *send*, nurse receives the message that measurement has been sent successfully. The Telemedicine kit is very easy to use; after the access to the Internet, the software application opens instantly, and displays 4 images, representing the access to separate pages of 4 vital signs measurement (saturation, blood pressure, weight, and ECG); all data measured from medical devices are acquired by the software installed on a tablet, via a Bluetooth connection. When data are transmitted from medical devices to software, they will appear in defined boxes on display; the nurses have to control if data transmitted on tablet correspond to data obtained by the medical device; afterwards the nurses have to push button *send* and wait until a message that confirms that data have been sent successfully appears. This procedure is repeated for each of four measurements.

Every morning, one of cardiologists at cardiology ward accesses the software application by logging with his username and password; the application will open by displaying a list of patients enrolled in the trial.

When clicking on patient name and choosing clinical data option, the patient's page will appear; it contains all measurement sent by the user, with date of the performed measurement. The cardiologist has the opportunity to consult previous measurements

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and to visualize all data graphically; graph contains all changes in patient's vital signs from the first measurement.

H. Quality of life Evaluation and cost effectiveness analysis

The Minnesota living with Heart failure questionnaire will be used for evaluation of quality of life improvement. The Minnesota living with Heart Failure questionnaire is a patient self-assessment measurement, being developed to evaluate the therapeutic response to intervention for heart failure [13].

VI. RESULTS

During the project pilot, 23 patients affected by cardiovascular disease who were living in a SLH were monitored three times per week for the period of 6 months. The results showed limitation in regard to the readability of ECG and medical doctors' culture about telemedicine. After conclusion of pilot project on the end of 2013, these issues were addressed. Then, the clinical trial protocol presented in this paper was developed.

On March 2014, we started with selection of new SLH and consultation with senior living house board managers, in order to establish their interest and their point of view regarding benefits of telemedicine service in SLH setting. The consultation process has been concluded by the recipient with positive feedback in regard to our request to conduct our project at SLH. In June 2014, we have presented telemedicine platform and Telemedicine kit, with following Telemedicine training to health professionals at SLHs [7].

From June 2014 to September 2014, SLH nurses and medical doctors had opportunity to test the platform and kits in order to evaluate, amount of time necessary for measurements and its process of sending to cardiology department. On September 2014, we received written response of their consent to participate at the project and to use telemedicine platform. We are at the moment enrolling the patients with CHF who are living in a SLH, as well we are enrolling new SLH located in Region Marche, Italy. Major results are not still available.

VII. CONCLUSION

The promise of technology development allows a healthcare system to provide service in a simplified manner from a distance.

The telemedicine allows continuity of care, versus episodic encounters between patients and physician seen in usual care, and better secondary prevention. A lack of large clinical trials on telemedicine and healthcare system's rigid attitude towards interventions with scarce evidence based results, are the reason why telemedicine is not widely used for monitoring and consulting of elderly population.

We believe that secondary prevention intervention provided through cardiology department to institution where elderly population resides may permit better healthcare services for elderly population wherever they lives.

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Development of eHealth Applications Applying the eHix Framework

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***Abstract*—This paper presents, as part of the Hightech@home project, the development of eHealth applications applying the eHix framework. The eHix framework is presented together with comparable approaches. Then, a development method based on the Value Proposition, the User Requirements, the Technology Scan and the Design cells of the eHix framework is described. Following a case-based approach, this development method was applied to design eHealth applications intended to support clients and client guides of an organization caring for people with intellectual disabilities. This resulted in a design of an alarm system augmented with video communication and sensor technology. The method is considered suitable for small-scale development processes with a high degree of client customization, although it was recognized that the resulting applications represented a more general concept.**

Keywords- eHealth; development framework; requirements analysis; user-centred design.

I. INTRODUCTION

Despite numerous promising eHealth initiatives it has not gone unnoticed that many of the implemented systems did not survive beyond the pilot phase [1][2]. A participatory development process involving stakeholders, such as patients' associations, government officials, insurers, and decision-makers [3][4], preferably embedded within a business-model approach [5], has been advocated to improve the development and implementation of eHealth. In such an approach, application design based on an investigation of end-user requirements [6] plays an important role. In this paper, requirements elicitation and design of eHealth applications in cooperation with the intended users will be presented.

The eHealth development was carried out in association with Frion as part of the Hightech@home-project [7]. Frion is an organization in the Dutch province of Overijssel that supports some 950 people with intellectual disabilities. More specifically, eHealth applications were considered for both an intramural and an extramural department.

This paper is organized as follows. In Section II, existing approaches for the development of eHealth will be discussed including the eHix framework [5]. This approach, which is being developed by the Research group IT Innovations in Health Care, has been adopted as the basic framework for this study. In Section III, the method applied for requirements elicitation and design are presented, followed by the results achieved in Section IV. Finally, in Section V, the paper is completed with a discussion, a conclusion, and a description of future work.

II. BACKGROUND

In this section, the eHix framework will be discussed together with related work.

A. The eHix framework

The *eHealth innovation Matrix* (eHix) is intended as a tool to achieve successful implementations of eHealth innovations [1][5]. In this approach, the business model domains of the STOF method [8] are utilized, namely:

- the Service domain describing the service offering, its added value, and the market segment in view.
- the Technology domain describing the technology necessary to realize this service.
- the Organization domain describing the network of parties which together will provide the service.
- the Financial domain describing, amongst other things, the way in which these parties will generate revenues from the service offering.

To these four domains five phases, which describe the innovation process, are added:

- the Inventory phase, in which needs and conditions of the users of the new service are explored, as well as what is necessary to realize and maintain it.
- the Design & Development phase, in which the intend service is realized.
- the Experimental phase, in which the newly created service is tested, typically in laboratory conditions.
- the Pilot phase, in which the service is tested under realistic conditions, typically involving end users.
- the Implementation phase, in which the service is launched once it is considered feasible.

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The four domains and five phases together form a matrix with 20 cells as depicted in Figure 1. A cell describes the steps and choices for a specific domain and phase. The accompanying website [9] contains information and tools for that purpose. Because in this paper requirements elicitation and design are considered, it is only necessary to focus on the four cells in the upper-left corner of the matrix:

- the Value-Proposition cell comprising aspects such as the envisaged end users, their needs, and the value the new service will offer them.
- the User-Requirements cell comprising aspects such as e-readiness and the elicitation of requirements for the service, fulfilling the needs of the end users.
- the Technology-Scan cell containing a scan to investigate the available technology for realizing the intended service.
- the Design cell comprising the aspects of the application's design, such as the architecture and the development method.

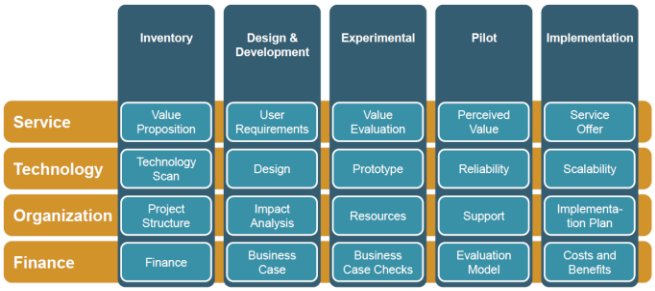

Figure 1. The eHix, comprising twenty cells

B. Related work

In this section, related work will be discussed, not only to demonstrate similarities and differences with the framework of choice, but also to present useful notions from the literature which will be applied in Section III.

1) Technical Action Research

The design-science approach presented in [10] does not start with a general problem for which an artefact is then designed, but at the opposite end with the design of the artefact, which is iteratively improved. To distinguish this artefact-driven approach from a problem-driven one it is called *technical action research* (TAR).

The notion of an engineering cycle for the development of a useful artefact (e.g., an eHealth application; it should be noted that the artefact concept is taken broadly by the authors: "Artifacts may consist of software or hardware, or they may be conceptual entities such as methods and techniques or business processes.") plays a central role in Technical Action Research. This cycle consists of a Problem Investigation task, comparable to the Inventory phase of the eHix, followed by an Artefact Design task comparable to the Design & Development phase. The engineering cycle presented in [10] does not explicitly contain a counterpart for the Experimental phase, although it is recognized that the artefact should be tested first under idealized circumstances in a laboratory. It does, however, contain a Design Validation task resembling the Pilot phase, followed by an Implementation task, in which the artefact is transferred to the economy. The results of the following Implementation Evaluation may lead to new questions for a next Problem Investigation, thus closing the cycle.

The Design Validation task may be carried out by performing one or more pilot studies. Each of these studies again contains all the steps of the engineering cycle.

2) The CeHRes Roadmap

The CeHRes Roadmap is designed for planning, coordination, and execution of eHealth development in which stakeholder participation is of vital importance. Ideally, at the outset a multidisciplinary team is formed which carries out research and development in five main phases. In the Context Inquiry phase problems, end users, and stakeholders are identified. In the subsequent Value Specification phase, values of stakeholders are identified and user requirements are defined. Then, in the Design phase, technology (including prototyping and business modelling) is developed, preferably in a joint effort by the design team, prospected users and stakeholders. Next, the technology is launched in the Operationalization phase, after which it is evaluated in a final Summative Evaluation phase (preceding phases are evaluated formatively). This last phase, comparable to TAR's Implementation Evaluation, complements the eHix phases.

A requirements development approach, embedded in the CeHRes Roadmap, is treated in [11][12]. This approach again consists of five phases coinciding with the first three phases mentioned above. Again the process starts with forming a multidisciplinary team deciding on the goals of the eHealth technology. After this Preparation phase requirements development passes through an End User and Stakeholder Identification phase. In the subsequent Requirements Elicitation phase stakeholders are consulted to determine what the application should do and how it should be implemented. After a Requirements Analysis phase a design document is eventually created in the final Requirements Communication phase.

3) User-centered design

The importance of user involvement, pointed out in [11] [13], is fundamental in User-centred design (UCD). In [14] eHealth applications are designed applying UCD together with a conceptual model for the analysis of interactions between agents. Here, the design process comprises four phases: Analysis, Design, Implementation, and Evaluation. In all four phases, medical specialists were involved while patients were consulted in the last three phases.

The development of an eHealth system for fall detection based on end-user centred design is presented in [15]. Not only care takers and elderly and their relatives are involved, but also health professionals and electricians.

In [16], user requirements are investigated using UCD for a tool to stimulate physical activity. A detailed user requirements document was written after three stages: Identification of end users and concepts, Concept development, and Tool (Re)design. To attain this result literature research, expert meetings, and (focus group) interviews were carried out.

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III. METHOD

To develop a concrete method for requirements elicitation and realization of eHealth applications the four cells of the eHix matrix (i.e., Value Proposition, User Requirements, Technology Scan, and Design) were augmented with insights from the studies mentioned above. Following the ideas of Technical Action Research, an artefact-driven approach was adopted taking a limited number of cases as a starting point. The development was carried out by a multidisciplinary team which collaborated closely with users or their representatives from the beginning [11][14]-[16]. In the remainder of this section the main participants in the process will be introduced, after which the steps which were carried out will be discussed.

A. Participants

An overview of the main participants is presented in Table I. Since halfway the project a new Project Manager was appointed, two managers are mentioned in the table. The first five participants are members of the Research group IT Innovations in Health Care, while the next five are employed by the healthcare organization. Participants 7 to 10 possess a long-term experience in guiding clients.

TABLE I. MAIN PARTICIPANTS

No.	Organization	Position	Gender
1	Research Group	Project Manager	F
2	Research Group	Project Manager	F
3	Research Group	Researcher (requirements)	M
4	Research Group	Junior Researcher	F
5	Research Group	Researcher (technical)	M
6	Frion	Operations Director	M
7	Frion	Member team Care and Home Automation	M
8	Frion	Member team Care and Home Automation	M
9	Frion	Client Guide (intramural)	F
10	Frion	Client Guide (extramural)	F
11	TriVici	Consulting engineer #1	M
12	TriVici	Consulting engineer #2	M

Contrary to one of the major principles of UCD no clients could be invited to participate in the user requirements elicitation, because it is unreasonable to expect a significant contribution from the clients in the intramural setting. Observing or interviewing the extramural clients living at home was not only considered an infringement of their privacy but false expectations should also be avoided. However, the clients were represented by experienced employees of Frion (Participants 7 – 10), who expressed the client's needs to the best of their knowledge.

B. Steps for Value Proposition

Value Proposition started with a kick-off meeting, attended amongst others by the Project Manager and the Operations Director. This led to two interviews with both Client Guides, in which researchers received information about the clients of the care facility. Moreover, eHealth opportunities were explored. The Client Guides were then invited to present concrete cases. Desk research was performed to gain further insight into the target group. Since Technical Action Research is intended as an evaluation tool in the Pilot phase, a problem investigation scheme adopted from [10] was applied to complete the Value Proposition steps.

C. Steps for User Requirements

Based on the concrete cases put forward by the Client Guides, scenarios were written: short stories sketching the situation of the clients. The purpose of the scenarios was not only to verify whether the researcher's picture of the situation of the clients was correct, but also to present possible solutions. Further, the researchers had the opportunity to carry out observations in the intramural setting. Subsequently, mock-ups were made, which were then reviewed in a focus group interview. Finally, a report summarizing the results was written.

D. Steps for Technology Scan

After determining the criteria for the intended applications, a technology scan was carried out. Additionally, experience with the resulting technology was gained in two preliminary implementations. Based on the outline of the intended applications from the previous investigations, a study of literature was carried out.

E. Steps for Design

Upon entering the design phase it was decided to focus mainly on the extramural cases. Because of the clear outline of the intended applications and a well-developed requirements analysis, the V-model [17] was selected as a development methodology.

IV. RESULTS

Based on four cells of the eHix framework a method to develop an eHealth application was presented in the previous section. In the present section the results obtained are described, again taking the four cells of the eHix matrix as a starting point.

A. Results for Value Proposition

The kick-off meeting and the additional interview showed a need to deploy eHealth technology: in the intramural setting to better ensure the safety of the clients and in the extramural setting to give the clients a sense of security. Moreover, the healthcare organisation wished to set off at a micro level, working closely with (end) users, which corresponded to TAR's artefact-driven approach.

The invited client guides informed the development team about the living conditions of their clients, the difficulties people with intellectual disabilities face in modern society, and what it meant for them to guide their clients. It was agreed that the guides would come up with specific cases, describing real clients for which they expected eHealth to be promising. In a subsequent interview with the client guide from the intramural setting a case was presented describing a client for whom it is important to know his whereabouts, mostly indoors but also outside. For the extramural situation, two cases were presented: a client who might ask for

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assistance in difficult situations and a client who needed help to get up after a fall, which occurs frequently.

Desk research made clear that in the Netherlands the prevalence of people with intellectual disabilities is estimated to be between 0.7 and 1.4 % [18][19]. This percentage is expected to remain stable in forthcoming years, although the proportion of elderly is expected to increase. Moreover, a trend toward "extramuralisation" is visible [20], which means that fewer people are eligible for admission to a nursing home. This will only increase the need for eHealth to support clients living at home.

The problem investigation scheme mentioned in Section III C listed for example the stakeholders and their goals, such as the increased independence of a client as well as better and more efficient care.

B. Results for User Requirements

Based on the needs which had become clear from the cases presented, scenarios were written. For privacy reasons fictitious names were used for clients, guides and others.

In the intramural case, the scenario depicted the everyday life of the client, sketching a tool helping him to structure his daily activities, while the tool informed his guides about his localisation indoor and outdoor. For the extramural case of the client who would ask for assistance, an incident was described in which the client would be lost driving his microcar. During a video call his guide would manage the situation, reassuring the client, after she had recognized the surroundings. For the other extramural case three scenarios could be formulated, suggesting a solution with a personal alarm, a solution in which a fall was automatically registered after a certain period, and a smartphone application that enabled the exchange of messages via text or simple buttons.

In all three cases, these scenarios appeared to be a good basis for discussion and feedback, although the response differed. In the intramural setting it became clear that the case described was too limited: there appeared to be a broader need for the application of sensors such as bed sensors and nurse call applications. Discussing the extramural case for the client in his microcar, it proved desirable to add Global positioning system (GPS) localisation. In the other extramural case there was a general agreement on the last-mentioned option.

As mentioned before, extramural clients could not be observed at home by the development team for privacy reasons. Instead, their guide asked them about their opinion. This had to be done very carefully to avoid unrealistic expectations. The clients reacted positively. However, the development team did have the opportunity to observe the intramural clients and speak with the client guide's colleagues. This provided a better understanding of the target group, and made clear why the intramural scenario mentioned above was less appropriate. Moreover, it became clear that the required sensors would particularly be used at night, when the clients slept unobserved in a large home with only a single client guide present. Other homes within the organisation are overseen at night from an incident room. Visiting this incident room revealed the important role of audio surveillance.

Elicitation of user requirements was completed by making mock-ups in the form of sketches of the computer screens for the intended applications. These drawings were not intended as a definitive design of the application's user interface, but as a means for further reflection on the required functionality.

The focus group discussing the mock-ups consisted of researchers (requirements and technical), members of the Care and Home automation team and client guides, so that aspects such as usability, e-readiness of users, and technical details could be taken into account.

These requirements elicitation efforts culminated in a report summarizing the considerations made together with a list of concrete requirements. This report was again reviewed within the development team.

C. Results for Technology Scan

The technology scan carried out was partially determined by the agreements that were set out in the Hightech@home project plan. The use of open source software was required [7]. Moreover, WebRTC was chosen at the outset of the project for video and data communication [21]. The open source portal made available by the TriVici Foundation [22] implied the application of the Joomla! content management system [23].

Based, among other things, on this technology two preliminary implementations were realised in order to increase the understanding of the chosen technology. The first implementation focused on WebRTC video and data communication together with the real-time Session Initiation Protocol (SIP). In addition to WebRTC two other approaches for data transport were considered: HTML5 Local Storage and a direct connection between a single-board computer and a server. Building on the results of the first implementation the second rudimentarily realised the connection of sensors to a Joomla! website using the direct-connection approach. After considering a number of data-transmission protocols Message Queue Telemetry Transport (MQTT) was selected.

In their search for devices for the intended applications the development team realized that a smartphone was not only suitable to implement video contact and GPS location, but also added the opportunity of adding a fall detection sensor, using the accelerometer available in many smartphones [24]. An accompanying study of literature for the extramural cases therefore focused on four themes: (a) personal alarm [25][26], because clients would seek contact with their guides in case of an emergency or in a difficult situation, (b) video communication [27][28], which was expected to be a more effective means to reassure clients compared to audio contact, (c) fall detection [24][29]-[31], aimed at client who fall frequently, and (d) GPS localisation [32][33] to determine the location of clients in need of help. This study made clear that, besides technical aspects, attention should also be paid to issues such as privacy, acceptance, ease of use, autonomy of users and wishes of other stakeholders. It could further be noticed that the development of fall sensors receives much attention in the literature. Literature studied regarding the intramural setting showed that commonly used nurse call systems may be

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augmented with additional information, making the systems context aware [34].

D. Results for Design

Although at the time of writing the design, realization and testing of the intended applications were not completed, a sketch of the application, as depicted in Figure 2 can be presented. On the left of the figure, the device for the client is visible, equipped with an alarm button, fall detection and/or GPS functionality. The Internet connects the client application with devices for the client's guides together with functionality for administration and logging. A storage and processing unit stores logging data and generates the web pages of the TriVici portal.

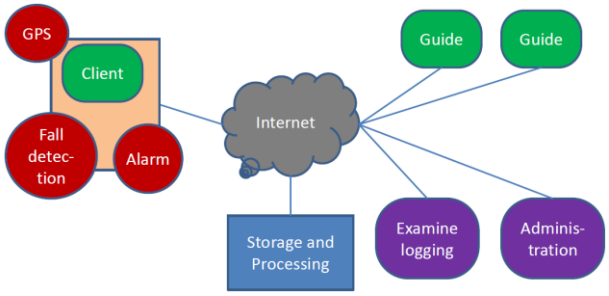

Figure 2. Sketch of the intended application(s)

The design of Figure 2 may be considered as an expansion of the well-known personal alarm with sensors as well as video instead of audio communication. Note that other sensors could be applied as well. In this concept the guide will be better informed about conditions of her clients (including the possibility of an automatically generated alarm, e.g., in the case of a fall) and has better means of communication at her disposal, compared to traditional personal alarm systems.

V. DISCUSSION AND CONLUSION

In the previous sections, the development of eHealth applications to support clients and client guides of an organization entrusted with the care of people with intellectual disabilities has been sketched. This resulted in an alarm system augmented with video communication and sensor technology.

The development process, carried out by a multidisciplinary team, was based on a few well-documented but anonymous cases put forward by the client guides. The development process followed the relevant cells of the eHix framework and included written scenarios and mock-ups.

A. Discussion

Although the actual clients were described in the scenarios, unfortunately it was not possible to interview them directly, which in a user-centred approach is undesirable. They were, however, represented by their guides, who know them well, but only after a pilot it will become clear whether the applications are suitable for them.

It may further be noticed that the design is based on only a small number of cases, contrary, for example, to the development of personas found in [35]. However, the clients considered here often demand a higher degree of customization. In that case the more lightweight approach presented here may be advantageous. Moreover, focusing on concrete cases makes the researchers aware of relevant details. Remarkably, the resulting design was recognized by Frion's employees as a generic concept. Following a case-based method, a generally applicable approach has been derived.

A further characteristic of the specific approach used here is the tight connection of user-requirements elicitation, finding solutions, selecting technology, and design of solutions. We may notice, in other words, a risk of "jumping to solutions" with too little room for the creativity of the design team [11]. Again, a balance should be found between thoroughness and the practical demands of a development process with a high degree of client customization.

Finally, it was found that in the process of co-creation the scenarios and mock-ups proved their value in facilitating the communication between members of the multidisciplinary development team.

B. Conclusion and future work

Based on the experiences described, it may be concluded that a practicable development approach for eHealth applications with a considerable degree of user customization has been presented. Clearly, the design should be completed for the intended applications, and the other cells of the first two phases should be taken into account. Then, in the subsequent Experimental and Pilot phase the usefulness of the result should be established, after which it can be determined whether further implementation will be promising.

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eLabEL: Technology-supported Living Labs in Primary Care

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***Abstract*— Telecare technologies and eHealth applications can support patients and care professionals. However, these technologies are currently not being implemented in primary care. The eLabEL project aims to contribute to a solution for this problem by establishing Living Labs in which patients, healthcare professionals, entrepreneurs and researchers collaborate during the selection, integration, implementation and evaluation of such technologies in primary care. So far, seven primary care centers across the Netherlands have been included. Needs and requirements of healthcare professionals and patients regarding telecare technologies and eHealth applications were studied using semi-structured interviews and focus group interviews respectively. Healthcare professionals and patients were positive towards the use of technologies that can improve accessibility of care for the entire patient population and also expressed a need for technologies that can support self-management in patients with chronic conditions. Requirements voiced by care professionals were the need for clear organization of the user-interface, availability of workflow directives for eHealth usage, minimal steps to perform a task, and integration with their current information system. Patients indicated that care technology should be easy to use and easy to learn, should provide real-time feedback based on self-measured data, and should improve communication between patients and healthcare professionals. Entrepreneurs from the eLabEL consortium will integrate their eHealth and telecare services to meet the requirements of the end-users. The large scale implementation of these technologies will be monitored and the impact on experiences of patients, professionals and organization of care will be studied during a two-year follow-up study. Stakeholders of the eLabEL consortium will join forces to advance the large scale implementation of telecare technologies and eHealth applications in primary care.**

Keywords- eHealth, Co-creation, Living Labs, Primary Care, Implementation

I. INTRODUCTION

The number of older adults and persons with chronic conditions is increasing in Western societies [1]. At the same time, the labor force that provides care to this growing group of patients is decreasing [2]. Due to these societal changes, the focus has shifted from intramural and curative care towards extramural care and prevention. As a consequence, the role of primary care will become more important. A large variety of telecare technologies and eHealth applications exist that can be used in primary care practice to support patients in their independence and self-management, to improve accessibility of care services, and to increase quality of care. Such technologies can also facilitate a shift from care provided in care practices to care provided at home [3][4][5].

Previous (small-scale) studies have shown that telecare technologies and eHealth applications can have positive effects [6][7]. However, many of these technologies are currently not being implemented in primary care practices in a structural way [8] because there is a suboptimal 'fit' between the needs in care practice and the technical solutions. In addition, the supply of care technologies is very fragmented; many applications are stand-alone solutions that are not connected with each other nor are they integrated with information and communication systems that are being used in primary care centers [9].

The eLabEL project, that is conducted by the Centre for Care Technology Research (CCTR), aims to contribute to a solution for these issues that impede the implementation of telecare technologies and eHealth applications by establishing ten primary care 'Living Labs' in which such technologies will be implemented on a large scale. According to Bergvall-Kareborn et al. (2009) a Living Lab is "a gathering of public–private partnerships in which businesses, researchers, authorities, and citizens work together for the creation, validation, and test of new services, business ideas, markets, and technologies in real-life contexts" [10]. During the first phase of the eLabEL project, patients, healthcare professionals, entrepreneurs and researchers collaborate to select telecare technologies and eHealth applications that meet the needs of end-users and to integrate these devices and services so that they can be implemented seamlessly in a primary care

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context. This could be technologies which can be used by the general patient population, such as online appointment planning and e-consultation as well as technologies that can support patients with a chronic condition, such as e-coaching and self-monitoring applications. During the second phase, these integrated technologies will be implemented in the primary care Living Labs to facilitate the transition from 'traditional care' to 'technology-supported care'. The implementation of these technologies on a large scale will be monitored during a two-year follow-up study to investigate the impact that this has on experiences of patients and professionals and organization of care. During the third phase of the eLabEL project, effective implementation strategies for telecare technologies and eHealth applications in primary care will be developed based on the findings from the longitudinal study and experiences of partners that are involved in the eLabEL consortium. In addition, the telecare technologies and eHealth applications and related services will be optimized throughout and at the end of the project based on the (interim) results of the follow-up study. This paper gives an overview of the current state of the eLabEL project. Section II describes the establishment of the Living Labs. Section III describes the methods and results of needs assessment of healthcare professionals and patients. Section IV and V describe the integration and implementation of technologies and how this will be monitored during a two-year follow-up study. A short note about the development of implementation strategies is described in section VI. Finally, in the last section several barriers and challenges that have been identified so far are discussed.

II. ESTABLISHING LIVING LABS

Recruitment of primary care centers who wanted to be involved in the eLabEL project as Living Lab started in September 2013. Inclusion criteria were that at least 5,000 patients should be registered in the center and the following healthcare professionals should work in the center: General Practitioner (GP), Practice Nurse (PN), and Physiotherapist (PT). Potential primary care centers were recruited via the professional and informal network of the researchers using snowball sampling. So far, seven primary care centers, with patient populations ranging from 3,500 to 13,000 patients, have been included in the project. These primary care centers are scattered across the Netherlands. Primary care practices that were included vary in: type of organization, experience and implementation of eHealth applications, average age of the patient population and social economic status of patient population.

III. NEEDS ASSESSMENT HEALTHCARE PROFESSIONALS AND PATIENTS

From March 2014 healthcare professionals' and patients' needs regarding care technology have been explored. This has been done for healthcare professionals using semi-structured interviews and for patients using focus group interviews. The process of needs assessment is still ongoing and will be continued till January 2014.

A. Healthcare Professionals

In total, 9 GPs, 8 PNs, and 9 PTs participated in a semi-structured interview. Interview schemes were based upon six themes: demographics, computer skills, organizational management, organizational IT infrastructure, professionals' understanding of eHealth and its possibilities, and finally, personal experiences with and future expectations of eHealth usage.

During the interviews healthcare professionals mentioned several technologies that their primary care practice could benefit from and that they would like to implement, such as: online appointment planning, online prescription refill, e-consult, video-consult, and online triage. Such services can potentially improve the accessibility of care and increase efficiency. Preferences for these services differed across centers and professionals. In addition, healthcare professionals also expressed a need for technologies that can facilitate remote monitoring of health conditions in patients with chronic conditions in order to support self-management. Requirements voiced by care professionals were the need for clear organization of the user-interface to encourage intuitive usage, availability of workflow directives for eHealth usage, minimal steps to perform a task, single sign on, and integration of eHealth applications with the information system that they currently use in their practice.

B. Patients

To explore patients' needs regarding care technology, patients from eLabEL Living Labs will be sorted in different groups for the focus group interviews based on the following chronical conditions: COPD, Diabetes, Cardiovascular condition and patients with an enduring condition who are treated by a physiotherapist. The aim of these focus group interviews is to investigate if care technology can support self-management in patients with a chronical condition and which requirements should be met to stimulate the uptake and usage of care technology.

Up to now, one focus group interview has been conducted with seven persons with Diabetes (mean age 70,0 years; 71,4% male). Patients indicated that care technology should be easy to use and easy to learn, should provide real-time feedback based on self-measured data and should improve communication between patients and healthcare professionals. At least seven more focus group interviews are scheduled in the upcoming months.

IV. INTEGRATION AND IMPLEMENTATION OF TECHNOLOGIES

Entrepreneurs from the eLabEL consortium are integrating their telecare products/services and eHealth applications based on the outcomes of the semi-structured interviews with healthcare professionals and the focus group interviews with patients from the seven Living Labs. In this process, they also take into account the most recent

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standards and guidelines that such an integrated and interoperable eHealth architecture should comply with. In addition to this, the entrepeneurs will develop a joint business model for the exploitation of the architecture and associated services. Researchers from the eLabEL project will monitor the proces of technology integration and business development to study the possibilities, barriers and facilitating factors that occur.

V. MONITORING IMPLEMENTATION AND EXPERIENCES

In 2015, the selected technologies will be implemented in the primary care centers. During a two-year follow-up study, the implementation process will be closely monitored. During two years the impact of using technology as part of the care process on a general level will be studied. This will be done by monitoring the experiences during and consequences of the transition from 'traditional care' to 'technology-supported care', from a patient, professional and organizational perspective. The study can be divided in four sub-studies that were approved by the Medical Ethical Committee Atrium Orbis Zuyd (NL 14-N-107).

A. Overall patient panel

To study the experiences during and consequences of the implementation of care technology of the general patient population, a panel of 250 patients will be established in each primary care Living Lab. Acceptance, usability and use of implemented technologies that are available for the entire patient population of the primary care practices will be monitored in this panel. In addition, experienced quality of care will be measured in this patient panel. To measure these constructs questionnaires will be handed at baseline and one and two years after the technologies have been implemented. To investigate actual usages of technology, log data will be gathered and analyzed on the level of the general patient population.

B. Patients with chronic conditions

We will also study the experiences during and consequences of the implementation of care technology that can support self-management of persons with a chronic condition. Technology acceptance, use and usability of the implemented technologies will be measured in patients with COPD, Diabetes, and Cardiovascular condition who are offered eHealth by their healthcare professional. In addition, self-management, experienced quality of care, and care consumption will be monitored in these patients. These patients will fill out questionnaires at baseline and after they have used a telecare technology and/or eHealth application for six and twelve months. To investigate data regarding care consumption (contacts with care professionals, number of referrals to specialists and prescription rate), data will be extracted from the information system of the general practitioners on the level of individual patients. These data will be compared with Dutch general practices which are not participating in the eLabEL project [11].

C. Healthcare professionals

A panel of healthcare professionals will be established to study the experiences of general practitioners, practice nurses, and physiotherapists during the implementation and use of different care technologies in their primary care practice. Acceptance, usability, and use of the technologies as well as job satisfaction and fit between the technology and tasks that these healthcare professionals have to perform, will be monitored. Questionnaires will be sent to the healthcare professionals at baseline and one and two years after the implementation of the technology. Parallel to the questionnaires, interviews will be conducted with at least one general practitioner, practice nurse, assistant and physiotherapist of each primary care center to gain more in-depth insight into their experiences with the technologies and the consequences of using these technologies on job satisfaction, care procedures and organizational changes that were needed or happened because of the increased offer of technology.

D. Organisation of care

This study will focus on the experiences during and consequences of the implementation of care technology on an organizational level. Interviews will be conducted with at least one director, manager or senior staff member of each primary care Living Lab to investigate changes in care logistics and procedures, organizational aspects, efficiency of care and financial aspects. These interviews will be conducted at baseline and one and two years after the implementation of care technology. Furthermore, to investigate changes in care consumption in the overall patient population, data regarding characteristics of the center (number of patients, number of patient visits, and number of staff) and care consumption (contacts with care professionals, number of referrals to specialists and prescription rate) will be extracted from the information system of the general practitioners.

VI. IMPLEMENTATION STRATEGIES

Since most relevant stakeholders were involved in the eLabEL project from the start onwards, attention has been paid to issues that are related to implementation and valorization from the start onwards. Perspectives from patients, healthcare professionals, and entrepreneurs were taken into account during all phases. Based on the experiences of all stakeholders during the eLabEL project and the outcomes of the two-year follow-up study, effective implementation strategies will be developed that can be used to advance the use of telecare technologies and eHealth application in primary care.

VII. DISCUSSION

Thus far, many primary care centers across the Netherlands showed an interest to collaborate in the eLabEL project. Implementation and use of telecare technologies and eHealth applications appears to be a prominent topic.

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Using a Living Lab approach to ensure that input from relevant stakeholders is incorporated in the plans form the beginning onwards is appealing according to patients, professionals, and entrepreneurs that collaborate in the project.

Despite the fact that many primary care practices were enthusiastic about the ambition and approach of the eLabEL project, several of them choose not to participate yet. The main reason for this was that general practices need to invest quite a lot of resources and time (e.g., for purchasing and installing new equipment, training staff, training patients, etc.) to facilitate a shift from 'traditional care' to 'technology-supported care' and that it was unclear to most practices whether healthcare insurance companies would facilitate this. Many eHealth and telecare applications for primary care are currently not included in the regular healthcare financing system of healthcare insurance companies which makes it difficult for healthcare professionals and patients to find out or estimate whether the 'technology-supported care' that they provide/receive will be reimbursed or not. An issue that is related to this topic is that entrepreneurs who collaborate in the eLabEL project indicated that, partially due to the uncertainties surrounding reimbursement of eHealth applications, it is difficult for them to decide on a fair price for their products and services once they start providing these in an integrated way on a larger scale. A solution for this issue might be forthcoming since healthcare insurance companies in the Netherlands are currently in the process of developing financing structures for the use of telecare products and eHealth applications in primary care. The eLabEL project will most likely be influenced by introduction of these new financing structures in the beginning of 2015.

Since several large primary care centers decided not to participate, the eLabEL consortium decided to include smaller general practices that were not officially a multidisciplinary primary care center but a GP practice combined with a PT practice. This facilitated the inclusion process and in addition it also increased the variability between the eLabEL Living Labs which can provide valuable input for the development of effective implementation strategies.

Based on the experiences so far, several challenges have been identified that the eLabEL consortium will encounter in the near future. Firstly, integration of telecare technologies and eHealth applications with information systems that are currently being used in general practices is a very important requirement for the successful implementation and adoption of these technologies according to healthcare professionals. This requires cooperation of companies that deliver such healthcare information systems. Involving these companies and getting their commitment will be a challenge that deserves high priority in the next phases of the eLabEL project. Secondly, interoperability standards for telecare technology evolve quickly on both a national and an international level. For example, HL7v3 has been launched in 2005 and already its follow-up HL7FHIR has been introduced in April 2014. Such quick developments make it difficult to create the basis for interoperability in healthcare information systems. Stakeholders of the eLabEL consortium will join forces and combine their strengths, expertise, experiences, and contacts to face these challenges to advance the large scale implementation of telecare technologies and eHealth applications that support patients and healthcare professionals in primary care.

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Developing an Interactive Web Tool, the DecideGuide, to Facilitate Shared Decision Making in Dementia Care Networks: Lessons Learned

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***Abstract*—An interactive web tool, the DecideGuide, is developed to support case managers in facilitating shared decision making in care networks of people with dementia. The DecideGuide is developed in collaboration with the end users: people with dementia, informal caregivers, and case managers. The development consisted of five sub studies. In retrospection, reflections are made on these sub studies. Lessons learned concerned: the importance and value of involving people with dementia in the development of assistive technology such as the DecideGuide, the importance of involving people with dementia from the start, the importance of taking time for people with dementia, and the importance of being aware about the role of end users from the very beginning. Moreover, developing an interactive tool for end users with different capacities and interests requires attuning to the most vulnerable end user group of people with dementia; just ask them rather than decide for them. This paper provides an overview of the lessons learned in the development of the DecideGuide.**

Keywords- dementia; decision making; assistive technology; participatory design

I. INTRODUCTION

The voice of people with dementia is often ignored [1][2]. Relatives and professionals tend to shield people with dementia because of the cognitive decline. This is often done with the best intentions. As a consequence of this shielding attitude, people with dementia are not always involved in decision-making about their own situation [3][4]. When the experiences and wishes of people with dementia are not taken into account, it is difficult to make decisions that are attuned to their needs. Although relatives tend to decide for people with dementia rather than with them, the research shows that people with dementia can express their needs and experiences, even in an advanced stage of dementia [3][5].

Decision-making in dementia is complex because of the multiple participants involved who have different capacities and interests and the progressive cognitive decline that adheres to the disease dementia [6]. Well-known decreasing abilities address memory, route planning, behavior change, and orientation. As we all get older, the chance that dementia will affect us increases. Predictions about this increase of dementia worldwide range from 66 million in 2013 to 114 million in 2050 [7][8]. Life expectation of people with dementia after diagnosis runs between 6-10 years. During this period people with dementia and their relatives have to face many problems and decisions [9][10][11]

Shared decision making (SDM) has its roots in the clinical encounter. It is an approach that involves patients in making medical decisions in collaboration with their professionals [12]. Moreover, shared decision making results in increased autonomy [4] and well-being [13] of both the person with dementia and the informal caregiver. It gives a voice to people with dementia. Shared decision making is often supported by paper or web based tools.

This paper concerns the development of an interactive web tool to facilitate shared decision making in dementia care networks, called the DecideGuide. The DecideGuide and its development is a part of a major research program on shared decision making in care networks of people with dementia aiming to improve professional care and thus contributing to dementia care practice. Besides developing an interactive web tool, the research program focuses on developing theory building and competency descriptions for case managers [14].

This study has an iterative participatory design process. We involved end users and particular people with dementia [15] in developing a user-friendly and usable IT application. Involving people with dementia in the development of supportive IT applications results in better and user-friendlier applications [15][16]. Involvement of people with dementia is necessary; it enables researchers to gain insight into views, needs, and experiences of people with dementia [3][4][17][18].

In this paper, we aim to gain insight into the development of the DecideGuide, which is an interactive web tool to facilitate shared decision making in dementia by looking back on the development process. Our research question is: what lessons can be learned of the design and development process, and the involvement of people with dementia?

The outline of the paper is as follows: Section II explains the DecideGuide, Section III describes the methods used in the sub studies, in Section IV the results of the different development phases are briefly presented, Section V describes the lessons learned, and Section VI ends with the conclusion.

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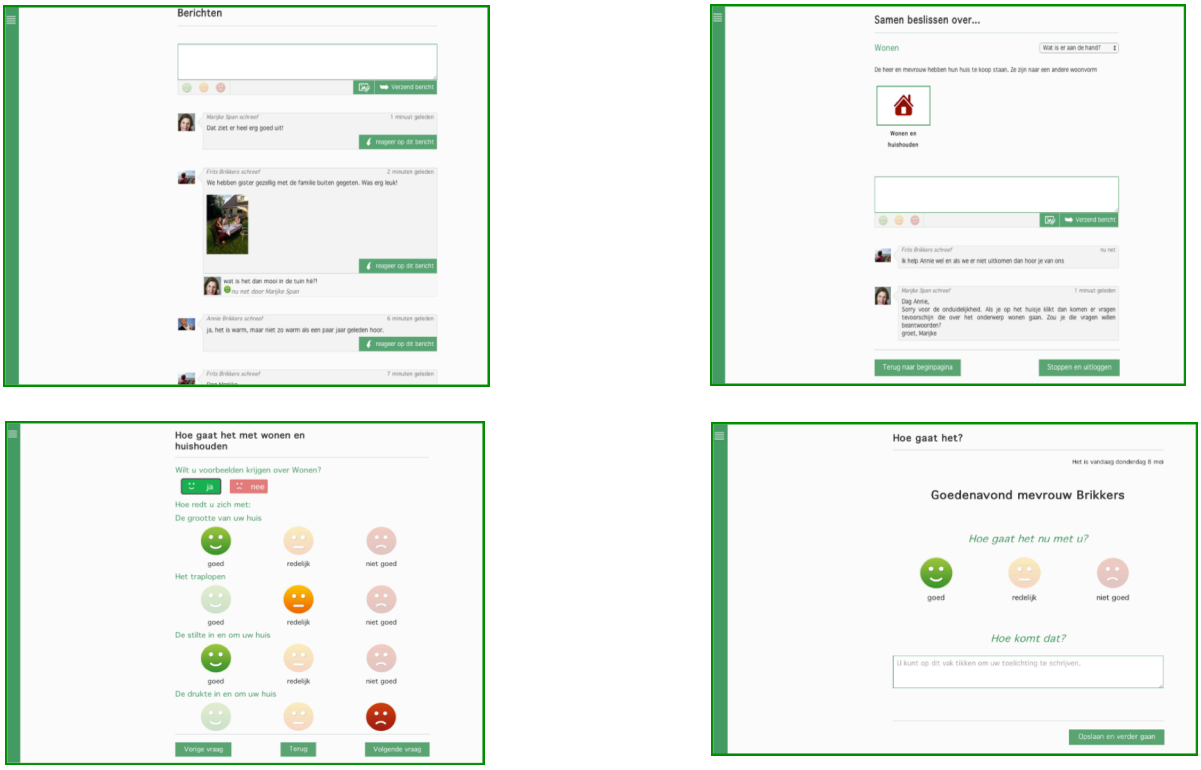

Figure 1. Final layout of three pillars of the DecideGuide (screen view for the person with dementia). Clockwise starting top left: chat function (belonging to the first pillar), deciding together (second pillar), individual opinion "How are you right now?" and individual opinion in questionnaire with examples (both belonging to the third pillar) [21]

II. THE DECIDEGUIDE

We developed the DecideGuide, which is an interactive web tool facilitating shared decision making in care networks of people with dementia. People with dementia, informal caregivers and case managers communicate in this tool with each other in making shared decisions.

The DecideGuide has three functions: 1) a *chat function* where network members can communicate with each other, 2) a *deciding together* part that supports step by step decision-making, and 3) an *individual views* part, where network members can give their individual opinion about eight dementia related themes (Fig. 1). All participants have an individual login and attend the tool on their own or after an alert of the case manager. The DecideGuide is a safe and shielded web tool that is accessible via tablet, a laptop or a computer.

III. METHODS

In this paper we look back on the development trajectory of the DecideGuide with a bird's-eye view. We look back at the development process and the involvement of people with dementia. The development consisted of five sub studies: (1) a systematic review of literature about involvement of people with dementia in the development of supportive IT applications, (2) identifying user requirements based on needs and wishes of end users, (3) determining the design reflected on (5) the participation of people with dementia in developing the DecideGuide. Table I provides a brief overview of the methods of the sub studies.

We used the Center for eHealth Research and Disease Management (CeHRes) roadmap for the development of the DecideGuide, because this approach connects a Human Centered Design with eHealth Business Modeling and emphasizes the importance of involving all stakeholders to develop sustainable innovations [19]. The CeHRes roadmap offers a holistic framework consisting of five phases: contextual inquiry phase, value specification phase, design phase, operationalization phase, and summative evaluation phase.

IV. RESULTS

Consecutively, we will present the general study findings, and conclusions and reflection of the four steps of the development briefly per study. Then, findings addressing the participation of people with dementia will be presented and discussed.

A. Systematic literature review

1) General findings [15]: From a list of 893 relevant citations, 26 publications could be included. The findings suggest that most researchers acknowledge the importance of involvement of people with dementia in the development but they differed in how they involved people with dementia. Most people with dementia were mainly involved in the first phases of the development process, the explorative and

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TABLE I. CHARACTERISTICS OF METHODS OF SUB STUDIES OF THE DEVELOPMENT OF THE DECIDEGUIDE

	Development process of the DecideGuide: sub studies				
	1. Systematic review	***2. Identifying user requirements***	***3. Determining the design***	***4. A 5-month field study***	***5. Participation of people with dementia: case study***
Research questions	How are people with dementia involved in the development of supportive IT applications?	1) What topics can be identified for an interactive web tool facilitating shared decision-making in dementia? 2. What additional needs and preferences regarding an interactive web tool facilitating shared decision making in dementia can be identified?	1) What design issues can be identified for a user-friendly interactive web tool that helps people with dementia with shared decision making? 2) What is the unique contribution of people with dementia to the design?	1) How do end users value the user friendliness, and the user acceptance and satisfaction of the tool, and 2) how do end users value the DecideGuide as tool in decision-making processes?	How participated people with dementia (phaese, role, and impact) during the design and development of the DecideGuide?
Participants		People with dementia (n=19), informal caregivers (n=31), case managers (n=24), and experts (n=14).	People with dementia (n= 12), informal caregivers (n= 8), older adults (n=3), case managers (n= 7) and experts (n=3).	Four dementia care networks (n = 20) consisting of people with dementia (n=4), informal caregivers (n=13), and their case managers (n=3).	People with dementia who participated in the sub studies 1-4 (n=48)
Data collection	A systematic search was conducted using Cochrane Library, PubMED, PsychInfo, EMBASE, and CINAHL, concerning the involvement of people with dementia in the development of supportive IT applications.	50 semi structured interviews with end users Eight separate focus group interviews with end user groups Expert consultation Two multi-disciplinary workshops	Two focus group sessions with mock-ups with all end user groups. Cognitive walkthrough with experts. Individual usability tests with three indiviudals of all end user groups	Structured interviews at t0,t1, t2 Observations of case managers' home visits Log files in tool Log book	Use of data gathered in sub studies 1-4: Semi structured interviews (n=23) Four focus groups (n= 18) Usability tests (n=3) Pilot study (n=4) Log book
Analysis	Content analysis focused on involvement characteristics: phase of involvement, methods used to involve, role, and impact of involvement.	Content analyis was applied to the data addressing the research questions.	The five steps of framework analysis were used. Analysis focused on the three levels of the CeHRes assessment of design quality: system, content, and service quality.	Content analysis was applied to the data and focused on: 1) how the end users valued the user friendliness, and user acceptance and satisfaction, and 2) how end users valued the DecideGuide as tool in decision-making processes.	Seondary analysis, using the patient participation ladder of Abma and the phases of the CeHRes roadmap.

technical development phases. People with dementia played mainly the role of study objects and informants (n = 24) rather than being co-designer (n=2).

2) Conclusions and reflections: People with dementia can participate in the development of supportive IT applications and they provide useful feedback that leads to more user friendly and usable IT applications. The findings of the review confirmed our intention to involve people with dementia in all phases of the development, despite their declining capacities and despite the opinions of informal caregivers and professionals. In order to know what is important to people with dementia, we have to involve them unless they refuse to participate.

B. Identifying user requirements

1) General findings [20]: Two sets of user requirements were identified. The first set was based on experienced problems and decisions of people with dementia, informal care givers, and case managers addressing: social contacts, daily activities, mobility and transport, safety, living, future, care, and finances. The second set of user requirements was based on additional needs and preferences of participants addressing: participation of the person with dementia in the decision-making, insight into the decision history, anticipation of possible future problems and decisions, and the degree of self-management and autonomy preservation of the person with dementia.

2) Conclusions and reflections: The iterative participatory approach – individual interviews followed by two sequential focus groups per target group – helped us to identify two sets of user requirements. Decision making in dementia care networks concerns mainly problems of the well-being of people with dementia and their informal caregivers rather than more care related problems. The views of all people involved were of importance to achieve a well-funded set of user requirements. We invested much time in individual interviews with people with

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dementia, informal caregivers, and case managers and separate focus groups per target group to enable participants to speak freely. This provided us with useful feedback. People with dementia mentioned fewer problems than the other participants but they described values that were important to them, e.g., independency and social contacts. This could be due to a possible fear that reporting problems may have undesirable consequences with respect to their autonomy.

All participants found it hard to describe requirements for a supportive SDM tool. They could not imagine how such a tool should look like. Beforehand, we expected this for people with dementia, but it proved also to be difficult for both informal caregivers and case managers. Discussing requirements for a supportive tool to facilitate SDM seemed to be too abstract for participants.

C. Determining the design of an interactive web tool, the DecideGuide

1) General findings [21]: The design of the interactive web tool, the DecideGuide, arose from four iterations. These iterations were based on feedback of all end users groups. The different participants experienced weaknesses that addressed mainly the system quality: user-friendliness of the tool (e.g., too many screens and too much information per screen, operating a touch screen, unclear interface, meaning of buttons), unclearness of navigation (in screens and between screens) and persuasiveness of the design (presentation of information, use of icons, size of icons/smiley's). Weaknesses addressing the content quality concerned the accuracy of wording and relevance of the content. Experienced strengths concerned the possible future extensions, monitoring caregivers' well-being, use of smileys and the green interface color. Disagreements of participants regarding design issues addressed the number of screens and examples, use of smileys, and the design rationale of open communication and transparency.

People with dementia provided us with detailed and unique feedback about their focus on the present, the 'here and now' of their time perception; a careful use of language; and a pleasant graphical layout.

2) Conclusions and reflections: Designing an interactive web tool for people with different capacities and interests is challenging but possible. All perspectives were included with special attention for the most vulnerable target group of people with dementia. The specific and detailed feedback of people with dementia was very valuable and made their contribution unique. However, other participants doubted whether the tool would be useful and usable for people with dementia.

From the start informal caregivers and case managers emphasized their concerns about the participation of people with dementia regardless of the phase of the study. They thought that participation would be too difficult and intrusive for people with dementia. Besides their concerns, we asked people with dementia themselves about their willingness to participate. We wanted to ask them instead of deciding for them. People with dementia were open to participate. They mentioned no objections and showed no signs of distress. Paper prototyping (mock-ups) was difficult for them and confirmed findings of other researchers [22]. We chose a fictive person with dementia for this session because we thought that it would be less intrusive for them. But they commented that they found the session difficult because they could only speak and decide for themselves, rather than for the fictive person presented on paper. It confused them. The fictive person was not a problem for informal caregivers and case managers. Nevertheless, the paper prototype session proved also to be difficult for them. They found it hard to imagine from paper how such an interactive web tool could look like.

D. Field study: using the DecideGuide in daily life

1) General findings: Preliminary findings of the field study show that the user-friendliness of the DecideGuide needs improvement, in particular for older adults (70+) including people with dementia. The deciding together part provided insufficient guidance and the navigation in the user interface needs further simplification. The user acceptance and satisfaction were sufficient: all participants appreciated the easy way of communicating in the chat function, and the option to express individual views. Participants felt more involved and shared more information with each other about daily life issues. Informal caregivers and case managers appreciated the DecideGuide as tool in decision-making: it structured their thoughts and provided a structure for making decisions.

2) Conclusions and reflections: The use of the DecideGuide is feasible in dementia care practice but the navigation needs further refinement. The DecideGuide has meaningful impact on its users: it stimulates people with dementia and their care networks in communicating more frequently with each other, opens difficult issues to discussion, takes into account all perspectives, and leads to more involvement of informal caregivers and case managers in the daily lives of people with dementia.

The current generation of older adults of whom most are not familiar with computers needs support to use IT applications. Including personalized 'nice to haves' like an agenda, photo gallery, or daily paper to the tablet can help to make the use of a tablet more attractive for this target group. Also the participation of more (younger) people in the network stimulates the interaction in the network and therefore the activities of the older participants. We did not expect the 'chat function' to be such a success as network members experienced it. This way of communicating with each other and sharing daily life issues/information within the network was less common than we expected. It proved to be of great value for participants, in particular for informal caregivers and case managers.

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E. *Participation of people with dementia in developing the DecideGuide*

1) General findings: People with dementia participated in most phases of the CeHRes roadmap [19] and in different roles of Abma's patient participation ladder [23]: during the contextual inquiry phase in the role of research object, during the value specification phase as information provider, and during the design and operationalization phase as advisor. Their participation resulted in unique feedback leading to a more attuned version of the DecideGuide.

The impact of participation of people with dementia on themselves as persons addressed their intrinsic motivation to participate in the development; their enjoyment in learning new skills, their wish to be of use for research activities as long as possible, and their wish to contribute to a better quality of life for future dementia patients.

We invested much effort in involving people with dementia in the development. Taking time is a key for meaningful inclusion of people with dementia e.g., taking time for small talk before research activities, taking time to get to know them better, taking time during research activities, and taking time for an ongoing consent to be sure about their voluntary participation [24]. Besides, a safe environment is important e.g., their home or the day care center they are attending.

2) Conclusions and reflections: We involved people with dementia in the same phases of the development as informal caregivers and case managers and we listened carefully to them. We involved people with dementia mainly as information providers and advisors. We chose for this place on the participation ladder because we wanted to gain experience in involving a vulnerable target group like people with dementia. A lower place on the participation ladder would have resulted in less useful feedback. In a subsequent study, we might aim for involving people with dementia as co-designers. But a higher place on the participation ladder does not automatically lead to more participation. More researchers stress the importance of a horizontal participation ladder rather than a vertical one: availability of different roles dependent on which role is suitable for the situation is more important than reaching higher levels on the participation ladder [25][26].

However, as participation of people with dementia is not self-evident, we challenged ourselves, all participants and in particular people with dementia, to participate meaningfully in the development of an interactive web tool that facilitates shared decision making for people with different capacities and interests. In our research the role of advisor was a suitable and valuable role and resulted in meaningful participation of people with dementia.

Nowadays, many research proposals are assessed on participation of patients. Participation of patients is time consuming and in particular participation of vulnerable patient groups. Time is scarce in research and might lead to patient participation on paper, and thus becoming a sham. Participation of people with dementia in research is important to attune to their needs and to give them a say, but investing in meaningful inclusion of people with dementia might do more justice to this target group than reaching for higher steps on the patient participation ladder.

V. LESSONS LEARNED

- The CeHRes roadmap helped is in offering a structured way to develop the DecideGuide. It provided us with criteria to assess the activities in the different phases.
- Informal caregivers and case managers do not always have a good view of people with dementia's preferences.
- People with dementia can give unique and valuable feedback that differs from the feedback of other participants.
- Spending time with people with dementia and taking time for small talk supports them in expressing themselves.
- Asking people with dementia what they like, what they want, and if they want to participate and how sounds plausible, but requires attentiveness, time, and dedication of researchers. Deciding for people with dementia is a pitfall despite good intentions (e.g., *we thought* a fictive person in the mock-ups would be less intrusive, but we were wrong).
- A meaningful participation of people with dementia requires involving them in a very early phase in research activities so they really have a say in what will be investigated and which role they will play.
- Older adults (70+) need more support in order to get familiar with a tablet and the DecideGuide.
- More participation does not automatically lead to better participation.
- Aiming for meaningful inclusion of people with dementia in research might do more justice to people with dementia than trying to achieve a higher step on the participation ladder.

VI. CONCLUSION

An interactive web tool for people with dementia, their informal caregivers, and case managers was developed to facilitate shared decision making in dementia care networks. Developing an interactive web tool, for participants with different capacities and interests is challenging. It requires open communication and attuning to the most vulnerable end user group of people with dementia because they are easily overruled. This includes balancing between the benefits of people with dementia's contribution and the impact on their well-being.

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Self-monitoring of Physical Frailty; a Proactive Approach in Community-dwelling Elderly People

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***Abstract*—The main objective of the dissertation was to develop and evaluate a self-monitoring and feedback system that can be used by community-dwelling elderly people to gain insight into (changes in) indicators of physical frailty that are predictors of increased risk of disability. To achieve this, the following research questions were addressed: 1) What is the predictive value of physical frailty indicators on disability in community-dwelling elderly people?, 2) Can simple, innovative technologies be used to obtain valid and reliable estimates of physical frailty indicators?, and 3) How can simple, innovative technologies be integrated into a self-monitoring system that provides regular feedback to elderly people regarding (changes in) physical frailty indicators? The studies described in the dissertation show that physical frailty indicators (e.g., physical activity, weight, grip strength, balance) are predictive of disability development in community-dwelling elderly people. Simple, innovative technologies that can be used by elderly people to obtain valid and reliable estimates of these indicators are a bathroom scale that can measure weight and balance, a Grip-ball that can measure grip strength, and a smartphone that can measure the amount of daily physical activity. These devices were incorporated into a self-monitoring and feedback system during a user-centered design process. Small scale usability tests and a pilot study show that the system satisfied most needs of the end users and, despite a few technical errors, elderly people considered the system easy-to use which resulted in good adherence to the daily monitoring regimen.**

Keywords- frailty; elderly people; physical functioning, telemonitoring; self-management

I. INTRODUCTION

The number of frail elderly people is increasing in the Netherlands and other Western societies [1]. Frail elderly people have an increased risk of adverse health outcomes such as disability, fall incidents, hospitalization, institutionalization and even death compared to non-frail elderly people [2]-[4]. As a consequence, frailty is also strongly associated with increased use of (informal) healthcare and community services [5] [6].

A difficulty in offering interventions to (frail) community-dwelling elderly people aimed at disability prevention or reduction is to identify people who might benefit most from such programs at a stage that disability is not yet present or still reversible. Various methods are currently being used to screen elderly people in the community to determine their level of frailty; and with that their eligibility for participation in preventive intervention programs since frailty is considered to be a state of pre-disability [7]. Most frequently used screening methods are self-report questionnaires, checklists used by care professionals (sometimes including physical performance tests), and clinical judgment of care professionals [8] [9]. Disadvantages of these screening methods are that the decision to offer a preventive intervention program is based on a single cross-sectional assessment of frailty, that the number of false-positive classifications is too high [10], and that screening methods are often not part of daily routine in primary care [11]. Finally, and more importantly, the current top-down approach in which care professionals decide whether preventive interventions should be started based on the outcome of a frailty screening instrument, does not facilitate the participation of frail elderly people in making decisions regarding their own health care. This is unfortunate since involvement of elderly people in their own care process can empower them and improve patient outcomes [12] [13]. The increasing uptake of every day technologies, such as smartphones, computers, and internet among elderly people and in health care, creates opportunities to support elderly people in their own health behaviors and involve them in the care process [14].

The main objective of this thesis is to develop and evaluate a self-monitoring and feedback system that can be used by community-dwelling elderly people to gain insight into (changes in) indicators of physical frailty that are predictors of increased risk of disability. To achieve this, the following research questions are addressed:

1. What is the predictive value of physical frailty indicators on disability in community-dwelling elderly people?
2. Can simple, innovative technologies be used to obtain valid and reliable estimates of physical frailty indicators?
3. How can simple, innovative technologies be integrated into a self-monitoring system that provides regular feedback to elderly people regarding (changes in) physical frailty indicators?

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II. PREDICTIVE VALUE PHYSICAL FRAILTY INDICATORS

A systematic review and longitudinal study with one year follow-up were conducted to study the predictive value of physical frailty indictor, such as weight, gait speed, balance, physical activity, grip strength, and exhaustion, on disability development in older adults aged above 65 years.

A. Systematic literature review

A systematic search was performed in 3 databases (PubMed, CINAHL, and EMBASE) from January 1975 until April 2010. Prospective, longitudinal studies that assessed the predictive value of individual physical frailty indicators on disability in Activities of Daily Living (ADL) in community-dwelling elderly people aged 65 years and older were eligible for inclusion. Articles were reviewed by two independent reviewers who also assessed the quality of the included studies. After initial screening of 3081 titles, 360 abstracts were scrutinized, leaving 64 full text articles for final review. Eventually, 28 studies were included in the review. The methodological quality of these studies was rated by both reviewers on a scale from 0 to 27. All included studies were of high quality with a mean quality score of 22.5 (SD 1.6). Findings indicated that physical frailty indicators can predict ADL disability in community-dwelling elderly people. Slow gait speed and low physical activity/exercise seem to be the most powerful predictors followed by weight loss, lower extremity function, balance, muscle strength, and other indicators. These findings should be interpreted with caution because the data of the different studies could not be pooled due to large variations in operationalization of the indicators and ADL disability across the included studies. Nevertheless, the review suggests that monitoring physical frailty indicators in community-dwelling elderly people might be useful to identify elderly people who could benefit from disability prevention programs [15].

B. Longitudinal study

The aim of this one-year follow-up study was to investigate the predictive value of self-reported decline in weight, exhaustion, walking difficulty, grip strength and physical activity on development of disabilities in community-dwelling elderly people. Community-dwelling elderly people aged 70 years or older were recruited via four Dutch general practitioners. 687 participants received a questionnaire at baseline regarding weight loss, exhaustion, walking difficulty, grip strength, physical activity, and disability. The same questionnaire was sent to them after one year follow-up. Disability was operationalized in two ways: as increased dependence and as increased difficulty in daily activities. Univariate and multivariate logistic regression analyses were used to determine whether self-reported decline in five physical indicators at baseline predicted development of dependence or increased difficulty in daily activities after 1 year. The analyses were controlled for age, gender and baseline disability. 401 participants with a mean age of 76.9 years (SD 5.2) were included in the analyses. 84 of them reported increased dependence (21%) and 76 reported increased difficulty (19%) in daily activities after one year follow-up. All physical indicators, except weight loss, were significant univariate predictors of disability. Multivariate analyses revealed that self-reported decrease in physical activity (e.g., walking, cycling, gardening) was a significant predictor of development of dependence (OR = 1.89, 95% CI = 1.02-3.51) and development of difficulty (OR = 1.98, 95% CI = 1.05-3.71) in daily activities. Based on the findings from this study, it can be concluded that community-dwelling elderly people who report decreased physical activity have a higher risk to develop disability after 1-year follow-up [16].

III. VALIDITY AND RELIABILITY OF SELF-MONITORING TECHNOLOGIES

Four studies were conducted to evaluate the validity and reliability of balance measurements conducted with a modified bathroom scale, grip strength measurements conducted with a Grip-ball, and physical activity measurements conducted with a smartphone-based activity monitoring application. These validation studies have revealed that simple self-monitoring technologies can be used to provide valid and reliable estimates of indicators of physical frailty in community-dwelling elderly people.

A. Balance measurements of a bathroom scale

Validity and reliability of balance measurement of a modified bathroom scale were studied during a cross-sectional study and a six-month follow-up study. The aim of the cross-sectional study was to investigate the construct validity of a bathroom scale measuring balance in elderly people. Participants for this study were recruited via nursing homes and an organization that provides exercise classes for community-dwelling elderly people. Eligibility criteria for both groups were: aged 65 years or older and being able to step onto a bathroom scale independently. The balance measurements of the bathroom scale were compared to the following three clinical balance measurements that were conducted by a geriatric physiotherapist: Performance Oriented Mobility Assessment (POMA), Timed Up and Go (TUG), and Four Test Balance Scale (FTBS). An independent samples t-test was performed to determine whether nursing home patients scored lower on these four balance tests compared to community-dwelling elderly people. Correlations were calculated between the bathroom scale balance scores and those of the clinical balance tests for nursing home patients and community-dwelling elderly people separately. Forty-seven nursing home patients with a mean age of 81 years (SD 6.40) and 54 community-dwelling elderly people with a mean age of 76 years (SD 5.06) participated in the study. The results showed that nursing home patients had significantly lower scores on all four balance tests compared to community-dwelling elderly people. Correlations between the bathroom scale scores and

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the POMA, TUG, and FTBS in nursing home patients were all significant: .49, -.60, and .63 respectively. These correlations were not significant in active community-dwelling elderly people, -.04, -.42, and .33 respectively. Linear regression analyses showed that the correlations for the bathroom scale and POMA, bathroom scale and TUG, and bathroom scale and FTBS did not differ statistically between nursing home patients and community-dwelling elderly people. These results suggest that the modified bathroom scale is useful for measuring balance in elderly people. However, the added value of this assessment method for clinical practice remains to be demonstrated [17].

The aim of the six-month follow-up study was to study the relation between balance scores of a modified bathroom scale and falls and disability in a sample of older adults. Participants were recruited via physiotherapists working in a nursing home, geriatricians, exercise classes, and at an event about health for older adults. Inclusion criteria were similar to the cross-sectional study described above. Forty-one nursing home patients and 139 community-dwelling older adults stepped onto the modified bathroom scale 3 consecutive times at baseline to measure their balance. Their mean balance score on a scale from 0 to 16 was calculated; higher scores indicated better balance. Falls and disability were measured at baseline and after 6-months follow-up using questionnaires. The cross-sectional relation between balance and falls and disability at baseline was studied using t-tests and Spearman correlations. Univariate and multivariate logistic regression analyses were conducted to study the relation between balance measured at baseline and falls and disability development after 6 months follow-up. Hundred twenty-eight participants with complete data sets (25.8% male, 24 nursing home patients) and a mean age of 75.33 years (SD 6.26) were included in the analyses of this study. Balance scores of participants who reported at baseline that they had fallen at least once in the past 6 months were lower compared to non-fallers, 8.9 and 11.2 respectively (P < .001). The correlation between mean balance score and disability sumscore at baseline was -.51 (P < .001). No significant associations were found between balance at baseline and falls after 6 months follow-up. Baseline balance scores were significantly associated with the development of disability after 6-months follow-up in the univariate analysis (OR = .86, 95% CI = .76-.98) but not in the multivariate analysis when correcting for age, gender, and baseline disability (OR = .95, 95% CI =.80-1.12). Therefore, it can be concluded that there is a cross-sectional relation between balance measured by a modified bathroom scale and falls and disability in older adults. Despite this cross-sectional relation, longitudinal data showed that balance scores have no predictive value for falls and might only have limited predictive value for disability development after 6-months follow-up.

B. Grip strength measurements of a Grip-ball

The purpose of this cross-sectional study was to evaluate the reliability and validity of grip strength measurements obtained with a Grip-ball in older adults. Forty nursing home patients and 59 community-dwelling older adults aged 60 years or older were invited to participate in this study. Grip strength in both hands was measured 3 consecutive times during a single visit using the Grip-ball and Jamar dynamometer. Test-retest reliability was described using Intraclass Correlation Coefficients (ICCs). Concurrent validity was evaluated by calculating Pearson's correlations between the mean Grip-ball and Jamar dynamometer measurements and between the highest measurement out of 3 trials. Known-groups validity was studied using t-tests. Eighty eight participants (33 men) with a mean age of 75 years old (SD 6.8) were included in this study. ICCs for the Grip-ball were .97 and .96 for the left and right hand respectively (P<.001). ICCs for the Jamar dynamometer were .97 and .98 for the left and right had respectively (P<.001). Pearson's correlations between the mean scores of the Grip-ball and Jamar dynamometer were .71 (P <.001) and .76 (P <.001) for the left and right hand respectively. Pearson's correlations between the highest scores out of 3 trials were .69 (P <.001) and .78 (P <.001) for the left and right hand respectively. T-tests revealed that the Grip-ball and Jamar dynamometer both detected grip strength differences between men and women, and not between nursing home patients and community-dwelling older adults. Grip-ball measurements did not confirm higher grip strength of the dominant hand whereas the Jamar dynamometer did. Based on these finding, the conclusion an be drawn that the Grip-ball provides reliable grip strength estimates in older adults. Correlations found between the Grip-ball and the Jamar dynamometer measurements suggest acceptable concurrent validity. The Grip-ball seems capable of detecting 'larger' grip strength differences but might have difficulty detecting 'smaller' differences that were detected by the Jamar dynamometer. The Grip-ball could be used in practice to enable home-based self-monitoring of grip strength in older adults. However, for the implementation of the Grip-ball as a screening and monitoring device in practice, it is important to gain insight into intersession reliability during home-based use of the Grip-ball and clinical relevance of changes in grip strength.

C. Measuring physical activity with a smartphone

Since smartphones are equipped with built-in accelerometers they can be used for self-monitoring of physical activity which is an important health behavior and predictor of functioning, especially in older adults. The objective of this study is to investigate the validity of a smartphone-based activity monitoring application in adults aged below and above 65 years old. Ten adults aged below 65 years and ten adults aged 65 years or older were asked to monitor their daily physical activity with a smartphone and an ActiGraph GT3X for 7 consecutive days. Spearman

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correlations between the counts per minute of the two devices were calculated for adults aged below and above 65 years separately. For both devices, each monitored minute was classified into four categories of activity intensity based on the counts per minute: sedentary, light, moderate, and high activity intensity. Association and agreement between the two devices was analyzed using Pearson's correlations, paired t-tests and Bland-Altman plots. Data from 8 adults aged below 65 years and 7 adults aged above 65 years could be included in the analyses due to malfunctioning of the Actigraph GT3X (n=3) or smartphone (n=1) or due to usability problems with the smartphone-based application that had to be operated to monitor activity (n=1). Spearman correlations between the counts per minute of the smartphone and the ActiGraph were .76 and .84 for adults aged below and above 65 years respectively. Pearson's correlations between the two devices for total number of minutes spent in different activity intensity categories per day per participant were high in both groups (range .79-.99). Paired t-tests and Bland-Altman plots revealed that the smartphone underestimates the number of sedentary minutes per day in participants aged below and above 65 years with 5.74% and 6.35% respectively compared to the ActiGraph. In addition, the smartphone overestimated the number of minutes spent at moderate intensity in adults aged below 65 years by indicating almost twice as many minutes spent in this activity intensity category compared to the Actigraph. Furthermore, the number of minutes spent at light activity intensity in adults aged above 65 years was overestimated with 8.22% by the smartphone compared to the ActiGraph. In conclusion, the activity monitoring application needs to be optimized before it can be implemented in practice. Concurrent validity of the smartphone-based activity monitoring application was better in adults aged above 65 years compared to adults aged below 65 years. Differences seem to exist between individual participants.

IV. USER-CENTERED DEVELOPMENT AND TESTING OF THE MONITORING AND FEEDBACK SYSTEM

The modified bathroom scale, Grip-ball, and smartphone were integrated into a monitoring and feedback system in close collaboration with elderly people and care professionals during a User-Centered Design (UCD) process. The iterative user-centered development process consisted of the following phases: (1) Selection of user representatives; (2) Analysis of users and their context; (3) Identification of user requirements; (4) Development of the interface; and (5) Evaluation of the interface in the lab. Subsequently, the monitoring and feedback system was tested in a pilot study by five patients who were recruited via a geriatric outpatient clinic. Participants used a bathroom scale to monitor weight and balance, and a mobile phone to monitor physical activity on a daily basis for six weeks. Personalized feedback was provided via the interface of the mobile phone. Usability was evaluated on a scale from 1 till 7 using a modified version of the Post-Study System

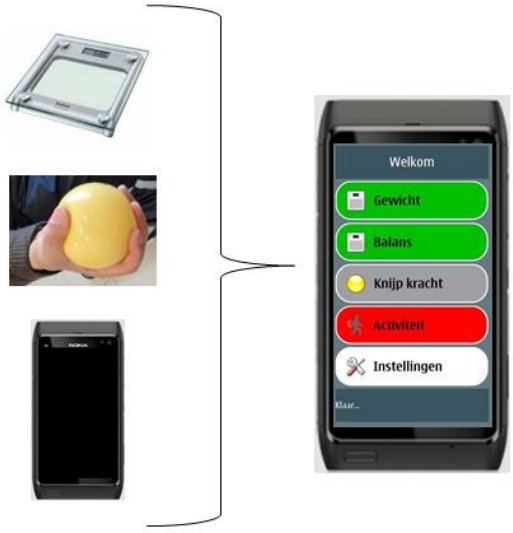

Figure 1: The monitoring and feedback system

Usability Questionnaire (PSSUQ); higher scores indicated better usability. Interviews were conducted to gain insight into the experiences of the participants with the system. The developed interface uses colors, emoticons, and written and/or spoken text messages to provide daily feedback regarding (changes in) weight, balance, and physical activity. Figure 1 shows a screenshot of the interface. Participants of the pilot-study rated the usability of the monitoring and feedback system with a mean score of 5.2 (SD .90) on the modified PSSUQ. The interviews revealed that elderly people were able to use the system and appreciated the feedback that was provided to them. The monitoring and feedback system satisfied most needs and preferences of the elderly people and, despite a few technical errors that occurred during the pilot study which annoyed the users and sometimes caused confusion, they considered the system easy-to-use which resulted in good adherence to the daily monitoring regimen. It can be concluded that involvement of elderly users during the development process resulted in an interface with good usability. However, the technical functioning of the monitoring system needs to be optimized before it can be used to support elderly people in their self-management [18].

Collaboration with end-users during user-centered design (UCD) of telecare products as described above can help to take the needs and requirements of potential end-users into account during the development of innovative telecare products and services. However, this multidisciplinary collaboration often poses challenges to the persons involved. Understanding how members of multidisciplinary development teams experience the UCD process might help to gain insight into factors that members with different backgrounds consider critical during the development of telecare products and services. Therefore, a qualitative study

 ISBN: 978-1-61208-384-1

that was conducted to gain insight into experiences of 25 members of multidisciplinary development teams of four different Research & Development (R&D) projects during the UCD process of telecare products and services. The R&D projects aimed to develop telecare products and services that can support self-management in elderly people or patients with chronic conditions. Seven participants of this study were representatives of end-users (elderly persons or patients with chronic conditions), three were professional end-users (geriatrician and nurses), five were engineers, four were managers (of R&D companies or engineering teams), and six were researchers. All participants were interviewed by a researcher who was not part of their own development team. The following topics were discussed during the interviews: aim of the project, role of the participant, experiences during the development process, points of improvement, and what the project meant to the participant. These interviews revealed that multidisciplinary collaborations can be challenging and that various barriers and facilitators influenced the development process. Multidisciplinary team members from different backgrounds often experience similar barriers (e.g., different members of the development team speak a 'different language') and facilitators (e.g., team members should voice expectations at the start of the project to prevent miscommunication at a later stage). However, some barriers and facilitators are only experienced by stakeholders who share a similar background (e.g., only managers of R&D companies experience that differences of opinion about a business case is a barrier and only end-users express that the project manager has an important facilitating role in end-user participation). Insights into these similarities and differences can improve understanding between team members from different backgrounds which optimizes collaboration during the user-centered development of telecare products and eHealth applications that support care and wellbeing [19].

V. DISCUSSION AND RECOMMENDATIONS

The studies described in the dissertation show that physical frailty indicators (e.g., weight, balance, grip strength, and physical activity,) are predictive of disability development in community-dwelling elderly people and that simple, innovative technologies can be incorporated in a self-monitoring and feedback system that elderly people can use to obtain valid and reliable estimates of (changes in) these indicators. Based on the research presented in this dissertation, the self-monitoring and feedback system was further optimized so that it can be used by community-dwelling elderly people to gain insight into (changes in) indicators of their physical functioning. This could support and facilitate a more pro-active approach in early detection of increased risk for disability with a stronger focus on self-management. The system, or its separate parts, can be used by elderly people with different levels of physical functioning as long as they are able to learn how to use the system, which makes it less applicable for elderly people with cognitive deficits.

Based on the current (lack of) knowledge regarding the variability of indicators of physical functioning and the clinical relevance of changes in such indicators, feedback can now only be based on current guidelines of healthy/normal weight, grip strength, and physical activity. Since the modified bathroom scale is a new measuring instrument for which no guidelines are available, feedback regarding balance is currently more difficult to interpret compared to the other indicators that are measured by the self-monitoring system. The disadvantage of using current guidelines to provide feedback is that these guidelines are mostly reactive. They only signal changes in indicators of physical functioning when they are already below the cutoff point for 'healthy' or 'normal' functioning. Due to this, current guidelines might not stimulate a pro-active approach. Furthermore, separate guidelines exist for separate indicators of physical functioning which does not facilitate interpretation the combination (of changes in) indicators that are present in one person. A possible strength of the self-monitoring and feedback system could be that the combination of four physical frailty indicators is taken into account which makes it possible to detect changes in multiple indicators at once.

Some elderly persons might prefer to use the system independent of professional care processes whereas others, for example those who already have lower physical functioning, might use the system in a care context with support of care professionals. In case of the latter, a database should be developed in which the self-monitoring data of the elderly person can be stored and presented to a care professional. This database should be seamlessly embedded in the care process and should communicate with existing information infrastructures of involved care professionals. Depending on the care context and purpose with which the monitoring and feedback system is being used, the monitoring regimen that elderly persons choose to follow can differ.

The system can be integrated with other care technologies or services that support health and independent living in community-dwelling elderly people. Examples of such technologies could be Ambient Assisted Living (AAL) technologies (e.g., sensors for fall detection or detection of activity), health risk appraisal services, or services that provide interventions that support people in maintaining an active lifestyle or improving physical functioning. Such integrated pro-active systems can support independence in older persons. However, in order for such integrated systems to succeed, new business models should be developed in which the costs and benefits of such interventions for different stakeholders are specified. Such business cases are needed to facilitate implementation of innovations.

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Before the self-monitoring and feedback system can be implemented in practice, future research is needed regarding several issues. Currently, a study is being conducted in which 13 community-dwelling elderly people use the optimized monitoring and feedback system on a daily basis for 6 months independent of a care context. This study will provide insight into the long-term experiences and acceptance of the system. Furthermore, information will be collected regarding falls, disability, illness, health care use, and physical functioning using questionnaires, diaries, and bi-monthly examinations by a geriatric physical therapist. Combining this information with the self-monitoring data that was collected by community-dwelling elderly people using the self-monitoring and feedback system will provide insight into how the home-based self-monitoring measurements can be interpreted and into the clinical relevance of changes that are detected. Besides the ongoing feasibility study, future research should focus on the clinical relevance of changes in (a combination of) indicators of physical frailty that predict disability development should be studied. Large scale cohort studies can provide insight into the development of such indicators in elderly people over time. Big data or data mining methodologies could be used to identify patterns or pathways that lead to adverse outcomes. Furthermore, ways to integrate the system in daily care (or welfare) routines should be explored. Different organizations and elderly users of the system might have different requirements for this integration. Needs and preferences of elderly persons and professionals working in such organizations should be taken into account. Finally, the possibilities to provide training and/or tailored disability prevention programs to community-dwelling elderly people using the system to support them in their self-management should be examined. Such research should also focus on (cost-)effective components of such interventions. Physical activity might be considered a relevant component of such training or intervention programs since it is an important health behavior for preventing and reducing disability. Further exploration and improved understanding of the issues mentioned above can support the implementation of the self-monitoring and feedback system in practice which might facilitate a more proactive approach regarding frailty and disability prevention in community-dwelling elderly people.

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Use of Mobiles for Reducing Infant Mortality by Increasing Adherence to Vaccinations in a Low Resource Setting

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Abstract— **Infant mortality is inversely proportional to immunisation. In India, due to lack of awareness and knowledge about the benefits of immunisation, the infant mortality stands at 61%. With the need to reduce this high percentage, the use of technology has proved to be beneficial. The growing penetration of mobile technologies and the sending of alerts over mobile devices has helped extend the reach of healthcare services to resource limited settings. mHealth has numerous applications in child healthcare and one such mobile application that aims to address a long standing issue of high infant mortality rate is Child Immunisation Alert System (CIAS). This paper highlights the design and outcome of CIAS, which uses various communication modalities to send vaccine alerts to the parents for high vaccine adherence.**

Keywords-mhealth; child immunization; mobile health; vaccination; CIAS; infant mortality rate.

I. INTRODUCTION

Infant mortality has been inversely associated with the immunisation given to children [1][2]. In 2008, WHO estimated that 1.5 million deaths of children under the age of five were due to diseases that could have been prevented through vaccinations. In India, for the year 2012, the immunization coverage in the rural areas stood at 58.5% whereas the national average was 61% [3]. The major reasons for such dismal indicators are:

a) Lack of awareness: Majority of the mothers are not aware about the vaccines and its benefits [2][3].
b) Lack of knowledge: With the prevalence of traditional beliefs, people feel that their child should develop 'natural immunity'[4]
c) Lifestyle: Owing to frenetic lifestyles in an urban setting, parents tend to forget.

Numerous studies by healthcare providers indicate that technology enabled methods could be adopted to overcome the apprehensiveness of parents and prevent diseases from spreading [5]. For increasing awareness about vaccines, the use of mobile technology and text messages have achieved success in different parts of the world [6][7][8]. Given the scope and penetration of mobile technologies and its advantages in improving healthcare services, Child Immunization Alert System (CIAS), a mobile application was conceptualised to reduce infant mortality. For each registered child up to the age of five years, the application displays a set of immunisations along with its benefits, as recommended by India's Ministry of Health and Family Welfare (MoHFW). Alerts about the vaccines to be administered to the child are sent using either emails or SMS or push messaging (instant notifications). Key reasons for selecting these modalities are:

a) High penetration: In India, mobile communications services are amongst the cheapest in the world. As a result, in India, mobile phone's penetration is 70%+ and the market share of smartphones is increasing at a noteworthy rate [9].
b) Affordability: the three modalities for alerting users are cost effective and encourage higher adoption rates and speedier diffusion of the application.

This paper brings out the design of the system CIAS that was deployed in the Indian landscape. Section II of the paper describes the requirements taken from the doctors while designing CIAS. Section III, highlights the CIAS system design and its key components. Section IV, discusses the methodology adopted for deploying the mobile app CIAS. Section V, highlights the outcome of the CIAS system and discusses the feedback received from the users. Section VI, brings forth the future work to be done as part of CIAS and section VII concludes the paper.

II. USER REQUIREMENTS

The user requirements for preparing the functional specifications requirement (FRS) were gathered by having detailed discussions with 09 paediatricians from various healthcare delivery institutes in and around Chandigarh, India. The average experience of these medical experts was 11.77 years with a high of 28 years of experience and a low of 06 years of experience. The post-graduate work experience of the paediatricians was considered. Post discussions, the following user requirements were compiled: 1) it was felt that regular alerts along with the importance of vaccines be sent to the users by exploring maximum possible communication modalities available; 2) most of the clinicians highlighted the need to have a parallel web based system. This was required mainly to address the users who did not use smartphones but had access to internet for which the users are increasing at a significant rate [9]; 3) system to include sending of alerts for non-smart-phone users as the majority of the population uses such phones.

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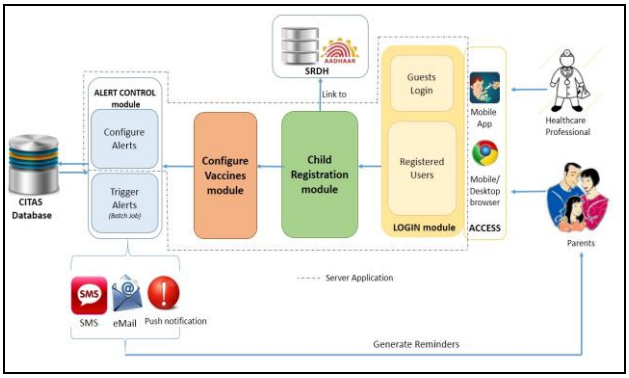

Figure 1. CIAS Architecture

User requirements lead to FRS, which were then transformed into CIAS system requirements and based on these, CIAS architecture was conceptualised (see Figure 1).

III. DESIGN

The application CIAS is designed based on open source technology. The key features of CIAS are:

A) Access:

CIAS has been designed both as a mobile application and a web based application. The data is stored in a web-based database for various advantages. These advantages include the provision of updated information, enabling real time alerts and easy retrieval of information anytime and anywhere. Also, for program managers, the collective data provides an effective source for some trend visualisations.

- The mobile application is developed on Android OS version 2.3 and provides upward compatibility [10]. Using the mobiles' internet connection (4G-LTE/ 3G/ 2G/ GPRS/ Wi-Fi), the child details including vaccine information is stored on the web server..
- The web based application has been designed using HTML5 as it helps to render the content according to the screen size of the device, which may be a mobile, tablet or a workstation [11].
- The database selected for CIAS is MS-SQL. To enable the exchange of information, web services were deployed. The web service was called in the mobile app and the mechanism for the exchange of data was established.
- For non-smart-phones users, the pull-SMS feature was introduced in which the user could text the name and date of birth of the child to a pre-defined number (51969) for receiving SMS-based alerts on their non-smart phones.

Apart from the parents, CIAS addresses the needs of field healthcare professionals who can type-in the details of the children born without having their parents need to register. This feature was enabled in concordance to the users' requirement.

B) Alert Control

The Alert Control mechanism comprises of two components: a) the alert type and b) the alert configurations.

- Alert type:
  i. SMS: The Mobile Service Delivery Gateway (MSDG) of the Government of India, was integrated with CIAS and is being utilised for sending free SMSes to the users [12].
  ii. Emails: Numerous studies have indicated that people who prefer emails feel that it provides a quick and convenient access to healthcare information [13]. Hence, this communication modality was also integrated in CIAS to send alerts.
  iii. Real time notifications: 'Push Messages' in Android makes use of Google Cloud Messaging service, which enables the sending of real-time notifications directly to the user [14].
- Alert Configuration: In CIAS, the users can select as per their convenience the different communication modalities for receiving alerts and also customise the periodicity of the alerts. The users can opt for either or a combination of sms, email and push notifications as the medium of receiving the alerts. Further, the alerts sent have been classified into three categories: *upcoming-vaccine, vaccine-due* and *vaccine-overdue*. Users can configure the upcoming vaccine alert according to their convenience. By default, alert for '*upcoming-vaccine'* is sent one-day ahead of the date of vaccination and alert for '*vaccine-due*' is generated on the day of vaccination. If the vaccination is not done on the due date then a one-time '*vaccine-overdue*' alert is sent the following day. In this case, the parent is prompted to provide the reason for the delay, as this would help to design suitable interventions to plug the gaps. Another configurable option is the schedule of vaccines. Though CIAS displays the schedule of the vaccines as recommended by MoHFW, however, in certain cases where the need is felt, the parents can alter/ configure the schedule of vaccines as recommended by their consulting doctor. All these configurations can be done on the mobile application, CIAS. Figure 2 shows the user interface for configuring the vaccination schedule.

All these alerts are sent through a *batch job* configured in the Task Scheduler, which calls a web service. This web service compiles the lists of alerts to be sent for that particular day from the database and then triggers the alerts.

C) *Linkage to State Resident Data Hub (SRDH)*

Unique Identification (UID) project is a biometric project being implemented by the Government of India, which uniquely identifies an Indian citizen and captures information such as their biometrics and demographic details [15]. For using UID, State

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Resident Data Hub (SRDH) is the application framework being created by UID Authority of India (UIDAI) having the resident's data for each state at the State Data Centres (SDCs). Linking of CIAS to SRDH would enable child's information to be mapped with the parents (UID) so that timely interventions could be designed.

IV. METHODOLOGY

The mobile app 'CIAS' has been developed indigenously by Centre for Development of Advanced Computing (C-DAC) at Mohali. The initial version of the mobile app CIAS, was released in December 2013 on the mGov mobile app store. mGov app store has been provisioned by the Government of India to provide various citizen centric mobile applications. This app store is available at apps.mgov.gov.in. CIAS was made available free of charge to the end users. Also, various camps were held in Post Graduate Institute of Medical Education and Research (PGIMER) Chandigarh, Civil Hospital, Mohali and dispensaries in Mohali district of Punjab state to create awareness amongst the citizens and encourage them to download and use the mobile app. Vaccinations in these hospitals are administered only on Wednesdays and Saturdays during the week, hence the camps were held accordingly. During the camp, interactions were held with the parents to increase the adoption of the CIAS mobile application. Based on the inputs, the application was enhanced with a user friendly and an intuitive interface using 'material design' technology. Figure 2 shows the user interface of the CIAS application.

V. RESULTS

CIAS was made available in December 2013, and by December 2014, the mobile app had been downloaded by 1314 users from the mGov store. Table 1 shows the count of SMS and emails sent as alerts to the users. Push notifications are managed by Google, hence, its count was not available. A look at the figures in the table indicate that users have opted for SMS as a preferred means for receiving vaccine alerts.

TABLE 1: COUNT OF ALERTS SENT

Sr. No.	Modality	Total sent
1	SMS	1641
2	Email	929
	TOTAL	2570

A feedback was taken from 134 randomly selected users. Their responses are shown in Table 2. The 3.74% of the users who did not get information on time, were inquired upon to get the reason. These specific users had opted for push notifications and did not receive those alerts because of intermittent internet connectivity. Hence, information could not be received on their mobile devices.

TABLE 2: USER FEEDBACK

No.	Question	Agree
1	CIAS is a useful service	94.02%
2	CIAS provided information on time and has helped improve vaccine adherence	96.26%
3	CIAS was easy to use	82.83%
4	I'm satisfied with the use of CIAS	78.35%

The data before the introduction of CIAS application could not be recorded as the mGov store does not have the option to register the users. Hence, the demographic details of the users also could not be obtained. Also, the feature 'overdue-alert' was introduce at a later stage and was not a mandatory field.

With the application being user-centric, the users highlighted the need to have local language support for deeper diffusion. Another feedback received, was the need of information of nearby hospitals where vaccinations could be administered. For this, CIAS was made context-aware and the list of hospitals was included based on the users' current location. A screen in Figure 2 shows the list of nearby hospitals. Also, in order to increase the penetration of CIAS amongst the public, the mobile application has also been published on the Google Play Store.

VI. FUTURE SCOPE OF WORK

The scalability of the CIAS system would need to be considered for a nation-wide deployment. Also, the integration of CIAS with the Mother and Child Tracking System (MCTS), a program of the Ministry of Health and Family Welfare, Government of India, would include detailed information about the pre-natal and post-natal care. The addition of voice based alerts in CIAS would enable speedier and deeper diffusion. Also, the inclusion of the child's growth and development patterns would make the system more comprehensive. Sending alerts for administering polio drops during the Indian Government's Pulse Polio Campaign, which is held twice a year, is also being considered.

With India having vast regional diversity, the CIAS system could be made multilingual. This would make the system more customised to the local requirements of the citizens and would help in bringing down the infant mortality rate.

VII. CONCLUSION

With the developing countries looking at a large infant mortality rate, the use of mobiles and associated technologies have certainly brought a positive change. With CIAS, it can be concluded that cost effective alerts, such as emails and SMS, can be introduced to provide timely vaccination alerts. However,for deeper penetration, the system needs to be made available across platforms. For the section of populace that still uses traditional

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phones, a web based system and pull-sms facility is provisioned. Also, efforts are being made on the localisation factors like support for regional languages, training, and empowerment of local experts to achieve speedier and deeper diffusion [8].

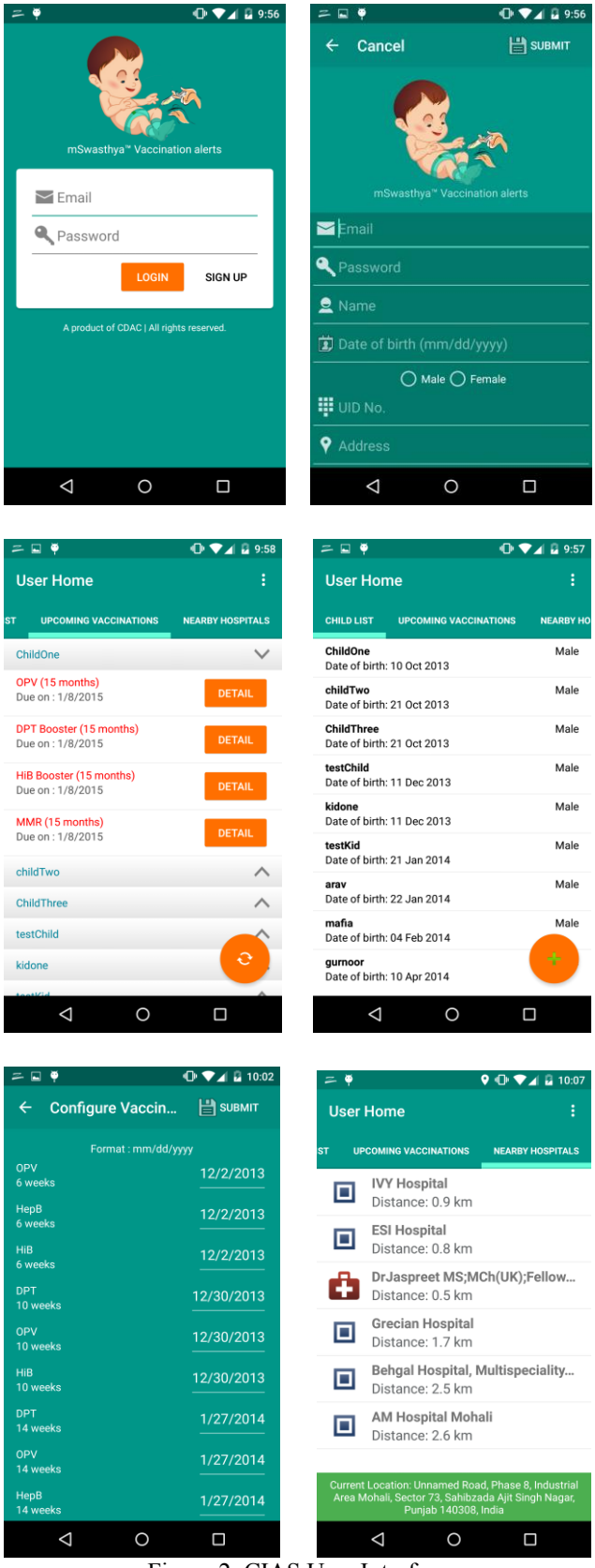

Figure 2. CIAS User Interface

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Mobile Health & Medical Apps: Possible Impediments to Healthcare Adoption

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***Abstract*—According to the World Health Organization use of mobile, wireless and communication technologies to support healthcare and the achievement of health objectives is known as mHealth. This paper investigates sub-topics of mHealth, mobile health apps (MHAs) and mobile medical apps (MMAs), which have emerged with the increasing prevalence of smart phones and tablets. The number of health related apps available in 2014 is estimated at 100,000. However, various reports highlight details, such as: 40% of health apps are unused after the initial novelty has worn off; people with chronic diseases who need this technology are not using it; and that due to clinicians having issues with quality and trust of such systems they are not confident in using or in recommending to patients. The paper discusses issues for MMAs which are deterring development and innovation within the industry and the adoption of MMAs by the medical field. The discussion includes, the regulatory background, difficulties such as communication and vagueness surrounding the regulatory status of MMAs, time and cost, safety issues and the security and privacy concerns.**

Keywords: mHealth; mobile medical apps; regulation.

I. INTRODUCTION

Mobile Health (mHealth) has an increasingly significant role to play in healthcare, both in terms of diagnosis and treatment. Perceived benefits of mHealth include; patient-focused medical care [1]; greater personalization and improved responsibility of the individual for their health [2]; an opportunity to provide medical support when and where people need it [3]; reduction of healthcare costs [4]; management of chronic diseases and outreach to remote areas [5]. This paper examines mobile health apps (MHAs) and mobile medical apps (MMAs) and the possible impediments deterring their impact on healthcare. The current regulatory process entails many overlapping analyses [6] that app developers and manufacturers need to consider with regard to their products. A MMA is an app that qualifies as a medical device (MD) and as a result is required to follow the applicable necessary MD regulatory requirements. In developing apps for the health market, an underpinning question for the developers is whether an app qualifies as a MD. MHAs and MMAs to a lesser extent, are currently the most dynamic in medicine and establishing appropriate and clear regulatory processes will support this potential [7]. Despite the overabundance of apps available to the general public and medical professionals, there is still the issue of identifying apps suitable for use [8], the safety of the apps [7][9], as well as the privacy and security of consumer-protected health information (PHI) [3][6]. Further considerations include that apps are not being targeted to those that actually require them, uptake among late adopters of new technology is hesitant and the successful apps are those used by younger healthier populations [10].

II. REGULATION BACKGROUND

The eruption of the MHA and MMA markets has resulted in regulating bodies being challenged to keep pace. Consequently mHealth applications are largely unregulated [11]. Guidelines have been released in the US and Europe to support developers and manufacturers ensure public safety.

A. U.S.

Regulators in the US are the Food and Drug Administrators (FDA), which issued a Final Guidance on Mobile Medical Applications on September 25, 2013. The guidance indicated the focus will be on regulating a small number of MMAs considered high risk [12]**.** The FDA ambiguously outlined three categories for mobile apps (MAs). The three categories are:

1. MAs that are considered MDs and will be regulated under the US Federal Food, Drug and Cosmetic Act (FD&C Act) of 1938 and are subject to regulation before and after it is marketed. The guidance defines a mobile medical app as "a mobile app that meets the definition of a [MD] and either is intended to be used as an accessory to a regulated MD; or to transform a mobile platform into a regulated MD [12]."

2. MAs that may be considered MDs but will not be regulated, as they are not deemed high risk, identified by the FDA to be "mobile apps that may meet the definition of MD but for which FDA intends to exercise enforcement discretion";

3. MAs that are not considered MDs.

The FDA has provided an extensive list of examples for each of the categories. The FDA intends to oversee "only those MAs that are MDs and whose functionality could pose a risk to patient safety if the MAs were to not function as intended [13]." It will regulate MAs just like MDs if the app is intended to treat or diagnose disease. The intended use of the app is defined by the developer or manufacturer and not whether the device actually is used as an accessory or actually transforms a mobile platform for a MD [6]. If the app is not developed, designed and marketed for healthcare it will not be subject to FDA regulation. FDA stated in 2013, it would begin regulating apps and gadgets that collect or track medical information as MDs. As MMAs become more abundant and ambitious, targeted FDA oversight will help to protect the public health, sustain consumer confidence in

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mHealth products, and encourage high value innovations [13].

B. Europe

To date there is no direct legislation relating to lifestyle and wellbeing apps in Europe. The European Commission launched a consultation on mHealth, the Green Paper on Mobile Health (mHealth) on April 10 2014, which invited comments and opinions from professionals, patients, health organizations, administrations and industry. An objective was to discover barriers and issues related to the use of mHealth [14]. The Commission additionally published a Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps to accompany the Green Paper [15]. This document was put in place to support software developers and manufacturers in identifying whether their products are subject to the European Medical Devices Directive (MDD) 93/42/EEC and 2007/47/EC or the In Vitro Diagnostic Device Directive (IVDD) 98/79/EC. Additional guidance (i.e., MEDDEV 2.1/6) was published in January 2012 to provide guidelines on stand-alone software for MMAs [16]. The guidance states that an app must have a medical purpose to be a MD. In order to market an app as a MMA in the European Union, a CE Mark must be obtained which indicates that your device meets the requirements of either the MDD or the IVDD. Further guidelines are provided in the Manual on Borderline and Classification section in the Community Regulatory Framework for MDs 1.16 published July 2014 [17].

III. POSSIBLE IMPEDIMENTS

A. Regulatory Requirements & Communication

A Price Waterhouse Coopers (PwC) report stated "uncertainty in regulatory requirements would likely dampen the growth of mHealth" [18]. A commissioned PwC report states innovation in mHealth is being impeded by the application of inappropriate regulations from earlier technologies [19]. Over 150 countries have not yet developed regulatory guidance or frameworks [18]. The category of MMAs is not experiencing the same rush of innovation and market share as MHAs. Reasons indicated in the literature include, frustration with regulation [20] and the complexity of the rules associated with bringing a MMA to market [11]. In 2013, there were no MMAs that pursued 510(K) pre-market approval [21] in the U.S. In the EU due to the highly regulated nature of MDs, app developers face a lengthy and unpredictable process, which can delay product launches impacting profitability and market lead. FDA states that the guidance is not a regulation and not all devices require premarket clearances. This is based upon the safety classification of such devices, which depends on the level of harm that may result if a device fails. The classification of devices ranges from the low risk Class I, to the higher risk Class III devices which determines the level of regulatory control requirements. The complexities and overlapping reviews in the regulatory requirements become time-consuming and create demanding complexity for developers and device manufacturers [6], which require expert advice.

B. Regulatory Grey Areas

The definition of the boundary between general wellness and diagnosis or treatment of a disease or health condition is a grey area [11]. In both the U.S. and the EU, one of the biggest concerns is how vague the legal lines are between monitoring various vital signs for general wellness and crossing over into the realm of MDs. Clarification in terms of at what stage an app intended to support self-awareness and well-being becomes subject to the MD regulation [22]. It is believed that due to the FDA guidance on MAs being broad that the regulatory environment is ambiguous to MMA developers [23]. The enforcement discretion category in the FDA guidelines establishes a significant grey area concerning products that obviously must be regulated to ensure safety and those that pose little or no risk to patients [13]. The Food and Drug Administration Safety and Innovation Act (FDASIA) recommended a "risk-based regulatory framework for health information technology, including MMAs, that promotes innovation, protects patient safety, and avoids regulatory duplication [24]." The report recommended classifying health IT products into three categories: 1) "administrative" health IT functions e.g., claims; 2) "health management" functions, e.g., clinical decision support; and 3) products that perform "MD" functions [24]. FDA focuses on MD functionality because they present greater risks to patient safety than administrative or health management functionality. The benefit gained from classifying being legislation can be directed to particular apps without stifling the innovation of such technology.

C. Regulation Time & Cost

Modern app development is fast-paced with emphasis on cost effectiveness and time to market. Regulatory overhead concerns do not encourage innovation as app developers shy away due to perceived costs and the added time required. Advice from the FDA and those marketing MMAs, is to engage early in collaboration with the regulators [25]. This will reduce time to market, cost and increase the rate of success in regulation submission. Manufacturers unfamiliar with the regulatory requirements may find it useful [11] to seek advice from regulatory experts. The time to clearance issue is an ever constant issue and with limited resources in the FDA, expectations for reducing time to market are slight. Once an app crosses into the MMA category, it then becomes subject to applicable regulations. This then requires investigation in relation to complying with regulations, applying for approval etc., and any other requirements the regulatory bodies impose upon MD manufacturers. The FDASIA Health IT Working Group recommend that the FDA provide greater clarity to several aspects of MD regulation involving health IT, including: 1) The distinction between wellness and disease- related

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claims; 2) MD accessories; 3) MD clinical decision support software; 4) MD software modules; and 5) MMAs [24].

D. Safety Issues

Safety issues include concerns relating to the development, medical involvement and validity of app claims [26], software and medical updates of apps [3], and customer access [27]. Currently the market is flooded with apps that have many claims relating to uses for the health of the users [28]. There is little to no understanding relating to who is involved in the development and how the apps were developed and validated [8][7][9]. For apps that do not meet the definition of a MD establishing the validity of the app is challenging [29]. Classification schemes for MAs have not been widely established. The National Health Service in the UK has a Health App Library, which a developer can apply to have their app reviewed. Happtique Health App Certification Program (HACP) is a company in the U.S intended to support healthcare clinicians and consumers in identifying medical, health and fitness apps. Both perform assessments to assess operability, privacy, security and content [3] and remain voluntary. Pursuing the right ideas concerning how and why an app is used will return better results [6] and lead to focused and valuable development of MHAs and MMAs. Consumers have far greater access to these apps than consumers have had with traditional MDs [6]. Current regulation focuses on the device itself, but more attention also needs to be given to the effects of consumer access and actual use [6], otherwise the apps cannot be expected to properly improve healthcare.

In the U.S regulatory context, a loop hole in the regulation enables the development of an app that would not require 501(k) clearance [30]. A healthcare system can develop an app that would be used only by clinicians within that system and not put onto the open market. The FDA states that as long as the app was used within the system's own practice and not marketed outside that healthcare system it does not require clearance. It is at the discretion of the developers and companies to present their app for regulation. An app for iPad Mobile MIM that enables a healthcare professional to view medical images on an iPad and make a diagnosis [3] was offered for download as early as 2008, before the FDA had cleared it [31]. The FDA oversaw the removal of the app from the store pending regulatory review it was cleared in 2011 as the first app for "viewing images and making medical diagnoses [32]." Apps for general wellness and health monitoring may be rendered harmless, but may pose higher risk than believed [6] when placed in the hands of the consumer. Consideration is required about the possibilities that health and wellness apps can go beyond what the manufacturer initially intended [6]. Disclaimers used by the developers stating the apps are not intended to be marketed as a MD but for educational purposes, have the potential to harm users. Users may believe naively that the evaluation given by an app is a substitute for medical advice [9]. Medical clinicians need be aware that some apps contain unreliable, non-peer-reviewed content and should choose carefully which apps to use in clinical care [33].

E. Security & Privacy

Increasing reliance on mHealth raises questions about compromised patient privacy, the cross-jurisdictional practice of medicine, and legal liability for injuries [34]. Concerns relating to MMAs are security and privacy risks associated with mobile app deployment, which come from multiple sources, including networks, carriers, operating systems and MMAs. One of the risks related to MAs is the potential for breaches of confidentiality [7]. Currently, there is a lack of understanding that healthcare information is not yet fully protected. It is recognized that improved methods of data protection will evolve and enable mobile medical apps to attain greater patient outcomes [35]. The FTC in the U.S has released a staff report recommending that the mobile industry provide consumers disclosures about what data is being collected and how that data is being used [36].

CONCLUSION

Mobile app developers and manufacturers are presented with many regulations, standards, and guidelines to understand, implement and comply with. They are required to understand different regulatory requirements depending on the market where the app is intended to be geographically marketed. One major recommendation from the FDASIA to the FDA was clarification in relation to where a well-being app would fall into the category of a MD. The FDASIA report [24] also suggested a simple framework developers could follow to work through the regulatory requirements. Regulation in this field requires a clearer and streamlined regulatory system in order to keep pace with this quickly evolving technology [6]. Other concerns persist relating to apps available that are MMAs but have not been through the regulatory process. It is left to the developers to interpret the regulations and, given the associated difficulty and time issues many market their apps as having an intended use relating to health and wellness. It is difficult to see a growing impact in healthcare for MHAs and MMAs until the regulatory authorities take responsibility to ensure safety. Without the assurance of safety, MHAs will only ever be seen as a novelty. Equally, until the users can be ensured their data is safe and their privacy is intact, use for apps in the realm of serious health issues will be slow to follow in developing. Further consideration is also required to ensure the integrity, usability and safety aspects with apps if they are going to be fully embraced by medical clinicians and users.

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A Holistic Framework for Assisting Decision Makers of Healthcare Facilities to Assess Telemedicine Applications in Saudi Arabia

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***Abstract*—This paper outlines some of the challenges that currently face healthcare systems in Kingdom of Saudi Arabia (KSA). Increasing and continuing demand for healthcare services is aggravated by a critical shortage of health human resources (HHR) and healthcare facilities (HCFs) especially in rural areas. In 2013, 17.8% of the population lived in rural and remote areas with a huge disparity in HCFs distribution, and 76% of physicians and 44.7% of nurses are non-Saudis. Current studies have shown the potential of telemedicine to alleviate these challenges. The use of telemedicine has been adopted and the telemedicine roadmap has been developed by the Ministry of Health (MOH) in KSA in collaboration with Canada Health Infoway (Infoway). This roadmap has identified many barriers and challenges likely to face the implementation of telemedicine in KSA. This paper describes a holistic framework to address these challenges and to assess telemedicine applications in order to assist decision makers of HCFs in KSA. The proposed framework is developed in collaboration with the National eHealth Strategy and Change Management Office in the Ministry of Health (MOH) and Prince Mohammad Medical City (PMMC) in KSA.**

Keywords- Telemedicine; Healthcare challenges; Holistic framework; Saudi Arabia.

I. INTRODUCTION

Saudi Arabia's government is committed to provide free healthcare services to all Saudi citizens [1]. The Ministry of Health (MOH) is responsible for managing the country's healthcare system through the healthcare facilities (HCF) who are the core provider and represent 60% of the total healthcare services in the KSA. While some HCFs, who are under governmental sectors, provide services to their employees and their families, other HCFs, who provide private healthcare, are mostly located in urban areas [2].

The healthcare system in KSA is complex as the MOH is responsible for the supervision of HCFs in all sectors [2]. In 2013, MOH operated 2,279 Primary Healthcare Centres (PHCs) and approximately 3,000 hospitals with 37,921 beds [3]. It delivers healthcare services at three levels: (1) the primary healthcare centres (PHCs), (2) public hospitals (Outpatient Clinic), and (3) central or specialised hospitals (Medical City) [2][4]. The PHCs are the primary level and the cornerstone of the Saudi healthcare system allowing the MOH to provide healthcare services to the population in KSA that includes vaccinations, common procedures, and mother-and-child services [2]. The public hospitals (Outpatient Clinic) are the secondary level where cases that require more advanced care both preventive and curative are referred to be detected by specialists or consultants, while cases that need more complex levels of care are transferred to central or specialised hospitals (medical city) (the tertiary and third level of healthcare) [4]. In some exceptional cases, where the cases are very complex or rare, patients are referred to either King Faisal Specialist Hospital and Research Centre (KFSHRC) or outside KSA for treatment (the quaternary and fourth level) [1].

This paper is organised as follows. Section II presents the healthcare challenges in KSA. Section III discusses the use of telemedicine in KSA. In section IV, a proposed holistic framework for telemedicine in KSA is outlined. Section V concludes the paper and outlines future work.

II. HEALTHCARE CHALLENGES IN KSA

Like many countries, the Saudi healthcare system faces many challenges. The first set of challenges is caused by its geography. KSA is one of the developing countries where some of the people are living in rural and remote areas with a huge disparity in HCFs distribution. KSA is vast country, with an area of 2.2 million km², 150 cities, and more than 2,000 Villages [2]. In 2013, the total population was roughly 30 million, the population growth rate was over 3%, and nearly 18% of residents live in rural and remote areas [5][6]. The impact of geography on healthcare system has been proven [7].

The second set of challenges is caused by its lack of medical expertise and shortage of medical and qualified HHR [8]. Saudi's healthcare services are provided largely by expatriates and the high adoption of expatriates in HHR in KSA can be deduced from the statistics that are issued by MOH. The latest statistics indicate that 76% of physicians and 44.7% of nurses who are working in KSA are non-Saudis [2]. Furthermore, in KSA, the numbers of physician consultants are mostly less than the number of hospitals and in the worst case, the consultant physicians are permanently unavailable in all hospitals in some provinces. Besides, 55% of the total private hospitals and 83% of the total private clinics of the private HCFs sectors are concentrated in two provinces of KSA, Riyadh and Makkah, representing 49% of KSA population [2].

The third set of challenges is related to the increase in the population and the elderly, in particular, leading to the growing demand for healthcare services [9][10]. The

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expectancy, in medium variant, of the population growth of KSA is expected to reach approximately 40.4 million in 2050 and that is 35.1% increase compared to 2012; the number of people over 65 years old is predicted to represent 18.4% of the population in Saudi Arabia by 2050 [11]. In addition, cultural and traditional factors, such as dealing with the opposite sex and the driving ban for women, increase the burden of HHR shortage challenges and could be a huge obstacle [12].

The fourth set of challenges is related to equity of access to resources as most of the resources are concentrated in the main cities, with varying disparities [12]. A concentration of physicians in capital cities is a common feature in many countries [7]. Consequently, the density of physicians is commonly greater in urban regions which reflect the concentration of specialised services [7]. In 2012, 50% of the world's population lived in rural and remote areas served by only 25% of the world's physicians and less than 33% of the world's nurses [13]. In KSA, in 2013 alone, around 90,000 patients were referred from varies hospitals to other hospitals inside KSA for treatment [14]. Correspondingly, MOH has an 'Outreach' programme that enables specialists to conduct visits to rural/remote hospitals [3].

To address these challenges, MOH in KSA has begun investigating telemedicine as a potential solution and learning from other countries and consulting organisations such as the World Health Organization (WHO).

III. TELEMEDICINE IN SAUDI ARABIA

The quality and accessibility of healthcare have been successfully improved by telemedicine applications [15][16]. Telemedicine would serve to replace some of the in-person visits through video conferencing and provide healthcare services to patients regardless of their geographic location. In other words, while the traditional medical care relies on face-to-face communication between a patient and a physician, in telemedicine concept a patient is treated by a physician who is a distance away by utilising ICTs [17]. Therefore, telemedicine is particularly beneficial for groups that traditionally suffer from lack of access to healthcare since patients can be consulted and treated miles away by specialists [15][18].

In the 1990s the innovation of new technologies, the rapid growth of computer and information technology as well as the rapid declines in the cost of ICTs has created new possibilities and opportunities for healthcare services and delivery [19][20]. They have enabled HCFs to visualise and consider the implementation of new methods and more effective and efficient ways of providing healthcare [21].

The developments in telemedicine applications as well as new projects for implementation including the Saudi Telemedicine Network (STN) and a proposed holistic framework for KSA will be presented in this section.

A. Development of Telemedicine in KSA

Many telemedicine projects are being implemented by individual HCFs in KSA. In 1994, the first telemedicine application had been successfully applied in King Faisal Specialist Hospital and Research Centre (KFSHRC) [22]. In 1998, KFSHRC established its telemedicine network to connect several hospitals in different provinces in KSA to assess patients' medical status prior to transferring them to KFSHRC thus minimising the needs for moving patients. In 2013, more than 27 hospital sites were connected and each site was considered as 'a health partner' as well as 'a triage point' by taking advantage of available equipment and HHR management via the KFSHRC telemedicine network [17].

B. Saudi Telemedicine Network (STN)

In 2010, the MOH planned to implement telemedicine, as one of its key National e-Health Strategy projects, to cover all HCFs and to provide services to all patients in KSA [23]. For the first step of the implementation to be successful, MOH cooperated with Infoway Canada, a pioneer in the telemedicine field, to provide guidance to MOH in the development of a telemedicine roadmap for KSA. The Infoway report indicated that telemedicine would have a significant positive impact on healthcare in KSA and would alleviate many of the issues currently facing the KSA healthcare challenges [17]. It has confirmed that KSA has a degree of readiness for telemedicine as successful projects already exist and the necessary technical infrastructure expertise for telemedicine is either existing or under development [17].

However, the report has also identified many barriers and challenges likely to face the implementation of telemedicine in KSA given the healthcare complex structure system as the HCFs are divided into three sectors and supervised by different regional zones and directorates [17]. In addition, the majority of them are autonomous and each HCF has different business strategies and funding incentives [17]. Other barriers, identified by WHO are equally relevant to KSA, namely issues of cost, legal, culture, infrastructure, police, priorities, standards, knowledge, and expertise [24]. El-Mahalli et al. [25] carried out a case study to investigate the successes and challenges in the implementation of telemedicine in the eastern province of KSA. Their study concluded that, although the MOH in KSA has allocated a huge budget for eHealth, the telemedicine modalities used were very limited [25]. The top barriers as perceived by HCFs in KSA were lack of infrastructure and knowledge about the services and benefits of telemedicine, difficulty in the application of telemedicine, and HHR's resistance [25].

To address these barriers and ensure a successful implementation for STN, the report proposed to divide these barriers into two levels: a national level and an organisational (HCFs) level [17].

To resolve the national level challenges, the report advocated the establishment of a fully funded STN agency as an enabler and a provider of telemedicine services in KSA to oversee governance, infrastructure and common services used by participating organisations (HCFs) [17]. Other duties to be included are the setting of national telemedicine policies and STN connection standards for all end-point equipment, software, and processes to ensure security, interoperability and compatibility for all features and capabilities across the network [17].

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C. *The Proposed Holistic Framework for Telemedicine for KSA*

The aim of this research is to develop a framework to support the adoption and development of telemedicine based on the findings of the Infoway report. This framework is designed to assist decision makers (stakeholders) of HCFs in KSA to evaluate the viability and effectiveness of telemedicine applications. This research is collaborating with two organisations: PMMC as one of the HCFs in KSA [26] and the National eHealth Strategy and Change Management Office in MOH in KSA who is the sponsor and owner of STN project [27].

We have also collaborated with PMMC as this is one of five newest medical cities in KSA, and provides healthcare services to residents in remote areas and different [28].

Based on the findings of the Infoway report it became apparent that any proposed framework must take a holistic approach to address the many barriers and challenges at national and organisational levels. The proposed holistic framework is also designed to provide guidance to HCF's decision makers to identify critical barriers and challenges of their HCF based on STN standards and produce tangible and measurable criteria to support the adoption of telemedicine applications.

To develop this framework, three initiatives have been undertaken. The first initiative focused on identifying the fundamental pillars (barriers) and their concepts (sub-factors) specific to ensure a successful implementation of telemedicine applications. The concepts (sub-factors) of each fundamental pillar are specific to each HCF's requirements and challenges; they are used to generate critical success factors (CSF) for that fundamental pillar. The CSF is defined as an element of characteristics, conditions or variables that is necessary for an organisation or project to achieve its mission; it has a direct impact on viability, efficiency and effectiveness of a project, program or an organisation [29].

To identify the fundamental pillars (barriers) and their concepts (sub-factors) a survey has been carried out and individual-depth interviews (IDI) have been undertaken with experts and stakeholders in eight different HCFs in KSA, located in both rural and remote areas [26][27]. These interviews and survey have led to the identification of five fundamental pillars for the proposed framework, namely Human, Organisational, Technological, Environmental, and Business-Financial pillars, as shown in Figure 1.

Since the majority of HCFs in KSA are autonomous and have different business strategies and funding incentives, the concepts of each pillar in the proposed framework is to be adapted to address the challenges and needs of HCFs at national and organisation levels. Although the literature review offers a wide range of CSFs for telemedicine implementation in different countries or organisations, CSFs are unique to the environment and the organisation context and may not be easily shared by all countries or organisations [30]. Many of the old barriers and challenges that limited telemedicine applications in the past may no longer exist or their influences may have partly diminished; furthermore, some barriers may now be an opportunity [31].

The second initiative was to identify appropriate theories to support the fundamental pillars (barriers) and understand their interactions. Mitchell and Jolley [32] claimed that theories tend to be more internally consistent with existing facts than common sense, so theories do not ignore facts. Furthermore, theories link individual facts, give them meaning, and try to explain and measure them.

Technological, *Organisational*, and *Business-Financial* are three of the five pillars of the proposed framework. These three pillars are complementary so require a carefully balanced understanding of the pillars and concepts associated with each HCF. The framework is based on the Information

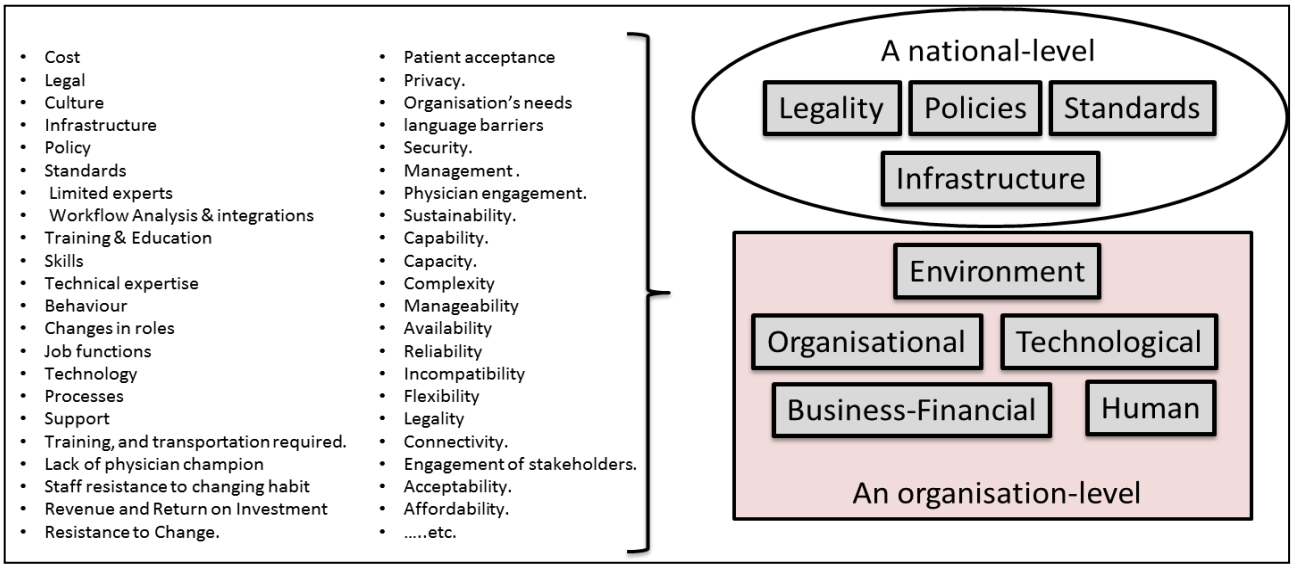

Figure 1: Identifying the Fundamental Pillars and their Concepts for the Proposed Framework

Systems Strategy Triangle (ISST) of Pearlson and Saunders [33] which argue that business strategy (*Business-Financial* pillar) drives both the organisational strategy (*Organisational* pillar) and the information system (IS) strategy (*Technological* pillar) and therefore organisations must carefully balance these three strategies [34][33]. In other words, any change in the IS strategy must be accompanied by changes in the organisational strategy and must accommodate the whole business strategy so the balance needed for successful operation is perpetuated and success can only be achieved by balancing these three components of the strategy triangle [33]. In our framework, the *Business-Financial* pillar is a fundamental barrier for each HCF which has specific funding incentives and seeks distinct return on investment and impact on costs.

The *Environmental* pillar, which is not included in the ISST framework, is another important pillar in our framework since the adoption of technology in HCFs has to conform to the various demographic needs of their residents and their geographic locations. The Technology-organisation-environment (TOE) is a theoretical framework, developed by Thornatzky and Fleischer in 1990, to identify the features of technology *(Technological* pillar), the readiness of the organisation *(Organisational* pillar), and the environmental conditions *(Environmental* pillar) as key drivers of technology adoption [35].

The *Human* pillar, which refers to the HHR in the HCFs and their citizens/patients, is the fifth fundamental pillar which focuses on human's specific problems related to acceptance and use of technology as well as individual attitudes and behaviours of groups [36]. Tough telemedicine is not aimed at replacing face-to-face healthcare with technology; it affects the nature of healthcare and needs additional provision to address the new challenges by HHR to ensure that they are able to use their skills, judgement and knowledge within this new context [37]. Brewster et al. [37] clarified that HHR is the key to the successful delivery and implementation of telehealth or any health information technology (HIT) in HCFs. HHR acceptance is critical to service innovation in healthcare, and is currently an ignored area of research [37]. The decision of whether or not to adopt a telemedicine solution, by an organisation, involve many stakeholders or adopter groups which the majority of them are HHR [38]. HHR are commonly considered the end users of telemedicine and can comprehensively influence the outcome of telemedicine adoption [38]. For these reasons, the Unified Theory of Acceptance and Use of Technology (UTAUT2) are relevant theories to support the *human* pillar in our framework. UTAUT2 theory is an extension of the Unified Theory of Acceptance and Use of Technology (UTAUT) which was developed through the review, mapping and integration of eight dominant theories and models in order to provide a unified theoretical basis to facilitate research on information system and information technology adoption and diffusion [39]. UTAUT was developed by Venkatesh, Morris, Davis, and Davis [40] in the field of information systems, and it has been employed by many studies in the field of telemedicine such as [41], [42], and [43]. Figure 2 shows the theories have contributed to formulate our framework.

Finally, the third initiative is to identify a suitable technique to classify each fundamental pillar and its concepts for each HCF telemedicine application to produce tangible and measurable results to support the adoption activities and to assist HCFs' decision-makers. This initiative is to be developed after the first two initiatives are tested and

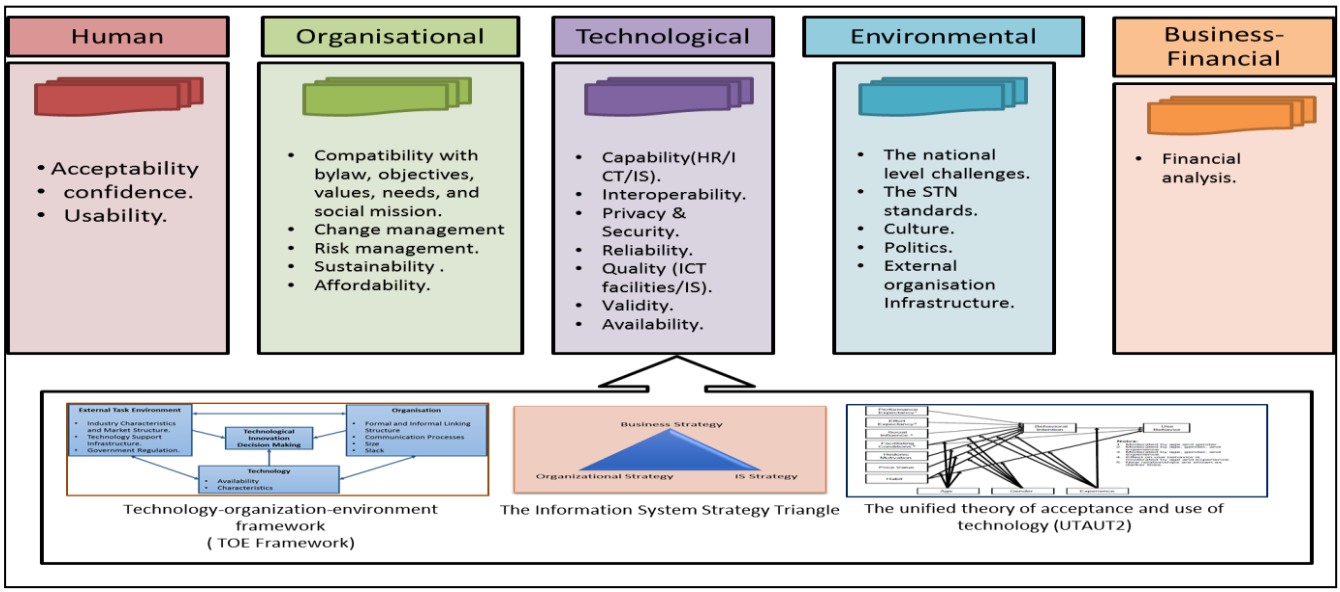

Figure 2. The Proposed Holistic Framework for Telemedicine for KSA

evaluated. We expect that some of the concepts of each fundamental pillar may be extended or enhanced to cover all HCF barriers that may affect the fundamental pillars of our framework which in turn may affect HCF decisions in adopting telemedicine solution.

IV. CONCLUSION AND FUTURE WORK

To summarise, there are a number of challenges currently facing the healthcare system in KSA; these could be alleviated or reduced by adopting telemedicine solutions. This paper has outlined these challenges and proposed a holistic framework to assist decision makers in HCFs to assess the adoption of telemedicine applications. This framework is based on the findings of the Infoway report, the extensive survey and interviews carried out with stakeholders in eight different HCFs in KSA.

Our future work is to evaluate our proposed framework. We propose to use questionnaires and focus groups to collect and substantiate the necessary data amongst Saudi healthcare stakeholders to address any new emerging challenges. This will assist us in determining practical and measurable results to support the adoption activities at national and organisational levels. In the longer term, the intention is to extend the framework to be suitable not only for telemedicine applications but also for all technological innovations in healthcare in KSA.

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The Circulation Assessment of Daily E-health by Using Instantaneous Pulse Rate Variability during Nonstationary Conditions

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***Abstract*—Heart rate variability (HRV) and pulse rate variability (PRV) are used as meaningful indicator of cardiovascular circulation assessment. However, both HRV and PRV are limited by the timescale of the heart beat and pulse wave series. Recently, a novel adaptive method based on Hilbert-Huang transform (HHT), named instantaneous pulse rate variability (iPRV), was proposed. It provides a new indication, called very high frequency band (VHF; 0.4-0.8Hz) for the neural regulatory estimation and peripheral responses. Ten healthy subjects participated this study and photoplethysmography (PPG) signal was recorded in supine baseline and during head-up tilt (HUT) and passive leg raising (PLR). The results showed that the spectral power of VHF decreased during HUT and increased during PLR, which might present the compensated regulation of venous return and fluid responsiveness. This study showed that VHF index has potential to indicate the fluid responsiveness and provides the meaningful information for homecare application, which only requires the simple PPG measurement.**

Keywords-PPG; Hilbert-Huang transform (HHT); instantaneous pulse rate variability (iPRV); passive leg raising (PLR); fluid responsiveness.

I. INTRODUCTION

Autonomic nervous system (ANS) regulates the homeostasis of body system, including heart beat rhythm. Previous studies showed that the variability of heart rate, named heart rate variability (HRV), presents the ANS activities within specific frequency band. Heart rate variability is widely used as a meaningful indicator of cardiovascular circulation assessment in clinic. However, HRV studies are restricted by the feasibility and the reproducibility with inconvenient measurement [1].

A substitute measurement of HRV was proposed, named pulse rate variability (PRV). Gil's study examined that PRV is as a surrogate of HRV during non-stationary conditions [2]. But both HRV and PRV are limited by the timescale of the heart beat and the series of pulse wave time intervals.

Recently, a novel adaptive method, named instantaneous pulse rate variability (iPRV), was proposed [3]. It adopted PRV technique and applied the frequency range extension method based on Hilbert-Huang transform (HHT) [4]. Hilbert-Huang transform is a data-processing technique which can deal with non-stationary and nonlinear data owing to its preprocess, called empirical mode decomposition (EMD). However, the intermittency phenomenon, called mode-mixing problem, is involved in EMD. The mode-mixing problem was eliminated by noise-assisted technique, known as ensemble EMD (EEMD) [5]. It provides a reliable indicator for ANS assessment and, furthermore, breakthroughs the limitation of beat-to-beat series spectral analysis. It provides a new indication, called very high frequency band (VHF; 0.4-0.8Hz) for the neural regulatory estimation and peripheral responses. The literature has examined that iPRV is reliable by using photoplethysmography (PPG) during non-stationary condition, such as head-up tilt (HUT) [6]. But its interpretation of VHF indication still needs further exploration and examination. It had been examined that VHF of HRV is as a novel index of left ventricular function evaluation [7], which further indicates the cardiac function, venous return, and fluid responsiveness. There is a common clinical experiment, named passive leg raising (PLR), which induces the increase of venous return and helps for the quantitative assessment of fluid responsiveness [8].

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The aim of this study is to examine the neural regulatory estimation and fluid responsiveness of iPRV on VHF during non-stationary condition, such as HUT and PLR.

The remainder of the paper is structured as follows. The next section presents data collection and introduces the iPRV analysis. Section III illustrates the results of iPRV spectrum. Section IV provides the discussion about mechanism of the VHF indication in iPRV. Conclusion is given in the last section.

II. METHODS

A. Subjects and data collection

All measurements were performed in a quiet temperature controlled room and the experiment was approved by institutional review board of the hospital. Ten healthy subjects (male: 5; age: 24±1) participated this study. The PPG signal was recorded by Nonin 8500 (Nonin Medical Inc., Plymouth, MN) with a sampling frequency 200Hz. All recruited subjects performed four trials in whole experiment. First, subjects were rest in supine position with 10-minute recording as baseline. Second, subjects were tilting up passively (HUT) on the automatic tilting table and kept in tilt-up position for 10 minutes. Then, subjects were back to the supine position with 5 minutes for recovering to baseline. Finally, subjects were raising leg passively (PLR) for 10 minutes. This study was approved by institutional review board of Tungs' Taichung Metro Harbor Hospital. Informed consent was obtained from all participants before the experiment.

B. Ensemble empirical mode decomposition

EMD extracts components by several steps. First, EMD performs an iteratively detrending operation, named sifting process. The sifting process is based on energy-associated extraction in each timescale, which determined by the local extrema. Local extrema of data $x(t)$ are identified by peak-valley detection. The upper envelope $U(t)$ and lower envelope $L(t)$ are generated by cubic spline interpolation according to the local maxima and local minima. The trend in current timescale is computed by calculating the mean of $U(t)$ and $L(t)$, as $M(t)$.

$$M(t) = (U(t) + L(t))/2 \quad (1)$$

The original data $x(t)$ subtracts the trend, as detrending operation.

$$h_1(t) = x(t) - M(t) \quad (2)$$

After k times iteratively detrending operation, if the trend of $h_k(t)$ satisfies the criterion as the steady constant trend, then the components $h_k(t)$ were extracted from $x(t)$, called intrinsic mode function (IMF). After n sifting process, $x(t)$ was decomposed into n IMFs, $IMF_1(t) \sim IMF_n(t)$, and one residue $r(t)$.

$$x(t) = \sum_{i=1}^{n} IMF_i(t) + r(t) \quad (3)$$

The EMD decomposes data into IMFs without information loss or distortion, but it contains mode-mixing problem. Ensemble empirical mode decomposition eliminates this phenomenon by noise-assisted technique [5]. The ensemble IMFs are computed by averaging each corresponding IMF decomposed from different mixtures of added noise and source data. This study used EEMD for the PPG signal decomposition as feature extraction method.

C. Instantaneous pulse rate variability

The iPRV analysis contains several steps as follows (Figure 1). First, the blood pulse signal was extracted from PPG signal as one of the IMFs by using EEMD. Second, the instantaneous period of the blood pulse signals were calculated by normalized Hilbert transform (NHT) [9]. Finally, fast Fourier transform was performed as the spectral analysis of instantaneous period. The spectral power of low frequency (LF; 0.04-0.15Hz), high frequency (HF; 0.15-0.4Hz), and VHF (0.4-0.8Hz) were calculated by spectral integration as the clinical indicators. The spectral analysis programs in this study was developed by using commercial software platform (LabVIEW version 2013, National Instruments Corp., Austin, USA).

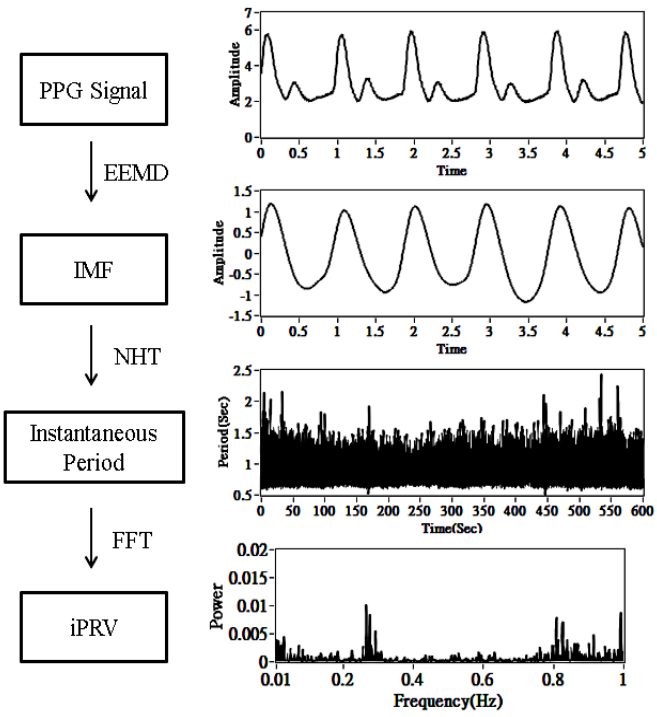

Figure 1. The flow illustration of the algorithm of instantaneous pulse rate variability (iPRV).

III. RESULTS

The results of the iPRV spectrum were summarized in Table I and illustrated in Figure 2 in one of the subjects as an example. The results of all participants' iPRV spectrum were similar with subtle change of the frequency peaks' locations. The power of LF increased both in HUT and PLR. The power of HF decreased during HUT and increase during PLR. The

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power of VHF decreased in HUT and increased during PLR. The relevant features were observed in the corresponding spectrum in Figure 2. The locations of the major spectral peaks were found around similar locations with those in iPRV spectrum.

TABLE I. THE RESULTS OF IPRV SPECTRUM

	Position		
	Baseline	***Head-up tilt (HUT)***	***Passive leg raising (PLR)***
LF	222.20±185.87	291.20±263.87	287.60±221.97
HF	297.00±212.79	274.20±188.25	417.80±302.50
VHF	366.10±382.74	234.20±179.83	505.40±506.27

The form is (mean ± standard deviation). LF denotes low frequency band (0.04-0.15Hz); HF denotes high frequency band (0.15-0.4Hz); VHF denotes very high frequency band (0.4-0.8Hz).

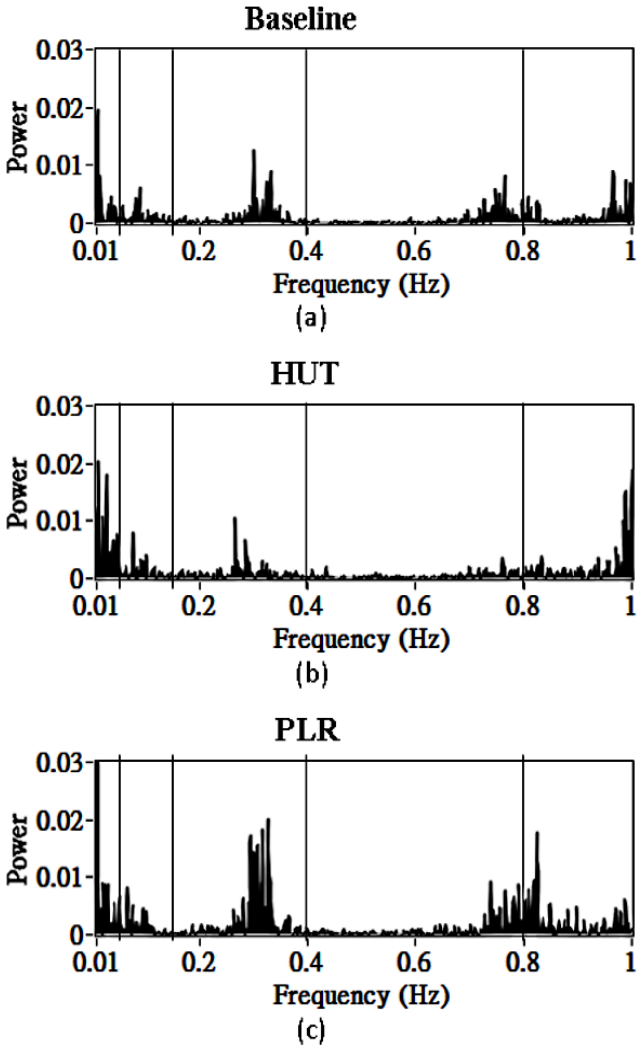

Figure 2. The illustration of the iPRV spectrum during (a) baseline, (b) head-up tilt (HUT), and (c) passive leg raising (PLR) in one of the participant as an example.

IV. DISCUSSION

It had been examined that the reliable iPRV spectrum can be assessed by PPG signal [6] and the new indicator (VHF) can be assessed through iPRV spectrum. Though some literatures investigated that VHF of HRV is a reliable evaluation of left ventricular function [7], VHF of iPRV still needs further examination. It had been examined that VHF contains parasympathetic activities and peripheral responses, which are influenced by venous return and cardiac function. The influences of respiration on VHF were examined by paced respiration study [10]. The mechanism of the VHF indication needs more exploration.

This study performed the clinical experiment, known as HUT and PLR, for the further examination. HUT causes temporarily decrease of blood volume in upper body and then causes the decrease of venous return. These changes induce the auto-regulation for the compensation. The sympathetic activities increased during HUT, and the power of LF also increased, which quantitatively assessed the sympathetic activation. On the other hand, the parasympathetic activities decreased, and so did the power of HF and VHF.

PLR causes the increase of blood volume in upper body and then causes the increase of venous return. The cardiac function was increased temporarily and induces the peripheral fluid responsiveness. These changes induced the regulation mechanism for the compensation. The parasympathetic activities increased during PLR and the power of HF and VHF also increased. The results showed that VHF has potential to indicate the relevant change of venous return and monitor the fluid responsiveness, which can be used in homecare monitoring.

Though VHF provides much more information of auto-regulation and has potential to indicate the parasympathetic activities and fluid responsiveness. It has several limitations as follows. First, the success of iPRV analysis is mainly depends on the waveform integrity of the PPG signal, which is sensitive and easy to be influenced by body movement and unstable measurement. Second, the EEMD of iPRV contains large computational power and causes huge time consumption, which means that it is hard to be applied as real-time application by recent technique. Third, the results in this study depend on ten healthy participants, and the population study needs to be performed for further examination, which is undergoing currently. Furthermore, VHF index should be examined with different group of subjects , such as not healthy people by using iPRV in future.

V. CONCLUSION

This study showed that the iPRV spectrum can be assessed by simple PPG measurement, which is suitable for homecare application, and the reliable VHF can be estimated by iPRV analysis. The power of VHF decreased during HUT and increased during PLR. The results showed the potential usefulness of VHF indication in venous return and fluid responsiveness.

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Enhancing the Wellbeing at the Workplace

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***Abstract*—Physical and psychological issues are a common problem for elderly employees. Working in an sitting position with not ergonomically designed working places, too little exercises in combination with unhealthy nutrition and stress are the main causes of the problems. In order to prevent such problems, we propose to monitor the workplace in an holistic way, thus detecting unergonomically workplaces, too little exercises, stress and an unbalanced diet automatically. The proposed system is able to detect unhealthy behavior by using a 3D sensor in combination with a camera and speech recognition. The proposed approach will be evaluated at least at 50 work places in order to prove its feasibility.**

Keywords–workplace; ergonomics; AAL; elderly; physical activity; stress management; nutritional balance;

I. INTRODUCTION

A significant amount of jobs require employees to sit for eight hours (or even longer) while performing their tasks [1]. During younger years, employees are not bothered with physical problems, but while getting older, more and more issues due extensive sitting occur. In combination with unergonomically designed working places, malnutrition (nutrition requirements change during our lifetime) and only little exercising, severe problem can arise, especially for people in the age of 50+ [2][3]. Furthermore, the cognitive capability decreases, whereas (together with many other factors) the stress level increases. This leads to employees feeling not very well, which indicates a reduced quality of life due to physical (e.g., back) and psychological (e.g., stress) problems. The aim of this paper is not to counteract on physical and psychological issues, but to prevent them already at an early stage. The proposed system is suitable for all employees performing their job in an sitting position, e.g., secretaries, office clerks, technicians, lawyers, etc. at the same level. Moreover, even employees not performing their jobs using a desk (e.g., bus driver) benefit from this approach since the system is flexible enough to be adapted to different needs easily. The proposed system consists of four different modules, which in combination lead to an enhanced quality of life of older adults in their working environment, but also to an increase of the overall wellbeing. The combination of these modules provides an training program for physical and psychological exercises and consists of the modules physical training, workplace ergonomics, nutritional balance and stress management optimized for the needs and wishes of older adults. Only by combining physical, ergonomic, nutritional and cognitive aspects, a holistic approach to enhance the wellbeing and quality of life of older adults can be developed. The focus is on providing a well-balanced and holistic system that is able to meet the end-users needs and offers benefits and an enhanced quality of life for older adults at the workplace. The rest of this paper is structured as follows: Section 2 provides an overview of the system, its modules are described in detail in Sections 3-6, a conclusion is drawn in Section 7.

II. OVERVIEW

The proposed system helps to increase the health of elderly people at their workspaces, focusing on providing an all-in-one solution for increasing the wellbeing of older adults at their workplace. The system focuses on workplaces where employees are performing their work in a sitting position, i.e., office workers. It can mainly be divided into two parts, which are the online wellbeing service for processing the data and generating feedback in real time, for logging, storing and representing results and a combination of sensors in order to gather input data (Figure 1). The quality of the physical training, as well as the performance of the stress management are handled by a 3D sensor (e.g., Kinect), the ergonomic workplace is obtained by exploiting a camera in combination with the 3D sensor, and the nutrition optimization is conducted by a combination of a camera and speech recognition. The workflow of the proposed approach is illustrated in Figure 2 and illustrates the combination of different sensor types.

However, since employees are monitored at their workplaces, privacy issues need to be addressed. The system is developed in order to ensure that only the employee is able to access his or her health data. This is extremely important since 1) only the person itself is allowed to access the data and 2) the obtained data is health data and thus need to be protected. Hence, appropriate measures to ensure privacy are taken and they include the implementation of proper user role management and encryption mechanisms. Moreover, the system needs to be unobtrusive in order to avoid negative side effects (e.g., employees are concerned of a misuse of the system). In combination with guidance of the company medical officer of each company, the system is not expected to trigger negative effects.

All modules, except the one for nutritional balance, are based on a correct pose estimation of the user. Pose estimation can be done by first extracting features in the image which describe local changes between different poses. After collecting the images, the system needs to be trained and novel input poses need to be classified based on this training data. Determining the pose of a human is done in 3D space. To overcome the ill-posed problem of extracting 3D poses out of 2D images, the RGB images were replaced by depth images obtained from a 3D sensor. By using depth images,

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Figure 1. Wellbeing platform and modules

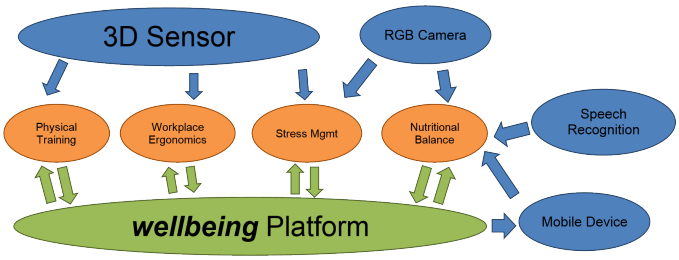

Figure 2. Workflow of the proposed approach

Fanelli et al. in [4] use regression in combination with a random forest is used for determining a human's head pose. Similar features are also used by Shotton et al. [5] where the first system for obtaining a human's pose is described. Each body part casts votes for a single class. The final pose is estimated by generating confidence-scored 3D proposals of how the body parts are connected. As a 3D sensor is able to overcome the ill-posed problem of extracting 3D information out of 2D images and is proven to be very robust against clutter and environmental changes, the input for the proposed system will also be based on this sensor for human pose estimation. Nevertheless, RGB images provide valueable information necessary to perform other task than 3D pose estimation (e.g., detection of a chair or a desk). As this information is also needed for the proposed framework, RGB images serve as an additional input source. The aim of speech recognition is to enable a very natural interaction with the computer by speaking instead of using traditional input devices and not only have the machine understand the verbal content, but also more subtle cues such as affect that any human listener would easily react to. However, so far real-time emotion recognition has scarcely been attempted and if so, only in prototypical applications. Technical challenges that arise when equipping human-computer interfaces with the ability to recognize the users vocal emotions are almost endless. Lately, several tentative studies were published recently on the interpretation of speech signals in terms of certain application-dependent affective states [6]. As can be seen, there is a research shift towards the analysis of spontaneous human behavior [7], which means that the analysis of acoustic information will not only suffice for identifying subtle changes in vocal affect expression. There are two driving trends focusing on (i) audiovisual analysis which combines linguistic and nonlinguistic analysis and (ii) visual analysis coming from multiple cues (facial expressions, head movements, and/or body gestures). This way, great outcomes are expected when merging both frontline cues into one single technology.

III. PHYSICAL TRAINING

Health and well-being oriented companies today offer their employees either the use of a gym or even provide the possibilities for other forms of exercising (e.g., aerobics). However, providing such facilities is very cost intensive and hence, only a small number of companies offer these activities to their employees. Nevertheless, companies are getting aware that many health related issues their older and more experienced employees are suffering from, could have been prevented if detected already at an early stage. However, since aerobics lessons and gyms are expensive, especially in bigger companies with a high number of employees, other ways of exercising were found. A common way of motivating employees to exercise is to provide them information about small exercises to perform on their own. There are different ways of presenting these exercises, e.g., in books, videos or on the Internet. The main problem with these techniques in comparison to a personal trainer is the lack of feedback since employees cannot verify if their movement during the exercise is correct. This issue is tackled by the use of a 3D sensor, which is able to detect the movement of the person. Furthermore, together with the proposed framework, wellbeing is able to provide feedback during the exercises automatically. The advantages of using this sensor is twofold: on the one hand, feedback about the accuracy of the movement is gathered and tips to improve the exercises on an individual level can be given without having high costs of a personal trainer. On the other hand, the activity can be logged automatically and thus can be used to motivate the end-user to exercise more often if only sporadic use is detected. The exercises itself can be presented in different ways, e.g., by using the conventional way where the exercise is shown and explained using a video, but also more entertaining ways of explanation can be used, e.g., as mini games, combining physical exercise together with gaming elements. These mini games are called exergames and are not simply video games, but are based on fundamental research by physicians. Hence, this type of games being able to tackle health related problems in a very entertaining way will be integrated during the project.

Physical training is based on pose estimation, during the performance of exercises in front of the system. These exercises are divided into conventional training and so called exergames, which should help to motivate the user for the workout. There is already a variety of different fitness games on the market, which use 3D information as input for tracking the user (e.g., Kinect Fitness, Nike+ Kinect Training, Kinect Sports, Kinect Zumba, etc.). Studies performed at the University of Chester show that the fitness games boosted the heart rates by up to 194 percent over sedentary games and increase the energy expenditure by 263 percent over resting values [8]. When having the human pose by using the real-time method described in [5][9], it is also possible to track body parts over time. Then, this enables keeping track of certain regions, which

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are more important than others for playing exergames and performing conventional training (e.g., arms, legs, head). As the input coming from the sensors is then sent to an online service, it is implicitly possible to also play against other users over the Internet. Having the components of first packing exercises in games and second competing against colleagues or other persons over the Internet increases the motivation for the user to perform the workout needed for a healthier working environment.

IV. Workplace Ergonomics

Work place ergonomics is the key factor of a healthy work place. Paying attention to ergonomic standards cannot only prevent back pain or postural deformity, but also vision problems and tensions. Work place ergonomics consists of guidelines for finding optimal distances to e.g., a monitor, adjusting the height of the chair and table, but also recommends regular breaks for relaxation, e.g., of the eyes. These rules already exist, but it is often hard to apply them in practice since you might sit correctly for a specific time after reading these rules, but getting lazy and forget them after a while. Since especially older adults are prone to postural deformity and vision problems, we propose to detect and track the position of the employees during their work using the 3D sensor introduced above and offer possibilities for improving the actual position. These offers range from reminders for taking breaks at regular intervals, analysing the sitting position while performing tasks and reminding the person to correct the pose (together with tips on how to correct them) and to provide relaxation exercises for the muscles, as well as the eyes. Since the system is based on an end-user centred approach, a non-intrusive system meeting the end-users requirements is designed. In contrast to regular reminders, the system does not remind the user at pre-defined intervals but takes the overall fitness of the user into consideration. The system is highly customized in order to consider the individual needs of different users, where one might benefit from more breaks or others from specific exercises.

Also for this module, it is necessary to obtain the users 3D pose first by using the 3D sensor. Additionally, objects in the environment need to be detected (e.g., desk, chair, etc.). As the 3D sensor is not providing any colour or texture information, an RGB camera is used to extract additional information necessary in order to assure these object detection tasks. Conventional object detection is performed by extracting some features first which represent the local structure of a patch. A classifier (e.g., support vector machine, random forest) is then used to train the system and to obtain a classification scheme. As in [10] or [11], the system can be trained on a variety of different objects. Felzenszwalb et al. [10] present a system for 2D object detection of rigid objects with manually labeled training images. The object is not detected as a whole but by using the combination of the parts, which make up the object. Since the images are labeled manually, the system is also able to estimate the 3D pose of the object in the scene. Liebelt et al. [11] provide a different approach, which is based on existing 3D models. Features are extracted from projections of these rigid models and the system is then able to estimate both the type of object and its pose in 3D space. These methods need to be extended in order to handle the type of objects needed for wellbeing.

V. Nutritional Balance

According to the WHO many diseases of older adults and elderly are diet-affected. These diseases are, amongst others, cardiovascular and cerebrovascular disease, diabetes, osteoporosis, and cancer, which are among the most common diseases affecting older persons. However, the WHO found out that only increasing the consumption of fruit and vegetables by one or two servings per day could reduce the cardiovascular risk by 30%. Since these results are achieved by only very simple measures, the proposed system aims at even increasing this percentage by ensuring the nutritional balance in a holistic way. The integration of this module is strongly motivated by the fact that older adults often do not have many possibilities to pay attention to their nutritional balance when they are in the office due to reduced time and resources. Furthermore, old habits and stress during work even worsens these problems and thus the consortium focuses on providing information for enhancing the nutritional balance. This module consists of a food recognition unit, with which the food can be recognized by providing a picture and/or spoken information. The food recognition unit consists of computer vision algorithms in order to estimate the amount of carbohydrate, protein and vegetables. These results are enhanced by providing spoken information, e.g., the approximate weight of meat, the type of protein/carbohydrate/vegetables. Offering this easy to use multi-modal interface, an individual nutrition schedule is recommended and monitored. In addition, information about the nutrition schedule, as well as unobtrusive reminders (e.g., ensuring the intake of the right amount of water) are provided.

Different to all other modules, surveying the nutritional balance is performed without using the 3D sensor but by exploiting a RGB camera and a speech recognition module. As both an RGB image and speech recognition is also available on a mobile device, this task can also be performed on such devices. Pouladzadeh et al. [12] use a support vector machine classifier and feature extraction using colour, texture, size and shape of the food. Bosch et al. [13] also use food identification for diet measurement. Due to the significant variations in appearance, Yang et.al. introduce an algorithm, which exploits the spatial relationship between ingredients [14]. Different to existing approaches, the goal is to gather a rough idea of the ingredients of the meals and determine e.g., how much carbohydrates, fat, or vitamins are present in the meal. Answering these questions is a different task compared to state of the art methods, which aim for determining e.g., which meat is on the plate. As the complexity of finding the ingredients of a meal is much lower compared to the complexity of a full food recognition system, the proposed task can be solved much more accurate and more efficient and is therefore a perfect fit for the needed purpose. To make the recognition even more robust, the visual detection system is combined with a speech recognition module, which provides the possibility to record spoken information about the meal, e.g., I had smashed potatoes and beef, a cup of peas and a cup of sauce. After a few weeks of taking pictures of daily meals, there is already enough data to suggest a perfect food plan. The user then receives individualized suggestions for improvements, or recipes. As can be seen, for a full food recognition system it is necessary to outsource the computation of segmentation, features and classification on an external server for a fast and reliable recognition. This makes it a

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perfect fit for the proposed wellbeing system. Image processing on RGB images in combination with speech recognition are exploited in order to detect the food on a plate. In order to deal with non-centred food in the image or cluttered background, the system has to segment the important parts of the image (the food) and discard objects in the background. The final decision is passed to the user interface from the computation server. If the result is incorrect, the user can send the feedback from the user interface to the server with the correct food information.

VI. Stress Management

Job stress is a serious problem among older workers that leads to physical and psychological health conditions and, in a mid-term perspective, to early retirement [15][16]. Stress at work occurs when occupational demands are higher than resources (excessive demand), and the mediating variables job autonomy and social support are low [17]. Our technology will prevent job stress by a) increasing personal internal resources (cognitive and physical abilities) and b) increasing social interaction among the employees by playing exergames together and in competition among each other. In order to enhance the communication and exchange between different employees, the games developed in wellbeing also contains a social component and can therefore either be played together in teams or the competition between different players is used as motivating factor for performing exercises from different modules. Furthermore, tools for stress management will be provided. These tools can also be combined with exergames introduced earlier and thereby these games not only offers physical training, but also relaxation and fun.

The proposed solution analyses stress related factors in order to estimate the current stress level. This analysis is mainly based on physiological factors, caused by stress (e.g., more reddish colour of the face). The application then gives each indicator a certain weight and measures the stress level. If the stress level exceeds a certain threshold, short exercises are proposed by the system, e.g., relaxation, acupressure, breathing-technique or any other slight movement. Similar to physical training, exergames can also be proposed here which can be played against other persons. The type and length of an exercise proposed depends on the level of stress. This diversity of different types of exercise and stress-reducing measures increases the motivation of the user. The stress management system is using the 3D sensor as an input device and the workflow of the module is based on the scientific background in the fields of the analysis of stress related facial signs and the execution and the impact of stress-reducing exercises.

VII. Conclusion

Monitoring ergonomical aspects at the workplace together with motivating user to exercise regularly reduces physical problems. In combination with the monitoring of stress related factors, as well as the nutrition ensures that employees stay healthy and fit. The wellbeing platform uses a 3D and color (RGB) sensor in order to motivate elderly employees to exercise more often by providing exercises on the one hand, and social exergames on the other hand. Moreover, ergonomical aspects about the workplace (sitting posture, distance to the monitor, etc.) are analyzed by the platform and feedback to correct the position is provided immediately. By analyzing the employees food and stress level, appropriate interventions can be suggested at the right time, ensuring a healthy lifestyle. The system will be evaluated on more than 50 users during the course of the wellbeing project, testing the system for the duration of 12 months in order to obtain reliable results.

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Intelligent Insulin Pens

A luxurious instrument or an essential gadget ? — A qualitative study

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***Abstract*—Insulin pens were first introduced in 1985. Since their introduction, insulin pens have been remarkable for their simplicity and accuracy. They have played a major role in the Multiple Dose Injection therapy (MDI). Until today, insulin pens, along with insulin pumping therapy, have been considered the only two reliable methods for external insulin delivery. Nevertheless, there has been always a wide gap between the two from the technological perspective. While pumps were enhancing through the utilization of several technologies, insulin pens have not had any major upgrades for a long period. Just recently, a couple of specialized diabetes companies have just introduced new types of intelligent insulin pens to the diabetes market. In this paper, we gave a brief introduction about the intelligent insulin pens technologies, and then we drew some general technological comparison between insulin pens and pumping equipments. In addition, we wanted to evaluate the current status of intelligent insulin pens technology among diabetic community, we went through a number of case studies among patients and obtained some feedback from their sides. We summarized the results from the case studies, and then we followed that by some discussions regarding the current technologies and our future vision for intelligent insulin pens. We believe that rather than focusing only on the development of intelligent insulin pens itself, we suggest that developers should give more focus on utilizing current ubiquitous technologies (i.e., smart devices, cloud computing, wearable computing, etc.). The main focus should aim on creating applications that can ease the diabetic management mission, and promote a better diabetic patients' compliance.**

Keywords—Electronic Medicine; Diabetes Mellitus; Insulin Therapy; Ubiquitous Computing; Cloud Computing

I. INTRODUCTION

A. Brief History

Insulin pens were first introduced in 1985 by the Danish company *Novo Nordisk* [1]. From that time, insulin pens have managed to promote a better adherence to insulin medication, and despite their high costs compared to regular syringes, insulin pens have always been remarkable for their accuracy and simplicity. Consequently, this led them to be the most convenient instrument for Multiple Dose Injection therapy (MDI) [2]. During their lifecycle, insulin pens had a series of several upgrades—mostly, minor ones (i.e., size, smoothness, shapes, etc.), but none of them had any major upgrades with high-tech functions [3]. The cycle has remained like that until *Eli Lilly* and company came in 2007 and introduced their *HumaPen® Memoir™* model. It was the first model that had electronic components and memory ability within its system. It could record time, date and dosage amount for a certain number of taken doses [4]. This encouraged *Novo Nordisk* in 2012 to release their own version of memory function in two of their models *NovoPen® 5* [5] and *NovoPen Echo®* [6]. Although the previous models had electronic components within their systems, the dosing action remained totally mechanical (i.e., force-driven motor). The Intelligent Insulin Pen *Pendiq®*, produced by the German company *Pendiq GmbH*, and manufactured by the Korean company *Diamesco Co.,Ltd*, was the first model to come and change the concept from "mechanical dosing" into "electronic dosing" (i.e., electronic driven-motor). In addition to that, the pen introduced several useful functions, which never existed before in any models [7]. Until today, it remains the only insulin pen model available with high-tech features within its system.

B. Comparisons Between MDI and Pump Therapies

For many years, there were several attempts to invent new methods for insulin delivery, but till this moment, only MDI and insulin pump have remained the most preferred methods among insulin dependent patients. Each one of these two methods has its own positive and negative aspects; yet from the technological side, there has been a wide gap between them. Table I summarizes the general comparisons between insulin pens and insulin pumps.

TABLE I. COMPARISON BETWEEN INSULIN PENS AND INSULIN PUMPS

Comparison between insulin pens and insulin pumps		
Features	*Insulin Pens*	*Pumps*
Level of accuracy and precision	Lower	Higher
Flexibility and convenience	Higher	Lower
Costs	Lower	Higher
Performance and glycemic control	Lower	Higher
Level of risks	Lower	Higher
Ease of mastering	Higher	Lower
Level of complexity	Lower	Higher
Hight-tech and upgradability	Lower	Higher

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Overall, insulin pumps have always been featured with high-tech type of equipments, while MDI, using insulin pens, have remained just simple without any sophisticated parts. Nevertheless, the technological nature of insulin pumps have made them highly extendable; for example, modern pumps right now can show you the current level of insulin within body, calculate bolus (i.e., meal doses) from an internal carbohydrates database, create reports from the collected data and transfer data (e.g., reports or records) to other devices (i.e., PCs or smart phones) [8]. One notable example, which shows the extendibility of pumps technologies, is the utilization of wireless technologies within pump devices. Some pumps now are embedded with wireless modules to make them tubeless and packed as one complete unit—contains the pump, cannula and medication. Once they are placed on the skin, they can be operated wirelessly through an external remote. The advantage here is that the skin is prevented from the exposure to the outer environment, and at the same time, it does not hinder daily activities and movements [9]. The researches on enhancing the operation of insulin pumps are still going on till today, and the latest trend is focusing on creating what is called a closed-loop artificial pancreas (i.e., a fully automated system for insulin dosing) [10].

The notable downside about pumps is that they require much dedication and training to master their operation, while on the other hand, insulin pens are still considered simple and easy to master. In addition to that, insulin pens do not require on-body attachment—taken when they are just needed, while pumps in contrast require constant on-body attachment, which is considered bothersome for some patients.

We can consider the German *Pendiq*® insulin pen model as the first attempt in creating a solution between pumps and regular insulin pens. It borrowed some of the sophisticated features existing within pumps, such as precise scales and dose recording, and at the same time it kept the simplicity and convenient features of insulin pens.

Here, we can raise a question: "Is this type of in-between solution essential for diabetic management?" We conducted a couple of survey and qualitative analysis among individuals from the diabetic communities. The main aims were evaluating the importance of intelligent insulin pens within diabetic management, and then guiding these kinds of researches toward new approaches, which promote a better diabetic patients' compliance.

The paper is organized in the following manner: In Section 2, we present our research method and summary of results. In Section 3, we present a brief discussion and analysis based on the obtained results. The discussion highlights the status of current technologies and our vision for future solutions. Finally, in Section 4, we conclud this paper by summarizing its contents and outcomes, and then pointing to the limitation and future directions within this research.

II. ASSESSMENT AND QUALITATIVE STUDY AMONG DIABETIC PATIENTS

A. Research Method

We conducted qualitative surveys and interviews among individuals in diabetes communities either by sending them direct emails, or recruiting them through diabetes Internet groups. The total number of participants was **76 individuals**.

We surveyed only individuals who were under insulin therapy as part of their medication. We excluded all the cases that reported they were not using insulin during the time of study. We directed the questions to either the patients themselves or their caring persons; this also included practitioners, who were related to diabetic healthcare. The questions focused on the following information: patients' diabetic profile (i.e., age, gender, period of diagnoses, diabetes types, etc.); patients' diabetic management (i.e., types of insulin therapy, data tracking, data management, etc.); patients' diabetic daily condition (i.e., Hypoglycemia vs. Hyperglycemia). The last two parts from the study focused on surveying current technologies of smart insulin pens (i.e., best two functions features, expected improvement in their diabetic management or overall impression) and on surveying patients' views about future technologies (i.e., communication with smart devices and ubiquitous technologies).

B. Summary of Results

Patients' profile: The majority of our participants were from the middle age groups 45%, i.e., between the age of 20s and 40s, while young and teenage groups came in the second place 40%. The remaining groups were people in their 50s or above 15% (Figure 1). Female groups were about 61% and male groups were about 39%. The majority were from the Type1 groups 80%.

Patients' diabetic management: For insulin delivery, 67% of participants reported that they were using insulin pens (and syringes sometimes), while patients, who were using syringes only, were about 22%. Insulin pump users were about 15%. 58% of participants reported that they either frequently or sometimes were running into some mistakes with their insulin

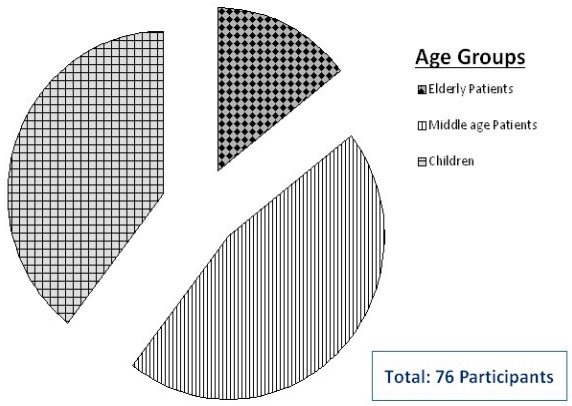

Figure 1. Total number of participants & age groups

medication (i.e., missing doses, double doses, inaccurate dosage, etc.). For diabetic daily management, 66% of participants were keeping tracks of glucose level data, 26% of participants were keeping tracks of nutrition data and 53% of participants were keeping tracks of insulin doses. 42% of participants reported that they were preferring paper format (i.e., physical dairies) for keeping their records, while 34% of them were preferring digital format. Only 21% of participants reported that they preferred both (digital and paper) formats at the same time. The remaining 3% of participants indicated another preferences other than the two methods, such as the usage of voice memo or self-memory. We surveyed about smart devices utilization for diabetic management as well; we found out that most of the participants were regularly using smart devices 79%, but only few were using them for diabetic management 29%.

Patients' diabetic daily condition: As per diabetic daily conditions, 79% of participants reported that they either frequently or sometimes were encountering episodes of Hypoglycemia, while 84% of participants reported that either sometimes or frequently were encountering episodes of Hyperglycemia. The noted reasons for encountering Hypoglycemia were due to: 50% insufficient amount of carbohydrates in meal, 29% excessive activities, 20% over medication or mistakes and only 1% indicated other reasons (i.e., not from the specified list), such as illness, high insulin sensitivity or oversleeping. On the other hand, the noted reasons for Hyperglycemia were due to: 58% extra amount of carbohydrates in meal, 21% lack of activities, 12% insufficient amount of insulin or mistakes and and 9% indicated other personal reasons (i.e., not from the specified list), such as stress, illness or poor control.

Patients' views about intelligent insulin pens technologies: We presented the patients with latest technologies of intelligent smart pens through demonstration. visual aids and few usability studies. We found out that the majority of the patients 79% never heard of or used smart insulin pens before this survey. After that, we highlighted the current features available within current models through a list, and then we asked the participants to pick the most preferable features considered essential for the diabetic management. The highlighted features were (ranked by the highest collected scores from patients' sides):

1) *Memory feature (i.e., keeping records of doses, date and time).*
2) *Alarming system (blockage, dripping and low battery)*
3) *Transferring data to PC through diabetic management software.*
4) *Precise scale (i.e., 0.1 unit scale).*
5) *The ability to switch between manual and digital mode in case of emergency (e.g., in case of battery outage).*
6) *Pre-saving time period and amount for doses (i.e., automatic repeatable dosing process).*

As one can see in the list, the memory feature was ranked as the most useful feature within current technologies. Following that, we questioned the patients about the expected improvements after using this type of technology. The majority

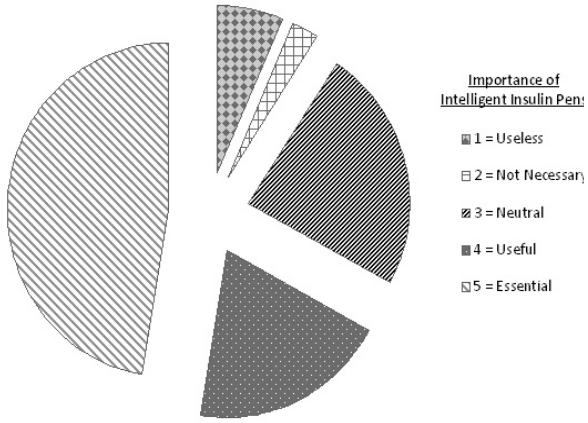

Figure 2. Importance of intelligent insulin pens

of the participants were expecting to encounter less Hypoglycemia and Hyperglycemia episodes. Easier management and data collection came in the second place. precise dosing capability for each meal and then encountering fewer mistakes came as the last two expected improvements in the rank.

We asked the patients what types of hindrances would prevent them from obtaining this type of technology. The top hindrance went to the high cost. Availability within the local market came as the second one. Complexity and then compatibility with insulin brands came as the least two reasons.

Finally, we asked the patients to rate the importance of intelligent pens for diabetic management. Overall, 67% of participants thought that smart insulin pens were either essential or useful for diabetic management, while only 9% thought they were not necessary or useless for diabetic management. The rest 24% were neutral about them (Figure 2).

Patients' views about future technologies: In the last section, imagining that intelligent insulin pens could have the ability to communicate with smart devices through various methods, and they could manage to provide the following functions (Figure 3):

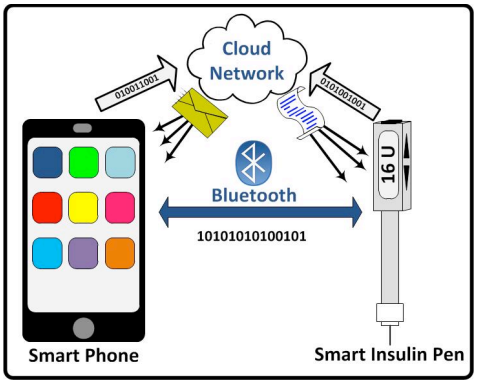

Figure 3. Connectivity with smart devices through different methods

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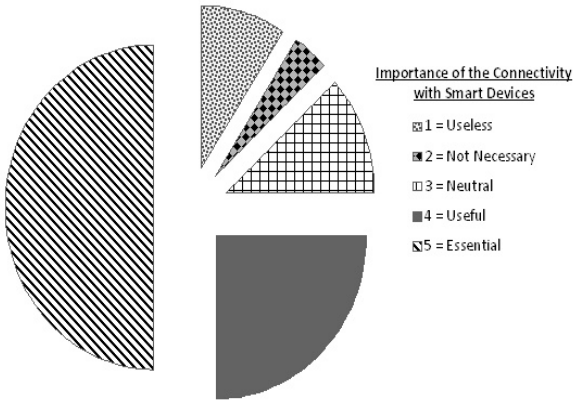

Figure 4. Importance of the connectivity with smart devices

1) *Automated reminders and confirmation for doses*
2) *Automated data collection and synch with software managers*
3) *Warning and error detectors while dosing*
4) *Remote controlling through smart devices*

We asked our participants once again how they would evaluate the importance of using smart devices under this vision. 75% of the participants rated this type of communication as either essential or useful, while only 13% the participants considered this as either not necessary or useless. The rest 12% were neutral to the idea (Figure 4).

We also asked the participants which feature from the above could be considered essential for their managament. The automated reminder and collection features were ranked as the first and second respectively, while the warning and remote controlling features were ranked the third and fourth respectively.

III. DISCUSSION AND ANALYSIS

A. Opinions about Current Technology

In general, although the collected data showed that most of the participants had little knowledge about intelligent insulin pens, but the idea of using them, as a part of the diabetic management routine, was still welcomed among them. However, it is difficult to infer the absolute popularity of the insulin pens, as compared with the pumping equipments, from this current survey of patient feedback.

First, let us observe the current features in the latest intelligent insulin pens models, the memory function was ranked as the most useful feature, at the same time, over half of the participants 58% reported about having mistakes with their doses. This could explain why this feature was considered significant and ranked higher than the other features. Nevertheless, the remaining percentage, for those who reported no mistakes, is quite large too. Also, if we go and look back at the results related to the causes leading to Hypoglycemia and Hyperglycemia episodes among participants, it was found that dosage mistakes were marked third in place among the other causes for both cases. This can imply that the memory feature could be essential only for certain group (i.e., for those who are having serious issues with their own memory), but for the rest, it could be a convenient feature to raise the assurance factor [11]. Similarly, for the precise scale (0.1 U), this feature is critical for those who are having high insulin sensitivity, children as an example [12], but not necessarily it is the same case for other patients. Precise scale feature was ranked as the fourth in place; probably, this feature did not get a higher rank because the majority of participants were from the middle age group (i.e., insulin sensitivity is not critical among this group). Data transfer is similar to the previous two; it only eases the process for those who would like to keep records about their doses. In our data, this was only less than half of the participants, which explains why this feature did not get a higher rank. The other features mainly ease the dosing process, but they do not necessarily help promote a better adherence to the insulin medication itself, for example, unlike the same feature available in latest pumps, patients cannot keep tracks of the current level of insulin while using intelligent insulin pens.

We can conclude here that the current technology of intelligent insulin pens can be a convenient instrument, but not an essential solution for the general type of patients, who are under insulin therapy. This means that they can offer useful features, but they might not guarantee a better management for insulin therapy. In contrast, if we go back and look at the pumps features in the previous section regarding the comparison between MDI and pump technologies, many of the pumps features promote a better management process, which, as a result, leads to a better adherence to insulin medication. Achieving a high level of insulin adherence can help achieve a tight glycemic control as well. (i.e., few episodes of Hypoglycemia\Hyperglycemia). If we return to the results section, and then observe the results related the expected improvements after using intelligent pens, we will find most of the participants were concerned about the encounter of Hypoglycemia and Hyperglycemia episodes. This is actually a common issue among diabetic patients. Generally, we will find many concerned patients, who are looking for convenient ways that would help them minimize the fluctuation in their glucose readings.

B. Next Steps in Technology Development

Dr. John Walsh gave an interesting design for intelligent insulin pens in his own website [13]. If we want to follow the same suggested model by adding some high-tech features, such as carbohydrate calculator or insulin level tracker, there is a high risk that this would cause a negative impact on the unit cost and simplicity of use.

Cost was ranked as the highest hindrance within our collected data. If we compare the unit price of the intelligent insulin pens and average price of regular insulin pens, you will find a noticeable difference between the two. Nevertheless, high cost does not necessarily imply a product failure. For example, pumps have always been known for their high costs—even under insurance coverage, but many patients still favor pumps over MDI for their performance and remarkable outcomes [14]. So, this implies that patients are willing to pass on costs as long as they can achieve a better level with their glycemic control.

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Simplicity was always a wining factor in insulin pens, and at the same time, it could be the main reason for their slow movements within the technological development [15]. When we did a comparison between the intelligent insulin pens and regular insulin pens, it was obvious that the intelligent insulin pens way of use was slightly more complicated than the usual ways, but it was not as complicated as pumps , which require longer training to master. The point here is that when you add more functions to a certain device, you will need to add more controls to it, and the more controls you would have, the more complex it would become [16].

An alternative approach to the previous solution is to focus on the communication with smart devices and ubiquitous technologies. Smart devices today (e.g., *Apple*®'s *iPhone* and *iPad* or *Android* based devices) are remarked for their simplicity of use—even among non-technical users [17][18]; moreover, they have a powerful processing capability with a multiple way of communication (e.g., WiFi, Bluetooth and cloud computing). In the next sections, we will go through some details regarding this point; this will be followed by a suggested example to support our argument.

C. Smart Devices and Diabetes

Current smart devices have high connectivity and processing capabilities. They offer different types of functions, and allow achieving multiple kinds of tasks instantly (i.e., phoning, gaming, music players, photographing, Internet surfing, etc.). As a result, people have become more attached to them more than before. Nowadays, smart devices connectivity is being utilized to create smart systems with unique features. For example, Google created their own Smart Glasses system by utilizing the connectivity between smart phones and wearable computing [19].

Within diabetic management, there are multiple types of applications available within smart phones, which have been created to help patients to manage their diabetic daily routines; however, if you would go back and look at the summary of our results, you would find that 79% of the participants were using smart devices, but only few of them 29% were using them for diabetic management. In one of our study, after conducting a couple of reviews to these applications, we found that the most notable reason, for that low usage, was they were actually adding extra workload rather than saving. Most of these applications lack intuitive features and require a lot of dedication from the patients' side; for example, some of these applications require patients to enter their daily information manually each time; they lack the automated entry capability. The task for managing diabetes by itself is exhausting and require so much dedication; so if the tools are not going to be intuitive and smart enough, they are just going to be bothersome rather than helpful.

In the result section, you remember that the participants gave generally a positive rating to the communication of smart devices with intelligent insulin pens. This was under the conditions that smart devices could provide a couple of useful functions for diabetic management. If the patients could not sense a benefit from this type of communication, they would simply be neutral or negative about this idea. So we can conclude that unless smart devices would provide practical functions that would help effectively with diabetic management, they are just going to remain an optional tool for diabetic management.

D. Connectivity of Smart Devices and Intelligent Insulin Pens

A US company, called *Telcare Inc.* [20], released a cellular based glucometer, named by the same name as the company (*Telcare BGM*). As soon as the patient makes a blood glucose test, it will automatically send the record to all the registered devices through the cloud server. The good part here is that rather than downloading the data from the glucometer into the personal devices each time, all the data can be automatically available for the patient anytime in any of the patient's personal device.

Imagine that same above feature can be applied within intelligent insulin pens. So as soon as the patient would take the required dose, the intelligent pen will send that record automatically into the cloud server, and then from the cloud server into the diabetic manager software installed in the patient's devices. This will ease the process for creating the daily diabetic trend (i.e., glucose level data associated with other information), which is considered valuable information for diabetic management. As we have mentioned before, the use of diabetes management apps might not be that beneficial for all patients, but with technologies like the cloud, the process of entering patient's daily data can be totally automated, and as a result, it will save the time and efforts.

There are several types of communications today, which allow a direct communication between different types of devices (e.g., Bluetooth, ZigBee, WiFi, etc.), but the current trend and most promising one is the communication through cloud technology. Although a lot of sectors (e.g., communication, gaming, e-commerce, etc.) are already utilizing the cloud computing technology effectively today, the healthcare sector is still a little bit slow in adapting this technology [21]. The reasons might go back to the differences between regulations in handling healthcare data globally [22], or the risks associated with the multiple threats surrounding the cloud technology [23]. Nevertheless, we cannot ignore how useful the cloud computing have become in handling our daily data; there is actually a huge grow in the size of usage because of that. Healthcare can also benefit from the cloud technology either through the cost reduction, better health service at home or continues processing of medical data [24]. The good news is that experts are aware of this potential and they are trying multiple ways to overcome the sensitivity within the healthcare data.

We are suggesting here some applications, as an example, which can utilize the cloud technologies and smart devices to encourage a better diabetic routines:

The suggested system (Figure 5) is similar to the current iOS "Reminders" cloud-based system; in the *Apple*®'s "Reminders" app, as soon as the user would set a reminder, it will be activated in all the devices associated with the user's iCloud account. The user can deactivate (i.e., check the reminder) from any device available in hands at that moment. Imagine that we can apply the same concept for doses

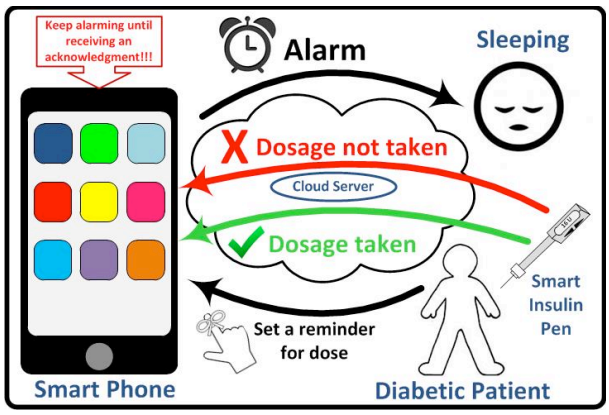

Figure 5. A cloud-based doses reminder system for MDI therapy

reminder; however, rather than letting the patients deactivate the reminder alarm manually, the device should check the collected records and verify if the patient has taken the required dose or not. If the device could not find the required record, it would keep snoozing until it would make sure that the patient has taken the required dose. This system can be useful for the daily basal type of doses (i.e., background insulin dose such Glargine or Detemir). This type of doses requires to be taken within a fixed period of time (within 12 or 24 hours) in order to assure a better glycemic control [25]. Applying this type of systems can encourage the patient to follow a better adherence to the medication. Remember in our collected data, patients ranked the reminder system and automated collection of dose records as the most desirable features within the communication between intelligent insulin pens and smart devices.

Diabetic technology has probably advanced a lot in the last recent years, but diabetic researchers might need to expand their vision by utilizing technologies, such as cloud computing and smart systems, and offer more smart ways to manage the diabetes milieus.

IV. Conclusion and Future Work

Since their early days, insulin pens have been known for their simplicity and accuracy among MDI therapy adopters. Nevertheless, insulin pens were too slow in catching up with their counterpart, the pumping therapy, which have been known for their continues enhancements all the way long. Intelligent insulin pens models have recently been introduced to the market—as a new attempt to raise insulin pens technology to the next level. In order to evaluate the necessity of this technology, we conducted a couple of case studies among a group of insulin dependent patients. The case studies involved a couple of questions related to diabetes mellitus management itself among this group, and the evaluation of current and future vision about intelligent insulin pens. We thought that the current technologies could be an optional instrument for general patients, and only essential for those who have serious issue with their active memory, or for those who have high insulin sensitivity. We concluded that future enhancement of intelligent insulin pens should target general patients and focus on easing the diabetic management activities—for example, adding features like carbohydrate calculators or insulin level trackers; however, we have some concerns regarding this point, we think that enhancing the technology within pens themselves might cause a negative impact on the final product—elevation of unit price and complexity of use. We suggest an alternative approach that focuses on the utilization of current ubiquitous technologies, such as smart devices and cloud computing. Smart devices today are featured with high utilities and processing power. Cloud technology as well has grown effectively in the recent years. In our particular case—the diabetes milieus—we believe that these types of technologies can be utilized to provide many useful applications for diabetic management, which could help saving a lot of workload associated with diabetic management routines.

Finally, we want to point that our conducted study was too limited. First, the sample size was a small number. Results from small sample size are not representative. So if we want to have an absolute opinion about replacing regular pens with intelligent insulin pens, we need to collect a larger sample size, which can be enough for conducting a statistical analysis. Second, the collected data were mostly from online communities. This means that the data will exclude patients who have limited technological background, or who have limited access to the wide world network. A Future move can focus on recruiting people through medical centers and clinics, and let them doing the surveys during their regular visits. Lastly, the participants' feedback was based on demonstration, visual aids and few usability studies. This type of feedback cannot uncover all the pros and cons related to the usage of intelligent insulin pens. More longer and deeper usability studies are needed in order to provide a full picture about the effectiveness of of intelligent insulin pens for insulin therapy.

Future studies should also focus on the importance of using technologies, such as smart devices, within diabetic management, and how to make them more accessible for most patients. Also, in order to support the argument concerning the communication of intelligent insulin pens with smart devices, we suggest creating prototypes that utilize latest technologies, such as cloud computing, and test their usability among diabetic patients. We hope that these findings would provide a positive contribution toward simplifying the complexity of diabetic management.

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High Tech for Sports Medicine

Supporting employees improving their health and fitness

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***Abstract*—This work in progress paper describes the development of a eHealth system for sports physicians who support employees in improving their health and fitness. Regular physical activity improves quality of life and has various health benefits. Companies have an interest in the health and fitness of employees. Besides, sporting together can improve interaction between employees of different departments. For employers it is important to encourage this in a safe way. To this end, the sports physicians of Isala Hospital in Zwolle, The Netherlands, offer sports medical examination and guidance programs to companies. The sports physicians want to use smartphone technology to improve and expand their services. To that end, an online data tracking system will be developed that makes it possible to: give employees access to their medical examinations results with personalized standard values; insert goals and training schedules by participant, trainer or sports physician; couple sensors and apps for data entry by participants themselves; compare one's results with those of (company) peers; automatically provide feedback to individual participants; support contact between participants and sports physician or trainer; produce management reports and perform scientific analyses. Since details of the end product are not clear yet, the incremental and iterative development method Scrum will be used to develop the system. We will further 'feed' the project with an elaborated state of the art study, small pilot studies and an expanded evaluation study. A first version of the central database and app has already been developed.**

Keywords-sports medicine; guidance; employees; training; medical examination.

I. INTRODUCTION

This work in progress paper describes the foundation and development of a eHealth system for sports physicians who support employees of companies in improving their health and fitness.

Sports Medicine is the medical specialty that focuses on promoting, safeguarding and restoring the health of people who (want to) sport or exercise. It also aims to promote and restore the health of people with chronic conditions through sports or exercise. For both facets, the balance between specific physical load and capacity are explicitly taken into account [1].

Regular physical activity improves quality of life and has various health benefits [2][3]. However, about 40% of the Dutch population does not meet the Dutch Standard for Healthy Exercise for their age group [4]. This standard focuses on maintaining health in the long term.

Companies have an interest in the health and fitness of employees as this may have an effect on sickness absenteeism and productivity. This is especially relevant nowadays because of the ageing of the working population. Besides, the increase of screen work contributes to non-compliance with the guidelines for sufficient exercise. Employers may want to actively maintain or even improve their employees' health and fitness. A company could present itself as a good employer to offer its employees counseling by sports physicians as part of occupational health care and fringe benefits.

The sports medicine department of Isala in Zwolle, The Netherlands, performs sports medical examinations and guidance for groups of employees of external companies with the aim of encouraging movement and improving the health of the workers. Participants are periodically examined and supervised regarding their training and health during a year. With the aid of the physician, each participant determines his own goal. To this end, employers can choose specific sporting events in which their employees can participate at the end of the year, such as a half marathon or bike ride. Participants receive an individual report with advice and the companies receive a general management report.

Until recently, only data of the sports medical examinations were locally stored in individual files per participant. This had several major drawbacks: a) participants could not see their own data, b) training activities of participants were not included, c) health parameters of the participants could not be followed during the training period, d) it was not clear whether the individual goals were met, and e) it was not possible to analyze data about groups and set up management reports.

The method of data storage of medical examinations and the way of guiding participants needed renewal. The sports physicians wanted to use smartphone technology to improve and expand their services. They wanted more insight in the progress of health and fitness status of the participants, and to provide the participants themselves with meaningful and motivational information. To that end, we looked for an online data tracking system with the following features:

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1. Central, secure and adequate data storage;
2. User-friendly and reliable data entry by the sports medicine staff;
3. Various authorizations for different types of users;
4. Insert goals and training schedules by participant, trainer or sports physician;
5. Coupling of sensors and apps for data entry by participants themselves;
6. Give participants meaningful insight in their own sports medical examination results and progress in training and health parameters, e.g., compared to personalized standard values or goals, and/or results of their (company) peers.
7. Automatic feedback to individual participants via an app to stimulate or warn;
8. Support contact between participants and sports physician or trainer;
9. Automated standard analyzes and reports;
10. Basis for scientific sports medical research.

The sport physicians searched by asking colleagues and on the internet for systems that met these requirements. A system that fully supported the sports physicians' guidance model was not found.

Therefore, the sports physicians contacted the research group ICT-innovations in Health Care of Windesheim University of Applied Sciences, Zwolle, The Netherlands. Together they started a project of which the primary objective was to build a system that met all the requirements of the sports physicians and made use of new technology in the field of monitoring and communication of sports and health parameters, such as web services, database servers, sensors, apps and smartphone technology. The secondary objective was to make students of information sciences acquainted with, and train them for a position in the field of medical informatics. Furthermore, we wanted to encourage knowledge exchange between the hospital and the university of applied sciences and to stimulate the development and use of technology for the benefit of health and healthcare. The project was named Hightech4SportsMedicine.

In Section 2, we will present the approach that we have chosen in order to develop the system. In Section 3, we show the first, preliminary results and in Section 4, we discuss the work that has to be done in the future.

II. APPROACH

A. State of theArt study

We initially performed a short literature study on systems that were available for sports physicians and athletes to share their training progress, training experiences and health parameters to support medical guidance. Later we will conduct a more comprehensive, systematic inventory through literature review and desk research. The findings provide further input for the system to build.

B. Students, integration with education

We deploy ICT students to develop the system. In this way we give the students the opportunity to develop skills in the field of medical informatics. The school of Information Sciences and the research group ICT-Innovations in Health Care have expressed the intention to give three to four students the opportunity to participate in the project in the context of the minor App Development. Different groups of students will be provided this opportunity during four consecutive semesters. The school will provide additional and customized education and guidance, and contribute to the continuity of the project. Three ICT students have, as part of an internship, developed a first basic version of the central database for a data-tracking system. Three other students now further develop the system and work on an app and sensors for the employees. For next semesters we will recruit new students.

C. Agile / Scrum

Many things in this project are still unclear. Research to investigate the needs, desires and possibilities forms a major part of this project. Therefore, an ease of communication and social integration with the stakeholders and end users are heavily desirable. Besides, working iteratively and incrementally makes it possible to quickly obtain the advantage of new insights because the planning and the priorities can be easily adjusted once new information becomes available. Also, good control and coordination mechanisms are important for delivering usable increments. Scrum provides us with the needed instruments to clarify the needs and manage the project [5]. It also provides defined meetings and activities and gives structure and clarity for the team and stakeholders.

The role of the students regarding the important elements of Scrum are:

1) Product backlog

The product backlog is basically a prioritized list of features that the customer wants, described using the customer's terminology. The ICT students of each semester together with the product owner (a sports physician) are responsible for setting up the product backlog document and managing it.

2) Sprint planning

A scrum sprint is a confined to a regular, repeatable work cycle. Sprint planning is a critical meeting. The functionality to be delivered in the sprint is planned at this meeting. The ICT students plan this meeting and invite the product owner to attend the meeting. They discuss the product backlog and decide which functionality is to be delivered in the next sprint, taking the following factors into consideration:

- The sprint length;
- The available capacity and resources;
- The priority and importance of the functionality;
- The scope of the functionality;
- The time estimate for the functionality.

The meeting results in a sprint backlog document. The ICT students ensure that all the privies are provided with a copy of the sprint backlog document.

3) Sprint

The sprint is the heart of Scrum. Within the sprint the needed functionality is implemented, tested, integrated and accepted. To make the feedback cycles short and effective

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enough, the sprint is limited to two weeks. The ICT students start the sprint with making an appropriate design. The design should fit the overall architecture of the software. The ICT students distribute the functionality to be implemented among them. Regardless who is implementing the functionality, all the ICT students are responsible for the performed work. Working in this way should enhance the team spirit and ensure the distribution of knowledge. The sprint is closed with a sprint review. In the sprint review the ICT students demonstrate the work done within the sprint and get the performed work accepted by the stakeholders. The functionality that has not been accepted by the stakeholders or finished by the ICT students will be put back in the product backlog. For a delivered functionality to be accepted, it should satisfy a set of rules that has been defined by the ICT students and the product owner. This set of rules is called a Definition of Done. After the sprint review, the ICT students plan the next sprint planning meeting to start the scrum cycle again.

D. Evaluation study.

If parts of the system have been developed that can be tested on end users, we will set up pilot projects with the aim to evaluate the system. We will first evaluate the performance and usability of the system, and the information value for participants and sports physicians. The aim is primarily to improve the system. After the pilots, we want to evaluate the value of the system in terms of routine use of the system, satisfaction of end users, compliance to training programs and effectiveness of medical support in terms of health, fitness and goal achievement.

Once the database is filled with sufficient data, we hope to scientifically evaluate the effectiveness of several sport medical advices and do subgroup analyses.

III. PRELIMINARY RESULTS

A. Preliminary State of the Art

There are information systems that support sports physicians in recording patient data and are thus in fact electronic patient records (EPRs). However, these EPRs do not usually give patients access to their data. Besides, there are no specific EPRs for sports medicine. Additionally, there are apps that support the physician or athlete in the diagnosis and treatment of a specific sports injury. Examples are the “Medical iRehab AnkleSprain” [6] and the “Medical iRehab Tennis Elbow" [7]. Furthermore, there are countless apps for athletes focusing on the monitoring of training and health parameters, whether or not equipped with training schedules and advice. We found, however, no systems specifically aimed at sports medical examination, advice and guidance where the main objective is to assist employees in safe sports practice and promoting health and fitness. Moreover, the systems found showed no alignment of data collection by the athletes and the information needs of the sports physicians, no fitting with the care processes of the physicians and no provision of an own, secure and insightful database for management reports and scientific analysis.

B. The proposed architecture

The proposed architecture of the system consists of several elements, see Figure 1. These include:

1) Central database

A centralized database where monitoring data and health measurements will be saved. No personal data will be saved that can be directly or indirectly linked to physical persons. The database will also give the possibility for retrieving data for management reports as well as scientific analysis.

2) Web Services

For achieving data quality and data security, secure web services are built. They are a set of functionality, which is used for data entry and data retrieval. It forms the only entry point to the central database.

3) User applications

In this context the term user applications refers to the applications that could be used by the end users for data entry and data retrieval, and for communication between participants and sports physicians. A web site is built for this goal and a native mobile application is being implemented.

4) Sensors

The ICT students will investigate the possibility to integrate sensors. The sensors will also be used for data entry. The sensors will be placed on the body of the employee and send measured data to the mobile application installed on the mobile device of the patient. The way the sensors will be coupled with the mobile application is still unclear. The ICT students are investigating the following options:

- The coupling through ANT+ [8];
- The coupling through Bluetooth Low Energy (Bluetooth LE) [9].

C. Central database, data quality

A first basic version of the central database for a data-tracking system, called the "Isala Sport Monitor", has been developed. The sports physicians currently use this version of the system. At this time, the results of the periodical sport medical examinations can be recorded in a simple manner.

Data quality is achieved by working with value limits for data entry, automatic alerts when capturing improbable values and automatic calculation of values from other values, e.g., BMI from length and weight, and body fat percentage from multiple skinfold measurements.

D. Sports Medicine App with sensor

A first, but not yet complete version of the app has been developed for the iPhone. This version allows participants to see their sports medical test results, like peak expiratory flow, cholesterol level, fat percentage, orthopedic tests, maximum heart rate, ECG, etc. Personified, age and sex dependent standard values, will be added soon. Further, trainings data like type of sports, duration, distance, speed, route, heart rate zones and energy consumption have been implemented. The app works with a heart rate sensor.

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IV. CONCLUSION AND FUTURE WORK

No information system can be found on the market that supports the sports medical guidance model of the sports physicians of Isala in all its facets. Therefore, we started an innovative project in which a system is built using new technologies. The innovation mainly concerns the integration of the use of apps, sensors, web services, smartphone technology and a database server with a feedback function to participants, sports physicians and employers in one sports medical guidance program and not as separate parts. This makes it possible in the future to link advised training programs to actual training and health data in the course of time for large groups of participants who are employees and mostly recreational, non-performance-oriented athletes.

Since details of the end product are not clear yet, the incremental and iterative development method Scrum will be used to develop the system. We will further 'feed' the project with an elaborated state of the art study, small pilot studies and an expanded evaluation study.

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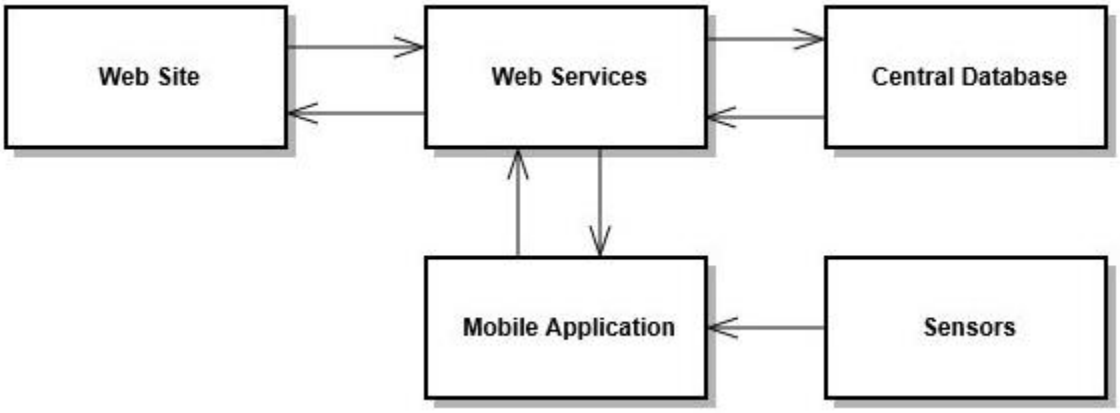

Figure 1. The architecture of the Isala Sport Monitor.

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A Proposal of Remote Rehabilitation System for Cerebrovascular Patients Combined with Video Call Center

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***Abstract*— Japan's low birthrate and rapidly aging population are causing medical expenses to take up ever more of the national budget. As the result, rehabilitation therapy is being shifted from hospital-care to home-care. We thus propose a remote rehabilitation system combined with a video call center to make up for the shortage of rehabilitation therapy done by visiting physiotherapists. In this paper, we focus on cerebrovascular patients and adopt MS-KINECT for home usage to measure strain of the upper body. Measuring tools and expression formats of measured data are also introduced.**

Keywords- rehabilitation; remote rehabilitation; motion capture; KINECT; video call center

I. INTRODUCTION

Japan's low birthrate and rapidly aging population are causing medical expenses to take up ever more of the national budget. To suppress this increase in medical expenses, medical treatments, including rehabilitation, are being shifted from hospital-care to home-care. The amount of rehabilitation therapy in a home done by a visiting physiotherapist is limited by law and is insufficient for patients to recover completely. We thus propose a remote rehabilitation system combined with a video call center to make up for the shortage of rehabilitation done by visiting physiotherapists.

Sixty-two percent of rehabilitation patients suffer from cerebrovascular diseases [1]. These diseases also have the longest rehabilitation term as shown in Figure 1 [1]. Therefore, we focus on cerebrovascular patients in the first part of our research.

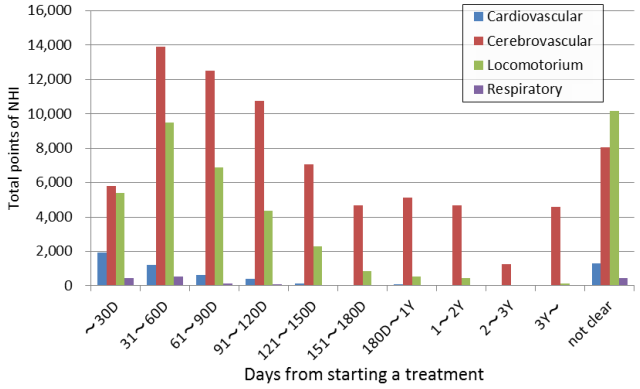

Figure 1. Total points of the national healthcare insurance (NHI) according to the duration of feeding period from treatment start date in Japan

In case of cerebrovascular disease, most patients have paralysis on one side of the body, and their bodies lean and twist to the paralysis side. Also, because of unusual muscle strain, their hands and feet become stiff. In some cases, muscles of the upper body go into convulsions.

In case of a hand or foot, a joint angle is easy to measure with a protractor. However, a joint angle of a body is very difficult to measure with a protractor, because the joint angle combines the lead and the twist. A motion monitoring system, Vicon [2], that uses multiple video cameras, has been introduced to big hospitals and rehabilitation centers. Unfortunately, it is too expensive for a small facility to introduce. As a matter of course, it is impossible to adopt for a remote rehabilitation system, because the remote rehabilitation system is used personally.

It is very difficult for patients to continue the self-rehabilitation at home, so our system has two features to help them continue:

- A patient can check data to see the effect of rehabilitation.
- A call center operator guides patients through the therapy and encourages them with images and conversation through the Internet.

We believe that patients should see practical data showing them getting better and hear a person's voice to improve their morale and to motivate them to continue rehabilitation.

After introducing related works in Section 2, we describe the concepts and features of the remote rehabilitation system in Section 3. Expression formats of the ante-flection, lean, and twist of the body are explained in Section 4. Measuring applications for the ante-flection, lean, and twist of the body are described in Section 5 and evaluated in Section 6. The key points are summarized in Section 7.

II. RELATED WORK

In this section, we introduce existing remote rehabilitaion systems, tools for measuring the strain of upper body, and MS-KINECT usage applications adopted in rehabilitation.

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A. Remote rehabilitaion systems

Traditionally, remote rehabilitation has been administered between a therapist and a patient through a video conference system or video phones, without using measuring and monitoring tools [3]. In accordance with evolution of remote monitoring tools, robotics and virtual reality technologies, they are combined with video conference system. Holden et al. applied virtual reality technologies to their telerehabilitation system [4]. Carignan reported rehabilitation system for which robotics was applied including remote rehabilitation [5]. Bradley et al. reported investigations of the design, control and implementation of a form of the intelligent exoskeleton, web-based strategies and robotics for remote rehabilitation [5]. In these researches, therapists directly guide or coach patients through their systems. Therefore, existing remote rehabilitation systems can shorten convey time for a visiting therapist. However, these systems are insufficient to make up for the shortage of therapists.

B. Measurement tools for the strain of upper body

Vicon is one of the most famous companies in the motion capture industry. They can measure complex motions of joints in a body [2]. Vicon's system needs plural specialized video cameras, and know-how is needed to measure motions of joints. Thus, this system is too expensive for a small rehabilitation center or an individual to purchase and operate. Akimoto et al. developed a measurement tool for scoliosis [7]. It uses MS-KINECT to measure undulations on a body. This tool can express measurement data with an image, a graph, and numerical data and store them. Jing Tong et al. developed new scanning technology that can fully scan the body and show VR images of it [8]. It uses three MS-KINECTs. However, they did not account for measuring the lean and twist of a body. Burba et al. applied MS-KINECT to measure breathing rates derived from motions of the chest, and the number of shakes of tapping the knee derived from motions of the knee [9].

C. Applications adopted MS-KINET to rehabilitation

Garrido et al. applied MS-KINECT rehabilitations for patients who have trouble with their sense of balance [10]. They express the lean of the body by an image of the balance scale and show arrows to correct a patient's posture.

There are also many video games for rehabilitation that use MS-KINECT [11], [12], [13].

III. CONCEPT OF REMOTE REHABILITATION SYSTEM

Our remote rehabilitation system is based on the following ideas:

- Practical data that shows the patients getting better will more effectively encourage them to continue rehabilitation than simply giving them vague information such as "you are a little better than yesterday".
- Hearing a person's voice is likely to cheer patients up.

Additionally, we plan to employee non-professionals as operators instead of physiotherapists to hold down operation costs.

We introduce roles of a physiotherapist and operator, and necessary functions to realize above concepts.

A. Roles of a physiotherapist and operator

Roles of a physiotherapist are as follows:

- Teaching operators how to guide patients through rehabilitation and supervising the operators.
- Deciding and changing therapy programs on the basis of diagnostics data and measured data.

Roles of an operator are as follows:

- Monitoring motions of a patient and measuring joint angles by the measuring tools.
- Coaching a patient in how to move his or her body using the administration tools and therapy contents on the basis of therapy programs.

B. Necessary functions

As shown in Figure 2, this system comprises following components:

- Administration tools: An operator uses these tools to guide patients.
- Measuring tools: An operator uses these tools to measure joint angles.
- Supervising tools: A physiotherapist uses these tools to coach operators. A physiotherapist can monitor how an operator is coaching patients and instruct him or her in therapy with these tools.
- Communication exchange application: This application connects a patient with an operator. This application works on a video conference server.
- Therapy contents: Presentation contents to explain how to train, or training content such as video games for rehabilitation.
- Patient database: Patient data which include profile data, measured data, therapy programs, and coaching video are stored and managed by this database. The access permission policy for this database has to be decided by the management organization of this system.

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The supervising tools and communication exchange application are newly added to introduce operators to the remote monitoring system. However, existing remote rehabilitation systems have also same roles for the other components. As a matter of course, practical functions of these components are different in each system.

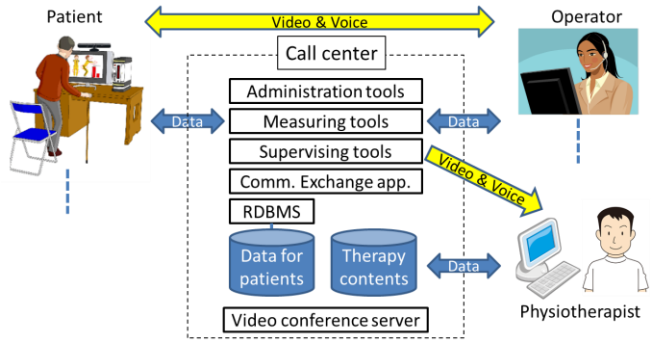


Figure 2. System concept of the remote rehabilitation

IV. EXPRESSION FORMATS

In this paper, strain of the upper body is shown from the ante-flexion, lean, and twists. We describe how to express the ante-flexion, lean, and twist in this section.

A. *Ante-flexion*

In the case of a skeleton model of the pre-packaged program in MS-KINECT, measuring points on the spine are the neck and the navel. However, these points are not sufficient to express the ante-flexion. Therefore, we add three measuring points between the neck and the navel as shown in Figure 3 and measure the depth of each point. We decided to express the ante-flexion as shown in Figure 4.

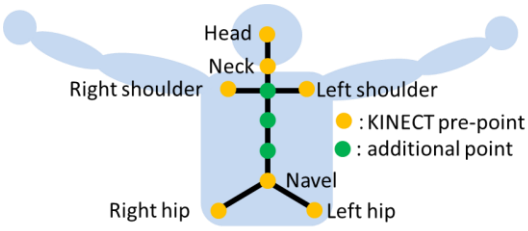


Figure 3. Skeleton model used in this research

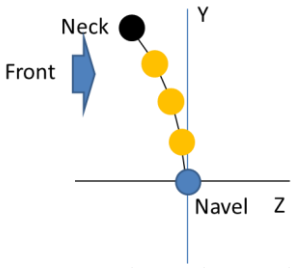
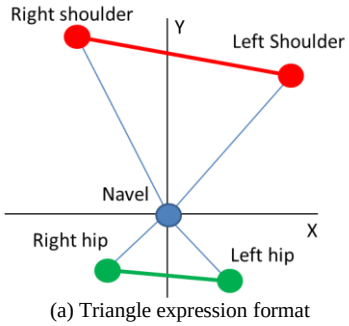


Figure 4. Expression format of the ante-flexion

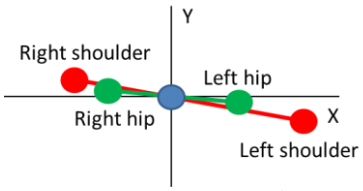
B. *Lean*

We express the lean of the upper body with both a line connecting the right shoulder and the left shoulder and a line connecting the right hip and the left hip from the front view. Two types of front view formats are considered to express the lean of the upper body. One is making a triangle between the right shoulder, left shoulder, and navel, and a triangle between the right hip, left hip, and navel as shown in Figure 5 (a). The other is that both a line connecting both shoulders and a line connecting both hips are plotted on the X-Y plane on which middle points of both lines are plotted on the origin as shown in Figure 5 (b).

We asked 30 people which expression more easily explained the lean of the upper body. Results of answers to this question are shown in Table 1. Most respondents chose the triangle expression format.



(a) Triangle expression format



(b) No triangle expression format

Figure 5. Expression format for the lean of upper body

C. *Twist of upper body*

We express the twist of the upper body with both a line connecting both shoulders and a line connecting both hips from the top view. Two types of top view formats are considered to express the twist of upper body. One is plotting positions of the head and navel in addition to the above mentioned two lines as shown in Figure 6 (a). The other is plotting just the above mentioned two lines on the X-Z plane in which middle points of both lines are plotted on the origin as shown in Figure 6 (b). We asked 30 people which expression more easily explained the twist of the upper body. Results of answers to this question are shown in Table 1. Most students chose the lines-only plotting format. On the other hand, 9 of 14 workers who responded chose the relative position consideration format. Every healthcare worker (3 people) said that positions of lines of the shoulders and the hips relative to the head were important to understand the twist. They all chose Figure 6 (a).

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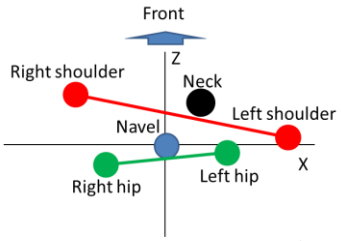
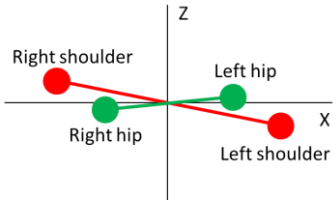


(a) Relative position consideration format



(b) Lines-only plotting format

Figure 6. Expression format for the twist of upper body

TABLE I. RESULTS OF QUESTIONNAIRE ABOUT WHICH EXPRESSION FORMATS ARE EASIER TO UNDERSTAND

		(a)	(b)
Lean	Students	15	1
	Workers	13	1
Twist	Students	0	16
	Workers	9	5

V. MEASURING TOOLS

We developed a tool for measuring the strain of the upper body that will be a component of our remote rehabilitation system. We use MS-KINECT, Kinect for Windows SDK 1.7, and WPF framework in this tool.

A. *Ante-flexion measuring application*

Depth of the neck, the navel, and three points that divide the neck and the navel into four equal parts are measured in this application. The number of measuring points can be increased. An example picture of the display is shown in Figure 7. A video image is shown for a call center operator to easily guide a patient on the upper-right portion of a display. Measured data include error caused by the curve of body and clothes. Therefore we recommend measuring not the front view but the back view as shown in Figure 8.

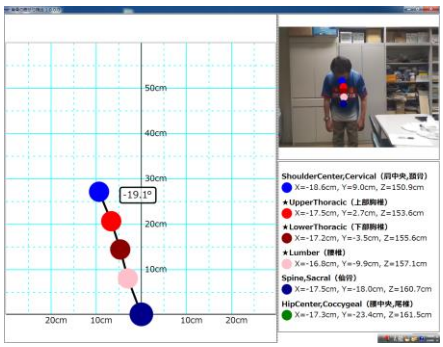


Figure 7. Example of front view measuring the ante-flection

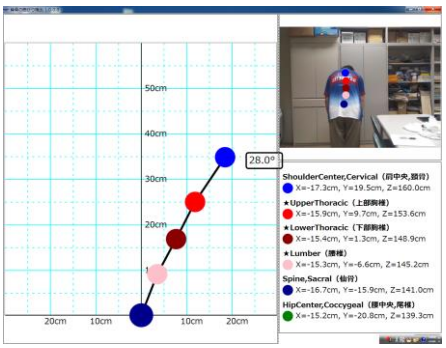


Figure 8. Example of back view measuring the ante-flection

B. *Lean measuring application*

Since most respondents chose the triangle expression format as shown in Table 1, we adopted it. We showed numerical angles between the X axis and the line connecting both shoulders and between the X axis and the line connecting both hips to make practical data easy to understand as shown in Figure 9.

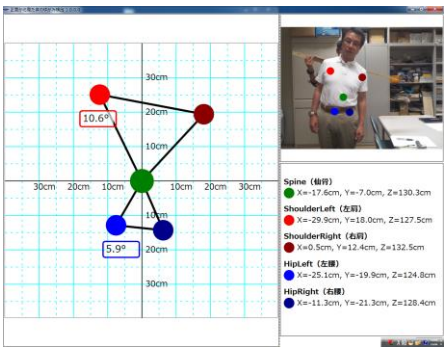
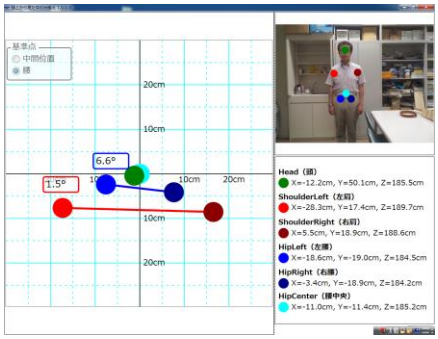


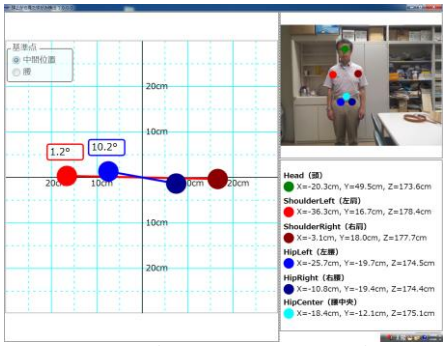
Figure 9. Example of measuring the lean

C. *Twist measuring application*

Since 30% of healthcare workers chose the relative position consideration format and 70% of them chose the lines-only plotting format in Table 1, we designed both of them. We showed numerical angles between the X axis and the line connecting both shoulders and between the X axis and the line connecting both hips to make practical data easy to understand, the same as the lean. Example screenshots are shown in Figure 10.



(a) Example of the relative position consideration format



(b) Example of the lines-only plotting format

Figure 10. Example of measuring the twist

VI. EVALUATION OF MEASURED DATA

Since the depth value in MS-KINCT is the shortest distance between the X-Y plane on the depth measuring camera and a measuring point, a tape measure or an acoustic measure is not useful. Hence, we evaluated the angle of the ante-flection, lean, and twist by comparing between values measured by MS-KINECT and by a big protractor (see Figure 11). We fixed a string to a protractor that had a weight at one side for indicating it was the perpendicular to the earth.

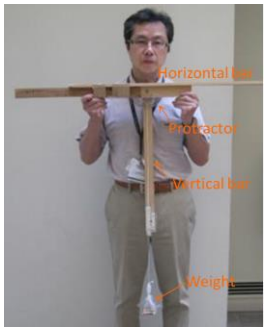


Figure 11. Protractor used in this research

A. *Ante-flexion*

The horizontal bar of the protractor is set on the floor. A rectangular board is fastened to the vertical bar; and an upper body is placed along with the rectangular board to remove influence derived from the curve of the body as shown in Figure 12.

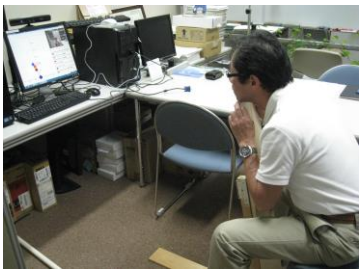


Figure 12. Measuring image of the ante-flection

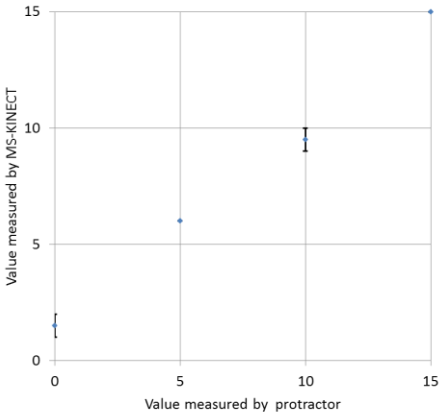


Figure 13. Measured data of the ante-flection

We varied the angle between the horizontal bar and the vertical bar from 0 to 15 degrees. Data measured by the ante-flexion measuring application corresponding to an angle of a protractor is shown in Figure 13. We measured 20 samples. Average and standard deviation data are plotted on the graph. Errors are a few degrees, which would be small enough for practical use.

B. *Lean*

The angle between the X-axis and the line connecting both shoulders was varied from -20, -10, 0, +10, +20 degrees instead of the lean angle. These values were measured by the protractor fitted on both shoulders from the back. We measured the lean of the body by the lean measuring application, and measured data is shown in Figure 14. There are no errors.

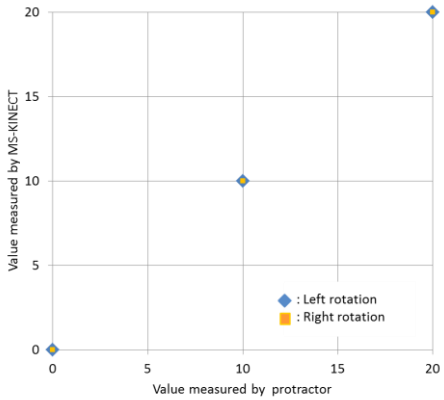


Figure 14. Measured data of an angle between X-axis and a line connecting both shoulders

C. *Twist*

We measured the angle between the X-axis and a line connecting both shoulders from the top view. The horizontal bar of the protractor is fastened to both shoulders, and the vertical bar points to the MS-KINECT to remove the influence derived from the curve of the body as shown in Figure 15. We also measured the line of hips the same as the line of shoulders. Measured data is shown in Figure 16.

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Errors for the right rotation in both the shoulders and the hips are very small. However, errors for the left rotation are a few degrees. We are not sure of the reason for this difference.

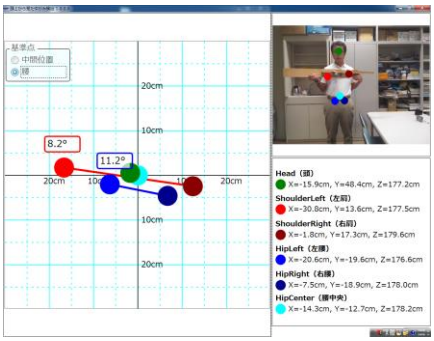
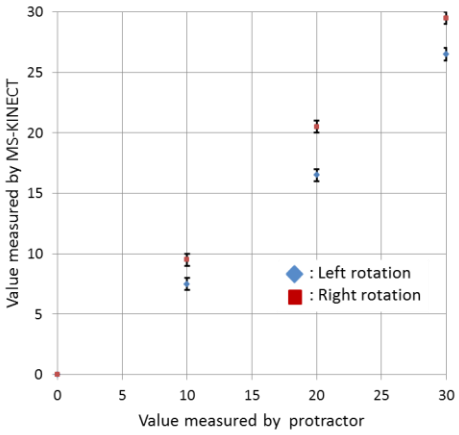
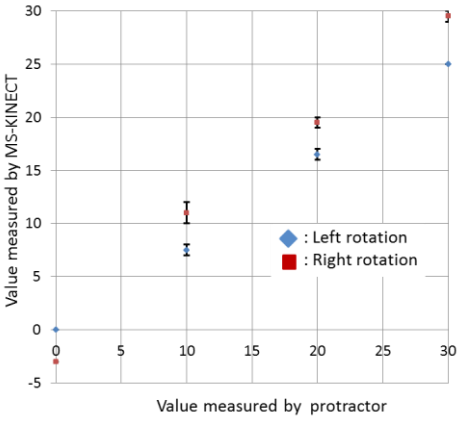


Figure 15. Measuring image of the twist



(a) Measured data for the shoulders



(b) Measured data for the hips

Figure 16. Measured data of the twist

VII. CONCLUSION

We proposed a remote rehabilitation system combined with a video call center to make up for the shortage of rehabilitation therapy done by visiting physiotherapists. We focused on cerebrovascular patients and adopted MS-KINECT for home usage to measure the strain of the upper body. We also proposed to express strain of the upper body by dividing the ante-flexion, lean, and twist and developed an application for measuring them. In the results of evaluating these measuring applications, their measurement errors are sufficiently small.

We are still in process of completing the remote rehabilitation system. The concept that is employing non-professionals as operators instead of physiotherapists to hold down medical expenses is novel. This concept probably would suppress increment of medical expense; and affect institutions of the national healthcare insurance. New business schemes thus have to be created in addition to developing the system to introduce as a service.

ACKNOWLEDGEMENTS

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CyMED: a Plateform for Supporting Collaboration and Coordination of Home Care Teams using a Process Oriented Approach

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***Abstract* — Recently, more and more patients are treated in their homes by multiple health and social care actors, from different organizations, public or private, characterized by their mobility and their schedule variability. In this paper, we investigate the difficulties inherent in home care collaboration related to communication, process orchestration and planning. To handle these kinds of difficulties, we present our coordination platform called Cyber Management of Elderly and the Disabled (CyMED), whose ambition is to use a mix of cooperation and process oriented tools, in order to facilitate the cooperative work of health and social care actors. With this approach, we aim to highlight the importance of organizational aspects in the context of homecare.**

Keywords-HomeCare; Coordination; Flexible Workflow; Declarative Workflows; Healthcare social network.

I. INTRODUCTION

Recently, healthcare in industrialized countries is facing great challenges regarding the increase in the elderly population and people with chronic diseases which require monitoring and care management on a long-term basis [5] [6]. Consequently, industrial countries have to reconcile different goals: improving efficiency, personalization and equity of healthcare delivery while limiting financial resources [5]. Nowadays, to handle this issue, more and more patients are treated and taken care of in their own homes. Home healthcare (i.e., homecare) includes all health services (e.g., medical, para-medical and nursing), social services (e.g., domestic home-help) and financial services (e.g., insurance) provided for the needs of the patient at home [14]. Moreover, modern homecare propose new technological services (sensors, robots and applications) to monitor patients at home [1][5][6]. Homecare services (human, technique, technological) are often delivered completely independently by stakeholders belonging to various organizations from the public or private sectors. Family members and relatives are also involved in the care delivery [14]. Consequently, the collaboration and the coordination get more complicated between the homecare providers due to the fact that they belong to different organizational units often with different organizational structures, goals, knowledge, way of working and responsibility regarding health and life privacy [1] [6]. Over the last few years, many European or French projects have been developed for the homecare improvement [5]. Most of these projects focus on a dissemination of tele-monitoring solutions via an extensive use of sensors and robots at home, leaving issues related to process (coordination) aspects unanswered [5] [12]. From our viewpoint, the needs of homecare stakeholders are more focused on improving the organization and the coordination of their activities than on increasing the use of telemedicine at home [4]. In particular, managers from different homecare organizations need to set up common goals and routines for collaboration at the operational level and means to follow-up the quality of delivered services [14]. In this paper, we explore further the needs for collaboration between different health and social care providers, relying on interviews, surveys and scientific literature. To handle the coordination issues in homecare, we are developing a platform called Cyber Management of the Elderly and the Disabled (CyMED), for the orchestration of the different kind of homecare services. The suggested solutions are based on a patient and process oriented perspective to emphasize the importance of the organizational aspect. The remainder of this paper is organized as follows. Section II presents the different types of homecare processes. Section III presents our approach to define and orchestrate homecare processes. Next, the CyMED platform is presented in Section IV. Section V presents a survey of healthcare social networks and platforms existing in the market or from research projects. Finally, section VI concludes the paper.

II. HOMECARE PROCESSES

Compared with hospital-based care, Homecare introduces new functions, new activities and new actors (such as the family, the coordinator, the equipment provider) in the process of care (see Figure 1) [1][6]. The only means of communication between the different homecare stakeholders is a simple physical notebook where each stakeholder notes the date of the visit, the actions performed or the patient health's change [3][4][17]. A multitude of other information media may also be used: medical records, social service records, fax, telephone, etc. Indeed, the cooperation of these stakeholders is asynchronous since they communicate rarely directly or meet face to face [16].

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Moreover, homecare stakeholders differ widely regarding their way of working, need of information and technical skills. For instance, healthcare providers are often computer literate and possess their own information system support. On the contrary, social providers and elderly people have often little computer literacy and may be reluctant to use a computer-based system in their daily work.

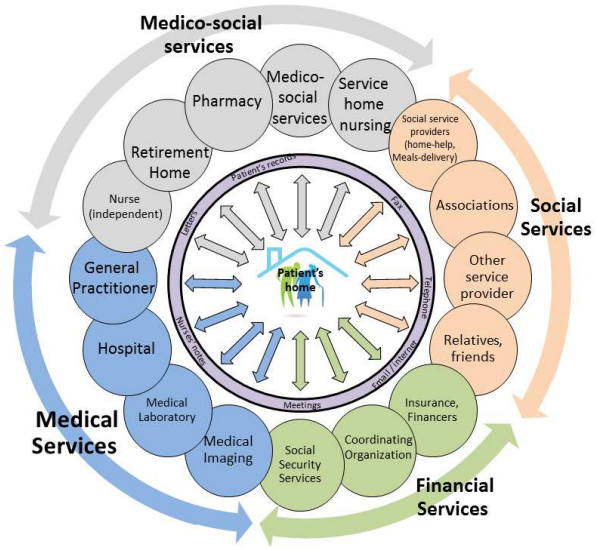

Figure 1. Homecare ecosystem

From our study of the activities in the field of homecare, we deduced that homecare processes are by nature **inter-organizational, collaborative and ad-hoc**. We distinguish, principally, two types of homecare processes [4]:

- An **organisational care process** which encapsulates administrative and logistic sub-processes and can be broken down into several phases: patients' requests and admissions**,** organisation of care processes (e.g., the elaboration of care plans and patients' discharges) and support processes (related to the logistical, financial and quality aspects).
- A **care process** made up of day-to-day care activities delivered at home by nurses, doctors, social services or the family's patient members.

Managing this kind of processes with traditional workflow systems is complex due their following features [1][3]:

A. *Personalized processes*

Although, homecare administrative and logistic processes are generally well-structured and often repetitive, care processes are, on the contrary, unstructured and very specific to each patient's heath state and environment.

B. *Collaborative Processes*

Homecare processes and responsibilities are distributed over multiple participants, with their own goals and procedures, working together to achieve a common objective (the wellbeing of the patient). They are also strongly influenced by the experience and the knowledge of the stakeholders (i.e., knowledge-intensive processes) [7].

C. *Dynamic processes*

Homecare processes require continuous adaptation of their structures due to the change in laws and care protocols. They also need to adapt their behavior when exceptional situations occur (arising from human or material issues) [9].

D. *Time constrained processes*

There are different types of temporal constraints on homecare processes: scheduled tasks (with a fixed start and end date), unscheduled tasks (e.g., when a physician consults blood test results) and tasks with frequency over time (e.g., a patient need two nurse visits per week for three months).

E. *Regulated Processes*

The homecare domain is governed by general rules and constraints related to healthcare protocols, data privacy and actions' traceability.

III. A FLEXIBLE WORKFLOW APPROACH TO MANAGE HOMECARE PROCESSES

There is a need for technological support in controlling and monitoring homecare processes to increase their efficiency and ensure the continuity of care. Workflow technology is potentially a means for achieving this end. Given the specificity and the inherent flexibility of homecare processes, we selected the Yet Another Workflow Language (YAWL) workflow management system for the coordination of work among homecare participants [10]. We justify the choice of the YAWL system as follows: First of all, YAWL is an open source academic system and its modelling language is very expressive. In particular, YAWL allows modelling and implementing cancellation and multiple instantiation of tasks (e.g., shared tasks), which are often encountered in homecare processes (see Figure 2). Second, YAWL offers unique support for flexible processes through the use of "*worklets*". In this way, specific activities, whose implementation is left open, are linked to a repository of possible actions (i.e. worklets). Based on contextual information, the desired action is chosen. Also, during enactment it is possible to add new actions to the repository. Finally, YAWL offers a link to the workflow engine DECLARE [13] which allows the enactment of loosely structured processes. DECLARE provide powerful ways of supporting "*extreme*" flexibility because it uses a declarative constraint-based approach. In this way, DECLARE allows specifying in a process model what should be done and not how to do it, using a set of tasks and constraints between these tasks. The users can execute activities in any order and as often as they want, but they are bound by the defined constraints. Furthermore, DECLARE also supports dynamic change, so that it is possible to deviate from the pre-modeled process template by adding or removing tasks or constraints. YAWL and DECLARE work

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together in such a way that structured parts of the process are handled by YAWL while unstructured parts are handled by DECLARE. In addition, DECLARE supports decision making by providing the users with history based recommendations [15] during process execution using its link to the process mining tool ProM [8][11].

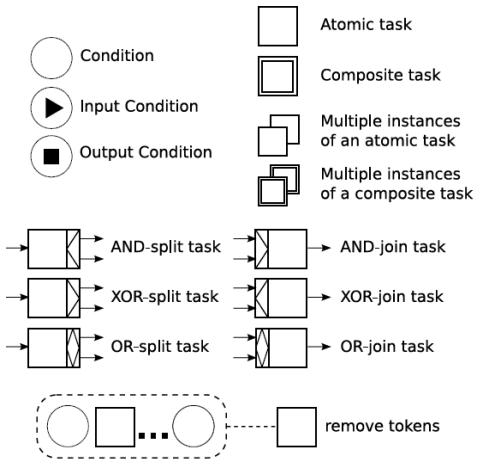

Figure 2. Symbols used in YAWL.

We illustrate the suitability of YAWL for homecare process enactment through a simplified medical prescription process, depicted in Figure 3. After the preparation of the required medicines, the delivery is organized in different modes depending on the patient's context (e.g., pick up medicines from the pharmacy or home delivery). We used the *worklet* service for modeling the different delivery mode by linking a multiple atomic task "*Medicines delivery*" to the *worklet* service. After the diffusion of a medical prescription, at any stage of the care process, it is possible for a doctor to cancel the care plan and to reschedule another one via the cancellation task "*Prescription cancellation*". During a treatment, a supervision of a patient is organized, illustrated by the *composite* task "*Treatment Supervision*". This task is linked to the *Declare* service. In this way, it is possible for the homecare participants to execute their assigned tasks ("*Check blood pressure*", "*Ask for drug tolerance*" and "*Give breakfast*") in any order as long as they respect the constraints defined on these tasks. It is also possible to dynamically add or delate tasks, on the fly. Despite the expressive power of the YAWL system, which make it one of the best candidate to orchestrate homecare processes (structured or loosely structured), there are some limitations: YAWL is an academic workflow management system therefore we need to teste its limitations for implementing real-life workflows. The predefined rules' templates embedded in the DECALRE system can't express temporal frequency constraints (i.e., a task has to be redone every day, once time, during a week). The DECALRE designer may also seem not easy to use for homecare participants to add and remove tasks dynamically.

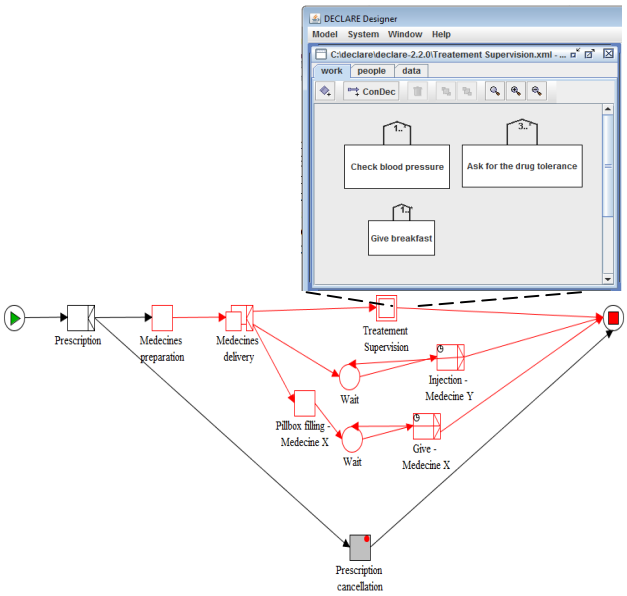

Figure 3. A simplified prescription plan

IV. THE CYMED PLATEFORM

A. *CyMED target architecture*

The architecture of the CyMED platform is based on the following main components (see Figure 4):

- A multi-modal communication system, combining tablets, PCs, TVs, fax and telephone. Information sharing may be via email, chat, audio messages or video meetings.

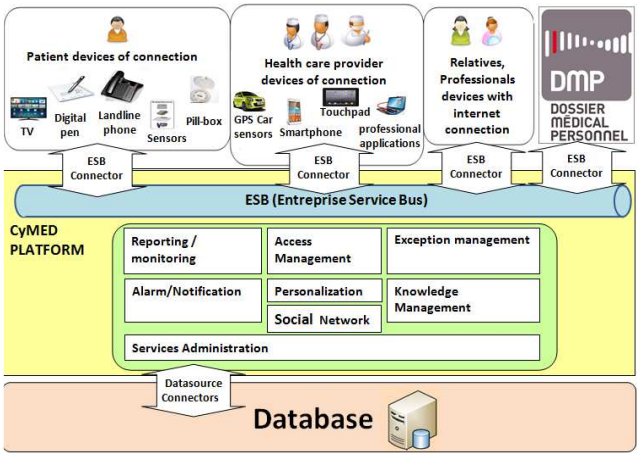

Figure 4. CyMED overall architecture

- A flexible workflow management system (YAWL system) to orchestrate the different services.
- An Enterprise Service Bus (ESB) which guarantees the interoperability and integration of the data sources and applications.

The CyMED platform will also be connected, when deployed, to diverse medical applications and to the National Electronic Health record in France, called DPM. The DMP was designed to enable coordination based on medical data sharing. However, we believe that an efficient coordination of homecare participants can be done only via an integrated approach using advanced technologies for data sharing, communication, and process orchestration.

B. *CyMED main services*

Let us note that the CyMED platform is under construction and a first version containing the healthcare social network is already available. The main functionalities of our platform are the following:

The healthcare social network

CyMED encapsulates a collaborative social network tailored to homecare services coordination and exchange of information. Each community is private and is built around one patient. It may involve the patient's relatives, homecare professionals and different organizations (laboratories, hospitals, insurers or coordination centers). A member may have several profiles depending on the community where he/she belongs. For instance one person may be invited in the community of the patient A as a relative and also be invited in the community of another patient B as a healthcare professional. Each profile has access to specific functionalities of the platform and has different access rights on the information displayed on a community. There are also different means to communication between the same community members via text, audio or private messages (see Figure 5).

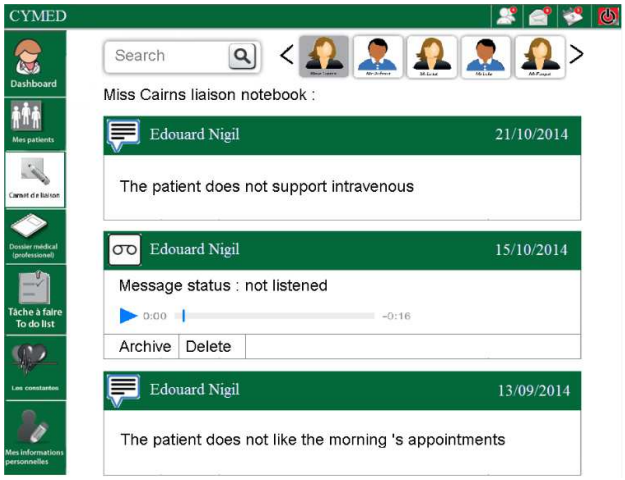

Figure 5. An example of a patient's community wall (user interface of healthcare professionals)

The voice messenger is a functionality proposed in our platform to improve communication among homecare participants, allowing them to record voice messages from their mobiles devices. We also propose a system of private chat and video meeting accessible by all the member of a patient's community.

Personalized Human Machine Interface

Our goal is to design a Human Machine Interface that is customizable (color, text size and font, etc.) and adjustable to the patients' deficiencies and loss of autonomy, at one hand, and to the responsibilities of homecare participants, on the other hand. For instance, we have worked on the specification of a personalized and adaptable event reminder service used by the patients and the homecare participants in their daily work. This service allows customizing, per type of events and per profile: the reminder type (sound, visual, contacting a relative, etc.), the frequency, and the reminder message content (key information to be transmitted).

The to-do-list functionnality

The tasks assigned to each member of a patient's community are managed via the *to-do list functionality* (see Figure 6).

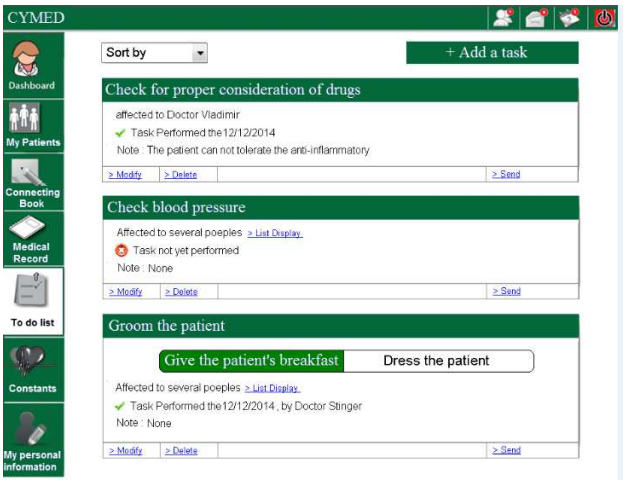

Figure 6. An example of a to-do-list (user interface of healthcare professionals)

This to-do-list acts as the *worklist* of the YAWL engine and acts also as an interface between the DECLARE designer and the DECLARE engine. Using such a To-do-list, a homecare participant or a patient, may define and assign tasks or care plans (if they are healthcare professionals) to other members of the same patient's community.

Social networks Key Performance Indicators (KPIs)

The homecare system in France is funded by regional public units which need to be reliably informed of the involvement, interaction and service efficiency of homecare participants. To answer these kinds of questions, we identified the following list (table 1) of key performance indicators (KPIs) which allow measuring the engagement and service levels of a patient's community on the CyMED platform (see Figure 7).

 ISBN: 978-1-61208-384-1

TABLE 1. DETAILED LIST OF SOCIAL NETWORKS KPIS

Social network Capital	Number of contacts with a direct relationship with the patient. It is measured by yearly total volume of contacts, vol. and % of contacts / category.
Number of social network gaps	Number of contacts categories within a patient private community with no contact. It is measured by total volume of contacts categories with 0 contacts per private community.
Patient medical data exceptions	Number of patient health abnormal data requiring actions to be taken, e.g., number of medications administrated but not taken. It is measured by daily total volume of exceptions notified.
Level of community engagement	Number of new events submitted by private community members. It is measured by monthly total volume of events generated by a category of the community or by a member of the private community.
Quality of service provided by the community	Share of alerts and/or tasks managed and completed by the private community. It is measured by monthly total volume of managed alerts and total volume of completed tasks by the community, or by a category of the community or by a member of the community.

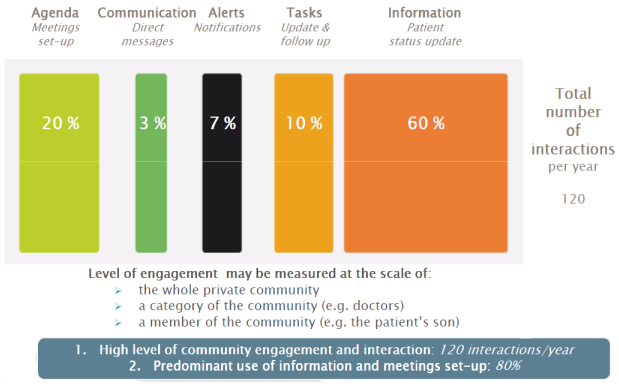

Figure 7. Social networks KPIs- Patient network involvement level

Health monitoring and detection of loss of autonomy

CyMED will encapsulate a monitoring system in order to detect alarming situations (e.g., falls) or any degradation of the patient's status (e.g., loss of autonomy). The detection of loss of autonomy is based on information reported by different types of sensors (weight, fall detection, power consumption, etc.) or questionnaires from the patients, caregivers, social providers and relatives. The CyMED platform will introduce flexibility in alert diffusion by allowing: (1) to customize alert thresholds per patient, (2) to adapt the alert diffusion process depending on the patients' context and the availability of his/her member community, and (3) to cancel alert diffusion process any time by authorized homecare participants.

Planning service

The CyMED platform encapsulates a scheduling service to organize the appointments and events of the patients and all the homecare participants. A patient agenda is shared between all his/her community members with different views on its details. The planning service can also provide optimization functionalities if the users want to optimize their daily scheduling. In this case, several criteria are taken into account expressed in terms of: unavailable or available time slots per type of service, availability per geographic areas, and distance between appointments' locations, etc. If an appointment is cancelled, the planning service will propose to a homecare participant the nearest provider who can replace him/her, relying on a homecare participants' locator.

C. *Implementation*

CyMED platform is based on a Service Oriented Architecture (SOA) architecture using an Enterprise Services Bus (ESB). We have chosen to use ESB architecture in order to have a flexible architecture allowing easily plugging of new applications, data sources and web portals. The standard parts of the social network will be generated from the framework LifeRay. The presentation layer will be provided by the Apache Web server. The processing layer and the business services are provided by the J2EE application server (Tomcat), communicating via asynchronous messaging. These autonomous services are integrated on an ESB (e.g., Mule) controlled and sequenced by the workflow engine YAWL. A secure connection layer protocol (Secure Sockets Layer - SSL) will be used to ensure the environmental safety of the platform. It will allow the encryption of the connection and also guarantee authentication through the use of cryptography. Finally, to ensure the interoperability of data exchange between the different services we are going to use international healthcare standards, such as DICOM (Digital Imaging and Communications in Medicine) and Health Level-7 (HL7).

V. RELATED WORKS

The issue of collaboration and coordination between homecare participants was treated by few European projects and studies [2][5][14][12][17]. For instance, in [16] the authors suggested a number of methodological measures and IT solutions, to support organizational development and coordination on both the managerial and operational levels. However, no solution was implemented. In [6], two design concepts were presented to improve homecare coordination, based on a voice messenger and on augmented paper binder. However, the proposed approach focus on enhancing communication rather than improving homecare processes enactment. A model of coordination for homecare processes was proposed in [4] based on recursive description of actions and shared reference. However, the proposed coordination model is not flexible and therefore is not adequate to manage homecare processes. More recently, an approach to automatically adapt the process of homecare for elderly people needs was proposed in [17]. This approach relies on ontology matching between homecare domain and concepts of Business Process Modeling Notations (BPMN). The drawback is that the produced process models are specified

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in BPMN notation which is not adequate to model flexible or loosely structured processes. Moreover, this approach doesn't take into account the agenda of the different homecare participants when the tasks of homecare processes are scheduled. Social networks approach was also successfully used in order to ease the access to healthcare information, collective learning, manage health conditions, and crowd sourced eHealth research. *PatientsLikeMe* is an example of patient-driven healthcare social network that encourages information exchange and collaboration between patients and doctors. *Hellohealth* (*hellohealth.com*) is another kind of social network which enables healthcare providers' identification and appointments' management. In comparison, we can say that the advantage of the social network of CyMED is that it combines a communication approach (chat, video, text and voice messages) with a process oriented approach (process orchestration via the YAWL system). Its goal is also to integrate different healthcare applications and sensors to facilitate patient's monitoring and the communication between different homecare participants and systems.

VI. CONCLUSION

In this paper, we present the overall architecture of our coordination platform, currently under construction, which offers a package of services, such as: the orchestration service (via the flexible workflow management systems YAWL and DECLARE), the communication service (via a dedicated homecare social network), and the monitoring service, etc. Future work will involve: (1) Implementing and deploying the system in real-life environments. (2) Implementing the optimization planning service and test its synchronization with the YAWL system [10] when tasks and appointments are rescheduled. (3) Defining constraint templates for the declarative workflow engine DECLARE [13] tailored to homecare. (4) Defining a mechanism based on ontologies and on the *worklets* service of YAWL to represent domain knowledge and patients' context [2] in order to facilitate the personalized construction of homecare workflows. (5) Extending the proposed approach with process mining capabilities applied on real-life data to extract, analyze and improve running homecare processes (e.g., extract homecare best practices) [11]. Moreover, it will be interesting to adapt the recommendation mechanism (relying on process mining) implemented in DECLARE to recommend tasks to homecare participants following the patients' health state contexts, preferences and constraints [15].

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IT-supported Double Medication Check for Home care

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***Abstract*—This paper presents the work in progress for the Double Medication Check project. The aim of this project is to provide an IT-supported solution for the Double Medication Check (DMC). The need for DMC is pressing. Failures are being made during the dispense of medicines, which costs lives and increases the costs of health care. The practice of DMC puts strain on home care organizations, where increased costs and high workload are practical constraints. With the use of the eHix method, we hope to develop a sustainable IT support for DMC so safe and effective DMC will occur in the home care.**

Keywords: double medication check; IT support; home care; effective medicine dispense.

I. INTRODUCTION

Many elderly people in long-term care programs (extra mural as well as intramural) use combinations of different medications, which increases the risk of failure during the dispensing of medications by healthcare professionals. Different studies show that faults are being made due to dispense errors of medicine. Each year 1735 patients die in Dutch hospitals because of unintended injury caused mostly during the dispense of medication [1]. The HARM (Hospital Admissions Related to Medication) study of 2006 concluded that 2.4% of all hospitalizations in the Netherlands are due to medication-related issues. This results in about 41.000 hospitalizations each year from which 19.000 are avoidable [2]. Again, this report concludes that most of these hospitalizations are caused by faults during the dispense of medications.

Medication errors cause much suffering for the patients as extra treatments thereby mean higher healthcare costs. The effects of medicine errors are even higher for elderly people [3]. At this moment, 16% of the Dutch population is older than 65 years (2,7 million). This number will increase. The Dutch Central Statistical Office estimates that by 2060 about 26% of the Dutch population will be 65 years or older. About 30 to 45% of this population uses five or more different medicines on a daily basis [4]. The most common problems concerning this population's medications are the use of unnecessary medication, the incompatibility of different medicines, and avoidable side effects [4].

A. Double Medication Check

In 2009 and 2010, the Dutch Healthcare Inspection (IGZ) exercised thematic supervision of medication in nursing homes, homes for the elderly and disabled and home care. The study concluded that the medication safety for vulnerable groups in long-term care and home care is inadequate [5]. The study also suggested that the use of technology could improve medication safety [5].

Based on this conclusion, a taskforce consisting of leading actors in the Dutch health sector developed a national directive called "Safe Principles in the Medication Chain". In this directive, the double medication check (DMC) is defined as an important practice/safeguard for reducing medication errors during the dispensing of medications [6]. This directive also describes the medication process (see Figure 1).

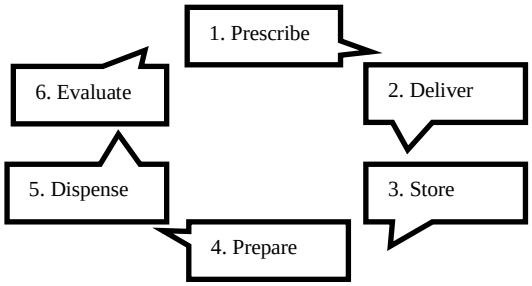

Figure 1. Medication process

DMC is conducted in the 'dispense' phase of the medication process. The medication is dispensed by a licensed healthcare professional and has to checked by either another licensed healthcare professional, an informal carer or the patient him/herself. In practice, it is difficult to apply DMCs. It is rather expensive and time-consuming and therefore, in many cases, these DMCs are not always performed. On top of this, many care organizations have to deal with declining budgets, which puts pressure on labor-intensive practices such as DMCs.

B. IT-Supported Double Medication Check

As suggested in many studies, the use of IT technology could improve medication. This might also be the case for the DMC. To our knowledge, the use of IT-supported DMC has not been validated considerably worldwide. There are some studies that have been done on the use of videoconferencing for DMC. Results have not been possitively overwhelming [7]. In this paper we pose the research question: In what way can IT support contribute to

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a safer way of dealing with medication in home carehome care that needs to be double checked?

The research group IT Innovation in Health Care at Windesheim University of Applied Sciences (Zwolle, The Netherlands) is involved in a research center called Tech for Future. Within this center, the research group is developing an IT-supported solution for DMC at home care. The aim of this research is to develop a working beta-version of an IT - supported DMC and to understand and measure whether IT-supported DMC is able to lower the costs and improve the process and user satisfaction of DMC in home care. The project will be conducted with one Dutch care organization, which provides intramural and extramural care to the elderly and chronically ill. For the project, we focus on the DMC in the dispense of medicines in extramural care.

II. APPROACH

In order to develop a feasible IT solution in a structured manner, the eHealth Innovation framework will be used. In former projects, the research group IT Innovations in Health Care at Windesheim University of Applied Sciences developed a business model approach as an instrument to bridge the gap between innovative eHealth ideas and successful IT-based care services. This approach is well suited to the characteristics of an IT service innovation like the IT-supported DMC [8].

The starting point of the eHix-method is the STOF model [9]. The STOF model describes the business model based on four perspectives or domains. the *Service* perspective—a description of the service, the value proposition (the value of the service for users), and the intended audience. The *Technology* perspective—a description of the required technical functionality and architecture to deliver the service. The *Organization* perspective—a description of the resources, activities, roles, and structure in which the value network partners provide the service. And the *Finance* perspective—a description of how the service generates revenue (earnings) and the distribution of costs and benefits among the parties involved in the value network.

The eHix combines the STOF model with a phasing that provides support for the lifecycle of the innovation process. See Figure 2. The five phases proposed by Hettinga [10] form the basis for the phasing: inventory phase, design & development phase, experimental phase, pilot phase and implementation phase. In the *inventory* phase, the ideas of a new service are created, and the needs and requirements of the users are analyzed. In the next phase, the technology is designed and developed, and thoughts about the business model of the service are initiated. In the *experimental* phase, users try out the new application in a laboratory setting, while in the pilot phase, more users are involved testing the application of the service in their daily practice and giving input for a successful deployment in the *implementation* phase.

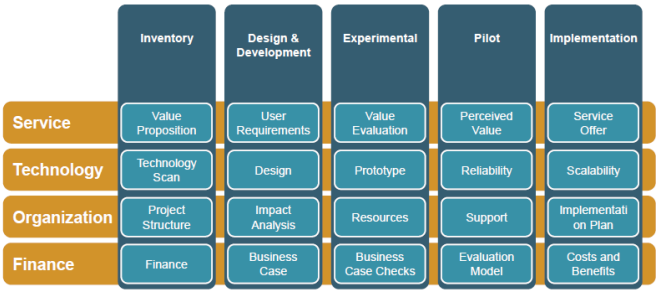

Figure 2. eHix matrix structure combining business model domains with innovation phases

The eHix thus combines the five stages in the innovation process (concept phase, design phase, test phase, pilot phase, implementation phase) with the four aspects of the business model (service, technology, organization, finance), resulting in a matrix containing 20 (4 by 5) cells. Each cell contains the essential steps and choices to be made in the innovation process for a specific domain within the business model in a particular phase. The eHix matrix structure is shown in Figure 2 with the main keyword in the cell displayed.

A. Inventory Phase

To lay a good fundament for this project, we first take a broad view by mapping and analyzing all the stakeholders involved. A good stakeholder analysis is crucial to enhance the project's chances of success; it makes sure all parties are being taken into account, all interests are being mapped, and the evidence needed to prove the IT solution's value is clear [11]. At the same time, we familiarize ourselves with the care organization and its needs. We specify which clients are involved, which scenarios of DMC are currently used at the care organization, and the most pressing needs according to the stakeholders. To retrieve this information, we first interview the most important stakeholders. The initial interviews at the care organization are with the home carehome care manager, a number of professional carers, and the IT manager. Based on the results of these interviews we observe five carers while they do their rounds and perform the DMC at their clients' homes. From here on, we are able to sketch the different scenarios of DMC currently practiced. We will complete these scenarios with process analysis, which will be the focus in a following brown paper session with the care manager, five carers, and the IT manager. This brown paper session allows us to verify the detailed scenarios with the stakeholders and to take stock of the most pressing needs according to these stakeholders. Involving the most important stakeholders in this way creates ownership and involvement. It makes the stakeholders take responsibility for the whole process of identifying needs and forming solutions. This will add to the acceptation of changes to come.

Even though user-requirement analysis is usually done in the phase following the Inventory phase, we will also use the brown paper session in this phase to already draw up the user requirements. There is a pressing need to work as efficient as possible with the stakeholders' availability, since the care organization's manager and carers are strapped for time.

To put the challenge of DMC in a broader context, interviews are held with carers of selected home carehome care organizations in the region. In addition, national and

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international eHealth entrepreneurs are consulted on the DMC. At the same time desk research is done on the IT solutions currently on the market.. Scientific studies on DMC and eHealth in publications in online and eHealth magazines are accessed to make sure the DMC issue is approached from all angles.

The costs of this current project are financed by a subsidy provided by the Tech For Future research center. In this Inventory stage, however, we do initiate the revenue and cost model with the care organization's manager. Developing the possible financial scenarios of sustainable financial resources at this first stage of the project increases the chances of embedding the project in the standing organization.

B. Design and Development Phase

We have already drawn up the user requirements and contextual conditions iteratively with our most important stakeholders. In this next phase, we follow up translating this inventory of user requirements and specific organizational context into technical specifications and user specifications. We also construct mock-ups together with the care organization's home carehome care manager and IT manager. Keeping these stakeholders involved is crucial at this point in the project. Active involvement of stakeholders at this stage enhances the chance of structural embedment of the envisaged IT supported solution in the organization.

At the same time, we draw up the specifications of the envisaged solution with the stakeholders. We also analyze the technical and user specifications of the most fitting IT solutions currently on the market. Once the specifications of the envisaged solution are clear, we make a fit-gap analysis between the envisaged solution and the most fitting existing IT solution. This analysis will give an indication of whether or not it is feasible to even experiment with this most fitting IT solution in our Telecare Skillslab (for further explanation see Experimental Phase).

Being in constant dialogue with the care organization, we can then sketch the impact of the envisaged IT solution on the organization. By drafting a scenario that embeds the envisaged solution into the work processes and technical infrastructure, we are able to analyze the impact of the solution on the standing organization. Being clear on the requirements and impact the device will have on the organization, we then follow up with a first outline of the business case, including the costs/benefits and operationalization of the less tangible elements that are prominent in the care organization's strategy.

The outcome of the impact analysis and first outline of the business case can be decisive factors in the continuation of the project to the next phase, the Experimental Phase. Depending on the outcomes, the care organization or other stakeholders might decide it is not (yet) worthwhile in terms of effectiveness, efficiency, or other interest that they carry to continue with the realization of a beta version of the envisioned IT solution. However, since this project's goal is to test the feasibility of an existing device and no costs are being made to realize a new beta version, this phase in the project is not decisive.

C. Experimental Phase

With an existing IT device available, experiments with potential users (carers) will be done in our Telecare Skillslab to assess the value proposition of the IT solution. The research group IT Innovations in Health Care established the Telecare Skillslab to contribute to education in eHealth and facilitate telecare research. The Skillslab consists of two locations situated at the Windesheim campus. One location has been furnished as a living accommodation, which makes it possible to experiment with domestic applications of sensors in a realistic manner. The other location aims at facilitating formal or informal carers, providing care at a distance. Cameras installed in the ceiling provide the researchers with possibilities for non-obtrusive observation.

During the experiments with the existing IT-supported DMC found on the market, the focus is not only on the technology, but also on important issues such as privacy and embedding the technology in daily routines. For the resources needed in this phase—the Telecare Skillslab, the existing IT-supported DMC, and the necessary people—our project planning is most important. It is not until the experiments are completed that we can do the business case check and adjust our initial cost/benefit analysis, an important indicator of structural embedding of the IT solution in routine care. Not only should overall costs be evened out with overall benefits, but a proper balance between costs and benefits of individual stakeholders within the care chain should also be pursued. The adjustment of the business case after the experiments can give a good indication as to whether or not the IT device should be brought into the next phase.

D. Pilot Phase

In the pilot phase, we will test the IT-supported DMC on site, with the carers performing the various DMC scenarios at selected clients' homes. The aim of the pilot is a final test for functionality, reliability, and usability. The pilot will be of small scale with the focus on technical functionality as well as user friendliness. During the pilot, we will also explore whether end-users intend to keep using the technology and to what price. Once the results of the pilot study are finalized, the business case will be adjusted again to the findings of the pilot. The final business check is to ensure whether the use of the technology leads to the intended effects: a more effective DMC for home care leading to the same or higher quality of care against lower costs.

Since the project's scope excludes implementation, we have made the decision for now not include the last phase, the Implementation Phase.

III. PRELIMINARY RESULTS

Initial research regarding the DMC at the care organization started in February 2014. The project will conclude at the end of January 2015. Hence, at the time of writing, only six months of the project can be considered. This section highlights some preliminary results and lessons learnt from these months.

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While the process of DMC seemed to be quite straightforward initially, during the inventory phase, we came across the practice of various scenarios of DMC at the care organization. Many of these scenarios were not included in the care organization's official guidelines but were adjustments of the DMC process by the carers on site. Even though these adjustments are not officially recognized scenarios, these practice adjustments done by the carers have to be taken into account while mapping out all the scenarios of DMC. By not taking into account the 'hidden' adjustments done in the work field by carers could we could miss vital information on the work field, thereby excluding practical user requirements.

After extensive desk research and field research, we could only find one existing IT solution for DMC currently on the market. This made the selection of IT solutions in the technology scan of the Inventory Phase redundant. This existing IT solution is used in a few care organizations for DMC in home care and will be considered in this project.

During the interviews with other care organizations, a small number of respondents mentioned the use of Social Media, such as WhatsApp and SMS, as alternatives to dedicated IT-supported solutions for DMC. These IT solutions were not endorsed by the care organizations but 'inventions' used by the professionals themselves. The care professionals using these 'solutions' were not aware of the issues of privacy and legislation around the distribution of personal data like medicine use.

IV. CONCLUSION AND FUTURE WORK

In this paper, we described the DMCs project's ambition to deliver eventually: impetus for the realization of an IT support for DMC in home care. It is our hope that with this IT support, including administration and registration of risky medication, will contribute to a safer dealing with medication. We also presented the first months of progress of the DMC project.

The main conclusion to be drawn from the current progress is that, in general, there is a consensus that IT support has the potential to improve the DMC as it is currently practiced in the field. The technology scan in the Inventory phase resulted in only one 'official' IT supported solution and several 'informal' IT supported solutions. This interests shows that our research does fill the need for more evidenced based IT solutions regarding DMC.

Future work on the project concerns the plans to improve the existing IT solution based on the results of our experiments and pilot study. When the existing IT solution does not fulfil the expected requirements at all, we will develop a complete new IT solution for DMC at distance together with our IT students and our Health Care students.

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Respiratory Movement for Health Assessment by Using Internal-external Cross Correlation Investigation

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***Abstract*—Respiratory belt is a full-service home medical equipment to monitor respiration for homecare. Respiratory belt indicates breathing strength and characterizes breathing patterns. This paper describes a noninvasive respiratory movement monitoring using Magnetic Resonance Imaging (MRI) and respiratory belt simultaneously to investigate internal-external correlation. Twenty healthy subjects participated in this study and they all performed paced breathing (12 cycles/minute) during experiment. The diaphragmatic movement area and the anterior-posterior (AP) diameter of the body contour were represented as indexes of internal respiratory movement. The respiratory belt signal was represented as the external index. Cross correlation was used to evaluate the similarity between internal and external respiratory movement. The results indicated that diaphragmatic movement area versus respiratory belt signal performed strong negative correlation (R value is -0.847±0.06). The AP diameter of the body contour versus respiratory belt performed strong positive correlation (R value is 0.837±0.09). In conclusion, respiratory belt correlates strongly with diaphragmatic movement area and AP diameter of the body contour. Therefore, respiratory belt is a reliable external respiratory monitoring technique to detect respiratory movement in homecare.**

Keywords-cross correlation; respiratiory movement; respiratory belt; internal-external information

I. INTRODUCTION

The measurement of lung function is predominantly based on conventional spirometry that measures the lung volume at the corresponding flow. Such measurement provides an averaged performance of the lungs at a point. There is no information that reflects the contributions from various regions of the lungs [1]. Therefore, a non-invasive method for recording lung function that primarily relies on cross sectional area of both thorax and abdomen called respiratory belt. Respiratory failure is too difficult to predict. Continuous monitoring of respiratory activity and appropriate monitoring equipment could be life-saving. Therefore, respiratory belt is a full-service home medical equipment to monitor respiration for homecare [2]. With such a device, the changes in the volumes of the thoracoabdominal compartments respectively measures anterior-posterior and lateral diameter changes of different conditions. It can provide respiratory volume, respiratory rate and pulmonary ventilation [3].

Applications of respiratory belt are the most widely used technique and play an essential role in clinic. For examples, respiratory belt measures the variation of thoracic or abdominal circumference during respiration which indicated breathing strength and characterized breathing patterns. Synchrony of the breathing pattern has promised to evaluate chest wall movement and stability in preterm infants [4]. Thoracoabdominal asynchrony during upper airway obstruction in small children can be documented by phase angle analysis of the Lissajous figure from the output of a respiratory inductance plethysmography as respiratory belt [5]. In gated radiotherapy, the accuracy of respiratory-gated treatments based on external body monitoring usually relies upon the assumption of a strong correlation between the external motion and internal respiratory motion [6]. However, there are several studies to verify the time series correlation of internal and external movement by Magnetic Resonance Imaging (MRI).

MRI is a feasible technique to investigate the anatomy and physiology of the body, especially diaphragmatic movement. The technique is widely used in hospitals for medical diagnosis, staging of cancers and for follow-up without exposure to ionizing radiation.

Cross correlation is commonly used for measuring the similarity of two waveforms [7]. Therefore, this study used

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cross correlation to analyze the interaction between internal and external respiratory movement. The diaphragmatic movement area represents the respiratory movement. The AP diameter of the body contour represents the internal index. The respiratory waveform measured by respiratory belt represents the external index.

Section II presents the methods about data collection and imaging processing. Section III presents the results about cross correlation. Section IV presents the discussion and Section V presents the conclusion.

II. METHODS

A. Subjects and data collection

Twenty healthy subjects (10 males and 10 females; age: 23±1.8; height: 167±9.3 cm; weight: 60±11.45 kg) participated in this study and they all performed paced breathing (12 cycles/minute) during experiment. All subjects followed the instruction during breathing for 2 minutes in MRI exam room (Figure 1).

The diaphragmatic movement represented the internal respiratory index. And the images were projected in the sagittal plane with the subject in the supine position. The projection plane was placed sagittally in the coronal scout view directed through on the right side, midway through the most highest of the right diaphragm. All imaging experiments were performed on a Siemens 1.5-T Magnetom Sonata scanner (Siemens Medical Solutions, Erlangen, Germany) with a two-channel body array coil. No intravenous contrast medium was administrated. We have used Fast Low Angle Shot pulse sequence to acquire MRI images configured as follows: TR= 2.18 ms, TE= 0.74 ms, slice thickness=10 mm, field of view= 400 mm. The length of each trial recorded sequence was 129 s. During this time, 512 images were recorded at regular intervals; one image was acquired every 0.252 s.

The respiratory belt (Siemens "Physiological Measurements Unit") located on xiphoid was used to measure the external respiratory movement. This study was approved by institutional review board of National Chiao Tung University and Chung Shan Medical University Hospital. Informed consent was obtained from all participants before the experiment.

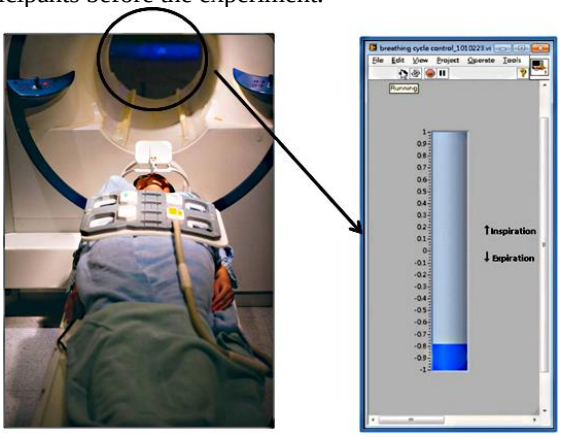

Figure 1. Left picture showed experimental environment and right picture showed the following instruction.

B. Imaging and signal processing

The MRI image files were converted to analyze format with DicomWork 1.3.5 software. The imaging processing programs in this study were developed by using commercial software platform (LabVIEW version 2013, National Instruments Corp., Austin, USA). The experimental analysis was assessed under the following.

1) Diaphragmatic movement area

The diaphragmatic area movement is an internal respiratory movement. The images analysis contains several steps as follows. First, the boundaries of the diaphragm are extracted from edge detection algorithm [8]. Edge detection is aimed to identify points in the MRI image, where the image brightness changes sharply. Green color is diaphragm which is extracted from edge detection (Figure 2). Secondly, it demonstrates the "cresent" shaped image of diaphragm area during paced breathing cycle and converts to the waveform. The calculated area method is maximum inspiratory volume as a reference to calculate the ups and downs area of diaphragmatic movement.

2) AP diameter of the body contour located on xiphoid

Drawing the horizontal line at the location of respiratory belt as a reference recorded AP diameter of the body contour in sagittal MRI image. The AP diameter of the body contour represents the internal respiratory movement (Figure 3). The anterior-posterior boundary is extracted from edge detection algorithm. Then, it measures the diameter of the boundary.

3) Respiratory belt signal

The respiratory belt was used to measure the external respiratory movement (Figure 4).

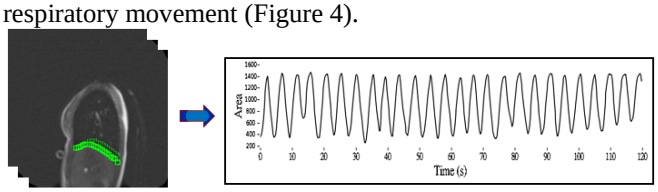

Figure 2. Diaphragmatic movement area as internal index during paced breathing cycle.

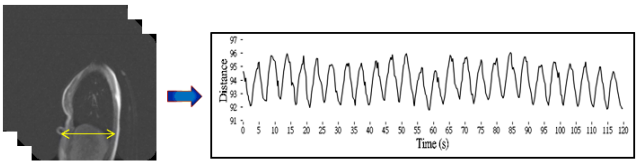

Figure 3. AP diameter of the body contour as internal index during paced breathing cycle.

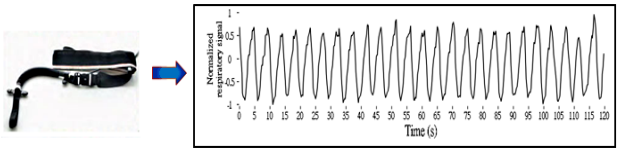

Figure 4. Respiratory signal which was extracted by respiratory belt based on pressure difference as external index.

Three indexes represent different meanings on physiology. Diaphragmatic area movement means pulmonary efficiency. The AP diameter of the body contour is that it outlines AP diameter of the body contour changes at sagittal MRI images. Respiratory belt means AP and lateral diameter changes.

C. Cross correlation function

Cross correlation function is commonly used for measuring the similarity of two waveforms as a function of a time-shift applied to one of them. The process of calculation opened a fixed window size about one breathing cycle then calculated the quantity *R*, called correlation coefficient with time shift point by point. The mathematical formula for *R* is:

$$R = \frac{\sum_{i=1}^{n}(x_i-\bar{x})(y_i-\bar{y})}{\sqrt{\sum_{i=1}^{n}(x_i-\bar{x})^2}\sqrt{\left(\sum_{i=1}^{n}(y_i-\bar{y})\right)^2}} \quad (1)$$

where n is number of points data during a breathing cycle and x, y are two different waveforms data respectively. The value of *R* is such that $-1 \leq R \leq 1$.

III. RESULTS

Cross correlation is commonly used for measuring the internal-external correlation. The results of cross correlation were illustrated in one of the participants as an example (Figure 5,6,7) and the statistical results of 20 subjects are summarized in Table I. Diaphragmatic movement area versus AP diameter of the body contour performed strong negative correlation (R value is -0.908±0.09) after time shift zero. Diaphragmatic movement area versus respiratory belt signal performed strong negative correlation (R value is -0.847±0.06). Diaphragmatic movement itself versus AP diameter of the body contour and respiratory belt is opposite direction during breathing. AP diameter of the body contour versus respiratory belt performed strong positive correlation (R value is 0.837±0.09).

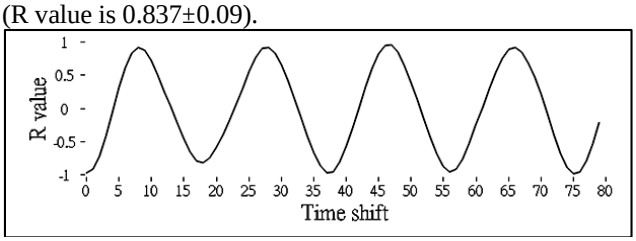

Figure 5. R value of diaphragmatic area versus AP diameter of the body contour in MRI images.

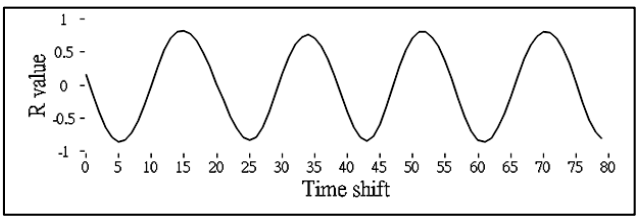

Figure 6. R value of diaphragmatic area in MRI images versus respiratory belt signal.

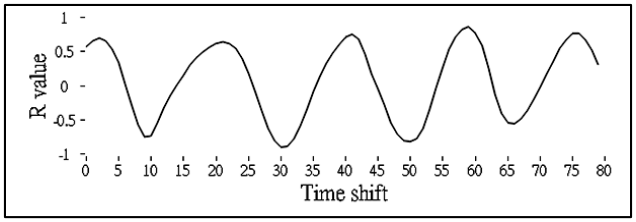

Figure 7. R value of AP diameter of the body contour in MRI images versus respiratory belt signal.

TABLE I. THE RESULTS OF CROSS CORRELATION

	Correlation coefficient	
	Diaphragmatic movement area	***AP diameter of the body contour***
AP diameter of the body contour	-0.908±0.09	-
Respiratory belt signal	-0.847±0.06	0.837±0.09

The form is (mean±standard deviation)

IV. DISCUSSION

Cross correlation is commonly method for quantifying the internal-external correlation. This research verified the correlation of organ movement (internal index) and respiratory belt signal (external index) in the sagittal MRI images. There are two indexes from MRI images. One is the internal diaphragm represented soft tissue and the other is external body contour represented rigid structure. Therefore, diaphragmatic movement area versus AP diameter of the body contour performed strong negative correlation but no time shift. However, respiratory belt is another respiratory reference to discuss. Cross correlation about respiratory belt performed strong positive correlation but had several time shifts. The result showed that there is time difference between internal and external. Vedam *et al.* [9] measured the correlation between the respiratory signal and the superior-inferior location of the diaphragm. Results from statistical analysis indicated a strong linear relationship between the respiratory signal and diaphragm motion ($p < 0.001$) but this only gave one dimensional internal information. Ionascu *et al.* [6] studied the internal-external correlation investigation of respiratory induced motion of lung cancers. The results showed that internal-external correlation along the anterior-posterior with values larger than 0.97 was better than along superior-posterior with values in the range 0.77-0.88.

In other studies of quantifying the internal-external correlation, they have been tried to get the internal information by fluoroscopy, sonography or other imaging techniques for synchronization. Gierga *et al.* [10] showed that the information of internal organs by fluoroscopy and the correlation of the respiratory motion of external patient markers as body contour are important for image-guided therapy techniques, such as respiratory gating, that monitor the movement of external fiducials. However, fluoroscopy which uses X rays to obtain real-time overlapping flat plane. The limitation of fluoroscopy is on spatial orientation. Sawada *et al.* [11] carried out that using a moving-target

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phantom simulated a patient respiratory movement and observing the variation of the calculated real-time correlation index synchronizes with the periodical motion of the moving-target. Though sonography is able to obtain the good time resolution, it is unable to set the same anatomy landmark on free hand mode. The research is a precise verification for analyzing the correlation of internal-external on fixed landmark by MRI images. It is hoped to investigate the correlation of internal-external information during breathing patterns such as thoracic breathing or abdominal breathing further. However, MRI has been limited in acquisition speed, so the pulse sequence of good time resolution is to be considered for the future.

The physiology or imaging monitoring is often used respiratory belt as recording the external information. Ya-Chen *et al.* [12] acquired the respiratory movement with four respiratory effort transducers based on using ensemble empirical mode decomposition for breathing patterns recognition. A long-term monitoring of respiration particularly becomes suitable for homecare application for chronic pulmonary diseases [13]. Respiratory belt helps a person who has obstructive sleep apnea breathe to monitor respiration. Therefore, respiratory monitoring is essential for health assessment.

The location of respiratory belt is an important impact on the changing of the external information. For example, the displacement changes largely, which respiratory belt tied on abdomen during abdominal breathing. It is obvious changing of the belt as xiphoid during thoracic breathing. Therefore, the aim of our research is to investigate the correlation of different breathing types such as thoracic breathing or abdominal breathing in future work.

V. CONCLUSION

Based on cross correlation, this study attempts to verify that diaphragmatic movement versus signal of respiratory belt assumes a better similarity on correlation coefficient and can be a reliable non-invasive respiratory monitoring system to detect internal respiratory movement. Therefore, respiratory belt can be a home medical equipment to monitor respiration for homecare.

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Seamless Medical Image Processing on the Grid on the Example of Segmentation and Partition of the Airspaces

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***Abstract*—In this paper, we present method to process medical images on the grid in the seamless manner. The only software required on the client side is a web browser which is used to upload files, submit analysis and present results. The proposed solution is easy to deploy and use. It meets user requirements to focus on medical diagnosis rather than technical details. The proposed system is built based on the UNICORE grid middleware including recently developed UNICORE Portal. It is deployed on the Polish National Grid Infrastructure (PL-Grid). Due to the novel grid technology, the whole process is handled in the secure way without additional inconveniences. The developed infrastructure has been used to segment and partition the airspaces in a human head.**

Keywords–Medical imaging; Segmentation; Grid computing; Web portal.

I. INTRODUCTION

The development in the imaging techniques makes analysis of the medical images important part of the medical doctor activities [1]. However, an automatic analysis of the images still cannot be trusted and the process depends on the doctor's experience and knowledge.

The number of different approaches and tools used for processing and analysis of the medical images is large which makes diagnoses more complicated [2]. Progress in the computer technology leads to more and more sophisticated and resources consuming applications. Usage of emerging technologies, such as clouds and grids, leads to the security and privacy issues which have to be addressed properly. In addition, access to the remote resources is still not easy and requires dedicated software which has to be installed on the user's computer.

Based on the grid technology, we have developed solution to process medical images in the seamless manner. With the web browser available on the user's computer it is possible to upload files, submit analysis and present results with no additional software needed. Due to the novel grid technology used, the whole process fulfills security requirements without additional inconveniences.

The analysis is based on the 3D CT images of the patient head. The traditional segmentation of the airspace is difficult and leads to uncertain results [3][4]. Therefore, we rely on the atlas based, non-linear registration paradigm that allows for high level automation of the whole volumetric processing.

The developed IT infrastructure [5][6] has been used to segment and partition the airspaces in a human head. In particular, the detailed analysis of the separated sinuses in terms of their shape, symmetry and anatomy deviations are detected. The computer analysis of the images requires significant computer resources and cannot be performed in the short time using typical desktop or workstation computer.

The paper is organized as follows: in Section II, we present algorithm used to to segment and partition the airspaces in a human head as well as overview of the computational infrastructure. Section III provides description of the grid middleware used. In Section IV the SinusMed application written in the Java language and installed on the high performance computing system together with the portal access is presented. The conclusions are presented in the Section V.

II. IMPLEMENTATION

To address the problem, we have created a segmented and partitioned atlas model using healthy patient data. The aerial segments were separated using interactive tools with a guidance of skilled throat specialist. For every single patient data, we selected automatically the most suitable data from the series of measurements differing with the volume size and spatial orientation.

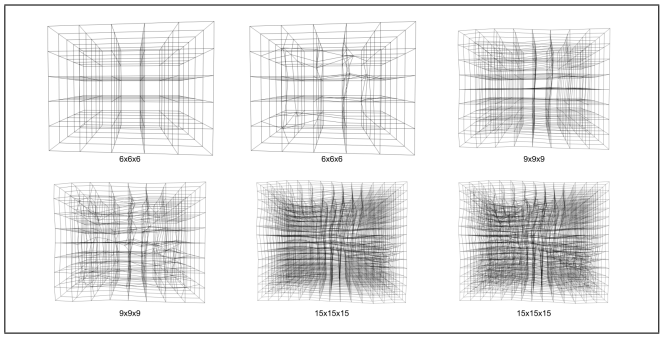

Figure 1. The schematic view on the detection of the airspaces through deformation.

After that, the registration phase of model CT data and selected volume begins. We apply the affine registration followed by the non-linear Free Form Deformation parametrized by B-splines. The resulting deformation field is applied to the

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segmented and labeled sinuses atlas to delineate the proposed partitioning of aerial spaces for a given patient. Due to the significant differences in anatomy, the result is used as a starting point for a final segmentation. The last stage consists of the volumetric tuning of every segment boundary using patients original data. The segmentation process as a sequence of the deformation fields starting form a rough estimate to more detailed approximation is presented in the Figure 1.

The whole process is time consuming. It can take several hours on a typical computer if a high resolution is required. Another problem is access to the atlas data. With the availability of new image data, the atlas can be extended leading to the better quality of the segmentation. This leads to a frequent updates and can be difficult while locally installed software is used. The ultimate solution is to use external resources to perform whole analysis.

Non-linear registration portion of the algorithm is parallelized on the level of optimizing position of a single control points of B-spline grid, with respect to energy function. The main challenge is that multiple threads can't work on a close control points, because each has an impact on energy function in a significant portion of adjacent voxels. In current implementation, the work manager spawns work to separate threads by finding non colliding areas that need to be registered. It is possible to allow slight overlay between these areas, since the effects of deformation by single control point are very slim on edges of these areas. We found that allowing control points to be as close as 3.5 units in index space is suitable. Each thread works locally and tries to minimize local energy function. After receiving results from the thread, the manager tries to allocate new job for that worker. Threads don't need to communicate with each other during local minimization. Spawning jobs and gathering results are the only points where threads communicate with manager.

The presented parallelization strategy does not scale to the larger number of threads. Therefore we are working on a new implementation that will make use of a multiple nodes of the most time consuming registration phase. As more atlas data with variant anatomical structures will be available, it will be natural to process input data against all atlases in parallel. Final result will be constructed from atlas that fits the input the best, i.e. requires the smallest deformation to achieve the same level of energy function.

The CT images uploaded to the remote storage can be analyzed using high performance systems with multiple processors. Such model allows to reduce processing time to several or even single minutes. In addition, the extensive repository of patient data can be built.

Since processing of patient data requires high level of the security and privacy, the grid technology is ultimate choice [5]. The grid middleware allows for an access to the distributed resources with secure manner. The tools vary and depend on the software used. The typical grid middleware has three tier architecture with the client layer exposed to the end user. The technology used ranges from the command line type of access through libraries, graphical clients up to a web interfaces. The web access is particularly important for the medical users, since they are focused on the analysis of the images rather than technical issues.

The web access to the remote resources have been developed by the numerous groups using different technologies, such as web gateways or web portals [7][8][9]. Unfortunately, most of them is complicated and requires extensive software stack. In result they are difficult to install and manage. The extensions such as introduction of new functionality or adoption to new application areas is especially time consuming. The ultimate solution is UNICORE, which provides whole software stack including web interface. What is also important, the UNICORE does not require significant effort to install and maintain.

III. UNICORE INFRASTRUCTURE

Typical UNICORE [10][11] infrastructure consists of two groups of services. First one contains services UNICORE Registry, UVOS, Service Orchestrator and Workflow Engine. They are run at ICM with redundant instances of Registry and UVOS at WCSS site. Second group contains services which allows access to sites' resources. Those are UNICORE/X and UNICORE TSI together with the UFTPD for fast file transfer.

After UNICORE 7 has been released, there has been started migration to new main attribute source for UNICORE servers. This was mostly because of new features allowing users to access resources without complicated certificate setup. For that reason, new service called Unity IDM [12] was designed and developed. The goal is to replace UVOS in nearest future and to use it as the main authentication and authorization service in PL-Grid for UNICORE users.

The Rich Client based on the Eclipse Rich Client Platform is the main access tool for the users. The Rich Client is easy to install and configure, however for the unexperienced user this task is still too complicated. The UNICORE Portal is the recently added element to the UNICORE portfolio of client applications [13]. It is much different from the other, already existing, client software, as it is using two separate software components to realize the clients functionality: a thin web browser client (UNICORE unaware) and the Portal servlet which serves as a Grid gateway. Such design, typical for the Web applications, brings several challenges: the Portal application has to be used by multiple users simultaneously what requires proper context separation and careful management of resources (disk space, memory) which are much more constrained than in the standalone client case. The UNICORE Portal provides ready to be used interface for a generic jobs. This interface is a web version of the Generic Grid Bean available in the UNICORE Rich Client. The UNICORE portal allows for the development of a domain specific interfaces tuned for the particular use cases. This work still requires programming skills, but is much more easier compare to the other science gateways software stacks.

IV. RESULTS

The described algorithm for the segmentation of airspaces has been implemented as a SinusMed application written in the Java language and installed on the high performance computing system. It has been parallelized using Java threads which allowed us to reduce computation time from hours to several minutes. Further parallelization is in progress and should lead to reduction of the analysis time to few minutes with hundreds of cores used.

The disk space and computational resources are provided by the Polish National Grid Infrastructure (PL-Grid) [6][14]

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which is open for research and education usage and is provided to the Polish research community free of charge.

The UNICORE Portal has been installed and integrated with the PL-Grid infrastructure as presented in the Figure 2. In particular, it has been integrated with the Unity authorization and authenticated system. Unity allows its users to enable authentication (or login) to their web services using various protocols, with different configurations for many relaying parties. The authentication can be performed using the built-in, feature-rich users database or can be delegated to one of the supported upstream identity providers (IdPs). The information obtained from the IdPs can be flexibly translated and merged with the local database (if needed) and re-exported using other protocols.

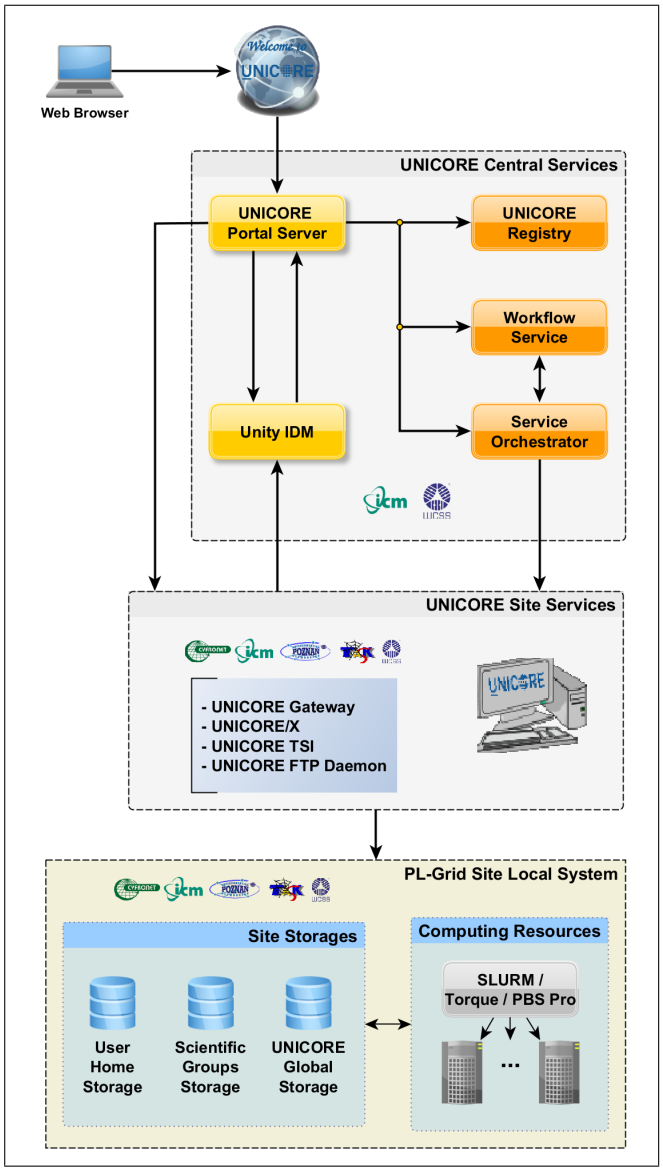

Figure 2. The UNICORE Portal Deployment in the PL-Grid.

In terms of the PL-Grid infrastructure, users using the UNICORE Portal or working with the standalone clients like UCC or URC, may use login and password provided during their registration in the PL-Grid portal. Those credentials are stored using central LDAP server. Unity binds to this server during authentication and reads user attributes and groups. This data is further processed by the Unity using input translation rules. The details of the authorization and authentication process in the PL-Grid are presented in the Figure 3. The main benefit is that user do not have to hassle with the certificates and the communication stays secure and trustworthy which is especially important while processing medical data.

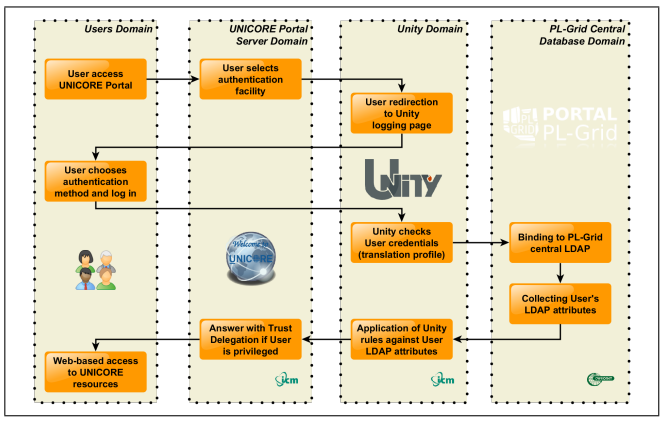

Figure 3. The communication flow between different infrastructure components during user authentication and authorization.

Unity is not yet another bundle of several, coupled together systems. It is a solution built from the ground up. All pieces perfectly fit together. Startup is fast, administration of all parts is performed in the same style and the whole solution is fully web and cloud ready.

Thanks to the the UNICORE Portal solution, user can submit a job, monitor it and see results from all UNICORE clients. Using the portal he can switch to simple mode where jobs for only one application type are displayed in the web browser.

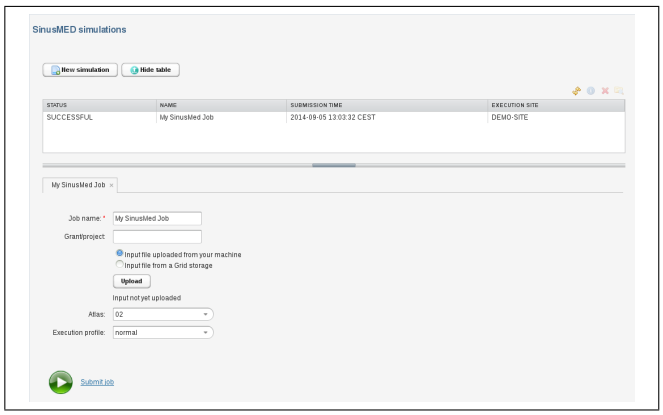

Figure 4. The interface to the SinusMed application: input data for the analysis.

The developed by us SinusMed extension to the UNICORE Portal allows to upload packed images in the DICOM-Dir format and process them on the grid. As presented in the Figure 4, the user has to select the atlas to be used and quality of the results. Than simulation is started using Submit button.

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In return, the user obtains set of images with the paranasal sinuses areas marked. He can modify display parameters with the buttons and display different 2D layers with the navigation bar (see Figure 5).

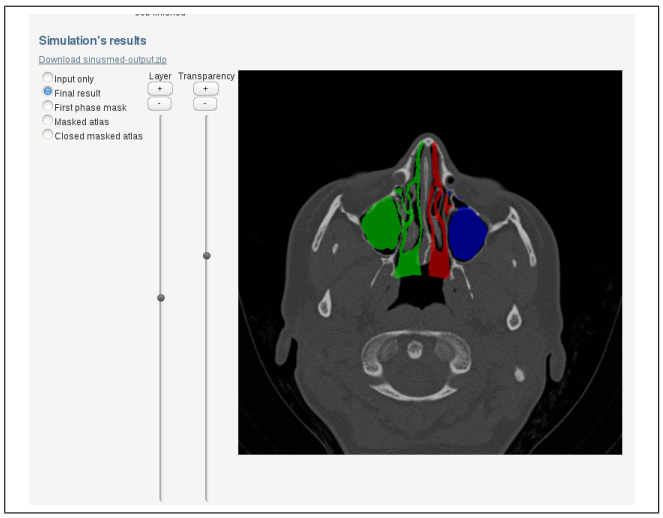

Figure 5. The interface to the SinusMed application deployed in the UNICORE Portal. The results of example analyses are presented.

The images are processed on the grid with the parallel application described above. It produces high quality images and allows for reliable determination of the important regions, their size and volume in the reasonable time. Since SinusMed application is parallelized, it can benefit from the multicore nodes available in the PL-Grid. The same time, the access is simple and no dedicated software is required on the client side.

V. Conclusions

Presented example clearly shows that grid technology became mature enough to offer reliable, high quality services designed to suit requirements of a different scientific communities. In particular, web interface as well as automation of the processing of selected applications have been developed using UNICORE Portal. In result, the medical doctors can focus on the diagnosis instead of writing complicated scripts, transferring the files and mastering complicated IT infrastructure.

With the UNICORE Portal, creation of the application and domain specific solution become simple and straightforward. The software stack necessary to build full featured gateway is now small and easy to handle. Presented work shows, that based on the UNICORE framework service to support medical diagnosis can be bring to the users.

In the near future, we plan to extend system by additional functionality such as estimation of the key parameters of the segmented areas and extraction of the segmented objects for further processing. The database of the patient data will be used with the extensive search functionality and will be used to improve segmentation results and to aid doctors in the diagnosis process.

Acknowledgment

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Technology Assisted Self-management Support for Improving Cancer Pain Control

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***Abstract*—Pain continues to be a prevalent and distressing symptom in patients with cancer. Integration of patient self-management and professional care through care technology provides promising opportunities in the outpatient setting. Researchers, technicians, health professionals and patients collaborated during an iterative development process. Co-creation resulted in a technology assisted multi-component self-management support intervention delivered by specialized nurses to outpatients with cancer pain. The intervention consists of an iPad application for patients, which is connected to a web application for nurses. Both applications are embedded in a multidisciplinary care organization. This paper provides a description of the intervention.**

Keywords-cancer pain; self-management support; telemonitoring; education; feedback; outpatients; nursing; eHealth intervention.

I. INTRODUCTION

Patients with cancer experience multiple physical and psychosocial symptoms, having an enormous impact on their daily functioning and quality of life [1]. Pain is considered one of the most common symptoms, reported by 59% of patients on active treatment, 64% of patients with advanced disease, and 33% of patients after curative treatment [2]. Despite available treatment options, pain control is still suboptimal in 50% of all patients with cancer pain [3]. Fragmentation of care organization, deficient pain communication, and reluctance towards pain medication contribute to inadequate pain management in the outpatient setting [4][5][6]. Actively involving and remotely supporting patients seems conditional to improving outcomes, since the actual pain management of cancer patients is performed at home [7].

Various valuable attempts have been made in developing and evaluating interventions to support cancer pain self-management. Nurses specialized in pain were found to make substantial contributions to day-to-day pain management in the outpatient setting [8]. Due to differences in content, structure and outcomes of interventions, it remains difficult to draw firm conclusions about how to provide optimal self-management support [9]. Recommendations have been formulated with regards to the implementation of multiple components, the importance of self-efficacy and the integration of interventions into routine practice [10][11][12]. Care technologies could contribute to the integration of patient self-management and professional care.

Therefore, this project is focused on the development and evaluation of a self-management support intervention that integrates multiple components and is delivered by specialized nurses to outpatients with moderate to severe cancer pain. Requirements for self-management support [13] include assisting patients to access information about their pain and adverse effects and telling them what is normal and when and how to get help. It also involves empowering patients to recognize and monitor their symptoms and providing them with insight and feedback about how they are doing. Supporting patients to undertake strategies to manage their symptoms better and to have confidence is extremely important. Based on these requirements, researchers and

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technicians as well as health professionals and patients collaborated in an iterative development process. Involving these different perspectives was meant to ensure an intervention fit with daily practice and preferences in order to increase implementation success, while at the same time taking previous research and technological opportunities into account. This paper provides a description of the intervention.

II. INTERVENTION

The intervention consists of an iPad application for patients, which is connected to a web application for nurses. Both applications are embedded in a multidisciplinary care organization. Patients receive the intervention alongside the pain treatment that is provided to them by their treating physician.

Patients and nurses obtain log-in information to gain access to the applications. Accordingly, pain medication can be entered into the nurse application and activated to be visible in the patient application. Monitored data are saved on secured servers.

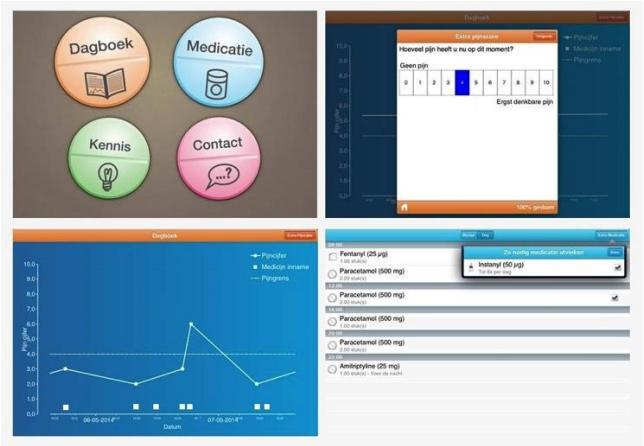

Figure 1. Screenshots of the application for patients (in Dutch): a) home screen, b) extra pain intensity score, c) graphical feedback, and d) medication intake schedule

A. Patient application

The application for patients involves pain, side effects and medication monitoring, graphical feedback, education, and nurse support (Fig. 1). Patients are reminded to complete diaries, take medication, read education materials and check text messages from the nurse by visual and sound notifications.

1) Diary: The pain diary is presented to patients twice daily and involves questions about their pain, adverse effects, interference of pain with activity or sleep, and satisfaction with pain treatment. Diary questions were based on the present-day pain anamnesis and composed together with a multidisciplinary palliative team. Providing nurses with enough information without burdening patients too much was considered important. The pain diary contains a skip pattern; affirmative answers on particular questions result in sub-questions to obtain more information. In between, these diaries, registration of extra pain intensity scores is optional. These optional scores may provide a better reflection of pain over time, as cancer pain is characterized by fluctuations.

2) Medication: The application includes a personalized medication day schedule. In accordance with this schedule, patients are requested to register intake of medication in time. A restricted 4-hour time frame, starting 2-hours before and finishing 2-hours after the scheduled intake time should motivate patients to take and register their medication on time. Accurate registrations are important for graphical feedback as well as nurse advice. General medication icons were added to support patients visually.

Pain intensity scores from the diaries, as well as the extra pain intensity scores, are depicted in a graph together with the medication intake moments. Pain scores are indicated with bullets, closed and open squares represent intakes of respectively ‘around the clock’ and ‘as needed’ medication. The graphical information provides insight into pain patterns over time and the possible influence of medication intake and daily routines.

3) Education: Patients receive education about causes of pain, treatment of pain, recognition of symptoms that require action, and methods that patients themselves can implement to better control pain. The education is divided into three ‘obligatory’ sessions, in which information is presented dosed and in a logical sequence. Each session consists of several topics. After completion of these sessions, specific topics, as well as additional information about pharmacological and non-pharmacological treatments, can be ‘voluntarily’ reread. Based on prescriptions of patients, the information about pain medication is tailored by “The information presented here is (is not) applicable to your situation, since you do (do not) take this medication”.

4) Contact: In case of questions, patients have the opportunity to send text messages to the nurse via the application. Nurses attempt to answer these messages within one workday.

B. Nurse application

Nurses enter the application to monitor and analyze the situation of patients regarding pain once every workday. In addition to the composition of the medication overview, the application for nurses includes completed pain diaries, composite graphs, information about scheduled and actual medication intake, and a text message function (Fig. 2).

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In case of red flags or text messages from patients, nurses receive an email notification.

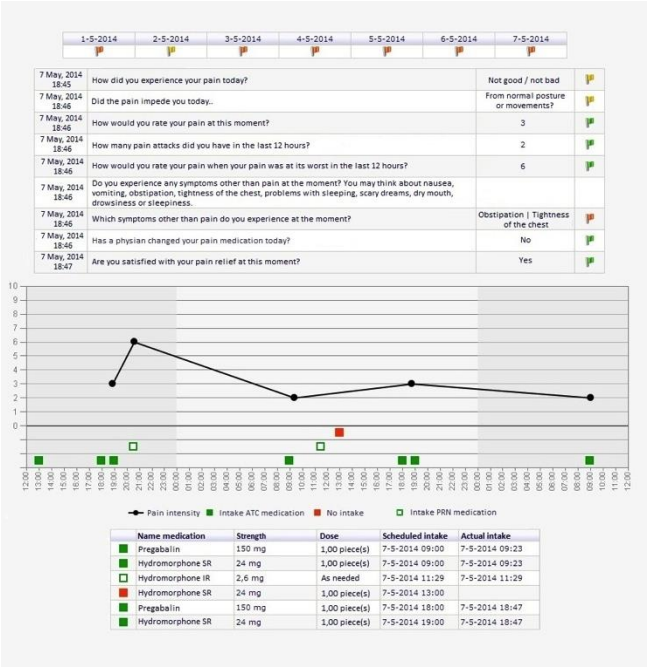

Figure 2. Screenshots of the application for nurses: a) weekly overview of overall risk flags, b) evening diary, c) composite graph with pain intensity scores and medication intake moments and d) medication intake details

1) Completed diaries: Diary questions and answers are tagged with colored flags that support nurses in their monitoring tasks: red flags required immediate action, yellow flags asked to keep an eye, and green flags indicated everything is okay. Frequency of certain answers during subsequent diaries determines the color of flags.

2) Composite graph and medication details: Pain intensity scores as registered by patients are summarized in a composite graph together with their pain medication intake. Pain scores are depicted with bullets. Squares differentiate between registration of 'around the clock' medication (green, closed) and 'as needed' medication (green, open) as well as medication that has not been registered (red, closed). The graphic view can be adapted by changing the date. Pain medication details, including strength, dose, scheduled and actual intake time provide nurses with additional information.

3) Multidisciplinary organisation of care: Besides sending text messages, nurses have the opportunity to consult patients by phone. When necessary, and also on a regular basis, nurses will inform the treating physician about the situation of patients regarding pain. In case pain relief is inadequate, the nurse consults the pain specialist or the multidisciplinary palliative team for advice. Advice is reported to the treating physician who decides on follow-up, changes in prescription or other interventions.

III. CONCLUSION

The intervention integrates patient self-management and professional care through care technology, facilitating partnership with shared responsibilities. The proposed intervention, which is to be tested in a randomised controlled trial, is believed to improve pain management in outpatients with cancer.

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